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Tools for advancing tobacco control in the 21st century

Tobacco control legislation: an introductory guide

D. Douglas Blanke and Vera da Costa e Silva
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This legislative guide is the work of many hands. A confluence of several related projects of the World Health Organization (WHO), it was prepared under the supervision and direction of Dr Vera da Costa e Silva, Director of the WHO's Tobacco Free Initiative, and Dr Douglas Bettcher, WHO's Coordinator of the Framework Convention on Tobacco Control. A draft template of the guide was prepared by William Onzivu, Legal Officer of the WHO Tobacco Free Initiative in Geneva, Dr Mirta Molinari, Technical Officer of the Tobacco Free Initiative in Buenos Aires, Argentina and Dr Vera da Costa e Silva, Director, Tobacco Free Initiative. The guide was edited, and most chapters were written by D. Douglas Blanke of the Tobacco Law Center at William Mitchell College of Law in Saint Paul, United States of America. Dr Vera da Costa e Silva was also an editor of this book.

Most of the guide is adapted from three sources. The first is an important and insightful paper by Professors Ruth Roemer and Barbara Berman of the School of Public Health of the University of California at Los Angeles, United States of America. The second is an equally valuable paper by Professors Lawrence Gostin and James Hodge of the Center for Law and the Public's Health at the Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland, with contributions by Gabriel Eber. The third is the Pan American Health Organization's outstanding publication *Developing Legislation for Tobacco Control, Template and Guidelines*, 2002, prepared by Heather Selin and Dr Monica Bolis.

The chapter on international law and its implications was written by Sarah Galbraith, Legal Officer of WHO's Tobacco Free Initiative in Geneva and Dr Allyn Taylor, Health Policy Adviser to WHO and Adjunct Professor at the University of Maryland School of Law and the Johns Hopkins Bloomberg School of Hygiene and Public Health Professor in Baltimore, Maryland, the United States of America.

Country studies were prepared by Cristiane Vianna, Legal Adviser, National Cancer Institute of Brazil in Rio de Janeiro; Dr Hosam Abo Youssef of Guiza, Egypt; and Dr Jonathan Flavier of the Philippines. The source materials were organized, integrated and supplemented by William Onzivu, Legal Officer of the Tobacco Free Initiative in Geneva and Dr Mirta Molinari, Technical Officer of the Tobacco Free Initiative, in Buenos Aires, Argentina.

William Onzivu assumed the challenge of coordinating production of the publication and organizing and verifying footnotes and other reference materials. Text was copy edited by Mary Falvey of Brussels, Belgium, proof read by William Onzivu, D. Doug Blanke and Professor Ruth Roemer reviewed the finished text. Joy Adriano provided the typesetting assistance. More specific discussion of the roles of the contributors will be found in a Note on Contributors and Sources following the text of the guide.

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FOREWORD

This introductory guide on legislation for tobacco control represents an important step in strengthening global and national tobacco control programmes. Tobacco now kills 4.9 million people a year and the figure continues to rise. The recent conclusion of the negotiations of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) presents a strong global complement to national and local legislative action for tobacco control. Many developed and developing countries have also continually called for the World Health Organization (WHO) to produce tools for the development of legislation in Member States. This guide aims to meet such an important requirement.

These guidelines are part of a series of national capacity background manuals and tools that the WHO Tobacco Free Initiative has developed specifically to support countries in their task of addressing the WHO FCTC implementation. To ensure that we had a broad range of views and different scenarios in the guide, which reflected experiences both from developing and developed countries, a consultation meeting was held in PAHO/Washington D.C. in June 2002 that brought together experts, lawyers, activists and national focal points. One strategy that will be employed to expedite the implementation of this material will be its use in several regional and sub-regional workshops to update and facilitate human resources training for tobacco control at country level.

WHO and its Member States recognize that a lack of legislation or ineffective legislation combined with the failure to understand how vital the law-making process is to successful implementation hamper meaningful progress in containing the tobacco problem. Ad hoc tobacco control programmes cannot be sustained in the long term if they are not deeply rooted in comprehensive tobacco control legislation—including provision for adequate financing of actions.

This guide systematically discusses the information that will be needed to develop tobacco control legislation. It can be applied to the enactment of legislation at the national, subnational and local levels. The guide considers the role of legislation, key terms and concepts, capacity-building, strategic choices in legislation, elements of comprehensive legislation, the drafting process, the legislative process, obstacles, implementation of legislation and evaluation. It also provides selected case studies of various national laws as well as an introductory discussion of international legal instruments pertaining to tobacco control.

WHO is disseminating this guide as a necessary tool for those working in tobacco control or in health promotion. These actors include governmental agencies, public health practitioners, lawyers, nongovernmental organizations and academia. It is hoped that the guide will add value to existing reference materials for tobacco control. Nothing in this guide should be construed to represent the official views of the WHO Secretariat on the interpretation and application of the WHO FCTC, or to influence or prejudice interpretation of the Convention by the parties. This applies in paticular to references made to specific provisions of the Convention.

Dr Vera da Costa e Silva
Director
Tobacco Free Initiative
World Heath Organization

ملخص

أولاً: مقدمة

إن وباء تعاطي التبغ يعد اليوم أحد أكبر التهديدات المحدقة بالصحة في العالم. فثلث البالغين في العالم تقريباً يتعاطى التبغ. ونصفهم سيلقى حتفه نتيجة لهذا التعاطي. وثمة مثال واضح على ذلك هو الصين التي يبلغ عدد سكانها من الذكور دون سن الثلاثين نحو ٣٣١ مليون شخص. ومن المحتمل أن يتسبب التبغ في وفاة نحو ١٠٠ مليون منهم تقريباً قبل الأوان. ويشكل هذا الوباء تحديات أهول من تحديات المشاكل الصحية التقليدية، لأنه ينطوي على إدمان شديد وعلى أعراف ومعتقدات اجتماعية عميقة الجذور، وصناعة عالمية لها تاريخ في تقويض الجهود الخاصة بالصحة العمومية. ولحسن الحظ أننا نعلم ما العمل المجدي، ألا وهو اتباع نهج تشريعي شامل. فالتشريع يمكن أن يحد بشكل كبير من تعاطي التبغ من قبل الشباب، وأن يساعد المدخنين على الإقلاع عن التدخين، وأن يحمي غير المدخنين من التعرض لدخان التبغ. وستعطي اتفاقية منظمة الصحة العالمية الإطارية التاريخية بشأن مكافحة التبغ قوة دفع جديدة لتنفيذ القوانين السارية. ويعد هذا الدليل نقطة انطلاق للمسؤولين الصحيين والمناصرين من الأوساط غير الحكومية وسائر المهتمين بسَن هذا التشريع.

ثانياً: التشريع ووباء التبغ

إن التشريع يحتل موقعاً مركزياً في مكافحة التبغ الفعالة. وهو يجسد القيم الراسخة في المجتمع ويضفي طابعاً مؤسسياً على التزام البلدان ويجعل للأنشطة محور تركيز ويضبط السلوك الخاص على نحو لا تستطيع التدابير غير الرسمية أن تحققه. بيد أن سن تشريع قوي أمر ينطوي على تحديات صعبة. وكثيراً ما تشمل هذه التحديات محدودية فهم الناس للمشكلة، وضرورة بناء "قدرة" وطنية، أي البنية الأساسية والموارد اللازمة للحد الأدنى من الدعم. وربما تكون أشد عقبة تعوق النجاح هي المعارضة غير العادية التي تبديها دوائر صناعة التبغ هي ومن يتحالفون معها. ومن شأن فهم استراتيجياتهم وحججهم الأكثر شيوعاً أن تهيئ المؤيدين للتغلب على هذه المعارضة. بيد أن النجاح يتطلب عادة إرادة سياسية وطيدة تملك مقومات البقاء خلال المحن. والغرض من هذا الكتيب الإرشادي أن يكون أداة للتغلب على هذه العقبات. والقصد منه أن يكون دليلاً تمهيدياً، أي يوفر توجهاً للمسؤولين الصحيين والمناصرين وغيرهم ممن ليست لهم خبرة أساسية في مجالي التشريع وصنع السياسات. وهو يجمع بين منظورين: منظور فكري، لإعطاء القارئ إطاراً منطقياً مرجعياً بشأن ما يتعين عمله؛ ومنظور عملي تطبيقي لمساعدته على البدء في تناول الموضوع. وليس الهدف هو الإجابة على كل سؤال وإنما الهدف هو مساعدة القارئ على فهم الأسئلة التي تطرح، وضمان ألا يخشى من العملية التشريعية حتى وإن ظلت مستعصية على التنبؤ بها.

ثالثاً: دليل تمهيدي للمصطلحات والمفاهيم

إن اتخاذ القرارات الخاصة بالتشريع على أساس من المعلومات يقتضي فهم الأشكال الأساسية التي يمكن أن تتخذها القوانين، وفهم بعض من السمات التي تميز الحكومات والنظم القانونية المختلفة. والقوانين التشريعية، وهي شكل القوانين الذي يستخدم غالباً لتنظيم تعاطي التبغ، هي قوانين تسنها الأجهزة التشريعية على المستوى الوطني أو دون الوطني. وللتشريع الوطني ميزاته وعيوبه. وهي ميزات وعيوب تتفاوت فيما بين البلدان حسب توزيع السلطة فيما بين مختلف مستويات الحكومة ونوع التمثيل الانتخابي. ويُستخدم التشريع دون الوطني بنجاح في بعض البلدان، على الرغم من مواطن ضعفه وقوته أيضاً. وطالما كانت مسائل "الأسبقية" التي يمنع فيها مستوى أعلى في الحكومة، الحكومات التابعة، من سن القوانين في مجال موضوعي محدد، مصدر خلاف ونزاع. وتعد اللوائح الإدارية شكلاً آخر شائعاً من أشكال القانون، وخصوصاً في المجالات التي تتطلب خبرة تقنية. وستتأثر جاذبية هذا النهج بنطاق السلطة القانونية للوكالات والخطوات الإجرائية لاعتماد القواعد ويحد القانون الدستوري من سلطة الأجهزة التشريعية والوكالات الإدارية ومن خلال عملية "المراجعة القضائية" تطبق المحاكم هذه القيود الدستورية وتفصل في المنازعات الخاصة وتفسّر التشريعات بطرق يمكن أن تقرر مصير برامج مكافحة التبغ. وستؤثر جميع هذه الاعتبارات في اختيار استراتيجية التشريع.

يتناول هذا الفصل أيضاً بعض جوانب قانون المعاهدات من حيث صلته بإعداد الاتفاقية الإطارية بشأن مكافحة التبغ. ويقتضي دور القانون الدولي في مكافحة التبغ إدراك المفاهيم الرئيسية لهذا المجال القانوني ذي الجوانب المتنوعة وفهم طبيعته. وقد وضعت الاتفاقية الإطارية بشأن مكافحة التبغ من خلال عملية قانونية دولية. وستقوم الدول الأطراف أيضاً بتنفيذ المعاهدة على المستوى الوطني من خلال عمليات قانونية وطنية. وبالإضافة إلى ذلك يعرض هذا الفصل بإيجاز قانون الجماعة الأوروبية بشأن تنفيذ المعاهدات.

رابعاً: أساس النجاح: بناء القدرات

إن الأساس الضروري للنجاح هو "القدرة" المؤسسية للبلدان على دعم جهود مكافحة التبغ، وهي قدرة تتخذ شكل الموارد البشرية والمالية والخبرات التقنية والإرادة السياسية. وينبغي إرساء هذا الأساس قبل اقتراح التشريع. ومن العناصر الرئيسية للنجاح إعداد المناصرين – القادة بالخبرات والمعارف والالتزام الحماسي بالقضية. ومن الأمور الحاسمة في هذا الصدد وجود "مركز تنسيق" وطني أو سلطة معينة وطنية بمسؤولية رئيسية عن القضية، وكذلك المشاركة النشطة من المجتمع المدني. وينبغي توسيع قاعدة التأييد عن طريق الوصول إلى إشراك دائرة دائمة الاتساع من المؤيدين. وثمة جانب هام من جوانب بناء القدرات هو القدرة على إنتاج معلومات يعول عليها عن الوسط السياسي، والأثر الطبي والاقتصادي المترتب على تعاطي

التبغ، والرأي العام واعتقادات الناس، وأنشطة دوائر صناعة التبغ. ويتطلب بناء القدرات بذل جهود منسقة لتثقيف الجماهير، وهي عملية تقتضي اتباع استراتيجية اتصال منسقة. وأخيراً، فإن بناء القدرات عملية تتعلق بتغيير ثقافة المجتمع من مجتمع يتقبل تعاطي التبغ باعتباره "أمراً عادياً" إلى مجتمع يرفضه باعتباره يتسبب في الوفاة والإدمان والإضرار بالمجتمع.

خامساً: معالجة التشريع: الاختيارات الاستراتيجية

قبل سن التشريع يلزم أن يتخذ مؤيدو مكافحة التبغ سلسلة من القرارات الأساسية، وهذا الفصل يناقش الاعتبارات التي تنطوي عليها هذه الاختيارات الحاسمة. أولاً، يجب على المؤيدين أن يقيّموا مدى استعدادهم للجهد الذي سيبذل. ثانياً، يجب عليهم أن يبحثوا ما إذا كان ينبغي العمل على وضع تشريع شامل دفعة واحدة أم ينبغي اتباع نهج تدريجي مع إضافة العناصر بمرور الوقت. ويجب أن يقيسوا مزايا العمل على المستوى الوطني مقابل خيار التشريع على المستوى دون الوطني. وينبغي كذلك النظر في اللوائح الإدارية كبديل مطروح. ومن المهم أن يفكر المناصرون ملياً في تحديد ما إذا كانوا سيناصرون أفضل تشريع ممكن أم سيقترحون قانوناً أقل قوة قد يبدو أكثر جدوى، وينبغي أن يتوصلوا مسبقاً إلى اتفاق على أية مجالات تحظى فيها الحلول الوسط بالقبول. وإذا تعذر سن تشريع شامل فيجب على المناصرين أيضاً أن يحددوا عناصر القانون الشامل التي يتم العمل على إعدادها أولاً.

سادساً: عناصر التشريع الشامل

لدى صياغة التشريع ينبغي أن يسترشد المناصرون بالقيم الأساسية لمجتمعهم وبقرائن وفيرة تتعلق بأشد الاستراتيجيات فعالية. وقد وردت في قرارات جمعية الصحة العالمية التابعة لمنظمة الصحة العالمية وكذلك في دراسات البنك الدولي نظرات ثاقبة بشأن أكثر العناصر فعالية في استراتيجية شاملة لمكافحة التبغ. وهذا الفصل يناقش عناصر القانون الشامل والاختيارات الرئيسية التي تنطوي عليها صياغة السياسات في كل مجال من المجالات التالية:

- *المؤسسات والآليات*. ينبغي للتشريع أن ينشئ ويفوض ويمول سلطة لتنفيذ التشريع وتوجيهه.
- *تثقيف الجماهير*. تُعد الحملات الواسعة النطاق لتثقيف الجماهير عناصر هامة في تغيير مواقف الجماهير واعتقاداتهم.
- *الإعلان والترويج والرعاية*. يعد فرض حظر شامل على الإعلان عن التبغ والترويج له ورعايته جزءاً أساسياً في برنامج فعال لمكافحة التبغ.
- *الضرائب*. أثبتت زيادة الضرائب أنها من أشد الوسائل فعالية للحد من استهلاك التبغ، وخصوصاً فيما بين الشباب.

- *دخان التبغ غير المباشر*. يوفر منع التدخين في أماكن العمل والأماكن العمومية الحماية لغير المدخنين من أخطار التعرض للدخان، ويثني عن الشروع في التدخين ويروج للإقلاع عنه.
- *التوسيم والتغليف*. ينبغي اشتراط أن تحمل عبوات التبغ تحذيرات صحية ورسائل إعلامية كبيرة وواضحة، باستخدام الرسائل المتغايرة التي تضعها السلطات الوطنية، ولا ينبغي الترويج لمنتجات التبغ باستخدام عبارات مضلّلة.
- *تنظيم المنتجات*. ينبغي إعطاء سلطة تنظيمية لإحدى الوكالات المتخصصة من أجل معالجة مسائل مثل الكشف عن المكونات، وإمكانية السماح بعناصر ضارة، ومأمونية المضافات، وحصائل القار والنيكوتين.
- *مبيعات التبغ*. ينبغي أن تحظر التشريعات بيع التبغ للقصر.
- *التهريب*. ينبغي للتشريع الشامل، من أجل مكافحة الاتجار غير المشروع، أن يتضمن تدابير مثل الشروط الخاصة بتعليم العبوات، أو إنشاء نظام لتتبع سير المنتج وتحديد منشئه على امتداد سلسلة التوزيع.
- *مسائل أخرى*. يمكن أيضاً أن يتضمن التشريع الشامل أحكاماً من أجل معالجة مسألة الإقلاع عن التدخين، أو إنشاء برامج في المدارس، أو تعديل السياسات الزراعية، أو معالجة المسائل الخاصة بالمسؤولية القانونية.

سابعاً: عملية الصياغة

تُعد الصياغة، وهي عملية وضع النص الفعلي للتشريع، مجالاً تخصصياً، ويجب أن يتم تناولها بعناية. ومن المهم عدم الخلط بين دور الشخص القائم بالصياغة ودور الشخص المناصر، وإقامة شراكة بين دوائر الصحة العمومية والدوائر القانونية، وضمان كون النص المقترح صحيحاً من الناحية القانونية وتدبيراً صحياً فعالاً بشرك مجموعة واسعة النطاق من المشاركين من أجل التوصل إلى توافق الآراء والتأييد. وينبغي أن تسترشد عملية الصياغة بمبادئ الوضوح والبساطة والاتساق وعدم التكلف والمرونة. ومن شأن التشريع النموذجي والمساعدة من الخبراء، على كل من المستوى المحلي والدولي، أن ييسرا عملية الصياغة.

ثامناً: تمرير القوانين

يتطلب النجاح في مناصرة التشريع عادة إطلاق حملة متعددة الجوانب تسترشد بخطة مناصرة منسقة. ومن الأمور الحاسمة حشد الرعاة والعمل بفعالية معهم ومع سائر المشرّعين. ويتعين أن تحشد الحملات ذات الصلة قاعدة التأييد القائمة لمكافحة التبغ وأن توسع هذه القاعدة، وأن تمارس أنشطة الاتصال للوصول إلى عامة الناس. والمعالم البارزة للعملية التشريعية، بما في

ذلك التقديم للنص المقترح وجلسات الاستماع العلنية والنقاش بشأن التعديلات، تتيح جميعها فرصاً للدعاية للنقاش الدائر وتوليد الدعم. وينبغي تنسيق أنشطة الاتصال العديدة التي تنطوي عليها الحملة المركبة في إطار استراتيجية اتصال شاملة. وعندما يُسن قانون معين لا ينتهي النضال من أجله. فالتشريع عملية لا تنتهي: ينبغي أن يستعد المناصرون للجهود المستمرة لتعزيز القانون وحمايته من التعطيل.

تاسعاً: التحديات المطروحة والعقبات

تتسم معارضة تشريع مكافحة التبغ بضراوة فريدة من نوعها بسبب الدور الذي تلعبه دوائر صناعة التبغ. وتعطي وثائق شركات التبغ، التي كانت وثائق سرية، رؤى منبصرة في الوسائل التي تحشد بها دوائر هذه الصناعة كل مورد متاح لها عندما تشعر بالتهديد. فشبكة تأثير دوائر هذه الصناعة تتغلغل في نسيج المجتمع وتتيح لها أن تناهض مكافحة التبغ بطرق علنية وخفية على السواء. وينفذ قدر كبير من هذه المناهضة من خلال وكلاء، بمن فيهم حلفاء من طرف ثالث ومجموعات تتخذها واجهة لها ومصادر "مستقلة" يدفع لها المال سراً من حملات الترويج للتبغ. وعن طريق كل هذه القنوات تنشر حملات الترويج للتبغ عدة حجج متكررة تقلل إلى أدنى حد من خطورة وباء التبغ، وتصر على أن تعاطي التبغ أمر يدخل في نطاق الحرية الشخصية، وتنفي أن التدابير التشريعية ستكون ناجحة، وتوحي بأن مكافحة التبغ ستؤدي إلى خسائر اقتصادية.

عاشراً: إنجاح التشريع: تنفيذ التشريع

لضمان ألا يكون سن التشريع نصراً زائفاً يتعين على المؤيدين ألا يهملوا عملية التنفيذ والإعمال. وتتسم نقطة البداية بأهمية خاصة لتحقيق امتثال الجماهير. ومن الأمور الحاسمة للإعمال الفعال اختيار سلطة الإعمال السليمة ومجموعة الجزاءات السليمة وإجراءات الإعمال السليمة. وثمة جانب حيوي آخر لعملية التنفيذ هو ضمان وجود آليات مناسبة لرصد مدى الامتثال. وأخيراً، فإنه على الرغم من ذلك فإن أفضل قانون هو القانون الذي يشكل المعايير الاجتماعية بحيث يُعمل نفسه تلقائياً.

حادي عشر: التقييم

إن التقييم هو العملية الحيوية التي تتيح لصانعي السياسات معرفة ما إذا كان التشريع يحقق غاياته أم لا. وينبغي أن تسترشد عملية التقييم بخطة مفصلة معدة سلفاً، وأن تشمل "تقييم العمل" و"تقييم الحصائل". ويقيس تقييم العمل مدى التقدم في تنفيذ البرنامج المعني، عن طريق تقييم الأنشطة التي ينطوي عليها تنفيذ ذلك البرنامج، وكذلك تقييم الآثار القصيرة المدى المترتبة

على البرنامج، وكثيراً ما يتم ذلك من خلال الإجابة على أسئلة أكثر تركيزاً بشكل متزايد. أما تقييم النتائج فيقيس تأثير القانون في النتائج الدالة على النجاح. وتتيح "المؤشرات الأساسية" المعترف بها والتي تدل على النجاح – أي معدلات الوفاة، واستهلاك التبغ، ومعدلات انتشار التعاطي، والسياسات – نهجاً لتقييم حصائل قوانين مكافحة التبغ. واختيار المؤشرات الدالة على الحصائل وأدوات واستراتيجيات القياس، وتفسير البيانات، هي جميعها أمور تنطوي على مسائل تقنية معقدة. ولن يكلل التقييم بالنجاح إلا إذا نشرت النتائج على نطاق واسع واستخدمت استخداماً فعالاً.

ثاني عشر: دروس في التشريع: دراسات حالة من تسعة بلدان

سنت بلدان كثيرة تشريعات لمكافحة التبغ، ولقي كل منها معارضة قوية، وليست هناك صيغة وحيدة للنجاح، وكل حملة تأتي بمفاجآتها الخاصة. ومازالت هناك دروس يمكن استخلاصها من تجارب بلدان أخرى تبين الأشكال التي يمكن أن تتخذها المعارضة والطرق التي تم بها التغلب عليها. ويعرض هذا الفصل بإيجاز الوسائل التي اتبعت في تسعة بلدان:

- البرازيل، حيث أصبح البلد رائداً عالمياً بفضل تشريع قوي وجديد، ولوائح صارمة، واتباع نهج منسق إزاء النشاط الوطني والرسمي والمحلي.
- كندا، التي تغلبت بمثابرة على العقبات التي اعترضت سبيل وضع معايير عالمية لأفضل الممارسات فيما يتعلق ببطاقات التحذير وبمجالات أخرى.
- مصر، حيث فُرض حظر على الإعلان بعد أن عملت شركات التبغ المتعددة الجنسيات على تعطيل وتقويض هذا الإجراء في حقبة التسعينيات.
- النرويج، حيث يوفر قانون رائد سُن في عام ١٩٧٣ إطاراً مرناً لتشريع شامل مازال يضع معايير عالمية.
- الفلبين، حيث يؤيد كل من السلطات الصحية ومجلس الشيوخ الوطني سن تشريع شامل وقوي، ولكن مجلس النواب يجمد المشاريع المقترحة منذ عقد من الزمان تقريباً.
- بولندا، التي تعدها منظمة الصحة العالمية "نموذجاً لبقية أنحاء العالم" نظراً للتشريع الشامل الذي سنته.
- جنوب أفريقيا، التي تحولت، خلال أقل من عقد من الزمان، من بلد يبدي اهتماماً قليلاً بمكافحة التبغ إلى بلد يطبق بعضاً من أقوى التدابير الشاملة في العالم في مجال مكافحة التبغ.
- تايلند، حيث أدت محاولات شركات التبغ المتعددة الجنسيات شق طريقها إلى السوق التايلندية إلى الإسراع بسن بعض من أقوى التشريعات وأكثرها ابتكاراً في العالم.

- الولايات المتحدة الأمريكية، حيث تتأتى مكافحة التبغ الفعالة من المستوى دون الوطني، في إطار مجموعة تشريعات على مستوى كل من الولايات والبلديات.

وتشير هذه القصص إلى عدة دروس: أهمية التأييد القوي من مسؤولي الصحة العمومية، وضرورة المشاركة النشطة من المنظمات غير الحكومية، وضرورة المرونة في التشريع، وضرورة الإعداد لمواجهة المعارضة المحتملة، وأهمية النظر في آثار المسائل التجارية فيما يتعلق بالتشريع.

ثالث عشر: القانون الدولي وآثاره

يستهدف الفصل الثالث عشر تحري أهمية القانون الدولي بالنسبة إلى التدابير الوطنية لمكافحة التبغ. ويمكن أن يكون هذا الفصل بمثابة وصف موجز فحسب لهذا المجال المعقد من مجالات الاهتمام الدولي؛ فهو فصل غير شامل ولا يقصد منه أن يستقصي كل القوانين الدولية القائمة التي يمكن تطبيقها على مكافحة التبغ. وهو يبحث الالتزامات المحددة بموجب الاتفاقات الدولية القائمة ذات الصلة، كما يبحث أثرها المحتمل في سلطة ومسؤولية الدول في وضع وتنفيذ سياسات وطنية لمكافحة التبغ. وتشمل هذه الالتزامات الدولية، على الصعيد العالمي، الالتزامات الخاصة بالتجارة الدولية المحددة برعاية منظمة التجارة العالمية، والالتزامات الدولية في مجال حقوق الإنسان والمحددة عملاً بعهود حقوق الإنسان الصادرة عن الأمم المتحدة، والالتزامات المحددة برعاية منظمة الجمارك العالمية. ويستعرض هذا الفصل الالتزامات القانونية ذات الصلة بمكافحة التبغ والمحددة برعاية المعاهدات الصادرة عن شتى المنظمات الإقليمية مع التركيز بوجه خاص على الاتحاد الأوروبي. وأخيراً، يبحث هذا الفصل المغزى القانوني المحتمل لاتفاقية منظمة الصحة العالمية الإطارية المقترحة بشأن مكافحة التبغ، والعلاقة بين هذه الاتفاقية المقترحة وسائر الالتزامات القانونية الدولية، والعملية التي يمكن من خلالها للدول الأطراف في الاتفاقية المقترحة أن تطبق المعاهدة على قوانينها وسياساتها المحلية.

رابع عشر: خاتمة

لقد تزايد بسرعة الوعي بوباء التبغ خلال السنوات الأخيرة، وأصبحت مبررات سن التشريع راسخة بشكل جيد الآن. وليس ثمة مجال للعودة إلى الوراء. وستحفز الاتفاقية الإطارية بشأن مكافحة التبغ اعتماد قوانين جديدة، وستضع معايير عالمية للعمل. وتعود الآن من جديد مسؤولية المضي قدماً في هذا المضمار إلى حكومات العالم. وإذا ما استطاع هذا الدليل تيسير تلك العملية بعض الشيء فسيكون قد حقق الغرض منه.

前言

烟草使用的流行是今天对全球卫生的最严重威胁之一。全世界约三分之一的成年人使用烟草，其中半数将因此而死亡。举一个生动的事例，中国是约3.31亿30岁以下男性的家园，其中约1亿可能因使用烟草而过早死亡。这一流行病比传统的卫生问题提出更为艰巨的挑战，原因是它涉及一种强有力的成瘾，根深蒂固的社会习俗和信仰，以及具有损害公共卫生努力史的全球行业。幸运的是，我们知道什么能起作用——一种广泛的立法措施。立法可大幅度减少青少年使用烟草，帮助吸烟者戒烟和保护非吸烟者避免接触烟草烟雾。具有历史意义的世界卫生组织烟草控制框架公约将为实施有效的法律提供新的动力。本指南为卫生官员、非政府倡导者和关心发展这一立法的其它方面提供一个出发点。

II. 立法与烟草流行

立法是有效的烟草控制的核心。它表达社会深刻信奉的价值观念，使一国的承诺制度化，建立活动的重点，并以非正式措施不能实现的方式控制私人行为。然而，制定强有力的法规涉及困难的挑战。这些通常包括公众对问题的有限了解，以及必需为足够数量的支持发展国家"能力"——基础设施和资源。成功的最大障碍或许在于烟草业及其同盟的异乎寻常的反对。了解它们最常用的战略和论点将使支持者能克服这种反对。但是，成功通常需要通过逆境保持的坚定政治意志。本立法指南预定作为一种手段克服这些障碍。其本意是作为介绍性指南——面向缺乏立法和决策方面经历的卫生官员、倡导者和其它方面的情况介绍。它将两种观点结合起来：就必须做的工作给读者以合理参考标准的理论观点，以及帮助他们开始行动的切实可行的实习观点。目标不是解答每一个问题，而是帮助读者理解要问的问题，并确保即使立法过程仍不可预知，也不必产生恐惧。

III. 本术语和概念的介绍性指南

为对立法作出知情决定，必需了解法律可采取的基本形式以及区分不同政府和法律制度的一些特征。法规这一管制烟草使用最常用的法律形式是由立法机构在国家或地方级制定的法律。国家立法有利有弊，国家之间因不同政府级别的权力分配和选举代表制的形式而不同。虽然地方立法有弱势和强势，但是它已在一些国家成功应用。上级政府阻止下级政府在指定的主题领域制定法律的"预先制止"问题一直是经常发生的争议和疏松的根源。行政条例是另一种常见的法律形式，尤其在需要技术专长的领域。一机构法定权力的范围和通过规则的程序步骤将影响这一做法的吸引力。宪法限制立法机构和行政机构的权力。通过"司法审查"过程，法院应用这些宪法限制，决定私人争端和以可决定烟草控制规划命运的方式解释法规。所有这些考虑将影响立法战略的选择。

本章还阐明条约法与制定烟草控制框架公约有关的一些问题。国际法在烟草控制中的作用要求了解这一不同法律领域的主要概念和性质。烟草控制框架公约是通过一个国际法律过程制定的。该条约还将由缔约国在国家级通过其国家法律程序予以实施。此外，在本章中对欧洲共同体条约实施法作了扼要介绍。

IV. 成功的基础：能力建设

一国支持烟草控制工作的机构"能力"——以人力和财力资源、技术专长和政治意志的形式——是成功的必要基础。在提议立法之前应具备这一基础。取得成功的关键之一是培育奋斗者——具有经验、知识和对问题充满激情承诺的领导者。对该问题负有领导责任的国家"联络点"或指定权力机构如同民间社会的积极参与一样至关重要。应通过主动接触使日益广泛的支持者参与来扩大支持的基础。能力建设的另一重要方面是就政治环境、烟草使用对医疗和经济的影响、公众舆论和信仰以及烟草业的活动产生可靠信息的能力。能力建设需要协调的努力，以教育公众，这是需要协调的传播战略的一个过程。从根本上说来，能力建设是关于改变社会的文化，从接受烟草使用为"正常"的一种文化转变为将其作为致命、成瘾和对社会有害而拒绝的一种文化。

V. 着手处理立法：战略性选择

在形成法规之前，烟草控制的提议者必须作出一系列基本决定。本章讨论在这些至关重要的选择中所涉及的考虑。首先，提议者必须评估他们对此项工作的准备就绪状况。其次，他们必须考虑是否立即试图全面立法或采用渐进办法，随着时间推移增加组成部分。他们必须权衡在国家级进行与地方立法方案的益处。行政条例也应作为一种选择方案予以考虑。重要的是，倡导者应认真思考他们是否提倡最佳可能的立法或提出看来更为可行的较弱法律，并且应事先就可接受妥协的任何领域达成一致意见。如不可能全面立法，倡导者还必须决定首先处理一项全面法律的哪些内容。

VI. 全面立法的内容

在制定法规时，倡导者应以其社会基本的价值标准和关于最有效战略的大量证据为指导。世界卫生组织的世界卫生大会决议和世界银行的研究提供了对一项全面烟草控制战略最有效内容的深刻了解。本章讨论一项全面法律的内容和在每一领域制定政策方面所涉及的主要选择：

机构和权利。法规应设立、授权和资助实施和指导此项法规的权力机构。

公众教育。广泛的公众教育运动是改变公众态度和信仰的重要部分。

广告、促销和赞助。全面禁止烟草广告、促销和赞助是有效烟草控制规划的核心部分。

税收。提高税收已被证明是减少烟草消费的最有效手段之一，尤其在青少年中间。

二手烟雾。在工作场所和公共场所取缔吸烟保护非吸烟者避免接触烟雾的危害，阻止开始吸烟和促进戒烟。

标签和包装。应在烟草包装上规定大而明确的健康警语和宣传信息，使用国家当局制定的可更换的信息，并且不应使用误导词语推销烟草制品。

产品管制。应赋予一专门机构以管制权力，处理成份披露、有害成份的容许性、添加剂安全性以及焦油和尼古丁含量等问题。

烟草销售。法规应禁止向未成年人销售烟草。

走私。为打击非法贸易，全面立法应包括规定包装标志或建立追踪制度和通过销售链追踪产品等措施。

其它问题。全面立法还可包括处理戒烟、建立以学校为基础的规划、修订农业政策或处理法律责任问题等规定。

VII. 起草过程

起草是一个制定用于立法的实际文本的过程。它是一个专门学科，必须审慎处理。重要的是不混淆起草人和倡导者的角色，并且建立公共卫生与法律的伙伴关系，以确保提案在法律上是正确的，同时又是一项有效的卫生措施。有大量参与者形成共识和支持。起草工作应以明晰、简单、一致、熟悉和灵活等原则为指导。示范法规以及地方和国际专家的帮助可使起草过程更加容易。

VIII. 通过法规

成功的立法宣传通常需要以协调的宣传计划为指导的多方面运动。征集有效的立法提案人并有效地与他们和其他立法者协作至关重要。运动必须为烟草控制动员现有支持基础，扩大这一基础，并主动接触使一般公众参与。立法过程的里程碑，包括介绍提案，公开听证会和对修正案的辩论，所有这些均为引起公众对辩论的注意和产生支持提供机会。一场复杂运动的许多传播活动应在一项全面传播战略内进行协调。在法律制定时，战斗并未结束。立法是一个无限的过程；倡导者应准备持续不断的努力以加强该项法律和防范破坏。

IX. 挑战和障碍

由于烟草业的作用，对烟草控制立法的反对是十分强烈的。一度保密的烟草公司文件对烟草业受到威胁时动员其拥有的一切资源的各种途径提供了深刻的了解。烟草业的影响同普遍存在于社会结构中，并使之能以公开和隐蔽的方式反对烟草控制。其中许多是通过代理人进行的，包括第三方同盟、掩护团体和由烟草公司秘密付酬的“独立”来源。通过所有这些渠道，烟草公司提出若干重复的论点，极力缩小烟草流行的重要性，坚持烟草使用是个人自由的问题，否认立法措施将会起作用，并且提出烟草控制将对经济造成损害。

X. 使之起作用：实施法规

为确保法规的制定不是一次虚假的胜利，提议者必须重视实施和执行过程。起始阶段对于赢得公众遵守尤为重要。选择正确的执行当局、正确的处罚组合以及正确的执行程序，对于有效执法至关重要。实施的另一个重要方面是确保适当机制以监测遵守情况。但是，最终说来，最好的法律是形成社会规范从而使其本身具有强制力的法律。

XI. 评价

评价是一个重要过程，使决策者能了解法规是否正在实现其目标。评价过程应以事先制定的详细计划为指导，并应包括“过程评价”和“结果评价”，通过评估实施规划所涉活动以及通常通过解答一系列越来越集中的问题评估规划的短期效果，过程评价判断一项规划已得到良好实施的程度。结果评价衡量法律对表明成功的结果的影响。公认的成功的“基本指标” — 死亡率、烟草消费、使用发生率和政策 — 为评价烟草控制法律的结果提供了一种做法。选择结果指标，衡量手段和战略，以及数据解释，所有这些均涉及复杂的技术问题。除非结果得到广泛传播和有效利用，否则评价是不成功的。

XII. 立法方面的教训：九个国家的案例研究

许多国家已制定烟草控制法规，并且各自面临强烈的反对。不存在单一的成功公式，并且每一运动都会带来惊奇。然而，可从其它国家的经验中吸取教训，说明反对可采取的形式以及克服这种反对的办法。本章简要描述在九个国家采取的途径：

巴西，该国强有力的新法规、坚定的条例以及对国家、州和地方活动协调一致的措施已使该国成为全球领导者。

加拿大，它已始终如一地克服障碍，以便为警语标签和其它方面的最佳做法确定全球标准。

埃及，该国在1990年代被多国烟草公司破坏和挫败之后已制定广告禁止。

挪威，该国一项具有开拓性的1973年法律为全面立法提供灵活的框架，迄今仍然确定全球标准。

菲律宾，卫生当局和参议院支持强有力的全面立法，但是众议院已在近十年内阻止议案。

波兰，具有全面立法，世界卫生组织称之为“世界其它国家的榜样”。

南非，在不到十年内已从一个对烟草控制甚少关注的国家转变为全世界一些最强有力综合措施的发源地。

泰国，那里多国烟草公司试图强制进入泰国市场加速了全世界一些最强有力和最具创新性的法规的制定。

美利坚合众国，有效的烟草控制来自次国家级，在州和市两级已制定一堆混杂的法规。

这些事例提示若干教训：来自公共卫生官员的强有力支持的重要性；非政府组织积极参与的必要性；需要立法方面的灵活性；需要对可能的反对作好准备；以及考虑贸易问题对立法影响的重要性。

XIII. 国际法及其影响

第XIII章旨在探讨国际法对国家烟草控制措施的意义。本章仅提供国际关注的这一复杂领域的简要描述。它是不全面的，并且不打算调查对烟草控制可能适用的所有现行国际法。它审查在有关现行国际协定下确定的义务及其对国家制定和实施国家烟草控制政策的权力和责任的可能影响。在全球级，此类国际承诺包括在世界贸易组织支持下确定的国际贸易义务；根据联合国人权公约确定的国际人权义务；以及在世界海关组织支持下确定的义务。本章回顾在各区域组织的条约支持下确定的与烟草控制有关的法律义务，特别注重于欧洲联盟。最后，它审议拟议的世界卫生组织烟草控制框架公约的潜在法律意义、拟议的烟草控制框架公约与其它现行国际法律义务之间的关系以及拟议的公约缔约国结合国内法律和政策实施该条约的过程。

XIV. 结束语

在近几年，已迅速促进对烟草流行的认识，并且立法的理由现已得到充分确认。已经没有退路。烟草控制框架公约将促进通过新的法律和确定全球行动标准。前进的责任现已转回到世界各国政府。如本指导可使这一过程略为容易一些，则已达到其目的。

Summary

I. Introduction

The epidemic of tobacco use is one of the greatest threats to global health today. About one-third of the world's adults use tobacco. Half of them will die from it. To take one vivid example, China is home to some 331 million males under the age of 30. Some 100 million of them are likely to die prematurely from tobacco use. This epidemic poses more daunting challenges than traditional health problems, because it involves a powerful addiction, deeply established social customs and beliefs, as well as a global industry with a history of undermining public health efforts. Fortunately, we know what works—a comprehensive legislative approach. Legislation can significantly reduce tobacco use by young people, help smokers quit and protect non-smokers from exposure to tobacco smoke. The historic WHO Framework Convention on Tobacco Control (WHO FCTC) will provide new impetus for the implementation of effective laws. This guide offers a starting point for health officials, nongovernmental advocates and others interested in developing this legislation.

II. Legislation and the tobacco epidemic

Legislation is at the heart of effective tobacco control. It expresses society's deeply held values, institutionalizes a country's commitment, creates a focus of activity, and controls private conduct in ways that informal measures cannot. Enacting strong legislation involves difficult challenges, however. These often include limited public understanding of the problem, as well as the need to develop national "capacity"—the infrastructure and resources for a critical mass of support. Perhaps the greatest barrier to success is the extraordinary opposition of the tobacco industry and its allies. Understanding their most common strategies and arguments will equip supporters to overcome this opposition. Success usually requires firm political will, sustained through adversity, however. This legislative guidebook is intended as a tool for overcoming these barriers. It is meant as an introductory guide—an orientation for health officials, advocates and others with no background in legislation and policy-making. It combines two perspectives: a theoretical perspective, to give readers a logical frame of reference for what must be done, and a practical, hands-on perspective to help them get started. The goal is not to answer every question, but to help the reader understand the questions to ask, and to ensure that, even if the legislative process remains unpredictable, it need not be intimidating.

III. An introductory guide to terms and concepts

To make informed decisions about legislation, it is necessary to understand the basic forms laws can take and some of the features that distinguish different governments and legal systems. Statutes, the form of law most often used to regulate tobacco use, are laws created by legislative bodies, at the national or subnational level. National legislation has advantages and disadvantages. These vary among countries, depending on the distribution of power among different levels of government and the form of electoral representation. Subnational legislation has been used successfully in some countries, though it has weaknesses as well as strengths. Issues of "pre-emption," in which a higher level of government

blocks subordinate governments from creating laws in a designated subject area, have been a source of frequent controversy and litigation. Administrative regulations are another common form of law, especially in areas requiring technical expertise. The scope of an agency's legal authority and the procedural steps for adopting rules will affect the attractiveness of this approach. Constitutional law limits the power of legislative bodies and administrative agencies. Through the process of "judicial review," courts apply these constitutional limits, decide private disputes and interpret legislation in ways that can determine the fate of tobacco control programmes. All of these considerations will influence the choice of a strategy for legislation.

This chapter also elaborates on some aspects of treaty law as it relates to the development of the WHO FCTC. The role of international law in tobacco control requires an understanding of key concepts and the nature of this diverse area of law. The WHO FCTC has been developed through an international legal process. The treaty will also be implemented by State Parties at the national level through their national legal processes. Furthermore, the law of the European Community on treaty implementation is briefly introduced in this Chapter.

IV. Foundation for success: capacity-building

A country's institutional "capacity" to support tobacco control efforts—in the form of human and financial resources, technical expertise and political will—is the essential foundation for success. This foundation should be in place before legislation is proposed. One of the keys to success is to develop champions—leaders with experience, knowledge and a passionate commitment to the issue. A national "focal point," or designated authority with lead responsibility for the issue, is critical, as is the active involvement of civil society. The base of support should be widened by reaching out to involve an ever-broadening circle of supporters. Another important aspect of capacity-building is the ability to generate reliable information about the political environment, the medical and economic impact of tobacco use, public opinions and beliefs, and the activities of the tobacco industry. Capacity-building requires coordinated efforts to educate the public, a process that requires a coordinated communications strategy. Ultimately, capacity-building is about changing the culture of the society, from one that accepts tobacco use as "normal," to one that rejects it as deadly, addictive and harmful to society.

V. Approaching legislation: strategic choices

Before developing legislation, proponents of tobacco control need to make a series of fundamental decisions; this chapter discusses the considerations involved in these critical choices. First, proponents must assess their readiness for the effort. Second, they must consider whether to seek comprehensive legislation at once, or to use an incremental approach, adding components over time. They must weigh the benefits of proceeding at the national level against the option of subnational legislation. Administrative regulations should also be considered as an alternative. Importantly, advocates should think carefully about whether they will advocate the best possible legislation or propose a weaker law that

may seem more feasible, and should reach agreement in advance on any areas where compromises are acceptable. If comprehensive legislation is not possible, advocates must also decide what elements of a comprehensive law to pursue first.

VI. The elements of comprehensive legislation

In formulating legislation, advocates should be guided by the fundamental values of their society and by the abundant evidence regarding the most effective strategies. Resolutions of the WHO's World Health Assembly and studies by the World Bank have provided an insight into the most effective elements of a comprehensive tobacco control strategy. This chapter discusses the elements of a comprehensive law, and the key choices involved in formulating policies in each area:

- *Institutions and mechanisms.* Legislation should create, empower and fund an authority to implement and direct the legislation.
- *Public education.* Large public education campaigns are important parts of changing public attitudes and beliefs.
- *Advertising, promotion and sponsorship.* A comprehensive ban on tobacco advertising, promotion and sponsorship is a centrepiece of an effective tobacco control programme.
- *Taxes.* Tax increases have been proven to be one of the most effective means of reducing tobacco consumption, especially among young people.
- *Second-hand smoke.* Eliminating smoking in workplaces and public places protects non-smokers from the hazards of exposure to smoke, discourages smoking initiation and promotes cessation.
- *Labelling and packaging.* Large, clear health warnings and informational messages, using rotating messages developed by national authorities, should be required on tobacco packaging, and tobacco products should not be promoted using misleading terms.
- *Product regulation.* Regulatory authority should be given to a specialized agency, to address such issues as ingredient disclosure, permissibility of harmful constituents, additive safety, and tar and nicotine yields.
- *Tobacco sales.* Legislation should prohibit the sale of tobacco to minors.
- *Smuggling.* To combat illicit trade, comprehensive legislation should include measures such as requirements for package markings or creation of a regime for tracking and tracing products through the distribution chain.
- *Other issues.* Comprehensive legislation may also include provisions to address smoking cessation, create school-based programmes, modify agricultural policies or address issues of legal liability.

VII. The drafting process

Drafting, the process of creating actual text for legislation, is a specialized discipline, and must be approached carefully. It is important not to confuse the roles of the draftsperson and the advocate, and to create a partnership of public health and law, to ensure that the proposal is both legally correct and an effective health measure, involving a large circle of participants to build consensus and support. Drafting should be guided by principles of clarity, simplicity, consistency, familiarity and flexibility. Model legislation and assistance from experts, both local and international, can ease the drafting process.

VIII. Passing legislation

Successful legislative advocacy usually requires a multi-faceted campaign, guided by a coordinated advocacy plan. Recruiting effective legislative sponsors, and working effectively with them and other lawmakers, are critical. Campaigns must mobilize the base of existing support for tobacco control, expand that base, and reach out to engage the general public. Milestones of the legislative process, including the introduction of the proposal, public hearings and debate over amendments, all offer opportunities for publicizing the debate and generating support. The many communications activities of a complex campaign should be coordinated within an overall communications strategy. When a law is enacted, the battle does not end. Legislation is a never-ending process: advocates should prepare for ongoing efforts to strengthen the law and guard against sabotage.

IX. Challenges and obstacles

Opposition to tobacco control legislation is unusually ferocious because of the role of the tobacco industry. Once-secret tobacco company documents offer insights into the ways this industry mobilizes every resource at its disposal when threatened. The industry's web of influence runs through the fabric of society, and enables it to fight tobacco control in both overt and covert ways. Much of this is done through surrogates, including third-party allies, front groups and "independent" sources secretly paid by tobacco companies. Through all these channels, tobacco companies put forth several recurring arguments, minimizing the importance of the tobacco epidemic, insisting that tobacco use is a matter of personal freedom, denying that legislative measures will work, and suggesting that tobacco control will cause economic injury.

X. Making it work: implementing the legislation

To ensure that the enactment of legislation is not a false victory, proponents must not neglect the process of implementation and enforcement. The start-up period is especially important for winning public compliance. The selection of the right enforcement authority, the right mix of penalties, and the right enforcement procedures, is critical to effective enforcement. Another vital aspect of implementation is to ensure adequate mechanisms for monitoring compliance. Ultimately, though, the best law is one that so shapes social norms that it becomes self-enforcing.

XI. Evaluation

Evaluation is the vital process that enables policy-makers to know whether legislation is achieving its purposes. The evaluation process should be guided by a detailed plan prepared in advance, and should include both "process evaluation" and "outcome evaluation." Process evaluation gauges how well a programme has been implemented, by assessing the activities involved in implementing the programme, as well as the programme's short-term effects—often by answering a series of increasingly more focused questions. Outcome evaluation measures the law's impact on results that indicate success. Recognized "essential indicators" of success—mortality rates, tobacco consumption, prevalence of use and policies—offer one approach for evaluating the outcome of tobacco control laws. Selection of outcome indicators, measurement tools and strategies, and data interpretation all involve complex technical issues. Evaluation is not successful unless the results are disseminated widely and put to effective use.

XII. Lessons in legislation: case studies from nine countries

Many countries have enacted tobacco control legislation, and each has faced stiff opposition. There is no single formula for success, and each campaign brings its own surprises. Still, lessons can be drawn from others' experiences, which illustrate the forms opposition can take and the ways it has been overcome. This chapter describes briefly the paths taken in nine countries:

- Brazil, where strong, new legislation, firm regulations and a coordinated approach to national, state and local activity have made the country a global leader.
- Canada, which has persistently overcome obstacles to set global standards for best practices in warning labels and other areas.
- Egypt, where an advertising ban has been enacted after having been sabotaged and defeated by multinational tobacco companies in the 1990s.
- Norway, where a groundbreaking 1973 law provides a flexible framework for comprehensive legislation that still sets global standards.
- The Philippines, where health authorities and the national Senate support strong comprehensive legislation, but the House of Representatives has blocked proposals for nearly a decade.
- Poland, with comprehensive legislation the World Health Organization (WHO) calls "an example to the rest of the world."
- South Africa, which has transformed in less than a decade from a country with little interest in tobacco control to the home of some of the world's strongest comprehensive measures.
- Thailand, where attempts by multinational tobacco companies to force their

way into the Thai market accelerated development of some of the world's strongest and most innovative legislation.

- The United States of America, where effective tobacco control comes from the subnational level, in a jumble of legislation at the state and municipal levels.

These stories suggest several lessons: the importance of strong support from public health officials; the need for active involvement of nongovernmental organizations (NGOs); the need for flexibility in legislation; the need to prepare for the likely opposition; and the importance of considering the implications of trade issues for legislation.

XIII. International law and its implications

Chapter XIII aims to explore the significance of international law for national tobacco control measures. This chapter can provide only a summary description of this complex area of international concern; it is not comprehensive and does not purport to survey all existing international law with potential applicability to tobacco control. It examines the obligations established under relevant existing international agreements and their potential impact on the authority and responsibility of States to develop and implement national tobacco control policies. At the global level, such international commitments include international trade obligations established under the auspices of the World Trade Organization (WTO); international human rights obligations established pursuant to the human rights covenants of the United Nations; and obligations established under the auspices of the World Customs Organization (WCO). The chapter reviews legal obligations relevant to tobacco control established under the auspices of treaties of various regional organizations, focusing in particular on the European Union (EU). Finally, it considers the potential legal significance of the WHO FCTC, the relationship between it and other existing international legal obligations and the process by which State Parties to the Convention can implement the treaty into domestic law and policy.

XIV. Conclusion

Awareness of the tobacco epidemic has accelerated rapidly in recent years, and the case for legislation is now well established. There is no turning back. The WHO FCTC will spur the adoption of new laws and set a global standard for action. Responsibility for moving forward now shifts back to the world's governments. If this guide can make that process slightly easier, it will have served its purpose.

RESUME

I. Introduction

Le tabagisme est l'une des plus grandes menaces actuelles pour la santé mondiale. Environ un tiers des adultes dans le monde font usage du tabac et la moitié d'entre eux en mourront. Pour prendre un exemple frappant, la Chine compte environ 331 millions d'individus de sexe masculin âgés de moins de 30 ans. Près de 100 millions d'entre eux risquant de mourir prématurément à cause du tabac. Les défis que pose le tabagisme ont une autre dimension que ceux qui découlent des problèmes de santé traditionnels, car cette épidémie se caractérise par un haut degré de dépendance, par des coutumes et des croyances sociales profondément ancrées et par la présence d'une industrie mondiale qui sape depuis longtemps les efforts de santé publique. Mais, nous savons ce qui est efficace : une approche législative globale. La législation peut contribuer à réduire notablement l'usage du tabac chez les jeunes, aider les gens à arrêter de fumer et protéger les non-fumeurs contre l'exposition à la fumée du tabac. L'événement historique constitué par l'avènement de la Convention-cadre de l'OMS pour la lutte antitabac donnera une nouvelle impulsion à la mise en œuvre de lois efficaces. Le présent guide offre une base de départ aux responsables de la santé, aux organisations non gouvernementales prônant la lutte antitabac et aux autres personnes intéressées par l'élaboration de cette législation.

II. La législation contre l'épidémie de tabagisme

La législation est au coeur d'une lutte efficace contre le tabac. Elle exprime les valeurs fondamentales de la société, institutionnalise l'engagement d'un pays, focalise l'action menée et contribue à encadrer le comportement des particuliers d'une manière impossible à obtenir avec des mesures informelles. Toutefois, l'adoption d'une législation stricte pose des problèmes difficiles. Parmi eux figurent souvent la compréhension limitée du problème par le public et la nécessité de développer une «capacité» nationale – c'est à dire l'infrastructure et les ressources nécessaires pour mobiliser une «masse critique» de soutien. Mais l'obstacle le plus grand est peut-être l'opposition extraordinaire de l'industrie du tabac et de ses alliés. Une meilleure compréhension de leur stratégie et de leurs arguments classiques aidera les tenants de la lutte antitabac à vaincre cette opposition. Toutefois ils devront généralement faire montre d'une volonté politique ferme et soutenue face à l'adversité. Le présent guide législatif vise à les aider à surmonter ces obstacles. Il s'agit d'un guide introductif destiné à donner des orientations aux responsables de la santé, aux partisans de la lutte antitabac et aux autres personnes intéressées qui n'ont pas de formation de base dans le domaine de l'élaboration de la législation ou de la formulation des politiques. Il combine deux perspectives : une approche théorique, pour donner aux lecteurs un cadre logique de référence sur ce qui doit être fait, et une approche pratique pour les aider à «démarrer». Le but n'est pas de répondre à toutes les questions mais d'aider les utilisateurs à comprendre quelles sont les questions à poser et à se rendre compte que même si le processus législatif reste imprévisible, il n'a pas lieu de les intimider.

III. Introduction aux termes et notions de base

Pour pouvoir prendre des décisions éclairées concernant la législation, il est nécessaire de comprendre quelles sont les formes fondamentales que peuvent prendre les règles de droit et de connaître certains traits qui distinguent les différents systèmes de gouvernement et les différents systèmes juridiques. Les lois, c'est à dire les instruments de droit les plus souvent utilisés pour réglementer l'usage du tabac, sont élaborées par les organes législatifs au niveau national ou infra-national. La législation de portée nationale présente des avantages et des inconvénients qui varient selon les pays en fonction de la répartition des pouvoirs entre les différents niveaux de gouvernement et la forme de la représentation électorale. Des lois adoptées au niveau infra-national ont aussi été utilisées avec succès dans certains pays bien que cette solution présente à la fois des points forts et des points faibles. Des questions de «prééminence» qui permettent à un niveau de gouvernement supérieur d'empêcher des pouvoirs publics qui leur sont hiérarchiquement subordonnés d'adopter des lois dans un domaine donné ont été une source fréquente de controverses et de litiges. L'adoption de règlements administratifs est une autre manière courante d'édicter des règles de droit, notamment dans les domaines qui requièrent des connaissances techniques. L'étendue de l'autorité juridique d'un organisme donné et la procédure à suivre pour adopter des règles peuvent réduire l'intérêt de cette approche. Par ailleurs, le droit constitutionnel limite les pouvoirs des organes législatifs et des instances administratives. Par le biais du «contrôle juridictionnel», les tribunaux font respecter ces limites constitutionnelles, tranchent les différends privés et interprètent la législation d'une manière qui peut déterminer le sort des programmes de lutte antitabac. Toutes ces considérations vont influencer le choix de la stratégie adoptée pour la mise en place d'une législation.

Le présent chapitre aborde en outre certains aspects du droit des traités qui se rapportent à l'élaboration de la Convention-cadre pour la lutte antitabac. Compte tenu de l'importance que revêt le droit international dans la lutte antitabac, il est essentiel de bien comprendre les concepts fondamentaux et la nature de ce domaine de droit diversifié. La Convention-cadre a été élaborée dans le respect du droit international. Le traité sera aussi appliqué par les Etats Parties au niveau national dans le respect de leur droit national. Le droit de la communauté européenne relatif à l'application des traités est également présenté brièvement dans ce chapitre.

IV. Les fondements du succès : le renforcement de la capacité

La «capacité» institutionnelle d'un pays d'appuyer les efforts de lutte antitabac, que ce soit en terme de ressources humaines et financières, d'expertise technique ou de volonté politique, est la base du succès. Cette base doit avoir été mise en place avant de proposer une législation. L'une des clés de la réussite est de mobiliser des «champions», c'est à dire des dirigeants qui ont une expérience et une connaissance de la question et qui se passionnent pour le sujet. La création d'un «point focal» national ou la désignation d'une autorité assumant la direction des opérations dans ce domaine est essentielle, de même qu'une participation

active de la société civile. Il faut élargir la «base de soutien» en mobilisant un cercle toujours plus large de partisans. Un autre aspect du renforcement de la capacité est l'aptitude à réunir des informations fiables sur l'environnement politique, sur l'impact de l'usage du tabac aux plans médical et économique, sur les opinions et les croyances du public et sur les activités de l'industrie du tabac. Le renforcement de la capacité requiert des efforts coordonnés pour éduquer le public, processus qui demande une stratégie de communication coordonnée. A terme, le renforcement de la capacité vise à modifier la culture de la société en lui faisant rejeter l'usage du tabac comme mortifère, dépendogène et socialement nocif, alors qu'elle le considérait jusque là comme «normal».

V. Comment aborder la législation : choix stratégiques

Avant d'élaborer une législation, les partisans de la lutte antitabac doivent commencer par prendre une série de décisions fondamentales ; ce chapitre passe en revue les considérations qui interviennent dans ces choix cruciaux. Tout d'abord, ces partisans doivent évaluer leur propre volonté de faire l'effort nécessaire. Deuxièmement, ils doivent examiner s'il faut chercher à mettre en place tout de suite une législation complète, ou procéder par paliers en ajoutant de nouveaux éléments au fil du temps. Ils doivent peser les avantages et inconvénients de l'adoption d'une législation nationale par rapport à une législation infranationale. La réglementation par les voies administratives doit aussi être une solution envisagée. Il est important de bien réfléchir sur le point de savoir si l'on va préconiser d'emblée l'adoption de la meilleure législation possible ou proposer des règles moins strictes paraissant plus faciles à faire accepter, et permettant de s'entendre par avance sur les domaines dans lesquels des compromis seront envisageables. Si l'adoption d'une législation complète n'est pas possible, il faut aussi déterminer quels éléments de cette législation globale doivent être mis en place en premier.

VI. Eléments d'une législation globale

Dans la formulation de la législation, ses partisans doivent se laisser guider par les valeurs fondamentales de leur société et par les multiples preuves concernant les stratégies les plus efficaces. Ce chapitre passe en revue les éléments d'une législation complète, en expliquant quels sont les choix clés qui doivent être faits pour la formulation des politiques dans chaque domaine:

- *Institutions et mécanismes.* La législation doit créer, habiliter et financer une autorité chargée d'orienter et de faire appliquer les lois.
- *Education du public.* De vastes campagnes d'éducation du public sont importantes pour faire changer les comportements et les mentalités.
- *Publicité, promotion et parrainage.* Une interdiction complète de la publicité pour le tabac, ainsi que de la promotion et du parrainage, est la pièce maîtresse d'un programme efficace de lutte anti-tabac.

- *Taxes.* Il a été prouvé que les augmentations de taxes étaient l'un des moyens les plus efficaces de réduire la consommation de tabac, notamment chez les jeunes.
- *Tabagisme passif.* L'interdiction de fumer dans les lieux publics et sur les lieux de travail protège les non-fumeurs contre les dangers de l'exposition à la fumée de tabac, dissuade les gens de commencer à fumer et favorise le sevrage tabagique.
- *Etiquetage et emballage.* L'apposition de mises en garde et de messages d'information sanitaire clairs et en gros caractères sur les emballages des produits du tabac en utilisant par roulement les textes mis au point par les autorités nationales devrait être exigée et la consommation de produit du tabac ne devrait pas être encouragée par l'emploi de termes trompeurs.
- *Réglementation du produit.* La réglementation devrait être confiée à un organisme spécialisé chargé de traiter des questions telles que la publication de la liste des ingrédients, le caractère autorisé ou non des constituants nocifs, l'innocuité des additifs et les teneurs en goudrons et en nicotine.
- *Ventes de tabac.* La législation devrait interdire la vente de tabac aux mineurs.
- *Contrebande.* Pour lutter contre le commerce illicite, une législation complète devrait comprendre des mesures telles que des prescriptions pour le marquage de paquets de tabac ou la création d'un système de traçage des produits tout le long de la chaîne de distribution.
- *Autres questions.* Une législation complète peut aussi comprendre des dispositions concernant le sevrage tabagique, la création de programmes d'éducation en milieu scolaire, la modification des politiques agricoles ou les questions de responsabilité juridique.

VII. Rédaction

La rédaction, qui est le processus consistant à élaborer les textes de loi proprement dits, est une discipline spécialisée qui doit être abordée avec prudence. Il est important de ne pas confondre le rôle des rédacteurs et celui des partisans de la législation et d'établir un partenariat entre les responsables de la santé publique et les juristes, de manière à assurer que les projets soient à la fois corrects sur le plan juridique et efficaces sur le plan de la santé, et de veiller à ce qu'un grand nombre de participants y soient associés pour en favoriser le soutien et faciliter l'obtention d'un consensus. La rédaction devrait être guidée par les principes de clarté, de simplicité, de cohérence, de facilité de compréhension et de souplesse. La référence à une législation type et l'assistance d'experts tant locaux qu'internationaux peuvent faciliter le processus.

VIII. L'adoption d'une législation

Pour réussir à faire adopter une législation, il faut généralement mener une campagne multiforme s'appuyant sur une action de sensibilisation bien coordonnée. Il est essentiel de recruter d'authentiques partisans de la législation et de travailler efficacement avec eux et avec d'autres parlementaires. Les campagnes doivent viser à mobiliser la base des partisans de la réglementation du tabac et à développer cette base pour atteindre le grand public et l'associer à l'action. Toutes les étapes du processus législatif, y compris la présentation des projets de lois, les audiences publiques et les débats au sujet des amendements, sont autant d'occasions de faire de la publicité autour de cette question et d'obtenir un appui. Les multiples activités de communication faisant partie d'une campagne complexe doivent être coordonnées dans le cadre d'une stratégie globale de communication. Lorsqu'une loi est adoptée, la bataille n'est pas terminée. La législation est un processus sans fin : les partisans doivent se préparer à faire des efforts soutenus pour renforcer la loi et faire échec au sabotage.

IX. Défis et obstacles

L'opposition à l'adoption d'une législation antitabac est particulièrement féroce en raison du rôle joué par l'industrie du tabac. Des documents des cigarettiers jadis gardés secrets donnent une idée de la manière dont cette industrie mobilise toutes les ressources à sa disposition lorsqu'elle se sent menacée. Son champ d'influence traverse tout le tissu de la société et lui permet de combattre la lutte antitabac à la fois de façon ouverte et de manière insidieuse. Ce combat est mené en grande partie par des acolytes, y compris des tiers, des prête-noms, ou des sources «indépendantes» secrètement rétribuées par les cigarettiers. Par leur intermédiaire, les fabricants de tabac font valoir toutes sortes d'arguments récurrents qui tendent à minimiser l'importance de l'épidémie de tabagisme, insistent sur le fait que l'usage du tabac est une affaire de choix personnel, prétendent que les mesures législatives ne seront pas efficaces et laissent entendre que la réglementation du tabac entraînera des préjudices économiques.

X. Faire en sorte que cela fonctionne : mettre en oeuvre la législation

Pour que l'adoption de la législation ne soit pas une fausse victoire, ses partisans ne doivent pas négliger les questions de mise en oeuvre et d'exécution de la loi. La période de démarrage est particulièrement importante pour gagner l'adhésion du public. Le choix de l'autorité chargée de faire appliquer la loi, le bon dosage des peines applicables et l'adoption de procédures d'exécution appropriées sont essentiels pour que la législation soit appliquée efficacement. Un autre aspect crucial de la mise en oeuvre est la création de mécanismes adéquats de surveillance. A terme, toutefois, la meilleure législation est celle qui aboutit à remodeler si bien les normes sociales qu'elle finit par s'appliquer d'elle-même.

XI. Evaluation

L'évaluation est un processus crucial qui permet aux responsables de la politique de savoir si la législation atteint les buts recherchés. Le processus d'évaluation doit s'appuyer sur un plan détaillé préparé à l'avance et doit comprendre à la fois une «évaluation du déroulement du programme» et une «évaluation des résultats».

L'évaluation du déroulement du programme permet de juger de l'efficacité avec laquelle le programme a été mis en oeuvre, en examinant les activités liées à cette mise en oeuvre ainsi que les effets à court terme – ce qui consiste souvent à répondre à une série de questions de plus en plus ciblées. L'évaluation des résultats mesure l'impact de la loi sur certains indicateurs qui témoignent d'un succès. Les principaux «indicateurs de succès» reconnus – à savoir les taux de mortalité, la consommation de tabac, la prévalence de son usage et les politiques appliquées offrent un moyen d'évaluer l'effet des lois sur la lutte antitabac. La sélection d'indicateurs de résultat, d'outils et de stratégies de mesure, ainsi que l'interprétation des données font intervenir des questions techniques complexes. L'évaluation n'est pas efficace si ses résultats ne sont pas largement diffusés et utilisés dans la pratique.

XII. Les leçons à tirer de la législation existante : études de cas concernant neuf pays

De nombreux pays ont adopté une législation antitabac et chacun d'eux s'est heurté à une vive opposition. Il n'y a pas de formule unique pour réussir dans ce domaine, et chaque campagne apporte avec elle ses propres surprises. Cela n'empêche que l'on peut tirer des leçons de l'expérience des autres pays, qui illustre les diverses formes que peut prendre l'opposition et les manières dont elle a été surmontée. Ce chapitre décrit brièvement les approches qui ont été adoptées dans neuf pays :

- L'Afrique du Sud qui s'intéressait peu à la lutte antitabac et qui est devenue en moins d'une décennie le pays appliquant l'une des panoplies de mesures de lutte parmi les plus énergiques au monde.

- Le Brésil, où la nouvelle législation énergique, la réglementation stricte et l'approche coordonnée des activités au niveau national, au niveau des Etats et au niveau local ont fait du pays un leader mondial en la matière.

- Le Canada, qui s'est acharné à surmonter les obstacles pour fixer des normes globales concernant l'adoption des meilleures pratiques tant en ce qui concerne l'apposition de mises en garde sur les emballages que dans d'autres domaines.

- L'Egypte, où une interdiction de la publicité a été décrétée après avoir été contrecarrée et mise en échec par les multinationales du tabac dans les années 90.

- Les États-Unis d'Amérique où l'initiative de mesures efficaces de lutte antitabac a été prise au niveau infranational aboutissant à une mosaïque de lois et réglementations à l'échelon des États et des municipalités.

- La Norvège, où une loi novatrice de 1973 fournit un cadre souple pour l'adoption d'une législation complète fixant des normes globales.

- Les Philippines, où les autorités sanitaires et le Sénat appuient l'adoption d'une législation globale énergique, mais où la Chambre des représentants bloque les propositions de lois depuis près d'une décennie.

- La Pologne, qui a adopté une législation globale dont l'Organisation mondiale de la Santé (OMS) dit qu'elle est «un exemple pour le reste du monde».

- La Thaïlande, où les tentatives des multinationales du tabac pour s'imposer sur le marché thaïlandais ont accéléré la mise en place d'une des législations les fermes et les plus novatrices au monde.

Ces exemples nous apportent plusieurs enseignements : l'importance d'un soutien vigoureux des responsables de la santé publique ; la nécessité d'une participation active des organisations non gouvernementales (ONG) ; le besoin de souplesse dans la législation ; la nécessité de se préparer à l'opposition prévisible ; et l'importance de prendre en compte les effets de la législation sur le commerce.

XIII. Le droit international et ses conséquences

Le chapitre XIII examine l'importance du droit international en ce qui concerne les mesures nationales de lutte antitabac. Ce chapitre ne peut fournir qu'un descriptif sommaire de ce domaine complexe de préoccupation de la communauté internationale ; il n'est pas exhaustif et ne prétend pas passer en revue toutes les règles de droit international existantes qui seraient potentiellement applicables à la lutte antitabac. Il se contente d'examiner les obligations découlant des accords internationaux pertinents en vigueur et leur impact potentiel sur le pouvoir et le devoir des Etats d'élaborer et de mettre en œuvre des politiques nationales de lutte antitabac. Au niveau mondial, ces engagements internationaux comprennent les obligations commerciales internationales contractées sous l'égide de l'Organisation mondiale du Commerce (OMC) ; les obligations internationales concernant les droits humains qui découlent des Pactes internationaux des Nations Unies relatifs aux droits de l'homme ; et les obligations contractées dans le cadre de l'Organisation mondiale des douanes (OMD). Ce chapitre passe également en revue les obligations juridiques en matière de lutte antitabac qui découlent des traités et conventions conclus par diverses organisations régionales, en mettant notamment l'accent sur l'Union européenne (UE). Enfin, il examine l'importance juridique potentielle de la future Convention-cadre de l'OMS pour la lutte antitabac, les liens entre la Convention-cadre et les autres obligations juridiques internationales existantes et le processus par lequel les Etats parties à la Convention pourront lui donner effet dans leur droit et leur politique internes.

XIV. Conclusion

La prise de conscience des ravages causés par l'épidémie de tabagisme s'est rapidement accéléré ces dernières années, et l'utilité d'adopter une législation en la matière est maintenant tout à fait établie. Il n'y aura pas de retour en arrière. La Convention stimulera l'adoption de nouvelles lois et fixera un cadre mondial pour l'action à mener. Il appartient maintenant aux gouvernements des différents pays du monde d'aller de l'avant. Si ce guide peut leur rendre la tâche un peu plus facile, il aura atteint son objectif.

Резюме

I. Введение

Эпидемия употребления табака сегодня является одной из наибольших опасностей для здоровья в мире. Приблизительно одна треть взрослых людей в мире употребляет табак. Половина из них умрет от употребления табака. Возьмем один яркий пример: в Китае проживает приблизительно 331 миллион мужчин в возрасте до 30 лет. Приблизительно 100 миллионов из них, вероятно, умрут преждевременно в результате употребления табака. Эта эпидемия ставит более серьезные задачи, чем традиционные проблемы здравоохранения, так как она связана с сильной зависимостью, глубоко укоренившимися социальными привычками и убеждениями, а также с глобальной промышленностью, имеющей давний опыт подрыва усилий общественного здравоохранения. К счастью, мы знаем, что является эффективным – всеобъемлющий законодательный подход. Законодательство может значительно уменьшить употребление табака молодыми людьми, помочь курильщикам отказаться от этой привычки и защитить некурящих от воздействия табачного дыма. Историческая Рамочная конвенция ВОЗ по борьбе против табака (РКБТ) обеспечит новый стимул для осуществления эффективных законов. Настоящее руководство обеспечивает отправную точку для должностных лиц здравоохранения, не связанных с правительством сторонников и других людей, заинтересованных в разработке такого законодательства.

II. Законодательство и табачная эпидемия

Законодательство находится в центре эффективной борьбы против табака. Оно отражает глубоко укоренившиеся в обществе ценности, институционализирует обязательства страны, придает целенаправленность действиям и обеспечивает контроль над индивидуальным поведением таким образом, который не могут обеспечить неформальные меры. Однако принятие сильного законодательства связано с трудными задачами. Они часто включают ограниченное понимание этой проблемы населением, а также необходимость развития национального "потенциала" – инфраструктуры и ресурсов – для создания критической массы поддержки. Возможно, наибольшим препятствием для успеха является экстраординарное сопротивление табачной промышленности и ее союзников. Понимание их наиболее распространенных стратегий и аргументов даст возможность сторонникам преодолеть это сопротивление. Однако успех обычно требует твердой политической воли, не прекращающейся даже в неблагоприятных условиях. Настоящий справочник по законодательству предназначен для использования в качестве средства для преодоления этих препятствий. Он предназначен для использования в качестве вступительного руководства, дающего ориентацию для официальных лиц здравоохранения, пропагандистов и других людей, не имеющих опыта в области законодательства и разработки политики. В нем сочетаются две перспективы: теоретическая перспектива, чтобы дать читателям логическую базисную информацию о том, что должно быть сделано, и практическая перспектива, чтобы помочь им начать действовать. Цель состоит не в том, чтобы ответить на все вопросы, а в том, чтобы помочь читателю понять, какие вопросы следует задать, и обеспечить, чтобы законодательный процесс, несмотря даже на то, что он остается непредсказуемым, не был отпугивающим.

III. Вступительное руководство по терминам и понятиям

Для принятия информированных решений в отношении законодательства необходимо понять основные формы, которые могут приобретать законы, и некоторые характеристики, которые отличают различные правительства и правовые системы. Статуты, которые являются формой закона, наиболее часто используемой для регулирования употребления табака, представляют собой законы, разработанные законодательными органами на национальном или субнациональном уровне. Национальное законодательство имеет преимущества и недостатки. Они варьируются между странами в зависимости от распределения полномочий между различными уровнями правительства и формы выборной представленности. Субнациональное законодательство успешно использовалось в некоторых странах, хотя оно и имеет как слабые, так и сильные стороны. Вопросы "преимущественного права", при котором более высокий уровень правительства не дает подчиненным уровням правительства возможности разработать законы в конкретной предметной области, были источником частых дискуссий и споров. Административные постановления являются другой распространенной формой нормативных актов, особенно в областях, требующих технического опыта. Сфера юридической компетенции учреждения и процедурные меры для принятия норм повлияют на привлекательность этого подхода. Конституционный закон ограничивает полномочия законодательных органов и административных учреждений. Посредством процесса "судебного надзора" суды применяют эти конституционные ограничения, решают частные споры и интерпретируют законодательство таким образом, что это может определить судьбу программ борьбы против табака. Все эти аспекты будут влиять на выбор стратегии для законодательства.

В этой главе подробно рассматриваются также некоторые аспекты международного договорного права в той мере, в какой они касаются РКБТ. Роль международного права в борьбе против табака требует понимания основных концепций и характера этой многообразной области права. РКБТ разрабатывается посредством международного правового процесса. Этот договор будет также осуществляться государствами-участниками на национальном уровне посредством их национальных правовых процессов. Кроме того, в этой главе вкратце представлены законодательные положения Европейского сообщества, касающиеся исполнения договоров.

IV. Основа для успеха: создание потенциала

Институционный "потенциал" страны для поддержки усилий по борьбе против табака – в виде кадровых и финансовых ресурсов, технического опыта и политической воли – является важной основой для успеха. Эта основа должна существовать до предложения законодательства. Одним из ключевых факторов успеха является формирование сторонников – лидеров, имеющих опыт, обладающих знаниями и проявляющих сильную приверженность этому вопросу. Национальный "координатор" или назначенный орган с основной ответственностью за этот вопрос имеет важное значение, так же как и активное участие гражданского общества. База поддержки должна быть расширена посредством достижения всех людей для их вовлечения в постоянно расширяющийся круг сторонников. Другим важным аспектом создания потенциала является способность генерировать достоверную информацию о политической среде, медицинском и экономическом воздействии употребления табака, общественном мнении и убеждениях, а также о деятельности табачной промышленности.

Для создания потенциала необходимы скоординированные усилия по просвещению населения – процесс, требующий скоординированной стратегии в области передачи информации. В конечном счете создание потенциала состоит в изменении культуры общества от культуры, воспринимающей употребление табака в качестве "нормального", к культуре, которая отбрасывает его как смертоносное, вызывающее зависимость и вредное для общества.

V. Подход к законодательству: стратегические варианты

До разработки законодательства сторонникам борьбы против табака необходимо принять ряд фундаментальных решений; в этой главе обсуждаются аспекты, связанные с этими важными вариантами выбора. Во-первых, сторонники должны оценить свою готовность к таким усилиям. Во-вторых, они должны рассмотреть вопрос о том, следует ли сразу же стремиться к всестороннему законодательству или же использовать поэтапный подход, со временем увеличивая число компонентов. Они должны взвесить преимущества работы на национальном уровне по сравнению с вариантом субнационального законодательства. Административные постановления также должны быть рассмотрены в качестве одной из альтернатив. Чрезвычайно важным является то, что сторонникам следует тщательно продумать, будут ли они пропагандировать наилучшее возможное законодательство или предлагать более слабый закон, который может казаться более осуществимым, и им следует заранее достичь согласия по любым областям, в которых компромиссы являются приемлемыми. Если всестороннее законодательство является невозможным, сторонники должны также решить, к каким элементам всеобъемлющего закона следует стремиться.

VI. Элементы всестороннего законодательства

При формулировании законодательства сторонники должны руководствоваться фундаментальными ценностями своего общества и использовать изобилие фактических данных, касающихся наиболее эффективных стратегий. Резолюции Всемирной ассамблеи здравоохранения ВОЗ и исследования Всемирного банка дают возможность глубокого осмысления наиболее эффективных элементов комплексной стратегии по борьбе против табака. В этой главе обсуждаются элементы всестороннего закона, а также ключевые варианты выбора, связанные с определением политики в каждой области.

- *Учреждения и механизмы.* Посредством законодательства должен быть создан, наделен полномочиями и финансирован орган для осуществления законодательства и руководства им.
- *Просвещение населения.* Крупные кампании просвещения населения являются важной частью изменения позиций и убеждений людей.
- *Реклама, стимулирование продажи и спонсорство.* Всеобщий запрет рекламы, стимулирования продажи и спонсорства табака является центральным элементом эффективной программы по борьбе против табака.
- *Налоги.* Увеличение налогов оказалось одним из наиболее эффективных средств уменьшения потребления табака, особенно среди молодых людей.
- *"Вторичный" дым.* Ликвидация курения на рабочих местах и в общественных местах защищает некурящих от опасностей воздействия дыма, отвращает от начала курения и способствует прекращению курения.
- *Маркировка и упаковка.* Следует потребовать, чтобы табачная упаковка содержала крупные, четкие предупреждения о вреде для здоровья и сообщения, использующие меняющуюся время от времени информацию, разработанную

национальными органами, и не допускать использования вводящих в заблуждение терминов для продвижения на рынок табачной продукции.

- *Регулирование продукции.* Регулирующие полномочия должны быть даны специализированному учреждению для рассмотрения таких вопросов, как разглашение информации об ингредиентах, допустимое содержание вредных составляющих, аддитивная безопасность, а также выделение смол и никотина.
- *Продажи табака.* В законодательном порядке следует запретить продажу табака несовершеннолетним.
- *Контрабанда.* Для борьбы с незаконной торговлей всестороннее законодательство должно включать такие меры, как требования в отношении маркировки упаковки или создание режима для прослеживания и отыскания следов продукции в цепи распределения.
- *Другие вопросы.* Всестороннее законодательство может также включать положения, направленные на прекращение курения, создание школьных программ, изменение сельскохозяйственной политики или рассмотрение вопросов юридической ответственности.

VII. Процесс составления

Составление – процесс создания фактического текста законодательного акта – является специализированной областью, и к нему следует подходить с осторожностью. Важно не перепутать роли составителей и сторонников и создать партнерство между общественным здравоохранением и законом для обеспечения такого положения, при котором предложение будет как законодательно корректной, так и эффективной мерой здравоохранения, привлекающей широкий круг участников к формированию консенсуса и поддержки. Составление должно определяться принципами четкости, простоты, последовательности, близости и гибкости. Образец законодательства и помощь со стороны экспертов, как местных, так и международных, могут облегчить процесс составления.

VIII. Принятие законодательства

Успешная пропаганда законодательства обычно требует многосторонней кампании, руководство которой осуществляется с помощью скоординированного плана пропаганды. Привлечение на свою сторону эффективных спонсоров законодательства, а также эффективная работа с ними и другими законодателями имеют чрезвычайно важное значение. Такие кампании должны мобилизовать основу существующей поддержки для борьбы против табака, расширять эту основу и простираться за ее пределы для привлечения всего населения. Вехи законодательного процесса, включая внесение предложения, публичные слушания и обсуждение поправок, – все дают возможности для публичного обсуждения и формирования поддержки. При проведении комплексной кампании многие мероприятия по передаче информации должны координироваться в рамках общей информационной стратегии. Когда закон принят, битва не заканчивается. Законодательная деятельность представляет собой бесконечный процесс. Сторонники должны быть готовы к постоянным усилиям по укреплению закона и защите от саботажа.

IX. Проблемы и препятствия

Оппозиция законодательству по борьбе против табака является необычно сильной из-за роли табачной промышленности. Некогда секретные документы табачных компаний дают возможность понять способы, с помощью которых эта промышленность мобилизует любые ресурсы, имеющиеся в ее распоряжении, когда для нее создается

угроза. Сеть влияния этой промышленности пронизывает все общество и дает ей возможность как открыто, так и тайно противодействовать борьбе против табака. В большинстве случаев это делается с помощью подставных лиц, включая союзников в числе третьих сторон, передовых групп и "независимых" источников, секретно оплачиваемых табачными компаниями. Через все эти каналы табачные компании выдвигают ряд повторяющихся аргументов, минимизирующих значение табачной эпидемии, утверждающих, что употребление табака является вопросом личной свободы, отрицающих тот факт, что законодательные меры будут работать, и утверждающих, что борьба против табака нанесет вред экономике.

X. Обеспечение эффективности: осуществление законодательства

Для обеспечения такого положения, при котором принятие законодательства не будет ложной победой, сторонники не должны пренебрегать процессом осуществления и применения. Начальный период является особенно важным, чтобы привлечь на свою сторону общественное мнение. Выбор правильного исполнительного органа, правильного сочетания мер наказания и правильных процедур применения является важным для эффективного применения законодательства. Другим жизненно важным аспектом осуществления является обеспечение адекватных механизмов для мониторинга соблюдения. В то же время, в конечном счете, наилучшим законом является такой закон, который формирует общественные нормы таким образом, что сам обеспечивает свое исполнение.

XI. Оценка

Оценка является важным процессом, который дает возможность лицам, разрабатывающим политику, узнать, достигает ли законодательство своих целей. Процесс оценки должен определяться подробным планом, составленным заранее, и должен включать как "оценку процесса", так и "оценку результатов". Оценка процесса определяет, насколько хорошо осуществляется программа посредством оценки деятельности по осуществлению программы, а также краткосрочных последствий программы – часто путем ответа на ряд все более сконцентрированных вопросов. Оценка результатов измеряет воздействие закона на показатели успеха. Признанные "важные показатели" успеха – коэффициенты смертности, потребление табака, распространенность употребления и политика – дают один подход к оценке результатов законов по борьбе против табака. Выбор показателей результатов, средств измерения и стратегий, а также способов интерпретации данных – все это является сложными техническими вопросами. Оценка будет успешной только в том случае, если результаты широко распространяются и эффективно используются.

XII. Опыт в области законодательства: тематические исследования из девяти стран

Многие страны приняли законодательство по борьбе против табака, и каждое из них столкнулось с жестким сопротивлением. Для успеха нет одной формулы, и каждая кампания приносит свои собственные неожиданности. Все же из опыта других можно извлечь определенные уроки, которые иллюстрируют, какие формы может принимать сопротивление, а также способы его преодоления. В настоящей главе кратко описываются пути, по которым шли эти девять стран:

- Бразилия, где сильное, новое законодательство, твердые нормы и скоординированный подход к национальной, государственной и местной деятельности сделал эту страну глобальным лидером.

- Канада, которая постоянно преодолевает препятствия к созданию глобальных стандартов наилучшей практики в отношении предупреждающих этикеток и в других областях.
- Египет, где принят запрет на рекламу после того, как она саботировалась и потерпела неудачу в результате действий многонациональных табачных компаний в 1990-е годы.
- Норвегия, где очень важный закон 1973 г. обеспечивает гибкие рамки для всестороннего законодательства, которое продолжает обеспечивать глобальные стандарты.
- Филиппины, где органы здравоохранения и Сенат страны поддерживают сильное всестороннее законодательство, однако Палата представителей блокирует предложения в течение почти десятилетия.
- Польша с ее всесторонним законодательством, которую Всемирная организация здравоохранения (ВОЗ) называет "примером для остальной части мира".
- Южная Африка, которая в течение менее чем десяти лет превратилась из страны, в которой отмечался незначительный интерес к борьбе против табака, в страну, в которой принимаются одни из самых сильных в мире всесторонних мер.
- Таиланд, где попытки многонациональных табачных компаний проложить путь на рынок этой страны ускорили разработку одного из самых сильных в мире и самого новаторского законодательства.
- Соединенные Штаты Америки, где эффективная борьба против табака инициируется на субнациональном уровне в условиях запутанного законодательства на уровне штатов и муниципалитетов.

Эти истории дают нам несколько уроков: значение решительной поддержки со стороны должностных лиц общественного здравоохранения; необходимость активного участия неправительственных организаций (НПО); необходимость гибкости в законодательстве; необходимость быть готовым к возможному сопротивлению; и значение рассмотрения последствий законодательства для торговли.

XIII. Международное право и его последствия

Глава XIII имеет целью изучить значение международного права для национальных мер борьбы против табака. Эта глава может дать лишь краткое описание этой сложной области международной обеспокоенности; она не является всеобъемлющей и не стремится рассмотреть все существующее международное право, имеющее потенциал для применения к борьбе против табака. В ней изучаются обязательства, сложившиеся в рамках соответствующих существующих международных соглашений, и их возможное воздействие на полномочия и обязанность государства в отношении разработки и осуществления национальной политики по борьбе против табака. На глобальном уровне такие международные обязательства включают обязательства по международной торговле, взятые под эгидой Всемирной торговой организации (ВТО); международные обязательства по правам человека, взятые в соответствии с конвенциями Организации Объединенных Наций о правах человека; и обязательства, взятые под эгидой Всемирной таможенной организации (ВТО). В этой главе рассматриваются юридические обязательства, относящиеся к борьбе против табака, взятые в соответствии с договорами различных региональных организаций, концентрируясь особенно на Европейском союзе (ЕС). И наконец, в ней рассматривается потенциальное юридическое значение предложенной ВОЗ РКБТ, связь между предложенной РКБТ и другими существующими международными

юридическими обязательствами и процессом, посредством которого государства – участники предложенной конвенции могут включить этот договор во внутренний закон и политику.

XIV. Заключение

Осознание табачной эпидемии в последние годы расширяется быстрыми темпами, и доводы в пользу законодательства сейчас хорошо определены. Пути назад нет. РКБТ ускорит принятие новых законов и определяет глобальные стандарты для действий. Ответственность за дальнейшее продвижение сейчас возвращается правительствам стран мира. Если данное руководство сможет сделать этот процесс несколько более легким, оно достигнет своей цели.

RESUMEN

I. Introducción

La epidemia de tabaquismo constituye hoy una de las máximas amenazas para la salud mundial. Casi un tercio de los adultos del mundo consumen tabaco. La mitad de ellos morirá por esa causa. Un ejemplo patente es el de China, donde viven unos 331 millones de hombres menores de 30 años de edad. Unos 100 millones de éstos tienen la probabilidad de morir prematuramente por causa del consumo de tabaco. Esta epidemia plantea retos más intimidantes que los problemas de salud tradicionales porque conlleva una fuerte adicción, costumbres sociales y creencias profundamente arraigadas, así como una industria mundial que siempre ha socavado los esfuerzos de salud pública. Afortunadamente, sabemos que un enfoque legislativo integral resulta eficaz. La legislación puede hacer reducir significativamente el consumo de tabaco por parte de los jóvenes, contribuir a que los fumadores abandonen el hábito y proteger a los no fumadores de la exposición al humo del tabaco. El histórico Convenio Marco de la OMS para el Control del Tabaco (CMCT OMS) dará un nuevo impulso a la aplicación de leyes eficaces. La presente guía ofrece un punto de partida a los funcionarios de salud, los activistas no gubernamentales y otros interesados en el desarrollo de esta legislación.

II. La legislación y la epidemia de tabaquismo

La legislación es la base de un control eficaz del consumo de tabaco. Expresa valores profundamente enraizados en la sociedad, institucionaliza el compromiso de un país, centra las actividades y regula el comportamiento privado como no pueden hacerlo las medidas oficiosas. Sin embargo, la promulgación de una legislación fuerte conlleva retos difíciles. Éstos a menudo abarcan un conocimiento público limitado del problema, así como la necesidad de desarrollar «capacidad» nacional, es decir infraestructura y recursos para un apoyo de magnitud decisiva. Quizás el principal obstáculo sea la extraordinaria oposición de la industria tabacalera y sus aliados. El conocimiento de sus estrategias y argumentos más comunes dará a los activistas la posibilidad de contrarrestar esa oposición. El éxito requiere generalmente una voluntad política firme y sostenida frente a la adversidad. Esta guía legislativa está concebida como instrumento para superar esos obstáculos. Servirá de introducción y orientación a los funcionarios de salud, activistas y otros interesados sin conocimientos o experiencia en materia de legislación y formulación de políticas. Combina dos perspectivas, una perspectiva teórica que presenta a los lectores un marco de referencia lógico sobre lo que debe hacerse y otra práctica que tiene por objeto ayudarlos a empezar. La meta no es responder a toda pregunta, sino contribuir a que el lector conozca las preguntas por hacer y sepa que, aunque el proceso legislativo sea impredecible, no tiene por qué intimidar.

III. Una guía introductoria sobre expresiones y conceptos

Para adoptar decisiones fundamentadas acerca de la legislación, es necesario conocer las formas básicas que pueden revestir las leyes y algunas de las características que distinguen

a los diferentes gobiernos y sistemas jurídicos. Para regular el consumo de tabaco, los órganos legislativos de nivel nacional o subnacional suelen establecer reglamentos. La reglamentación de nivel nacional tiene ventajas y desventajas. Éstas varían según los países, la distribución del poder entre los diferentes niveles de gobierno y la forma de representación electoral. La reglamentación de nivel subnacional se ha utilizado con éxito en algunos países, pero también tiene ventajas y desventajas. Las cuestiones relacionadas con la supremacía en las que un nivel más alto de gobierno impide que las instancias subordinadas legislen sobre determinada, cuestión, han sido objeto de controversias y litigios frecuentes. El establecimiento de reglamentos administrativos suele ser otra forma de legislar, especialmente en las esferas que requieren conocimientos técnicos especializados. El interés por esta opción dependerá de la autoridad jurídica del organismo y del procedimiento de adopción de normas. El derecho constitucional limita el poder de los órganos legislativos y los organismos administrativos. Mediante el proceso de «examen judicial», los tribunales aplican esos límites constitucionales, deciden sobre controversias privadas e interpretan la legislación de manera que pueden determinar el destino de los programas de control del tabaco. Todas estas consideraciones influirán en la elección de una estrategia legislativa.

En este capítulo también se analizan algunos aspectos del derecho de los tratados en relación con el desarrollo del CMCT OMS. Para que el derecho internacional ejerza una influencia en el control del tabaco se requiere un conocimiento de los conceptos fundamentales y de la índole de esta esfera específica del derecho. El CMCT OMS se ha elaborado mediante un proceso legislativo internacional, pero los Estados Partes aplicarán ese Convenio a nivel nacional previos procesos legislativos nacionales. Además, en este capítulo se presenta brevemente la legislación de la Comunidad Europea sobre la aplicación de tratados.

IV. Bases para el éxito: creación de capacidad

La «capacidad» institucional de un país de respaldar los esfuerzos de control del tabaco - mediante recursos humanos y financieros, conocimientos técnicos y voluntad política es la base indispensable para el éxito. Ésta debe existir antes de que se proponga la legislación. Una de las claves para el éxito consiste en promover a líderes con experiencia, conocimientos y un compromiso apasionado con el tema. El establecimiento de un «punto focal» nacional, o de una autoridad encargada del asunto y la participación activa de la sociedad civil son elementos fundamentales. La base del apoyo se debe hacer extensiva a un círculo cada vez más amplio de defensores. Otro aspecto importante de la creación de capacidad es la posibilidad de generar información fidedigna acerca del ambiente político, las repercusiones médicas y económicas del consumo de tabaco, las opiniones y creencias del público y las actividades de la industria tabacalera. La creación de capacidad requiere esfuerzos coordinados para educar al público, proceso que requiere a su vez una estrategia de comunicaciones coordinada. En último término, la creación de capacidad cambia la cultura de la sociedad, que pasa de aceptar el consumo de tabaco como «normal», a rechazarlo como letal, adictivo y nocivo para la sociedad.

V. Enfoque de la legislación: opciones estratégicas

Antes de establecer una legislación, los partidarios del control del tabaco deben adoptar una serie de decisiones fundamentales; este capítulo versa sobre las consideraciones asociadas a éstas. Primero, los partidarios deben evaluar su disposición para el esfuerzo. Segundo, deben considerar si optarán inmediatamente por una legislación integral o adoptarán un enfoque gradual y añadirán componentes con el transcurso del tiempo. Deben sopesar los beneficios de proceder a nivel nacional frente a la posibilidad de una legislación subnacional. Los reglamentos administrativos también deben considerarse como una opción. Es importante que los activistas piensen detenidamente si abogarán por la mejor legislación posible o propondrán una legislación más débil que parezca más factible y lleguen a un acuerdo previo sobre cualquier esfera en la cual sea aceptable establecer fórmulas conciliatorias. Si una legislación integral no es factible, los activistas también deben decidir qué componentes de una ley integral reclamarán primero.

VI. Elementos de una legislación integral

Al formular una legislación, es preciso guiarse por los valores fundamentales de la sociedad y por las abundantes pruebas relativas a las estrategias más eficaces. Este capítulo aborda los componentes de una ley integral y las principales opciones que conlleva la formulación de políticas en cada esfera:

- *Instituciones y mecanismos*. La legislación debe establecer una autoridad encargada de aplicar y dirigir la legislación, dar poder de decisión a esa autoridad y financiarla.
- *Educación pública*. Las grandes campañas de educación del público son importantes para cambiar las actitudes y creencias del público.
- *Publicidad, promoción y patrocinio*. Una prohibición total de la publicidad, la promoción y el patrocinio del tabaco es un elemento fundamental de un programa.
- *Impuestos*. Los aumentos de los impuestos han demostrado ser uno de los medios más eficaces para reducir el consumo del tabaco, especialmente entre los jóvenes.
- *Humo de segunda mano*. La eliminación del humo de tabaco en lugares de trabajo y lugares públicos protege a los no fumadores de los riesgos de la exposición al humo de tabaco, desalienta el inicio del tabaquismo y promueve el abandono del hábito.
- *Etiquetado y empaquetado*. Debe exigirse que el empaquetado de productos de tabaco lleve advertencias sanitarias grandes y claras e información en forma de mensajes rotativos establecidos por las autoridades nacionales, los productos de tabaco no deben promocionarse con erminos engañosos.

- *Reglamentación de los productos*. Se debe dar autoridad normativa a un organismo especializado, encargado de abordar cuestiones tales como la divulgación de información sobre ingredientes, la permisibilidad de los componentes nocivos, la inocuidad de los aditivos y el contenido de alquitrán y nicotina.
- *Venta de tabaco*. La legislación debe prohibir la venta de tabaco a los menores.
- *Contrabando*. Para combatir el comercio ilícito, la legislación integral debe comprender medidas tales como requisitos sobre el marcado de los paquetes o la creación de un sistema de seguimiento y localización de los productos a lo largo de la cadena de distribución.
- *Otras cuestiones*. La legislación integral puede incluir también disposiciones para promover el abandono del hábito de fumar, crear programas escolares, modificar políticas agrarias o abordar cuestiones relacionadas con la responsabilidad jurídica.

VII. El proceso de redacción

La formulación o redacción de textos legislativos es una disciplina especializada y debe abordarse cuidadosamente. Es importante no confundir las funciones del redactor de esos textos con las del activista, y establecer una alianza entre la salud pública y la ley para que la propuesta sea jurídicamente correcta y sirva como medida de salud eficaz en la que participe un amplio círculo de interesados con el fin de crear consenso y apoyo. La redacción debe guiarse por los principios de claridad, sencillez, coherencia, familiaridad y flexibilidad. La legislación modelo y la asistencia de expertos, tanto locales como internacionales, puede facilitar el proceso de redacción.

VIII. Adopción de leyes

La promoción eficaz de una legislación requiere generalmente una campaña multifacética orientada por un plan coordinado. El reclutamiento de patrocinadores eficaces y la colaboración eficaz con ellos y con otros legisladores son fundamentales. Las campañas deben movilizar la base de apoyo existente para el control del tabaco, ampliar esa base y abrirse al exterior para hacer participar al público en general. Los hitos del proceso legislativo, incluida la introducción de la propuesta, las audiencias públicas y las deliberaciones sobre las enmiendas constituyen oportunidades para dar a conocer el debate y generar apoyo. Las numerosas actividades de comunicación de una campaña compleja deben coordinarse en el marco de una estrategia general de comunicaciones. La batalla no termina cuando se sanciona una ley. La legislación es un proceso que no acaba nunca: los activistas deben prepararse para desplegar esfuerzos progresivos de fortalecimiento de la ley y protegerse contra el sabotaje.

IX. Retos y obstáculos

La oposición a la legislación de control del tabaco es excepcionalmente feroz debido a la función de la industria tabacalera. Los documentos antes secretos de las tabacaleras presentan apreciaciones sobre la manera en que, cuando se ve amenazada, esta industria moviliza todos los recursos que tiene a su disposición. La industria tiene una influencia que abarca toda la sociedad y le permite combatir el control del tabaco de maneras tanto evidentes como ocultas. Esto se hace en gran parte por intermedio de secuaces, incluidos aliados de terceros, grupos frontales y fuentes «independientes» pagadas secretamente por las tabacaleras. Por todos estos canales, las tabacaleras proponen varios argumentos recurrentes, minimizando la importancia de la epidemia de tabaquismo, insistiendo en que el consumo de tabaco es un asunto de libertad personal, negando que las medidas legislativas serán eficaces y sugiriendo que el control del tabaco causará perjuicios económicos.

X. Aplicación eficaz de la legislación

Para que la promulgación de legislación no sea una victoria estéril, quienes la proponen no deben descuidar el proceso de aplicación y cumplimiento. El periodo inicial es especialmente importante para conseguir la observancia del público. La selección de la autoridad apropiada para velar por el cumplimiento de la ley y una buena combinación de sanciones y procedimientos son fundamentales. Otro aspecto esencial de la aplicación consiste en establecer mecanismos adecuados para vigilar el cumplimiento. En último término, sin embargo, la mejor ley es una que modele las normas sociales de manera que se aplique espontáneamente.

XI. Evaluación

La evaluación es el proceso que posibilita que los formuladores de políticas sepan si la legislación consigue los objetivos previstos. El proceso de evaluación debe estar orientado por un plan detallado preparado con antelación y comprender tanto la «evaluación de procesos» como la «evaluación de resultados». La primera permite conocer la forma en que se ha aplicado un programa, porque evalúa las actividades intervinientes en la puesta en práctica del programa, así como los efectos de corto plazo de éste; a menudo mediante respuestas a una serie de preguntas cada vez más específicas. La evaluación de resultados permite determinar las repercusiones de la legislación en los resultados satisfactorios. Los «indicadores esenciales» reconocidos del éxito - tasas de mortalidad, consumo de tabaco, prevalencia del consumo y políticas - ofrecen un enfoque para evaluar los resultados de las leyes de control del tabaco. La selección de los indicadores de resultados, instrumentos de medición y estrategias, así como la interpretación de los datos, son asuntos técnicos complejos. La evaluación será estéril a menos que los resultados se difundan ampliamente y se utilicen eficazmente.

XII. Lecciones de la legislación: estudios de casos de nueve países

Muchos países han adoptado una legislación de control del tabaco, y todos ellos se han enfrentado con una dura oposición. No hay ninguna fórmula que garantice el éxito, y cada campaña presenta sus sorpresas. De todos modos, de las experiencias de los demás se pueden extraer lecciones que muestran las formas que puede revestir la oposición y diversas maneras de vencerla. Este capítulo describe brevemente las vías trazadas en los nueve países siguientes:

- El Brasil, que ha adoptado una nueva legislación fuerte, reglamentos firmes y un enfoque coordinado de la actividad nacional, estadual y local y ha pasado a ser el líder mundial.
- El Canadá, que ha superado constantemente los obstáculos y ha establecido criterios mundiales aplicables a las mejores prácticas relativas a las etiquetas de advertencia y otras áreas.
- Egipto, donde se ha adoptado una prohibición de la publicidad que había sido saboteada y derrotada en los años noventa por las tabacaleras multinacionales.
- Noruega, cuya innovadora ley de 1973 ofrece un marco flexible para el establecimiento de una legislación integral y sigue marcando pautas mundiales.
- Filipinas, donde las autoridades sanitarias y la Cámara de Senadores están a favor de una legislación integral fuerte, pero la Cámara de Diputados ha bloqueado las propuestas durante casi un decenio.
- Polonia, cuya legislación integral ha sido calificada por la Organización Mundial de la Salud (OMS) como «un ejemplo para el resto del mundo».
- Sudáfrica, que en menos de un decenio se ha transformado de país poco interesado por el control del tabaco en uno donde se aplican algunas de las medidas integrales más fuertes del mundo.
- Tailandia, donde los intentos de las tabacaleras multinacionales de forzar su ingreso en el mercado local aceleraron el desarrollo de una legislación que es de las más fuertes y más innovadoras del mundo.
- Los Estados Unidos de América, donde el control eficaz del tabaco es de nivel subnacional, mientras que a nivel estadual y municipal, la legislación es muy variada.

Estas noticias conllevan varias enseñanzas: la importancia de un apoyo decidido de los funcionarios de salud pública; la necesidad de una participación activa de organizaciones no gubernamentales (ONG); la necesidad de flexibilidad en la legislación; la necesidad de prepararse para una probable oposición; y la importancia de considerar las repercusiones de

los asuntos comerciales en la legislación.

XIII. El derecho internacional y sus repercusiones

En el capítulo XIII se procura examinar la importancia del derecho internacional en las medidas nacionales de control del tabaco. Este capítulo sólo puede ofrecer una descripción resumida de compleja esfera internacional; no es exhaustivo y no tiene por objeto pasar revista a toda legislación internacional vigente posiblemente aplicable al control del tabaco. Examina las obligaciones establecidas al amparo de convenios internacionales pertinentes y sus repercusiones potenciales sobre la autoridad y la responsabilidad de los Estados de formular y aplicar políticas nacionales de control del tabaco. A nivel mundial, esos compromisos internacionales abarcan obligaciones comerciales internacionales establecidas bajo los auspicios de la Organización Mundial del Comercio (OMC); las obligaciones internacionales en materia de derechos humanos establecidas de conformidad con los pactos de derechos humanos de las Naciones Unidas; y las obligaciones establecidas bajo los auspicios de la Organización Mundial de Aduanas (OMA). El capítulo analiza las obligaciones jurídicas pertinentes al control del tabaco establecidas al amparo de los tratados de diversas organizaciones regionales, en particular la Unión Europea (UE). Por último, se considera la importancia jurídica potencial del propuesto CMCT OMS, la relación entre el CMCT OMS propuesto y otras obligaciones jurídicas internacionales vigentes y el proceso por el cual los Estados Partes en el convenio propuesto pueden aplicar éste a la legislación y la política nacionales.

XIV. Conclusiones

La conciencia sobre la epidemia de tabaquismo se ha acelerado rápidamente en los últimos años, y ya se reconoce la necesidad de una legislación al respecto. No se dará marcha atrás. El CMCT OMS promoverá la adopción de leyes nuevas y establecerá pautas mundiales para la acción. La responsabilidad corresponde ahora a los gobiernos del mundo. Si esta guía puede facilitar algo ese proceso, no se habrá escrito en vano.

Chapter I. Introduction

Of all the rights cherished by human beings and enshrined in international law, none is more fundamental than the right to health.[1] Asked to rank their aspirations, men and women around the world name good health as their number one desire.[2] One of the greatest global threats to that desire today is the epidemic of tobacco use. About one-third of the world's adults are tobacco users. Half of them will die from it.

"About one-third of the world's adults are tobacco users. Half of them will die from it."

Already the single most preventable cause of death and disease in many countries, tobacco products kill nearly 5 million people each year.[3] Sadly, the future looks even worse. Because of the long time lag between the onset of smoking and the inevitable wave of deaths that follows, the full effects of today's globalization of tobacco marketing and increasing rates of usage in the developing world will be felt for decades to come.

Although tobacco use has declined in many high-income countries in recent decades, at the same time there have been sharp rises in tobacco use, especially among men, in developing countries. As the tobacco industry continues to target youth and women, there are also concerns about rising prevalence rates in these groups in some areas of the world. This shift in the global pattern of tobacco use is reflected in the changing burden of tobacco deaths. At present, about half of the nearly 5 million deaths each year are in developing countries, but by the time the annual death toll doubles to 10 million in 2020, 70% of the deaths will be in developing countries.[4] To take one vivid example, China is today home to an estimated 300 million males under the age of 30. Based on present projections, 100 million of them will die prematurely from tobacco use.[5]

This extraordinary epidemic is distinguished not only by its scale, but also by its nature. In some ways, it poses challenges more daunting than those presented by more traditional public health

[1] Constitution of the World Health Organization, Basic Documents, 43rd ed., 2001 at 1.
[2] Millennium Poll, United Nations, 2000.
[3] *The World Health Report 2002*. Reducing risks, promoting healthy life. Geneva, World Health Organization, 2002, 65.
[4] Murray CJL, Lopez AD. Assessing the burden of disease that can be attributed to specific risk factors. In: *Ad Hoc Committee on Health Research Relating to Future Intervention Options. Investing in Health Research and Development.* Geneva, World Health Organization, 1996 and *The World Health Report 2002*. Reducing risks, promoting healthy life. Geneva, World Health Organization, 2002, 65. See also, *Curbing the Epidemic: Governments and the Economics of Tobacco Control*. Washington, D.C., The World Bank, July 1999.
[5] Liu BQ et al. Emerging tobacco hazards in China. I. Retrospective Proportional Mortality Study of One Million Deaths. *British Medical Journal*. 317(7170):1,411-22.

problems. The tobacco epidemic will not be defeated in the laboratory alone. Unlike issues of sanitation or malnutrition, this epidemic involves a powerful addiction and strongly held opinions and values. Unlike communicable diseases, tobacco use is promoted aggressively by a sophisticated global industry with a history of undermining and subverting public health initiatives.[6] And unlike most health problems, this problem cannot be reversed without challenging deeply established social customs and institutions.

Fortunately, the tobacco epidemic also differs from some other health challenges in that we know what works. What works is not a new medicine or a single strategy. What works is instead a comprehensive, concerted, sustained, multisectoral approach, combining effective measures in many areas simultaneously. For the most part, these measures are not clinical, but regulatory.

"What works is instead a comprehensive, concerted, sustained, multisectoral approach, combining effective measures in many areas simultaneously."

The value of a comprehensive regulatory approach has been recognized for some time. As long ago as 1986, the World Health Assembly recommended the adoption of comprehensive programmes, combining measures to discourage young people from using tobacco, public information programmes, progressive elimination of tobacco advertising, protections against involuntary exposure to tobacco smoke, prominent health warnings on cigarette packets, use of taxation to discourage tobacco use, and other measures.[7]

Today, abundant and growing evidence shows that these measures work, and that they work best when combined. Together, they can significantly reduce tobacco use by young people, help smokers quit and protect non-smokers against exposure to tobacco smoke. In recognition of this evidence, Member States of the World Health Organization (WHO) spent nearly three years negotiating strong terms for WHO's first international health treaty, the WHO Framework Convention on Tobacco Control (WHO FCTC). This historic treaty obligates signatory countries to adopt or strengthen legislation addressing tobacco advertising, packaging, sales practices, smuggling, public smoking, and more.[8] The treaty sets a floor of minimum standards for comprehensive tobacco control

[6] Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents. Geneva, The World Health Organization, 2000, 113-119 .

[7] World Health Assembly Resolution WHA39.14 (1986), supplemented by WHA43.16.

[8] Parties to the treaty are required, acting in accordance with their capabilities, to "adopt and implement effective legislative, executive, administrative and/or other measures . . . for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke." WHO Framework Convention on Tobacco Control, Article 5, Paragraph 2.

programmes around the world, while encouraging countries to go beyond these minimum requirements to adopt recognized best practices.[9]

The WHO FCTC will give even greater impetus to global efforts to reverse the tobacco epidemic. Already, however, the process of treaty negotiation has educated officials from around the world, documented the case for acting decisively, and helped build the political will to do so. This process has laid a foundation for accelerated legislative action in many countries—among them, countries with no experience developing tobacco control legislation.

That is where this legislative guide comes in. It is offered as a starting point for health officials and others who are interested in developing tobacco control legislation, but unfamiliar with the lawmaking process. As an introduction to legislation, policy advocacy and tobacco control legislation, it identifies elements critical to success and suggests strategies for overcoming some of the likely obstacles. In making it available, WHO hopes to assist Member States in implementing the WHO FCTC and in enacting the most effective policies possible.

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[9] WHO Framework Convention on Tobacco Control, Article 2, Paragraph 1.

Chapter II. Legislation and the tobacco epidemic

The role of legislation

By definition, a comprehensive tobacco control programme requires the adoption of legislation or the introduction of regulations.[10] Indeed, legislation is at the heart of an effective programme.

There are a number of reasons for this. Most fundamentally, a society's laws are the most solemn and formal articulation of its values; they recognize, reinforce and make more permanent the society's important norms. When a government prohibits the sale of cigarettes to minors, for example, it not only regulates business practices, but also declares the will of the society that children not smoke.

"...a society's laws are the most solemn and formal articulation of its values; they recognize, reinforce and make more permanent the society's important norms."

Further, legislation serves to institutionalize the programme. In contrast to the ad hoc and intermittent initiatives that might be undertaken by a health ministry or other government office in the absence of legislation, a programme grounded in comprehensive legislation helps to ensure continuity as officials, governments and government priorities change over time. Legislation helps to integrate the diverse components of a multifaceted programme. Importantly, it typically establishes a national focal point for activity, and mobilizes public resources and institutions in support of the programme.

"...the convergence of many recent developments makes conditions favourable for the globalization of effective legislation for tobacco control..."

Furthermore, comprehensive measures require steps to restrict the conduct of tobacco companies, private businesses and individuals—steps that can be taken only through legislation. Finally, only through legislation can a government mobilize the resources of tobacco manufacturers and sellers in support of health measures, including tobacco taxes and duties, as well as requirements that manufacturers display government-approved warning messages on tobacco packets.

Fortunately, the convergence of many recent developments makes conditions favourable for the globalization of effective legislation for tobacco control:

[10] *Smoking control strategies in developing countries: Report of a WHO Expert Committee.* Geneva, World Health Organization, 1983.

- Overwhelming scientific evidence has now firmly documented the effects of tobacco use on health.
- Similarly, abundant research has documented the effectiveness of recommended legislative strategies.
- Compelling research by the World Bank, the World Health Organization (WHO) and academic experts has refuted economic arguments against tax increases and other legislative measures.
- The sophisticated and ruthless efforts of multinational tobacco companies to conceal the truth about tobacco use and to undermine public health efforts around the world have been exposed.
- Countries in every region of the world have gained hard-won experience with tobacco control legislation, and offer valuable lessons for others.
- Around the globe, public awareness of the health effects of tobacco use and the conduct of tobacco companies has increased sharply in recent years.
- Spurred partly by the negotiation of the WHO Framework Convention on Tobacco Control (WHO FCTC), nongovernmental organizations (NGOs) from many countries have been mobilized and are increasing their capacity to support strong legislative proposals.
- The WHO FCTC negotiations have raised international understanding of this issue and helped mobilize the political will for action in many countries.

"Even when supported by careful planning and adequate resources, strong legislative proposals frequently encounter formidable obstacles that can test the will of even the most dedicated advocates."

Together, these developments offer support for the enactment of comprehensive legislation, even in nations with no history of strong tobacco control.

Obstacles ahead

Despite the improved climate for action, enactment of tobacco control legislation remains, in most cases, an extraordinary

challenge. Even when supported by careful planning and adequate resources, strong proposals frequently encounter formidable obstacles that can test the will of even the most dedicated advocates. These obstacles are likely to be greatest in countries with little history of tobacco control activity. While these obstacles can be overcome, it is important to anticipate the likely difficulties, to understand the best strategies for responding, and to be prepared for the intensity and duration of the campaign that may be necessary.

"In many nations, in fact, the level of public awareness regarding these issues and the seriousness of the threat posed by tobacco use remains low. Even where smoking is recognized as dangerous, the magnitude of the danger may not be understood."

Lack of awareness

While the hazards of tobacco use are now well understood among medical and public health experts worldwide, this understanding is not shared by the broader public in all countries. In many nations, in fact, the level of public awareness regarding these issues and the seriousness of the threat posed by tobacco use remains low. Even where smoking is recognized as dangerous, the magnitude of the danger may not be understood.

This is particularly true in some developing countries, for understandable reasons. In areas threatened by immediate and acute health crises, from the epidemic of HIV/AIDS to tuberculosis or drought and malnutrition, tobacco-related diseases may, at first glance, appear to be a concern of richer nations. Low levels of literacy, limited channels for educating the public, limited awareness within the news media, and the absence of a well-developed medical infrastructure all contribute to the problem.

In addition to the traditional burden of communicable diseases, developing countries today are faced with a huge increase in noncommunicable diseases. Tobacco is a major contributor to these diseases, which now account for more than half the disease burden in those countries. This alarming increase threatens to undermine developing countries' economic and social development. Countries and development agencies are increasingly recognizing that tobacco use has negative implications for development that go beyond damage done to health outcomes and life expectancy of tobacco users and people exposed to second-hand smoke. These include a heavy household financial burden due to significant expenditures on tobacco products and health care expenditures, as well as an environmental degradation caused by tobacco farming.

"Because tobacco-related diseases often appear many years or even decades after a tobacco user begins to use tobacco products, the nexus between the problem and its consequences is not self-evident."

Because tobacco-related diseases often appear many years or even decades after a tobacco user begins to use tobacco prod-

ucts, the nexus between the problem and its consequences is not self-evident. Tobacco use may not figure significantly in public consciousness, therefore, and this issue may seem less important than other health concerns, even if the ultimate burden of tobacco on a society far exceeds that of more visible problems.

Cultural practices in particular societies may also complicate the challenge of raising public awareness. Long-accepted practices associated with tobacco use—water pipes in coffee-houses, smoking in pubs and bars, the use of snus, bidis or kretek—may be so deeply rooted in a local culture that it is difficult for members of the culture even to conceive of them as dangerous. In addition, through the sustained efforts of multinational tobacco companies, Western cigarettes have come to be seen, in some developing countries and parts of eastern Europe, as a symbol of status, achievement or sophistication. In some cases, this distorted perception has such force that smoking remains an accepted practice even among physicians.

"To succeed, a legislative initiative must have a critical mass of sustained support."

Health concerns aside, a public unfamiliar with the economic facts may also assume that any reduction in tobacco use will result in economic injury, in the form of lost jobs in the agriculture, manufacturing or small-business sectors, when in fact any negative economic impact will be more than offset by the economic benefits to a society, in the form of improved worker productivity and longevity, and reduced medical costs. Moreover, any jobs lost in the tobacco sectors will be offset by increases in the production and sale of other goods and services. Similarly, if the public is not fully aware of the medical facts, tobacco use may be falsely associated with "freedom" and "rights," whether in the form of "freedom" to smoke in public places, "freedom" to advertise or "freedom" to promote international trade in tobacco products, even though "freedom" has little meaningful application to the use of products that addict their users, most of whom become addicted before they reach adulthood, and that endanger innocent bystanders exposed involuntarily to smoke. In this context, lack of public awareness about the hazards of tobacco use can pose a serious obstacle to legislation.

"Ideally, support will also come from diverse sectors in civil society..."

Limited capacity

A second important obstacle in many countries is the paucity of infrastructure for developing, supporting and implementing controversial public health legislation. Ideally, a campaign to en-

act comprehensive legislation will draw on many diverse sources of expertise, commitment, influence, authority—and resources. Countries that have yet to develop significant tobacco control initiatives may have little or no such capacity. This problem is exacerbated in poorer countries, where there are fewer institutions, resources, and sources of expertise devoted to public health in general.

To succeed, a legislative initiative must have a critical mass of sustained support. This support must ordinarily include a national lead agency, or focal point of responsibility for tobacco issues—usually in the ministry of health. It must also include one and preferably many champions: smart and committed leaders willing to devote themselves, heart and soul, to the success of the campaign. Success is much more likely if an expert and outspoken NGO is also committed to the struggle.

Ideally, support will also come from diverse sectors in civil society, including, for example, medical societies, health organizations, consumer and women's groups, academic institutions and others. Other desirable components of effective capacity include engaged media representatives, committed sponsors within the legislative bodies, and an educated public.

A final important form of capacity is the ability to collect and generate reliable country-specific information about tobacco usage, tobacco-related diseases, economic effects of tobacco usage, and the impact of policy proposals. These data can be critical in building awareness of the problem and support for legislative measures.

Few developing countries are likely to have all these resources at hand. But some combination of key resources of the type described here is usually essential to success, and the absence of this minimum capacity represents an obstacle that must be addressed if a legislative proposal is to succeed.

Powerful opponents

Effective tobacco control legislation is likely to encounter stiff opposition in most countries, even apart from the opposition of the tobacco industry. Where the truth about tobacco and health is not well understood, parliamentarians who mistakenly perceive tobacco use as a matter of "freedom" and "choice" or who are philosophically disposed toward a minimal role for government regulation, will often be sceptical, at least initially, as will some elements of the general public. Users of tobacco are likely to resist tax increases, in particular.

Understandably, groups with a direct economic interest, real or perceived, in the continued sale and use of tobacco, are natural sources of opposition. Growers, processors, and sellers of tobacco, are likely to constitute a natural core of this opposition, especially if their concerns are not taken into account and addressed. Operators, and even employees, of some businesses often oppose smoke-free policies out of fear that the policies will reduce their profits. Broadcasters, publishers and advertising agencies dependent on tobacco adver-

tising fees can be expected to oppose an advertising ban.

These types of opposition should not be underestimated. They are serious and must be addressed. But they are not insurmountable. They have been overcome in country after country, first by educating opponents about the extent to which their economic fears are misplaced and, ultimately, by persuading lawmakers that these fears are far outweighed by the overwhelming benefits to the entire society when tobacco use is reduced.

"What makes tobacco control legislation unusual is the extraordinary opposition mounted by the tobacco industry—which can dwarf opposition to other controversial proposals."

What makes tobacco control legislation unusual is not these traditional sources of opposition, but rather the extraordinary opposition mounted by the tobacco industry—which can dwarf opposition to other controversial proposals. This industry opposition is usually invisible, because the industry takes pains to conceal it from the public eye. In fact, its scale and ferocity may not be apparent even to the proponents of the legislation.

The hidden practices of the industry are now well proven, however, because litigation in the United States of America has exposed secret industry documents that open a window onto these shadowy strategies. These documents recount elaborate industry campaigns to undermine health programmes or legislation at WHO[11] and in the Gulf Cooperating Council,[12] the Islamic Republic of Iran,[13] numerous countries in Latin America,[14] Switzerland,[15] the United Kingdom,[16] Zimbabwe[17], and elsewhere, and demonstrate how sophisticated, sustained and successful these campaigns can be.

These and other examples make it clear that manufacturers can be expected to respond aggressively to any proposal likely to have a significant impact on their sales. Indeed, the absence of

[11] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, 113-119.
[12] Voice of Truth Volumes I and II. Multinational Tobacco Industry Activity in the Middle East: a Review of Internal Documents. Geneva, World Health Organization, 2002. Published at web site: www.emro.who.int/tfi/tfi.htm.
[13] Coveting Iran: The Infiltration and Exploitation of Iran by Global Cigarette Companies. Geneva, World Health Organization, Regional Office for the Eastern Mediterranean, September 2001. Published at web site: http://www.emro.who.int/tfi/tfi.htm
[14] *Profits Over People, Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean*, Pan American Health Organization, December 2002. Published at web site: http://repositories.cdlib.org/tc/reports/LA2
[15] Lee CY, Glantz S. *The Tobacco Industry's Successful Efforts to Control Tobacco Policy Making in Switzerland* University of California, San Francisco, January 2001. Report requested by WHO/TFI. Published at web site: http://repositories.cdlib.org/ctcre/tcpmi/Swiss2001/
[16] House of Commons Health Committee, Second Report, The Tobacco Industry and Health Risks of Smoking, Volume 1, Report and Proceedings of the Committee, 2000. Published at web site: http://www.gea2000.org/documenti/industry_and_health.htm
[17] Political economy of tobacco control in low-income and middle-income countries: lessons from Thailand and Zimbabwe. Geneva, World Health Organization, Global Analysis Project Team, *Bulletin of the World Health Organization*, 2000, 78:7.

such opposition should be reason for concern, because it may suggest that manufacturers have concluded a proposal poses little threat to their interests. Opposition can be expected from local manufacturers, especially state-owned enterprises, but multinational manufacturers are usually behind massive campaigns of opposition. Even in a country where multinationals have only limited market presence, they may nevertheless be the secret masterminds of a comprehensive campaign to defeat legislation.[18]

These campaigns have several features in common:

- They work to shift public attention away from health issues—where the overwhelming facts make it difficult for opponents to mount persuasive arguments—toward other issues such as fear of job losses or other economic fears, or arguments about "rights" and "choice." The goal is to distract attention, raise a flurry of opposing voices from different directions, and confuse the debate.
- These campaigns may have lavish financing, some of it open and much of it indirect or hidden. Tobacco companies have been known to spend millions of dollars on television advertising campaigns to defeat legislation. They are among the largest contributors to politicians' election campaigns and to political parties. They direct money to charities favoured by political leaders. They use their financial power to mobilize resistance from groups dependent upon them, including their distributors, retail sellers, tobacco growers, advertising agencies, and the publishers and broadcasters dependent upon their advertising.
- To reduce their own visibility, manufacturers usually oppose legislation by working through surrogates. This includes mobilizing and funding opposition from growers, sellers, smokers and others, as well as creating phoney "front groups" or co-opting the agendas of legitimate groups.[19]
- To further conceal their role and create the appearance that the legislation is opposed by a diverse group of neutral experts and objective observers, tobacco companies frequently make secret payments to third parties to criticize policy proposals. This has included secret payments to scientists in dozens of countries, payments to journalists, payments to labour union leaders, payments to advisers to top government officials, and, of course, payments to lawmakers.
- Tobacco companies will use every available mechanism for disrupting or

[18] See, e.g., the Egyptian case study in Chapter XII and Hammond R, White C. *Voices of Truth Volume I, Multinational Tobacco Industry Activity in the Middle East: a Review of Internal Industry Documents*. World Health Organization, 2002, at 13-15. http://www.emro.who.int/tfi/tfi.htm, describing a secret Philip Morris strategic plan to defeat a 1993 proposed advertising ban in Egypt.

[19] See, e.g., Political economy of tobacco control in low-income and middle-income countries: lessons from Thailand and Zimbabwe. Geneva, World Health Organization, Global Analysis Project Team, *Bulletin of the World Health Organization*, 2000, 78(7), describing the role of multinational tobacco companies in the formation and manipulation of the International Tobacco Growers' Association.

impeding the proposal. If possible under the country's legal system, they may force officials to produce the government's internal plans for the legislation, either to understand and defeat the government's strategies, or to burden and harass the officials. They may bring costly and time-consuming legal actions to challenge or pre-empt the legislation. Further, they may arrange for third parties to accuse officials or advocates of personal or professional misconduct, or create a political scandal in connection with some unrelated matter, to distract, frighten and exhaust the champions of the legislation.

"Building the political commitment to take on a difficult struggle is only part of the challenge; that commitment must be sustained when opposition stiffens, momentum slows and the outcome becomes uncertain."

Uncertain political will

A final obstacle to successful legislation is the need to generate and sustain sufficient political will to overcome powerful opposition.[20] This must be done at several levels: among the staff-level government professionals or others who will become the personal champions of the issue; among the senior political leaders of the government or political party supporting the measure; and among the parliamentarians who sponsor the measure in the legislative body. Building the political commitment to take on a difficult struggle is only part of the challenge; that commitment must be sustained when opposition stiffens, momentum slows and the outcome becomes uncertain.

If the general level of awareness of tobacco issues is low among the public and decision-makers, and if public health infrastructure and capacity for advocacy are limited, then building the initial will to act may take time. However, the explosion of knowledge in recent years about the health effects of tobacco, the effectiveness of policy interventions and the conduct of tobacco companies has made this process less difficult. The negotiation process for the WHO FCTC has accelerated global understanding of these issues, laying further groundwork.

The true challenge, however, is likely to be in sustaining the will to act over an extended period. As opposition mounts, and political pressure becomes intense, political leaders will find many

[20] The WHO Framework Convention on Tobacco Control acknowledges that developing the necessary comprehensive measures requires "strong political commitment." WHO Framework Convention on Tobacco Control, Article 4, Paragraph 2.

temptations to change course. Over time, priorities may shift as new issues come to the fore. Tobacco companies may threaten to close facilities, or may offer politicians campaign contributions or other payments. Choices that seemed clear at the outset may appear more ambiguous as powerful interests object, or as the proposal appears to lose popularity. In this environment, it may become easy for the government to lose enthusiasm for tobacco control.

This challenge makes preparation critical. Before initiating legislation, not only must adequate groundwork be laid, but those involved must also have a full understanding of the commitment required and the likely difficulties. For this reason, champions of the legislation should understand these risks and the need for an unwavering commitment to the project.

The role of this guide

This guide to tobacco control legislation is a tool for overcoming these obstacles. As attention to the epidemic of tobacco use has increased, more countries have turned to WHO for technical advice and assistance in responding. Through its Tobacco Free Initiative (TFI) and regional offices, WHO has answered these requests by organizing international consultations, providing direct support and assistance, and developing background and technical materials. Perhaps most importantly, it helped to make the three-year negotiating process for the WHO FCTC an intensive "global university" in the underlying medical, scientific and policy issues of tobacco prevention and control.

"WHO has begun developing a series of practical and complementary tools to support the national capacity-building process and the successful implementation of the WHO FCTC. "

As the treaty has been negotiated, the need for support and assistance in developing legislation has intensified. Countries with little or no history of legislating in this area are beginning to consider doing so. Those that ratify the WHO FCTC will accept a legal duty to adopt or strengthen their legislative, administrative or other policy measures, and, indeed, the momentum built in the global negotiating process can be expected to foster interest in legislation in many countries, independent of the countries' decisions on treaty ratification. To ease this process, WHO has begun developing a series of practical and complementary tools to support the national capacity-building process and the successful implementation of the WHO FCTC.

Against this backdrop, WHO has prepared this guide as one such tool, recognizing that, in many countries, those who take up

this assignment may be professionals whose backgrounds are not in the fields of advocacy or legislation. In many countries, responsibility may fall to public health professionals in a ministry of health or similar office of government, whose experience is in more traditional settings for population-based health measures—community clinics, hospitals or epidemiological programmes. In other cases, leadership for the legislative process may come from NGOs with small staffs, few resources and no history of fighting for legislation. To a public health physician or an NGO advocate trained in another field, the legislative process may be completely foreign or even intimidating.

This publication removes the mystery from the process. The goal has been to combine two important perspectives: the theoretical perspective of an academic observer and the practical, hands-on perspective of a practitioner.[21] The first perspective provides a logical framework for understanding the process and the rationale for what must be done, while the second offers useful "how-to-do-it" lessons for action. From this dual perspective, this guide seeks both to familiarize the reader with the terms, concepts and procedures necessary to think intelligently about developing legislation and to give a road map for getting started.

"the goal of this guide is not to answer every question, but to help the reader know the questions to ask—and to ensure that, even if the legislative process will always remain unpredictable, it need not be intimidating."

With these purposes in mind, this guide provides an orientation to key terms and concepts involved in lawmaking. It explains the advocacy process, emphasizing the necessity of building local capacity for action and suggesting strategies for doing so, and continuing through the process of legislative advocacy, with ideas for developing a powerful and successful campaign of support. It introduces the process of legislative drafting and examines the content of key components of comprehensive tobacco control legislation, discussing many of the important considerations and policy trade-offs involved in deciding on specific proposals. It explains the critical choices involved in implementing and enforcing legislation and carefully examines the crucial, but often neglected, process of monitoring and evaluating the legislation's effectiveness. Case studies from nine countries then illustrate the application of these ideas in practice, highlighting the hard-won lessons of experience in varied legal and cultural settings. Finally, an examination

[21] As discussed in the Acknowledgements, this guide is derived in large part from valuable papers prepared by leading academicians, but also reflects the insights and suggestions of two dozen global experts, including parliamentarians, senior health officials, advocates and others, who gathered in Washington for three days in June 2002 to offer guidance on making this information practical, useful and user-friendly.

of international law and its implications for tobacco control places national legislation within its global context.

This overview is not a step-by-step rulebook for every situation. Each country is unique, and some lessons can be taught only by experience. Still, a solid introduction, illuminated by sample legislation and specific examples from many countries, can provide a head start in approaching the process and anticipating the likely problems. Thus the goal of this guide is not to answer every question, but to help the reader know the questions to ask—and to ensure that, even if the legislative process will always remain unpredictable, it need not be intimidating.

Chapter III. An introductory guide to terms and concepts

To make informed decisions about developing legislation, it is necessary to understand some of the forms that legislation may take and some of the features that distinguish different systems of government and law. These concepts, which may be axiomatic to readers who work regularly with law or legislation, are sometimes confusing to those whose expertise is in other areas.

The diversity of national governments across the world complicates the classification of legal systems into distinct categories. Still, it is useful to consider certain common features and issues that hold implications for the success of proposed policies. Similarly, "the law" can take any of several forms. Each of these types of law can be a tool for legal intervention, and an effective tobacco control strategy may use them all. Familiarity with these distinctions, and an understanding of the powers and limitations of different types of law, will equip policy-makers to:

- decide which type of legislation to pursue, and at what level of government;
- understand the likely legislative timetable within their system of law;
- consider the challenges and obstacles they will face at each phase of the legislative process;
- use multiple legal strategies in concert with one another; and
- assess whether legislative models developed elsewhere are likely to work in their own country.

"Statutes have many qualities that make them excellent instruments of tobacco control."

Statutes and other legislative enactments

The legislative interventions most frequently employed to regulate tobacco use are the laws—sometimes known as statutes—created by legislative bodies. Statutes can be enacted at the national or subnational levels, or at the municipal level—where they may be known as bylaws or ordinances. Statutes have many qualities that make them excellent instruments of tobacco control. They are binding and potentially powerful, and are enforceable through a wide variety of mechanisms. They can be used to address diverse subject matters, limited only by constitutional restrictions on the

government's legislative power. Through statutes, legislative bodies can not only regulate the actions of tobacco companies and other private parties (e.g. by banning advertising, requiring warning labels or ingredient disclosures and controlling sales practices), but also generate revenue (by raising taxes, fees or duties) and form new agencies and programmes. Often, statutes combine multiple subjects to create a comprehensive act, making them well suited for creation of a comprehensive tobacco control programme.

Statutes are semi-permanent, ordinarily remaining in force until they are repealed or replaced by another statute, or are overturned by decision of a court. Despite this durability, they are readily amended to reflect changing circumstances. This legislative flexibility is particularly advantageous in countries with rapidly evolving political, social, health or economic conditions. In addition, where comprehensive legislation is not possible initially, amendments may allow a country to proceed by steps toward a more comprehensive programme, as has been done in South Africa and Poland.[22]

"In most countries, tobacco control policies are the result of national legislation."

National legislation

In most countries, tobacco control policies are the result of national legislation. By 1993, 91 countries had enacted such national laws,[23] and since that time, many more have enacted new laws or strengthened their existing legislation.[24] As discussed in Chapter V, this national approach has both advantages and disadvantages, as compared to the use of legislation at a subnational level.

Distribution of legislative powers

The distribution of legislative and executive powers among different levels of government varies considerably among countries. This will affect the decision whether to proceed at the national level. Often, power is highly concentrated in a centralized national government, with little legislative authority permitted to regional or local governments. In these "unitary systems," the national

[22] The South African and Polish experiences are described in Chapter XII.
[23] Roemer R. *Legislative Action to Combat the World Tobacco Epidemic*, 2nd ed. Geneva, World Health Organization, 1993, xi.
[24] See, for example, national laws compiled by the "NATIONS" database maintained by the World Health Organization and the United States Centers for Disease Control, at web site: http://apps.nccd.cdc.gov/nations/nations/Country_Specific_indicators.asp, and laws collected by Globalink, the worldwide electronic tobacco control network, at http://www.tobaccopedia.org/.

legislative body has exclusive responsibility for the promulgation of tobacco control laws and may be the only avenue for legislation.

Other countries (e.g. Argentina, Australia, Canada, Mexico and the United States of America) have a "federal" system of government, in which subnational governments have varying degrees of inherent authority, independent of the national government. In these systems, the power to make laws is shared between the subnational governments and the national legislative body. The national government may enact some types of tobacco control policies, while leaving regional or local governments significant power to legislate in other areas of tobacco control. For example, the national government may prescribe warning label requirements for cigarette packets, while allowing other units of government to regulate the places where public smoking is permitted, as is done in the United States of America. Or, as frequently happens, the national and subnational governments may have simultaneous and overlapping powers.

"Proponents of tobacco control legislation need to understand the division of power in their country, to know which level or levels of government have the power to enact a proposal, and to decide which of these options will provide the most effective results."

Many countries are hybrids of these two models, with various forms of power sharing or allocation of responsibilities among the different levels of government. Proponents of tobacco control legislation need to understand the division of power in their country, to know which level or levels of government have the power to enact a proposal, and to decide which of these options will provide the most effective results.

Form of electoral representation

Another consideration may be the country's form of electoral representation. In the system known as proportional representation, citizens vote for a political party and its candidates. Parties receive seats in the legislative body in proportion to the party's share of the popular vote in the election, so that a party receiving one-third of the vote will constitute one-third of the legislative body. This system allows small political factions to be represented, encourages wide diversity of parties, and lends itself to coalition governments. If other alternatives are available, advocates may be wary of pursuing tobacco control laws in legislatures where the composition of representatives is shifting or the government coalition is unstable. Sustaining long-term support for controversial proposals in these settings may be difficult.

In contrast, a plurality system of representation uses a "winner take all" approach to elections: the candidate who receives the most votes wins. Thus a representative may take office with the support of barely half—or, in a contest with multiple candidates, less than half—of the voters. In countries with this system, the legislative body may not reflect the political composition of the public, and legislators' views on tobacco control may not reflect the level of support among the public.

In these plurality systems, it can sometimes be difficult to enact legislation, even with broad public support. Conversely, it may be possible, with the support of the government, to enact legislation even without corresponding public support. This result can be equally risky, because successful implementation of some tobacco legislation—for example, smoke-free policies—depends, ultimately, on public support. Thus, in plurality systems, advocates for tobacco control legislation need to build support both within the legislative body and in the public at large.

National electoral system

Finally, and independent of the question of whether legislators are elected through proportional representation or plurality representation, many countries use an electoral system in which leadership of the national government and control of its executive departments are determined by vote of the legislative body. In this system, sometimes known as a parliamentary system, the political party or coalition of parties controlling the legislative body also controls the national government, including the health ministry or other agency responsible for health matters. This means that tobacco control legislation developed by the health ministry or national government under this system ordinarily commands the support of a majority of the legislative body and will have relatively higher expectation of legislative success. In these countries, building legislative support for a proposal developed by the government will not represent the same challenge as it may elsewhere.

In other countries, the national leader is elected directly by the public, independently of members of the legislative body, and controls the health ministry and other executive agencies. In these countries, the political party controlling the national government, including the health ministry, will not necessarily hold a majority of votes in the legislative body. Where this is the case, there is no assurance that legislation proposed by the government and its health specialists will be able to win support of members of the legislature, thus the need for an effective campaign to build legislative support will be paramount.

Subnational legislation

In some countries, tobacco control legislation has been most successful at subnational levels. In Brazil, for example, a strategy of developing legislation at the municipal level has worked with remarkable success, and has reinforced the country's strong national laws.[25] In

[25] A case study describing Brazilian legislative experiences appears in Chapter XII.

Canada, the Province of British Colombia has enacted pioneering laws requiring manufacturers to disclose ingredients and setting liability standards for tobacco litigation, while dozens of municipalities have passed local legislation ("bylaws") requiring smoke-free public places. In the United States of America, most tobacco control legislation is at the state and municipal level, with every state and many cities regulating tobacco sales to minors, and with some states, and literally hundreds of cities, enacting laws to require smoke-free public places and workplaces.[26]

"Subnational laws offer several distinct advantages over national legislation, but also come with disadvantages. Advocates must weigh these competing considerations carefully to decide which approach offers the greatest promise in their country.[27]"

Subnational laws offer several distinct advantages over national legislation, but also come with disadvantages. Advocates must weigh these competing considerations carefully to decide which approach offers the greatest promise in their country.[27]

A local or regional approach is not an option, of course, if these units of government lack the underlying legal authority to enact laws addressing matters of public health such as tobacco control. This will depend on a country's general system of government and constitutional limitations on the powers of lesser governments. Tobacco companies and their allies have frequently challenged the legislative power of local governments. To date, few of these efforts have succeeded.[28]

"Some aspects of tobacco control may, by their nature, require a single national policy; regional or municipal governments may not be legally authorized to legislate in these areas. Even if legal authority exists, these areas may be best addressed at a higher level."

This analysis varies from country to country, however, and may also depend upon the particular tobacco control policy in question. Some aspects of tobacco control may, by their nature, require a single national policy; regional or municipal governments may not be legally authorized to legislate in these areas. Even if legal authority exists, these areas may be best addressed at a higher level. For example, warning-label requirements for cigarette packaging or bans on broadcast advertising may be impractical at the municipal level.

Pre-emption

If municipal or regional governments have the underlying power to legislate, then there remains the additional question of whether a higher level of government has nevertheless barred these

[26] A case study describing subnational legislation in the United States of America appears in Chapter XII.
[27] These tradeoffs are discussed in Chapter V.
[28] A discussion of the success of local and state legislation in the United States of America, and of the related issue of legal pre-emption, prepared by the NGO Americans for Non-smokers' Rights, can be found at web site: http://www.no-smoke.org/pospre.html.

lesser governments from acting in a particular area, such as tobacco control. This concept, known as legal "pre-emption," rests on the idea that the national government holds a country's ultimate lawmaking authority—authority that ordinarily includes the power to circumscribe the lawmaking powers of subordinate units of government. Where the national government "pre-empts" lesser governments from acting, whether by enacting an express decree stripping them of power, or by fashioning its own legislation with such a level of detail that, by implication, the national government has shown an intent to reserve this entire subject area exclusively to itself, then subnational governments are precluded from lawmaking. The possibility of pre-emption exists equally where an intermediate level of government, such as a state or province, takes steps to pre-empt legislation by municipal authorities.

"Pre-emption is a frequent source of litigation by the tobacco industry and its supporters, particularly in countries with federal systems of government."

Pre-emption is a frequent source of litigation by the tobacco industry and its supporters, particularly in countries with federal systems of government. Advocates report, and tobacco company documents confirm, that the tobacco industry works strenuously to block the adoption of legislation at lower levels of government, because its political influence is usually most concentrated, and most powerful, at higher governmental levels. The proliferation of many legislative campaigns in local or regional governments necessarily dilutes that influence. Thus, in federal systems, legislation at the local or regional level is often stronger and more threatening to the tobacco industry than the legislation that can be enacted at the national level.

"Understanding which governments have the power to act and anticipating potential issues of pre-emption will help advocates avoid conflicts among levels of government and avoid strategies that may be vulnerable to legal challenge."

Accordingly, the industry actively promotes legislation to pre-empt or block action by lesser governments, and frequently challenges municipal or regional laws in courts, arguing that these laws are invalid because the authority of these governments has been pre-empted. Pre-emption arguments have been used successfully, for example, to invalidate regulations restricting tobacco advertising in the State of Massachusetts in the United States,[29] and to overturn legislation imposing business franchise fees on tobacco in the State of New South Wales in Australia.[30]

These issues make it important to consider the distribution of legislative power among levels of government. Understanding which governments have the power to act and anticipating potential

[29] See Lorillard Tobacco Co. v. Reilly 121 S. Ct. 2404 (2001).
[30] Ngo Ngo Ha and Anor v State of New South Wales & ORS; Walter Hammond & Associates Pty Limited v State of New South Wales & ORS (1997) 146 ALR 355.

issues of pre-emption will help advocates avoid conflicts among levels of government and avoid strategies that may be vulnerable to legal challenge.

Administrative regulations

Administrative regulations are the rules or decrees made by administrative agencies of government, acting on the basis of authority delegated to them by the legislative body. In some countries where administrative rules have the same effect as statutes passed by the legislature,[31] advocates for tobacco control may choose to pursue tobacco control strategies at the administrative level.

"In some countries where administrative rules have the same effect as statutes passed by the legislature, advocates for tobacco control may choose to pursue tobacco control strategies at the administrative level."

National and subnational legislative bodies often delegate rulemaking authority to agencies of government with specialized skills. Although the degree to which legislatures defer to the expertise of these agencies varies, as does the level of resources available to agency administrators, this approach is usually used to address issues that are complex and highly technical, requiring detailed regulation based on highly specialized expertise. Unlike legislative bodies, administrative agencies are staffed by professionals with the specialized expertise and knowledge to formulate these detailed measures. Typically, legislators enact a general statute setting out legislative goals, creating the broad framework of the intended system of regulation and empowering the appropriate ministry or bureau to elaborate more detailed law by fashioning rules consistent with the goals of the statute.

Tobacco control is well suited to administrative regulation. Aspects of tobacco regulation involve the interaction of complex factors requiring extensive knowledge of public health, medicine, economics, commerce, environmental health, communications, marketing and law enforcement. Some aspects of tobacco control, such as the formulation of ingredient disclosure standards, warning labels or product content regulations, require standards much more specific and detailed than most statutes, and may require frequent revision. For these reasons, lawmakers frequently assign administrative agencies—usually a health ministry or comparable bureau—to develop rules in this area. Rulemaking for specific aspects of tobacco control may also be assigned to agencies with expertise in areas other than health: for example, a finance ministry

[31] *Evaluating tobacco control activities: Experiences and guiding principles*. Geneva, World Health Organization, 1996, 205

might adopt rules concerning excise taxes, while a customs bureau might develop rules related to import duties or smuggling.

"Depending on the country, adopting rules may be faster and easier than enacting legislation, or may be slow and cumbersome. In some countries, rulemaking involves few procedural steps and takes place behind closed doors; in others, rules are only adopted after a lengthy and open process of public consultation."

Agencies may be given relatively unbridled authority to fashion a comprehensive programme, or may be limited to "filling in" specifics in particular areas. In Thailand, the National Assembly passed the 1992 Tobacco Products Control Act, outlining several tobacco control goals and policies. The Ministry of Health was empowered to regulate the composition of cigarettes, designate non-smoking areas, and promulgate other specific rules that further the purposes of the Act.[32] In Canada, Parliament authorized the Minister of Health to require warning labels on tobacco products, leaving the Minister to prescribe, through rules, the content, design and typeface of the warnings, and that they be bi-lingual.[33]

Procedures for rulemaking vary. Depending on the country, adopting rules may be faster and easier than enacting legislation, or may be slow and cumbersome. In some countries, rulemaking involves few procedural steps and takes place behind closed doors; in others, rules are only adopted after a lengthy and open process of public consultation. The resources available to administrative agencies also vary greatly. These variables will affect the attractiveness of administrative regulations as an alternative to legislation in a given country.

"Voluntary agreements are fraught with problems and should be ordinarily avoided."

Voluntary agreements

"...voluntary agreements serve the industry well and the public badly."

Another device for setting standards—one that should ordinarily be avoided—is a voluntary agreement. A voluntary agreement is a written record of unilateral commitments or mutual obligations. In unilateral agreements, one party expresses its desire to self-regulate its behaviour. For example, the advertising industry in some countries has adopted a code of practice promising to limit the advertising and promotion of tobacco products in certain circumstances. In contrast, with multilateral agreements, two or more parties assume mutual obligations and responsibilities. Although voluntary agreements often address subjects appropriate for traditional legislative approaches, these agreements are not laws. Unlike statutes or administrative regulations, voluntary agreements (a) do not undergo the usual law-making process, (b) are not subject to judicial review, and (c) are generally non-binding and

[32] The Thai legislation is described in Chapter XII.
[33] Tobacco Act, S.C. 1997, ch. 13. (amended by S.C. 1998, ch. 38).. See discussion of the Canadian legislation in Chapter XII.

unenforceable by the government. There are often no legal consequences, such as fines, injunctions or sanctions, for violating the agreements.

While voluntary agreements may have some value in certain narrowly limited circumstances, they are laden with problems.[34] As discussed in Chapter V, they are frequently ignored in practice and are often proposed by the tobacco industry and its allies as a ploy to avoid genuine solutions. In the words of a Parliamentary inquiry in the United Kingdom of Great Britain and Northern Ireland, where voluntarily agreements were formerly used to "regulate" tobacco advertising, "voluntary agreements serve the industry well and the public badly."[35]

Constitutional law

Constitutional law is the highest and most fundamental form of law in most countries. Constitutions, whether at the national or subnational level, generally prescribe the structure of the government; the basic guiding principles and character of the government; the distribution of power among the sub-units of the government; structural limitations on the power of the government; and the fundamental rights and freedoms guaranteed to citizens. Unlike other types of law, constitutional language is stable and changes infrequently.

Because of its breadth, constitutional law is unlikely to offer a direct avenue for tobacco control legislation. Nevertheless, a nation's constitutional law is important, because it can both support and thwart legislation. First, a constitution may contain provisions that lend support to arguments for adoption of legislation. Constitutions in some countries (e.g. Bangladesh, India and the Philippines), guarantee citizens the right to life and health, and create a fundamental obligation on the part of the government to protect these rights. Though broad, these obligations do provide a legal argument for adoption of legislation to address the leading cause of preventable death and disease. In India and Uganda, they have even been used to support litigation to compel governments to regulate tobacco use.

Conversely, constitutions may limit a nation's ability to legislate for tobacco control. Fundamental rights guaranteed by the constitution, or constitutional limits on the powers of the legislative body, may provide a basis for successful legal challenges to tobacco control legislation. In some countries, courts may interpret a constitutional guarantee of freedom of expression as prohibiting the legislature from banning tobacco advertising. Or courts may determine that tobacco control legislation at the subnational level exceeds the constitutional authority of the subnational government. Understanding the possible constitutional issues will help advocates shape legislation to avoid possible legal challenges.

[34] Voluntary agreements should be viewed as a strategy of last resort for use only when other legal strategies, such as enacting statutes, promulgating regulations, or litigating a case in court, are clearly impossible. For example, in some countries, certain legal advertising restrictions might be struck down under judicial review as violating constitutionally guaranteed rights to free speech. However, the tobacco industry might voluntarily agree to these restrictions as part of a larger agreement that carries no penalties for violations, or as a voluntary concession in settlement of litigation. Even in these exceptional cases, enforcement of the agreement often remains a concern.

[35] House of Commons, Select Committee on Health, Second Report: *The Tobacco Industry and the Health Risks of Smoking*. HC 27-I, 14 June 2000.

"Understanding the possible constitutional issues will help advocates shape legislation to avoid possible legal challenges."

The role of the courts

"Courts, too, make law. Through the process of judicial review, and by deciding cases, they define legal rights and powers in ways that may determine the fate of a tobacco control initiative."

Courts, too, make law. Through the process of judicial review, and by deciding cases, they define legal rights and powers in ways that may determine the fate of a tobacco control initiative. Judicial review refers to the process by which judges and courts may overrule, modify, or advise on a given law. Generally, the power of judicial review is exercised by a national-level body, sometimes called a supreme court, council or tribunal. Lesser courts may also make decisions at subnational levels. The authority of the national court to rule on legislative matters varies significantly by country. In some countries, the court may only consider legislative matters if they pertain to national-level or constitutional issues. In other systems, the court may offer advice on legal matters based on the facts of a given case. Depending on the legal tradition, the rulings of the supreme judicial body may serve as binding precedents on future matters. Alternatively, the court's decisions may carry only persuasive value in future cases. In some countries, courts can review the legality of a statute only if an appropriate citizen or member of the government has formally requested the review. Elsewhere, courts are free to review laws on their own prerogative. While the authority to review laws is frequently determined by the national constitution, in practice, the extent of review may be influenced greatly by the personalities and philosophies of individual members of the court.

"Judicial review can have a critical impact on tobacco control legislation, especially in countries with powerful judiciaries."

Judicial review can have a critical impact on tobacco control legislation, especially in countries with powerful judiciaries. It is through this process that a legal challenge to the legislation—for example, a challenge by the tobacco industry on the grounds of alleged pre-emption, as discussed above—will be decided. Those developing legislative proposals should consider:

- who has authority to review the proposed law and how much discretion they are afforded;
- whether the proposed law conflicts, either expressly or implicitly, with provisions of the national constitution;
- who might be likely to challenge the legislation;
- how the court is likely to rule on the challenge; and
- how the legislation could be modified to better

withstand judicial review.

Courts also make law by deciding cases, in what is known as case law. Historically, this process was associated with countries whose jurisprudence is grounded in what is known as the common law, in which many of a society's legal rules are made by judges, through the continual process of deciding individual cases. In common-law legal systems, in particular, entire fields of law are governed, not by statutes, but by the decisions of courts in individual cases. In other countries, notably those where the jurisprudence rests on a comprehensive civil code, the underlying premise, historically, was that legal rules were made only by legislative bodies, and that the judges were not to "make" law, but only to apply the law, as set by lawmakers, to individual cases. Over time, the once-sharp distinction between these approaches has blurred.

It is through the case law or common law process that most tobacco litigation is decided. In many countries, for example, legal cases based on theories of negligence, deception, and other theories of manufacturer liability are common-law matters, making common law a critical component of litigation against tobacco manufacturers by injured smokers. When deciding a case or controversy, judges examine previously decided cases to understand how other courts have dealt with similar matters in the past.

In common law legal systems, the principles and rules articulated in these earlier cases can have theoretically binding force in later cases, and the accumulated body of cases, or "precedents," is sometimes known as the "common law" of that jurisdiction. In theory, this distinguishes common law systems from those based in civil codes, where judges look primarily to legislative enactments for guidance. In practice, however, this distinction is less sharp. Because no two cases are ever exactly alike, judges in common law systems constantly re-interpret, adapt and qualify prior rulings to accommodate the circumstances of each individual controversy. Once a ruling is reached, the judge's written decision is officially recorded and becomes part of a growing body of common law. In general, high courts may overrule and invalidate the common law decisions of lower courts.

Introductory concepts in international law

While the preceeding discussion in this chapter encompasses terms and concepts on national law, this section will define certain terms and concepts related to the discussion on international law, found in Chapter XIII: Tobacco control and international law.

International law consists of rules and principles which govern the relations of nations with each other. Article 38.1 of the Statute of the International Court of Justice sets forth the generally accepted sources of international law, one of which is treaty law.

Treaty law involves "international conventions, whether general or particular, establishing rules expressly recognized by the contesting states." As treaty law is the primary source of international rules related to tobacco, the discussion in Chapter XIII focuses on

treaty law rather than other sources of international law. The Vienna Convention on the Law of Treaties that entered in force on 27 January 1980, is the authoritative source of law and procedure for creation, operation and termination of a treaty. The full text of the treaty can be accessed at http://www.unog.ch/archives/vienna/vien_69.htm.

The Vienna Convention on the Law of Treaties defines a treaty as "an international agreement concluded between states in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation." Treaties may be either bilateral or multilateral in nature. A bilateral treaty is generally one between two states; a multilateral treaty represents agreement between three or more states. Chapter XIII also discusses regional treaties in the areas of trade and human rights; these are multilateral within a specific region.

There are many different names for a treaty, such as convention, framework convention**,** protocol**,** covenant or pact. The WHO Framework Convention on Tobacco Control (WHO FCTC) is a framework convention, a type of international agreement that establishes legal parameters and structures. If the political will exists, detailed provisions can also be included in the framework convention itself. Protocols to a framework convention are separate, detailed agreements that build upon the substantive provisions elaborated in the framework convention; these are specific measures designed to implement goals of the framework convention or to add further institutional commitments.

International instruments can be generally classified as either legally binding instruments or as non-binding international resolutions. For example, comprehensive treaties or conventions, the framework convention-protocol approach, and international regulations are legally binding; while resolutions (expressions of common interest of numerous states in specific areas of international cooperation) are non-binding and do not normally entail any substantive commitments of a legal nature. The importance of non-binding instruments should not be underestimated; while they are more flexible than legally binding instruments, they play an important role in developing international norms.

As a general rule, treaties are binding only upon those states that have consented to them; the process of consenting to a treaty are described in more detail below. While a treaty represents the express legal rights and obligations to which all the parties of the treaties have agreed, at times there may be certain provisions of a treaty that one or more parties refuse to accept. A reservation is defined in the Vienna Convention on the Law of Treaties as "a unilateral statement, however phrased or named, made by a State, when signing, ratifying, accepting, approving or acceding to a treaty whereby it purports to exclude or modify the legal effects of certain provisions of the treaty in their application to that State." An interpretative declaration aims to clarify a State's understanding of certain provisions of a given treaty. Like reservations, interpretative declarations are unilateral acts, but can be made at any time whereas a reservation must be formally confirmed by the State at the time of expressing its consent to be bound by a given treaty (Article 23 (2)), when ratifying, accepting or approving it.

Steps in the treaty-making process

Steps in the treaty-making process include, but are not limited to, adoption; deposit; signature; and ratification, acceptance, approval, formal confirmation or accession. These are summarized below, with particular reference to the WHO FCTC; a figure is provided at the end of the section.

Adoption is the formal act through which the form and content of a proposed treaty text is established. Final acts of an adopting forum will include the adoption of the convention text; confirmation that the text is identical in all languages, resolutions with respect to interim arrangements; financial arrangements and so forth; and a Final Act. In May 2003, the Final Draft Framework Convention on Tobacco Control was submitted to the Fifty-sixth World Health Assembly. The WHO FCTC was adopted unanimously by the World Health Assembly by means of a resolution to this effect, standard practice with respect to the adoption of treaties by international organizations. The text as adopted unanimously by the World Health Assembly is the text that was deposited with the Secretary-General of the United Nations and opened for signature.

The Convention was deposited with the Secretary-General of the United Nations, in accordance with WHO FCTC Article 37. The depositary of an international treaty is responsible for preparing the original text of the Convention in all authentic languages and receives signatures, as well as any instruments, notifications and communications related to the Convention, and notifies all interested parties accordingly.

Signature is the act whereby a State expresses its consent to the text of the treaty, but not its consent to be bound by it. A State that has signed a treaty that is subject to ratification is not obliged to ratify it; instead, signature represents an act expressing political approval of the treaty concerned, and raises an expectation that the signatory will in due course take the appropriate domestic actions to become a contracting party. Signature produces limited rights and obligations even before entry into force: a signatory has the right to receive notifications by the depositary concerning the treaty and is obliged to refrain from acts which would defeat the object and purpose of the treaty, until it has made it clear that it does not intend to become a party to the treaty.

Article 34 of the WHO FCTC provides that the final text of the treaty will be opened for signature by WHO Member States, and by any States that are not WHO Member States but are members of the United Nations and by regional economic integration organizations, during the following periods:16 June to 22 June 2003: at the WHO headquarters in Geneva; and 30 June 2003 to 29 June 2004: at the United Nations headquarters in New York.

Ratification, acceptance, approval, formal confirmation or accession involve the deposit (to the treaty depositary) of written instruments providing formal evidence of consent of a state or a regional economic integration organization to be bound by an

international agreement. According to Article 35 of the WHO FCTC, states may consent to be bound through ratification, acceptance, approval or accession; regional economic integration organizations may consent to be bound through formal confirmation or accession. These terms differ as follows:

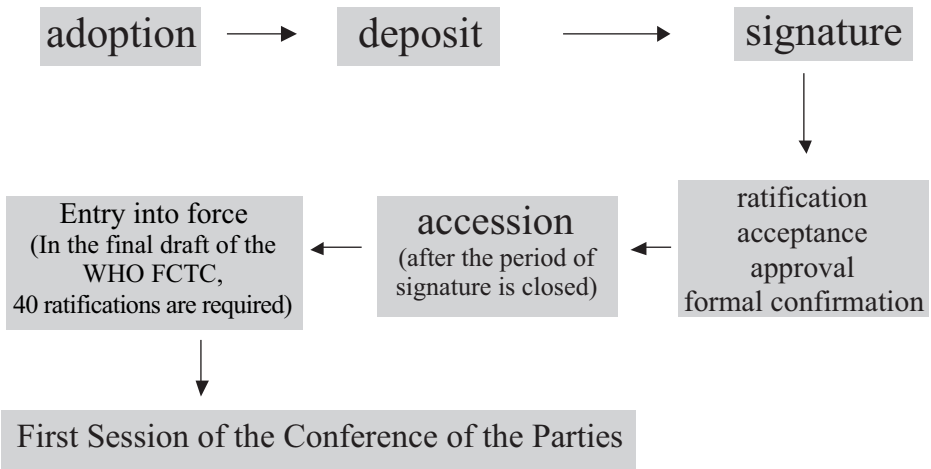
- *Ratification* describes the international act whereby a state indicates its consent to be bound by a treaty. For multilateral treaties (such as the WHO FCTC), instruments of ratification are collected by the depositary.
- *Acceptance* and *approval* have the same legal effect as ratification; these terms are used instead of "ratification" in certain States in which national constitutional law does not require the treaty to be ratified by the head of state.
- *Formal confirmation* has the same legal effect as ratification; this is the term for the procedure by which an international organization (such as a regional economic integration organization) indicates its consent to be bound by a treaty.
- *Accession* also has the same legal effect as ratification. Accession differs from ratification, acceptance, approval or formal confirmation in that it is not preceded by signature. Accession will therefore be an option for those States or regional economic integration organizations which have not signed the Convention before the date on which it is closed for signature. According to Article 35 Paragraph 1 of the WHO FCTC, the Convention will be open for accession from the day after the date on which it is closed for signature, i.e. from 30 June 2004.

Entry into force of the convention refers to the point at which the Convention becomes effective and binding for States that have ratified the Convention. Article 36 paragraph 1 of the WHO FCTC provides for entry into force on the 90th day following the date of deposit of the 40th instrument of ratification, acceptance, approval, formal confirmation or accession by Member States or regional economic integration organizations.

This means that 40 Member States or regional economic integration organizations would need to ratify, accept, approve, formally confirm or accede before the Convention becomes effective and binding for those Parties. The Convention would then enter into force for those Member States or regional economic integration organizations which had indicated their consent to be bound by the treaty 90 days after the 40th instrument of ratification, acceptance, approval, formal confirmation or accession was received. For those States or regional economic integration organizations ratifying, accepting, approving, formally confirming or acceding to the Convention after it has entered into force, the Convention would enter into force on the 90th day after the date of deposit of their instrument of ratification, acceptance, approval or accession.

The internal procedures for consent to be given by each State vary according to the constitution of each State or the statutory arrangements of regional economic integration organizations.

The Conference of the Parties will be the governing body of the Convention that advances implementation of the Convention through the decisions it takes at its periodic meetings after the WHO FCTC enters into force. Article 23 of the WHO FCTC provides for the establishment of a Conference of the Parties, the governing body of the Convention, immediately upon its entry into force. This body "shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation and may adopt protocols, annexes and amendments to the Convention, in accordance with Articles 28, 29 and 33."



Law of Regional Economic Integration Organizations

European Community law constitutes an independent legal system that takes precedence over national legal provisions. There are three general sources of European Law: these are primary sources (treaties), secondary sources (legislation) and tertiary sources (case law). Secondary sources are based upon EC treaties and may include regulations, directives, decisions, and recommendations or opinions. Regulations are automatically law in all EU Member States, and need no national implementing legislation. Directives bind Member States as to the objectives to be achieved within a certain time-limit; national authorities have the choice of method to use in achieving these objectives. Decisions are addressed to a specific party (this could be a company, and individual or Member State) and are binding to those Member States, enterprises or individuals to which they are addressed; they require no national implementing legislation. Recommendations and opinions are not binding but are persuasive.

Chapter IV. Foundation for success: capacity-building

Before beginning a campaign for tobacco control legislation, advocates must first consider their country's institutional "capacity" to support the effort. This capacity, in the form of the necessary human resources, technical expertise, financial resources, and political will, is the essential foundation for success. Without adequate capacity, in terms of both the quantity and quality of the resources potentially available to support tobacco control, a country is unlikely to be able to develop scientifically valid proposals, build the necessary political support for enactment, or sustain meaningful enforcement after the legislation is in place.

"Without adequate capacity, in terms of both the quantity and quality of the resources potentially available to support tobacco control, a country is unlikely to be able to develop scientifically valid legal proposals, build the necessary political support for enactment, or sustain meaningful enforcement after the legislation is in place."

Capacity matters: developing the ability, finding the will

The need for appropriate national capacity cannot be overstated. Building political, managerial, technical, institutional and legal capacity at the national level is key to long-term sustainability of tobacco control. For many countries, the necessary first step toward legislation may therefore be to improve the country's ability to plan and implement a comprehensive programme.

This capacity-building process involves strengthening and supporting the country's institutional and human capacity to assess, plan, develop, monitor and evaluate comprehensive tobacco control in ways that reflect national realities and priorities. This may be a difficult and lengthy process. Insufficient financial and technical resources, and lack of sufficient knowledge and experience, may hinder the country's ability to develop a multisectoral law.[36] The health and socioeconomic impacts of the tobacco epidemic may not be widely recognized. Existing health capacity may not be available for use in tobacco control. Existing tobacco control policies may be ineffective because a lack of human, institutional and financial resources prevents meaningful enforcement.

"In a country with limited existing capacity, those interested in tobacco control may find it strongly tempting to proceed with legislation without first working to expand this national infrastructure. In most cases, this is likely to be a mistake."

In a country with limited existing capacity, those interested in tobacco control may find it strongly tempting to proceed with legislation without first working to expand this national infrastructure. In most cases, this is likely to be a mistake. Even if legislation has the support of the government, putting legislative efforts ahead

[36] Onzivu W. Public Health and the Tobacco Problem, International Legal Implications for Africa, *Georgia Journal of International and Comparative Law,* 29, *223-52,* at 243 (2001), concluding that tobacco control in Africa continues to be ad hoc, with no meaningful legislation in most of the countries.

of capacity-building is likely to lead to problems, if not in winning adoption of the law, then in implementing it and sustaining support for tobacco control over time.

Increased capacity and strengthened political will go hand in hand. As the national infrastructure grows, as awareness of the evidence about tobacco and health increases, as the number of organizations concerned about these issues increases, as centres of expertise deepen their knowledge, and as the core group of individuals dedicated to the success of tobacco control expands, political support will grow with them. It is this base of political support and commitment that will provide the foundation for success.

Champions

"...one of the keys to success is the involvement of leaders whose commitment to tobacco control is personal, heartfelt and unshakeable."

Because tobacco control legislation is commonly met with fierce opposition, successful advocacy requires not only knowledge and resources, but also passion. For this reason, one of the keys to success is the involvement of leaders whose commitment to tobacco control is personal, heartfelt and unshakeable. Ideally, these individual champions will combine commitment with knowledge, wisdom, imagination, courage and tenacity. Champions may come from anywhere: a public health official within the ministry of health, an advocate from an outspoken nongovernmental organization (NGO), a member of the legislative body, a health professional, a leading expert from a university or research centre, or even a national political leader. The potential impact of even one such champion cannot be overstated; in many countries, a single such leader has been the catalyst for national change. It is highly important to identify and nurture these leaders whenever possible.

Getting started: a national focal point

"An essential starting point for developing a nation's capacity is the designation of a national focal point for tobacco control within the government. One highly successful approach to establishing a national focal point is to create a national committee, task force or working group for tobacco control."

An essential starting point for developing a nation's capacity is the designation of a national focal point for tobacco control within the government. Most often a unit within the ministry of health or comparable administrative agency, this focal point has first responsibility for organizing the nation's response to the tobacco epidemic. The focal point agency is pivotal in mobilizing other ministries and units of government to support tobacco control, reaching out to civil society, increasing public awareness, organizing training efforts to increase the core group of tobacco control advocates in the country and, eventually, developing comprehensive legislation. A focal point can begin as nothing more than a single

official with responsibility for tobacco issues, although the government's commitment must then be expanded, and support broadened within civil society, before the nation will be prepared to support a comprehensive tobacco control programme.

One highly successful approach to establishing a national focal point is to create a national committee, task force or working group for tobacco control.[37] These committees, which have been used in Australia, Brazil, China, Paraguay, Singapore, South Africa, Thailand, Zambia, and other countries, are often convened by the ministry of health, but are multisectoral. They often include representatives of other agencies of government such as ministries of finance, justice, trade, agriculture, environment, customs and education, as well as NGOs, universities, health organizations, professional associations committed to health, consumer groups and other representatives of civil society. The broadest possible representation is desirable, although organizers must be careful not to include members who will dilute the committee's commitment to its mission.

"While a committee can be created on an ad hoc or informal basis, in the long run, it is important that it be established in law, given permanent status and provided with national funding."

The purpose of these committees is to develop a national plan of action for tobacco control, and to plan and coordinate education, cessation, litigation, legislation and other activities. The most successful committees use a regular reporting mechanism to ensure accountability and allow public involvement and participation. While a committee can be created on an ad hoc or informal basis, in the long run, it is important that it be established in law, given permanent status and provided with national funding.

"In many countries, outspoken advocates from NGOs have established themselves as the leading voices for tobacco control and the driving force behind governmental action."

Getting started: civil society

Another, equally important key to success is the active involvement of civil society. In many countries, outspoken advocates from NGOs have established themselves as the leading voices for tobacco control and the driving force behind governmental action. Just as the WHO Framework Convention Tobacco Control (WHO FCTC) recognizes the participation of civil society as essential to achieving the goals of the Convention,[38] these nongovernmental voices are a critical part of the formula for legislative victory.

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[37] Roemer R. *Legislative action to combat the world tobacco epidemic*. 2nd ed. Geneva, World Health Organization, 1993, at 165.
[38] WHO Framework Convention on Tobacco Control, Article 4, Paragraph 7.

Of course, there are many voices in civil society, and many types of NGOs. Some, such as medical societies, research centres and specialized health organizations, have unique credibility and authority based on their expertise. Others, such as environmental, consumer and women's groups, may have influence based on the importance of the constituencies they represent or their skills in organizing and advocacy.

NGOs and their advocates add unique contributions to a legislative campaign, playing vital roles that representatives of government agencies cannot. When political constraints and the responsibilities of public office require government ministries to moderate their positions or to avoid offending powerful interests, advocates can be outspoken, insisting that policies stay true to the scientific evidence. When competing priorities distract the government's attention, NGOs can maintain a single-minded focus on tobacco control. Over time, as governments come in and out of power, and official interest in tobacco control fluctuates, nongovernmental advocates can deliver a steady chorus of support for strong policies. And when tobacco companies use their political and financial power to pressure or entice political leaders to abandon tobacco control programmes, nongovernmental advocates can often counter this influence.

"NGOs and their advocates add unique contributions to a legislative campaign, playing vital roles that representatives of government agencies cannot."

Broadening the base

Increasing national capacity requires an ongoing effort to involve an ever-growing coalition of interests and to continue broadening the base of both individual and organizational support for tobacco control. The wider and more diverse the coalition of supporters, the more quickly public support will grow and the more sustainable legislation will be. Some interests will constitute a ready core of support in most countries. The ministry of health, other public health institutions, physicians and their associations, hospitals and medical centres, and similar interests, may all be natural supporters. But building meaningful national capacity requires that this core be expanded to include important interests outside the health sector.

"Coalitions will differ from country to country, but advocates need to assemble a critical mass of support from different sectors to begin to change the norms and beliefs of the society."

Coalitions will differ from country to country, but advocates need to assemble a critical mass of support from different sectors to begin to change the norms and beliefs of the society. Schools, teachers and youth groups are all potential supporters, as are women's organizations, consumer organizations, environmental

groups and human rights organizations. In some countries, religious leaders may be likely to support tobacco control programmes as they gain an understanding of the medical facts about tobacco use. Labour unions have sometimes become advocates for smoke-free workplaces after learning about the health effects of second-hand smoke. Law enforcement officials may be willing to support laws preventing the sale of tobacco to minors. Each of these interests has been willing to support tobacco control in some countries, and successful capacity-building will require an effort to involve as many of them as possible.

"Advocates can also extend their country's capacity by drawing on international resources or forming partnerships with governments or groups in other countries."

Advocates can also extend their country's capacity by drawing on international resources or forming partnerships with governments or groups in other countries. International health and professional associations, networks of nongovernmental tobacco control organizations, and WHO's TFI all provide opportunities for liaison among countries. Creating a partnership with a country with successful legislation may provide valuable experience and encouragement, and a small or poor country may be able to stretch its limited resources by working with neighbouring countries for joint efforts in data collection, legislative drafting, enforcement, monitoring or evaluation.

Evidence is power: data collection

A key part of capacity-building involves the need for data to support effective policies. Developing the ability to collect and generate reliable information is important because the right information can be decisive in:

- helping the public understand the impact of tobacco on health;
- building public support for tobacco control;
- designing the right policy proposals;
- persuading lawmakers to adopt comprehensive legislation;
- monitoring and evaluating the effects of legislation; and
- developing improvements to strengthen policies.

At least four types of information are important. The first

involves a process sometimes known as legal and political "mapping." This is the process of assessing the current environment for introducing legislation.[39] This process begins with assessing the state of tobacco control in the country, including analysing the existing laws and their enforcement. The role of the tobacco industry in the country, including its major facilities, programmes and activities, its relationship to the government, its allies and affiliates, and its sources of influence, should all be identified. Existing and likely sources of support for legislation should be identified, along with likely sources of opposition. The likely reactions of influential institutions such as business organizations, the news media and religious institutions should be considered.

"Opinion polls make it possible to understand the public's views, and to identify areas in which the public is not supportive of tobacco control, where more education is required."

Second, a country needs the capacity to collect data about the medical and economic impact of tobacco use and the effectiveness of legislative interventions. These "surveillance" data begin with information about the prevalence of tobacco use in the population and the per capita consumption of tobacco by age group, gender, ethnic and racial group.[40] Data on morbidity and mortality are also valuable, as are estimates of the economic impact of tobacco-related diseases, in terms of increased health care costs, worker illness and lost productivity. These surveillance data are important not only for purposes of educating the public and supporting legislative proposals but also for later evaluation of the impact of legislation: a "before and after" study cannot be conducted without information about tobacco use before the law was enacted.

Third, it is important to collect information on public opinions and beliefs. Opinion polls make it possible to understand the public's views, and to identify areas in which the public is not supportive of tobacco control, where more education is required. Most often, opinion polls are valuable because they offer proof of strong public support—proof that may be necessary to persuade elected officials to act.

Finally, effective capacity for tobacco control includes the ability to monitor and expose tobacco industry activities. This includes identifying, tracking and analysing the industry's public and

[39] See: *Guidelines for controlling and monitoring the tobacco epidemic*. Geneva, World Health Organization, I-9 and Chapter IV, 1996.

[40] For a discussion of epidemiological surveillance of the tobacco epidemic, see *Guidelines for Controlling and Monitoring the Tobacco Epidemic*, Geneva, World Health Organization, 1996, Chapters VI -IX.

hidden activities and sources of influence, especially its efforts to influence public policies and its relationship to political leaders. The most important source for this information, for many countries, will be the internal tobacco company documents of multinational manufacturers made public as the result of litigation in the United States of America. These documents should be analysed for information they may reveal about secret tobacco industry efforts to undermine public health in the country in the past.[41] Uncovering and revealing this information, and exposing the industry's secret relationships, can have a dramatic impact on public opinions and can reduce tobacco companies' political influence.

"the importance of data collection should not be underestimated. In policy-making, evidence is power."

Generating all this information may seem a daunting task. Full data collection programmes may simply be too expensive or difficult for some countries, at least initially. Despite these difficulties, the importance of data collection should not be underestimated. In policy-making, evidence is power.

Moreover, straightforward, inexpensive methods are available for conducting and presenting many types of tobacco control research.[42] If resources are limited, it may be possible to simplify data collection methods used in other countries, or to estimate national data from existing regional or global information. Help in designing and conducting more formal data collection programmes may also be available from such sources as universities, foundation-funded programmes, or health programmes in other countries.

A communications strategy

A fundamental goal of capacity-building is to raise public understanding of tobacco and health, and thereby create a climate in which legislation can succeed. This includes increasing public understanding of the impact of tobacco use on health and of the importance of these hazards relative to other public concerns. It also involves educating the public about the effectiveness of proven strategies for reducing tobacco use. Just as importantly, it involves education about the role of tobacco companies in perpetuating the tobacco epidemic.

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[41] For an introduction to research on tobacco industry documents, see Tobacco Fact Sheet – Searching Tobacco Industry Documents: Basic Information, Steps and Hints, 11th World Conference on Tobacco or Health, Published at web site: www.tobaccofreekids.org/camapign/global/docs/searching.pdf.

[42] A helpful and practical guide to simplified data collection and presentation for tobacco control has been published by PATH Canada and is available online. *PATH Canada Guide: Low Cost Research for Advocacy*, Dhaka, 2002, available at http://www.pathcanada.org.

Accomplishing these goals requires a sustained and coordinated programme of education, guided by a communications strategy. A communications strategy is a plan for the effective, coordinated use of multiple channels of communications for achieving a set of established goals.

"A communications strategy is a plan for the effective, coordinated use of multiple channels of communications for achieving a set of established goals."

If resources permit, this strategy should provide for the use of advertising as well as free publicity through the news media and other channels. Communications campaigns using advertising, or "paid media," can be expensive. Depending on the resources available, this expense may be worth incurring at an early point, because effective media campaigns can themselves help reduce tobacco use and create the environment for the success of the other elements of a comprehensive programme. There may also be ways to reduce the cost of advertising campaigns. For example, in some countries, it may be possible to obtain access to television broadcast time at nominal costs. It may also be possible to use existing advertisements created in other countries at little or no cost, thus avoiding the cost of production.

In any event, abundant opportunities exist for creative use of the news media and other unpaid channels to educate the public. Developing the capacity to do this effectively is important to the success of a long-term tobacco control effort. This requires a process of skill-building, in which advocates develop the media skills necessary to mount effective communications campaigns. Media spokespeople should be trained in working with media representatives, and in such specific media skills as conducting interviews, writing news releases, conducting editorial board visits, writing letters to the editor and news articles, organizing news conferences, monitoring news coverage, and so on.[43] These spokespeople should then work to begin creating personal relationships with media representatives—relationships that will become important later, when legislation is debated.

Working imaginatively, these spokespeople should then create opportunities to make news. This can be done in many ways.[44] News opportunities can be built around:

[43] Helpful, easy-to-use guidance in many of these skills, including checklists, tips and samples, can be found in: Must E and Efroymson D. *PATH Canada Guide: Using the Media for Tobacco Control*, Dhaka 2002, available at web site: http://www.pathcanada.org.
[44] The PATH Canada Guide cited above suggests dozens of ideas for creating tobacco-related news. Must E and Efroymson D. *PATH Canada Guide: Using the Media for Tobacco Control* Dhaka 2002, at 7 – 41.

- human-interest stories: for example, stories involving victims of smoking-related diseases, people affected by second-hand smoke or young people working for tobacco control;
- the release of a report about patterns of tobacco use or the impact of a tobacco control policy;
- analysis of tobacco industry documents for evidence of activities in the country;
- celebrity spokespeople;
- public opinion polls;
- a presentation by a prominent visiting expert;
- support for tobacco control from a non-traditional source, e.g. religious leaders or labour unions; and
- organized events, e.g. a protest against the volume of point-of-sale advertising at a retail store or the circulation of a petition for a workplace to go smoke-free.

Over time, creative news-making using these and similar approaches can raise public awareness, re-shape opinions and build a supportive environment for legislation. Even in countries where legislative decisions are not tied closely to public opinion, public support will be critical to the long-term acceptance and enforceability of tobacco control laws.

Norms and values

Ultimately, the goal of capacity-building and, indeed, of all tobacco control, is to change the society's culture. Legislation is important, but, in the final analysis, it is the norms and values of a society that determine whether tobacco use is accepted. The underlying goal of the effort to build national capacity is to begin to transform the society's culture—from one that tolerates tobacco as a legal product used by people exercising supposedly free "choice," to one that rejects tobacco as a deadly and highly addictive product that injures not only tobacco users, but also their families, innocent bystanders and society as a whole.

" Legislation is important, but, in the final analysis, it is the norms and values of a society that determine whether tobacco use is accepted."

Chapter V. Approaching legislation: strategic choices

Before a country develops legislation, it must make a series of fundamental decisions about the approach it will pursue. The wisest course of action will differ from country to country. The choices a country makes, however, will determine not only the form and content of the country's legislation, but also its chances of succeeding.

"The readiness assessment must be realistic: the difficulties are easily underestimated before the process begins."

Are you ready?

Before embarking on a legislative programme, a country should consider carefully whether it is prepared for the effort. This readiness assessment is partly a matter of assessing the general political environment for enacting and implementing the law, and partly a matter of gauging the specific strength of support within the government and the legislative body. It is also a matter of assessing supporters' capacity to sustain the effort. Where the legislative body is directly responsive to public opinion, it may also be important, if resources permit, to evaluate public support for tobacco control.[45] The readiness assessment must be realistic: the difficulties are easily underestimated before the process begins. Still, with effort, it is also possible to create and build an environment supportive of tobacco control.

"One fundamental choice is whether to pursue a single law creating a comprehensive set of policies, or instead to proceed step by step, adding the components of a programme over time."

Step by step or all in one?

One fundamental choice is whether to pursue a single law creating a comprehensive set of policies, or instead to proceed step by step, adding the components of a programme over time. Each country must weigh these options in the light of its political circumstances.

"Legislation should promote a smoke-free culture."

The goal of legislation should be to promote a smoke-free culture. There is little question that the adoption of a comprehensive law, integrating all the essential components of an effective, multifaceted programme is the most effective strategy to this end. A single law provides a unified vision and ensures that the elements are designed to complement and reinforce one another.

[45] Formal public opinion polling may be necessary to measure public support. Existing survey instruments can be used to reduce the expense of this process. One particularly useful instrument is the Smoking Policy Inventory. Velicer WF, et al. The development and initial validation of the smoking policy inventory. *Tobacco Control,* 1994, *3,* 347-55. See also Laforge RG, et al. Measuring support for tobacco control policy in selected areas of six countries. *Tobacco Control,* 1998, *7,* 241-46.

This synergy has a measurable value: research indicates that implementing the full complement of measures has greater impact on tobacco use than do the individual measures if implemented in isolation. Enacting legislation in one step may also take maximum advantage of the political momentum built up by an advocacy campaign, rather than requiring advocates to rebuild political support for action for each step in an incremental approach. Many countries have used a comprehensive or multifaceted approach successfully. Experiences in Canada, Norway, Poland, South Africa and Thailand are described elsewhere in this guide.[46]

"research indicates that implementing the full complement of measures has greater impact on tobacco use than do the individual measures if implemented in isolation"

Other countries have proceeded incrementally. While adopting a series of separate laws over time can result in a fragmented approach, comprehensive legislation may not be feasible in some countries. In that case, it is possible to begin with more limited legislation dealing with only one or two aspects of tobacco control. New laws can be added over time to expand the programme. This step-by-step approach may be the only realistic option in some countries. Poland is an example of a country that has achieved a complete ban on tobacco advertising in two legislative steps.

Moreover, this approach does offer some advantages. It allows a country to move forward in one area while continuing to build political support for progress in other areas. Depending on the culture and norms in a society, some aspects of tobacco control may have much stronger political support than others. For example, the legislative body may be willing to enact legislation to control the sale of tobacco to young people, but unwilling to increase tobacco taxes, or it may be willing to control smuggling, but reluctant to regulate smoking in public places. A step-by-step approach allows the country to seize the available opportunities, enacting those components of a programme that are possible, and to use the resulting partial programmes to build tobacco control capacity and further educate the public and lawmakers.

"A step-by-step approach allows the country to seize the available opportunities, enacting those components of a programme that are possible"

Where to begin?

If comprehensive legislation is not feasible initially, and a decision is made to proceed with an incremental approach, then a country must decide which elements of a comprehensive programme to pursue first. There are several logical options.

[46] See case studies in Chapter XII.

One logical place to begin is with formal legislation creating and funding the national focal point for tobacco control or a national tobacco control committee. This will provide a catalyst for expansion of national capacity and the eventual development of broader legislation.

Another approach strongly recommended by many tobacco control experts is to start with one of the most powerful of all tobacco control tools—increased taxes on tobacco products. Tax increases offer a dual benefit. By increasing the price of tobacco products, they deter young people from becoming smokers and encourage current smokers to quit. At the same time, they generate substantial government revenue that can be used to support a public tobacco control programme, fund a health-promotion foundation or help offset the health care costs that tobacco imposes on society. Tax increases are an effective strategy in countries of all income levels.[47] Tax increases can sometimes generate stiff political opposition, but linking tax revenues to public health programmes often increases their popularity. If a tax increase is politically feasible, it may be an appropriate place to begin.

A third alternative is to begin with warning labels on packages. The benefit of this approach is that it uses the products and resources of tobacco companies themselves as a platform for a large-scale process of public education. This can provide what is, in effect, a national information campaign, at minimal expense to the government, helping to alter the general climate in the country and build support for additional legislation. Although packaging regulations require a certain level of technical expertise, ready-made models for regulation are available from other countries.[48]

"It is most effective to begin with a measure that is politically feasible and that will contribute directly to increasing the support for movement toward a comprehensive programme."

Still another alternative is to begin with a statute restricting smoking in public places and workplaces, if possible. Control of smoking in public places has proven to be one of the most widespread types of tobacco control legislation enacted. Initial resistance to these laws may be strong, but smoke-free policies are very popular once implemented.

Whether a country follows one of these approaches or chooses a different starting point, the first step should be chosen strategically. It is most effective to begin with a measure that is

[47] Jha P, Paccurd F, Nguyen S. Strategic priorities in tobacco control for governments and international agencies. In Jha P and Chaloupka F. *Tobacco Control in Developing Countries*, New York, Oxford University Press, 2000, 449-464, at 453.
[48] See discussion in Chapter VI.

politically feasible and that will contribute directly to increasing the support for movement toward a comprehensive programme.

National or subnational?

"A country should give careful thought to the decision of whether to seek legislation at the national level, or instead at one or more subnational levels."

A country should give careful thought to the decision of whether to seek legislation at the national level, or instead at one or more subnational levels. This choice exists only if subnational governments have the legal competence to legislate in this subject area, and will be affected by the country's form of electoral representation, the availability of administrative regulations as an alternative, and possible issues of legal pre-emption (see Chapter III). Still, in most countries, the possibility of proceeding at a regional or municipal level will be an option, and it will be important to weigh the benefits and disadvantages of the alternatives.

National laws have several distinct strengths. The national legislative body will usually have undoubted legal competence to enact a comprehensive tobacco control law, and pre-emption will not be a concern. Because they apply throughout the country, national statutes offer maximum impact. A single national law provides national uniformity and consistency, and requires only one process of adoption, compared to the adoption of many subnational laws.

"A single national law provides national uniformity and consistency, and requires only one process of adoption, compared to the adoption of many subnational laws."

Most importantly, the resources available for developing and enacting legislation are usually greatest at the national level, and national laws are able to raise larger revenues than are subnational laws. Advocates may conclude that some aspects of tobacco control (e.g. an advertising ban or a requirement for package warning labels) lend themselves naturally to a single national solution. Or, they may find that some strategies (e.g. regulation of tobacco product contents or additives) require a level of enforcement funding and technical expertise that can be found only at the national level.

Despite these apparent advantages, however, many arguments favour approaching legislation from a lower level of government, whether through regional ("departmental," "provincial," "state," or "territorial") laws or municipal ("local," "city") laws, as has been done in Brazil and the United States of America.[49] First, regional and municipal governments are "closer

[49] See case studies in Chapter XII.

to the people," and may be more directly responsive to popular will. If tobacco control has strong public support, local or regional governments may be more willing than the national legislative body to translate this support into legislation. Second, enforcement mechanisms may be more vigorous at these levels as well, because enforcement agents are present in the community and because the public may have a higher awareness of the local laws and the level of compliance.

Moreover, subnational lawmakers may be less responsive to the influence of tobacco companies. The tobacco industry's political clout is ordinarily greatest at the national level, where the industry concentrates its political contributions, financial influence and efforts to cultivate political leaders. This influence is diluted when legislation originates in many municipal or regional governments, where the industry has no established local political presence and where the lawmaking process may be more transparent. When legislation is debated in a national capital, tobacco companies' lobbyists are close friends of many lawmakers; when it is debated in a remote municipality, the lobbyists are strangers from far away. For these reasons, as discussed in Chapter III, tobacco companies go to considerable lengths to try to prevent legislation from being considered at lower levels of government. For example, they may use procedural manoeuvres to block debates, encourage higher levels of government to pre-empt the subordinate government from acting, or threaten litigation, all to prevent the proposal from reaching subnational decision-makers.

"The tobacco industry's political clout is ordinarily greatest at the national level, where the industry concentrates its political contributions, financial influence and efforts to cultivate political leaders."

Most importantly, legislation adopted at levels "closer to the people" may be most effective in achieving the long-term goal of tobacco control—permanent change in the norms and attitudes of the society. Advocacy campaigns for local and regional legislation, and the public debate and discussion that frequently accompany them, actively engage the participation of ordinary individuals in ways that are less likely with national legislation. This personal involvement educates the public, increases understanding and changes beliefs and attitudes. These changes can produce the public support to ensure nearly universal compliance with the legislation and, most importantly, to move the society towards a fundamental rejection of tobacco use.

"...legislation adopted at levels "closer to the people" may be most effective in achieving the long-term goal of tobacco control..."

Legislation or regulation?

Another pivotal decision is whether to pursue a tobacco control law through administrative regulations rather than legislation. Rulemaking is an option if the ministry of health or another appropriate agency has the legal authority, under existing legislation, to promulgate rules for tobacco control. Some agencies have very broad power to adopt any rules necessary to achieve their general mission. In other cases, an existing statute may give the agency specific authority to issue rules for tobacco control.

"If rulemaking power exists, advocates should consider this alternative to legislation."

If rulemaking power exists, advocates should consider this alternative to legislation. To evaluate this option, it is necessary to understand a country's rulemaking process. As discussed in Chapter III, these procedures vary widely.

One consideration is the timetable for rulemaking. In some countries, rulemaking may be faster than legislation. Similarly, rulemaking in some countries is a relatively simple, informal and inexpensive process, in which the administrative agency has broad discretion. These qualities may make rulemaking attractive.

On the other hand, the resources available to administrative agencies also vary greatly. If an agency lacks the specialized expertise, the number of personnel, or the financial resources to develop and administer a comprehensive programme, then rulemaking may not be appropriate. Enforcement mechanisms also vary. In many cases, they are weak or even nonexistent. Without meaningful enforcement, rulemaking is not a worthwhile alternative.

Finally, in some countries, rulemaking takes place largely behind closed doors, with little public involvement or input. A tobacco control law adopted in this way may bear no correlation to public sentiment. Even the strongest law will not succeed in practice if it is contrary to the views of the public and is adopted without the public's knowledge or support. A tobacco control proposal may be more successful in the long run if it is developed through a legislative process with full public participation and support than through a more isolated rulemaking process.

"Inevitably, the legislative process involves compromise. As has often been said, politics is the art of the possible."

The perfect versus the possible

Inevitably, the legislative process involves compromise. As has often been said, politics is the art of the possible. Before

developing legislation, advocates need to consider the extent to which they will work for the strongest possible legislation, representing "best practices" supported by scientific evidence and experience in other countries, and the extent to which they will instead moderate their proposal, in recognition of political, economic or other constraints in their country. These are difficult choices.

Compromise is sometimes necessary and even advantageous. Where a country has little history of tobacco control, and where members of the legislative body have little familiarity with the issues, a full-scale comprehensive programme may appear unrealistic. Where resources are very limited, specific elements of a comprehensive programme may appear impractical. Moreover, honest assessment of the situation may convince advocates that insisting on the best possible legislation will lead to a long delay or even jeopardize the ability to enact any legislation at all. Faced with these hurdles, advocates often must confront the argument that, if they hold out for too strong an approach, "the perfect may become the enemy of the good," and they will thwart progress. In addition, it should be recognized that even limited legislation can lead to increased public support for tobacco control. Laws evolve, and even a doubtful beginning may be the seed that grows in time into a strong programme.

"When opposition to a legislative proposal becomes fierce and the outcome becomes uncertain, advocates can expect to feel intense pressure to weaken the proposal in an effort to accommodate opponents."

These considerations may argue for an approach that omits or weakens some features of an ideal strategy, in recognition of the realities in a particular country. At the same time, as discussed in Chapter IV, these concerns may also be evidence that the country should redouble its efforts to expand national capacity, to deepen the support underpinning the legislative proposal-support that will be welcome when the campaign intensifies. When opposition to a legislative proposal becomes fierce and the outcome becomes uncertain, advocates can expect to feel intense pressure to weaken the proposal in an effort to accommodate opponents.

Advertising offers an example. As discussed in Chapter VI, evidence indicates that a total ban on tobacco advertising, promotion and sponsorship is very effective in reducing tobacco use. In contrast, mere restrictions on advertising, or regulations that prohibit some forms of advertising while allowing others, have little or no effect.[50] Despite this evidence, advocates for an

[50] See discussion in Chapter VI.

advertising ban may encounter pressure to "compromise" by accepting advertising restrictions instead of a total ban. Some may argue that this weaker approach, even if ineffective in itself, will be a first step from which the country can move forward toward a total ban. Others will see restrictions as a false solution that will only create the illusion of action and that will actually impede adoption of a more effective law.

These are case-by-case decisions. As a general observation, however, the temptation to compromise will ordinarily feel strongest in the heat of the legislative struggle. It is important to prepare for this pressure by deciding in advance, when calm reflection is possible, where compromises can be made and where it is best to hold firm. Moreover, many experienced advocates believe that it is almost always better to set a high standard, and to work for proven, best practices approaches, even at the risk of initial failure.

Over time, they argue, support for the proposal will grow, whereas too great a readiness to compromise may be interpreted by legislators and the public as acceptance of watered-down approaches that accomplish little. This may dissipate political support for any later effort to improve the weaker law.

"...many experienced advocates believe that it is almost always better to set a high standard, and to work for proven, best practices approaches, even at the risk of initial failure."

One form of compromise that should ordinarily be avoided is the use of voluntary agreements with tobacco companies and their affiliated businesses. In addition to lacking the force of law, voluntary agreements are often ignored by tobacco companies after execution, and can insulate the tobacco industry against more restrictive, effective regulations. By voluntarily adopting codes of practice or other self-policing, the tobacco industry may suggest to the public that stricter laws are unnecessary.[51] The industry has pursued this tactic repeatedly.[52] For these reasons, WHO has condemned voluntary agreements for self-regulation in the tobacco industry, and instead encourages countries to adopt the most stringent and effective legislative interventions possible.[53]

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[51] See, e.g. Saloojee Y and Dagli E. Tobacco industry tactics for resisting public policy on health. 78 *Bulletin of the World Health Organization* 902, 2000); Mackay J. Lessons from the private statements of the tobacco industry, 78. *Bulletin of the World Health Organization*, 911, 2000.

[52] Voluntary agreements have been used in Australia (ingredient disclosures), the Czech Republic (advertising) the United Kingdom of Great Britain and Northern Ireland (advertising, promotion and sponsorship) and many other countries. See, e.g., Lee CY and Glantz SA. *The Tobacco Industry's Successful Efforts to Control Tobacco Policy Making in Switzerland.* UCSF. Report prepared for WHO/TFI. January 2001.

[53] Member States need to take action against tobacco advertising, *WHO Press Release* WHO/47, 1 November 2001.

Chapter VI. The elements of comprehensive legislation

The essential elements of an effective comprehensive programme are now widely recognized. Each country must consider how these elements will be adapted to its legal, cultural, economic and political context. In particular, the country will need to consider the broad goals of its tobacco-use reduction programme and the role of legislation in achieving those goals. Some elements may need to be modified in light of the country's policy priorities, the resources available and political or economic realities.

"Whatever local modifications may be needed, countries are encouraged to pursue policies that do not merely consider the scientific evidence, but also incorporate recognized best practices wherever possible."

Above all else, these decisions should be guided by the abundant and growing scientific, medical and economic evidence about what works. Tobacco control policies benefit from an extraordinary degree of reliable evidence on these questions, and of a developing global consensus about the most effective approaches. Whatever local modifications may be needed, countries are encouraged to pursue policies that do not merely consider the scientific evidence, but also incorporate recognized best practices wherever possible.

Other fundamental values of the society—such as concern for human rights and consumer rights—should also be kept in mind. The right of children to be free from addiction and manipulative advertising, for example, and the right of consumers to be informed about harmful product ingredients, reflect fundamental values of many societies, independent of concern for public health. Finally, a proposal should reflect the legal context. Because tobacco companies are quick to bring legal challenges to any law that threatens tobacco sales, a legislative proposal must be defensible in court. A law grounded in solid scientific evidence will usually have the best legal footing.

"A law grounded in solid scientific evidence will usually have the best legal footing."

In developing legislation, therefore, ordinarily advocates should work for the strongest possible laws. The growing global consensus about these best practices is now crystallized in the new WHO Framework Convention on Tobacco Control (WHO FCTC) (reprinted in Annex 1 of this guide). After it has entered into force, this important treaty will obligate countries that have ratified it to enact legislative or regulatory measures in a number of specific areas. Independent of its formal obligations, however, the treaty identifies the most effective legislative strategies in most areas. In this respect the WHO FCTC may be used as a truly global framework for action, even in countries that may not become Parties to the treaty.

This chapter describes the major elements of a comprehensive programme and the recommended legislative strategies in each area, consistent with the WHO FCTC. It identifies the underlying rationale for action in each area and the key issues and trade-offs in framing legislation. This discussion is reprinted or adapted primarily from *Developing Legislation for Tobacco Control: Template and Guidelines,* a valuable legislative "template" developed by WHO's Regional Office for the Americas, the Pan American Health Organization (PAHO).[54]

Institutions and mechanisms

One critical, though sometimes neglected, element of the comprehensive approach is a legislative provision creating institutions and mechanisms to oversee the programme of tobacco control. The WHO FCTC recognizes this logical starting point, and requires each Party, acting in accordance with its capabilities, "to establish or reinforce and finance a national coordinating mechanism or focal point for tobacco control…."[55] This mechanism may be a centralized office within the ministry of health or similar agency. Alternatively, responsibility for different aspects of the programme may be divided among several agencies, as is the case in Brazil, where the national tobacco control programme is directed by an office accountable to the Ministry of Health, while a separate regulatory agency is responsible for product regulation.[56]

Authority can also be vested in a multisectoral coordinating body, such as a national tobacco control committee, or a quasi-private entity, such as a health promotion foundation, a mechanism used with great success in Australia and Thailand. In the United States of America, several quasi-private foundations have also been created and funded as a result of litigation against tobacco companies. On one hand, these private or semi-private entities may have such advantages as greater independence along with reduced vulnerability to political pressure and the influence of the tobacco industry. On the other hand, they may lack some of the powers available to government agencies, such as the ability to impose fines or penalties.

Whatever institution is chosen, legislation should formalize the assignment of responsibility, empower the institution to act—for example, by adopting regulations or imposing enforcement sanctions on violators of the law—and provide a funding mechanism. In lieu of funding through the general process of public budgeting and appropriation, a source of dedicated funding can be created. For example, a portion of the revenue generated by cigarette taxes can be earmarked to fund part or all of the tobacco control programme, as has been done in Australia, Canada, Ecuador, Finland, Iceland, Indonesia, the Islamic Republic of Iran, Malaysia, Nepal, Peru, Portugal, the Republic of Korea, Romania, South Africa, Switzerland, Thailand and some states of the United States of America. A direct tax or fee on

[54] Published at web site: http://www.paho.org/English/HPP/HPM/TOH/tobacco_legislation.pdf (in English) and http://www.paho.org/Spanish/HPP/HPM/TOH/tobacco_legislationSpa.pdf (in Spanish).
Sample legislative language from the PAHO publication is reprinted in Annex 1 of this guide.
[55] WHO Framework Convention on Tobacco Control, Article 5, Paragraph 2.
[56] See the case study in Chapter XII.

tobacco manufacturers can be used to finance product regulation, as is done in Brazil. Another creative and highly successful approach, pioneered by the State of Victoria in Australia, is to use a portion of the tobacco tax to phase out tobacco industry sponsorship of sporting and cultural events by replacing the industry's sponsorship payments with tax revenues. Lawmakers are often reluctant to create these earmarked funding mechanisms, but they can stabilize and strengthen a nation's commitment to tobacco control.

"...legislation should formalize the assignment of responsibility, empower the institution to act—for example, by adopting regulations or imposing enforcement sanctions on violators of the law—and provide a funding mechanism."

Public education

Large, sustained public information campaigns are an important part of changing the attitudes, beliefs and norms of society. The WHO FCTC recognizes this. It requires countries to adopt legislative, executive, administrative or other measures that promote public awareness and access to information about the addictiveness of tobacco, the health risks of tobacco use and exposure to smoke, the benefits of cessation and the actions of the tobacco industry.[57]

"Where aggressive, well-funded counter-advertising campaigns, using multiple messages, have been maintained over a long period of time-they have been shown to contribute significantly to reduced tobacco use in youth and in overall tobacco consumption."

Where aggressive, well-funded counter-advertising campaigns, using multiple messages, have been maintained over a long period of time—as in the states of California and Massachusetts in the United States of America—they have been shown to contribute significantly to reduced tobacco use in youth and in overall tobacco consumption. A large advertising campaign can be expensive if broadcast time must be purchased from commercial broadcast services,[58] but free broadcast time may be available on state-owned broadcast services in some countries, and there may also be ways to reduce the costs of producing advertisements.[59] Moreover, these campaigns can be financed readily by increased tobacco taxes, as has been done in Ecuador, French Polynesia, Guam, Indonesia, Malaysia, Peru, Romania, some states of the United States of America and elsewhere.[60] In

[57] WHO Framework Convention on Tobacco Control, Article 12.

[58] The U. S. Centers for Disease Control has estimated that the cost of an effective mass media campaign in the United States, using purchased broadcast time on commercial broadcast channels, is between US $1 and US $3 annually per capita (that is, for each member of the population involved). Centers for Disease Control and Prevention, *Best practices for comprehensive tobacco control programs — August 1999.* Atlanta, Georgia: U.S. Department of Health and Social Services, Centers for Disease Control and prevention, August, 1999, web site http://www.cdc.gov/tobacco/bestprac.htm.

[59] For example, a collection of advertisements produced in the United States of America is maintained by the United .States. Centers for Disease Control. Some of these advertisements are available for re-use, with the permission of the organizations that created them. See http://www.cdc.gov/tobacco/mcrc/index.htm.

[60] Yurekli A and De Beyer J. *World Bank Economics of Tobacco Toolkit*, Tool 4: Design and Administer Tobacco Taxes

the United States of America, some advertising campaigns have also been financed with revenue from litigation against tobacco manufacturers.

Some evidence suggests that these United States campaigns have been most effective in dissuading young people from smoking when they have focused attention on the activities of tobacco companies and their efforts to manipulate youth, although this conclusion has not been tested across cultures.[61] In any event, large-scale education campaigns, using television, radio and other media, reinforce and complement other informational strategies, such as package warning labels and education programmes in schools. This provides the necessary informational background for other elements of a comprehensive programme and, in the largest sense, builds public support for tobacco control generally.

"The WHO FCTC requires each Party, "in accordance with its constitutions and constitutional principles," to "undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship."[62]

Tobacco advertising, promotion and sponsorship

The WHO FCTC requires each Party, "in accordance with its constitutions and constitutional principles, to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship."[62] This is a centrepiece of an evidence-based programme. Parties whose constitution or constitutional principles do not allow them to undertake a comprehensive ban must apply a series of restrictions on all advertising, promotion and sponsorship[63].

The extent to which tobacco products are promoted influences the level of tobacco use both in the general population and in particular target groups.[64] In addition, promotion has been associated specifically with smoking initiation among youth.[65] A study of more than 100 countries showed that countries with comprehensive restrictions or bans on tobacco promotion have

[61] Goldman, LK, Glantz, SA. Evaluation of antismoking advertising campaigns. *Journal of the American Medical Association* 1998;279:772-777.

[62] WHO Framework Convention on Tobacco Control, Article 13. The treaty defines "tobacco advertising and promotion" as "any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly." "Tobacco sponsorship" is defined as "any form of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly." Article 1.

[63] WHO Framework Convention on Tobacco Control, Article 13, paras 3-8.

[64] An excellent review of the evidence is found in Hammond R. Tobacco Advertising and Promotion: The need for a coordinated global response. Paper prepared for *the WHO International Conference on Global Tobacco Control Law: Towards a WHO Framework Convention on Tobacco Control*. New Delhi, 7 – 9 January 2000. See web site: http://tobacco.who.int/repository/tld94/ROSS2000X.doc

[65] Pierce JP, Gilpin EA and Choi WS. Sharing the blame: smoking experimentation and future smoking-attributable mortality due to Joe Camel and Marlboro advertising and promotions. *Tobacco Control 1999*; *8:*37-44; Pierce JP et al. Tobacco industry promotion of cigarettes and adolescent smoking. *The Journal of the American Medical Association. February 18, 1998; 279(7),* 511-15.

[66] *Curbing the Epidemic: Governments and the Economics of Tobacco Control.* Washington, World Bank, 1999. See web site: http://www1.worldbank.org/tobacco/reports.htm.

lower levels of tobacco use than countries with weak or no restrictions on tobacco promotion. The same study found that in order for restrictions to have an impact, they need to be total or near-total, and that weak restrictions have little or no impact on tobacco use.[66]

The experience of many countries graphically illustrates why this is so.[67] Partial restrictions are difficult to define and enforce, and have often resulted in unforeseen loopholes.[68] When tobacco promotion is restricted in one medium, such as billboards, companies simply increase the level of promotion in another. For example, in the United States of America, in 1998 the tobacco companies agreed under a legal settlement to eliminate outdoor advertising and advertising targeted at youth.[69] However, three years later the companies were spending even more money on promotion than they did before the settlement, with an increase in advertising in youth publications and a shift in advertising from outdoor settings to other media.[70] Even when all direct advertising has been prohibited, companies have successfully used other promotional tactics, such as sponsorships, distribution of tobacco-branded non-tobacco items such as T-shirts and hats, the tobacco-brand naming of coffee shops, bars, restaurants, travel agencies and other establishments, and massive displays of cigarettes at retail outlets, to promote their products. For these reasons, a prohibition should cover all advertising, promotion and sponsorship through direct and indirect means, whether through advertising, sponsorships, giveaways, discounts, displays at point of sale or the promotion of tobacco brand names through non-tobacco items or through venues. Sample language for such a prohibition is reprinted in Annex 2.

Despite the difficulties with partial advertising restrictions, the total prohibition on tobacco advertising and promotion would violate the constitutions of some countries. Where this is the case, the WHO FCTC nevertheless obligates Parties to apply restrictions. Countries will need to evaluate their constitutions to determine whether or not they may be limited in implementing a total ban. To protect the public health to the greatest extent possible, a country in which constitutional limits are not well settled should consider clarifying its law by implementing a total ban and defending it in court.

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[67] For information about countries that have enacted partial or total prohibitions on advertising, promotion or sponsorship, see Saloojee Y and Hammond R. *Fatal Deception: The Tobacco Industry's "New" Global Standards for Tobacco Marketing* 2, October 2001, and Corrao MA, et al. *Tobacco Control Country Profiles*, American Cancer Society, Atlanta, 2000.

[68] Cunningham R. R.R.R.-MacDonald Inc. v. Canada (A. G.): Reflections from the Perspective of Health. *McGill Law Journal 1995,40*, 229-267. See web site: http://journal.law.mcgill.ca/arts/401cunni.pdf.

[69] *Master Settlement Agreement with the Tobacco Industry*. National Association of Attorneys General. http://www.naag.org/upload/1032468605_cigmsa.pdf.

[70] King C & Siegel M. The Master Settlement Agreement with the Tobacco Industry and Cigarette Advertising in Magazines. *The New England Journal of Medicine, August 16, 2001, 345*, 504-511. http://content.nejm.org/cgi/content/abstract/345/7/504; Wakefield M. et al. Changes at the Point-of-Sale for Tobacco Following the 1999 Tobacco Billboard Ban. Research Paper Series, No. 4. ImpacTeen. July 2000. See web site: http://www.tobaccofreekids.org/reports/stores/.

[71] *Curbing the Epidemic: Governments and the Economics of Tobacco Control*. Washington, World Bank, 1999, at 39-43, http://www1.worldbank.org/tobacco/reports.htm

[72] WHO Framework Convention on Tobacco Control, Article 6, Paragraph 1.

Price and tax measures

"The WHO FCTC recognizes that price and tax measures are an important and effective means of reducing tobacco consumption especially among the youth."

Price and tax measures are an important and effective means of reducing tobacco consumption, especially among young people[71] —a fact specifically recognized by the WHO FCTC[72]. Indeed, many experts consider the use of fiscal policies to increase the price of tobacco "the single most effective measure known to reduce tobacco use."[73] Internal documents suggest the tobacco industry has reached a similar conclusion. These documents warn, for example, that increasing taxes is likely to be "one of the most successful methods of reducing the use of tobacco products," because large tax increases can 'place the product beyond the financial reach of many consumers."[74] Where tax revenues are in turn used to support comprehensive tobacco control, tobacco use has been reduced dramatically.[75]

Raising taxes—and thus the price of cigarettes and other tobacco products—has a double advantage: it not only generates revenue for government, but also produces a prompt decline in smoking, particularly among young people and low-income groups. As tobacco industry attorneys have acknowledged internally, "taxes influence the price of cigarettes" and "price affects the ability of young people to buy cigarettes."[76] A WHO analysis recommends tax increases, pointing to evidence that raising the price of tobacco products by 10% is likely to reduce demand for tobacco products by about 4% in high-income countries and about 8% in low- and middle-income countries.[77] If every country were to adopt such a tax increase, the WHO analysis concludes, 42 million smokers would stop smoking and 10 million lives would be saved.

Three principal arguments are raised against tobacco tax increases. Opponents say that:

- higher taxes will increase smuggling;

[73] Pan American Health Organization, *Developing Legislation for Tobacco Control: Template and Guidelines*, 2002, at 7. http://www.paho.org/English/HPP/HPM/TOH/tobacco_legislation.pdf (in English) and http://www.paho.org/Spanish/HPP/HPM/TOH/tobacco_legislationSpa.pdf (in Spanish).

[74] Confidential memo from Brown & Williamson attorney Ernest Pebbles to the company's public relations director, February 14, 1973, quoted in Glantz SA et al. *The Cigarette Papers*, University of California Press, Berkeley, CA, 1996, 249.

[75] Id.

[76] Glantz SA et al. *The Cigarette Papers*, University of California Press, Berkeley, CA, 1996, 249, quoting a document prepared for Brown & Williamson by a law firm retained to review internal documents for potentially damaging information.

[77] Guindon GE, Tobin S, Yach D. Trends and affordability of cigarette prices: ample room for tax increases and related health gains. *Tobacco Control 11*:35-43, 2002; citing *Curbing the Epidemic: Governments and the Economics of Tobacco Control*, Washington, World Bank, 1999, at 39-43, see web site:
http://www1.worldbank.org/tobacco/reports.htm. See also Stolberg SG. World Health Organization urges higher tobacco taxes to reduce smoking. *New York Times*, 29 February 2002, at 12.

- the burden of tax increases will fall most heavily on the poor; and
- higher taxes will lead to a loss of jobs, hurting the economy.

These arguments are rebutted by the economic evidence.[78] The smuggling threat is specious. Many countries have increased taxes without an increase in smuggling. While tax levels and tax and tax price differentials are important factors, the evidence suggests that others, including the presence of informal distribution networks, organized crime, industry participation, and corruption, may be as or more important.[79] Concerns about smuggling are best addressed through enhanced enforcement measures discussed elsewhere in this chapter.

As for arguments that tax increases are unfair to the poor, not every component of a tax system need be progressive; other tax programmes can offset any regressivity of tobacco taxes. Moreover, it can be argued that tobacco tax increases, in fact, benefit the poor, who are more likely than affluent smokers to quit smoking as tobacco prices increase, and who are least able to bear the costs of smoking and tobacco-related diseases. Linking taxes to services and programmes that help smokers quit smoking also helps answer this concern.

Nor do tobacco taxes hurt the economy. First, tax increases produce increased tax revenue to the government. Although tobacco consumption is reduced, the relative inelasticity of demand for tobacco products provides assurance that the tax revenue lost due to reduced consumption will be more than offset by the added revenue generated by a higher tax rate. Arguments that tax increases threaten jobs in tobacco-growing, manufacturing, wholesaling and retailing ignore the fact that employment in other sectors of society will increase correspondingly, as money formerly spent on tobacco is spent on other goods and services, so that the overall economy will not suffer.

As discussed previously, according to the World Bank, tax increases are not a one-time strategy; they should be increased regularly, not only to keep pace with wages and inflation, but also to create a progressive reduction in tobacco use. Earmarking a portion of these tax revenues to support a comprehensive tobacco control programme will amplify their beneficial effect.

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[78] Chaloupka FJ et al. The taxation of tobacco products. In Jha P and Chaloupka FJ. *Tobacco Control in Developing Countries*. New York, Oxford University Press, 2000, 237-277 at 265-8. See also Chaloupka FJ, Wakefield M, and Czart C. Taxing tobacco: the impact of tobacco taxes on smoking and other tobacco use. In: Rabin RL and Sugarman SD eds., *Regulating Tobacco*, New York, Oxford University Press, 2001, 39-71 at 52-6.

[79] Joossens L et al. Issues in the Smuggling of Tobacco Products. In: Jha and Chaloupka FJ. *Tobacco Control in Developing Countries,* Oxford University Press, 2000, 393-406. At web site: http://tigger.uic.edu/~fjc/

[80] WHO Framework Convention on Tobacco Control, Article 8, Paragraph 1.

[81] See, e.g., National Cancer Institute, *Health Effects of Exposure to Environmental Tobacco Smoke: The Report of the California Environmental Protection Agency*. Smoking and Tobacco Control Monograph No. 10, Bethesda, MD: U. S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 99-4645, 1999, http://cissecure,nci.nih.gov/ncipubs/ *International Consultation on Environmental Tobacco Smoke (ETS) and Child Health: Consultation Report*, Geneva, World Health Organization, 11-14 January 1999 (and related background papers) http://tobacco:who.int/page.cfm?sid=50

Second-hand smoke

"As the WHO FCTC recognizes, "scientific evidence has established unequivocally that exposure to tobacco smoke causes death, disease and disability."

As the WHO FCTC recognizes, "scientific evidence has established unequivocally that exposure to tobacco smoke causes death, disease and disability."[80] In fact, second-hand smoke produces illness and death from a litany of causes.[81] In the United States of America, for example, it is estimated to cause as many as 65 000 deaths each year, making it, by some calculations, the third leading preventable cause of death in that country.[82] It is also well established that there is no known "threshold" or safe level of exposure to tobacco smoke, and that the mere separation of smokers and non-smokers within the same airspace does not protect non-smokers from harm, regardless of the ventilation system used.[83] Therefore, strictly from a standpoint of health protection of non-smokers, there is a strong case for implementing smoke-free environments in every possible sector. The case is especially strong for protecting workers and others who are not free to leave a smoky setting.

However, there is an additional benefit of smoke-free environments: they are one of the most effective ways to reduce smoking. By striking at the heart of the social acceptability of smoking, smoke-free environments discourage smoking initiation, reduce young people's exposure to the poor role models set by smoking adults, and promote smoking cessation more effectively than many efforts directed at smokers. Studies conducted in the United States of America and Australia as well as internal tobacco industry studies, have attributed between 13% and 22% of the declines in tobacco consumption in these countries in recent years to the impact of smoke-free environments.[84] The conclusion of a 1985 Tobacco Institute document warns that, "At a dollar a pack, even the lightest of workplace smoking restrictions is costing this industry [in the United States of America] US$ 233 million a year in revenue."[85]

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[82] National Cancer Institute, *Health Effects of Exposure to Environmental Tobacco Smoke:* The Report of the California Environmental Protection Agency. Smoking and Tobacco Control Monograph No. 10, Bethesda, MD: U. S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 99-4645, 1999, https://cissecure.nci.nih.gov/ncipubs/

[83] Repace JL and Lowrey AH. Issues and answers concerning passive smoking in the workplace: rebutting tobacco industry arguments. *Tobacco Control* 1992; 1:208-219; Americans for Nonsmokers' Rights, *Smoking and Ventilation Standards*, (fact sheet), October 15, 1998, http://www.no-smoke.org/vent.html.

[84] Chapman S. et al. The Impact of Smoke-Free Workplaces on Declining Consumption in Australia and the United States. *American Journal of Public Health,* July 1999; 89:1018-23.

[85] The Tobacco Institute, *Public Smoking: The Problem.* 1985. http://www.tobaccoinstitute.com/getallimg.asp?if=avtidx&DOCID=TIMN0014554/4565

[86] Workplace Smoking: Trends, Issues and Strategies. Paper prepared for Health Canada, 1996. http://www.hc-sc.gc.ca/hecs-sesc/tobacco/facts/workplace/index.

Smoke-free environments also offer economic advantages. They lower the costs of health and fire insurance and of maintenance costs, create more productive workforces by offering a safer, healthier working environment, and in many cases may increase business (e.g. in the hospitality sector.)[86] Arguments against smoke-free policies—for example, arguments that such policies will reduce restaurant profits, that new ventilation systems make a smoke-free approach unnecessary, or that some locations (usually bars or restaurants) should be exempt from these laws—are invoked vigorously when these laws are proposed, but have been discredited by a large body of reliable evidence.[87]

The WHO FCTC requires Party States to adopt and implement effective legislative, executive, administrative or other measures "providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other places."[88] Where a country lacks legal jurisdiction to do this at the national level, it is to "actively promote" similar measures at subnational levels.[89] The scientific evidence leaves little doubt that the way to achieve genuine protection is to require smoke-free environments in these settings.

While this approach may seem difficult to achieve in some jurisdictions, it is far from impossible. Numerous jurisdictions around the world have successfully banned smoking in all public places and workplaces, with high compliance rates and few transitional difficulties,[90] and national legislation for such requirements has been proposed in Ireland and Norway. Sample language for such legislation is included in Annex 2.

Packaging and labelling of tobacco products

The tobacco package provides a potent vehicle for tobacco promotion, and has increased in importance within the "marketing mix" as other forms of promotion are restricted.[91] Aside from the obvious visibility of packages to smokers each time they light a cigarette, in many countries, tobacco retailers are paid by tobacco companies to prominently display tobacco packages row-upon-row near the cash register, providing an attractive promotional display just at the point when consumers are ready to purchase.[92]

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[87] See generally, the web site of Americans for Nonsmokers' Rights, http://www.no-smoke.org, and Repace JL and Lowrey AH, Issues and answers concerning passive smoking in the workplace: rebutting tobacco industry arguments. *Tobacco Control* 1992; 1:208-219.

[88] WHO Framework Convention on Tobacco Control, Article 8, Paragraph 2.

[89] Id.

[90] See, for example, American Nonsmokers' Rights Foundation, 1*00% Smokefree Ordinances,* March 29, 2002 (fact sheet) http://www.no-smoke.org/100ordlist.pdf and Canadian Cancer Society, *Municipalities in Canada with Smoke-Free Laws For Restaurants and Bars,* September 4, 2001 (fact sheet) http://www.ocat.org (go to "2nd hand smoke," then go to "by-laws"); Magzamen S, Charlesworth A and Glantz S. Print media coverage of California's smokefree bar law. *Tobacco Control* 2001;10:154-60.

[91] *Tobacco International* March 1, 1991: 14.

[92] Feighery EC et al. Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California. *Tobacco Control 2001; 10:*184-188.

[93] Mahood G. Warnings that tell the truth: breaking new ground in Canada. *Tobacco Control. 1999,* 8:356-362.

Conversely, if conspicuous health warnings are required on packages, their display becomes a valuable vehicle for health promotion messages. Seen by every smoker several times a day, packages are one of the most cost-effective communication tools available to governments to educate and inform consumers about the harmful effects of tobacco use.[93] Health information on or inside of packages that is effectively communicated in clear language, in a visible location and format and in a large size, has been found to motivate attempts to quit smoking both by adults and youth.[94] Studies in South Africa, Turkey and other countries provide evidence that the introduction of these health warnings reduces the demand for cigarettes.[95]

"The WHO FCTC requires Party States to adopt and implement, within three years after entry into force of the convention, effective measures requiring large, clear, health warnings, using rotating messages approved by a designated national authority."[98]

Youths are known to use packages and brands as symbols of the image that they would like to project to the outside world, whether that image is one of femininity, adventure, or sex appeal.[96] Health information on packages detracts from the glamour and appeal of the colourful brand images with factual, graphic information about the not-so-glamorous consequences of tobacco use.

Consistent with this, many countries use tobacco packages to educate the public, primarily by requiring manufacturers to place a prominent warning label on each package. The acknowledged best practice in this area is the approach taken by Brazil and Canada, where half of the main display panels of cigarette packages must be devoted to a rotating series of bold, full-colour warning labels, using photos and other visual images, and conveying a strong message.[97] The WHO FCTC makes this approach the global standard, requiring Party States to adopt and implement, within three years after entry into force of the Convention, effective measures requiring large, clear, health warnings, using rotating messages approved by a designated national authority.[98] The WHO FCTC provides that these warnings should cover 50% or more of

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[94] Environics Research Group Limited. *The Health Effects of Tobacco and Health Warning Messages on Cigarette Packages.* February 2001. http://www.hc-sc.gc.ca/hppb/tobacco/bureau/current_research/index.html; Environics Research Group Limited. *Evaluation of New Warnings on Cigarette Packages.* January 2001. http://129.33.170.32/ccs/internet/standard/0,3182,3172_334419_436437_langId-en,00.html

[95] Jha P and Chaloupka F. *Tobacco Control in Developing Countries*, New York, Oxford University Press, 2000, at 200.

[96] House of Commons, Canada. *Towards Zero Consumption: Generic Packaging of Tobacco Products. The Report of the Standing Committee on Health*. Ottawa, June 1994.

[97] Visual examples of the warning labels required in Brazil and Canada may be found at http://www.anvisa.gov.br/divulga/noticias/040601_1.htm (Brazil) and http://www.hc-sc.gc.ca/english/media/photos/tobacco_labelling/ (Canada). The Brazilian and Canadian laws are discussed In Chapter XII.

[98] WHO Framework Convention on Tobacco Control, Article 11, Paragraph 1.

[99] Id.

the principal display areas, as is done in Brazil and Canada, and must occupy at least 30%.[99]

Legislation to implement this standard should authorize a competent authority to issue administrative regulations, so that warning labels can be prescribed in great detail and so that rotating messages can be supplemented and revised over time. In accordance with the WHO FCTC, the legislation must require that warning labels appear not only on individual packets, but also on cartons and any other containers in which products are sold, so that health messages are always visible at the point of sale. Packages must be required to display any information about cigarette constituents or emissions that the national authority may prescribe.[101]

Rules can also provide for informational messages other than health warnings—such as toll-free telephone numbers for smokers to call for assistance in quitting smoking, as have been used in Australia, Brazil, Canada and South Africa. Another option is to require that more detailed health information be included in package inserts, as Canada has done. It may also be desirable to include a legislative provision ensuring that warning labels cannot be used by tobacco manufacturers as a defence against legal liability for injury to smokers, as has happened in some jurisdictions. Sample language for legislation in this area appears in Annex 2.

A second important role of packaging and labelling legislation is to prevent manufacturers from using packages to mislead consumers. The WHO FCTC requires that, within three years after entry into force of the Convention, each Party State shall adopt and implement, in accordance with its national law, effective measures to ensure that: "(a) tobacco product packaging and labelling do not promote a tabacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "utra-light", or "mild".[102] Given the importance of such measures, it would be highly desirable to include them in any comprehensive legislation on tobacco control, even in countries that are not Parties to the WHO FCTC.

One particular type of descriptive term is widespread and extremely misleading. For decades, manufacturers have referred to many of the most popular brands of cigarettes as "light," "low-tar," or "mild." Numerous studies have found that smokers believe these terms indicate that these brands are safer than "regular" brands. In truth, smokers of "light" or

[100] WHO Framework Convention , Article 11, Paragraph 3.
[101] WHO Framework Convention on Tobacco Control, Article 11, Paragraph 2.
[102] WHO Framework Convention on Tobacco Control, Article 11, Paragraph 1(a).
[103] *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine.* Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074, October 2001. http://cancercontrol.cancer.gov/tcrb/monographs/13/
[104] Canadian Council for Tobacco Control, McDonald S. *Putting an End to Deception: Proceedings of the International Expert Panel on Cigarette Descriptors*, A Report to the Canadian Ministry of Health from the Ministerial Advisory Council on Tobacco Control. See web site: http://www.ohpe.ca/ebulletin/FullFeature.cfm?ID=250&ROWNUMBER=31

"low-tar" cigarettes are at no less risk than are smokers of "high-tar" brands.[103] A substantial percentage of all smokers are misled by this deceptive terminology. An international expert panel on cigarette descriptors that convened in Canada examined this issue and called for a ban on misleading descriptors such as "light" and "mild," which the panel described as "a major public health problem."[104] Brazil and the European Union (EU) have already banned the use of these terms, and other countries are considering doing so.

"...cigarettes contain so many dangerous constituents and additives, and are engineered in such a sophisticated manner, that they have been described as miniature chemical factories."

Tobacco product regulation

Cigarettes, like some other tobacco products are, in the words of the WHO FCTC Preamble "highly engineered so as to create and maintain dependence, and many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic."[105] Indeed, cigarettes contain so many dangerous constituents and additives, and are engineered in such a sophisticated manner, that they have been described as miniature chemical factories. Their ingredients and design features can be and are manipulated by manufacturers in ways that affect their safety, appeal and addictiveness.[106]

For example, the pH level of smoke affects how easily nicotine is absorbed in the mouth or lungs. Tobacco company researchers have also discussed the need for "low irritation" cigarettes in response to the "impediments to starting smoking tracing to a physical intolerance at early experiences."[107] Since most new smokers are children and adolescents, this really refers to the problem of young people getting sick from smoking their first cigarette.

The ways in which tobacco products are formulated, manufactured and presented to the public raise a host of problems that invite a regulatory response:

- At present, consumers and bystanders in most jurisdictions have no trustworthy information

[105] WHO Framework Convention on Tobacco Control, Preamble.
[106] See generally, *Monograph: Advancing knowledge on Regulating Tobacco Products*, Geneva, World Health Organization, 2001. See web site: http://tobacco.who.int/page.cfm?sid=67.
[107] *Project Viking, Volume III: Product Issues.* The Creative Research Group Limited for Imperial Tobacco Limited, April 1987.
[108] *Advancing knowledge on regulating tobacco products.* Monograph prepared based on presentations made at the International Conference: Advancing Knowledge on Regulating Tobacco Products, Oslo, Norway 9-11 Feb. 2000. Geneva, World Health Organization, 2001. Published at web site: http://tobacco.who.int/page.cfm?sid=67, 99.

about the dosages of tar, nicotine, carbon monoxide and other dangerous substances to which they are exposed when cigarettes are smoked,[108] even though these dosages vary in unexpected ways among brands and from country to country.

- In most countries, the chemical contents of tobacco products remain a mystery not only to smokers, but even to the government.
- Current package statements about tar and nicotine "yields" rest on discredited testing methodology that may actually mislead consumers.[109]
- In most countries, manufacturers are free to add dangerous substances without any testing or legal restrictions.
- Increasingly, novel products and nicotine delivery mechanisms are introduced without government oversight.
- Cigarettes may be engineered in ways that create serious and needless fire hazards.

Designing measures to address these problems, and developing product regulations in general, raise highly complex and technical issues. In some of these areas, scientific understanding is incomplete or evolving. Some of the possible regulatory responses remain controversial, even among experts. This complicates the process of developing product regulation legislation.

"The WHO FCTC obligates countries to require that manufacturers disclose to governmental authorities information about product contents and emissions."

Some generalizations are possible, however. The regulatory framework should ensure that all aspects of tobacco products receive scrutiny. Regulation should be guided by the best available scientific evidence. Effects should be tracked continually, to maximize health benefits, minimize the substantial risk of perverse or unintended consequences, and foster self-correction.[110]

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[109] Id., 15-25

[110] *Advancing knowledge on regulating tobacco products.* Monograph prepared based on presentations made at the International Conference: Advancing Knowledge on Regulating Tobacco Products, Oslo, Norway 9-11 Feb. 2000. Geneva, World Health Organization, 2001. Published at web site: http://tobacco.who.int/page.cfm?sid=67 69-73,103.

[111] WHO Framework Convention on Tobacco Control, Article 10.

[112] WHO Framework Convention on Tobacco Control, Article 9.

Regulatory authority should include the ability to require disclosure of product constituents and emissions, regulate additives and manufacturing technologies, and set maximum levels of harmful constituents. The WHO FCTC obligates countries to require that manufacturers and importers of tobacco products disclose to governmental authorities information about product contents and emissions. Measures for public disclosure of information must also be adopted.[111] In addition, the Conference of the Parties is to develop guidelines for testing, measuring and regulating contents and emissions, that can be used by countries. Party States must adopt pertinent measures at the national level.[112]

Product regulation is especially dependent on the specialized expertise of the ministry of health or similar agency. Legislation should therefore delegate the specifics of regulation to administrative rules developed by these experts. These rules should be flexible to keep pace with changing scientific understanding, emerging product technologies and evolving views among global experts about regulatory policies. Sample legislative language consistent with these suggestions can be found in Annex 2.

Although this field involves many unresolved questions, effective product regulation holds great promise, as well. Just as manufacturers design tobacco products to sell them, regulation can force manufacturers to make these products in a way that reduces their appeal to children, decreases their addictive qualities, reduces some of the hazards they pose to users, and helps consumers make more informed decisions about starting or quitting smoking. Technical assistance and guidance are available through such mechanisms as WHO's Scientific Advisory Committee on Tobacco Products, a global panel of experts convened to clarify the evidence and options in this area. WHO's monograph *Advancing knowledge on regulating tobacco products*[113] provides a valuable distillation of the regulatory issues, including a summary of existing laws in a number of countries.[114] On a related note, WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob) has issued several recommendations on issues such as health claims derived from the ISO/FTC method to measure cigarette yield; the regulation of nicotine; tobacco product ingredients and emissions; and smokeless tobacco products. Additionally, it has issued a statement of principles on the evaluation of new or modified products.[115]

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[113] *Advancing knowledge on regulating tobacco products.* Monograph prepared based on presentations made at the International Conference: Advancing Knowledge on Regulating Tobacco Products, Oslo, Norway 9-11 Feb. 2000. Geneva, World Health Organization, 2001. Published at web site: http://tobacco.who.int/page.cfm?sid=67.

[114] *Advancing knowledge on regulating tobacco products.* Monograph prepared based on presentations made at the International Conference: Advancing Knowledge on Regulating Tobacco Products, Oslo, Norway 9-11 Feb. 2000. Geneva, World Health Organization, 2001. Published at web site: http://tobacco.who.int/page.cfm?sid=67 77-87. See Chapter XII for discussion of product regulation in Brazil, Canada and Thailand.

[115] All documents are available online at: http://www5.who.int/tobacco/page.cfm?sid=82.

[116] WHO Framework Convention on Tobacco Control, Article 16, Paragraph 1.

[117] DiFranza J. Active enforcement of minors' access laws: a moral and ethical imperative. *Tobacco Control 1995; 4:5.*

Tobacco sales

A comprehensive law will regulate the manner in which tobacco products are sold. Most of these restrictions flow from the desire to eliminate, or at least minimize, the sale of tobacco to young people. Most smokers begin using tobacco as adolescents and are addicted before they reach the age of adulthood. One of the most common features of a comprehensive tobacco control programme is a prohibition against the sale of tobacco to youth. The WHO FCTC requires such a prohibition.[116]

"One of the most common features of a comprehensive tobacco control programme is a prohibition against the sale of tobacco to youth. The WHO FCTC requires such a prohibition."

Evidence supporting the effectiveness of these measures in reducing tobacco use by youth is limited. Some of this evidence suggests that, for these laws to reduce tobacco use, compliance may need to approach 100%.[117] This speaks to the need for effective enforcement strategies. Enforcement can be strengthened by setting meaningful penalties, requiring purchasers to prove their age with specified forms of identification, and using various means to encourage active enforcement. Some jurisdictions have achieved high levels of compliance by enacting licensing laws under which every seller of tobacco obtains a licence. In this way, licence fees finance active enforcement, enforcement authorities test sellers' compliance by having unidentified minors make purchase attempts, and violations are punished by fines and licence suspensions. In other jurisdictions, where sellers are very numerous, street vendors and other informal sales channels are common, and enforcement resources are limited, this approach may not be practical.

An important corollary to prohibiting sales to minors is to prohibit self-service displays of tobacco products; the WHO FCTC identifies this as one method for controlling sales to minors.[118] When restrictions on sales to minors are enforced, open displays become a preferred method for young people to obtain cigarettes. Adolescents worried about being asked for proof of their ages can obtain tobacco by stealing it from these displays.[119] Open displays are also a method preferred by tobacco companies to increase sales to young people. Internally, tobacco companies

[118] WHO Framework Convention on Tobacco Control, Article 16, Paragraph 1(b).
[119] DiFranza J and Coleman M. Sources of tobacco for youths in communities with strong enforcement of youth access laws. *Tobacco Control 2001; 10:32*, 23-28.
[120] RJ Reynolds, *Pilferage Presentation,* 1985.
http://www.rjrtdocs.com/rjrtdocs/image_downloader.wmt?MODE=PDF&SEARCH=0&ROW=2&DOC_RANGE=514348983+-9015&CAMEFROM=2&tab=search
[121] WHO Framework Convention on Tobacco Control, Article 16, Paragraph 5.

acknowledge that elimination of self-service displays reduces tobacco sales.[120] To keep retailers from eliminating these displays as a theft-control measure, manufacturers pay them "product placement fees" that the manufacturers insist offset the inevitable losses from theft.

Vending machines represent one of the most conspicuous forms of self-service sales, and one of the easiest methods for young people to obtain cigarettes. While some jurisdictions require that these machines be kept inaccessible to minors, many jurisdictions ban them altogether; it should be noted that access restrictions are poorly enforced or ignored in practice. The WHO FCTC provides that the measures to prohibit the sales of tobacco to minors may include such measures to ensure that tobacco vending machines under its jurisdiction are not accessible to minors and do not promote the sale of tobacco products to minors. At the same time, the WHO FCTC provides, but does not obligate, a Party State to ban vending machines completely or to prohibit their introduction into its jurisdiction.[121]

Other important restrictions on sales methods include:

- Restrictions on the quantity in which tobacco products can be sold. In accordance with the WHO FCTC, Parties must try to prohibit the sale of cigarettes individually or in small packets that are more affordable for minors.
- Requirements that signs be posted at retail locations. Depending on the approach taken, signs may further the government's health goals or detract from them. Some signs, particularly those created in tobacco industry "youth smoking prevention" programmes, may actually send subtle messages that encourage youth smoking, while strong visual images combined with informational messages may reinforce the law and educate the public.
- A prohibition against any visible display of tobacco products, prevents the product packages themselves from being used as a promotional vehicle. Subnational governments in Australia and Canada have restricted or banned displays.
- A ban on the sale of tobacco by minors. Because the use of young people as sales employees increases the rate of sales to minors, the WHO FCTC provides that countries must take measures to prohibit the sale of tobacco by minors.[122]

Smuggling

Approximately one-third of all exported tobacco products are imported illegally.[123] The distribution of contraband tobacco products is widely acknowledged to be a problem that

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[122] WHO Framework Convention on Tobacco Control, Article 16, Paragraph 7.
[123] Joossens L and Raw M. Smuggling and cross border shipping of tobacco in Europe. *British Medical Journal* 1995; 310:1393-7.
[124] See generally Merriman D, Yurekli A, and Chaloupka F. How big is the worldwide cigarette-smuggling problem? In: Jha P and Chaloupka F. *Tobacco Control in Developing Countries*, New York, Oxford University Press, 2000, 365-406 at 400-401.
[125] WHO Framework Convention on Tobacco Control, Article 15, Paragraph 1.
[126] *Curbing the Epidemic: Governments and the Economics of Tobacco Control*, Washington: World Bank, 1999. Published at web site: http://www1.worldbank.org/tobacco/reports.htm.

diminishes government revenue from tobacco taxes, undermines the tobacco control aims of tobacco-tax increases by ensuring widespread availability of cheap tobacco products, and strains the law enforcement resources of all levels of government.[124] The WHO FCTC therefore recognizes that eliminating smuggling and other forms of illicit trade in tobacco products is an essential component of tobacco control.[125]

There is a widespread misperception that smuggling is the result of high taxes on tobacco products. A World Bank report indicates, however, that the level of smuggling is much more closely related to the level of corruption in a country than it is to the price of tobacco products.[126] In recent years, primarily through the release of internal tobacco industry documents, a compelling story has emerged of another possible explanation for the scale of the illicit trade—the apparent involvement of multinational tobacco companies in facilitating smuggling through distribution networks deliberately established to supply the contraband network.[127] Evidence of the industry's alleged role in smuggling has been detailed by several analysts, who point not only to industry documents but also to criminal investigations and convictions of tobacco executives in several countries.[128] This evidence has been sufficiently compelling for the European Union and a number of countries in Europe and the Americas to have initiated legal actions against tobacco companies to recover lost tax revenues, penalties or damages for the industry's alleged role in global smuggling.

Regardless of the root causes of illicit sales, comprehensive legislation should include measures to combat this problem. The WHO FCTC requires Party States to take a number of steps:[129] Among other things, they are to:

- strengthen anti-smuggling laws;
- take steps to see that all tobacco packages are marked to assist tracing;
- require that packages be marked to indicate their country of destination;
- cooperate with other countries in monitoring and controlling the movement of products and in investigating their diversion;
- consider developing a tracking and tracing regime;
- collect and exchange data on cross-border tobacco trade in illicit products; and
- take steps to seize and destroy contraband products and confiscate the proceeds of illicit trade.

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[127] Beelman M, Ronderos MT and Schelzig EJ. Major tobacco multinational implicated in cigarette smuggling, tax evasion, documents show. *The Public I: An Investigative Report of the Center for Public Integrity.* March 23, 2000.

[128] Joossens Luk et al. Issues in the smuggling of tobacco products. In: Jha P and Chaloupka F. *Tobacco Control in Developing Countries*, New York, Oxford University Press, 2000 at 393-406; Sugarman SD International Aspects of Tobacco Control and the Proposed WHO Treaty. In: Rabin RL and Sugarman SD eds., *Regulating Tobacco*, New York, Oxford University Press, 2001, 245-284.

[129] WHO Framework Convention on Tobacco Control, Article 15.

Parties are also to try to adopt additional measures, including, where appropriate, licensing, which can be used to identify, monitor and control the actors in the chain of distribution. Beyond these steps, the WHO FCTC calls for regional, subregional and international cooperation in combating illicit trade, including in investigating and prosecuting violations. These treaty obligations provide a checklist of possible legislative elements. Another possible strategy—the use of bonds to hold tobacco exporters accountable for the eventual arrival of tobacco products at their intended legal destination—is proposed in Annex 1.

Other issues

In designing comprehensive legislation, a country may also wish to consider a number of subjects not addressed here. These may include, for example, smoking cessation, the role of schools in tobacco control, agricultural policies, and issues related to litigation. The brevity of the discussion of these subjects here is not meant to minimize their importance.

Cessation

"The WHO FCTC requires Party States [to endeavour to] create cessation programmes."

Measures to encourage tobacco users to quit are an integral part of a comprehensive approach and complement strategies focused on education and prevention. It can be argued that as governments restrict smoking in public places, inform users about the hazards of tobacco use, and urge smokers to quit, there is not only a medical but also a moral imperative to assist them in doing so. Because of the long delay between smoking initiation and many tobacco-related diseases, helping current smokers to quit may be the only practical way to achieve reductions in health care expenditures in the near term.

The WHO FCTC requires Party States to meet this duty by endeavouring to:

- create cessation programmes, not only in health care facilities, but also in workplaces, educational institutions and other settings;
- include diagnosis and treatment of nicotine dependence in national health programmes;

[130] WHO Framework Convention on Tobacco Control, Article 14, Paragraph 2.

- establish programmes for diagnosis, counselling and treatment in health care facilities and rehabilitation centres; and
- collaborate with other countries to increase the accessibility of cessation therapies, including pharmaceutical products.[130]

Measures to support cessation can also include requiring private medical insurance programmes to pay for the cost of these services and products. A nation can provide cessation support through community-based clinics, as is done in Brazil, or can offer toll-free telephone counselling services and free medications, as is done in some states of the United States of America. These programmes are most effective if supported by large-scale information campaigns to make the public aware of the available services.

A WHO technical consultation emphasized the need for creating a supportive environment that would encourage smokers in their attempts to quit.[131] Raising tobacco taxes, banning advertising of tobacco products, smoke-free-environment policies, education and mass media campaigns to increase smokers' awareness and decrease accessibility of tobacco products, along with community-based smoking-cessation programmes were highlighted as pillars of the process for reducing the numbers of smokers. A smoking-cessation policy should be part of any comprehensive tobacco-control policy, that should encompass the following:

- a supportive environment, which includes a decrease in accessibility of tobacco products, a reduction in social acceptance of tobacco consumption and an increase in information, will increase the likelihood of smokers quitting;
- all tobacco-users should be offered effective treatment for tobacco dependence;
- Member States should develop evidence-based national policy guidelines for the treatment of tobacco dependence;
- awareness should be increased among health-care professionals, administrators, and policy-makers of both the benefits and cost effectiveness of smoking-cessation interventions relative to other health-care interventions;
- training should be provided to all health-care providers at primary care, community and national level to be able to deliver smoking-cessation interventions effectively; and

[131] A WHO technical consultation on smoking cessation, hosted by the Ministry of Health of the Russian Federation, Moscow in June 2002.
[132] WHO Framework Convention on Tobacco Control, Article 12.

- new partnerships are needed to increase commitment and the pool of financial and technical support for implementing evidence-based treatment.

"Because tobacco use often begins in early adolescence, it is appropriate to start teaching children about this topic at an early age and to continue these efforts throughout their education."

School programmes

The WHO FCTC also requires countries to promote broad access to effective comprehensive educational programmes on the health risks of tobacco use.[132] Schools are a natural channel for extending this education to children and adolescents. Because tobacco use often begins in early adolescence, it is appropriate to start teaching children about this topic at an early age and to continue these efforts throughout their education. Legislation can be used to create, test and implement effective school curricula and to require the adoption of strong policies about tobacco use in and around schools and by teachers and other school representatives. Evidence suggests that the effectiveness of classroom education in reducing tobacco use may vary greatly, depending upon the teaching curriculum used. Results may also depend on the adoption of a comprehensive approach, in which tobacco use prevention is not only taught in the classroom, but also reinforced by strong, consistent school policies about tobacco use. Clearly, in-school programmes are most effective when they operate as one element of a systematic approach, in which students receive consistent messages in the classroom and in the larger community.

Agricultural policies

Agricultural policies are another important area for consideration in tobacco-growing countries. WHO has long recommended the use of agricultural policies—for example, the elimination of price supports in some countries—to decrease the supply of tobacco.[133] These policies are often met with opposition based on fear that reduced tobacco production will result in the loss of jobs or export revenues. The WHO FCTC recognizes the need to assist tobacco growers and workers whose livelihoods are

[133] Resolution on Tobacco or Health, Geneva, World Health Organization, 1986, WHA 39.14.
[134] WHO Framework Convention on Tobacco Control, Article 4, Paragraph 6, Article 17.
[135] WHO Framework Convention on Tobacco Control, Article 26, Paragraph 3.
[136] Guindon GE, Boisclair D. Past, Current and Future Trends in Tobacco use. HNP Discussion Paper. *Economics of Tobacco Control.* Paper No. 6, Washington, D.C, The World Bank, 2003.
[137] *Curbing the Epidemic: Governments and the Economics of Tobacco Control.* The World Bank, Washington:, 1999, 67-72, http://www1.worldbank.org/tobacco/reports.htm.

seriously affected by tobacco control programmes,[134] and encourages countries to support crop diversification and other economically viable alternatives as part of sustainable development strategies.[135] It is important to understand, however, that economic analysis shows that even the most robust tobacco control efforts are unlikely to result in absolute reductions in tobacco consumption for decades to come.[136] Existing population trends and patterns of tobacco use are so firmly established that effective tobacco control is likely only to reduce the growth in tobacco consumption, and cannot be expected to reverse overall consumption for many years. This indicates that most fears about economic dislocation are misplaced. In all but a few countries, the World Bank explains, reduced tobacco production would not lead to a net loss of jobs, even in the long term, because money formerly spent on tobacco would be spent on other goods and services.[137]

"The WHO FCTC specifically directs countries to consider using legislation to deal with civil and criminal liability.[140] Possibilities exist for countries to enact a wide assortment of laws or rules to clarify legal responsibility for the harm caused by tobacco companies and their products."

Liability

Issues related to liability represent another important part of comprehensive tobacco control.[138] Possibilities exist for countries to enact a wide assortment of laws or rules to clarify legal responsibility for the harm caused by tobacco companies and their products.[139] The WHO publication, *Towards Health with Justice: Litigation and Public Health inquiries as Tools for Tobacco Control* explores options on litigation. These options could include legislation:

- defining the standard of liability in litigation;
- prescribing legal remedies for liability, such as punitive or exemplary damages;
- allowing the use of "contingent fee arrangements," in which claimants' attorneys take on expensive litigation at no initial expense to the claimant, in exchange for a percentage of any eventual recovery; the absence of such legislation is a primary obstacle to litigation in many countries;
- allowing aggregation of the claims of individual

[138] WHO Framework Convention on Tobacco Control, Article 4, Paragraph 5.
[139] Towards Health with Justice: Litigation and Public Health Inquiries as Tools for Tobacco Control, Geneva, World Health Organization, 2002

victims into "class actions" or other consolidated proceedings. Without these procedures, litigation is not economically viable in many countries, because the cost of litigating exceeds the value of a single claim;

- allowing third parties, such as government health services or private health insurance providers, to assert legal claims based on the costs they incur to provide medical care to sick tobacco users;
- authorizing groups of victims to bring claims against multiple tobacco manufacturers, with legal liability allocated among the manufacturers in proportion to their respective shares of the market; and
- increasing the accessibility and use in court of internal tobacco industry documents revealing the conduct of industry executives.

Developing legislation in this area involves complex issues, but technical support may be available. The WHO FCTC specifically directs countries to consider using legislation to deal with civil and criminal libility. The WHO FCTC calls for cooperation in creating programmes to provide legal technical assistance for this purpose.[140] The treaty specifically contemplates the possibility that the Conference of Parties will take up issues of liability, including support for legislative activities in this area.[141]

[140] WHO Framework Convention on Tobacco Control, Article 22, Paragraph 1.
[141] WHO Framework Convention on Tobacco Control, Article 19, Paragraph 5.

Chapter VII. The drafting process

When a decision has been made about the type of legislation to seek, and when the necessary capacity and support are in place, ideas must be turned into words. Creating specific text for a proposed law is known as legislative drafting.

The role of draft legislation

It is important to understand the place of drafting in the overall process of developing and enacting legislation. Drafting is a specialized and exacting discipline; as one expert has put it, drafting is "not for the do-it-yourselfer."[143] To create a successful tobacco control law, the drafters must have technical skills and knowledge of the many legal issues surrounding lawmaking, government powers and procedures, and any constitutional limitations. Such skills and knowledge must be integrated with a thorough understanding of the substantive issues of tobacco and public health.

"Drafting is a specialized and exacting discipline; as one expert has put it, drafting is "not for the do-it-yourselfer."

Drafting is much more than a technical function. Careless drafting can easily result in fatal errors. If not drafted correctly, legislation may conflict with existing laws, may prove to be unenforceable in practice, or may contain constitutional flaws that cause the law to be overturned by courts. Any inadvertent loopholes in the legislative language will be exploited aggressively by tobacco companies eager to undermine the law's impact. For these reasons, the drafting phase of the legislative process is critical.

"Any inadvertent loopholes in the legislative language will be exploited aggressively by tobacco companies eager to undermine the law's impact."

At the same time, it is important not to misunderstand the role of the drafter. Drafting is not the process for making fundamental choices about the type of legislation to pursue or the strategies for doing so; rather, drafting is a process for reducing those choices to a viable, legally correct written form. Advocates sometimes confuse these roles, and look to the drafters to shape the fundamental substantive nature of the proposal. Instead, these hard choices should be sorted out by proponents before the drafting begins, in active consultation among the chief proponents, experts, supporters within civil society and leading supporters within the legislative body. Advocates should avoid any temptation to move

[143] Grad FP. *The Public Health Law Manual*, 2nd ed., New York, American Public Health Association, 1990, 319.

to the drafting stage until they have built a consensus of support for the substance of the proposal.

Even after legislation is drafted, it is important not to misunderstand the status of a draft text. Some draft legislation is enacted into law with few changes. (This may occur, for example, where the legislation is proposed by a government with a large majority in the legislative body.) More often, however, the legislative process is unpredictable. The controversial nature of tobacco control and the opposition orchestrated by tobacco companies usually guarantee a spirited debate, with proposals, counterproposals, legislative amendments and arguments for compromise. In this context, the wording of draft legislation should not be considered final or sacred. Instead, supporters should focus on the underlying issues, maintaining a clear understanding of the points on which they are prepared to compromise or consider alternatives and the points on which they will not yield, while remaining flexible about adjustments to legislative wording.

"The public health and legal experts should collaborate in a process of mutual education. The collaboration should be a conversation, in which each partner poses questions to the other to sharpen their collective thinking, identify issues from the perspective of each specialist's discipline, and work toward language that meets both health and legal goals."

A drafting partnership

Drafting tobacco control legislation requires a partnership of public health and law. This may be a single public health expert and a single lawyer expert in legislative drafting, or may be a working group, combining public health experts, lawyers and others. For example, many legislative bodies have advisers who help lawmakers draft legislation; these are natural partners for the drafting process. The legal expert or experts chosen should have a thorough understanding of the country's legislative process, existing administrative and regulatory structures and constitutional provisions.

The public health and legal experts should collaborate in a process of mutual education.[144] Both need to be familiar with the general subject of tobacco control, with the specific legislative approach to be adopted, and with the principal questions to be decided. These experts should work together from the outset of the drafting process. It is not advisable, for example, for public health experts to prepare draft language and then look to a lawyer to translate the draft into "legal language." Instead, the collaboration should be a conversation, in which each partner poses questions to the other to sharpen their collective thinking, identify issues from

[144] See Grad FP. *The Public Health Law Manual*, 2nd ed., New York, American Public Health Association, 1990, 316.

the perspective of each specialist's discipline, and work toward language that meets both health and legal goals.

This interactive process should be part of a larger collaboration in which other important participants are consulted and their advice incorporated in the drafting. Among the appropriate sources to consult are:

- Members of the legislative body who will play leading roles in enacting the legislation, or their aides. Early involvement of these central figures will begin educating them about tobacco control, and establishing strong working relationships with these legislators is a key to effective advocacy.
- Principal supporters of the legislation, whether nongovernmental organizations (NGOs), political figures, academic experts or others.
- Recognized experts, whether at academic institutions or health care organizations.
- International experts in specialized aspects of tobacco control, or others familiar with laws in other countries that may serve as models for the legislation.
- Lawyers with expertise in constitutional law or international trade, to review draft language for any constitutional problems and for any possible challenge under trade agreements, on the theory that the legislation creates impermissible restraints on trade.

Involving a large circle of participants in the drafting process helps build consensus and gives those consulted a greater sense of commitment to the proposal. This strengthens the base of support for the legislative battles to come.

Guiding principles

Well-drafted legislation is usually characterized by several qualities:

Clarity. The wording should be direct and unambiguous. Simple declarative language is best.

Simplicity. Less is more. Simple structures and standards usually lead to fewer problems than elaborate schemes or rules riddled with exceptions and qualifications.

Consistency. The law must have a coherent internal structure that holds together without omissions or gaps of logic. It should also be consistent with existing laws, so the tobacco control programme will dovetail with other programmes. For example, definitions should resemble the definitions of similar terms in existing laws, unless there are good reasons for a different approach.

Familiarity. It is usually advantageous to use familiar concepts and mechanisms. For example, selecting well-established enforcement procedures already used by other laws, rather than designing completely new ones, is likely to minimize the risk of unexpected problems in implementation, and may be more readily accepted by the legislative body.

Flexibility. Tobacco control legislation should be flexible. Over time, changes will be needed as the impact of the legislation is evaluated, as new scientific evidence emerges, as technologies improve, and as new interventions are designed. Legislation should be written to give regulatory authorities latitude to adapt to these conditions.

The parts of a law

Certain elements are common to most legislation. Although the precise form of legislation differs from country to country, legislation typically includes an introductory statement of purpose, definitions, substantive provisions, enforcement provisions and final clauses.[145]

Laws often begin with a general statement of the purpose of the law or the principles it embodies. Although the wording may be general, the purpose of a law provides the framework within which the law will be implemented and interpreted. In the context of a

[145] This discussion is adapted from the Pan American Health Organization's *Developing Legislation; Template and Guidelines*, 2002.

legal challenge to the law or its regulations, this provision can play a critical role. Therefore, words should be carefully chosen and should clearly and accurately reflect the rationale and intentions behind the legislation.

"Although the precise form of legislation differs from country to country, legislation typically includes an introductory statement of purpose, definitions, substantive provisions, enforcement provisions and final clauses."

Definitions are very important in the interpretation of a legal instrument. Definitions generally should be limited to those terms that have potential for ambiguous interpretation, or for which the generally accepted dictionary definition does not adequately reflect the meaning of the term for the purpose of the law. Definitions should also generally parallel those used in existing laws for the same or similar terms. Clear and unambiguous definitions will greatly assist the efficient implementation of a law and reduce the likelihood of unanticipated loopholes.

The heart of legislation consists of the substantive provisions prescribing requirements, prohibitions and procedures in the subject area addressed. Comprehensive tobacco control legislation will contain sections addressing most or all of the subject areas discussed in Chapter VI. This will make up the bulk of the legislation.

Following the substantive provisions, a portion of the legislation will address enforcement and implementation. This section comprises basic components for effective enforcement, including sections identifying and empowering the enforcement authority, prescribing penalties, sanctions or other consequences for violations, and defining enforcement procedures. This section may also address implementation mechanisms such as surveillance, reporting and evaluation.

A series of final clauses may address general questions about the law and its legal status. Most common among these is language specifying the law's effective date or time for coming into force. Any phase-in period would be addressed here, as would any declarations about the intended treatment of the law in any judicial review. For example, a declaration may specify that if portions of the law are ruled invalid by a competent court, the remaining portions of the law are still to remain in force.

Model legislation

One invaluable resource for drafting is model legislation. Several models are available,[146] and others are in development. Any of these models can serve as a starting point, providing sound, general language that drafters can adapt to their country's circumstances.

This guide includes a legislative "template" in Annex 2 that provides sample text for legislation in the areas of tobacco product regulation, packaging and labelling, advertising and promotion, distribution, use and smuggling, as well as text for the necessary ancillary provisions, including definitions, enforcement procedures and final clauses. The template offers alternative approaches in some areas, and enables drafters to include or omit any of its modules. Importantly, it offers commentary explaining the rationale behind each of the sections.[147]

Resources and technical assistance

Assistance for the drafting effort can often be found by drawing on legal experts within the government—for example, within the legislative body, an administrative agency or a law enforcement office—or at a university or school of law. Tobacco control experts may be available within the appropriate ministry of government, at academic or health institutions, or in NGOs.

Where appropriate, assistance may also be sought from technical experts outside the country. WHO may be able to assist countries in identifying possible consultants for this purpose. For example, WHO's regional offices have developed rosters of attorneys with specialized expertise, who may be willing to serve as consultants. Other international experts include nongovernmental advocates, government officials in countries with successful legislation, leading academic researchers or specialists from international organizations. In some instances, WHO and its regional offices may be able to offer direct support and assistance.

Another important resource for drafting is the language of existing laws from other jurisdictions. Many of these laws are available on the "NATIONS" database.[148] Online sources for selected national laws are also collected in Annex 3 to this guide. Texts of most national laws enacted before 1999 can be found in WHO's journal *International Digest of Health Legislation*.

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[146] See, e.g. Mackay J, Sweanor D and LeGresley E. A Model of a Tobacco Products Control Act, web site: http://www.ingcat.org/assets/images/law.pdf; ; and Americans For Non-smokers' Rights, Model Ordinance for Smoke-Free Public Places, web site http://www.no-smoke.org/100ord.html.

[147] *Developing Legislation for Tobacco Control; Template and Guidelines*, Washington, Pan American Health Organization, 2002, web site http://www.paho.org/English/HPP/HPM/TOH/tobacco_legislation.pdf (in English) and http://www.paho.org/Spanish/HPP/HPM/TOH/tobacco_legislationSpa.pdf (in Spanish).

[148] http://apps.nccd.cdc.gov/nations/nations/Country_Specific_indicators.asp.

Chapter VIII. Passing legislation

When legislation has been prepared, efforts to enact the proposal will begin. Developing a strategy for these efforts is as important as developing the legislation itself. By the time the legislation has been drafted, proponents should have established the basic national capacity to support tobacco control, assessed their country's readiness for a legislative campaign and built consensus in favour of the proposal among key supporters.

"The keys to success, according to experienced advocates, are political will, government support, and effective advocacy from outside the government.[149] Legislative campaigns require tenacity, patience, imagination and flexibility."

Legislative advocacy is, in a sense, an extension of this capacity-building process, but in a highly intensified form. In many countries, especially those where legislative bodies are highly responsive to public opinion, successful advocacy will require a multifaceted campaign involving many coordinated elements. The keys to success, according to experienced advocates, are political will, government support, and effective advocacy from outside the government.[149] Whatever specific form they may take, legislative campaigns require tenacity, patience, imagination and flexibility.

An advocacy plan

In some legislative bodies, the procedures for guiding a proposal to passage are simple; in others, the process is complex and replete with possible pitfalls. Either way, supporters should prepare for stiff opposition. Overcoming this opposition often requires a large campaign with many facets, each of which should reinforce the others.

"Efforts within the legislative setting should be reinforced by efforts to mobilize many diverse supporters and to involve the news media in increasing public awareness."

An integrated campaign involves much more than interaction with members of the legislative body. Efforts within the legislative setting should be reinforced by efforts to mobilize many diverse supporters and to involve the news media in increasing public awareness. Supporters must collect the information and organize the events and activities that will generate public interest. Opinion polls and research findings will be used to build awareness and support. Often, a campaign will include a systematic effort to encourage individual members of the public to communicate with legislators. The campaign must communicate continuously with supporters so as to maintain their involvement.

[149] See, e.g. Cunningham R. *Smoke and Mirrors: The Canadian Tobacco War*. Ottawa, International Development Research Centre, 1996, 191.

Increasingly, the Internet will be used as a fast, powerful and cost-effective tool for reaching large audiences. The activities of tobacco companies and their allies must be monitored and exposed.

To ensure that these efforts take place, that they are timely, and that they indeed complement one another, supporters should have an advocacy plan. This plan need not be reduced to writing, but it requires at a minimum that supporters reach agreement in advance about the actions they will take to win passage of the proposal, the roles different organizations will play, and the way in which their activities will be coordinated.

Legislative sponsors

"Securing the strongest possible sponsor is one of the most important steps advocates can take to increase the odds of success."

An important preliminary aspect of the legislative campaign is the identification and recruitment of the lawmaker or lawmakers who will sponsor the proposal. Sponsors are the members of the legislative body who offer the proposal for consideration, become its principal advocates within the body, and often control its procedural progress. The selection of the right sponsor can make the difference between success and failure.

Ideal legislative sponsors will combine several distinct qualities. Ordinarily, these sponsors will be members of the political party holding a majority of seats in the legislative body. They will have a passionate commitment to tobacco control, based on a solid understanding of the health issues. At a personal level, they will have positive working relationships with leading advocates. They will be articulate, able to make a compelling case for the legislation, and skilled in legislative procedures and manoeuvres. Ideally, they will hold positions of leadership, such as the chairs of committees with jurisdiction over the proposal; at a minimum, they will be senior lawmakers widely respected by their colleagues.

Few real sponsors will measure up to this ideal. But securing the strongest possible sponsor is one of the most important steps advocates can take to increase the odds of success.

Communicating with legislators

The central component of any legislative campaign is direct communication between supporters and members of the legislative body. In a well-organized campaign, lawmakers will be contacted repeatedly and by multiple supporters from both government and

civil society. These contacts are the single most important channel for educating lawmakers and encouraging them to support the legislation.

Communicating with legislators for the purpose of winning their votes, sometimes called "lobbying," is often mistakenly assumed to be mainly about applying pressure or influence. Certainly, elected lawmakers can feel significant pressure to respond to the wishes of powerful interests, whether business interests, influential voices of civil society, or large numbers of individual citizens. Hearing from many individuals and organizations who support tobacco control legislation can be extremely influential in determining a lawmaker's vote.

In practice, however, these communications derive their real power not from pressure but from information. The essence of effective "lobbying" is information—credible, useful information. Legislators look to advocates for reliable information about the legislation, the reasons for supporting it, and its practical implications. They also look to a proposal's supporters to alert them to the likely arguments of the tobacco industry and other opponents, and to provide persuasive rebuttals to those arguments. Information about the likely effects of the proposal on people and organizations, information about the alignment of support and opposition, and information about the strategies and tactics of the legislative manoeuvring will all have value to lawmakers.

"Communications derive their real power not from pressure but from information. The essence of effective "lobbying" is information—credible, useful information."

It is the ability to provide credible information on issues like these, in a useful form, that gives these communications their power. Because most legislators are busy, with limited time and no specialized knowledge of health issues, this information is most influential if it is concise, easily understood and presented in everyday language. Examples of useful formats include brief handouts in question-and-answer format,[150] summaries of results of opinion polls, concise rebuttals to the major arguments of opponents and organized briefings on specific aspects of the legislation.

Communications with lawmakers should always be respectful and professional, and never accusatory or shrill, even if a lawmaker is openly hostile. Above all, advocates must be

[150] For an example of questions and answers used successfully in support of legislation in Brazil in 2000, see http://www.inca.gov.br/tabagismo/easaude/index.html.

scrupulously honest. If asked a question to which they do not know the answer, effective advocates do not speculate, assume or exaggerate; they offer to find an answer. Ultimately, advocates' influence rests on one thing: their credibility. Over time, by providing consistently reliable information, they will win the trust of legislators and build the influential relationships that can help determine the fate of legislation.

Communications with legislators are also invaluable as a means of gathering critical information. Especially as relationships of trust develop, these interactions will become advocates' most important source of insight into behind-the-scenes legislative manoeuvring, tactics and possible pitfalls. Moreover, these communications are the principal channels for gathering all-important information about the likely line-up of votes for and against the proposal.

Mobilizing supporters

The legislative campaign must mobilize the entire national capacity for tobacco control in active support of the legislation. This requires continuous, timely communication with supporters, to keep them well informed about the progress of the legislative process and upcoming developments, and to maintain their sense of involvement. At the same time, every effort must be made to continue expanding the coalition of support.

This is largely a matter of working through organizations to activate their representatives and members. It can be done by making presentations at meetings and conferences; tapping existing networks of members or volunteers; preparing articles and commentary for inclusion in organizations' newsletters and other publications; mailing information to members or volunteers, and, increasingly, using electronic communications. Organizations and their leaders can make public speeches, hold news conferences, prepare guest editorials for newspapers, and even purchase advertisements in support of the proposal.

"An important part of expanding the base of support is to seek the endorsement of as many organizations as possible for the legislation."

An important part of expanding the base of support is to seek the endorsement of as many organizations as possible for the legislation, even if those organizations do not become actively involved. Many organizations have formal procedures for determining their positions on legislative matters. Because these procedures can be very slow, supporters should be prepared to begin

seeking the endorsement of key organizations well in advance of the legislative debate.

Mobilizing support is also a matter of involving influential individuals. These can be individuals who are able to generate public attention, such as celebrities and prominent leaders of organizations. They can also be individuals who are likely to have particular influence with members of the legislative body, such as political leaders or distinguished experts, including experts from other countries. Particularly valuable are individual supporters with expertise in the legislative process and personal relationships with lawmakers, who can help supporters to gather information about developments and plan legislative strategy.

Engaging the public

In most countries, a fundamental part of the campaign will be to demonstrate to the legislative body that the proposal has broad public support. This is done in two ways.

First, public opinion polling can be used to document the level of support for the proposal. This information can be very powerful, because public support is often much higher than lawmakers expect.[151] Nationwide surveys have been used effectively in many countries. In Thailand, for example, surveys have shown strong public support for smoke-free public places, demonstrating that the public supports elimination of smoking in restaurants and that most employees want air-conditioned offices to be smoke-free.[152] Similarly, in South Africa, a 1998 nationwide survey found that 67% of the public approved of policies for smoke-free public places and a ban on tobacco advertising.[153]

Second, supporters can encourage individual members of the public to support the legislation by communicating directly with the legislative body—a process sometimes known as "grassroots lobbying." Advocates should not expect these expressions of support to appear automatically when a proposal is put forward. An organized effort is needed to inform people about the contents and importance of the proposal, and how, when and where to make their voices heard. This effort can be targeted toward

"An organized effort is needed to inform people about the contents and importance of the proposal, and how, when and where to make their voices heard."

[151] See, e.g. Measuring support for tobacco control policy in selected areas of six countries. *Tobacco Control, 7,* 241-46.
[152] Tobacco Use and Policy Profile for Thailand, http://www.tobaccofreeasia.net/Menu1/thailand/legislation.htm.
[153] See case study in Chapter XII.

likely supporters—for example, by contacting members of supportive organizations and networks face to face or through publications and mailings. Alternatively, supporters can use mailings or general-circulation publications to encourage the general public to become involved. This involvement can take the form of personal meetings with lawmakers, letters or telephone calls, signatures on petitions or letters to newspapers. Often, advocates facilitate the public's involvement by helping citizens understand how to contact lawmakers or how to present their views.

Introduction of legislation

Although legislative procedures vary greatly, certain milestones are common to the process in many countries. Understanding these procedures and the legislative timetable is vital to advocates' ability to influence the process and anticipate difficulties. The first legislative milestone comes when the proposal is formally "introduced," or submitted for consideration. This is not typically a point at which decisive action occurs, although it may be at this time that the principal legislative sponsor makes an important speech in the legislative body or the proposal is directed to a committee for consideration.

"The introduction of the legislation does represent a key opportunity for media publicity."

The introduction of the legislation does represent a key opportunity for media publicity, however. Often, advocates will arrange a major news conference or other event to announce the introduction of legislation. These events often include public statements or endorsements by supporting organizations, a coordinated series of media interviews, the release of new information such as a public opinion poll, or similar activities. Advocates should plan carefully to take full advantage of this opportunity.

Public hearings

After the proposal is introduced, it will ordinarily be directed or "referred" to one or several committees. Committees have jurisdiction over particular subject areas; typically, they review and debate proposals within their authority before deciding whether to send them forward to other committees and eventually to the full legislative body. Tobacco control legislation may be referred not only to a committee responsible for health matters, but also to those specializing in, for example, taxation or business regulation.

Before a committee debates and votes on a proposal, it will typically hold a public hearing, at which witnesses for and against the proposal are permitted to present testimony and evidence. A public hearing is one of the most important public milestones in the legislative process. Advocates should carefully orchestrate the presentation of evidence, arranging the testimony of experts, leading supporters, victims, and others best able to make a compelling case for the proposal. The best line-up of participants will depend on each country's circumstances, but witnesses should be chosen for their influence, expertise, and persuasiveness. Collectively, they should present a complete and compelling case for the proposal.

"A public hearing is one of the most important public milestones in the legislative process."

Public hearings provide ideal opportunities for media attention to the legislation. Advocates should actively encourage news media coverage. This can be done by contacting journalists individually, issuing news releases or conducting a news conference. News coverage of hearings can often be amplified by suggesting media interviews with witnesses or by arranging events or announcements to coincide with the hearings.

Amendments

Legislation is seldom enacted in exactly the form in which it is introduced. As every veteran of the legislative process can attest, the legislative process is dynamic and unpredictable, and laws are often the product of compromise. Compromises aside, amendments are frequently accepted to respond to issues and concerns that emerge in the course of debate.

"The legislative process is dynamic and unpredictable, and laws are often the product of compromise. Proponents should anticipate changes and respond strategically."

Proponents should anticipate changes and respond strategically. To the extent possible, they should seek advance agreement among supporters as to the provisions of the proposal that could be modified, or deleted altogether, without compromising its integrity and purposes. They should also be prepared to offer their own amendments as necessary to respond to new issues and objections that emerge during the process.

A communications strategy

As in the process of national capacity-building, the many-faceted communications of a legislative campaign should be guided by a coherent communications strategy.[154] As discussed throughout

[154] See Chapter IV.

this chapter, a full-scale advocacy campaign will involve many simultaneous forms of communication, ranging from one-on-one meetings with members of the legislative body to the generation of news coverage. These activities should be planned and coordinated.

This coordination will enable supporters to set the terms of the debate. A proactive strategy also helps ensure that every possible channel of communication is used effectively to maximize the campaign's impact and, ultimately, to win support within the legislative body. Coordination will make it possible to identify gaps and opportunities, and to see that lawmakers, the media and the public receive information that is timely, accurate and complete.

Just as importantly, a coordinated approach will allow proponents to agree on a set of simple key messages, and to ensure that all communications, in whatever form, repeat and reinforce those messages. This consistency is central to the effectiveness of the communications. Moreover, it is essential if proponents are to frame the debate.

"By the time a legislative campaign begins, proponents of tobacco control should have established capacity for an effective information campaign."

By the time a legislative campaign begins, proponents of tobacco control should have established capacity for an effective information campaign. Spokespeople and communications coordinators should be trained, and should have the basic skills to arrange interviews, hold news conferences, prepare news releases and press kits, conduct newspaper editorial board meetings, place human interest stories, and write articles, guest editorials and letters to the editor. They should have begun building personal relationships with key members of the news media.

With these skills, the campaign's communication coordinators should set about using as many different forms of communication as possible to reinforce the campaign's key messages. Supportive organizations should use their existing avenues of communication to reinforce these messages. For example, public health authorities, educational institutions, nongovernmental organization (NGOs) and government agencies may be willing to use their publications, web sites, public presentations and other channels to disseminate information that supports the law. If resources permit, supporters may use advertisements to sustain the campaign—perhaps reducing expenses by advertising selectively in specific media or in communities where messages will reach key decision-makers. In any event, a campaign for comprehensive legislation presents almost unlimited

opportunities for developing media coverage at minimal expense.[155] A coordinated strategy will increase the likelihood of capturing these opportunities.

The campaign never ends

When a legislative campaign succeeds, and the proposal becomes law, the legislative process does not end.[156] Legislation is always evolving. Weak laws are strengthened; hard-won gains are interrupted by setbacks.

Countries that are unable to enact a comprehensive programme initially will want to strengthen their laws over time. At the same time, those with even modest legislation will need to be constantly vigilant against the quiet sabotage of the tobacco industry. Moreover, even a jurisdiction that succeeds in implementing global best practices in every area of regulation may find that in one, two or five years, there are even "better practices." Any legislation will need to be updated periodically for a number of reasons, including:

"When a legislative campaign succeeds, and the proposal becomes law, the legislative process does not end. Legislation is always evolving."

- the need to close unintended loopholes;
- the need for improvements based on continuous evaluation of the law's effectiveness;
- new scientific evidence and consensus about effective measures; and
- advances in public support or political will that make it possible to enact stronger measures.

[155] See, e.g. Must E, Efroymson D. *PATH Canada Guide: Using the Media for Tobacco Control*, Dhaka 2002, available at web site http://www.pathcanada.org, suggesting many ideas for generating media coverage.

[156] This discussion is adapted from *Developing Legislation for Tobacco Control: Template and Guidelines,* Pan American Health Organization, 2002, at 6, web site http://www.paho.org/English/HPP/HPM/TOH/tobacco_legislation.pdf (in English) and http://www.paho.org/Spanish/HPP/HPM/TOH/tobacco_legislationSpa.pdf (in Spanish).

Chapter IX. Challenges and obstacles

Most major legislative proposals encounter opposition. The opposition to tobacco control legislation is unusual in its scale and ferocity, however. In the words of the Committee of Experts appointed to investigate tobacco industry sabotage of the World Health Organization (WHO):

"The opposition to tobacco control legislation is unusual in its scale and ferocity..."

"…Tobacco use is unlike other threats to global health. . . . . The evidence . . . suggests that tobacco is a case unto itself, and that reversing its burden on global health will be not only about understanding and curing disease, but, just as importantly, about overcoming a determined and powerful industry.[157]"

The challenge

Experience around the world teaches that tobacco industry opposition to effective legislation should never be underestimated. The long-secret records of some of the largest multinational tobacco corporations provide insight into this opposition.[158] These records confirm the first-hand accounts of health advocates around the world, and help explain why enacting strong laws can be so difficult.

As WHO's Committee of Experts emphasized after reviewing thousands of these documents, industry opposition to tobacco control is "elaborate, well financed, sophisticated, and usually invisible."[159] In terms that aptly describe the industry's response to legislation, WHO's report observed:

"That tobacco companies resist proposals for tobacco control comes as no surprise. What is now clear is the scale and intensity of their often-deceptive strategies and tactics.[160]"

PAHO reached a similar conclusion when it investigated evidence of industry attempts to undermine public health policies in Latin America and the Caribbean.

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[157] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, at 244.
[158] See generally Hammond R and Rowell A. *Trust Us, We're the Tobacco Industry*, Campaign for Tobacco-Free Kids and Action on Smoking and Health – U.K., 2001, http://www.tobaccofreekids.org, for excerpts from internal documents illustrating industry activities in more than 70 countries.
[159] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, at iii.
[160] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, at iii.

"The tobacco industry's actions are pervasive and persistently deceptive. It is imperative that tobacco control debate and policy be guided by keen knowledge of the industry's deceptive plans and practices. Knowledge is power and it requires great strength to fight back against an industry using financial muscle and dishonest strategies to market addictive products.[161]"

The tobacco industry and its tactics

"When threatened, the tobacco industry responds with every resource at its disposal."

When threatened, the tobacco industry responds with every resource at its disposal. In most countries, the industry's financial interests extend to every corner of the economy, and it uses these resources strategically to integrate itself into everyday life and culture. Advertisements shape public attitudes and define tobacco use as "normal" or "sophisticated." Other advertising campaigns depict tobacco companies themselves as "socially responsible," or purport to discourage young people from smoking. Sponsorships link manufacturers with—and give them influence over—popular sporting events, entertainment and culture. The chain of product distribution ties them directly to tobacco growers, local manufacturing facilities, importers, distributors, and retail sellers. Newspapers, radio and television outlets, advertising agencies and public relations firms depend on their advertising business. Through careful use of charitable contributions, they create dependence within nongovernmental organization (NGOs) and "independent" think tanks. Their payrolls include leading local attorneys, scientists, economists and other consultants. Universities count on their research grants and contracts.

All this weaves a web of influence that runs through the social fabric of most cultures. It enables tobacco manufacturers to help shape the way the society thinks about tobacco use, and to mobilize support from many quarters when threatened. This allows the industry to fight tobacco control legislation from many directions at once, in ways that are both overt and covert.

Overt opposition comes both in the form of direct intervention with legislators, and in the form of efforts to influence opinion leaders in civil society and the general public. At the individual level, tobacco companies employ representatives carefully selected for

[161] *Profits Over People, Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean* Pan American Health Organization, 2002, at 96.

their close, long-standing personal relationships with political leaders. These relationships guarantee them access to the decision-making process and can sometimes determine the outcome.

At a societal level, the industry may wage an overt campaign to influence public debate. This may be a paid advertising campaign, as in the United States of America, where tobacco companies spent tens of millions of dollars for targeted television advertising to defeat a national legislative proposal. Or it may take the form of unpaid communications, as in Senegal, where tobacco companies used the news media to argue successfully that a national advertising ban was ineffective and unfair to local companies.[162] This opposition may use any form of communication, from large-scale mailings to meetings with individual journalists intended "to persuade media to become allies in lobbying against smoking restrictions."[163] These campaigns can be highly effective, as in Argentina, where, in a successful effort to defeat national legislation, the industry was able to generate 105 favourable newspaper and magazine articles in one two-week period.[164]

"Because opposition is most credible if it appears to come from independent sources, tobacco companies prefer to work through surrogates."

Most industry opposition, however, is—as WHO's Committee of Experts put it—"invisible."[165] The industry is well aware that "[a] campaign … carrying the industry's signature would probably invite official resentment and would be provocative to decision-makers …."[166] Because opposition is most credible if it appears to come from independent sources, tobacco companies prefer to work through surrogates. They do this by mobilizing others whose interests are aligned with their own, by creating or co-opting "front groups" and by secretly purchasing support from other, supposedly independent, sources.

Some legitimate groups are usually inclined to oppose tobacco control legislation. Growers and sellers of tobacco may be fearful that their livelihoods will be threatened; advertising

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[162] See *Country Case Studies: Senegal*, http://tobaccofreekids.org/campaign/global/casestudies/senegal.pdf

[163] *Profits Over People, Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean*, Pan American Health Organization, 2002 at 30, quoting a 1993 document of British-American Tobacco Company Limited.

[164] Saloojee Y and Elif D. Tobacco industry tactics for resisting public policy on health. *Bulletin of the World Health Organization*, 78(7) 2000, 902 at 905; see also *Profits Over People, Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean* at 26, Pan American Health Organization, 2002.

[165] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, at iii.

[166] *Voice of Truth, Volume 2*, Regional Office for the Eastern Mediterranean, World Health Organization, 2002, at 22, quoting a 1991 Philip Morris document concerning activities in countries of the Gulf Cooperating Council.

agencies and newspapers may fear the loss of advertising revenues; and so on. Others may oppose the legislation on philosophical grounds: they may genuinely believe that tobacco use is a matter of individual "choice" that should not be regulated. Those who receive tobacco industry money, from universities to cultural, charitable and sports organizations, may feel pressure to protect these arrangements. Tobacco companies are masters at inciting these fears and concerns and mobilizing these groups in opposition—for example, by conducting organizing efforts and funding opposition campaigns.

Often, however, tobacco companies expand this opposition by co-opting existing organizations, or by creating new ones. These front groups may represent—or claim to represent—tobacco growers, sellers, restaurants, smokers, publishers or others. In other cases, they may present themselves to the public as independent NGOs, "think tanks" or charities.

Sometimes these "groups" are created from thin air, as in the case of the "New York Society for International Affairs," which supposedly promoted international understanding, but allowed Philip Morris to give high-ranking national officials subsidized travel to exotic destinations. A Philip Morris Vice President later described the Society's "offices" as "a chair in my apartment."[167]

More often, front groups are hybrid organizations, in which third parties are involved, but tobacco companies exert control over budgets and agendas. An example is the International Tobacco Growers' Association (ITGA). According to documents of the British American Tobacco Company, tobacco industry resources were used to "transform the ITGA from an introspective and largely ineffectual trade association to a pro-active, politically effective organization" so that "[t]he ITGA could front for our third-world lobby activities . . ."[168]

The industry extends its web of influence by secretly deploying scores of influential individuals to protect its interests without disclosing their affiliations. For example, in a worldwide project called the ETS Consultancy Program, dozens of seemingly independent scientific experts in chemistry, biochemistry, epidemiology, oncology, pulmonary and cardiovascular medicine and other disciplines were retained to speak publicly in opposition to regulation of public smoking, and to minimize public concerns about second-hand smoke.[169] "Independent" observers are paid to submit commentary to the media.[170] Freelance journalists

[167] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, at 68-69.
[168] *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, at 47-48, quoting British American Tobacco Company documents.
[169] Muggli M et al. The smoke you don't see: uncovering tobacco industry scientific strategies aimed against control of environmental tobacco smoke. *American Journal of Public Health*. 2001; 91(9):1419-1423.
[170] See, e.g. *Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization: Report of the Committee of Experts on Tobacco Industry Documents*, Geneva, World Health Organization, 2000, at 115-119.
[171] British-American Tobacco Company memorandum, 1994, quoted in *Profits Over People, Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean,* Pan American Health Organization, 2002, at 31.

are given expense-paid foreign trips, because they "are less likely to 'bite the hand that feeds them' as they will want to safeguard their place on any future trips."[171] Political figures and government employees may be given not only political contributions or subsidized travel, but also direct payments.[172]

Using all these agents, both open and concealed, tobacco companies have shown themselves willing to use almost any tactic to disrupt, delay and derail threatening legislation. These tactics include:

"Tobacco companies have shown themselves willing to use almost any tactic to disrupt, delay and derail threatening legislation."

- Using procedural manoeuvres in the legislative process to steer the proposal to unfriendly committees, to prevent it from receiving a public hearing, to prevent it from coming to a vote, or to secure a veto by the executive authority.
- Proposing weak and ineffectual alternatives to legislation, such as voluntary agreements or self-regulation.
- Amending legislation to make it pre-emptive — that is, to prohibit other units of government from implementing other measures.
- Secretly creating disruptions and distractions that have no visible connection to tobacco control— for example, fights about other programmes or budgets of the health ministry—to drain the energy and attention of supporters.
- Threatening or bringing legal actions to harass and intimidate advocates and the legislative body.

The combined impact of all these resources and tactics can be powerful indeed. This point is illustrated well by the findings of a review of tobacco industry activities prepared by WHO's Regional Office for the Eastern Mediterranean:

"The multinational tobacco companies in the [Eastern Mediterranean Region] have a long, well-documented history of collusion. They formed a series of trade associations … which fought health regulations with everything at their disposal. The

[172] Saloojee Y and Elif D. Tobacco industry tactics for resisting public policy on health, *Bulletin of the World Health Organization*, 78(7) 2000, 902 at 907.

companies coordinated strategy and developed and executed action plans to fight advertising bans, public smoking restrictions, tax increases and product regulations. They sought to protect and promote an environment in which smoking was socially acceptable and, when this conflicted with Islamic teachings, they sought to manipulate religious leaders in the region.

The tobacco industry actively lobbied prominent political figures, scientific standards officials, and the media. In addition, they planted pro-tobacco articles in newspapers and manipulated third-party organizations to lobby on behalf of tobacco industry interests. The companies spied on and infiltrated potential foes, such as the WHO and the Arab Gulf States Health Ministers' Council, and were therefore eminently prepared to react forcefully against every tobacco control policy proposed.

Despite the best efforts of committed public health officials, politicians, and public health groups in the [Eastern Mediterranean Region], the multinational tobacco industry continues to wield enormous power over the policy-making process in the region.[173]"

To overcome such powerful opposition, supporters of legislation must be determined and well prepared. An important part of that preparation is to understand the industry's most common arguments.

Arguments and answers

"The accumulated evidence about the consequences of tobacco use makes it impossible for opponents to deny that tobacco is harmful, as they did for many years."

Opponents of tobacco control raise many objections, some of which are specific to particular jurisdictions. These arguments are not always consistent. For example, one common approach is for opponents to raise an endless succession of unrelated questions and objections, never allowing discussion to settle on one topic. The goal of this scattershot approach is usually to cloud the debate and create the impression that the legislation must be poorly drafted. Nevertheless, most legislative debates do centre on certain common themes, all designed to shift attention away from issues of health.

"Tobacco problems are not very important"

The accumulated evidence about the consequences of

[173] *Voice of Truth,* World Health Organization, Regional Office for the Eastern Mediterranean, 2002, *Volume 2*, at 22-23.

tobacco use makes it impossible for opponents to deny that tobacco is harmful, as they did for many years. Now this argument takes a more subtle form. Today, the argument is that, although tobacco use may not be healthy, tobacco control is not an important priority. Opponents are therefore dismissive of the need for legislation.

This argument is partly a suggestion, sometimes only hinted at, that tobacco-related diseases are merely one of the risks of life. Opponents may liken tobacco's dangers to the risk of being injured in an automobile, struck by lightning or dying as the result of an unhealthy diet. This plays into widespread misunderstanding about the magnitude of the tobacco epidemic. These arguments are especially powerful in developing countries, where so many urgent and immediate problems compete for attention, and where the link between tobacco use and long-term illnesses is not self-evident.

"Arguments about "choices" and "decisions" have little meaning in the case of tobacco products. Most users begin before they are old enough to make informed decisions, and are fully addicted before they become adults. Surveys show that the preferred "choice" of most adult tobacco users is to quit, but that they are unable to break their addictions."

These arguments are rebutted conclusively by the overwhelming body of medical evidence and the unanimous views of the world's medical authorities. To respond, proponents of legislation must educate the legislative body and the public at large about these facts. This can be done most effectively by the best-respected local health experts, drawing on the definitive statements of WHO and other global authorities. The single most powerful reference point for this purpose is the WHO Framework Convention on Tobacco Control (WHO FCTC), with its unequivocal message about the importance of tobacco control for every country.

"Tobacco use is a personal choice"

Opponents' second theme characterizes tobacco use as an issue of "freedom," "rights," or "choice." This argument insists that tobacco control measures interfere with individual decisions and the autonomy of the individual tobacco user. This view is especially attractive to lawmakers who favour a limited role for government, who are likely to see the use of tobacco products as a private matter.

In reality, arguments about "choices" and "decisions" have little meaning in the case of tobacco products. Most users begin before they are old enough to make informed decisions, and are fully addicted before they become adults. Furthermore, surveys show that the preferred "choice" of most adult tobacco users is to quit, but that they are unable to break their addictions.

Nor is tobacco use a private matter, when its consequences extend far beyond the user. When smokers use tobacco near children, they injure the health of children and set examples that increase the likelihood the children will become smokers. When they smoke in public, those around them are endangered. When they are disabled or absent from work, their employers lose productivity, and the economy is affected. When they receive medical treatment, society bears the burden. And when they die, their loved ones suffer. These consequences make the tobacco epidemic more than a matter of individual concern. They make it a matter for legislation.

"Tobacco control measures won't work"

Opponents are often dismissive of tobacco control measures, asserting flatly that they will not work. These arguments are seldom based in evidence. Rather, they rest on intuition, assumptions and preconceived ideas. Tobacco is such an integral part of many cultures that most adults have strong opinions about tobacco and the reasons people use it. These objections appeal to these preconceived ideas.

"Internal documents prove that, contrary to its public arguments, the tobacco industry knows these interventions work; this is precisely why it fights them so fiercely."

The tobacco industry is quick to exploit these preconceptions. Invariably, it produces experts to advise lawmakers, for example, that advertising bans "will not work" because "advertising does not make people smoke cigarettes." Industry experts will similarly insist that tax increases "will not work" because smuggling will increase, or that smoke-free policies "will not work" because smoke-free businesses will lose revenue.

These arguments are thoroughly discredited by overwhelming evidence—evidence reflected in the positions of WHO, other health authorities and individual researchers, and most importantly, in the declarations of the WHO FCTC. Just as importantly, these industry arguments can be countered by exposing the truth about the industry's knowledge. Internal documents prove that, contrary to its public arguments, the tobacco industry knows these interventions work; this is precisely why it fights them so fiercely. As PAHO observed after analysing industry opposition to legislation in Latin America and the Caribbean:

"Measures recommended by WHO, PAHO and the World Bank to reduce tobacco use, such as legislated prohibitions on

tobacco promotion, tax increases, and the creation of 100% smoke-free environments, should be implemented as quickly as possible. Whatever tobacco companies express in public, the documents show the industry's acute awareness of the effectiveness of these measures in reducing tobacco use.[174]"

"Tobacco control will cause economic harm"

Finally, opponents insist that tobacco control measures will cause economic injuries that will outweigh any benefit to health. These arguments include the claim that, if tobacco control measures succeed in reducing tobacco use, government tax revenues will fall. Moreover, the argument goes, the economy will suffer because jobs will be lost throughout the production, manufacturing and distribution chains and in related sectors. Individual economic interests, including growers, distributors, sellers, advertising interests, groups dependent on sponsorships and charitable donations, and others are likely to argue desperately that legislation will endanger their livelihoods.

"This evidence shows that almost every country would benefit economically from tobacco control legislation."

To answer opponents' economic objections, proponents can draw on the research and conclusions of the World Bank, which has devoted considerable attention to these issues. This evidence shows that almost every country would benefit economically from tobacco control legislation. Arguments that jobs would be lost ignore the fact that money formerly spent on tobacco would be spent on other goods and services, creating new jobs; in all but a very few agrarian countries, there would be no net loss of jobs, and might even be a job gain.[175]

Similarly, arguments that jobs will be lost in a particular sector overlook the fact that if consumers buy fewer tobacco products, they will often buy other products. For example, representatives of Canadian billboard companies strongly opposed a ban on tobacco advertising, only to acknowledge later that the ban "was arguably one of the best things to happen to our industry," because it spurred them to develop new business that actually

[174] *Profits Over People, Tobacco Industry Activities to Market Cigarettes and Undermine Public Health in Latin America and the Caribbean,* Pan American Health Organization, 2002 at 96.
[175] *Curbing the Epidemic: Governments and the Economics of Tobacco Control.* Washington, World Bank, 1999, http://www1.worldbank.org/tobacco/reports.htm, at 67-71.
[176] Non-Smokers' Rights Association. *Chicken Little* brochure. Ottawa: NSRA, 1996, quoted in *Developing Legislation for Tobacco Control, Template and Guidelines,* Washington, Pan American Health Organization, 2002, http://www.paho.org, at 11.

increased their revenues.[176] The harm caused by tobacco use far exceeds revenues raised by tobacco taxes, and economic research shows that tax increases are a "win-win" strategy: they are highly effective in reducing demand for tobacco, and can be used in almost every case to generate substantial new revenues.[177]

Recent analysis has shown that the impact of tobacco control policies on the future of tobacco farmers and workers should no longer be an acceptable excuse to prevent the implementation of comprehensive tobacco control policies that can save millions of lives.

[177] *Curbing the Epidemic: Governments and the Economics of Tobacco Control.* Washington, World Bank, 1999, http://www1.worldbank.org/tobacco/reports.htm, at 72.

Chapter X. Making it work: implementing the legislation

A successful legislative campaign does not end when the law is signed; the law must be implemented and enforced in a way that makes it a reality in daily life. Too often, laws that appear strong on paper are ignored in practice. To ensure that legislation is not a false victory, its proponents must not neglect the process of implementation and enforcement.

"To ensure that legislation is not a false victory, its proponents must not neglect the process of implementation and enforcement."

Start-up

Implementing a comprehensive tobacco control law involves more than setting a date for the law to enter into force. Both the law's entry into force and the initial phase-in period should be designed to smooth the involvement and compliance of society at large. Entry into force and enforcement actions should be phased to allow an appropriate period of time to lapse to inform those affected about the law and their responsibilities. This phase-in period may need to be greatest where the law affects large numbers of people who are unaware of its existence—street vendors, for example, or owners of small workplaces—while less time may be required to phase-in duties of tobacco manufacturers, who will be thoroughly familiar with the law.

During the start-up period, affected interests and the general public need to be informed about the law. This can be done through the news media and through targeted outreach to affected businesses, through informational meetings, distribution of informational materials, mailings and the creation of web sites. Time will be required for businesses to take any preliminary steps required by the law, such as the posting of signs. The government may even consider providing the necessary signs or other materials; the added cost may be repaid in improved compliance and cooperation. Nongovernmental organization (NGOs) and other supporters of the legislation can often be enlisted in educating businesses and the public during this period.

"During the start-up period, affected interests and the general public need to be informed about the law."

The educational process is especially important in countries where awareness of the new law is low and imposition of enforcement penalties may create real hardship. In these settings, it may be necessary to extend the phase-in period to design incentives for compliance or to delay enforcement. For example, in enacting its nation-wide ban on smoking in bars and restaurants

in April 2003, Norway has delayed enforcement until spring 2004 to ease the transition to smoke-free bars and restaurants by sparing smokers the hardship of smoking outdoors in the winter as the law came into force.[178] One common approach is to designate an initial period during which violators will receive warning notices, rather than the sanctions provided by the law. Countries with government-owned broadcasting media may have access to free broadcast time for a large educational campaign.[179] Combining enforcement with implementation of other elements of the tobacco control programme, such as public information, programmes in schools and cessation activities, may also make introducing enforcement less threatening.

"Cultivating a sense of fairness surrounding the implementation is well worth the investment of time and money."

Whatever specific steps are chosen, the start-up period should involve sufficient outreach so that those affected will not be taken by surprise when enforcement begins. Cultivating a sense of fairness surrounding the implementation is well worth the investment of time and money. Sensitivity at this point will usually be repaid later, not only in improved compliance, but also in greater cooperation and a sense of shared responsibility for the law.

The enforcing authority

The law's effectiveness will be determined in part by the selection of an enforcing authority. Legislation can be enforced by public health authorities at the national or subnational levels; by police and other law enforcement officers; by health, business or other inspectors or by some combination of authorities.

"The enforcing agency should be completely free of any connection to the tobacco industry, competent to enforce the legislation effectively, and committed to its success."

Selection of an enforcement entity should be guided by several criteria. The enforcing agency should be completely free of any connection to the tobacco industry, competent to enforce the legislation effectively, and committed to its success. This commitment will be strongest if it has the public support of senior government officials. The agency's enforcement agents should be energetic, competent and motivated, and should receive adequate training in the content of the law, enforcement procedures, and methods for interacting with violators and the public so as to promote acceptance of the law. Some aspects of enforcement may best be handled at a national level, while others may require the involvement of local agents or officers.

[178] Smoking Ban in Norway Will Begin in Spring 2004. *New York Times*, 10 April 2003.
[179] This was done in Thailand. See country study in Chapter XII.

Enforcement resources and effort should be sufficient to create a reasonable likelihood that violators will face consequences. Enforcement programmes need not be massive, but do need to deter violations and demonstrate the society's commitment to the law. This requires resources for public education, training of enforcement agents, investigation and prosecution of violations, and monitoring activities. When the legislation is drafted, thought should be given to possible funding mechanisms to provide these resources. It may be possible to recover costs of enforcement from convicted violators, licencing fees, filing fees, or earmarked tobacco tax revenues.

Penalties and consequences

Appropriate penalties for violations need to be tailored to each jurisdiction and must be specified clearly to avoid enforcement difficulties. These penalties will vary greatly, but should satisfy several criteria. They must be serious enough to deter violations, but not so harsh as to seem draconian. Ordinarily, penalties should be greater than any direct financial benefit the offender realizes from the violation, and should be at least equal to the cost of enforcement. At the same time, penalties that are perceived as excessive will be counterproductive, because enforcing authorities may be reluctant to impose them in practice and because they will undermine public support.

"It is important that these sanctions be perceived by the affected parties and the public as proportionate to the offence."

Generally, penalty levels must be determined in the context of the penalties a jurisdiction imposes under its other laws. It is important that these sanctions be perceived by the affected parties and the public as proportionate to the offence. This purpose can best be achieved with a graduated penalty structure. Under many laws, for example, an offender's first violation results only in a warning notice. Penalties may increase for each subsequent offence.

Penalties will also vary under different components of the comprehensive law and among violators. For example, a manufacturer's violation of an advertising ban should ordinarily result in a much greater penalty than an individual's violation of a sales-to-minors law. This reflects the fact that some violations have much greater impact on society than others, and the fact that larger penalties are needed to deter misconduct by larger organizations.

Consequences for violations need not be limited to monetary penalties. For example, it is possible to impose criminal sanctions, under which violators face potential imprisonment. On one hand, criminal sanctions send the message that society takes the law very seriously, and provide added deterrence. On the other hand, in many countries a criminal approach will entail added procedural requirements and costs, and may require enforcing authorities to bear a higher burden of proof than they would otherwise face.

Other sanctions can be fashioned through the use of licensing and inspection systems. Licensing laws—for example for tobacco importers, distributors or sellers—allow sanctions that can include licence suspension or revocation. In many jurisdictions, the possible suspension of a seller's licence to sell tobacco products serves as an effective deterrent against illegal tobacco sales to young people. Other creative sanctions may include provisions subjecting violators to an increased frequency of inspections, seizure of illicit or mislabelled products, or restrictions on their business practices.

The procedures used to impose sanctions also vary widely. These may involve the same procedures used in criminal or civil cases before the country's courts. Alternatively, they may involve hearings or other administrative proceedings within the enforcement agency. If the agency has the legal competence and capacity to conduct administrative hearings, this approach may speed and simplify enforcement, while reducing expenses. Ordinarily it is desirable to select enforcement procedures that match those already in use under well-accepted laws, so that the enforcement process does not generate unnecessary and unexpected legal difficulties. Whichever procedures are chosen, proponents should ensure that they meet basic standards of fairness and transparency, and are consistent with the jurisdiction's legal and constitutional standards of due process of law and procedural fairness.

"A basic monitoring system should include a research and surveillance programme to monitor trends and patterns in tobacco use, public opinion and awareness, and other basic epidemiological information."

Monitoring

Part of the implementation and enforcement process involves ongoing oversight through monitoring, surveillance, reporting and inspections. Oversight is essential not only for strong enforcement, but also for the country's ability to improve the legislation over time. Many oversight mechanisms are available. A basic monitoring system should include a research and surveillance programme to monitor trends and patterns in tobacco use, public opinion and awareness, and other basic epidemiological

information. It should also include mechanisms to track the level and quality of enforcement and levels of compliance.

Other useful oversight tools include:

- Monitoring mechanisms to supplement enforcement of public smoking restrictions and sales-to-minors laws. These often include the use of periodic "compliance checks," or test purchases, using anonymous young people to test for illegal sales, and the use of toll-free telephone lines for the public to report violations.
- Reporting requirements, including requirements that manufacturers report tobacco product constituents and additives, as well as advertising and promotional expenditures.
- Inspections, including periodic inspections of tobacco manufacturing facilities and of places subject to smoking restrictions.
- Tobacco industry monitoring, through such activities as systematic reviews of tobacco advertising and promotion in the jurisdiction, investigation of industry efforts to influence public policy, analysis of tobacco industry documents for evidence of industry activities in the jurisdiction, monitoring of product packages for necessary health warning labels, and testing of tobacco products and additives for safety and compliance with regulatory standards.

The self-enforcing law

Meaningful enforcement is essential. It demonstrates the government's commitment to the law and to tobacco control. The impact of government efforts can be magnified by involving others in the enforcement process, as well. Because tobacco control usually has broad public support, this is relatively easy. The public can be invited to report violations—for example, by a toll-free telephone number. Supportive organizations are often willing to assist in educating the public about the law's requirements or even to assist in enforcement.

Those components of legislation that regulate tobacco companies will always require vigilant enforcement; tobacco companies can never be trusted to comply voluntarily. In the long term, however, most successful tobacco control laws are not enforced by police officers or other government agents, but by society itself. As the public becomes aware of the importance of these laws and support for them increases, formal enforcement becomes less necessary.

The ultimate goal of the legislation is to re-shape public attitudes and norms. As this shift takes place, the pressure of society's expectations becomes the strongest force for compliance. This can happen very quickly.

"In the long term, however, most successful tobacco control laws are not enforced by police officers or other government agents, but by society itself."

Smoke-free public places offer the best example. Legislation in this area is often opposed on the ground that enforcement will be expensive and difficult. In practice, these laws have such broad public support that formal enforcement actions are seldom needed. Once smoking is eliminated in these settings, the preference of most customers and employees for a smoke-free environment is so strong that they will enforce the law by expressing their displeasure to any violators. Many jurisdictions report implementing these laws successfully without having to bring a single enforcement case.

"The need for formal enforcement should decline as legislation alters society's customs and attitudes. The most successful law, of course, is one that, in time, enforces itself."

Similarly, when selling tobacco to young people comes to be seen by society as an unacceptable action that exploits and endangers children, sellers and their employees begin to police their own behaviour.

These examples suggest that the need for formal enforcement should decline as legislation alters society's customs and attitudes. The most successful law, of course, is one that, in time, enforces itself.

Chapter XI. Evaluation

Evaluation is a key element in the effort to bring about social change. The purpose of evaluation is to "produce information about the performance of a law or programme in achieving its objectives."[180] Without careful assessment, it is impossible to know whether legislation is working. Evaluation allows policy-makers to answer these questions, and to learn what mid-course changes in strategy are needed.

"Without careful assessment, it is impossible to know whether legislation is working. Evaluation allows policy-makers to answer these questions, and to learn what mid-course changes in strategy are needed."

This guide briefly introduces the techniques and methods of evaluation. For an expanded presentation of the subject—from which this discussion is drawn—see the publication *Strengthening enactment, enforcement, and evaluation of tobacco control legislation.*[181] The brief discussion presented here is intended to alert decision-makers to the issues involved and to assist them in working with evaluation experts in approaching these issues. In addition, it seeks to help decision-makers understand why evaluation is so important and what it takes to do it well.

The role of evaluation

The ultimate goal of tobacco control is to create cultural patterns and social norms that discourage tobacco use and favour a smoke-free society. Evaluation seeks to measure how well specific laws, or a comprehensive anti-tobacco programme of legislation, help a community or nation move toward this goal. This determination requires assessment of both the process by which the legislation is implemented—often known as "process evaluation"—and the legislation's impact on key tobacco-related outcomes, or "outcome evaluation."

There is no mystery to this evaluation process.[182] Sound evaluation is guided by basic ethical principles: commitment to systematic inquiry, competent performance, integrity and honesty,

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[180] Grembowski D. *The Practice of Health Program Evaluation*. Newbury Park, CA, Sage Publications, Inc., 2000, at 3.

[181] Roemer R, Berman B. *Strengthening enactment, enforcement, and evaluation of tobacco control legislation*. Geneva, World Health Organization, December 2001. Web site: http://www/tobacco.who.int.

[182] The ideas and concepts outlined in this section are presented in detail in a number of excellent texts on evaluation and research methodology. See, for example: Rossi PH. and Freeman HE. *Evaluation: A Systematic Approach*, Fifth Edition, Newbury Park, CA, Sage Publications, Inc., 1993; and Veney JE and Kaluzny AD. *Evaluation and Decision Making for Health Services*. Third Edition, Chicago, Illinois, Health Administration Press, 1998; Grembowski D. *The Practice of Health Program Evaluation*, Newbury Park, CA, Sage Publications, Inc., 2000; and Shortell SM and Richardson WC. *Health Program Evaluation*. St. Louis, The C.V. Mosby Co., 1978.

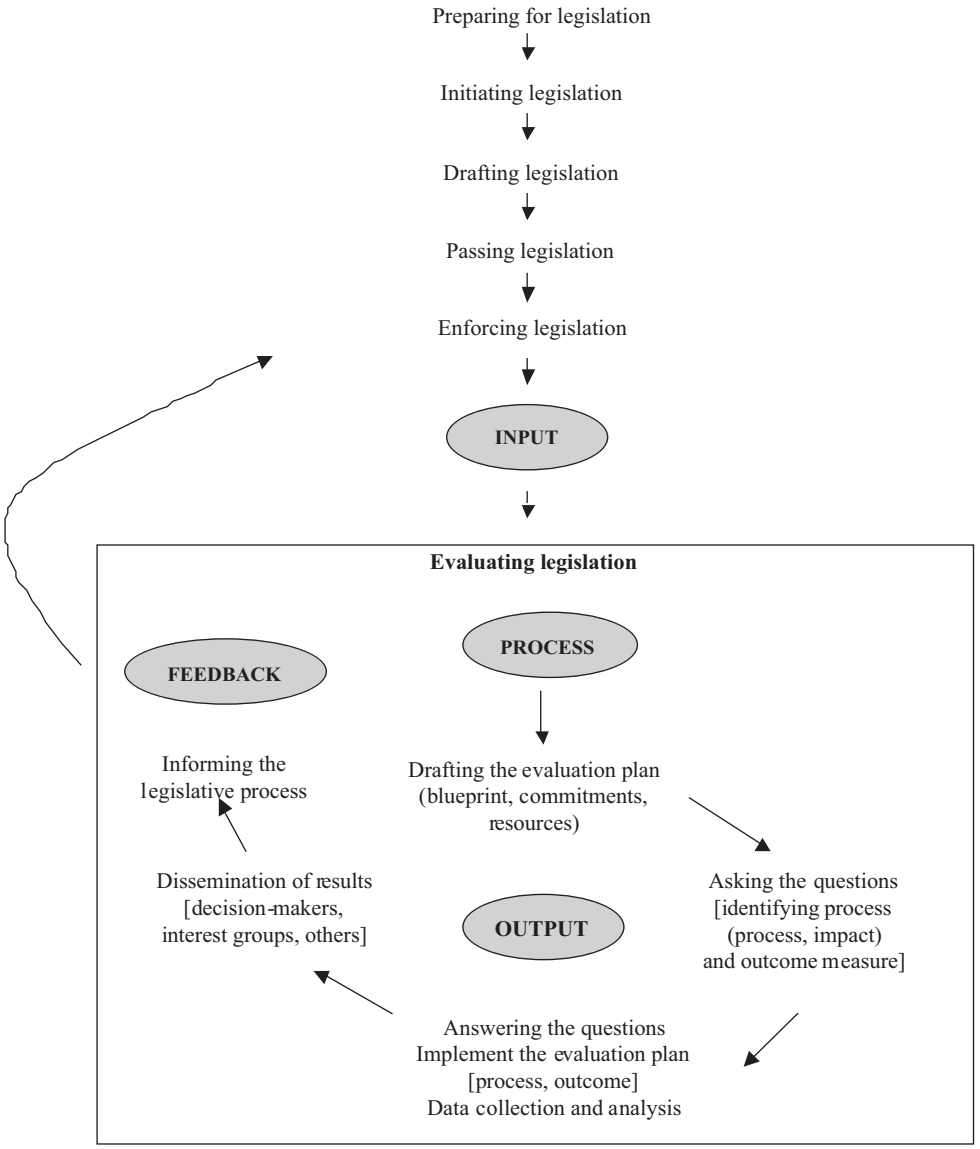
respect for the security, dignity, and self worth of people, and responsibility for the general welfare, taking into account the diverse cultural and other values of the population.[183] The evaluation process requires commitment, time, money and trained personnel who can ensure that results are accurate and trustworthy. The relationship between this process and lawmaking is depicted in Figure 1.

Evaluation is critical, but stands apart from other aspects of tobacco control. Although support from decision-makers and tobacco control advocates is key, evaluation must remain independent of political pressure or influence. Because evaluation can draw scarce resources from programmes, and because it calls attention to a programme's failures as well as its strengths, support for this process cannot be taken for granted, even among those who have fought to enact legislation. Significant effort may be needed to convince decision-makers of the importance of careful evaluation, and that it is in everyone's interest to identify and address problems in the programme. To ensure that the commitment to evaluation is maintained, it may be appropriate to mandate evaluation and to set aside funds for this purpose.[184]

[183] Grembowski D. *The Practice of Health Program Evaluation*. Newbury Park, CA, Sage Publications, Inc., 2000, at 28-29.
[184] Pierce-Lavin C and Geller AC. Creating Statewide Tobacco Control Programs after Passage of a Tobacco Tax, *Cancer*, 1998; 83:2659-65.

FIGURE 1

EVALUATION PROCESS



Adapted from: D'Costa A and Sechrest L. Program Evaluation Concepts for Health Administrators. Association of University Programs in Health Administration, Washington, D.C., 1976. As described in Shortell SM and Richardson WC. *Health Program Evaluation*, The C. V. Mosby Co., St. Louis, 1978.

The evaluation plan

The first step in evaluation is to develop a blueprint for the process that will be followed.[185] Taking into account the country's circumstances and resources and the specific requirements of its legislation, this plan will describe the overall evaluation design and identify the specific steps, procedures, and measures that will be used. Each plan will be different, because in evaluation, as in other aspects of tobacco control, strategies that work in some settings may be inappropriate or impractical elsewhere. What is imperative is that evaluators clearly identify the questions they will ask and how they will determine the answers.

The evaluation plan will discuss such topics as:

- the data needed for evaluation;
- the operational definitions—precise, objective, replicable statements of how each concept will be measured,[186] —that will be used;
- strategies for developing and testing data collection instruments;
- the steps necessary to collect, manage, analyse and interpret the information;
- the estimated budget for the evaluation, and the arrangements for administering these funds;
- the personnel needed to conduct the evaluation and the steps needed to recruit and train them;
- plans for maintaining cooperation among agencies and organizations; and
- mechanisms for making and tracking adjustments to the plan.

Establishing a detailed plan in advance provides important benefits. Having a plan in place before legislation is implemented:

- helps ensure that the necessary documentation and record-keeping arrangements are in place from the beginning;
- increases the likelihood that the necessary resources will be allocated and the necessary personnel recruited;
- guarantees that multiple strategies and the steps to implement them have been considered; and
- increases attention to "longitudinal assessment"—evaluation of the law's impact over long periods of time.

[185] The need for a plan and the elements of a successful blueprint are discussed in Grembowski D. *The Practice of Health Program Evaluation*. Newbury Park, CA, Sage Publications, Inc., 2000, at 66; and Rossi PH. and Freeman HE. *Evaluation: A Systematic Approach*. Newbury Park, CA, Fifth Edition, Sage Publications, Inc., 1993.

[186] Williamson JB, Kara DA, Dauphin JR. *The Research Craft*. Boston, Little, Brown and Co., 1977.

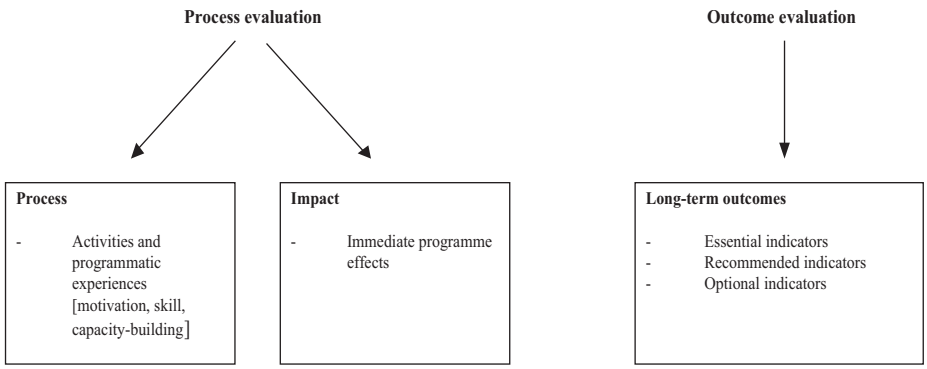
Evaluation should start before programmes begin, to measure the "baseline," or starting point, and should continue throughout the life of the programme. To the extent possible, measurement strategies should remain constant over the life of the programme so that consistency is maintained and trends can be understood. Once assessment is under way, changes in measurements or evaluation strategies can make it difficult to compare information across time.

Process evaluation

Is the legislation working as intended? Why, or why not? These questions are at the heart of evaluation. They involve two distinct issues: how well the programme has been implemented (process evaluation) and whether the programme has achieved results (outcome evaluation). Process evaluation focuses on the steps taken to achieve the law's goals. This, in turn, involves two levels of assessment, both focused on interim results: assessment of implementation activities and assessment of the immediate effects of the programme. These distinctions are summarized in Figure 2.

FIGURE 2

TYPES OF EVALUATION



Source: Adapted from Leob J. Evaluation: Methods and Strategy for Evaluation – Arizona. *Cancer* 1998; 83:2766-9 and Vilain C. *The evaluation and monitoring of public action on tobacco, smoke-free Europe*: 3, Copenhagen, WHO Regional Office for Europe, 1987.

To assess implementation activities, process evaluation asks such questions as: What did it take to put the programme in place? Was the programme implemented as intended? What opposition was encountered, and how was it overcome? Did the programme reach its intended audience? What could have been done better?

To evaluate the immediate effects of the programme, process evaluation focuses on short-term outcomes that can be identified in the short run and that can indicate progress toward longer-term goals. This assessment can be conducted by asking a series of broad, fundamental questions that, in turn, lead to an array of more narrowly focused follow-up questions. For example, process evaluation of an advertising ban may begin by asking whether advertising has declined. This question leads quickly to more narrow questions about changes in the level of specific types of advertising, and so on. This process and its application to the different aspects of tobacco control are explained in detail in an excellent WHO publication, *Evaluating tobacco control activities: Experience and guiding principles*.[187]

The best methods for answering these process evaluation questions will depend on the legislation being assessed. Some common indicators of progress in implementing most types of legislation might include the number of laws enacted, the population of the jurisdictions affected by the laws, the resources and personnel devoted to implementing and enforcing the laws, the number of enforcement actions, and the level of sanctions imposed on violators. Evidence of public awareness of and support for the legislation, as shown by opinion polls or similar measures, provides indications of progress, as well.

Other indicators will vary with the type of legislation. For example, evaluation of classroom programmes may involve collection of information about the programmes actually offered in schools, using qualitative and quantitative data collected from "key informants"—in this case, teachers, students and school administrators; audits of teaching materials and in-person visits to schools. Other tobacco control laws will call for different types of data. It is also necessary to consider, document and assess any tobacco industry resistance to implementation of the legislation.

Evaluation strategies will differ, but should always be tailored to the type of legislation involved. While each setting is unique, the body of tobacco control research already conducted around the world can offer evaluators a valuable starting point for this process. Whatever the approach, careful attention should be paid to the well-documented standards of evaluation methodology.

Outcome evaluation

Ultimately, evaluation is about measuring the effect of the legislation on "outcomes" —the results that indicate success or failure. In designing this outcome evaluation, evaluators

[187] Chollat-Traquet C. *Evaluating tobacco control activities: experience and guiding principles*. Geneva, World Health Organization, 1996.

must grapple with the fact that tobacco control legislation can have a wide range of health, economic, political, cultural, and other outcomes. Evaluators must undertake the difficult task of selecting a limited number of questions on which to focus. Only through this process of delineation and selection can evaluation move forward successfully.

To make this selection, many tobacco control evaluators turn to a series of recommended measures that can be categorized as "essential," "recommended," and "optional" indicators.[188] The "essential indicators" of success or failure are mortality rates, tobacco consumption, smoking prevalence and the prevalence of smoking control policies. "Recommended indicators" are those indicators that enable changes in the overall prevalence of smoking and other tobacco use to be monitored more precisely. "Optional indicators" focus primarily on morbidity data and the prevalence of smoking in certain key populations.

For each of the four essential indicators, there are recognized measurement tools:

- *Effect on mortality*. Tobacco-related changes in mortality rates can be determined by monitoring mortality rates by sex and age per 100 000 inhabitants annually for deaths due to malignant neoplasms of the trachea, bronchus and lung; chronic bronchitis, emphysema and asthma; and ischemic heart disease. Optional indicators of health outcomes, such as morbidity for ischemic heart disease, cancers of the trachea, bronchus, and lung in certain populations, may also be useful.

- *Effect on tobacco consumption*. The recommended indicator is the consumption of tobacco per person among the total population, or among the population age 15 years and older. The amount of tobacco sold is a rough indicator of tobacco consumption, but fraud, contraband, smuggling, duty-free sales, changes in smoking habits, or changes in the weight of tobacco per cigarette may make this measure unreliable.

- *Effect on smoking prevalence*. The recommended benchmark for measuring the impact of legislation on smoking prevalence is the proportion of non-smokers and the proportion of heavy smokers (more than 20 cigarettes per day). The percentage of the population who have never smoked, who have not smoked for two years, or who have reduced their tobacco consumption in the preceding two years are also useful measures. Data should be collected and analysed for relevant subgroups. It can also be valuable to monitor changes in tobacco-related knowledge, attitudes and beliefs.

- *Effect on tobacco control policies*. New tobacco control programmes

[188] This discussion is drawn from: Vilain C. *The Evaluation and Monitoring of Public Action on Tobacco, Smoke-Free Europe: 3*, Copenhagen, WHO Regional Office for Europe, 1987. The term "optional indicators" is used here for the indices Vilain describes as "facultative indicators."

created by legislation can, in themselves, be considered outcomes of legislation. Measures for this outcome include the number of tobacco control programmes, policies, laws, activities and interventions implemented on a local, regional, and national level; and the level of involvement of government and nongovernmental agencies.

A number of strategies are available for measuring these and other outcome indicators. In choosing among these strategies, feasibility and cost as well as cultural, political, and logistical considerations need to be taken into account. It can sometimes be efficient to use data collection systems already in place to monitor health issues, including tobacco-use patterns and health consequences. Existing data can be cost effective and can provide a basis for historical comparisons and comparison to other regions, but must be used cautiously.

"In choosing measurement strategies, evaluators must recognize that every strategy has limitations and complications. These should be weighed carefully."

In choosing measurement strategies, evaluators must recognize that every strategy has limitations and complications. These should be weighed carefully. Quantitative surveys are the most widely used tools for measuring tobacco use prevalence, tobacco consumption and tobacco-related attitudes. Surveys present complex issues related to sampling methods, inference, survey content, validity, reliability, implementation and data management. Qualitative tools, including interviews and focus groups, can be valuable, but have limitations related to cost, logistical considerations, sampling, data management and interpretation and the self-reported nature of the data. Objective validation methods—for example, medical testing for smoking status—offer reliability but may pose cost and logistical problems. Existing data systems may contain mortality data, but pose their own difficulties.

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After measurement strategies are selected and employed, the results must be interpreted. The "bottom line" of evaluation is to determine whether the legislation has worked. This requires the evaluator to determine what will be considered success, and to give the concept of "success" an operational definition using realistic and objective criteria.

Using the results

Information gained through evaluation is useful only if it is put to work. Dissemination of evaluation findings can play a

critical role in moving the tobacco control effort forward, but only if these results reach key audiences. Strategies are therefore needed for advising legislators and other decision-makers about the legislation's impact. Data summaries, reports, and monographs should not merely report findings, but should also interpret these results and make evidence-based recommendations for action. These results can serve as a guide for next steps, pointing to the need for new legislation or amendments, or for changes in implementation and enforcement.

Tobacco control advocates represent a second important audience. It is critical that those "on the ground" understand what is working and what needs to be changed. Advocates may not always welcome evaluation results, however—especially if the results are less than favourable. Appreciation for objective evaluation can sometimes be increased through the use of an "open system" model, in which programme evaluation does not occur "after the fact," but rather on an ongoing basis. In this model, evaluators serve as a continuing resource to the programme staff, and share responsibility for programme success.[189] In any event, thoughtful explanations and recommendations based on solid information can go far toward improving understanding of any need for change.

It is equally important to disseminate evaluation results to those who are not involved in tobacco control. This can increase understanding of successes and remaining challenges, and awareness of the value of committing scarce resources to tobacco control. Dissemination of findings to educators, researchers, and those in the health, legal and other professions helps these opinion leaders recognize the importance of tobacco use as a public health crisis. More broadly, the message regarding tobacco use, tobacco control legislation and programmes should be formulated and delivered in such a way as to reach the widest possible audience. As it reaches the general public, this information can contribute to changes in society's attitudes and norms about tobacco use.

[189] Loeb J. Evaluation: Methods and Strategy for Evaluation - Arizona. *Cancer* 1998; 83:2766-9.

Chapter XII. Lessons in legislation: case studies from nine countries

Enacting and implementing tobacco control legislation can be difficult. Many countries have passed laws, and each of them has faced stiff opposition and multiple hurdles. As their experiences demonstrate, there is no single formula for success. Still, common themes are apparent, and lessons can be drawn from others' experiences—positive and negative.

The case studies presented here describe briefly the paths taken in nine countries: Brazil, Canada, Egypt, Norway, the Philippines, Poland, South Africa, Thailand and the United States of America. These stories illustrate the forms opposition has taken, the twists and turns that are possible, and the creative ways these countries have overcome unexpected obstacles. As these accounts confirm, each campaign brings its own challenges. Above all, these stories show that, as powerful as the opposition may be, it is never as powerful as a united, determined and creative coalition of supporters.

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Brazil

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In recent years, Brazil[190] has established itself as a global leader in tobacco control. Brazil's legislation is noteworthy for its strength, comprehensiveness and integration of measures at the national, state and municipal levels. Strikingly, Brazil has achieved these results even though tobacco plays an important role in its economy.

Brazil is a country of continental dimensions. It has a population of 170 million, living in more than 5500 municipalities located in 26 states and the capital, the Federal District of Brasilia. With over 750 000 tobacco growers, Brazil is the world's largest tobacco leaf exporter, fourth-largest tobacco producer and eighth-largest cigarette exporter. In 2000, Brazilians consumed 853 cigarettes per capita. Souza Cruz and Philip Morris control much of the tobacco market.

Brazil's National Tobacco Control Programme is directed by the National Cancer Institute (INCA), the agency of the Ministry of Health that coordinates the country's cancer control programmes. INCA organizes national educational activities through campaigns on Brazil's National Day Against Smoking and World No Tobacco Day, and through programmes in schools, workplaces and healthcare facilities. As a WHO Collaborating Centre for Tobacco Control, INCA also pursues tobacco control measures at the state and local level, in partnership with other ministries and nongovernmental organizations (NGOs).

The heart of a comprehensive programme is legislation, however, and Brazil has adopted one of the world's most impressive sets of laws. These laws cover the full spectrum of tobacco control. They ban the sale of cigarettes to minors (those under the age of 18), the distribution of free samples and the sale of tobacco in health centres and schools. They eliminate smoking in most public places (smoking is still permitted in some separated areas meeting certain ventilation standards), as well as in aeroplanes and public transportation. They ban television and radio advertising for tobacco products. Point-of-sale advertisements are restricted and tobacco packages must include health warnings. Manufacturers must report on their production and sales, and on product composition. Stringent

[190] Discussion of the Brazilian legislation is adapted from materials prepared by Cristiane Vianna and also draws on material prepared by James Hodge. See the Note on Contributors and Sources.

new regulations require large colour images and warnings on cigarette packs and prohibit deceptive descriptive terms such as "light" and "mild." Brazil bans most tobacco sponsorships, with the exception of international sporting events, as discussed below. Sale of tobacco products on the Internet is prohibited, as is the manufacture of candy cigarettes.

In 2002, Brazil began providing free support for smoking-cessation services, including both pharmaceutical products and cognitive behavioural therapy. Legislative strategies also include excise taxation. Cigarette taxes accounted for more than 5% of the nation's revenue in 2001. Health authorities have also considered litigation against the tobacco industry.

A 1999 law created the National Agency of Sanitary Surveillance (ANVISA). ANVISA is responsible for regulating control and surveillance of cigarettes and other tobacco products. Each tobacco company must register its brands with ANVISA and pay annual taxes. Tax revenues will be used, among other things, to construct a laboratory to analyse cigarette constituents, including nicotine, carbon monoxide and tar yields. As a regulatory agency, ANVISA also has the power to issue binding rules under existing laws. ANVISA's Resolution No. 46 (28 March 2001), for example, established maximum tar, nicotine, and carbon monoxide yields for cigarettes, required yields to be clearly labelled on cigarette packages and further prohibited the use of any labelling or advertising of tobacco products as "mild," "light," "ultra light," or "low tar."

Legislation and regulation are not limited to the national level, however. Brazil is a federal republic. The Brazilian Federal Constitution authorizes the Union, the states, the Federal District and municipalities to legislate on health matters. This has permitted a decentralized, multi-layered approach to tobacco control. As smoking prevention activities increased in the 1980s, Brazil began to institutionalize this approach. A network of state tobacco control managers was formed under the direction of the Ministry of Health, and now extends nation-wide. The decentralization process starts with human resource development. Coordinators from state health offices are trained by the federal team on how to implement the National Tobacco Control Programme. State coordinators, in turn, train municipal coordinators, who carry the programme to the organizations and individuals in their communities. This capacity-building process has enabled Brazilian tobacco control programmes to reach even remote communities.

It is at the federal level that Brazil's comprehensive legislation has been implemented, but states and municipalities have also been enacting tobacco control laws since 1950. Since coordination of local, state and national efforts began in 1987, 70% of these laws have been adopted. A review by the National Tobacco Control Programme identified 70 of these tobacco control laws at the state level and 331 at the municipal level. Among other things, these state and municipal laws regulate smoking in enclosed places and public transport; promote smoke-free environments; restrict the places where cigarettes can be sold; prohibit tobacco sales to minors and establish focal points for tobacco control programmes.

This multi-faceted system was not created overnight or without difficulties. It is the product of a long series of campaigns, setbacks and innovations, at every level of government. Each of these initiatives has contributed to the expansion of national capacity and the strengthening of political will.

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One good example of this incremental process involves smoking on aeroplanes. Since 1990, a ruling has prohibited smoking on domestic flights of less than two hours' duration. A 1996 federal law relaxed this requirement, however, allowing smoking after one hour of flight if the airline provided a separate area meeting certain ventilation standards. Once enacted, this law was widely violated, because no airline was able to meet the necessary conditions. Consequently, the Prosecutor for Consumer Affairs brought litigation that resulted, in 1998, in the elimination of smoking on all Brazilian aircraft, regardless of the length of the flight. In 2000, this ban became law with the enactment of federal legislation.

A second example, from the city of São Paolo, illustrates the role of subnational legislation as a catalyst for national action in Brazil. By a Decree of 31 January 1995, over the strong opposition of tobacco companies and restaurant and bar owners, São Paolo prohibited smoking in many restaurants.[191] This action drew wide media attention and prompted a national debate among educators, journalists, legal experts, health professionals and individuals. Public opinion polls found strong public support, with 75% of those interviewed in an initial survey expressing approval of the law. When the decree took effect, São Paulo's Hotel and Restaurant Association filed a legal challenge, arguing that constitutional rights of free expression were being infringed. Eventually, the opponents' arguments were rejected, and the decree was held constitutional.

This experience helped lead to enactment of federal legislation in 1996. In recognition of their leadership, the city's mayor and the city lawmakers who had sponsored the proposal were honoured during celebration of World No-Tobacco Day in 1996. Enactment of this law demonstrated the critical importance of capacity-building, starting with the development of a local network with trained personnel to provide technical expertise regarding the law's provisions. Mobilization of the support of

[191] Restaurants with an area of less than 100 square metres were subject to a less restrictive standard, and were allowed to reserve half of their space as a smoking area. Decree no.34836, of 31 January 1995, to regulate State Laws no.9120/80 and 10862/90.

legislators, politicians, the media and the public was essential to the success of this initiative. The coalition persevered after the law was introduced, eventually overcoming the opposition of the tobacco industry and its lobbyists. This commitment was sustained after the law took effect, through inspections and firm enforcement.

A third experience, demonstrating the importance of enforcement and the power of mobilization at the local level, comes from the State of Amazonas, in the Amazon basin. In 1995, a municipal law prohibiting smoking in public places was enacted but was ignored in practice. The State Coordinator for the National Tobacco Control Programme helped mobilize public opinion and the media to support the law, writing to the Prosecutor for Consumers Affairs, meeting with shopping mall operators and contacting the news media. This generated such a strong public demand for enforcement that authorities were compelled to act.

Another example of activity at the subnational level involves tobacco industry programmes designed to undermine public health initiatives. In the mid-1990s, under the guise of encouraging compliance with laws against selling cigarettes to minors, a major tobacco company developed an advertising campaign designed to create the appearance of responsible corporate citizenship, while offering what many advocates considered to be subtle enticements to youth.

This campaign was introduced in schools and points of sale in the State of Paraná, using stickers, posters and pamphlets with slogans such as "Adults can choose. Youngsters must wait." Other materials "warned" that "To buy cigarettes you must be 18. It's the law," using a Portuguese double-entendre that also meant "it's cool." Many advocates considered these to be coded ways of saying that "smoking is an adult thing to do" or "it's great to reach 18 so you can buy cigarettes." In 1997, other state governments were approached by tobacco industry representatives about expanding this campaign to other regions of the country. These efforts failed, however, because the country's integrated network of tobacco control coordination enabled the appropriate focal points to learn of these plans and mobilize the Ministry of Health to help block the activity.

An example of the importance of public support involves the adoption, in December 2000, of the national law prohibiting print and broadcast advertising, restricting point-of-sale advertising, and prohibiting sponsorships. This bill caused wide debate and sparked powerful opposition from broadcasters, sports associations, advertising firms and others likely to be affected. The tobacco industry raised traditional arguments, alleging that the law infringed freedom of speech and comparing it to the regulation of alcohol. In response, proponents mobilized a broad network of supporters, including professional societies, NGOs and the general community. E-mails were sent to Members of Congress, urging their support. Fact sheets explaining the rationale for the law were distributed to legislators and the public. A survey was conducted to demonstrate the level of public support. Public hearings were held to increase public attention to the debate. On the day of the vote on the bill, Formula One racers, tobacco growers and media associations appeared at the National Congress, demanding rejection of the bill. The public health prevailed, and the bill was adopted.

Startling recent examples of tobacco companies' creativity in circumventing legislation come from the adoption of tough new rules that ban misleading product descriptors and require powerful warning labels on packages. These rules, developed by ANVISA Resolutions, followed public consultations in 2001. Resolution No. 46 set maximum tar, nicotine and carbon monoxide yields and banned the use of misleading descriptors such as "light," "mild," "ultra light," and "low tar." In this respect, Brazil pioneered the banning of misleading descriptors in the world. Tobacco companies promptly devised an ingenious strategy for circumventing this prohibition. Before the law came into force, they introduced new packaging, using different package colours to indicate different levels of tar and nicotine, so as to condition consumers to continue perceiving certain brands as "low tar" based on package colour alone after the misleading words were removed.

Similarly, ANVISA Resolution No. 104 required tobacco companies to use warnings labels with dramatic images occupying one entire side of the pack surface. A survey found that these new images caused 67% of smokers to think about quitting smoking and caused 54% to change their opinions about the health effects of smoking. Responding to this threat, the tobacco industry promptly began obscuring the warnings by inserting pamphlets similar in size to the warning labels between the cigarette pack and the wrapping film. As the agency responsible for enforcing Resolutions Nos. 46 and 104, ANVISA imposed fines for both violations.

Finally, a recent example shows how efforts to undo strong laws can continue long after the laws are enacted. Legislation adopted in 2000 prohibited tobacco industry sponsorship of international events, with implementation delayed until 2003, to allow the affected parties—particularly the organizers of Grand Prix Formula 1 auto racing events—time to find other sponsors. In early 2003, with the Formula 1 race in São Paolo approaching, race organizers retained some of the country's top lawyers to argue, among other things, that the legislation was ambiguous, that cars and drivers bearing brand logos were different from posters and billboards, and that the law was unconstitutional. Two days before the race, the Government yielded to this pressure. A Provisional Measure was published, exempting international sporting events from the sponsorship ban until August 2005, provided that health warnings are broadcast at the beginning of the event and repeated every 15 minutes. This special exemption will expire unless approved by the National Congress by August 2003.

Brazil's experiences have taught a number of lessons about enacting and implementing strong legislation. Building a broad base of support has been critical. Partnerships with NGOs, scientific societies and professional councils have helped amplify advocates' ability to educate the public. Regular meetings with legislators have kept attention focused on tobacco control. Providing legislators with printed materials, organizing briefings and seminars, and honouring legislative champions has helped deepen their support. Public hearings have provided opportunities to involve civil society, professional organizations and NGOs in raising the public's awareness of the benefits of legislation.

The impact of Brazil's tobacco control legislation remains difficult to measure. Nevertheless, the evidence is extremely suggestive. Official figures indicate that between 1989 and 2001, per capita cigarette consumption fell by an impressive 32%. Even allowing for the undocumented effects of cigarette smuggling, it seems apparent that tobacco use has dropped sharply. Scientifically verifiable information is not available to attribute this outcome to specific laws and programmes, but few observers doubt that Brazil's comprehensive laws are important factors in this achievement. Brazil's legislation is not perfect, but it has made great strides toward changing the perception of smoking as a natural and acceptable behaviour.

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Canada

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A number of countries have enacted excellent tobacco control legislation, but none has shown more persistence in overcoming obstacles than Canada.[192] Beginning in 1963, the Government of Canada set its sights on halting the tobacco epidemic. It has persisted toward its goal despite a lawsuit in which the Supreme Court of Canada invalidated advertising restrictions and unattributed health warnings. This was done despite smuggling, which led to reduced cigarette taxes and increased smoking, and despite continual efforts by the tobacco industry to thwart Canada's political will to protect its people against the health hazards of tobacco.

The modern story of Canada's experience with tobacco control legislation began in 1963 when the Minister of National Health and Welfare Judy LaMarsh, delivered a speech in the House of Commons on the harm to health caused by tobacco. The Federal Government then announced a five-year CAD$ 600 000 anti-smoking budget for scientific and behavioural research and health education, to begin in 1964. In that year, the United States Surgeon General's Advisory Committee on Smoking and Health issued its landmark report, which found that cigarette smoking was a cause of lung and laryngeal cancer in men, probably the cause of lung cancer in women and "a health hazard of sufficient importance in the United States [of America] to warrant remedial action."[193]

In 1964 and in the years that followed, the industry sought to stave off legislation by adopting a voluntary code to restrict advertising. A committee of the House of Commons held hearings and rejected the industry's position. In 1969 it called for a complete ban on advertising, for strong health warnings, disclosure of tar and nicotine yields on cigarette packages, standards setting maximum levels of tar and nicotine, and other specific measures. In 1971, a bill that would have banned cigarette advertising and required health warnings was introduced in Parliament, but was never debated.

Late in 1972 the Lalonde report, *A New Perspective on the Health of Canadians*, was issued. It became the rallying call for a healthy lifestyle with respect to nutrition, exercise, smoking, and

[192] Discussion of the Canadian legislation was prepared by Ruth Roemer, based largely on Cunningham R. *Smoke and Mirrors: The Canadian Tobacco War*, Ottawa, International Development Research Centre, 1996. See the Note on Contributors and Sources.
[193] *Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service.* United States Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, PHS Publication No. 1103, 1964.

use of alcohol, but no government legislation was introduced until 1987, when Minister of Health Jake Epp determined to take firm action on tobacco. He introduced Bill C-51, the Tobacco Products Control Act, which banned advertising and created regulatory authority to require rotating health warnings. The tobacco industry launched a wide-ranging campaign to oppose the bill, contending that the ban on advertising was an unconstitutional infringement of freedom of expression, that the ban would not reduce smoking, that arts and sports groups would be deprived of financial support, and that jobs would be lost. Nevertheless, Parliament passed C-51 in 1988, along with the Non-smokers' Health Act restricting smoking in federally regulated workplaces and public places.

Defeated in Parliament, the industry moved to challenge the legislation in the courts, contending that the advertising ban was an unconstitutional restriction on freedom of expression protected by the Canadian Charter of Rights and Freedoms. The trial court in Quebec invalidated the legislation on the grounds argued by the industry. On appeal, the Quebec Court of Appeal reversed the lower court and upheld C-51. But on 21 September 1995 the Supreme Court of Canada by a vote of five to four struck down the ban on advertising, indicating that it would have upheld a partial ban on lifestyle advertising and advertising relating to minors. It invalidated unattributed health warnings and the ban on use of tobacco trademarks on non-tobacco goods. All that remained were the ban on free distribution of tobacco products, the ban on incentive promotions, and the reporting requirements for manufacturers. The dissent of the four minority justices was powerful but unavailing.

The response of the Government was immediate. Three months after the Supreme Court's decision, in December 1995, the Minister of Health Diane Marleau, issued a report, *Tobacco Control: A Blueprint to Protect the Health of Canadians*, outlining the legislative directions that the federal Government proposed to take to confront this preventable cause of disease and death.

Between 1989, when the Tobacco Products Control Act took effect, and 1995, when the Supreme Court of Canada struck down major provisions of the Act, Canada took numerous steps to strengthen tobacco control. New, stronger, rotating health warnings were required, including, in some provinces, health warnings at point of sale in retail stores. Smoking was banned in the federal public service. Air Canada introduced smoke-free flights, and under the Non-Smokers' Health Act smoking was banned on all flights by a Canadian carrier, whether domestic or international. Many municipalities passed local bylaws restricting smoking in public places and the workplace. Most importantly, federal tobacco taxes were raised by CAD$ 4.00 a carton in 1989 and by CAD$ 6.00 a carton in 1991.

The tax increases were followed by an increase in Canadian cigarettes exported to the United States of America and back into Canada—much of it through a reservation of Native Americans straddling the border between the two countries. Thus, the Canadian tax was not paid, and the cigarettes were sold at US$ 2.50 a pack instead of US$ 4.50 a pack. By 1993 smuggling had become a major problem. Cigarette "exports" to the United States of America skyrocketed from 1.2 billion cigarettes in 1989 to 18.6 billion in 1993.

Despite efforts by health groups to introduce an export tax and other measures to control smuggling in 1994, the federal Government and five provincial governments adopted major reductions in tobacco taxes to curtail smuggling. The tax rollback led quickly to an increase in smoking rates, which had been declining steadily for more than a decade. Federal tax revenues fell by CAD$ 1200 million, more than twice as much as predicted.[194] Several surveys showed an increase in smoking among young people.[195] Fortunately, in subsequent years, tax increases have been re-imposed to levels higher than pre-rollback levels, and have been accompanied by export taxes that should discourage the illegal re-importation to Canada of exported Canadian cigarettes.[196]

Despite this setback for tobacco, in 1994 the Standing Committee on Health of the House of Commons held hearings on plain packaging of cigarettes. The industry was strongly opposed, but health groups were united in support of plain packaging as a way to reduce the allure of cigarettes and to generate negative images of smoking. The Committee supported plain packaging as "a reasonable step in the overall strategy to reduce tobacco consumption."[197]

On 25 April 1997, the Canadian Parliament adopted a new tobacco control Act—Bill C-71, the Tobacco Act. As stated in an official summary of the legislation, this statute "replaces the Tobacco Products Control Act and the Tobacco Sales to Young Persons Act. The purpose of this enactment is to protect the health of Canadians and, in particular, to protect young people from inducements to use tobacco products and to restrict access to tobacco products." The constitutionality of key provisions of the Act was promptly challenged on various grounds. After a lengthy and historic trial in 2002, the validity of the Act was upheld, although an appeal continues.

The Act empowers the Government to establish standards for tobacco products and to prescribe the amounts of substances that may be contained in the product, the substances that may not be added, test methods, and the information that manufacturers must provide to the Government about tobacco products and their emissions. Thus, the Act gives sweeping powers to the Government to regulate the contents of tobacco products.

The Act bans sales to persons under 18 years of age. It requires posting of signs by retailers that the sale or giving of tobacco products to persons under 18 is illegal. It prohibits sales of cigarettes in anything other than packages of 20, and prohibits sales of tobacco products from vending machines except for those situated in bars or in places to which the public does not have access.

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[194] Sweanor D. *The smuggling of tobacco products*. Ottawa, Smoking and Health Foundation, 1997.
[195] Cunningham R. *Smoke and Mirrors: The Canadian Tobacco War*, Ottawa, International Development Research Centre, 1996, at 134, www.globalink.org/tobacco/docs/na-docs/smokeandmirrors.
[196] Sugarman SD. International Aspects of Tobacco Control and the Proposed WHO Treaty. In: Rabin RL and Sugarman SD, eds., *Regulating Tobacco*, New York, Oxford University Press, 2001, 245-284 at 254-5.
[197] Cunningham R. *Smoke and Mirrors: The Canadian Tobacco War*. Ottawa, International Development Research Centre, 1996, at 134, www.globalink.org/tobacco/docs/na-docs/smokeandmirrors.

The statute mandates health warnings on packages of tobacco products and authorizes package inserts or leaflets about the health hazards of tobacco.

Advertising of tobacco products is prohibited except for product information and brand-preference advertising that is not lifestyle advertising, misleading or appealing to persons under 18. Permitted advertising may only appear in publications with adult readership of at least 85%, in materials mailed to adults, and in places where young people are not permitted by law.

The Act also prohibits free distribution of tobacco products as well as incentives associated with the purchase of a tobacco product (e.g. coupons, contests, frequent purchaser programmes). The 1997 statute also prohibits the distribution and promotion of tobacco products if any of their brand elements appear on a non-tobacco product that is associated with youth or a lifestyle.

Restrictions on tobacco company sponsorship of events provide that:

a) the tobacco brand elements may appear only in the bottom part of the promotional material and may occupy no more than 10% of the display surface; and
b) the promotional material is limited to publications with primarily adult readership, materials mailed to adults, and signs on the site of the event and in places where young persons are not permitted by law.

Effective 1 October 2003, there will be a total ban on tobacco sponsorship advertising.

In 2000, Canada pioneered another innovation in tobacco control. It requires one of sixteen strong, large, picture-based, rotated warnings on the top 50% of the front and back of cigarette packages. Inside the package one of the sixteen rotated messages is required, either on an insert or on the "slide" of "slide and shell" packages. Nine of the interior messages provide advice on quitting, and seven provide detailed health information. During negotiation of the WHO Framework Convention on Tobacco Control (WHO FCTC), these state-of-the art standards became a rallying point for international nongovernmental tobacco control organizations, which urged successfully that the treaty provide for strong warning labels, insisting that "if Canada can do it, so can every other country."

In January 2002, the Ministerial Advisory Council on Tobacco Control submitted a report to the Canadian Minister of Health entitled *Putting an End to Deception: Proceedings of the International Expert Panel on Cigarette Descriptors*. The report contains the testimony of international experts on many aspects of "light" and "mild" cigarettes—the epidemiology of low-yield cigarettes, public perceptions of the meaning of these descriptors, the role of consumer protection legislation, the law of deception, contrast with the process of food labelling, and experience in the European Union (EU) and Brazil.

The Advisory Council found that cigarette descriptions, such as "light" and "mild,"

are a major public health problem and have already contributed to the deaths of thousands of Canadians. It recommended:

- a complete ban on misleading descriptors, such as "light" and "mild,";
- assurance by the Government that other terms and devices that have a similarly misleading effect or that could have such an effect are eliminated or not allowed on the market;
- strong, effective and rapid governmental action to correct the "light" and "mild" deception;
- new regulations under the Tobacco Act as the quickest and most effective route to achieve the public health objective; and
- public education on the "light" and "mild" issue, focused specifically on the nature and causes of the deception.

With this report and the regulations and public education that are sure to follow, Canada has again pioneered an advance in tobacco control legislation that will be of inestimable value to other countries.

Also in 2002, legislation in the province of Saskatchewan came into force prohibiting the visible display of tobacco product packages in any store where minors have access. This groundbreaking measure, preceded only by Iceland, was strongly opposed by the tobacco industry. The legislation curbs an important form of promotional activity. The province of Manitoba subsequently adopted similar legislation to come into force 1 January 2004.

The Canadian legislation, enacted despite strong opposition from the tobacco industry, was successful because of a number of factors, most importantly, the exercise of persistent political will on the part of the national Government. In addition, Health Canada, the national department of health, received support from the Labour Department, the Treasury Board, the Transport Department, the Justice Department and the Finance Department. Critical work was done by nongovernmental agencies. The media were key in informing the public and the members of Parliament. Research on Canada's experience with tobacco, such as on smoking rates and costs of tobacco use, was essential in informing the public and Parliamentarians. Legislative action by the provinces increased the momentum for national legislation.

Finally, the quality, imagination and commitment of the leadership of the tobacco control movement led to success. All these factors combined to keep the political will of the Canadian Government focused on effective tobacco control to protect the Canadian people, and to make Canada an example for others. As advocates argued in holding up Canada's warning labels as a model for the world's treaty, "If Canada can do it, so can every country."

Egypt

Egypt's[198] experience with tobacco-related legislation began in 1933, when Decree No. 74 (1933) was enacted to organize the tobacco industry under state control. This was followed over the years by a series of laws and ministerial decrees to further organize the evolving Egyptian tobacco industry. These laws and decrees were focused on the structure and operation of the industry, rather than on controlling or preventing tobacco use.[199]

Egypt's principal tobacco control legislation dates from 1981. This legislation, Law No. 52 of 1981, Protection Against Smoking Harms (Official Gazette No. 26, June 1981) grew out of a call by the United Nations for Member States to declare 1980 a year for attention to the hazards of tobacco use. In response, a number of seminars were convened to discuss smoking-related issues. In particular, the First Lady of Egypt Jehan Sadat, Chairwoman of the Anti-Cancer Association and wife of then-President Anwar Sadat, sponsored the Middle East Meeting for Anti-Smoking, held in Cairo in June 1979.

As a result of this increased attention to the subject, Members of Parliament developed proposed legislation that was eventually adopted by the Egyptian Government and put forward as its official proposal for tobacco control. The bill was introduced in the Egyptian People's Assembly and referred to the Joint Committee on Health, Environment and Legislative Affairs.

The Committee prepared a report on the bill, emphasizing the harmful effects of smoking. This report cited the direct relationship between smoking and lung cancer, arteriosclerosis, angina and heart attacks, noting that heart diseases are responsible for most deaths. The report also identified smoking as the main cause of the increased incidence of pulmonary, laryngeal and pharyngeal cancer, and as a cause of gastric ulcers and other gastric diseases. The Committee stressed the economic, social and physiological effects of smoking as well, pointing out that Egyptian families were spending a larger percentage of their incomes on tobacco than on food—about 5.8% of family income in urban areas and 6.2% in rural areas.

The legislation was promptly adopted. Its major provisions were:

- a prohibition against importing, exporting or manufacturing tobacco products unless they comply with the standards and conditions prescribed by ministerial decisions of the Ministers of Health and Industry;
- a requirement that tar levels not exceed 20 milligrams per cigarette, and a provision allowing this maximum level to be reduced by ministerial decision;

[198] Discussion of Egyptian legislation is from material prepared by Dr Hossam Abo Youssef. See Note on Contributors and Sources.
[199] Ministerial Decree No. 91 (1933) and Law No. 92 (1964) (combating smuggling), Ministerial Decree No. 691 (1965) (establishing the tobacco industry as a fundamental industry), Ministerial Decree No. 104 (1969) (organizing certain sectors of the tobacco industry) and Ministerial Decree No. 414 (1986) (imposing fees to support the tobacco industry).

- a requirement that each package of cigarettes display the warning that "Tobacco Is Very Harmful To Health";
- a requirement that tar and nicotine levels be identified on the package;
- a prohibition against any public authority, public body, public sector entity, cinema, theatre or sports club advertising or promoting the selling of cigarettes or any other tobacco product;
- a prohibition against smoking in public transportation and enclosed public places;
- authorization for the Ministry of Health to supervise the manufacture of cigarettes and other tobacco products, both imported and locally produced, to ensure compliance with the law's requirements; and
- penalties of imprisonment and fines for violating this law.

"In 1993, Dr Sharif Omar, a leading member of the national People's Assembly, put forward legislation to ban all forms of tobacco advertising and promotion. A secret Philip Morris Corporate Affairs document, now made public, laid out a comprehensive strategy for defeating this proposal."

Since the passage of this law in 1981, tobacco control efforts in Egypt have achieved several successes and suffered several setbacks. Passage of Law No. 137 of 1981, creating penalties for smoking in public places, is an early example of follow-on legislation to implement the earlier law. In contrast, the tobacco industry was successful in defeating advertising restrictions throughout the 1990s.

In 1993, Dr Sharif Omar, a leading member of the national People's Assembly, put forward legislation to ban all forms of tobacco advertising and promotion.[200] A secret Philip Morris Corporate Affairs document, now made public, laid out a comprehensive strategy for defeating this proposal.[201] The objectives of the Philip Morris campaign were twofold: "Seek to defeat the proposed ban" and "As a fall back, insure that advertising freedoms ceded are kept to a minimum." The strategic plan called for the tobacco industry to:

[200] This discussion is from Multinational Tobacco Industry Activity in the Middle East: A Review of Internal Industry Documents. *Voice of Truth,* Volume 1, Regional Office for the Eastern Mediterranean, World Health Organization 2002, at 13 -16. www.emro.who.int/tfi/tfi.htm.

[201] *The Threat of a Total Ban on Tobacco Advertising in Egypt: Strategy Guideline and Action Plan*, 15 August 1993, PM 2501066298-6320, http://www.pmdocs.com/getallimg.asp?DOCID=2501066298/6320.

- determine the expected progress of the bill within the legislative and decision-making processes and identify key influential players within these processes;
- identify key allies that could be mobilized against the proposed bill and in defence of advertising freedoms in general;
- prepare adapted argumentation tailored to the particular perspectives of the allies who are expected to use them against the bill and in defence of advertising freedoms;
- seek to enlarge the cycle of committee review of the proposed bill and to defeat it through the intervention of key committee members with whom contact is established via natural allies;
- build and mobilize formal and informal coalitions against the proposed bill with natural allies and allied organizations;
- prepare broad-based opposition to the bill within the People's Assembly in the likely event that it's put to debate at plenary session.
- prepare a tailored media communication campaign in defence of marketing freedoms to be launched as appropriate in support of political and lobbying action undertaken;
- identify concessions that could be conceded as a last ditch defence; and
- consider pro-active measures that could be volunteered in defence of advertising freedoms.

Aware of its lack of credibility among policy-makers, the company pointed out that "It's not conceivable that PM [Phillip Morris] and the industry would seek to oppose the proposed bill publicly (in the media) in the early stages of the lobbying process." Instead, the tobacco companies used Members of the People's Assembly to put their views across to policy-makers. "When we met in June you asked me to prepare a 'scientific paper' on the smoking and health issue for use in your capacity as a Member of the People's Assembly," wrote GW Moore of Rothmans to legislator Hassan Soleib in October of 1980, writing on Rothmans' company letterhead. Moore stated that:

> …as tobacco manufacturers, we do not express opinions on the smoking and health controversy. You will note that the paper is unsigned and I would ask you not to disclose my or my company's name as the source of this paper. Otherwise, you are free to use it as you see fit.

Moore informed Soleib that he and Mike Scott from Brown & Williamson had been meeting with other international cigarette companies in Egypt who have:

> agreed [to] a common industry view on the approach we would like to see taken on the proposed restrictions on the marketing of cigarettes. We feel that it would be best if we were to meet with you again to go through this document, and if you are agreeable, we would welcome an invitation to visit you in Cairo.[202]

These efforts were successful, and the proposed advertising ban was defeated.

Another important focus of the tobacco industry's response to tobacco control initiatives has been on the role of Islam.[203] The tobacco industry has always been worried about the influence of Islam in predominantly Muslim countries. These worries reflect fear that health authorities and religious activists will use Islam's general prohibition against anything that represents a harm to persons as a basis for discouraging smoking and encouraging strict regulation of industry activities.

As a consequence, a debate among Muslim jurists about Islam's attitude toward smoking, and whether or not it falls under this general prohibition, was of great concern to the tobacco companies. The companies monitored publications and speeches to ensure that a stricter interpretation of what constitutes harm did not gain currency. This context explains the extraordinary importance of the *fatwa*, or ruling, made by the Mufti (one of the supreme religious figures in Egypt) that smoking is definitely prohibited and goes against Islamic *Shari'a* principles. This *fatwa* had a very important impact on smokers as well as non-smokers, especially considering the fact that religion remains at the core of the lives of the vast majority of Egyptians.

Despite the efforts of the tobacco industry, several important tobacco control initiatives were enacted by the Government of Egypt during the 1990s, including:

- Law No. 4 of 1994, prohibiting smoking in enclosed places and public transportation, and imposing financial penalties for violations;
- Minister of Health and Population Decree No. 289 of 1997, reducing the maximum permissible level of tar to 15 milligrams per cigarette;
- Minister of Health and Population Decree No. 344 of 1997, establishing a high committee on issues of tobacco control, comprising representatives of all ministries and authorities concerned about smoking; and
- the establishment of laboratories in Cairo, Alexandria and Port Said to analyse tobacco products to ensure compliance with the prescribed product standards.

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[202] Letter from Hassan M. Soleib, Eastern Co. SAE from GW Moore, Rothmans, 6 October 1980, PM 2501021931, http://www.pmdocs.com/getallimg.asp?DOCID=2501021931.

[203] See *Voice of Truth*, Volume 2, 2002, World Health Organization Regional Office for the Eastern Mediterranean 1-2, www.emro.who.int/tfi/tfi.htm.

In 2002, the People's Assembly enacted important amendments to the 1981 tobacco control law, strengthening its provisions. These amendments were prepared and presented to the People's Assembly by one of the leading advocates of tobacco control in Egypt, Dr Hamdi El-Said, Member of the People's Assembly and head of the Egyptian Medical Syndicate. The original draft of the legislation was comprehensive and very strong, and was written to address shortcomings of the 1981 legislation encountered during 20 years of implementation. The Minister of Health strongly supported the bill, emphasizing that smoking, particularly among youth, is a very dangerous phenomenon and describing it as the "royal gate" to addiction, making it imperative to use every possible means to discourage smoking. Nevertheless, the Government was more supportive of some elements of the proposal than others.

When the bill came to the floor of the Assembly, it faced many obstacles, modifications and compromises. A great deal of discussion centred on warning labels. Some Members suggested a single, standard warning, to simplify tobacco industry compliance. Other Members preferred a rotating set of warnings, to increase the impact of the warnings and make smokers more aware of the specific harmful effects of smoking. They suggested warning statements such as: "smoking causes sexual impotence," "smoking causes lung cancer," "smoking causes heart attacks" and "smoking causes low-birth-weight babies." After much debate, the general warning prevailed. The bill also proposed a prohibition against the sale of tobacco products in vending machines, but this provision, too, was defeated.

Another major provision of the bill was Article 6, which would have raised the price of cigarettes and tobacco products by 10% and would have used the proceeds to support children's health insurance. The Government refused to accept this proposal. It argued that raising the price of tobacco products would actually increase the demand for tobacco—a suggestion that defied basic supply and demand theory, as well as the experience of countries that have increased tobacco prices and the conclusions of organizations such as the World Bank. In addition, the Government argued that revenue sources in the public budget could not be earmarked for specific purposes.

Despite these setbacks, much of the proposed legislation was enacted, overhauling and greatly strengthening the 1981 law. In particular, these changes introduce an advertising ban of the type opposed so strenuously by tobacco companies for many years. The new amendments:

- prohibit advertising or promoting the sale or use of cigarettes and other tobacco products through newspapers, magazines, still photographs, motion pictures, radio, television or any other means;
- require a warning that "smoking destroys health and causes death," and requires that this warning occupy one-third of the front face of the cigarette pack;

- prohibit the sale of tobacco products to persons less than 18 years old;
- prohibit the distribution of cigarettes or other tobacco products in competitions as prizes or free gifts; and
- prescribe imprisonment and fines for persons found guilty of violating this law.

Although the financial concerns of the Government were a key factor in deciding which articles passed and which did not, the Government's overall support was important in making the legislation a reality. Expertise and advocacy from civil society also played a major role in the proposal's success. Unfortunately, the absence of extensive publicity limited the public's awareness of the legislation and its importance. Proponents believe the proposal would have been more successful if it had been accompanied by informational campaigns in the media.

Egypt has made important progress toward comprehensive legislation consistent with the recommendations of leading authorities, but more remains to be done. The improvements still needed include:

- tax and price increases to reduce demand;
- public information campaigns and school-based education programmes to educate people on the effects of tobacco use; and
- a prohibition against the sale of cigarettes in quantities less than a standard pack of 20 cigarettes.

Egypt's tobacco control leaders look ahead toward these improvements and to the role of the WHO FCTC in making them feasible.

Norway

The crux of tobacco control policy in Norway[204] is the reduction of consumption. This focus on the demand side may reflect the fact that no tobacco is grown in Norway and that domestic cigarette manufacturing is minimal. In 1995, only 300 Norwegians worked in tobacco manufacturing businesses.[205]

Norway was one of the first countries to undertake a tobacco control programme. Its legislative efforts to curb tobacco are constantly evolving. In 1971, the National Council on Tobacco and Health was founded. Operating under the auspices of the Ministry of Health and Social Affairs, the Council has the legal power to advise the Ministry on tobacco-related matters. In March 1973, the Ministry enacted comprehensive legislation aimed at reducing the damage to health caused by the use of tobacco.[206] The Act provided an initial framework of tobacco control strategies divided into 11 sections. Among the Act's procedural innovations is its future-oriented language; several of the sections authorize the promulgation of stricter regulations to be issued at the Ministry's discretion.

"Norway was one of the first countries to undertake a tobacco control programme. Its legislative efforts to curb tobacco are constantly evolving."

Substantively, the 1973 Act unconditionally bans all forms of tobacco advertising, and prohibits the free distribution of tobacco products. All tobacco packaging is required to disclose known health risks associated with use and to declare the ingredients. Other provisions include raising the minimum purchasing age to 18 and creating large, smoke-free zones. Tobacco manufacturers and importers are required to disclose any and all information requested by the Ministry.

The most comprehensive changes to the original Act became law in 1995. Responding to industry attempts to avoid existing laws by promoting its logos on non-tobacco products, the new legislation explicitly prohibits advertising tobacco through "brand-stretching," that is, indirectly promoting tobacco products as part of an advertisement for another service or product. Furthermore, the new law bans all forms of tobacco packaging that might promote a "positive attitude towards smoking." Similarly, tobacco packagers can no longer promote their product

[204] Discussion of the Norwegian legislation was prepared by James Hodge. See the Note on Contributors and Sources.
[205] *Tobacco or health: A Global Status Report, Country profiles by region.* Geneva, World Health Organization. 1997, http://www.cdc.gov/tobacco/who/norway.htm.
[206] Act No. 14 of 9 March 1973, Relating to the Prevention of the Harmful Effects of Tobacco.

using colourful logos or designs that might "incite collecting" among young people.

Other 1995 amendments included lowering the maximum permissible tar content and the adoption of ISO standards for the measurement of tar and nicotine yield.[207] Smoking in public places was further restricted. New labelling standards were adopted and air quality measures mandated. Excise taxation also remains an important feature of both tobacco control and fiscal policy. In 1995, taxes accounted for 78% of the retail price of cigarettes in Norway.

Other national tobacco control efforts include the "Action Plan for Tobacco-Free Norway 1994-2000," the "Action Plan for Smokeless Schools," and the "Stay Smokeless" campaign, which is targeted at adolescents.[208] In 1999, Norway adopted a National Strategic Plan for Tobacco Control that operationalizes WHO's recommendations.[209] Important to the early and persistent innovative tobacco control work in Norway was the leadership of the committed and charismatic Dr Kjell Bjartveit, who headed the Norwegian National Council on Tobacco and Health for many years.[210]

Although Norway has long been a role model for other countries, tobacco use and tobacco-related morbidity and mortality continue to be a serious public health problem.[211] The proportion of Norwegian women who smoke every day has remained constant since 1973. Similarly, the prevalence of smoking in the 16-to-24 age group has increased from 26.8% in 1989 to 31.2% in 1998.[212]

The Norwegian Government and its private citizens have also investigated the feasibility of tobacco litigation. In June 2000, a government commission completed a report investigating the possibility of successful litigation against the tobacco industry.[213] The report noted the types of lawsuits most likely to be successful: individual lawsuits from active smokers; lawsuits from passive smokers; claims from surviving relatives; and claims from hospital owners. The report predicted that up to US$ 256 million could be awarded each year through legal action.[214]

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[207] Regulation on the Labeling of Tobacco Products and on the Tar and Nicotine Yield of Cigarettes. Laid down by Royal Decree of 15 December 1995 pursuant to section 2, sixth paragraph, section 4 and section 9 of Act no. 14 of 9 March 1973 relating to Prevention of the Harmful Effects of Tobacco.

[208] United Nations Economic and Social Council. (1995). *Coordination questions: Multisectorial collaboration on tobacco or health.* Doc. E/1995/67. http://www.un.org/documents/ecosoc/docs/1995/e1995-67.htm.

[209] Høybratån, D. Opening speech given at the international conference *on Advancing Knowledge on Regulating Tobacco Products*. Oslo, Norway. 9-11 February 2000.

[210] Bjartveit K. Fifteen years of comprehensive legislation: Results and conclusions. Paper presented at the *Seventh World Conference on Tobacco and Health*, Perth, Western Australia, 4 April 1990.

[211] Haldorsen T. and Grimsrud T.K. Cohort analysis of cigarette smoking and lung cancer incidence among Norwegian women. *International Journal of Epidemiology,* 1999, *28,* 1032-36.

[212] Braverman MTet al.Tobacco use by early adolescents in Norway. *European Journal of Public Health 11*, 2001, 218-24.

[213] Kjønstad, A et al. Tort liability for the Norwegian tobacco industry: A science-based report to the Minister of Health, 2000. http://www.tobakk.no/english/nou_cont.htm.

[214] Tobacco claims case opens in Norway. *AP Online.* 2 October 2000.

Most recently, Norway has again set new global standards by enacting the world's first national ban on smoking in bars. A regulation on smoking in restaurants and other hospitality establishments had existed since December 1995. Unfortunately, this law allowed only partial restriction of smoking, and difficulties in its implementation limited its impact. As a result of these loopholes, the Norwegian Government drafted a White Paper on smoke-free restaurants, pubs and bars, for consideration by Parliament. In November 2002 the Government introduced draft legislation for smoke-free restaurants and bars, emphasizing that the proposal would satisfy demands of trade unions for smoke-free work environments. Labour organizations, the Norwegian confederation of trade unions, health professionals and NGOs supported the proposal.

"Norway has again set new global standards by enacting the world's first national ban on smoking in bars. The ban comes into force in spring 2004, and will be enforced by municipalities through inspections under labour laws. Implementation of this pioneering law will mark 30 years of Norwegian global leadership in tobacco control legislation."

On 8 April 2003, the Norwegian Parliament, Odelstinget, enacted the proposal, completely banning smoking in restaurants, cafes, bars, pubs, discos and other hospitality businesses that serve food or drinks for consumption on the premises. The ban comes into force in spring 2004, and will be enforced by municipalities through inspections under labour laws.[215] Implementation of this pioneering law will mark 30 years of Norwegian global leadership in tobacco control legislation.

[215] Communication from Hetland Tharald, Adviser, Norwegian Ministry of Health and Social Affairs to Dr Douglas Bettcher, April 2003.

The Philippines

"The Philippines offers a study in tobacco control legislation as a work in progress. Continuing efforts to enact comprehensive legislation have yet to achieve victory. However, the country's experience illustrates the persistence that may be needed for legislative success, the ways in which sustained political will can move a country forward over time, and the creative ways in which champions can fashion tobacco control initiatives even in the absence of legislation."

The Philippines[216] offers a study in tobacco control legislation as a work in progress. Continuing efforts to enact comprehensive legislation have yet to achieve victory. However, the country's experience illustrates the persistence that may be needed for legislative success, the ways in which sustained political will can move a country forward over time, and the creative ways in which champions can fashion tobacco control initiatives even in the absence of legislation. These efforts have set the stage for the enactment of the comprehensive legislation Philippine advocates have long proposed.

Tobacco companies and their allies wield substantial influence in the Philippines. The country ranks as one of the world's 25 leading producers of manufactured tobacco products.[217] In 1998, tobacco was grown on 47 500 hectares, yielding over 70 000 metric tons of raw tobacco.[218] According to the National Tobacco Authority (NTA), as of 1995, 75 000 farmers and 11 000 manufacturing employees received income from tobacco growing and manufacturing; more than 2 million vendors, resellers, small store owners, and others benefited from its sale, distribution and other downstream employment. In 1998, according to the NTA, revenue from tobacco taxes, duties and fees came to more than US$ 428 million.

Fortune Tobacco, a subsidiary of RJ Reynolds International holds 60% of the Philippine tobacco market . The next largest competitor, La Suerte—a subsidiary of Philip Morris—holds only 25% of the market but has recently made major manufacturing investments in the country. Fortune Tobacco alone spent US$ 17.9 million in 2000 to promote its cigarettes on television, billboards, magazines, newspapers, radio, and the movies, making the company the country's eighth-largest advertiser. This spending does not include Fortune's expenditure on non-advertising promotions, raffles, event sponsorships and merchandising, or the global advertising programmes of Fortune Tobacco's parent company, RJ

[216] Discussion of tobacco control in the Philippines is adapted from materials prepared by Dr Jonathan A, Flavier. See the Note on Contributors and Sources.
[217] Torres, EB (IHPD, NIH, UP Manila) Briefing paper: *Tobacco control in the Philippines and elsewhere* in NIH - National Institutes for Health (1999) Legislative advocacy lessons for national tobacco control programme (unpublished proceedings of the discussions at the Chancellor's Boardroom, PGH, Manila - 11 August 1999).
[218] Philippine Senate - Committee on Health and Demography (11th Congress 1998 to 2001) A white paper on tobacco and smoking Philippine Senate Committee on Health and Demography: Manila.

Reynolds International, and La Suerte's parent, Philip Morris—consistently one of the world's largest advertisers. Fortune Tobacco's advertising expenditure is more than 300 times the size of the public information and education budget of the Philippine Department of Health.

Most smokers today are adult males. Tobacco companies now target not only children, but also women, and an increase in smoking prevalence among women is feared. Moreover, many advocates foresee increasingly intense industry promotion and marketing as multinational tobacco companies focus their energies on exploiting the potential customer base of the poorer countries of Africa, Asia and Latin America. In addition, efforts to promote alternative crops in the Philippines are hindered by the subsidies and incentives provided to growers by cigarette manufacturers.[219]

Tobacco companies use these sources of influence to maximum advantage. They withhold vital information from consumers—for example, failing to include any information on cigarette packs about the product's ingredients. Moreover, they work to discredit information the public receives from other sources and to bury the truth about smoking under an avalanche of misinformation and lies. This is, of course, in addition to the influence of their extensive advertising. Most importantly, multinational cigarette companies, the local tobacco industry and their allies have used this influence to undermine the role of the Government in promoting policy reform and tobacco control legislation.

Despite these obstacles, the Government's support for tobacco control has been consistent in recent years. The last two presidents have supported the tobacco control programmes of the Department of Health. Former President Joseph E. Estrada even certified proposed tobacco control legislation as "urgent." Two successive Health Secretaries have made the tobacco control campaign one of the Department's top five priorities.

In 1992, the then-Health Secretary, and current Senator, Juan Flavier launched the successful Department of Health Campaign "Yosi Kadiri" (Filipino slang for "cigarettes are disgusting"). Yosi Kadiri was introduced to counter the handsome cowboy and cool sportsman images of smokers cultivated by tobacco industry advertising. Media coverage of Yosi Kadiri's unveiling, coupled with the involvement of movie and television personalities, made the campaign a great success, especially among children.

This success was short-lived, however. Philip Morris commissioned the Leo Burnett advertising agency to "neutralize" the Government's campaign. According to the *New York Times*, the agency encouraged cigarette companies to withhold advertising from media supporting the Yosi Kadiri campaign. Representatives of Philippine media companies concede that tobacco advertising revenue continues to influence their decisions about reporting news damaging to cigarette companies. In any event, tobacco companies knew the Government

[219] Lorenzo FME (IHPD, NIH, UP Manila) Briefing paper: Round table discussion - *Legislative advocacy lessons for national tobacco control program* in National Institutes for Health (1999) Legislative advocacy lessons for national tobacco control programme (unpublished proceedings of the discussions at the Chancellor's Boardroom, PGH, Manila - 11August 1999).

could not afford to continue the expensive Yosi Kadiri campaign for long, and it soon faded from the scene.

Despite this setback, the Department of Health has adhered to the goal of reducing the toll of smoking-related diseases. It has continued to organize not only successful educational campaigns, but also such activities as a Youth Congress convened on World No Tobacco Day in 2000, bringing together youth representatives from each of the country's political districts for a symbolic National Congress session to pass tobacco control legislation.

Most significantly, for nearly a decade, the Department of Health has united with other health advocates and citizens' groups to support effective tobacco control legislation. Since 1995, these legislative proposals have been thwarted, primarily in the Philippine House of Representatives. Legislative reforms are particularly difficult in the House, where many legislators represent tobacco-growing regions. The tobacco industry resources that go into local revenues in these regions, as well as the tobacco industry's contributions to political campaign funds and other "perks," have made it difficult to win the support of these legislators, and popular pressure for action has been limited.

The first tobacco control proposal, introduced in the 10th Congress in 1995, focused on prohibiting smoking in public places. The effort nearly succeeded, as both the House and Senate passed tobacco control bills. As events unfolded, however, no law was enacted, even though the two houses had reconciled the respective bills in a bicameral Conference Committee Report.

Since 1995, the Senate has been consistently supportive of tobacco control legislation. In 2001, all 24 Philippine Senators, led by the former Secretary of Health, Senator Juan Flavier, united to co-author the "STOP" ("Stop Tobacco and Other Products") for Health" bill, which passed the Senate in record time. A blueprint for strong comprehensive tobacco control, the STOP for Health bill would:

- phase out and eventually ban print and broadcast advertisements;
- ban sports, cultural, and art sponsorships by tobacco companies;
- eliminate smoking in public places and conveyances;
- require stricter labelling requirements and specifications;
- ban the distribution of free samples;
- ban the sale and distribution of tobacco to minors;
- ban cigarette vending machines;
- create a national smoking cessation programme;
- require education about the health risks of cigarette smoking in all elementary and high schools;
- recognize the right to file suit against the tobacco industry; and
- support tobacco farmers affected by these measures.

To date, this bill has not passed the House, but it remains the model for tobacco control in the

Philippines.

Although legislation has not been enacted, there does appear to be some progress in the formulation of bills introduced in the House. The latest bill contains measures that would appropriate revenue from existing tobacco excise taxes to support: a national tobacco-free public education programme, tobacco growers' assistance programme, smoking cessation programme, research and development programme, a displaced cigarette factory workers' assistance programme, health programmes and cessation clinics.

Lack of success in the Congress has not prevented the Department of Health and other health advocates from finding creative ways to advance tobacco control, even as they continue to promote legislation. Municipal and provincial government councils have enacted laws controlling smoking in public places. Educational efforts have continued.

In particular, the Department of Health has made creative use of executive policy-making and administrative orders. In 1994, the Secretary invoked the Consumer Act, an existing law designed to protect consumers against hazards to health and safety, to mandate warning labels that "Cigarette Smoking is Dangerous to Your Health" on the front and back of cigarette packs. The Philippine Tobacco Institute promptly filed a legal challenge. In 2001, after seven years of litigation, the Supreme Court rejected the challenge and authorized enforcement of the warning requirement, although this ruling has not yet been actively implemented.

Today, the quest for comprehensive legislation continues. Legislative efforts of recent years have laid groundwork for eventual success, and Philippine advocates are more hopeful than ever. The new WHO FCTC may hold the key to success, they suggest—pointing out that decisions to ratify treaties, including the WHO FCTC, are made by the Philippine Senate, which has consistently supported tobacco control. If ratified, the treaty will become Philippine law, and will obligate the Congress to act. Advocates are hopeful that, in the Philippines, the WHO FCTC will prove to be the catalyst for immediate policy change, and will propel their country to the front ranks of global tobacco control.

Poland

WHO has called Poland's[220] tobacco control programme "an example to the rest of the world."[221] Poland's legislation, first enacted in 1995[222] and amended in 1999 to include a complete ban on all tobacco advertising and promotion, is among the most comprehensive in existence. As early as 1974, epidemiological studies revealed that Polish men had the highest tobacco consumption in the world. From 1974 to 1982 smoking prevalence among women had increased from 20 to 30%. Associated with the growth of tobacco consumption after World War II were increased morbidity and mortality from tobacco-related diseases. Epidemiological studies estimated that 58% of all malignant tumours in middle-aged men were due to cigarette smoking, and 42% of cardiovascular deaths and 71% of respiratory deaths among middle-aged men were due to smoking.[223]

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Armed with these powerful data, Polish tobacco control advocates, encouraged by international contacts with the International Union Against Cancer (UICC) and WHO, and with the help of health experts from Finland and the United Kingdom, set about to build a movement for tobacco control. First, systematic studies of smoking and the cancer epidemic in the Polish population were undertaken.

In 1989, tobacco control legislation was prepared at the Maria Sklodowska-Curie Cancer Institute and the Central and Eastern European Tobacco Control Institute in Warsaw, established in collaboration with the US Centers for Disease Control and Prevention, the Advocacy Institute of the United States and WHO. The following year a conference, "A Tobacco-Free New Europe," was held at Kazimierz. It developed a framework for cooperation on tobacco control between central and eastern Europe, providing education and training for public health workers in the region. This conference led to the creation of the Polish Health Promotion Foundation, with the mission of enacting tobacco control legislation. Each autumn the Foundation sponsors a mass campaign, "The Great Polish Smoke-Out." The largest public health campaign in Poland,

[220] Discussion of the Polish legislation was prepared by Ruth Roemer, based on previous work by Dr Witold Zatonski. See the Note on Contributors and Sources.
[221] World Health Organization Regional Office for the Eastern Mediterranean, *Collaboration on a national level; Working together to bring about anti-tobacco legislation: A success story,* http://www.emro.who.int/TFI/OpenedDoor-Poland.htm.
[222] Official Gazette, No. 10 of 1996.
[223] Peto R et al. *Mortality from Smoking in Developed Countries, 1950-2000*, New York, Oxford University Press, 1994.

this event has become a community-based activity with immense popularity, extensive publicity on how to quit, 40 000 "quit-smoking declarations" filed in 2000, and such prizes as a week's stay in Rome and an audience with Pope John Paul II.

The legislation was introduced in the upper chamber of the Parliament, the Senate, to which a considerable number of physicians had been elected. Supporters of the bill emphasized the health arguments and stressed the catastrophic state of adult health in Poland due to smoking.

In November 1995, five years after the Kazimierz conference that had set forth the action plan for tobacco control, the legislation passed by an overwhelming majority. This was done despite strong opposition from the tobacco industry and delays in action caused by the industry's contention that "a parliamentary act, which is, after all, a piece of paper," cannot improve the health of a nation. In 1997, the tobacco industry tried, but failed, to reduce the size of the health warnings on cigarette packages, and the Parliament decided that the health warnings should occupy 30% of the two larger sides of the pack. Most importantly, after the tobacco law was passed, investigations were undertaken to ascertain the effect of tobacco price policies on prevalence of smoking. As a result, the tobacco tax was increased by 30% in 1999 and 2000, and by another 20% in 2001.

Not until 1999 did tobacco control activists succeed in convincing Parliament to amend the law to provide for a total ban on tobacco advertising and to allocate 5% of tobacco excise tax revenue to the National Tobacco Programme.

In summary, the Polish tobacco control law now:

- protects the right of non-smokers to live in a smoke-free environment;
- promotes a tobacco-free life style;
- creates legal and economic conditions to encourage reduction in tobacco use;
- informs the public about the adverse effects of smoking and the levels of harmful substances through messages on tobacco packages and in advertisements in magazines for adults;
- decreases the maximum levels of harmful substances in tobacco products;
- provides treatment and rehabilitation of tobacco-dependent persons in public health facilities free of charge;
- prohibits smoking in health and educational institutions and other public buildings, with specific authorization for local government to restrict smoking in additional places;

- prohibits the sale of tobacco products to minors, including sales through vending machines and in packages of fewer than 20 cigarettes;
- prohibits production and marketing of smokeless tobacco;
- prohibits advertising and promotion of tobacco products on television and radio, in cinemas, newspapers, magazines for children and teenagers, in educational and cultural institutions, and in sports facilities;
- requires on each package of cigarettes two different warnings on the adverse effects of tobacco and on levels of tar and nicotine contents, with the messages covering 30% of each side of the cigarette pack; and
- provides penalties of imprisonment and fines for violating the law.

"The number of smokers in Poland has been reduced from 14 million at the end of the 1970s to 10 million in 2000, from 62% of adult men to 40%, and from 30% of adult women to 20%."

Although the Polish law has been in force for only a few years, its effects are already apparent. The number of smokers in Poland has been reduced from 14 million at the end of the 1970s to 10 million in 2000, from 62% of adult men to 40%, and from 30% of adult women to 20%. Furthermore, the upward trend in mortality from lung cancer in the 1980s has been reversed; by the end of the 1990s mortality had decreased by about 20% compared to the peak level. By comparison, in Hungary, where trends in lung cancer had been the same as in Poland but effective tobacco control activity has not occurred, incidence of lung cancer is still increasing. Similarly, Poland has experienced a significant reduction in the burden of cardiovascular disease, part of which is attributed to reduced cigarette consumption. It is estimated that one-third of this reduction resulted from decreasing tobacco consumption, one-third from dietary changes, and another third from other causes.

With these positive changes already observable, Polish tobacco control advocates look ahead to further challenges, including using the strategies of medical advice to increase cessation, of price policy to reduce consumption, and of involving local communities even more actively in tobacco control activities.

A significant trade in smuggled cigarettes may compromise the efficacy of Poland's supply-side control initiatives. Smuggled

cigarettes are 50% less expensive than those sold legally. In 2000, they accounted for 15% of total sales.[224] It is unclear whether the rapid and sizeable increases in tobacco taxation have contributed to the emergence of this black market.

In addition, the tobacco industry still maintains a significant presence. One company, International Tobacco Machinery Poland (ITM) has expanded rapidly during the period in which Poland enacted most of its tobacco legislation. Since its founding in 1991, ITM has acquired 20 000 square metres of factory space in Poland and a workforce of 300 employees.[225] Recently, ITM unveiled the Capricorn, a tobacco production machine that can produce 16 000 cigarettes per minute.[226]

Poland's success in enacting effective, comprehensive tobacco control legislation was due to several key elements in its campaign: extensive epidemiological investigation of smoking patterns in Poland; competent, dynamic, persistent leadership of the campaign, which generated and sustained political will to combat the serious premature adult morbidity and mortality from tobacco-related diseases in Poland; and adopting the strategy of first achieving what was possible and then amending the legislation to strengthen it.

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[224] (2001). *Poland tobacco and products annual 2001.* GAIN Report #PL1015. Washington, DC: United States Department of Agriculture Foreign Agricultural Service. USDA. http://www.fas.usda.gov/gainfiles/200106/105680957.pdf; United States Department of Agriculture Foreign Agricultural Service. (2002). *Poland tobacco and products upda*te 2002. GAIN Report #PL2003. Washington, DC: USDA. http://www.fas.usda.gov/gainfiles/200201/135683235.pdf.

[225] Going strong: ITM has evolved from a machinery rebuilder into a full-fledged supplier, *Tobacco Reporter.* September 2001. http://www.tobaccoreporter.com/backissues/Sept2001/story2.asp.

[226] Exp ITM is expanding to keep up with demand for its Capricorn rod buffer system. *Tobacco Reporter.* April 2001. http://www.tobaccoreporter.com/backissues/Apr2001/story1.asp

South Africa

"The South African experience demonstrates that comprehensive tobacco control legislation can develop quickly and can lead rapidly to improved public health outcomes."

The South African[227] experience demonstrates that comprehensive tobacco control legislation can develop quickly and can lead rapidly to improved public health outcomes. Until the early 1990s, South Africa had done relatively little to control tobacco use. Between 1970 and 1990, the value of the tobacco excise tax had declined, in real terms, by over 70%. No health warnings were required on tobacco products. By the end of the 1990s, however, the situation had changed, and South Africa had adopted some of the world's strongest legislative measures. In 1993 South Africa passed its first tobacco control act; within six years, cigarette consumption had decreased by 22%.[228] By 2000, the American Cancer Society was recognizing South Africa's initiatives by awarding the Minister of Health the Luther L. Terry Award for Exemplary Leadership in Tobacco Control.

South Africa grows and manufactures tobacco, and under apartheid, the country's powerful tobacco sector had enormous production and profits. In the period between 1967 and 1991, manufactured cigarette smoking almost tripled. Because of the high smoking rates in this middle-income country (1500 cigarettes per adult per year in 1990), the morbidity and mortality due to lung and oesophageal cancer and ischemic heart disease showed trends similar to those of developed countries.[229] Although the Health Ministry recognized this threat to the people's health, other priorities took precedence over tobacco control.

In the dying days of apartheid, the policy on tobacco began to change. In addition to educational measures—posters and pamphlets—the Government of South Africa in 1993 passed its first Tobacco Products Control Act,[230] which was regarded as symbolic of the change occurring in the country at the time. Although the Act's provisions seem limited by today's standards, it enabled the Government to: (a) regulate smoking in enclosed public areas; (b) mandate health warnings and disclosures on tobacco packaging and advertisements; and (c) outlaw tobacco sales to those under 16 years of age.

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[227] Discussion of the South African legislation is from materials prepared by Ruth Roemer, drawing on previous work of Dr Yussuf Saloojee, and from materials prepared by James Hodge. See the Note on Contributors and Sources.

[228] Van Walbeek, C. The economics of tobacco control in South Africa. Paper presented at the *11th World Conference on Tobacco or Health*, August 2000, Chicago, USA, 2000.

[229] Muna SFT. Africa: Changes for Tobacco Control. In: Lu R et al. eds., *Tobacco: The Growing Epidemic: Proceedings of the Tenth World Conference on Tobacco or Health*, Beijing, China, August 24-28, 1997.

[230] Tobacco Products Control Act No. 83 of 1993.

The 1993 Act empowers the Minister of Health to issue regulations, consistent with the Act, and thus continues to serve an enabling function. In 1994, with the election of a new democratic Government, the Minister of Health Dr Nkosazana Zuma, strengthened the legislation. The Ministry of Health issued strict and innovative regulations specifying the appearance and content of warning labels on tobacco products. Instead of brief general statements concerning the health effects of smoking, the regulations require novel warnings such as "the babies of mothers who smoke during pregnancy are more likely to die before birth or to be born underweight" and "nine out of ten patients with lung cancer are smokers." In addition to cautioning about the dangers of smoking, the messages also stress the benefits of quitting. A hotline telephone number was created to support smokers interested in quitting.

The Government also used fiscal measures to support its health policy. The Ministry of Finance increased tobacco taxes for the specific purpose of protecting the health of the people. Between 1994 and 1999, real tobacco excise taxes rose 149%, increasing real cigarette prices by 81%. The Government's tobacco tax revenues doubled, while consumption decreased by 21%.

In 1999, the South African Parliament strengthened the 1993 legislation, effective in 2001.[231] The new legislation prohibited all tobacco advertising, promotion and sponsorship. No advertisement except for point-of-sale advertising may contain trademarks, logos, brand names, or names of tobacco companies. These identifications may not be used in connection with sports, cultural or educational events. The strengthened legislation also severely curtailed smoking in public places and required employers to provide smoke-free workplaces. Vigorous implementation of the law soon led to new regulations. These regulations banned smoking in all enclosed places, including workplaces; specified maximum permissible amounts of nicotine, tar, and other ingredients in tobacco products; banned free distribution of tobacco products and awards or prizes to induce the purchase of tobacco; and required supervision of vending machines to prevent children under 16 from obtaining cigarettes.

One incidental problem in enforcing these regulations provides an unintended lesson on the complications that often accompany tobacco control laws. In regulating point of sale advertising, the new regulations provided that retailers could indicate the price of tobacco products "only by means of signs" of less than a square metre in size, located within a metre of the point of sale. Although the Government's intent was to allow use of a single sign, the regulation's inadvertent use of the plural word "signs" has permitted retailers to display as many as a dozen signs at a single point of sale. This incident illustrates not only the importance of careful drafting, but also how aggressively tobacco companies and their allies will exploit any loophole.

South Africa's new policies have been met with stiff resistance from the tobacco industry. British-American Tobacco controls 95% of the market and remains a powerful opponent of tobacco control. In strengthening its laws in 1999, the Government had to

[231] Tobacco Products Control Amendment Act No. 12 of 1999.

overcome industry contentions that tobacco companies had not been properly consulted about the law, that jobs would be lost, and that "freedom" was being attacked. Attempting to delay parliamentary action on the bill, the industry sought a high court injunction compelling the Ministry of Health to make available all information it had used in preparing the bill and allowing the industry time to study the information. The injunction was denied, and the denial was upheld on appeal.

The industry also formed alliances with other businesses and labour unions that opposed the bill and claimed to be independent of the tobacco companies. Several South African business organizations formed the "Freedom of Commercial Speech Trust," which argued that the tobacco-advertising ban violated the free expression guaranteed in the South African Constitution.[232] During the legislative debate, the trust threatened to challenge the new law in the Constitutional Court, but it has not in fact done so. In addition, the industry employed prestigious local and international "experts" to testify before the Parliament Health Committee, where they attacked the constitutionality of the legislation and the science involved, and contended that the legislation would be ineffective.

"South Africa's new policies have been met with stiff resistance from the tobacco industry. Despite this opposition, the majority of the people supported the legislation."

Despite this opposition, the majority of the people supported the legislation. A nationwide survey in 1998 found that 67% of the respondents approved a ban on smoking in public places and on tobacco advertising, 11% were undecided, and 22% disagreed with the restrictions. Civil society and especially nongovernmental and medical organizations played a critical role in building this support, and have long played a critical role in tobacco-related issues in South Africa. As early as 1963, the *South African Medical Journal* recommended higher excise taxes, bans on tobacco advertising, and limits on smoking in public places.[233] In 1991, groups such as the National Council Against Smoking, the Heart Foundation of Southern Africa and the Cancer Association of South Africa formed the Tobacco Action Group to work closely with the Government to further develop effective tobacco control strategies.

In summarizing the South African experience, Dr Yussuf Saloojee, Director of the National Council Against Smoking,

[232] Saloojee Y. Tobacco Control. In: *South African Health Review.* Johannesburg: Health Systems Trust, 2001 http://www.hst.org.za/sahr/2000.
[233] Saloojee Y. Tobacco Control. In *South African Health Review.* Johannesburg: Health Systems Trust, 2001. http://www.hst.org.za/sahr/2000.

ascribed the country's success to the bold leadership of the Health Minister and then-President Mandela, and identified several other contributing factors, including:

- production of sound epidemiological and economic data on tobacco use in South Africa by the Medical Research Council and the School of Economics of the University of Cape Town;
- effective advocacy by NGOs in supporting the legislation and educating not only the Government, but also the media and the public;
- cooperation of the Ministries of Finance, Agriculture, and Sports with the Ministry of Health; and
- international developments, such as the decision of the British Government and the EU to ban tobacco advertising and promotion, thus making South Africa's action part of a global trend.

Thailand

Thailand[234] has developed an extensive body of strong, innovative and proactive laws that have made it a world leader in tobacco control. These laws take numerous forms. Some have been created through acts of legislative bodies and the King; others have been created through declarations of the Ministry of Public Health and cabinet resolutions; and still others are municipal legislation. Officials have also used existing laws in imaginative new ways. Most recently, Thailand's depth of experience has served to inform discussions in the formulation of the WHO FCTC.

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Thailand's tobacco control legislation dates from 1974, when the Thai Government issued an executive order requiring the Thai Tobacco Monopoly to print a single health warning on Thai cigarette packages. Two years later, the City of Bangkok passed an ordinance prohibiting smoking in cinemas and buses. In 1986 the Ministry of Communication banned smoking on interprovincial public buses. Without seeking new legislation, Thai authorities greatly expanded the scope of regulation in 1989 by reinterpreting the 10-year-old Consumer Protection Act to classify tobacco as a "dangerous product." This provided the basis for the Government to mandate warning labels on all cigarette packs and to ban tobacco promotion in all media.

"In 1990, multinational tobacco companies mounted an assault on Thailand that was to have the unintended effect of spurring Thailand to the forefront of global tobacco control."

Then, in 1990, multinational tobacco companies mounted an assault on Thailand that was to have the unintended effect of spurring Thailand to the forefront of global tobacco control. In an action brought against Thailand by the United States of America, a panel of the General Agreement on Tariffs and Trade (predecessor of the World Trade Organization) ruled that Thailand had violated international trade agreements by excluding foreign tobacco from the country. The panel ruled, however, that under a clause allowing protection of health, Thailand could continue to restrict the sale and promotion of tobacco if the restrictions were applied equally to all tobacco, both domestic and imported.

This decision prompted prominent physicians in the medical and public health systems of Thailand to address the high rates of smoking in the population—rates that were increasing with the modernization of Thailand. Already, in 1983, the first National

[234] Discussion of the Thai legislation is taken from materials prepared by Ruth Roemer, drawing on earlier work by Dr Hatai Chitanondh, and from materials prepared by James Hodge. See Note on Contributors and Sources.

Conference on Tobacco or Health had been held. In 1986, the NGO Action on Smoking and Health had been formed. Most importantly, in 1989 the Minister of Public Health had appointed the Law Subcommittee of the National Committee for the Control of Tobacco Use—an action viewed as essential for drafting legislation—composed of both public health professionals and lawyers, in recognition that "those knowledgeable about smoking and health needed to inform and assist those writing the law."[235]

From the start of the meetings on the legislation, Dr Hatai Chitanondh, Deputy Permanent Secretary of the Ministry of Health, fought for a ban on all forms of advertising and sales promotion. The Subcommittee's proposal interpreted "advertising" broadly, banned the free distribution of cigarettes, prohibited the sale of tobacco to persons under 18 (originally 16), and prohibited sales through vending machines. Although the Law Subcommittee had agreed on the law, there was no action to move the legislation forward for five months, for "lack of responsible persons who would push for proceeding."[236]

After this delay, the Minister of Public Health appointed a Tobacco and Health Law Drafting Committee, chaired by Dr Chitanondh, to prepare two laws: the Tobacco Products Control Act and the Non-Smokers' Health Protection Act. The drafting committee considered all relevant Thai laws and the model of the Tobacco Control Act of Norway. When completed, the legislation prepared by the committee was submitted to the Juridical Council, where minor changes were made, and then to the Cabinet, which approved the legislation, including a provision requiring tobacco companies to disclose the constituents of tobacco products to the Government. Extensive notices of the Cabinet's approval of the new laws were carried in the newspapers.

Throughout this process, and as the legislation went before the National Legislative Assembly, multinational tobacco companies criticized and opposed the legislation. They argued that it duplicated existing laws, intervened unnecessarily in business operations, opened the way to abuse of power, and had been prepared without giving affected businesses adequate opportunity to comment. Industry opposition was so adamant that the manager of Philip Morris in Thailand was even seen to enter a closed-door meeting of the committee considering the legislation, in violation of parliamentary rules.[237] Despite last-minute fears that the legislation was being undermined, the National Legislative Assembly passed both landmark bills. The Rural Doctors' Society expressed its support. Headlines praising the legislation emblazoned newspapers. Children presented flowers to tobacco control advocates.

Both 1992 laws employ a strategy of delegated authority, maximizing flexibility by using broad language to empower regulatory authorities to prescribe finely detailed

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[235] Chitanondh H. *The Passage of Tobacco Control Laws: Thai Davids versus Transnational Tobacco_Goliaths*, Thailand Health Promotion Institute, The National Health Foundation, Bangkok, 2000, at 13.
[236] Chitanondh H. *The Passage of Tobacco Control Laws: Thai Davids versus Transnational Tobacco_Goliaths*, Thailand Health Promotion Institute, The National Health Foundation, Bangkok, 2000, at 35.
[237] Chitanondh H. *The Passage of Tobacco Control Laws: Thai Davids versus Transnational Tobacco_Goliaths*, Thailand Health Promotion Institute, The National Health Foundation, Bangkok, 2000 at 119.

requirements as necessary. The first of these laws, the Tobacco Products Control Act of 1992, B.E. 2535:

- prohibits sale of tobacco products to persons under 18 years of age;
- forbids the sale of tobacco products in vending machines;
- prohibits giving tobacco products as add-ons to other products, and vice-versa;
- prohibits using tobacco products for the right of entry to games or shows or in exchange for other services;
- prohibits giving free samples of tobacco products;
- prohibits print, radio and television advertising and event sponsorship, except for live broadcasts or printed matter from abroad;
- prohibits advertising non-tobacco products bearing cigarette names or logos;
- prohibits the manufacture, importation for sale, distribution, or advertisement of any products looking like cigarettes or cigars or packages of tobacco products;
- requires manufacturers and importers of tobacco products to inform the Ministry of Public Health of their composition in accordance with criteria specified in Ministerial Rules, and requires tobacco products to have a composition consistent with standards prescribed by Ministerial Rules;
- prohibits sale of tobacco products without the required labels and health warnings; and
- provides for stringent enforcement by imprisonment and fines.

The second law, the Non-Smokers' Health Protection Act of 1992, B.E. 2535:

- grants authority to the Minister of Public Health to designate the public places where the health of non-smokers shall be protected, to designate any part or all of public places as a smoking or non-smoking area, and to prescribe the condition, nature, or standard of non-smoking or smoking areas with respect to ventilation;
- requires the operator of any public place to comply with the prescription of the Minister and to post signs in the smoking and non-smoking areas;
- prohibits smoking in a non-smoking area;
- authorizes entry to public places for inspection and supervision of implementation of the Act; and

- provides for enforcement by fines and imprisonment.

As noted, these laws confer broad authority on the Ministry of Health to adopt detailed regulations in many areas—for example, to set standards for smoke-free public places and to specify stringent standards for the composition and quality of tobacco. Rules also prescribe detailed requirements for health warning labels—setting innovative new standards in the process. For example, these rules made Thailand the first country to require a package warning about the link between smoking and sexual impotence.

Other rules require manufacturers to report the chemical composition and emission properties of each tobacco product, to report chemical additives and to measure tar and nicotine levels. Implementation of these disclosure requirements was repeatedly delayed because of the strong opposition of multinational tobacco companies and their governments. In 1998 and 1999, the United States Trade Representative lobbied the Thai Government on behalf of the tobacco industry to eliminate these requirements, claiming that disclosure of product ingredients would reveal tobacco companies' trade secrets, in alleged violation of intellectual property rights guaranteed by international trade agreements. Ultimately, the dispute was resolved through compromise: the tobacco companies agreed to disclose their ingredients to the Government, which agreed to keep the information confidential.

The Ministry of Public Health has mobilized substantial resources for enforcement of these important laws. It established a Tobacco Consumption Control Office to coordinate the country's tobacco control activities and appointed officials from the central and local governments to enforce the laws, in cooperation with the police. The NGO Thai Action on Smoking and Health and the Thailand Health Promotion Institute play important roles in enforcement by serving as watchdogs, especially of the multinational tobacco companies.[238]

Efforts to achieve full compliance continue. Some of the recurring violations of these laws have involved indirect advertising using tobacco names and logos on non-tobacco products. Also, owners of some air-conditioned restaurants, especially in smaller provinces, have failed to provide no-smoking areas as required by the law. Enforcement of the ban on sales of cigarettes to minors remains a challenge, but compliance has improved with an intensive campaign.[239] Among the factors limiting enforcement efforts are: an inadequate number of enforcement officials; officials' lack of knowledge of the provisions of the law; insufficient funding for training; and an inadequate surveillance system "to keep up with the endless tactics and tricks of the tobacco industry."[240] Thai experts offer two lessons from their country's enforcement experience:

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[238] Professor Parkit Vateesatokit, Executive Secretary, Action on Smoking and Health, Bangkok, Results of a Legislative Approach: Thailand's Experience. Lu R et al. eds., In: *The Growing Epidemic, Proceedings of the 10th World Conference on Tobacco or Health*, Beijing, China, 1997, at 621-623.

[239] Buasai S and Supawongse C. *Smoking Behavior of Thai Youths: A National Survey*. 1997.

[240] Srisangnam U, Deputy Minister of Public Health, *Tobacco Advertising Legislation: Thailand's Experience*, October 12, 1994.

a) Adequate funding is essential for public campaigns for awareness of the law, training of law enforcement officials, rewards for law enforcement officers, and campaigns for public compliance with the law; and

b) Where the government owns broadcast media, these media should provide free broadcast time for campaigns to encourage compliance with the law.

"Thailand's tobacco control programme has produced a significant decline in smoking. For men, smoking prevalence declined from 63.2% in 1981 to 42.6% in 1999. For women, prevalence has declined from 5.4% in 1981 to 2.6% in 1999. For both sexes, prevalence has declined from 35.2 % in 1981 to 22.4% of the population in 1999."

Thailand's tobacco control programme has produced a significant decline in smoking. For men, smoking prevalence declined from 63.2% in 1981 to 42.6% in 1999. For women, prevalence has declined from 5.4% in 1981 to 2.6% in 1999. For both sexes, prevalence has declined from 35.2 % in 1981 to 22.4% of the population in 1999.[241]

Thailand's tobacco control legislation and its achievements are impressive, but the country's tobacco control champions have further improvements in mind. Among the new measures they envision are:

- a stronger ban on smoking by children and adolescents;
- generic packaging;
- a ban on sponsorship by company name, and
- a ban on the sale of non-tobacco products with cigarette logos.

These are ambitious goals, but if the history of Thailand's initiatives is a guide, they are not beyond reach.

[241] The Thailand Health Promotion Institute has calculated the steady decline in smoking rates in Thailand for persons over 15 as follows:

	1981	1986	1988	1991	1993	1996	1999
Both sexes	35.2	31.3	28.4	29.0	25.5	25.9	22.4
Male	63.2	58.6	52.7	55.3	48.5	49.2	42.6
Female	5.4	4.8	3.0	4.3	2.8	2.8	2.6
Source: Dr Hatai Chitanondh.							

The United States of America

As a federal republic, the United States of America[242] divides its legislative authority among the national Government, 50 states, and an overlapping jumble of thousands of cities, counties and other subnational units of governments. In theory, tobacco control legislation could originate at any of these levels, and, indeed, elements of legislation do exist at each level. In practice, however, most meaningful tobacco control laws of the United States of America are found at the subnational level.

"Most meaningful tobacco control laws of the United States of America are found at the subnational level."

Nationally, the United States Congress has the power, under its authority to tax and to regulate interstate commerce, to enact any or all of the components of a comprehensive tobacco control programme. Furthermore, Congress has the ability, if it chooses, to reserve specific areas of legislation exclusively to itself and to cut off, or "pre-empt," the authority of subordinate units of government to act in those areas. In the field of tobacco control, Congress has exercised this pre-emptive power in only one respect, barring state and local governments from requiring localized cigarette package warning labels and from imposing certain advertising restrictions—a concession made to the tobacco industry at the time Congress enacted national warning label requirements. In all other respects, however, states, cities and other subnational governments remain free to adopt their own tobacco control programmes, so long as those programmes do not conflict irreconcilably with national laws or run afoul of Constitutional rights of the businesses affected.

The national Government itself has not implemented a comprehensive tobacco control programme. Instead, national legislation is piecemeal, weak and inconsistent. Text-only warning labels are required, and television and radio advertising are prohibited, but other forms of advertising continue. Modest excise taxes, of US$ 0.39 per pack of cigarettes, are imposed, but only as a revenue measure. Agricultural policies encourage tobacco growing, and trade policies have historically promoted the interests of tobacco manufacturers. Manufacturers file a secret and ineffectual aggregated annual report on cigarette ingredients and an aggregated tabulation of the amounts spent on advertising. Tar and nicotine content are disclosed, using largely discredited testing

[242] Discussion of legislation in the United States of America was prepared by D. Douglas Blanke. See the Note on Contributors and Sources.

methodology. In virtually all other respects, tobacco prevention and control are left to subnational governments or civil society.

"The result is a complex system of multi-layered laws and programmes, in which some jurisdictions have done very little, while others have set a standard for best practices"

The result is a complex system of multi-layered laws and programmes, in which some jurisdictions have done very little, while others have set a standard for best practices.[243] The most effective subnational legislation includes laws in several key areas:

- *Comprehensive tobacco control programmes*. Beginning with the states of California in 1989 and Massachusetts in 1993, a small number of states have implemented comprehensive, state-of-the art tobacco control programmes, combining aggressive, government-sponsored media campaigns with repeated tax increases, regulation of public smoking, community-based advocacy, regulation of retail sales practices, school-based education and policies, youth movements and other activities. These programmes are effective: not only have they reduced cigarette consumption and smoking prevalence, but the longest-running programme, in California, has already reduced lung cancer rates, relative to other areas of the United States of America, and has prevented tens of thousands of heart-disease-related deaths.[244] These programmes are cost-effective—saving an estimated US$ 3.62 in direct medical costs for each dollar spent—and, according to the United States Surgeon General, have the potential to cut tobacco use in half within a decade.[245] With funding from the United States tobacco litigation of the 1990s, as well as excise taxes and general revenues, states invested US$ 883 million in tobacco prevention and control in fiscal year 2001. Regrettably, an economic slowdown in 2002 and 2003 has impaired states' financial situations and threatens continuation of this investment in many jurisdictions.

"A small number of states have implemented comprehensive, state-of-the art tobacco control programmes. These programmes are effective: not only have they reduced cigarette consumption and smoking prevalence, but the longest-running programme, in California, has already reduced lung cancer rates, relative to other areas of the United States of America, and has prevented tens of thousands of heart-disease-related deaths."

[243] For a comprehensive overview and synopsis of state legislation in the United States of America, *see*: American Lung Association, *State Legislated Actions on Tobacco Issues, 13th Edition*. Washington, American Lung Association, 2001.
[244] Centers for Disease Control and Prevention, *Investment in Tobacco Control: State Highlights – 2001*, Atlanta, GA: U. S. Department of Health and Human Services, 2001, http://www.cdc.gov/tobacco/statehi/statehi_2001.htm.
[245] Centers for Disease Control and Prevention, *Investment in Tobacco Control: State Highlights – 2001*, Atlanta, GA: U. S. Department of Health and Human Services, 2001, http://www.cdc.gov/tobacco/statehi/statehi_2001.htm.

- *Excise taxes* . Increasingly, states, and even cities, have used their taxing authority not only to generate revenue, but also as a calculated strategy for reducing tobacco consumption and prevalence of use. While some tobacco-growing states collect excise taxes of as little as US$ 0.025 per pack of cigarettes, the national average for state taxes was US$ 0.44 per pack in January 2002.[246] Consistent with recommendations of the World Bank and others, governments have begun imposing substantial tax increases for health purposes. In January 2002, six states were already collecting taxes of US$ 1.00 or more per pack; since that time, with an economic downturn affecting states' fiscal conditions, 17 states have imposed additional tax increases.[247] Most recently, the City of New York has enacted a municipal tax of US$ 1.50 per pack, in addition to a state tax of US$ 1.50 and national tax of US$ 0.39, bringing retail prices for a pack of 20 cigarettes in New York to as much as US$ 7.50. Initial implementation of the tax has been successful, according to a spokesperson for the city's mayor, who reported, "We sold half as many packs of cigarettes, and revenues have gone up fivefold."[248]

- *Smoking restrictions*. The national Government does not regulate public smoking in the United States of America, but almost every state restricts smoking in certain places, as do hundreds of local governments. Many of these laws are weak, but many others are sweeping in scope and strong in their approach. In many jurisdictions, smoking is prohibited altogether in certain settings, such as schools, health care facilities, government buildings, and public transit. Typically, smoking in workplaces and public facilities is limited to designated smoking areas, but increasingly, in recognition of the worthlessness of efforts to "separate" or "ventilate" smoke-filled areas, subnational laws are eliminating all smoking in public settings. For example, five states (California, Delaware, Maine, Utah and Vermont) now prohibit smoking in restaurants, and two others (Florida and New York)[249] are in the process of doing so,[250] while an estimated 442 cities—including, recently, the cities of New York, Dallas and Boston—and counties tightly restrict smoking in restaurants and/or other private workplaces.[251] The

[246] American Lung Association, *State Legislated Actions on Tobacco Issues, 13th Edition*, 2001, at i.

[247] American Lung Association, *State Legislated Actions on Tobacco Issues, 13th Edition*, 2001, at i; and Center for Tobacco-Free Kids, Fact Sheet, "State Cigarette Taxes and Projected Benefits from Increasing Them," August 5, 2002, http://www.tobaccofreekids.org/research/factsheets/pdf/0148.pdf.

[248] "Cigarette Tax, Highest in the Nation, Cuts Sales in the City," *New York Times,* 6 August 2002.

[249] Voters of the State of Florida overwhelmingly approved a 2002 ballot measure requiring smoke-free public places and workplaces. Legislative maneuvering and resistance to implementation of this mandate is continuing. The legislative body of the State of New York enacted a similar measure in early 2003, but it has yet to enter into force, and efforts to prevent its implementation are possible.

[250] *See* American Lung Association, Chart, "State Laws Restricting Smoking in Public Places, 1999," http://www.lungusa.org/tobacco/slati99_chart2.html; and American Lung Association, Map, "Restrictions on Smoking in Public Places, 2000," http://www.lungusa.org/tobacco/map_301.html#2000.

[251] American Non-smokers' Rights Foundation, Table, "100% Smoke-free Ordinances," July 3, 2002, http://www.no-smoke.org/100ordlist.pdf.

trend toward such laws has reached a high intensity, with proposed smoking prohibitions currently under consideration in dozens of communities nation-wide, and many cities moving toward elimination of public smoking. Best known of the strong new laws is California's successful 1998 state-wide ban on smoking in bars and restaurants, a closely watched development that has achieved high public acceptance and set a standard for new laws elsewhere.[252] These restrictions have been shown not only to address the immediate dangers of exposure to tobacco smoke, but also to contribute strongly to changing social norms and attitudes about tobacco use.[253] Along with efforts to increase excise taxes, controlling public smoking now represents the leading focus of legislative activity in the United States of America.

"Along with efforts to increase excise taxes, controlling public smoking now represents the leading focus of legislative activity in the United States of America."

- *Youth access to tobacco.* The United States national Government does not regulate the sale of cigarettes to minors, but every state and many local governments do. Many state and local governments license tobacco sellers—often using these laws to control the way tobacco products are displayed and sold, and employing teenage investigators to conduct test purchases.[254] Most states also prohibit or limit the use of cigarette vending machines.[255] While important recent research calls into question whether sale-to-minors laws can reduce youth smoking rates, these laws remain an unmistakable expression of society's norms concerning the use of tobacco by young people. In many states and cities, these laws and their enforcement have been strengthened in the last decade, significantly

[252] *See*: California Department of Health Services, Tobacco Control Section, *Eliminating Smoking in Bars, Taverns and Gaming Clubs: The California Smoke-Free Workplace Act: A Case Study,* 2001, www.dhs.ca.gov/tobacco/html/evaluation_reports.htm.
[253] *See*: California Department of Health Services, Tobacco Control Section, *Eliminating Smoking in Bars, Taverns and Gaming Clubs: The California Smoke-Free Workplace Act: A Case Study,* 2001, www.dhs.ca.gov/tobacco/html/evaluation_reports.htm.
[254] For a review of the status of youth access enforcement in eight states, *see:* Tobacco Law Project, *Minding the Store, Curtailing the sale of Tobacco to Minnesota Teens,* Saint Paul, William Mitchell College of Law, 2001, at 14 - 33, http://www.smokefreecoalition.org/filerepository/downloads/MindingtheStore.pdf.pdf.
[255] *See:* American Lung Association, *State Legislated Actions on Tobacco Issues, 13th Edition*, 2001, at iii.

reducing the rate of illegal sales, and building community awareness of, and support for, tobacco control, generally.

- *Product regulation.* One important, but largely undeveloped, area of subnational legislative authority in the United States of America involves the regulation of tobacco products themselves—for example, by requiring ingredient disclosure or by restricting product constituents. Three states currently require certain product disclosures. Three others prohibit the sale of bidis. Texas requires manufacturers to identify all constituent ingredients of cigarettes, and Massachusetts requires disclosure of nicotine yields. An important 2001 legal ruling, affirming Massachusetts' authority to go forward with these requirements, opens the door for potential expansion of the role of states and other subnational governments in this area, particularly in the absence of national regulation.[256]

These initiatives are inevitably controversial, and every success has been hard-won: veteran legislators often say these proposals are among the most fiercely contested of their careers. While each of these stories is unique,[257] some general observations are possible, even across this diverse set of laws and jurisdictions:

- Successful legislative proposals are usually developed or shaped by a broad, multisectoral coalition of supporters from both government and civil society, typically including health and advocacy organizations, health officials and community groups, often joined by educational, religious and other interests.
- Essential to the success of most campaigns is the personal leadership of a resourceful and influential legislative champion, often a senior legislator or committee chair.
- Success usually requires a solid foundation of community support. Efforts at the grassroots level, in small communities, with wide public involvement, have had the greatest success, and have provided the base of political support from which success at a regional and state level has emerged. Efforts are least successful at the national level, where tobacco interests wield the greatest influence.

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[256] Massachusetts pioneered the use of state authority for tobacco product regulation, developing a comprehensive set of rules including ingredient disclosure requirements. In recent litigation, these requirements were overturned, on the ground that, as written, the rules improperly revealed trade secrets of manufacturers by, in effect, making public the product formulas for each brand of cigarettes. The implications of this ruling for future regulation in Massachusetts are unclear, but the decision does not place in question the authority of states to adopt product regulations, and the court appeared to approve ingredient disclosure laws if formulated differently, as in the State of Texas.

[257] For a detailed account of the enactment of one of the most prominent and controversial proposals, s*ee*: California Department of Health Services, Tobacco Control Section, *Eliminating Smoking in Bars, Taverns and Gaming Clubs: The California Smoke-Free Workplace Act: A Case Study,* 2001, www.dhs.ca.gov/tobacco/html/evaluation_reports.htm

Opponents, notably tobacco manufacturers and their allies, use a consistent approach in fighting these proposals:

- Opposition is always intense, and sometimes monumental. This opposition is highly organized, well financed and sophisticated, and many of its elements are invisible to the public.
- Tobacco manufacturers work diligently to conceal their involvement, instead using surrogates and front groups, or manipulating the involvement of third parties, especially legitimate local business interests.
- Opponents seek to shift public debate away from issues of health—on which they have difficulty winning—and to appeal instead to "freedom," "choice," "fairness," and other shared values.
- Opponents may engineer vicious and distracting personal attacks on proponents of the legislation, usually through seemingly-unrelated critics, and often on grounds that appear unrelated to tobacco.
- Above all, opponents attempt to turn every legislative proposal into an opportunity to "pre-empt" tougher laws. That is, they seek to ensure that every legislative proposal is written to prevent other, subordinate governments from taking stronger action.

"Supporters must agree on core principles, and be prepared to fight any compromise of those principles. In particular, this has required firm opposition to any legislation that pre-empts action by other governments."

Several strategies have proven critical to overcoming this opposition:

- Proposals must rest on a diverse and inclusive base of support from civil society, working from the community, and even neighbourhood level, upward to larger units of government.
- Supporters must agree on core principles, and be prepared to fight any compromise of those principles. In particular, this has required firm opposition to any legislation that pre-empts action by other governments. Similarly, supporters should have a clear consensus about the acceptability of possible compromises and trade-offs.

- Where lawmakers are too heavily influenced by the tobacco industry for success in the normal legislative process, strong legislation has sometimes been achieved by appealing directly to the general public, through a referendum or ballot initiative, permitted in some jurisdictions. This approach has had both strengths and weaknesses.
- Whatever the forum, supporters must expose the involvement and tactics of tobacco manufacturers and their allies. The availability of once-secret industry documents has aided these efforts.

None of these strategies guarantees success. Even the most well-conceived proposals face unpredictable outcomes, in the face of such fierce opposition. But these campaigns have been worth the effort. Careful and continuous evaluation has repeatedly confirmed the value and effectiveness of subnational legislation of the types described here.[258] Together with aggressive counter-marketing campaigns and a sustained commitment of financial resources, laws such as these constitute the backbone of effective tobacco control in the United States of America.

[258] *See, e.g.*: Centers for Disease Control and Prevention, *Investment in Tobacco Control: State Highlights – 2001*, Atlanta, GA: U. S. Department of Health and Human Services, 2001, available online at www.cdc.gov/tobacco; U. S. Department of Health and Human Services, *Reducing Tobacco Use: A Report of the Surgeon General*, Atlanta, Georgia: U. S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2000; Abt Associates, Inc., *Independent Evaluation of the Massachusetts Tobacco Control Program*, Fifth Annual Report. Cambridge, Massachusetts: Abt Associates, Inc., 1999; and eight extensive reports evaluating the California comprehensive tobacco control programme and its elements, available online at California Department of Health Services, California Program Evaluations, http://www.dhs.ca.gov/tobacco/html/evaluation_reports.htm.

Some lessons learned

The country studies presented here, like the experiences of other countries that have enacted legislation, offer many lessons for future tobacco control efforts. These lessons are discussed throughout this legislative guide, but several broad observations are appropriate here:[259]

- *Public health governmental support*. Strong support from the ministry of health or a similar agency is vital to the success of tobacco control policies, especially when statutes delegate significant regulatory authority to health authorities. Under these legislative frameworks, health authorities, and not the legislature, are largely responsible for designing, regulating, and, of course, implementing specific tobacco control policies. Health authorities have the discretion to promulgate strict regulations or to refrain from regulating altogether.

"Strong support from the ministry of health or a similar agency is vital to the success of tobacco control policies, especially when statutes delegate significant regulatory authority to health authorities."

- *A role for the civil society*. Controlling tobacco use through legislation may necessarily involve governmental action, but the role of civil society is also critical. NGOs, medical societies, public health advocates and other entities can provide advocacy and technical assistance in many areas, including science and policy formulation.

- *Flexibility*. Flexibility is an important feature of many countries' successful tobacco control laws. Statutes that are flexible in design and implementation can create a foundation for long-term tobacco regulation. Many successful tobacco control statutes are intentionally non-specific and future-oriented. By granting considerable authority to health agencies, these statutes can form the basis for promulgating new regulations for years to come. Promoters of legislative interventions also need to remain flexible in their advocacy, development, and implementation of various proposals, to respond to tobacco industry arguments and public concerns.

- *Opposition.* Tobacco industry representatives and allies work hard to defeat tobacco control laws. Tobacco proponents include tobacco manufacturers, distributors, retailers, farmers and others with ties to the industry, but also media sources and civil libertarian groups concerned about potential infringement of individual freedoms, as well as economists and members of the business community worried about the economy impact of tobacco measures. These proponents may be generously funded by the tobacco industry. Defeating opposition that comes from all sides is difficult, but not impossible. Keeping arguments firmly grounded in the population health effects of tobacco use and the misleading practices of the tobacco industry, among other themes, increases the likelihood of success.

- *International context.* As part of their legislative strategies, health authorities and advocates should consider the international implications of national tobacco control policies. The expansion of free trade and the globalization of tobacco markets require that prospective tobacco control policies be evaluated for their potential impact on trade and diplomatic relations.

- *International support.* Proponents of a legislation should integrate the standards in the (WHO FCTC) into the national legislative scheme. The negotiations of the WHO FCTC has stimulated national tobacco action for tobacco control around the world.

- *Public support.* Every legislation requires public support for its proper implementation. Raising awareness among the population is a critical element of legislative development.

[259] This discussion is from materials prepared by James Hodge. See Note on Contributors and Sources.

Chapter XIII. Tobacco control and international law

INTRODUCTION

This chapter will briefly explore the significance of international law for national tobacco control measures. It will first consider the potential legal significance of the WHO Framework Convention on Tobacco Control (WHO FCTC), the relationship between the WHO FCTC and other existing international legal obligations and the process by which State Parties to the WHO FCTC can implement the treaty into domestic law and policy. It will then examine the obligations established under relevant existing international agreements and their potential impact on the authority and responsibility of States to develop and implement national tobacco control policies. At the global level, such international commitments include international trade obligations established under the auspices of the World Trade Organization (WTO); international human rights obligations established pursuant to the human rights covenants of the United Nations; and obligations established under the auspices of the World Customs Organization (WCO). The chapter will also review legal obligations relevant to tobacco control established under the auspices of treaties of various regional organizations, focusing in particular on the European Union (EU). This chapter can provide only a summary description of this complex area of international concern; it is not comprehensive and does not purport to survey all existing international law with potential applicability to tobacco control.

The nature of international law[260]

International law is that body of law which regulates the relationships between states. While it is not possible to adequately discuss and clarify the nature of the rules and the process of international law within the confines of this chapter, it should be recognized that the rules of international law are very different in kind from those of municipal law as a consequence of the international legal system. Given the international political system of nation-states and the concept of state sovereignty, the sources of international law cannot be equivalent to those of municipal laws. Municipal rules generally derive from national constitutions, municipal statutes, executive regulations, and the decisions of

"Given the international political system of nation-states and the concept of state sovereignty, the sources of international law cannot be equivalent to those of municipal laws."

[260] An introduction to basic terms and concepts in international law can be found in Chapter III of this book.

municipal courts. Of course, some international organizations, such as the EU, have established law-making structures that approach municipal-like sources, but, overall, formal international legislative and executive organs are fairly rare in the international system. Article 38.1 of the Statute of the International Court of Justice sets forth the generally accepted sources of international law. As treaty law is the primary source of international rules related to tobacco, this chapter will focus on treaty law rather than other sources of international law. Despite their recognized limitations, treaties can be a useful mechanism for promoting international cooperation and stimulating domestic action.

Article 2 of the Vienna Convention on the Law of Treaties defines a treaty as "an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation."

"Conventional international law – treaty law — is a voluntary undertaking."

Conventional international law – treaty law — is a voluntary undertaking. Hence, when we consider the full range of international law relevant to tobacco control, the obligations established under any particular treaty may not be applicable to any particular State. Even if a State is party to a treaty, it may have submitted reservations, interpretive declarations and so forth that modify its legal commitments under that instrument.

"Treaties, like private contracts, are more than statements of goals and aspirations; treaties create legal rights and duties."

Treaties, like private contracts, are more than statements of goals and aspirations; treaties create legal rights and duties. International lawyers use the phrase *pacta sunt servanda* to express the fundamental principle that agreements, even those between sovereign States, are to be obeyed. This basic principle regarding the observance of treaties finds its place in Article 26 of the Vienna Convention of the Law of Treaties which provides that: "Every treaty in force is binding upon the parties to it and must be performed in good faith".

Binding commitments under treaties in force may both expand and limit a government's authority and responsibility to protect public health, including tobacco control. For example, national commitments established under the WHO FCTC may function to expand existing governmental legal responsibility to address tobacco. At the same time, national obligations pursuant to some treaties, such as the WTO General Agreement on Tariffs and Trade (GATT 1994) may operate to restrict the types of measures

that WTO Member States may advance to protect domestic health. Under the principle of *pacta sunt servanda*, a State will be obligated in international law to faithfully observe its treaty commitments and a state "may not invoke the provisions of its internal law as a justification for failure to perform a treaty." (Vienna Convention, Article 27).

"As a general rule, treaties are binding only upon those States that have consented to them."

As a general rule, treaties are binding only upon those States that have consented to them. While a treaty represents the express legal rights and obligations to which all the parties of the treaties have agreed, at times there may be certain provisions of a treaty that one or more parties refuse to accept. Such a refusal is generally called a *reservation*, defined in the Vienna Convention as "a unilateral statement, however phrased or named, made by a State, when signing, ratifying, approving or acceding to a treaty, whereby it purports to exclude or to modify the legal effect of certain provisions of a treaty in their application to that State". The practice of using reservations to modify or limit the effect of a particular treaty is not unusual in international practice. The Vienna Convention provides that States may formulate such a reservation unless it is prohibited by the treaty, is not one of the specified permissible reservations, or is "incompatible with the object or purpose of the treaty".

"International legal obligations established by a treaty may not be generally applicable to all States that are party to a particular agreement."

Because of the existence of mechanisms such as reservations or interpretive declarations, which modify legal commitments under an instrument, it must be emphasized that the international legal obligations established by a treaty may not be generally applicable to all States that are party to a particular agreement. For example, it is increasingly common in international practice for treaties to establish differential commitments for developed and developing countries. In addition, in considering implications of any treaty in force for its domestic tobacco control, each State must determine first whether it is a party to that treaty and second whether there are any reservations that modify its legal rights and obligations of that treaty domestically.

"Negotiations of this instrument represent the first time that WHO has acted under Article 19 of its Constitution, which authorizes the Organization to develop and adopt conventions or agreements."

I. The WHO Framework Convention on Tobacco Control

The WHO FCTC has been designed as an international legal instrument to circumscribe the global spread of tobacco and tobacco products. Negotiations of this instrument represent the first time that WHO has acted under Article 19 of its Constitution, which authorizes the Organization to develop and adopt conventions or

agreements. The target date for adoption of the treaty by the World Health Assembly, WHO's governing body, was May 2003.

A final draft text of the WHO FCTC (A/FCTC/INB6/5) was negotiated at the final Plenary meeting of the sixth session of the Intergovernmental Negotiating Body (INB6), charged with negotiations of the agreement, on 1 March 2003. INB6 agreed to transmit the text to the Fifty-sixth World Health Assembly for adoption in accordance with Article 19 of the Constitution. INB6 also agreed that the discussion on protocols should be postponed until the Fifty-sixth World Health Assembly, at which there would be ample time for consideration of the matter.

Provisions of the final draft of the WHO FCTC[261] include the issues of: advertising, promotion and sponsorship; illicit trade; liability; packaging and labelling; training and education; and research and surveillance. It also establishes institutions and mechanisms necessary for the functioning of the treaty, such as the Conference of the Parties, the Secretariat, and dispute settlement procedures.

A. Ratifying and implementing the WHO FCTC

Once negotiations have been completed, the text of the WHO FCTC must be "adopted". Adoption of a treaty represents the close of negotiations. Treaties may be concluded in virtually any manner that the Parties wish. In addition, after adoption of the WHO FCTC, a series of international and domestic requirements must be met before the Convention enters into force. Once the treaty enters into force, it will do so only for those States that have specifically consented to be bound by the treaty. As detailed by the eminent scholar Paul Szasz, the international and domestic requirements for entry into force follow:

- *International requirements*: The formal international requirements for the entry into force of the WHO FCTC will be detailed in the final clauses of the Convention itself. First, the final clauses will specify the mechanism by which State Parties may express their consent to be bound by the treaty. In virtually all cases, multilateral treaties allow States to accept the treaty by means of either (a) signature followed by ratification or (b) accession. In the former case, signature is merely a preliminary step in the process by which a State gives its consent to be bound, and must be followed by ratification. A treaty text maybe opened for signature by States at the same time as adoption, or at a later date. If a treaty specifies a limited period of time during which it may be signed, and that period of time has expired, then a State can become a party to the treaty by means of accession, which has the same effect as ratification. Second, the final clauses will specify how the treaty will enter into force, normally expressed in terms of

[261] At the time of this writing, the final text of the FCTC had been submitted for the May 2003 World Health Assembly to consider for adoption.

how many States must formally consent to the agreement by means of ratification or accession. The law of treaties does not specify any particular number of ratifications, and the requirement varies widely from treaty to treaty.[262] The WHOFCTC requires 40 ratifications for entry into force in Article 30.

"The WHO FCTC requires 40 ratifications for entry into force in Article 30."

- *Domestic requirements:* The domestic requirements for entry into force are governed by national law, most often the national constitution. "These specify which treaties may be entered into on the sole authority of the executive, and which require some sort of parliamentary legislative concurrence and, if so, by what house(s) and what majorities. They may also specify certain matters that a State may not do, and therefore, it cannot commit itself by treaty."[263]

"The domestic requirements for entry into force are governed by national law, most often the national constitution."

B. Promoting ratification and implementation of the WHO FCTC

As described above, a series of domestic and international requirements must be met before the WHO FCTC can enter into force. This section and the following consider formal constitutional procedures and other mechanisms that could be used to encourage prompt signature and ratification of the WHO FCTC.

Technical advice and assistance to the poorest nations may be required at the stages of ratification and implementation of the WHO FCTC. Domestic ratification requires a series of complex and costly tasks that may be particularly challenging for developing countries. Such steps may include: translation of the WHO FCTC and ancillary documents into the national language; a survey of the State's existing international legal obligations to assess whether conflicts exist between those treaties and the WHO FCTC; a similar survey of the State's constitutional and statutory prescripts; and an assessment of whether the legal regime established by the

"Which authorities within a State bear responsibility for these steps will vary widely depending upon the structure of government and the distribution of authority."

[262] In some cases, a convention's entry into force provision specifies additional requirements. See International Convention for the Prevention of Pollution from Ships, 2 Nov. 1973, art, 15(1) and the Kyoto Protocol to the United Nations Framework Convention on Climate Change, 11 Dec. 1997, art. 25(1).

[263] Szasz P. General Law-Making Processes. In: Joyner C. *The United Nations and International* Law 27, Cambridge University Press, 1997.

Convention is beneficial to the State. Which authorities within a State bear responsibility for these steps will vary widely depending upon the structure of government and the distribution of authority.

The elaboration and implementation of new legislation to implement the WHO FCTC may be a cumbersome task for many nations. Many States with limited resources simply lack an adequate legislative or regulatory foundation upon which to build such standards. The construction of an appropriate domestic regulatory apparatus is no simple or mechanical task; it entails many choices and requires scientific and technical judgment, bureaucratic capability and fiscal resources. Consequently, technical support programmes to assist developing nations in establishing appropriate legal frameworks may be a critical incentive to some countries to participate in the treaty regime.

"At country level, promotion, ratification and implementation is a case-by case approach and best practices, activities or strategies that have proved successful in other countries should be consulted."

At country level, promotion, ratification and implementation is a case-by case approach and best practices, activities or strategies that have proved successful in other countries should be consulted.[264]

After entry into force of the WHO FCTC, the Conference of the Parties will be the governing body of the Convention which advances implementation of the Convention through the decisions it takes at its periodic meetings. Article 23 of the WHO FCTC provides for the establishment of a Conference of the Parties , the governing body of the Convention, immediately upon its entry into force. This body "shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation and may adopt protocols, annexes and amendments to the Convention, in accordance with Articles 28, 29 and 33". According to Article 24 of the WHO FCTC, the secretariat of the WHO FCTC will be provided by the World Health Organization until the Conference of the Parties designates a permanent secretariat, and will provide administrative and logistic assistance to the Conference of the Parties.

C. Role of the World Health Assembly in promoting ratification and implementation of the WHO FCTC

Throughout the United Nations system, the general rule is that once a treaty has been adopted by an organ or conference of an

[264] The World Bank and WHO have produced a subseries describing case studies for the economics of tobacco control in different countries. This is available at http://www1.worldbank.org/tobacco/publications.asp.

international organization, then the organization "takes no substantive interest in the steps to bring the treaty into force that must be taken by individual States, except to the extent that the organization may act as a depositary and carry out formal steps required in that capacity".[265] The original organization's actions are limited to symbolic steps to encourage ratification, such as commending the treaty to its members, adopting resolutions encouraging member nations to participate in the treaty, or requiring its executive head to report periodically on the progress in bringing the treaty into force in Member States.

A very few organizations, including WHO, have specific constitutional provisions designed to encourage ratification and entry into force of conventions. Specifically, Article 29 of WHO's Constitution states:

> Each Member undertakes that it will, within 18 months, after the adoption by the Health Assembly of a convention or agreement, take action relative to the acceptance of such convention or agreement. Each Member shall notify the Director-General of the action taken, and if it does not accept such convention or agreement within the time limit, it will furnish a statement of reasons for non-acceptance…

"A very few organizations, including WHO, have specific constitutional provisions designed to encourage ratification and entry into force of conventions."

Since the WHO FCTC will be the first convention considered for adoption by WHO Member States, this constitutional provision has never been utilized.

II. INTERNATIONAL LAW WITH RELEVANCE FOR TOBACCO CONTROL

This section describes the authority and responsibility of States to develop and implement tobacco control law under existing international legal obligations. The discussion will briefly describe the areas of international trade law, international human rights law, and the relationship between the WCO and health, and then set out the relevant international instruments from each field. At the end of the chapter, a list of useful references within each of these areas is presented for those interested in acquiring more in-depth information in a particular subject.

[265] Szasz, P. General Law-Making Processes. In: Joyner C. *The United Nations and International Law* 27, Cambridge University Press, 1997.

As described above, domestic ratification of the WHO FCTC will normally require a State to survey its existing international legal obligations to assess whether conflicts exist between those treaties and the WHO FCTC. In the case of a conflict between two treaties, two general rules of international law apply. The principle of *lex specialis* in public international law represents the notion that treaties of a specific nature take precedence over treaties of a more general nature. Article 30 of the Vienna Convention on the Law of Treaties contains the principle of *lex posterior*, or the "later in time" rule, which stipulates that later treaties will take precedence over earlier treaties. It should be emphasized that these two rules can apply only to States which are parties to *both* treaties in question.

"As described above, domestic ratification of the WHO FCTC will normally require a State to survey its existing international legal obligations to assess whether conflicts exist between those treaties and the WHO FCTC."

A. World Trade Organization multilateral agreements

This section reviews existing international trade agreements developed under the auspices of the WTO that may have important implications for national tobacco control efforts by WTO Members, and it is important for States to explore national commitments in this respect. However, no litigation related to tobacco control has arisen under any agreement other than the General Agreement on Tariffs and Trade (GATT) (1947) and consequently the significance of the WTO agreements for tobacco control is not clearly defined.

1. Introduction to the World Trade Organization

As the primary international institution governing international trade, the WTO's principal aim is to reduce barriers to trade. Its general principles include: a commitment to achieving free trade and fair competition; limits on and eventual elimination of tariff and non-tariff barriers to trade; non-discriminatory treatment of all trading partners; the non-discriminatory treatment of domestically produced and foreign products; predictability, by ensuring that trade barriers are not erected arbitrarily; negotiated elimination of trade barriers; the settlement of disputes; and opposition to retaliatory sanctions.

Between 1947 and 1994, GATT 1947 had served as the framework for international trade. The WTO was formed at the conclusion of the Uruguay Round of GATT in 1994. The Uruguay Round brought about an overhaul of the international trade regime

through the conclusion of a number of agreements addressing contemporary trade issues. The WTO Agreement has four annexes that contain the agreements reached in the new Uruguay Agreements. GATT (1947), which is now known as GATT (1994), was amended and incorporated into the new WTO agreement, including case law and interpretive decisions, at the Uruguay Round. As a condition of membership in the WTO, Members must agree to 24 different agreements, located in Annexes 1-3 to the Marrakesh Agreement.

A number of the binding agreements established under the auspices of the WTO agreements have important implications for national tobacco control efforts. WTO jurisprudence indicates that the application of one WTO agreement does not preclude, and may well overlap with, the application of rules under WTO agreements. The remainder of this section will briefly review the most significant WTO multilateral agreements on national and international tobacco control.

"A number of the binding agreements established under the auspices of the WTO agreements have important implications for national tobacco control efforts."

2. GATT (1994)

The most significant of the WTO multilateral agreements with respect to tobacco control is GATT (1994). GATT (1994), which provides detailed rules and standards, governs all trade in goods, and contains rules that discipline the use of trade policy instruments by countries to reduce barriers to trade. Trade measures undertaken by WTO Members with respect to tobacco products must comply with the main GATT obligations contained in the relevant articles, including:

- Article I on the General Most Favoured Nation Treatment (MFN)
- Article II on the Schedule of Concessions
- Article III on National Treatment on Internal Taxation and Regulation (NT)
- Article XI on the General Elimination of Quantitative Restrictions; and
- Article XX on General Exceptions.

Articles II and XI are designed to guarantee access to markets. Article II prohibits WTO Members from imposing tariffs higher than the tariff bindings they agreed to in the Schedule of

Commitments. Article XI prohibits quantitative export and import restrictions.

Article I of GATT (1994) establishes the principle of most favoured nation that, with several exceptions, requires that products from one WTO Member be given no less favourable treatment than the products from any other WTO Member. Article III established the principle of national treatment that, subject to some exceptions, mandates that products imported into a country cannot be treated differently from "like" domestic products with respect to laws and regulations. Collectively, these rules enshrine the core principle that WTO Members are generally entitled to non-discriminatory treatment of their products in countries that are Members of the Organization.

"Collectively, these rules enshrine the core principle that WTO Members are generally entitled to non-discriminatory treatment of their products in countries that are Members of the Organization."

GATT (1994) recognizes that some governmental policies may justify measures contrary to the obligations cited above. In particular, Article XX provides a critical and highly limited exception for national measures designed to protect public health and would otherwise violate GATT (1994) obligations. Article XX, in relevant part, states (emphasis added):

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, *nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures…necessary to protect human …health (or) necessary to secure compliance with the laws or regulations which are not inconsistent with the provisions of this Agreement*

Article XX is a limited and conditional exception from obligations under other provisions of the Agreement and is only relevant if a trade violation is found. In addition, dispute resolution establishes that GATT panels examine Article XX only if it has been expressly invoked by a party to the dispute; that Article XX is narrowly interpreted; and that the party invoking the Article XX exception has the burden of proof.

GATT and tobacco control: the Thai cigarettes case

GATT has elaborated on the implications of Article XX in the context of national tobacco control measures in a 1990 case involving Thailand's ban on cigarette imports and advertising. In this case, American tobacco companies challenged Thailand's ban on advertising and imports, prompting an investigation by the United States Trade Representative who referred the matter to GATT. Article XI:1 of GATT (1947) provides that:

> No prohibitions on restrictions….made effective through…import license…shall be instituted or maintained by any contracting party on the importation of any product of the territory or any contracting party…

Although inconsistent with Article XI:1, Thailand contended that the prohibition on imports was justified by the objective of public health policy and was therefore covered under Article XX.

The GATT panel found that Thailand could 'give priority to human health over trade liberalization' as long as the proposed measures were 'necessary'. The panel concluded that Thailand's restrictions on imports could be considered 'necessary' in terms of Article XX only if there was no alternative measure consistent with the General Agreement—or less inconsistent with it—that Thailand could reasonably be expected to employ to achieve its health policy objectives. Based on its analysis of the 'necessity' of the Thai measures, the panel concluded that Thailand's practice of permitting the sales of domestic cigarettes, while banning the importation of foreign cigarettes, was not 'necessary' and, therefore, not justifiable under Article XX(b), since alternatives to banning the importation of cigarettes were available to protect public health.

The panel further found, however, that requiring foreign tobacco companies to abide by tobacco control regulations that applied equally to domestic and foreign tobacco was consistent with GATT obligations. The GATT panel upheld the advertising ban and went on to state that a variety of tobacco control measures could be adopted and applied to domestic and foreign tobacco, in lieu of an import ban, and still be consistent with GATT obligations. Given this decision, Thailand could have banned the sale of all cigarettes, domestic and imported , and remained consistent with GATT.

The Thai case was the first GATT case decision on manufactured tobacco products and sets a critical precedent. The Thai case sends the message that nations can adopt strong tobacco control legislation, as long as the measures are aimed at protecting health and do not discriminate between domestic and imported tobacco.[266]

"The Thai case sends the message that nations can adopt strong tobacco control legislation, as long as the measures are aimed at protecting health and do not discriminate between domestic and imported tobacco."

3. Other agreements

The following is a brief description of other WTO agreements with relevance for tobacco. These include the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); the Agreement on Agriculture; the Agreement on Subsidies and Countervailing Measures; and the Agreement on Technical Barriers to Trade. It should be emphasized that since no WTO dispute settlement cases have arisen in the context of tobacco control regarding these agreements, their significance for tobacco control is not clearly defined.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) constitutes the central body of international rights and obligations in the area of intellectual property. Article 7 of the agreement sets out its objective: the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer of technology to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare, and to a balance of rights and obligations. TRIPS requires the observation of the principles of national treatment and most-favoured nation treatment described above in the area of intellectual property. The agreement establishes minimum standards of protection for each area of intellectual property and requires Member governments to provide mechanisms for enforcement for these rights within domestic law.

[266] Notably, the Thai case was handled under the dispute resolution process applicable to GATT (1947). Resolutions of disputes concerning the substantive obligations of WTO Members under the new multilateral agreements are now governed by the Understanding on Rules and Procedures Governing the Settlement of Disputes. These new dispute resolution procedures are producing a new body of GATT jurisprudence, which differs in significant respects from the rules governing the Thai case –although not, thus far, in ways that would appear to change the Thai decision. In addition, the text of Article XX has been modified in GATT (1994) from the way it originally appeared in GATT (1947), although not in a way that appears relevant to the Thai decision.

International obligations related to patent and trademark protection may have important implications for tobacco control efforts. For example, patents for new processes to reduce tar and nicotine may receive intellectual property protection under TRIPS. Most importantly, brand names for all products, including tobacco, are subject to TRIPS trademark protections.

Article 15, the basic rule of the trademarks section in TRIPS, requires that any sign, or combination of signs, capable of distinguishing the goods and services of one undertaking from those of others, must be eligible for registration as a trademark provided that such a trademark is visually perceptible. Article 20 of TRIPS forbids the unjustifiable encumbrance of the use of a trademark.[267]

"For example, patents for new processes to reduce tar and nicotine may receive intellectual property protection under TRIPS."

The TRIPS trademark protection regime may impact the capacity of countries to regulate tobacco through the introduction of some labelling restrictions or plain or generic packaging requirements. The tobacco industry has argued that labelling restrictions are an unjustified encumbrance on the rights of the tobacco companies to use their trademarks and thereby violate Article 20 of TRIPS.

Agreement on Agriculture

The Agreement on Agriculture covers basically all agricultural products, including tobacco, and addresses the "three pillars" of the WTO: market access, domestic support and export subsidies. Market access commitments include the establishment of a tariff-only regime, reduction of tariffs, and the binding of all agricultural tariffs; domestic support provisions encourage countries to gradually adopt measures and policies with as little distorting impact on agricultural production and trade as possible; and basic rules are included in the agreement that govern export subsidies for agricultural products. This agreement addresses tariffs, subsidies and domestic supports for tobacco.

"This agreement addresses tariffs, subsidies and domestic supports for tobacco."

Agreement on Subsidies and Countervailing Measures (SCM)

WTO's Agreement on Subsidies and Countervailing Measures discourages the use of subsidies and regulates actions

[267] The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.

taken to counter subsidies. Three categories of subsidies—prohibited, actionable, and non-actionable—are recognized in the agreement. A subsidy may be challenged only if (a) it falls into the category of "prohibited" or (b) it falls into the category of "actionable" *and* causes adverse effects to the interests of another WTO Member. In either of these circumstances, the SCM agreement allows the injured country to either pursue WTO dispute settlement channels to seek the elimination of the subsidy or to conduct its own investigation in order to charge extra or "countervailing" duty on those subsidized imports that harm domestic producers. This agreement addresses subsidies for raw tobacco.

"This agreement addresses subsidies for raw tobacco."

Agreement on Technical Barriers to Trade (TBT)

The Agreement on Technical Barriers to Trade aims to ensure that technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to trade. This agreement may be particularly relevant for regulations concerning the processing of tobacco products and requirements, including health warnings, related to packaging and labelling. Members are accorded some flexibility in this respect; the Preamble to the Agreement states that "no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal, and plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate". However, technical regulations may not be more restrictive than necessary to fulfil the legitimate public health objective. A particular measure or policy may be considered an unnecessary obstacle to trade if it is more restrictive than necessary to fulfil a given policy objective or when it does not fulfil a legitimate objective.

"This agreement may be particularly relevant for regulations concerning the processing of tobacco products and requirements, including health warnings, related to packaging and labelling."

B. International human rights law

1. The right to health

Many international human rights instruments contain reference to the universal right to health or to the right to health with respect to specific populations. This section will consider the implications of these instruments for tobacco control.

The universal right to health

The principal legal bases for human rights and health are found in

the core instrument of international human rights law, the International Bill of Rights. The International Bill of Rights consists of the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Covenants, which are binding upon States party to them, decree a number of broad international civil, political, economic and social rights.

The Universal Declaration provides the normative framework for the most significant United Nations instrument guaranteeing the right to health—the ICESCR. Article 25.1 of the Universal Declaration of Human Rights declares that everyone has the right to health, insofar as it is necessary for an adequate standard of living. The International Covenant on Economic, Social and Cultural Rights evidences the legal obligation necessary to advance this right in Article 12, providing for "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". The ICESCR imposes a positive duty on States party to the instrument to promote and protect the health of their populations.

"The ICESCR imposes a positive duty on States party to the instrument to promote and protect the health of their populations."

The General Comment to Article 12 of the ICESCR contains mention of tobacco in three areas. With respect to Article 12.2(b), addressing the right to healthy natural and workplace environments, the comment notes that this provision discourages the use of tobacco. In a discussion of States Parties' obligations under the ICESCR, the comment explains that the Covenant imposes three types of obligations: to respect, protect and fulfil the right to health. The obligation to provide information campaigns with respect to, *inter alia,* the use of cigarettes, drugs and other harmful substances is classified by the General Comment as one state obligation to fulfil the right to health. Finally, the comment notes that the obligation of the right to protect health is violated when a State fails "to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties"; "the failure to discourage production, marketing and consumption of tobacco, narcotics and other harmful substances" constitutes a violation of this obligation. However, the status of the General Comment is unclear and in contemporary practice States take markedly different positions as to its legal significance.

"The obligation to provide information campaigns with respect to,* inter alia, *the use of cigarettes, drugs and other harmful substances is classified by the General Comment as one state obligation to fulfil the right to health."

The International Bill of Human Rights contains broad tenets of human rights law with applicability to tobacco control. However,

beyond the broad formulations contained in these instruments, it is difficult to define the content of the right to health in relation to tobacco control. In addition, no other global instrument has provided an authoritative interpretation of the Covenants in the context of tobacco control. Notably, the text of the WHO FCTC that was submitted for adoption to the World Health Assembly in May 2003 refers to some existing human rights instruments in its preamble, but does not elaborate upon human rights aspects of tobacco control.

It should also be mentioned that certain regional human rights instruments recognize the right to health; these include the European Social Charter of 1961 as revised (Article 11), the African Charter on Human and Peoples' Rights of 1981 (Article 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (Article 10).

"The strongest link to tobacco control can probably be made for Article 12 of CEDAW, which requires the elimination of discrimination against women in all aspects of health care."

The right to health for specific populations

Following the adoption of the Covenants, the General Assembly and other organs of the United Nations have produced numerous other international declarations and treaties addressing the human right to health of particularly vulnerable populations, including the elderly, disabled, women and children that have relevance for tobacco control.

Convention on the Elimination of Discrimination Against Women (CEDAW)

It has been argued that multiple articles of the Convention on the Elimination of Discrimination Against Women (CEDAW) are applicable to tobacco control. The strongest link to tobacco control can probably be made for Article 12 of CEDAW, which requires the elimination of discrimination against women in all aspects of health care. It has also been argued that these Articles 2, 7 and 11 of the Convention should be read to mandate the involvement of women in the formulation and implementation of tobacco control policy, the duty to inform women of the risks surrounding tobacco use, and the right of women to enjoy smoke-free workplaces.

Convention on the Rights of the Child

Like CEDAW, the Convention on the Rights of the Child

addresses the right to health in a specific population. This Convention includes four basic principles: children must not suffer from discrimination; children have a right to survival and development in all aspects of their lives; the best interests of the child must be of primary concern in consideration of potential measures that impact children; and the views and voices of children should be given respect. It has been argued that Article 3, containing the requirement pertaining to the consideration of the best interest of the child in the formulation of measures and policies, provides the strongest argument for the duty of Member States to adopt and implement legislative and regulatory provisions to protect children from tobacco. The State Party Reporting Guidelines of the Committee on the Rights of the Child requests States to report on measures to prevent the use of tobacco and the effectiveness of such measures.

"It has been argued that Article 3, containing the requirement pertaining to the consideration of the best interest of the child in the formulation of measures and policies, provides the strongest argument for the duty of Member States to adopt and implement legislative and regulatory provisions to protect children from tobacco."

International Convention on the Elimination of All Forms of Racial Discrimination

Additionally, the International Convention on the Elimination of All Forms of Racial Discrimination mandates in Article 5(e)(iv) that "…States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of the following rights: the right to public health, medical care, social security and social services". This too could be interpreted as requiring non-discrimination in the application of tobacco control measures.

"This too could be interpreted as requiring non-discrimination in the application of tobacco control measures."

It must be noted that the legal status of general comments issued under the auspices of other United Nations Treaty Bodies with implications for tobacco control has been subject to differing interpretations by States.

2. The right to health and tobacco

As cited above, the principles regarding the right to health contained in these instruments can and have been advanced by scholars to contain relevance for tobacco control measures. These may be interpreted as various rights; *inter alia* the right to adequate information about consumer products, the right to treatment and the right to protection from exposure to environmental tobacco smoke.

Although the right to health deriving from these binding international human rights instruments has been extensively discussed, no instrument has expanded upon the specific nature of States' obligations with respect to the right to health, and this lack of a precise obligation has proven inadequate to ensure effective execution. Vague agreements that affirm indeterminate norms have proven inadequate in propelling Member States to promote and protect the health of their populations. It is difficult to describe the right to health with sufficient precision to enforce it; it is exponentially more challenging to attempt to enforce tobacco-control measures by arguing that they are based in the right to health as opposed to the proven effectiveness of concrete interventions. These instruments do contain general principles with relevance to tobacco control; however, none is tobacco specific and they are too imprecise to assure effective execution of tobacco control measures.

"These instruments do contain general principles with relevance to tobacco control; however, none is tobacco specific and they are too imprecise to assure effective execution of tobacco control measures."

One possible and notable exception to this observation involves the right to non-discrimination, enshrined in Article 2.2 of the International Covenant on Economic, Social and Cultural Rights, which requires States Parties to the Covenant to "undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status"; a similar obligation is contained in Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination. The obligation of non-discrimination is a leit-motif running throughout international human rights law. It could well be argued that for States Parties, therefore, to the extent that a government provides tobacco-related health services, it must do so equitably.

"While these instruments do not create binding international law, they are not without legal significance and many reflected emerging principles that were eventually incorporated by participating States into negotiation of the WHO FCTC."

3. WHO and non-binding instruments and tobacco

While most binding instruments in international law are not tobacco-specific, there does exist a plethora of non-binding instruments that address the dangers of tobacco use. For instance, since 1970 the World Health Assembly has adopted numerous resolutions focusing on *inter alia* publicizing the findings of research on the health effects of smoking; consumer protection through warning labels and based on mass media counter-advertising; bans on advertising and promotion; school anti-smoking educational programmes; restrictions on smoking in public places and workplaces; cessation interventions; and restrictions on youth access to

tobacco. While these instruments do not create binding international law, they are not without legal significance and many reflected emerging principles that were eventually incorporated by participating States into negotiation of the WHO FCTC.

C. WCO conventions

The WCO is an independent intergovernmental body with the mission of enhancing the effectiveness and efficiency of customs administration; currently WCO constitutes the only global intergovernmental organization competent in customs issues. Treaties negotiated under the auspices of the WCO may hold significance for tobacco control efforts because of customs issues such as illicit trade in tobacco products and duty-free sales of tobacco products. Relevant WCO treaties may include the Customs Convention on the International Transit of Goods; the International Convention on the Simplification and Harmonization of Customs Procedures (Kyoto Convention); and the International Convention on mutual administrative assistance for the prevention, investigation and repression of Customs offences (Nairobi Convention).

"Treaties negotiated under the auspices of the WCO may hold significance for tobacco control efforts because of customs issues such as illicit trade in tobacco products and duty-free sales of tobacco products."

Given the significance and volume of illicit trade in and duty-free sales of tobacco products, a Memorandum of Understanding on Cooperation between WHO and the WCO was concluded in the summer of 2002. The Memorandum of Understanding includes articles on mutual consultation; exchange of information; reciprocal representation; technical cooperation; entry into force, modification and duration; supplementary arrangements; and disputes. Within this framework, many specific areas of cooperation are tobacco-specific and include the exchange of information on areas such as measures to combat tobacco smuggling; tobacco smuggling at global, regional and national levels to support the negotiation of the WHO FCTC; and the regulation of duty-free sales of tobacco products.

"Given the significance and volume of illicit trade in and duty-free sales of tobacco products, a Memorandum of Understanding on Cooperation between WHO and the WCO was concluded in the summer of 2002."

As this chapter emphasizes, several international agreements may overlap with the WHO FCTC. One such example is the potential inclusion of provisions on duty-free sales of tobacco products; this may overlap with the International Convention on the Simplification and Harmonization of Customs Procedure (Kyoto Convention) adopted and managed by the World Customs Organization. A recent revision to the Kyoto Convention (adopted by the 151 Members of the WCO in June 1999 but not yet entered into force) contains Annex Section 16 of the Annex addressing

"special procedures", which permits the duty-free sales of tobacco products and specifies permissible quantities. Notably, the Kyoto Convention does not preclude prohibitions or restrictions on goods that are subject to customs control (Article 3).

III. REGIONAL AND BILATERAL AGREEMENTS WITH RELEVANCE FOR TOBACCO CONTROL

A. Regional trade agreements

"These agreements, many of which were created with the primary aim of trade liberalization, may impact the range of available options for tobacco control, especially with respect to import and export control measures."

Like international trade agreements described above, regional trade agreements aim to promote trade liberalization but within a specific group of countries. Regional trade agreements, which may include customs unions, free trade areas or other preferential arrangements, have expanded exponentially over the last decade. The WTO reports that currently more than 150 such agreements are in force, and that since 1995 more than 100 regional trade agreements covering trade in goods, services, or both have been reported to the institution, and notes that most countries in the world are members of some species of regional trade agreements. The relationship between various regional trade agreements may be a complicated issue, due to the fact that many countries are members of multiple agreements that may not have identical rules.

Major trade agreements include *inter alia* the Association of Southeast Asian Nations Free Trade Area (AFTA), the Common Market of Eastern and Southern Africa (COMESA), the European Union (EU) and the European Free Trade Association (EFTA), the North American Free Trade Agreement (NAFTA), the Organization of American States (OAS), and the Southern Common Market (MERCOSUR).

"In considering public health options for tobacco control, countries must identify which, if any, regional trade agreements they are member to and construct their tobacco control measures accordingly."

These agreements, many of which were created with the primary aim of trade liberalization, may impact the range of available options for tobacco control, especially with respect to import and export control measures. For example, the entry into force of NAFTA, a trade agreement calling for the elimination of all tariff and non-tariff barriers to trade between Canada, Mexico and the United States of America, resulted in the abolition of a restrictive import licensing system in Mexico for tobacco and certain other agricultural products. In considering public health options for tobacco control, countries must identify which, if any, regional trade

agreements they are member to and construct their tobacco control measures accordingly.

B. The law of regional economic integration organizations: The EU[268]

The EU is the world's first regional economic integration organization. EU Member States have delegated sovereignty to EU institutions that represent the interests of the community as a whole on questions of joint interest. Treaties ratified by Member States form the basis for all decisions and procedures of the EU. The EU's principal objectives include the establishment of European citizenship; the assurance of freedom, security and justice; economic and social progress; and the promotion and assertion of Europe's role internationally.

"EU Member States are bound by directives relating to tobacco control."

European Community law constitutes an independent legal system that takes precedence over national legal provisions. Regulations are directly applicable and legally binding in all EU Member States without national implementing legislation; there are a number of regulations with respect to tobacco. Directives, a type of secondary legislation based upon these treaties, bind Member States as to the objectives to be achieved within a certain time-limit while leaving the national authorities the choice of form and means to be used, and must be implemented in national legislation in accordance with the procedures of the individual Member States. These are described in detail below. Other, non-binding forms of community-level legislation, such as recommendations, also exist with respect to tobacco control.

EU Member States are bound by directives relating to tobacco control. Furthermore, there are a number of directives such as the 1989 "Television without frontiers", which mandates completely banning television advertising of tobacco, and sponsorship of programmes by tobacco industry. Several directives address excise duties on and taxation of tobacco products. A 2001 directive addresses the laws, regulations and administrative provisions concerning the manufacture, presentation and sale of tobacco products. Notably, this directive banned the use of misleading descriptors, such as "light" and "mild". Most recently, on 2 December 2002 the European Council reached a political agreement on a proposed directive to ban tobacco advertising. The

[268] An introduction to basic sources of European Community Law can be found in Chapter III of this book.

directive addresses the laws, regulations and administrative provisions of EU Member States relating to the advertising of tobacco products and their promotion in various media (printed publications, Internet, radio and sponsorship). For EU Member States, tobacco control measures involve careful coordination with existing EU Law.

C. Bilateral treaties

"A wide range of bilateral agreements between States exists, which may modify the authority or responsibility of a State to address tobacco control."

While a detailed discussion of bilateral agreements between States is beyond the scope of this chapter, it should be mentioned that a wide range of bilateral agreements between States exists, which may modify the authority or responsibility of a State to address tobacco control. It should also be noted that not only regional trade agreements, but also bilateral agreements must be considered in assessing the obligations of a country under an international treaty such as the WHO FCTC. These agreements also aim to reduce tariff and non-tariff barriers to trade, and certain bilateral agreements specifically address trade in tobacco products. For example, one bilateral agreement, Section 301 of the United States Trade Act of 1974, United States legislation aimed at prying open foreign markets in order to allow entry of exports of United States goods and services, was instrumental in the late 1980s in opening markets in Japan, the Republic of Korea, Taiwan, and Thailand to American tobacco products.

IV. CONCLUSION

This chapter has attempted to discuss the significance of international law for national tobacco control measures.

The chapter opens by introducing the WHO FCTC, which may expand governmental authority and responsibility to implement tobacco control within Member States that become parties to the treaty. It explains the international and domestic requirements that must be met before an international agreement enters into force, and notes the importance of mechanisms that may facilitate the ratification and implementation of the WHO FCTC and the potential role of the World Health Assembly in this endeavour.

Before adopting and implementing tobacco control measures domestically, a country must carefully assess its existing obligations under international law. This assessment may be a complex undertaking; since mechanisms such as reservations or

interpretive declarations may alter a State's obligations under an international legal instrument, a given international agreement does not necessarily involve identical obligations for all parties.

With this understanding, the chapter has discussed existing international trade agreements developed under the auspices of the WTO that may be relevant in this respect, with particular concentration on GATT and the TRIPS Agreement. The relevance of the international human rights agreements to tobacco control measures has been briefly explored, as has the possibility of overlap between certain international agreements of the WCO and tobacco control measures relating to control of illicit trade in tobacco products or to duty-free sales. Provisions of regional and bilateral trade agreements, as well as the law of regional economic integration organizations such as the EU, must also be considered in assessing countries' obligations under international law.

Chapter XIV. Conclusion

Awareness of the tobacco epidemic has increased dramatically in recent years. Negotiation of the historic WHO Framework Convention on Tobacco Control (WHO FCTC) accelerated this process, providing a three-year global health seminar that deepened the understanding of officials from around the world. As these officials learned, the case for tobacco control legislation is now well established.

"There is no turning back. The WHO FCTC will continue to drive progress in combating this epidemic and to spur the adoption of legislation."

There is no turning back. The WHO FCTC will continue to drive progress in combating this epidemic and to spur the adoption of legislation. Even in countries that may not sign the treaty, it will set the global standard for action. The focus of effort now shifts back to national capitals, to health ministries, to regional lawmaking bodies and to municipal councils, as the world's governments consider their responsibility to move forward. If this legislative guide can make that process slightly easier, it will have served its purpose.

Annex 1

WHO Framework Convention on Tobacco Control

Preamble

The Parties to this Convention,

Determined to give priority to their right to protect public health,

Recognizing that the spread of the tobacco epidemic is a global problem with serious consequences for public health that calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response,

Reflecting the concern of the international community about the devastating worldwide health, social, economic and environmental consequences of tobacco consumption and exposure to tobacco smoke,

Seriously concerned about the increase in the worldwide consumption and production of cigarettes and other tobacco products, particularly in developing countries, as well as about the burden this places on families, on the poor, and on national health systems,

Recognizing that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, and that there is a time lag between the exposure to smoking and the other uses of tobacco products and the onset of tobacco-related diseases,

Recognizing also that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases,

Acknowledging that there is clear scientific evidence that prenatal exposure to tobacco smoke causes adverse health and developmental conditions for children,

Deeply concerned about the escalation in smoking and other forms of tobacco consumption by children and adolescents worldwide, particularly smoking at increasingly early ages,

Alarmed by the increase in smoking and other forms of tobacco consumption by women and young girls worldwide and keeping in mind the need for full participation of women at all levels of policy-making and implementation and the need for gender-specific tobacco control strategies,

Deeply concerned about the high levels of smoking and other forms of tobacco consumption by indigenous peoples,

Seriously concerned about the impact of all forms of advertising, promotion and sponsorship aimed at encouraging the use of tobacco products,

Recognizing that cooperative action is necessary to eliminate all forms of illicit trade in cigarettes and other tobacco products, including smuggling, illicit manufacturing and counterfeiting,

Acknowledging that tobacco control at all levels and particularly in developing countries and in countries with economies in transition requires sufficient financial and technical resources commensurate with the current and projected need for tobacco control activities,

Recognizing the need to develop appropriate mechanisms to address the long-term social and economic implications of successful tobacco demand reduction strategies,

Mindful of the social and economic difficulties that tobacco control programmes may engender in the medium and long term in some developing countries and countries with economies in transition, and recognizing their need for technical and financial assistance in the context of nationally developed strategies for sustainable development,

Conscious of the valuable work being conducted by many States on tobacco control and commending the leadership of the World Health Organization as well as the efforts of other organizations and bodies of the United Nations system and other international and regional intergovernmental organizations in developing measures on tobacco control,

Emphasizing the special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care

institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts,

Recognizing the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts,

Recalling Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,

Recalling also the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,

Determined to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations,

Recalling that the Convention on the Elimination of All Forms of Discrimination against Women, adopted by the United Nations General Assembly on 18 December 1979, provides that States Parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care,

Recalling further that the Convention on the Rights of the Child, adopted by the United Nations General Assembly on 20 November 1989, provides that States Parties to that Convention recognize the right of the child to the enjoyment of the highest attainable standard of health,

Have agreed, as follows:

PART I: INTRODUCTION

Article 1
Use of terms

For the purposes of this Convention:

(a) "illicit trade" means any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct intended to facilitate such activity;

(b) "regional economic integration organization" means an organization that is composed of several sovereign states, and to which its Member States have transferred competence over a range of matters, including the authority to make decisions binding on its Member States in respect of those matters;[1]

(c) "tobacco advertising and promotion" means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly;

(d) "tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;

(e) "tobacco industry" means tobacco manufacturers, wholesale distributors and importers of tobacco products;

(f) "tobacco products" means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing;

(g) "tobacco sponsorship" means any form of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly;

Article 2
Relationship between this Convention and other agreements and legal instruments

1. In order to better protect human health, Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law.

2. The provisions of the Convention and its protocols shall in no way affect the right of Parties to enter into bilateral or multilateral agreements, including regional or subregional agreements, on issues relevant or additional to the Convention and its protocols, provided that such agreements are compatible with their obligations under the Convention and its protocols. The Parties concerned shall communicate such agreements to the Conference of the Parties through the Secretariat.

PART II: OBJECTIVE, GUIDING PRINCIPLES AND GENERAL OBLIGATIONS

Article 3
Objective

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

Article 4
Guiding principles

To achieve the objective of this Convention and its protocols and to implement its provisions, the Parties shall be guided, *inter alia*, by the principles set out below:

1. Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke.

[1]Where appropriate, national will refer equally to regional economic integration organization.

2. Strong political commitment is necessary to develop and support, at the national, regional and international levels, comprehensive multisectoral measures and coordinated responses, taking into consideration:

(a) the need to take measures to protect all persons from exposure to tobacco smoke;

(b) the need to take measures to prevent the initiation, to promote and support cessation, and to decrease the consumption of tobacco products in any form;

(c) the need to take measures to promote the participation of indigenous individuals and communities in the development, implementation and evaluation of tobacco control programmes that are socially and culturally appropriate to their needs and perspectives; and

(d) the need to take measures to address gender-specific risks when developing tobacco control strategies.

3. International cooperation, particularly transfer of technology, knowledge and financial assistance and provision of related expertise, to establish and implement effective tobacco control programmes, taking into consideration local culture, as well as social, economic, political and legal factors, is an important part of the Convention.

4. Comprehensive multisectoral measures and responses to reduce consumption of all tobacco products at the national, regional and international levels are essential so as to prevent, in accordance with public health principles, the incidence of diseases, premature disability and mortality due to tobacco consumption and exposure to tobacco smoke.

5. Issues relating to liability, as determined by each Party within its jurisdiction, are an important part of comprehensive tobacco control.

6. The importance of technical and financial assistance to aid the economic transition of tobacco growers and workers whose livelihoods are seriously affected as a consequence of tobacco control programmes in developing country Parties, as well as Parties with economies in transition, should be recognized and addressed in the context of nationally developed strategies for sustainable development.

7. The participation of civil society is essential in achieving the objective of the Convention and its protocols.

Article 5
General obligations

1. Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.

2. Towards this end, each Party shall, in accordance with its capabilities:

(a) establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control; and

(b) adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.

3. In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.

4. The Parties shall cooperate in the formulation of proposed measures, procedures and guidelines for the implementation of the Convention and the protocols to which they are Parties.

5. The Parties shall cooperate, as appropriate, with competent international and regional intergovernmental organizations and other bodies to achieve the objectives of the Convention and the protocols to which they are Parties.

6. The Parties shall, within means and resources at their disposal, cooperate to raise financial resources for effective implementation of the Convention through bilateral and multilateral funding mechanisms.

PART III: MEASURES RELATING TO THE REDUCTION OF DEMAND FOR TOBACCO

Article 6
Price and tax measures to reduce the demand for tobacco

1. The Parties recognize that price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons.

2. Without prejudice to the sovereign right of the Parties to determine and establish their taxation policies, each Party should take account of its national health objectives concerning tobacco control and adopt or maintain, as appropriate, measures which may include:
(a) implementing tax policies and, where appropriate, price policies, on tobacco products so as to contribute to the health objectives aimed at reducing tobacco consumption; and

(b) prohibiting or restricting, as appropriate, sales to and/or importations by international travellers of tax- and duty-free tobacco products.

3. The Parties shall provide rates of taxation for tobacco products and trends in tobacco consumption in their periodic reports to the Conference of the Parties, in accordance with Article 21.

Article 7
Non-price measures to reduce the demand for tobacco

The Parties recognize that comprehensive non-price measures are an effective and important means of reducing tobacco consumption. Each Party shall adopt and implement effective legislative, executive, administrative or other measures necessary to implement its obligations pursuant to Articles 8 to 13 and shall cooperate, as appropriate, with each other directly or through competent international bodies with a view to their implementation. The Conference of the Parties shall propose appropriate guidelines for the implementation of the provisions of these Articles.

Article 8
Protection from exposure to tobacco smoke

1. Parties recognize that scientific evidence has unequivocally established that exposure to tobacco smoke causes death, disease and disability.

2. Each Party shall adopt and implement in areas of existing national jurisdiction as determined by national law and actively promote at other jurisdictional levels the adoption and implementation of effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places.

Article 9
Regulation of the contents of tobacco products

The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.

Article 10
Regulation of tobacco product disclosures

Each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures requiring manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products. Each Party shall further adopt and implement effective measures for public disclosure of information about the toxic constituents of the tobacco products and the emissions that they may produce.

Article 11
Packaging and labelling of tobacco products

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:

(a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild"; and

(b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:

(i) shall be approved by the competent national authority,

(ii) shall be rotating,

(iii) shall be large, clear, visible and legible,

(iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,

(v) may be in the form of or include pictures or pictograms.

2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.

3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.

4. For the purposes of this Article, the term "outside packaging and labelling" in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.

Article 12

Education, communication, training and public awareness

Each Party shall promote and strengthen public awareness of tobacco control issues, using all available communication tools, as appropriate. Towards this end, each Party shall adopt and implement effective legislative, executive, administrative or other measures to promote:

(a) broad access to effective and comprehensive educational and public awareness programmes on the health risks including the addictive characteristics of tobacco consumption and exposure to tobacco smoke;

(b) public awareness about the health risks of tobacco consumption and exposure to tobacco smoke, and about the benefits of the cessation of tobacco use and tobacco-free lifestyles as specified in Article 14.2;

(c) public access, in accordance with national law, to a wide range of information on the tobacco industry as relevant to the objective of this Convention;

(d) effective and appropriate training or sensitization and awareness programmes on tobacco control addressed to persons such as health workers, community workers, social workers, media professionals, educators, decision-makers, administrators and other concerned persons;

(e) awareness and participation of public and private agencies and nongovernmental organizations not affiliated with the tobacco industry in developing and implementing intersectoral programmes and strategies for tobacco control; and

(f) public awareness of and access to information regarding the adverse health, economic, and environmental consequences of tobacco production and consumption.

Article 13

Tobacco advertising, promotion and sponsorship

1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.

2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. This shall include,

subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

3. A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, restrictions or a comprehensive ban on advertising, promotion and sponsorship originating from its territory with cross-border effects. In this respect, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:

(a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;

(b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;

(c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;

(d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties, pursuant to Article 21;

(e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and

(f) prohibit, or in the case of a Party that is not in a position to prohibit due to its

constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.

5. Parties are encouraged to implement measures beyond the obligations set out in paragraph 4.

6 Parties shall cooperate in the development of technologies and other means necessary to facilitate the elimination of cross-border advertising.

7. Parties which have a ban on certain forms of tobacco advertising, promotion and sponsorship have the sovereign right to ban those forms of cross-border tobacco advertising, promotion and sponsorship entering their territory and to impose equal penalties as those applicable to domestic advertising, promotion and sponsorship originating from their territory in accordance with their national law. This paragraph does not endorse or approve of any particular penalty.

8. Parties shall consider the elaboration of a protocol setting out appropriate measures that require international collaboration for a comprehensive ban on cross-border advertising, promotion and sponsorship.

Article 14

Demand reduction measures concerning tobacco dependence and cessation

1. Each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence.

2. Towards this end, each Party shall endeavour to:

(a) design and implement effective programmes aimed at promoting the cessation of tobacco use, in such locations as educational institutions, health care facilities, workplaces and sporting environments;

(b) include diagnosis and treatment of tobacco dependence and counselling services on cessation of tobacco use in national health and education programmes, plans and strategies, with the participation of health workers, community workers and social workers as appropriate;

(c) establish in health care facilities and rehabilitation centres programmes for diagnosing, counselling, preventing and treating tobacco dependence; and

(d) collaborate with other Parties to facilitate accessibility and affordability for treatment of tobacco dependence including pharmaceutical products pursuant to Article 22. Such products and their constituents may include medicines, products used to administer medicines and diagnostics when appropriate.

PART IV: MEASURES RELATING TO THE REDUCTION OF THE SUPPLY OF TOBACCO

Article 15
Illicit trade in tobacco products

1. The Parties recognize that the elimination of all forms of illicit trade in tobacco products, including smuggling, illicit manufacturing and counterfeiting, and the development and implementation of related national law, in addition to subregional, regional and global agreements, are essential components of tobacco control.

2. Each Party shall adopt and implement effective legislative, executive, administrative or other measures to ensure that all unit packets and packages of tobacco products and any outside packaging of such products are marked to assist Parties in determining the origin of tobacco products, and in accordance with national law and relevant bilateral or multilateral agreements, assist Parties in determining the point of diversion and monitor, document and control the movement of tobacco products and their legal status. In addition, each Party shall:

(a) require that unit packets and packages of tobacco products for retail and wholesale use that are sold on its domestic market carry the statement: *"Sales only allowed in (insert name of the country, subnational, regional or federal unit)"* or carry any other effective marking indicating the final destination or which would assist authorities in determining whether the product is legally for sale on the domestic market; and

(b) consider, as appropriate, developing a practical tracking and tracing regime that would further secure the distribution system and assist in the investigation of illicit trade.

3. Each Party shall require that the packaging information or marking specified in paragraph 2 of this Article shall be presented in legible form and/or appear in its principal language or languages.

4. With a view to eliminating illicit trade in tobacco products, each Party shall:

(a) monitor and collect data on cross-border trade in tobacco products, including illicit trade, and exchange information among customs, tax and other authorities, as appropriate, and in accordance with national law and relevant applicable bilateral or multilateral agreements;

(b) enact or strengthen legislation, with appropriate penalties and remedies, against illicit trade in tobacco products, including counterfeit and contraband cigarettes;

(c) take appropriate steps to ensure that all confiscated manufacturing equipment, counterfeit and contraband cigarettes and other tobacco products are destroyed, using environmentally-friendly methods where feasible, or disposed of in accordance with national law;

(d) adopt and implement measures to monitor, document and control the storage and distribution of tobacco products held or moving under suspension of taxes or duties within its jurisdiction; and

(e) adopt measures as appropriate to enable the confiscation of proceeds derived from the illicit trade in tobacco products.

5. Information collected pursuant to subparagraphs 4(a) and 4(d) of this Article shall, as appropriate, be provided in aggregate form by the Parties in their periodic reports to the Conference of the Parties, in accordance with Article 21.

6. The Parties shall, as appropriate and in accordance with national law, promote cooperation between national agencies, as well as relevant regional and international intergovernmental organizations as it relates to investigations, prosecutions and proceedings, with a view to eliminating illicit trade in tobacco products. Special emphasis shall be placed on cooperation at regional and subregional levels to combat illicit trade of tobacco products.

7. Each Party shall endeavour to adopt and implement further measures including licensing, where appropriate, to control or regulate the production and distribution of tobacco products in order to prevent illicit trade.

Article 16
Sales to and by minors

1. Each Party shall adopt and implement effective legislative, executive, administrative or other measures at the appropriate government level to prohibit the sales of tobacco products

to persons under the age set by domestic law, national law or eighteen. These measures may include:

(a) requiring that all sellers of tobacco products place a clear and prominent indicator inside their point of sale about the prohibition of tobacco sales to minors and, in case of doubt, request that each tobacco purchaser provide appropriate evidence of having reached full legal age;

(b) banning the sale of tobacco products in any manner by which they are directly accessible, such as store shelves;

(c) prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors; and

(d) ensuring that tobacco vending machines under its jurisdiction are not accessible to minors and do not promote the sale of tobacco products to minors.

2. Each Party shall prohibit or promote the prohibition of the distribution of free tobacco products to the public and especially minors.

3. Each Party shall endeavour to prohibit the sale of cigarettes individually or in small packets which increase the affordability of such products to minors.

4. The Parties recognize that in order to increase their effectiveness, measures to prevent tobacco product sales to minors should, where appropriate, be implemented in conjunction with other provisions contained in this Convention.

5. When signing, ratifying, accepting, approving or acceding to the Convention or at any time thereafter, a Party may, by means of a binding written declaration, indicate its commitment to prohibit the introduction of tobacco vending machines within its jurisdiction or, as appropriate, to a total ban on tobacco vending machines. The declaration made pursuant to this Article shall be circulated by the Depositary to all Parties to the Convention.

6. Each Party shall adopt and implement effective legislative, executive, administrative or other measures, including penalties against sellers and distributors, in order to ensure compliance with the obligations contained in paragraphs 1-5 of this Article.

7. Each Party should, as appropriate, adopt and implement effective legislative, executive, administrative or other measures to prohibit the sales of tobacco products by persons under the age set by domestic law, national law or eighteen.

Article 17
Provision of support for economically viable alternative activities

Parties shall, in cooperation with each other and with competent international and regional intergovernmental organizations, promote, as appropriate, economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers.

PART V: PROTECTION OF THE ENVIRONMENT

Article 18
Protection of the environment and the health of persons

In carrying out their obligations under this Convention, the Parties agree to have due regard to the protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture within their respective territories.

PART VI: QUESTIONS RELATED TO LIABILITY

Article 19
Liability

1. For the purpose of tobacco control, the Parties shall consider taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability, including compensation where appropriate.

2. Parties shall cooperate with each other in exchanging information through the Conference of the Parties in accordance with Article 21 including:

(a) information on the health effects of the consumption of tobacco products and exposure to tobacco smoke in accordance with Article 20.3(a); and

(b) information on legislation and regulations in force as well as pertinent jurisprudence.

3. The Parties shall, as appropriate and mutually agreed, within the limits of national legislation, policies, legal practices and applicable existing treaty arrangements, afford one another assistance in legal proceedings relating to civil and criminal liability consistent with this Convention.

4. The Convention shall in no way affect or limit any rights of access of the Parties to each other's courts where such rights exist.

5. The Conference of the Parties may consider, if possible, at an early stage, taking account of the work being done in relevant international fora, issues related to liability including appropriate international approaches to these issues and appropriate means to support, upon request, the Parties in their legislative and other activities in accordance with this Article.

PART VII: SCIENTIFIC AND TECHNICAL COOPERATION AND COMMUNICATION OF INFORMATION

Article 20
Research, surveillance and exchange of information

1. The Parties undertake to develop and promote national research and to coordinate research programmes at the regional and international levels in the field of tobacco control. Towards this end, each Party shall:

(a) initiate and cooperate in, directly or through competent international and regional intergovernmental organizations and other bodies, the conduct of research and scientific assessments, and in so doing promote and encourage research that addresses the determinants and consequences of tobacco consumption and exposure to tobacco smoke as well as research for identification of alternative crops; and

(b) promote and strengthen, with the support of competent international and regional intergovernmental organizations and other bodies, training and support for all those engaged in tobacco control activities, including research, implementation and evaluation.

2. The Parties shall establish, as appropriate, programmes for national, regional and global surveillance of the magnitude, patterns, determinants and consequences of tobacco consumption and exposure to tobacco smoke. Towards this end, the Parties should integrate tobacco surveillance programmes into national, regional and global health surveillance programmes so that data are comparable and can be analysed at the regional and international levels, as appropriate.

3. Parties recognize the importance of financial and technical assistance from international and regional intergovernmental organizations and other bodies. Each Party shall endeavour to:

(a) establish progressively a national system for the epidemiological surveillance of tobacco consumption and related social, economic and health indicators;

(b) cooperate with competent international and regional intergovernmental organizations and other bodies, including governmental and nongovernmental agencies, in regional and global tobacco surveillance and exchange of information on the indicators specified in paragraph 3(a) of this Article; and

(c) cooperate with the World Health Organization in the development of general guidelines or procedures for defining the collection, analysis and dissemination of tobacco-related surveillance data.

4. The Parties shall, subject to national law, promote and facilitate the exchange of publicly available scientific, technical, socioeconomic, commercial and legal information, as well as information regarding practices of the tobacco industry and the cultivation of tobacco, which is relevant to this Convention, and in so doing shall take into account and address the special needs of developing country Parties and Parties with economies in transition. Each Party shall endeavour to:

(a) progressively establish and maintain an updated database of laws and regulations on tobacco control and, as appropriate, information about their enforcement, as well as pertinent jurisprudence, and cooperate in the development of programmes for regional and global tobacco control;

(b) progressively establish and maintain updated data from national surveillance programmes in accordance with paragraph 3(a) of this Article; and

(c) cooperate with competent international organizations to progressively establish and maintain a global system to regularly collect and disseminate information on tobacco production, manufacture and the activities of the tobacco industry which have an impact on the Convention or national tobacco control activities.

5. Parties should cooperate in regional and international intergovernmental organizations and financial and development institutions of which they are members, to promote and encourage provision of technical and financial resources to the Secretariat to assist developing country Parties and Parties with economies in transition to meet their commitments on research, surveillance and exchange of information.

Article 21

Reporting and exchange of information

1. Each Party shall submit to the Conference of the Parties, through the Secretariat, periodic reports on its implementation of this Convention, which should include the following:

(a) information on legislative, executive, administrative or other measures taken to implement the Convention;

(b) information, as appropriate, on any constraints or barriers encountered in its implementation of the Convention, and on the measures taken to overcome these barriers;

(c) information, as appropriate, on financial and technical assistance provided or received for tobacco control activities;

(d) information on surveillance and research as specified in Article 20; and

(e) information specified in Articles 6.3, 13.2, 13.3, 13.4(d), 15.5 and 19.2.

2. The frequency and format of such reports by all Parties shall be determined by the Conference of the Parties. Each Party shall make its initial report within two years of the entry into force of the Convention for that Party.

3. The Conference of the Parties, pursuant to Articles 22 and 26, shall consider arrangements to assist developing country Parties and Parties with economies in transition, at their request, in meeting their obligations under this Article.

4. The reporting and exchange of information under the Convention shall be subject to national law regarding confidentiality and privacy. The Parties shall protect, as mutually agreed, any confidential information that is exchanged.

Article 22

Cooperation in the scientific, technical, and legal fields and provision of related expertise

1. The Parties shall cooperate directly or through competent international bodies to strengthen their capacity to fulfill the obligations arising from this Convention, taking into account the needs of developing country Parties and Parties with economies in transition. Such cooperation

shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed, to establish and strengthen national tobacco control strategies, plans and programmes aiming at, *inter alia*:

(a) facilitation of the development, transfer and acquisition of technology, knowledge, skills, capacity and expertise related to tobacco control;

(b) provision of technical, scientific, legal and other expertise to establish and strengthen national tobacco control strategies, plans and programmes, aiming at implementation of the Convention through, *inter alia*:

(i) assisting, upon request, in the development of a strong legislative foundation as well as technical programmes, including those on prevention of initiation, promotion of cessation and protection from exposure to tobacco smoke;

(ii) assisting, as appropriate, tobacco workers in the development of appropriate economically and legally viable alternative livelihoods in an economically viable manner; and

(iii) assisting, as appropriate, tobacco growers in shifting agricultural production to alternative crops in an economically viable manner;

(c) support for appropriate training or sensitization programmes for appropriate personnel in accordance with Article 12;

(d) provision, as appropriate, of the necessary material, equipment and supplies, as well as logistical support, for tobacco control strategies, plans and programmes;

(e) identification of methods for tobacco control, including comprehensive treatment of nicotine addiction; and

(f) promotion, as appropriate, of research to increase the affordability of comprehensive treatment of nicotine addiction.

2. The Conference of the Parties shall promote and facilitate transfer of technical, scientific and legal expertise and technology with the financial support secured in accordance with Article 26.

PART VIII INSTITUTIONAL ARRANGEMENTS AND FINANCIAL RESOURCES

Article 23
Conference of the Parties

1. A Conference of the Parties is hereby established. The first session of the Conference shall be convened by the World Health Organization not later than one year after the entry into force of this Convention. The Conference will determine the venue and timing of subsequent regular sessions at its first session.

2. Extraordinary sessions of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat of the Convention, it is supported by at least one-third of the Parties.

3. The Conference of the Parties shall adopt by consensus its Rules of Procedure at its first session.

4. The Conference of the Parties shall by consensus adopt financial rules for itself as well as governing the funding of any subsidiary bodies it may establish as well as financial provisions governing the functioning of the Secretariat. At each ordinary session, it shall adopt a budget for the financial period until the next ordinary session.

5. The Conference of the Parties shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation and may adopt protocols, annexes and amendments to the Convention, in accordance with Articles 28, 29 and 33. Towards this end, it shall:

(a) promote and facilitate the exchange of information pursuant to Articles 20 and 21;

(b) promote and guide the development and periodic refinement of comparable methodologies for research and the collection of data, in addition to those provided for in Article 20, relevant to the implementation of the Convention;

(c) promote, as appropriate, the development, implementation and evaluation of strategies, plans, and programmes, as well as policies, legislation and other measures;

(d) consider reports submitted by the Parties in accordance with Article 21 and adopt regular reports on the implementation of the Convention;

(e) promote and facilitate the mobilization of financial resources for the implementation of the Convention in accordance with Article 26;

(f) establish such subsidiary bodies as are necessary to achieve the objective of the Convention;

(g) request, where appropriate, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies as a means of strengthening the implementation of the Convention; and

(h) consider other action, as appropriate, for the achievement of the objective of the Convention in the light of experience gained in its implementation.

6. The Conference of the Parties shall establish the criteria for the participation of observers at its proceedings.

Article 24
Secretariat

1. The Conference of the Parties shall designate a permanent secretariat and make arrangements for its functioning. The Conference of the Parties shall endeavour to do so at its first session.

2. Until such time as a permanent secretariat is designated and established, secretariat functions under this Convention shall be provided by the World Health Organization.

3. Secretariat functions shall be:

(a) to make arrangements for sessions of the Conference of the Parties and any subsidiary bodies and to provide them with services as required;

(b) to transmit reports received by it pursuant to the Convention;

(c) to provide support to the Parties, particularly developing country Parties and

Parties with economies in transition, on request, in the compilation and communication of information required in accordance with the provisions of the Convention;

(d) to prepare reports on its activities under the Convention under the guidance of the Conference of the Parties and submit them to the Conference of the Parties;

(e) to ensure, under the guidance of the Conference of the Parties, the necessary coordination with the competent international and regional intergovernmental organizations and other bodies;

(f) to enter, under the guidance of the Conference of the Parties, into such administrative or contractual arrangements as may be required for the effective discharge of its functions; and

(g) to perform other secretariat functions specified by the Convention and by any of its protocols and such other functions as may be determined by the Conference of the Parties.

Article 25

Relations between the Conference of the Parties and intergovernmental organizations

In order to provide technical and financial cooperation for achieving the objective of this Convention, the Conference of the Parties may request the cooperation of competent international and regional intergovernmental organizations including financial and development institutions.

Article 26

Financial resources

1. The Parties recognize the important role that financial resources play in achieving the objective of this Convention.

2. Each Party shall provide financial support in respect of its national activities intended to achieve the objective of the Convention, in accordance with its national plans, priorities and programmes.

3. Parties shall promote, as appropriate, the utilization of bilateral, regional, subregional and other multilateral channels to provide funding for the development and strengthening of multisectoral comprehensive tobacco control programmes of developing country Parties and Parties with economies in transition. Accordingly, economically viable alternatives to tobacco production, including crop diversification should be addressed and supported in the context of nationally developed strategies of sustainable development.

4. Parties represented in relevant regional and international intergovernmental organizations, and financial and development institutions shall encourage these entities to provide financial assistance for developing country Parties and for Parties with economies in transition to assist them in meeting their obligations under the Convention, without limiting the rights of participation within these organizations.

5. The Parties agree that:

(a) to assist Parties in meeting their obligations under the Convention, all relevant potential and existing resources, financial, technical, or otherwise, both public and private that are available for tobacco control activities, should be mobilized and utilized for the benefit of all Parties, especially developing countries and countries with economies in transition;

(b) the Secretariat shall advise developing country Parties and Parties with economies in transition, upon request, on available sources of funding to facilitate the implementation of their obligations under the Convention;

(c) the Conference of the Parties in its first session shall review existing and potential sources and mechanisms of assistance based on a study conducted by the Secretariat and other relevant information, and consider their adequacy; and

(d) the results of this review shall be taken into account by the Conference of the Parties in determining the necessity to enhance existing mechanisms or to establish a voluntary global fund or other appropriate financial mechanisms to channel additional financial resources, as needed, to developing country Parties and Parties with economies in transition to assist them in meeting the objectives of the Convention.

PART IX: SETTLEMENT OF DISPUTES

Article 27
Settlement of disputes

1. In the event of a dispute between two or more Parties concerning the interpretation or application of this Convention, the Parties concerned shall seek through diplomatic channels a settlement of the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation, or conciliation. Failure to reach agreement by good offices, mediation or conciliation shall not absolve parties to the dispute from the responsibility of continuing to seek to resolve it.

2. When ratifying, accepting, approving, formally confirming or acceding to the Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts, as compulsory, ad hoc arbitration in accordance with procedures to be adopted by consensus by the Conference of the Parties.

3. The provisions of this Article shall apply with respect to any protocol as between the parties to the protocol, unless otherwise provided therein.

PART X: DEVELOPMENT OF THE CONVENTION

Article 28
Amendments to this Convention

1. Any Party may propose amendments to this Convention. Such amendments will be considered by the Conference of the Parties.

2. Amendments to the Convention shall be adopted by the Conference of the Parties. The text of any proposed amendment to the Convention shall be communicated to the Parties by the Secretariat at least six months before the session at which it is proposed for adoption. The Secretariat shall also communicate proposed amendments to the signatories of the Convention and, for information, to the Depositary.

3. The Parties shall make every effort to reach agreement by consensus on any proposed amendment to the Convention. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a three-quarters majority

vote of the Parties present and voting at the session. For purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote. Any adopted amendment shall be communicated by the Secretariat to the Depositary, who shall circulate it to all Parties for acceptance.

4. Instruments of acceptance in respect of an amendment shall be deposited with the Depositary. An amendment adopted in accordance with paragraph 3 of this Article shall enter into force for those Parties having accepted it on the ninetieth day after the date of receipt by the Depositary of an instrument of acceptance by at least two-thirds of the Parties to the Convention.

5. The amendment shall enter into force for any other Party on the ninetieth day after the date on which that Party deposits with the Depositary its instrument of acceptance of the said amendment.

Article 29
Adoption and amendment of annexes to this Convention

1. Annexes to this Convention and amendments thereto shall be proposed, adopted and shall enter into force in accordance with the procedure set forth in Article 28.

2. Annexes to the Convention shall form an integral part thereof and, unless otherwise expressly provided, a reference to the Convention constitutes at the same time a reference to any annexes thereto.

3. Annexes shall be restricted to lists, forms and any other descriptive material relating to procedural, scientific, technical or administrative matters.

PART XI: FINAL PROVISIONS

Article 30
Reservations

No reservations may be made to this Convention.

Article 31
Withdrawal

1. At any time after two years from the date on which this Convention has entered into force for a Party, that Party may withdraw from the Convention by giving written notification to the Depositary.

2. Any such withdrawal shall take effect upon expiry of one year from the date of receipt by the Depositary of the notification of withdrawal, or on such later date as may be specified in the notification of withdrawal.

3. Any Party that withdraws from the Convention shall be considered as also having withdrawn from any protocol to which it is a Party.

Article 32
Right to vote

1. Each Party to this Convention shall have one vote, except as provided for in paragraph 2 of this Article.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their Member States that are Parties to the Convention. Such an organization shall not exercise its right to vote if any of its Member States exercises its right, and vice versa.

Article 33
Protocols

1. Any Party may propose protocols. Such proposals will be considered by the Conference of the Parties.

2. The Conference of the Parties may adopt protocols to this Convention. In adopting these protocols every effort shall be made to reach consensus. If all efforts at consensus have been exhausted, and no agreement reached, the protocol shall as a last resort be adopted by a three-quarters majority vote of the Parties present and voting at the session. For the purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote.

3. The text of any proposed protocol shall be communicated to the Parties by the Secretariat at least six months before the session at which it is proposed for adoption.

4. Only Parties to the Convention may be parties to a protocol.

5. Any protocol to the Convention shall be binding only on the parties to the protocol in question. Only Parties to a protocol may take decisions on matters exclusively relating to the protocol in question.

6. The requirements for entry into force of any protocol shall be established by that instrument.

Article 34
Signature

This Convention shall be open for signature by all Members of the World Health Organization and by any States that are not Members of the World Health Organization but are members of the United Nations and by regional economic integration organizations at the World Health Organization headquarters in Geneva from 16 June 2003 to 22 June 2003, and thereafter at United Nations headquarters in New York, from 30 June 2003 to 29 June 2004.

Article 35
Ratification, acceptance, approval, formal confirmation or accession

1. This Convention shall be subject to ratification, acceptance, approval or accession by States and to formal confirmation or accession by regional economic integration organizations. It shall be open for accession from the day after the date on which the Convention is closed for signature. Instruments of ratification, acceptance, approval, formal confirmation or accession shall be deposited with the Depositary.

2. Any regional economic integration organization which becomes a Party to the Convention without any of its Member States being a Party shall be bound by all the obligations under the Convention. In the case of those organizations, one or more of whose Member States is a Party to the Convention, the organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the Convention. In such cases, the organization and the Member States shall not be entitled to exercise rights under the Convention concurrently.

3. Regional economic integration organizations shall, in their instruments relating to formal confirmation or in their instruments of accession, declare the extent of their competence with respect to the matters governed by the Convention. These organizations shall also inform the Depositary, who shall in turn inform the Parties, of any substantial modification in the extent of their competence.

Article 36
Entry into force

1. This Convention shall enter into force on the ninetieth day following the date of deposit of the fortieth instrument of ratification, acceptance, approval, formal confirmation or accession with the Depositary.

2. For each State that ratifies, accepts or approves the Convention or accedes thereto after the conditions set out in paragraph 1 of this Article for entry into force have been fulfilled, the Convention shall enter into force on the ninetieth day following the date of deposit of its instrument of ratification, acceptance, approval or accession.

3. For each regional economic integration organization depositing an instrument of formal confirmation or an instrument of accession after the conditions set out in paragraph 1 of this Article for entry into force have been fulfilled, the Convention shall enter into force on the ninetieth day following the date of its depositing of the instrument of formal confirmation or of accession.

4. For the purposes of this Article, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by States Members of the organization.

Article 37
Depositary

The Secretary-General of the United Nations shall be the Depositary of this Convention and amendments thereto and of protocols and annexes adopted in accordance with Articles 28, 29 and 33.

Article 38
Authentic texts

The original of this Convention, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Convention.

DONE at GENEVA this twenty-first day of May two thousand and three.

Annex 2

Consolidated Template Without Notes
Tobacco Products Control Act
(A Template)

Part 1
Principles and Purpose

WHEREAS the use of tobacco products constitutes one of the major public health problems in the world, causing more than one third of all deaths from cancer and heart disease and responsible for numerous other debilitating and fatal diseases;

WHEREAS smoke from tobacco products is a serious health threat to non-smokers exposed to the smoke, causing serious diseases in adults, and particularly in children;

WHEREAS most smokers start smoking at a very young age, are not aware of the extent and nature of the harm caused by tobacco products, and because of the addictive properties of nicotine are often unable to quit even when they are highly motivated to do so;

WHEREAS the marketing of tobacco products though product design, promotion, packaging, pricing and distribution, is known to contribute to the demand for tobacco products,

Be enacted by… as follows:

An Act to regulate the manufacture, labeling, promotion, distribution, and use of tobacco products

1. The purpose of this law is to reduce tobacco use and its consequent harm by:
   a) protecting children and other non-smokers from inducements to use tobacco;
   b) protecting non-smokers from exposure to tobacco smoke;
   c) ensuring that the population is adequately informed about the risks of tobacco use and exposure to second-hand tobacco smoke and about the benefits of quitting smoking;
   d) ensuring that tobacco products are modified to reduce harm to the extent technologically and practically possible; and
   e) promoting a climate where non-smoking and the absence of tobacco promotion is the norm.

Part 2
Preliminaries, including Definitions

2. This Act may be cited as *The Tobacco Control Act.*

3. The definitions in this section apply to this Act:

appeal refers to the ability of a product to provide physical or psychological pleasure, satisfaction, or other positive quality to the consumer;

brand element includes the brand name, trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with those used for any brand of tobacco product;

character refers to the distinctive qualities of a tobacco product;

composition refers to the content, arrangement or combination of substances included in the processing and manufacture of tobacco products;

distribute means to sell, offer to sell, expose for sale, give, supply exchange, convey, consign, deliver, furnish, or transfer possession for commercial purposes, or offer to do so, whether for a fee or other consideration or as a sample, gift, prize, or otherwise without charge;

emission means any substance or combination of substances that is produced as a result of a tobacco product being lighted;

inspector/analyst means a person or class of persons designated as an inspector under clause xx;

manufacturer includes any entity that is associated with the manufacturer, including an entity that controls or is controlled by the manufacturer or that is controlled by the same entity that controls the manufacturer;

ministry means the Minister of Health or his or her designate;

package means the container, receptacle or wrapper in which a tobacco product is sold or displayed at retail, including a carton that contains smaller packages;

promotion is the practice of fostering awareness of and positive attitudes toward a product, brand or manufacturer for the purpose of selling the product or encouraging tobacco use, through various means including direct advertisement, discounts, incentives, rebates, free distribution, promotion of brand elements through related events and products through a public medium of communication;

tobacco product means a product composed in whole or in part of tobacco, including tobacco leaves and any extract of tobacco leaves. It includes cigarette papers, tubes and filters;

toxicity refers to the quality, relative degree or specific degree of being toxic or poisonous;

vending machine means any means of distribution of tobacco products that is not mediated by a human being;

youth means a person under 18 years old.

Part 3
Product Regulation

4. No person shall manufacture, sell, or import a tobacco product except in compliance with this Act and any regulations made under this Act.

5. Every manufacturer and importer of a tobacco product shall provide the Ministry/Government, in the prescribed manner and within the prescribed time, information about the product and its emissions as required by the Regulations.

6. No person shall sell, offer for sale, distribute, advertise or promote any brand of tobacco products that was not sold, distributed, advertised or promoted in the country at least one year before the effective date of this Act.

7. The Minister/Government may make regulations:
   a) establishing standards for the manufacture of tobacco products, including
      i) prescribing the amount of substances that may be contained in the product or its emissions;
      ii) prescribing substances that may not be added to tobacco products; and
      iii) prescribing product design standards to reduce the harmful effects of tobacco products and to reduce their appeal to youth.
   b) prescribing test methods, including methods to assess conformity with the standards;
   c) prescribing information that manufacturers must provide to the Minister/Government and/or the public about tobacco products and their emission, including sales data and information on product composition, ingredients, hazardous properties, and brand elements;
   d) generally as needed to carry out this part of the Act.

Part 4
Packaging and Labeling

8. No person shall manufacture, sell, or import a tobacco product unless the package containing it displays, in the prescribed form and manner including through an enclosed leaflet if prescribed, the information required by the regulations about the product and its emissions, about the health hazards and health effects arising from the use of the product or from its emissions, other health-related messages such as *inter alia* advice on how to quit smoking, and markings designed to facilitate efforts to identify illegally manufactured or distributed tobacco products or products on which tax has not been paid.

9. No person shall package tobacco in a manner that allows a consumer or purchaser of tobacco products to be deceived or misled concerning its character, properties, toxicity, composition, merit or safety.

10. Any requirements arising from the above-mentioned clauses, do not relieve a manufacturer or retailer of other obligations or liabilities arising from other applicable legal norms to warn consumers of the risks of using tobacco products.

11. The Ministry/Government may make regulations:

a) respecting the content and format of information described in section 8 of this Act that must appear on packages and in leaflets;
b) respecting information that may not appear on packages; and
c) generally as needed to carry out this part of the Act.

Part 5
Advertising and Promotion

[*Total ban clause:*

12. No person shall promote or cause to promote by any other person, a tobacco product or a tobacco product-related brand element through direct or indirect means, including through sponsorship of an organization, service, physical establishment or vehicle of any kind, or event.

13. No person shall sell, promote, distribute or cause to be sold, promoted or distributed, any item other than a tobacco product which bears the brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product.**]** ***End total ban clause***

[*Partial ban clause:*

12. No person shall promote or cause to promote by any other person, a tobacco product or a tobacco product-related brand element, except as prescribed by this Act or its regulations.

13. Notwithstanding any regulation made under this Act, no person shall promote or cause to promote tobacco products or brand elements:

a) in a manner that allows a consumer or purchaser of tobacco products to be deceived or misled concerning its character, properties, toxicity, composition, merit or safety;
b) that does not display, in the prescribed form and manner, the information required by the regulations about the product and its

emissions, about the health hazards and health effects arising from the use of the product or from its emissions, and other health-related messages such as *inter alia* advice on how to quit smoking;

c) through means of promotion that can be viewed from outdoors;

d) utilizing any item other than a tobacco product, or a physical establishment or vehicle of any kind, which bears the brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product;

e) utilizing any athletic, musical, artistic or any other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product;

f) nothing in clause 13 e) shall prevent a person from sponsoring or causing to be sponsored any athletic, musical, artistic or any other social or cultural event, or any entry or team in any event, in the name of a corporation which manufactures a tobacco product, provided that both the corporate name and the corporation were registered and in use in this country prior to (specify a date approximately 1 year prior to anticipated passage of the law) and that the corporate name does not include any brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product.**]**

End partial ban clause

14. Nothing in this subsection shall apply to the publication by a manufacturer of a tobacco product advertisement in a printed publication that is intended for distribution only to employees of the tobacco trade for trade purposes.

15. No person shall offer or provide any consideration, direct or indirect, for the purchase of a tobacco product, including a gift to a purchaser or a third party, bonus, premium, cash rebate or right to participate in a game, lottery or contest, or distribute a tobacco product without monetary consideration, or in consideration of the purchase of a product or service or the performance of a service.

16. The Ministry/Government may make regulations:
(**Note:** Subclauses a), b) and c) below are not necessary in the case of a total prohibition.)

a) prescribing the form and manner of any health messages to be required on promotional material or representations by any means;
b) prescribing the format, content and placement of any tobacco promotion;
c) requiring tobacco manufacturers to report the amount of monetary expenditures on tobacco promotion by brand and by type of media and prescribing the format and frequency of reporting;
d) prescribing schedules for the implementation of promotional restrictions;
e) generally as needed to carry out this part of the Act.

Part 6
Distribution

17. No person shall sell or offer to sell tobacco to a person who is less than [insert age] years old.

18. It shall not be a defense to the above-mentioned clause that the person appeared to be [insert age] years old or older.

19. It shall be a defense to clause 17, that the purchaser presented a prescribed form of identification showing his or her age and that there was no apparent reason to doubt the authenticity of the document or that it was issued to the person producing it.

20. Nothing in this section prevents a person from giving tobacco or a tobacco-related product to a young person if the gift is made solely for use in traditional Aboriginal spiritual or cultural practices or ceremonies.

21. No person shall sell or offer to sell tobacco products except in a package containing the quantities or number of units prescribed by regulation.

22. No person shall sell or offer to sell tobacco products in a place other than those prescribed by regulation.

23. Notwithstanding any regulation made under this Act, no person shall sell or offer to sell tobacco products in the following places:

a) health institutions, including hospitals, pharmacies, and health clinics;
b) educational institutions, including primary, secondary, and post secondary schools;
c) facilities with a significant portion of youth clientele, including amusement parks, movie theatres and sports stadia; and
d) such other places as may be prescribed by regulation.

24. No person shall sell or offer to sell a tobacco product unless it is hidden from view of the general public at point of sale.

25. Notwithstanding Section 24, retailers may post signs indicating that tobacco products are available for sale, the specific products or brands available for sale, and their respective prices, provided that brand elements are not visibly displayed.

26. No person shall sell or offer to sell a tobacco product by means of a display that permits a person to handle the tobacco product before paying for it.

27. No person shall sell or offer to sell tobacco products through a vending machine.

28. No person shall sell or offer to sell tobacco products through the mails or through the Internet.

29. No person shall sell or offer to sell tobacco at retail unless signs bearing health warnings and other information are posted at the place in accordance with the regulations.

30. No person shall, at any place or premises in which tobacco or tobacco-related products are sold at retail, display any sign respecting the legal age to purchase tobacco or tobacco-related products unless the sign is supplied or approved by the Ministry of Health.

31. The Ministry of Health/Government may make regulations:

a) prescribing acceptable forms of identification under clause 19;
b) prescribing quantities of tobacco to be sold in a single package;
c) prescribing places where tobacco products may be sold;
d) prescribing required signage at point of sale;
e) generally as needed to carry out this part of the Act.

PART 7
USE

32. No person shall smoke tobacco or hold lighted tobacco in enclosed, indoor areas of any private or public work place, or any public place.

33. For the purpose of this Act, private or public work places and public places include *inter alia* the following:

a) offices and office buildings including public areas, corridors, lounges, eating areas, reception areas, elevators, escalators, foyers, stairwells, restrooms amenity areas, laundry rooms and individual offices;
b) factories;
c) health institutions;
d) educational institutions of all levels;

e) any premises in which children are cared for a fee;
f) any means of transportation used for commercial, public or professional purposes and used by more than one person;
g) public transportation terminals;
h) retail establishments including shopping malls;
i) cinemas;
j) concert halls;
k) sports stadia;
l) bars and restaurants;
m)pool and bingo halls;
n) publicly owned facilities rented out for events;
o) any other facilities accessible to the public; and
p) any other facilities that employ paid personnel.

34. All private and public workplaces and public places shall post signs, in accordance with regulations, that clearly indicate that the establishment is smoke free.

35. The Minister/Government may make regulations:
a) prescribing the location, content and format of any signs required to identify smoke free establishments;
b) generally as needed to carry out this part of the Act.

Part 8
Measures to Combat Smuggling

36. Bond required for exported tobacco products.

a) No tobacco product shall be exported from [specify country name] without the posting by the manufacturer or exporter of a bond for each shipment with the [specify Ministry or agency] in an amount [describe how the bond amount will be determined] and containing the following information and documents, as applicable:

I. the name, license number, address, telephone, and telefax numbers of the manufacturer, including the country of manufacture;
II. the name, license number, address, telephone, and telefax numbers of the exporter, including the country of export;
III. the name, license number, address, telephone, and telefax numbers of the importer/purchaser, and any person who receives the shipment on the importer/purchaser's behalf;
IV. the name, address, telephone, and telefax numbers of the intended carrier(s) of the shipment and the means of transport;
V. the names of the cities and countries through which the shipment will be transported;
VI. identification of the country of final destination;
VII. the name, license number, address, telephone, and telefax numbers of any dis-

tributors and other intermediaries handling the shipment;

VIII. the date of the shipment, the period of time over which the shipment is to be in transit, the date of expected arrival in the country of final destination, and the itinerary correlated with dates of entry and exit for each point of entry and exit;

IX. physical description of the products (e.g., cigarettes, cigars, bidis, smokeless tobacco, etc.) shipped, including lot, batch or serial numbers of all products contained in the shipment;

X. number of individual packages, number of sticks in each package or gram amount, as applicable, number of bulk packages, number of individual packages contained in each bulk package, and the weight of each bulk package contained in the shipment;

XI. copies of all purchase orders, invoices, shipping or transport, and transit documents related to the shipment;

XII. a description of any tax stamps or special marking or design features on packages contained in the shipment;

XIII. an affidavit of the exporter stating that:

i. he or she has exhausted all reasonable means to investigate the degree of demand for the products in the country of destination and determined that there is legitimate demand there for the number of products ordered and shipped;

ii. there is no substantial basis for believing that any person receiving or handling the shipment has been or is involved in illegal commercial activity or that the products will be sold illegally;

iii. he or she has complied with all labelling and other legal requirements; and

iv. information and documents supplied are true and correct to the best of his or her knowledge.

b) The bond made pursuant to subsection (a) shall be forfeited unless the manufacturer or exporter, as applicable, provides [specify Ministry or agency] with the following information within [specify number] days of [specify triggering event (e.g., the date the goods are shipped)]:

I. evidence of the chain of custody and proof that all goods reached their final destination without any product being sold or distributed without the full payment of all applicable duties, including but not limited to:

i. copies of all bills of lading or other evidence of receipt by all importers and intermediaries;

ii. proof of payment of all applicable duties;

iii. copies of invoices received from any intermediaries handling the shipment;

iv. copies of delivery records;

v. copies of all payment records;

vi. [specify any other]

vii. and any other information required by the Minister in implementing regulations.

37. The Minister may make regulations under this Part to establish requirements that enable the tracking and tracing of tobacco products through the distribution chain from manufacture to the point where all relevant duties and taxes have been paid, for the purpose of assisting competent law enforcement authorities in detecting and investigating illicit manufacture and distribution of tobacco products and identifying those responsible for illegal activity. These requirements may include but are not limited to the use of:

a) overt or covert markings to uniquely identify each individual tobacco product and/or any of its packaging;
b) overt markings to clearly identify the legal intended end-market destination of tobacco products;
c) scanning of tobacco products and their packaging or other procedures that identify their origin and passage through the distribution chain; and
d) any other relevant technology that may emerge.

Part 9
Enforcement, Inspection, Offences and Punishments

38. For the purpose of this Act the Ministry/Government may appoint any person or designate any class of persons to perform the duties of inspector or analyst. The responsibilities of an inspector shall be specified in the act of appointment.

39. Every person authorized as an inspector or analyst under clause 38 may, at any reasonable time, to ascertain compliance with this Act and the regulation under it, enter and inspect any of the following places:

a) referred to in clause 33;
b) where tobacco is manufactured, tested, stored, packaged, labeled or sold;
c) where layouts and requirements stated in clauses 31, 34 and 35 are to be found;
d) where anything used in the manufacture, storage, packing, promotion, sale or testing of tobacco is to be found;
e) where information relating to the manufacture, storage, packaging, labeling, promotion, sale or testing of tobacco is to be found.

40. Authorized inspectors and analysts shall have the following powers, which no person shall deny, obstruct, or hinder:

(a) to examine, open, and test any equipment, tools, materials, packages or anything the authorized officer reasonably believes is used or capable of being used for the manufacture, packaging, labelling, storage, distribution, *or advertising or promotion* [if allowed] of tobacco products;
(b) to examine any operation or process carried out on the premises;
(c) to examine and make copies of or from any books, documents, notes, files, including electronic files, or other records the authorized officer reasonably believes might contain information relevant to determining compliance

with regulatory requirements;

(d) to interview or question any licensee or other person involved in manufacturing, importing, exporting, transporting, packaging, *marketing* [if allowed] or distributing tobacco products, any owner of the premises, or any person using the premises, and his or her employees, agents, contractors and workers, all of whom shall cooperate fully and truthfully with any inspection or investigation;

(e) to take samples of tobacco products or components of products anywhere they are found and have them tested;

(f) to stop, search, and detain any aircraft, ship, vehicle or other means of transport or storage in which the authorized officer reasonably believes tobacco products are contained or conveyed and examine, open, take samples of and have tested any tobacco products or product components found therein; and

(g) to seize and detain, or order the storage without removal or alteration of any tobacco product the authorized officer reasonably believes does not comply with regulatory requirements, upon providing the licensee or owner of the tobacco products, or if he or she is unavailable, any other person on the premises where the tobacco products are located, written notice of the seizure and detention and the grounds for it. If any tobacco product so seized and detained is determined to meet regulatory requirements, it shall be returned immediately to the premises from which it was seized. If any tobacco product is determined not to meet regulatory requirements, it may be confiscated and destroyed or subject to other disposal, as ordered by the adjudicator of the case.

41. An inspector or analyst entering a place to inspect it under this chapter must, on request, provide the operator of the place with proof of identity and produce a certificate or appointment signed by the Minister, or by a person designated in accordance with the regulations.

42. An inspector may not enter a dwelling-place except with the consent of the occupant or under the authority of a warrant issued in accordance with section … of the Criminal Code.

43. No person shall hinder in any way the performance of the duties of an inspector or analyst, mislead them by concealment or false statements, or refuse to provide them with any information or document to which they are entitled under this Act, or destroy any such information or document.

44. During an inspection under this Act, an inspector may seize any tobacco product or other thing by means of which or in relation to which the inspector believes on reasonable grounds that this Act has been contravened.

45. Any person found guilty of violating any provision under Part 3 of this Act shall be liable for a fine of

a) in the case of an individual, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.

46. Any person found guilty of violating any provision under Part 4 of this Act shall be liable for a fine of
a) in the case of an individual, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.

47. Any person found guilty of violating any provision under Part 5 of this Act shall be liable for a fine of
a) in the case of an individual, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.

48. Any person found guilty of violating any provision under Part 6 of this Act shall be liable for a fine of
a) in the case of an individual, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
b) in the case of the proprietor of a retail establishment, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
c) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.

49. Any proprietor, owner, and/or manager of any premise listed under Part 7 of this Act found guilty of failing to enforce the smoke-free policy applicable to the facility under his or her responsibility, including the posting of prescribed signs and ensuring that any designated smoking areas meet the requirements of the Act and its regulations, shall be liable for a fine of not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.

50. Any person found guilty of smoking in a place where smoking is prohibited under Part 7 of this Act shall be liable for a fine of not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.

51. Any person found guilty of violating any provision under Part 8 of this Act shall be liable for a fine of

a) in the case of an individual, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
b) in the case of a proprietor of a retail establishment, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
c) in the case of a wholesale distributor, not less than $xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
d) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.

52. In addition to any fines imposed, any person found guilty of violating any provision under Part 8 of this Act shall be liable for a penalty equivalent to the proceeds from the distribution of illegal tobacco products as well as taxes and duties owed on those products.

53. Nothing in this Act shall preclude the criminal enforcement of its provisions in a Court of competent jurisdiction.

54. Where a person is found guilty of an offence under any part of this Act other than Part 8, the judge may impose an additional fine in addition to any other penalty, following an application by the prosecuting party appended to the statement of offence, equal to the amount of monetary benefit gained by the person as a result of the offence, even if the maximum fine is imposed under another provision.

55. A person who commits or continues an offence under this Act on more than one day is liable to be convicted for a separate offence for each day on which the offence is committed or continued.

56. Any person found to have violated any requirement under this Act or implementing regulations may be ordered to pay the reasonable costs associated with any inspection, investigation, and enforcement action brought about by the noncompliance.

57. The Ministry of Health/Government shall make regulations:

a) respecting the powers and duties of inspectors and analyst;
b) respecting the taking of samples;
c) respecting the procedure to be followed by the inspector or analyst during an inspection;

d) respecting the procedure to be followed during an inspection for seizure, as well as the one to be applied and restoration of any tobacco product;
e) generally as needed to carry out this part of the Act.

Part 10
Final Clauses

58. This Act shall come into force no later than one year [or specify other time period] following its passage into law.

ANNEX 3

USEFUL WEB SITES

Legislation enacted worldwide is accessible at:

NATIONS:http://apps.nccd.cdc.gov/nations/nations/Country_Specific_indicators.asp
Globalink: http://www.tobaccopedia.org/

Successful legislation of other jurisdictions is accessible at:

Australia
Links to Australian tobacco control legislation:
http://www.aph.gov.au
Tobacco Act 1987, State of Victoria (Australia), including establishment of the Victorian health Promotion Foundation

http://www.dms.dpc.vic.gov.au/12d/T/ACT01228/2_1.html

Tobacco Act 1990, Part 3-Western Australian Health Promotion Foundation, State of Western Australia (Australia)
http://www.slp.wa.gov.au/statutes/swans.nsf/Current+Legislation+Version2?

Brazil
Links to Brazilian tobacco control legislation: http://www.inca.gov.br/tabagismo/tabagismo_legislacao.html

Resolucao-RDC n° 104, de 31 de maio de 2001(labelling regulations)
http://www.anvisa.gov.br/legis/resol/104_01rdc.htm

Visual examples of Brazilian health messages:
http://www.anvisa.gov.br/divulga/noticias/040601_1.htm

Canada
Links to Canadian tobacco control legislation:
http://www.hc-sc.gc.ca/hecs-sesc/tobacco/legislation/
http://www.cctc.ca/CCTCLAWweb.nsf/MainFrameset?OpenFrameSet

Visual examples of Canadian health messages:
http://www.hc-sc.gc.ca/english/media/photos/tobacco_labelling/

Egypt
Links to Egyptian tobacco control legislation
http://www.emro.who.int/TFI/Legislation.htm

European Union
Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products-Commission statement. *Official Journal* L194, 18/07/2001 P. 0026-0035
http://europa.eu.int/smartapi/cgi/
sga_doc?smartapi!celexapi!prod!CELEXnumdoc&1g=EN&numdoc=32001L0037&model=guichett

New Zealand
Smoke-free Environments Act 1990 108
http://www.govt.nz/nzgovt/leg.php3

Norway
Links to the Norwegian tobacco control legislation:
http://www.globalink.org/tobacco/docs/eu-docs/legislation/no-act.htm

Poland
Links to Poland's tobacco control law:
http://apps.nccd.cdc.gov/nations/European_region.asp

South Africa
Links to South African tobacco control legislation
http://196.36.153.56/doh/issues/index.html

Thailand
Links to Thai tobacco control legislation: http://www.tobaccofreeasia.net/Menu1/thailand/legislation.htm

United States
Section 104350-104495, Health and Safety Code, State of California (United States of America) also known as "Proposition 99")
http://www.leginfo.ca.gov/cgi-bin/
waisgate?WAISdocID=47204815307+1+0+0&WAISaction=retrieve

Medicaid Third-Party Liability Act, State of Florida (United States of America) http://stic.neu.edu/F1/2florida.htm

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General Laws of Massachusetts, Part I, Title XVII, Chapter 118E:Division of Medical Assistance, State of Massachusetts (United States of America)
http://www.state.ma.us/legis/laws/mgl/118E-22.htm

Commonwealth of Massachusetts' Testing and Reporting Constituents of Cigarette smoke
http://www.state.ma.us/dph/mtcp/report/smoktox.htm

Note on contributors and sources

This publication is derived from many sources and it is not possible to acknowledge all of them here. However, the primary sources for each of the sections of this guide are identified below.

Introduction and Chapter II. Legislation and the tobacco epidemic

The Introduction and Chapter II were prepared by D. Douglas Blanke, drawing on materials prepared by Dr Mirta Molinari and William Onzivu of WHO's Tobacco Free Initiative.

Chapter III. An introductory guide to terms and concepts

Chapter III was prepared by D. Douglas Blanke, and is based largely on the *WHO toolkit for tobacco control legislative interventions*, June 2002, by Professor Lawrence Gostin and Professor James G. Hodge, Jr., of Georgetown University Law Center and the Center for Law and the Public's Health of the Johns Hopkins Bloomberg School of Public Health, Baltimore, United States of America, with contributions by Gabriel B. Eber (cited below as Gostin and Hodge).

Chapter IV. Foundation for success: capacity-building

Chapter IV was prepared by D. Douglas Blanke, drawing primarily on *Strengthening Enactment, Enforcement, and Evaluation of Tobacco Control Legislation*, December 2001, by Professor Ruth Roemer and Professor Barbara A. Berman of the School of Public Health of the University of California, Los Angeles (cited below as Roemer and Berman).

Chapter V. Approaching legislation: strategic choices

Chapter V was prepared by D. Douglas Blanke, drawing on both the Roemer and Berman paper and the Gostin and Hodge paper.

Chapter VI. The elements of comprehensive legislation

As indicated in the text, Chapter VI is taken or adapted in large measure from the Pan American Health Organization's *Developing Legislation for Tobacco Control, Template and Guidelines*, 2002, prepared by Heather Selin and Dr Monica Bolis (cited below as the PAHO template). Portions of the chapter are taken verbatim, or nearly so, from this publication; others were adapted, supplemented or written by D. Douglas Blanke.

Chapter VII. The drafting process

Chapter VII was prepared by D. Douglas Blanke, drawing primarily on the Roemer and Berman paper, and secondarily on the PAHO template and material prepared by William Onzivu and Dr Mirta Molinari.

Chapter VIII. Passing legislation

Chapter VIII was prepared by D. Douglas Blanke, and draws on the Roemer and Berman paper and the PAHO template.

Chapter IX. Challenges and obstacles

Chapter IX was prepared by D. Douglas Blanke, and draws on the Roemer and Berman paper and the PAHO template. Discussion of tobacco industry arguments draws on the PAHO template. Portions of the chapter also draw on the Gostin and Hodge paper.

Chapter X. Making it work: implementing the legislation

Chapter X was prepared by D. Douglas Blanke, drawing upon the PAHO template and the Roemer and Berman paper.

Chapter XI. Evaluation

Chapter XI was adapted by D. Douglas Blanke from the Roemer and Berman paper.

Chapter XII. Lessons in legislation: case studies from nine countries

The introductory discussion was prepared by D. Douglas Blanke, who also adapted the case studies. The Brazilian case study was adapted from materials prepared by Cristiane Vianna, Legal Adviser of the National Cancer Institute of Brazil and a discussion in the Gostin and Hodge paper. The Canadian case study was taken from the Roemer and Berman paper, which, in turn, was based largely on Rob Cunningham's *Smoke and Mirrors: The Canadian Tobacco War*, International Development Centre, Ottawa, 1996. The Egyptian case study was adapted from a paper prepared by Dr Hosam Abo Youssef of Guiza, Egypt. The Norwegian case study is adapted from the Gostin and Hodge paper, with contributions from Dr Bettcher and Ruth Roemer. The Philippine case study was adapted from a paper by Dr Jonathan A. Flavier. The Polish case study was adapted from the Roemer and Berman paper, which, in turn, based its discussion on *Case Study of Poland's Experience in Tobacco Control*, by Dr Witold Zatonski of the Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw. The South African case study was adapted from a discussion in the Roemer and Berman paper, which drew on speeches by Dr Yussuf Saloojee, Director of the National Council Against Smoking of South Africa in 2000 and 2001, and from a discussion in the Gostin and Hodge paper. The Thai case study is adapted from a discussion in the Roemer and Berman paper, which was based largely on Hatai Chitanondh, *The Passage of Tobacco Control Laws: Thai Davids Versus Transnational Tobacco Goliaths*, Thailand Health Promotion Institute, the National Health Foundation, Bangkok, 2000, and from a discussion in the Gostin and Hodge paper. The case study from the United States of America was prepared by D. Douglas Blanke. The discussion of lessons learned was adapted from the Gostin and Hodge paper.

Chapter XIII. Tobacco control and international law

Chapter XIII was prepared by Sarah Galbraith, Legal Officer of WHO's Tobacco Free Initiative and by Dr Allyn Taylor, Health Policy Adviser to WHO and Adjunct Professor at the University of Maryland School of Law and the Johns Hopkins Bloomberg School of Hygiene and Public Health, in Baltimore, Maryland, the United States of America.

Chapter XIV. Conclusion

The conclusion was prepared by D. Douglas Blanke.

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