



Key considerations for the use of law to prevent noncommunicable diseases in the WHO European Region

Report of an intensive legal training and capacity-building
workshop on law and noncommunicable diseases

Moscow, 30 May–3 June 2016





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Background and context

Noncommunicable diseases (NCDs) are the leading cause of death, disease and disability in the WHO European Region, accounting for nearly 86% of deaths and 77% of the disease burden (1). They place an increasing strain on health systems, economic development and the well-being of large parts of the population, in particular people aged 50 years and older. As premature mortality is reduced, people live longer, with the disabilities that often result from chronic diseases. “Multi-morbidity” is increasingly common, with an estimated 65% of people over 65 years of age affected, requiring more complex, patient-centred care models (1). Additionally, NCD risk factors have begun increasingly to affect younger people, including children, with considerable consequences for future public health trends in Europe (2–4). Furthermore, NCDs are responsible for much of the growing health inequality observed in many countries in the European Region, with a strong socioeconomic gradient (5).

There is wide consensus, including among policy-makers, that more could be done to address NCDs in Europe and worldwide (6). By tackling the major risk factors (tobacco, alcohol, unhealthy diets and physical inactivity), at least 80% of all heart disease, stroke and diabetes and 40% of cancers could be prevented, and the increasing burden of obesity, particularly in children, could be reduced (7). Although certain risk factors are becoming less prevalent in some countries, the trends are often uneven (by gender or socioeconomic group, for example) or are improving too slowly; in other countries, the situation is unchanged or worsening (8). Some examples are given below.

- Alcohol remains the leading risk factor for disease in eastern Europe and is associated with alarming rates of injury and violence and fluctuations in rates of mortality from cardiovascular disease. The highest total alcohol consumption of all WHO regions is reported from the European Region, and “binge drinking” affects most countries, with a rising trend (9).
- Almost three quarters of young people in the European Region do not achieve the WHO recommendations for physical activity (10).
- The projected prevalence of overweight and obesity is a concern in both children and adults, with a worrying pace of increase in eastern Europe in particular, while the promotion of energy-dense foods high in saturated fats, trans-fatty acids, salt and free sugars is widespread (11).
- Finally, but certainly not least, tobacco use is highest and tobacco control most patchy in the lower-income countries of the Region, and tobacco use is the highest among lowest-income populations in all countries (12).

There is increasing awareness of the challenges posed by NCDs, greater understanding of their causes and significant efforts to consolidate the growing evidence for effective interventions. WHO and its Member States have thus committed themselves at global and regional levels to meet the challenge of NCDs by emphasizing the responsibility of governments at all levels to build healthy public policies and ensure action in all the sectors concerned; by pushing for the creation of health-supporting environments, thereby making healthy choices easier; and by encouraging wider implementation of more effective policies, focusing on the advantages of prevention as an investment in health and development.

The political declaration adopted at the United Nations General Assembly High-level Meeting on NCDs in 2011 urged implementation of effective policy in Member States, to “advance the implementation of multisectoral, cost-effective, population-wide interventions in order to reduce the impact of NCDs” (6). In 2013, the WHO Global Action Plan for the Prevention and Control of NCDs (2013–2020) proposed a more detailed set of policy options to address the main risk factors for NCDs, and these have been endorsed in European regional policy frameworks (see Table 1). This commitment and the sense of urgency were reiterated at a second high-level United Nations meeting to assess progress and achievements in tackling NCDs, and policies to reduce risk factors for NCDs are a priority in the Sustainable Development Goals (SDGs) (13,14). Within this global view, public regulation is an important mechanism for meeting the problem of NCDs, whereby governments use the law as a means to ensure the necessary conditions for people to be healthy.

Table 1. Examples of policy measures contained in regional WHO policy frameworks that are amenable to the use of law

Policy measure	Source
Undertake a comprehensive ban on all tobacco advertising, promotion and sponsorship.	Roadmap of actions to strengthen implementation of the WHO Framework Convention on Tobacco Control in the European Region 2015–2025 (12)
Ensure that unit packets and packaging of tobacco products carry large, clear, visible legible pictorial health warnings	Roadmap of actions to strengthen implementation of the WHO Framework Convention on Tobacco Control in the European Region 2015–2025 (12)
Consider restricting or prohibiting the use of logos, colours, brand images or promotional information on tobacco packaging.	Roadmap of actions to strengthen implementation of the WHO Framework Convention on Tobacco Control in the European Region 2015–2025 (12)
Develop and implement national policies to ban (or virtually eliminate) trans fats from the food supply.	WHO European Food and Nutrition Action Plan 2015–2020 (11)
Establish strong measures to reduce the overall impact on children of all forms of marketing of foods high in energy, saturated fat, trans fats, sugar or salt.	WHO European Food and Nutrition Action Plan 2015–2020 (11)
Establish easy-to-understand or interpretative front-of-package labels that help consumers to identify healthier options.	WHO European Food and Nutrition Action Plan 2015–2020 (11)
Reduce the density and opening hours of alcohol sales outlets through licensing.	European action plan to reduce the harmful use of alcohol 2012–2020 (15)
Regulate sponsorship activities that promote alcoholic beverages.	European action plan to reduce the harmful use of alcohol 2012–2020 (15)
Establish a minimum price per litre of pure alcohol.	European action plan to reduce the harmful use of alcohol 2012–2020 (15)

Despite these global commitments and the considerable scope for using law at various levels of government, Member States often face obstacles and barriers. For example, the Global action plan on the prevention and control of noncommunicable diseases recognizes the importance of the law in implementing effective policy measures such as taxation and subsidies, appropriate packaging, labelling and composition standards and marketing restrictions. Many Member States, however, have limited public health capacity to develop and implement such laws.

While progress has been made, existing legal instruments such as the WHO Framework Convention on Tobacco Control (WHO FCTC) (16) are not being used to their full potential, despite progress such as the 2014 European Union Tobacco Products Directive (17) (see Table 2). Similarly, few countries have fully implemented the WHO and UNICEF International Code on the Marketing of Breastmilk Substitutes (18) nor broadened the scope of their existing legislation to respond to modern challenges. A recent report from WHO, UNICEF and the International Baby Food Action Network showed that 135 of 194 countries analysed have some form of legal measure in place related to the marketing of breast-milk substitutes and subsequent resolutions adopted by the World Health Assembly (19), up from 103 countries in 2011, when the previous WHO analysis was conducted. Only 39 countries, however, have laws that cover all the provisions of the Code, and the number of products to which legislation applies remains limited. In both cases the link between having a law and full implementation also deserves greater attention.

Table 2. Status of implementation of the WHO FCTC and other actions against tobacco products in the 53 countries in the WHO European Region in 2015

Action with regard to smoking	No. of countries
Ratified the WHO FCTC	50
Raised taxes on tobacco products	29
Banned smoking in public places	10
Offer smoking cessation programmes	8
Banned advertising, promotion and sponsorship of tobacco products	4
Require pictorial warning labels on tobacco product packaging	3

Source: (20)

In the case of both alcohol and nutrition, self-regulation has often been the preferred option in many countries, particularly with respect to marketing. This is true despite a long-standing, re-stated recommendation by WHO that governments take leadership and consider regulation, such as in the WHO *Set of recommendations on the marketing of foods and non-alcoholic beverages to children* (21) and the more recent *Report of the Commission on Ending Childhood Obesity* (22).

Governments may also face challenges to legislation from market operators and political opponents who argue that voluntary approaches are more cost-effective, more flexible and easier to introduce than legislation or regulation (23). These perceptions persist, despite evidence that consistently highlights the shortcomings of self-regulation schemes (24,25). Laws might sometimes be challenged on procedural grounds, such as the legal authority to act, and substantive grounds. For example, it may be argued that legislation infringes upon the protected rights of people or commercial interests, arbitrarily targets one category of product or may be pre-empted by rules set at a higher level of government (such as the European Union). Governments also develop policy in the context of international trade and investment treaties, and, under such agreements, countries make a range of commitments that impose constraints on the way they regulate goods, services and investments (see Box 1).

While Member States have considerable autonomy and policy space to introduce legislation for protecting public health – that is, to choose, design and implement public policies that fulfil their regulatory aims – many aspects should be considered in preparing a new law. A combination of an uncertain evidence base, lack of technical legal capacity and the possibility of legal challenge can create what is referred to as “regulatory chill”, whereby legal uncertainty or a threat of legal challenge dissuades governments from acting. Member States thus require support in designing evidence-informed, well-designed, appropriately targeted laws to reduce the risk factors for NCDs.

The WHO Regional Office for Europe therefore organized a workshop for intensive legal training and capacity-building for a small group of Member States in the WHO European Region, with the McCabe Centre for Law and Cancer, the I.M. Sechenov First Moscow State Medical University and the Law and NCD Unit at the University of Liverpool. The workshop was designed for public health policy-makers, government lawyers and representatives of trade and/or the economy.

The objectives of the course were to:

- consider effective policy options to address tobacco, alcohol, unhealthy diets and obesity, including which legal approaches are the most appropriate;
- formulate practical legal approaches for reducing the burden of NCDs in participating countries and/or regionally;
- define relevant international and regional health, trade and investment instruments and processes with regard their use in legal approaches;
- identify ways to enhance effective multisectoral collaboration and improve policy coherence for NCD prevention, notably between health and trade; and
- establish and increase professional capacity and networks for reducing the burden of NCDs through the use of law.

Box 1. International trade, investment and public health

The nexus between international trade and investment and public health and the crucial role that each plays in sustainable development has been recognized in the 2030 Agenda for Sustainable Development and the Addis Ababa Action Agenda on Financing for Development. SDG 3.4 states a global commitment to reduce premature mortality from NCDs through prevention and treatment by one third by 2030, and in doing so highlights implementation of the WHO FCTC as a priority (26). The Addis Ababa Action Agenda describes the “enormous burden” that NCDs place on both developed and developing countries (27).

These internationally agreed instruments also recognize that:

- private business activity, investment and innovation are major drivers of productivity, inclusive economic growth and job creation;
- international trade is an engine for inclusive economic growth and poverty reduction and contributes to the promotion of sustainable development; and
- direct investment, including foreign direct investment, can make an important contribution to sustainable development.

SDG 17 (Strengthen the means of implementation and revitalize the global partnership for sustainable development) contains specific targets for trade, including:

- promote a universal, rules-based, open, non-discriminatory and equitable multilateral trading system under the World Trade Organization (WTO), including by concluding negotiations under the Doha Development Agenda (17.10); and
- significantly increase the exports of developing countries, with a view to doubling the share of global exports of least developed countries by 2020 (17.11).

Commercial interests are not to be promoted for their own sake but for the public interest, such as for health. Effective prevention and control of NCDs require regulatory measures, such as packaging and labelling, product content regulation and taxation, which have implications for business activity, trade and investment. Trade objectives do not therefore stand alone and have limits, as is evident from the preamble to the Marrakesh Agreement establishing the WTO member states (28):

“Recognizing that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development.”

In the first plenary session, participants shared their experience in and opinions on harnessing law and policy tools for the prevention and control of NCDs. While acknowledging the importance of international instruments such as the WHO FCTC, various impediments to effective implementation of policies to counter NCDs persist at a national level. In particular, participants noted:

- low public awareness about NCDs and their causes;
- limited financial support for preventive programmes, including for collecting and analysing data on NCDs on which to base policy;
- lack of confidence in implementing evidence-based measures and lack of inter-sectoral cooperation in national governments;
- strong resistance among part of the private sector to implementation of laws for the prevention of NCDs;

- lack of human, financial and data monitoring resources for designing, adopting and enforcing laws to support key international and national legal instruments on NCD prevention and control; and
- a continuing need for adaptable policy models, which are not to be followed blindly but to be used in response to specific national needs and priorities.

With regard to the role of law in the prevention and control of NCDs, the participants stressed the importance of learning:

- how law could be used to reduce the consumption of alcohol, tobacco and foods high in saturated fats, trans-fatty acids, salt and free sugars;
- what could be done to improve implementation of existing international and national laws on NCD prevention;
- how responsibility for implementing and enforcing laws related to NCDs could be distributed among relevant government ministries and agencies;
- how lobbying by industry can be countered and curtailed to prevent influence on both governments (interference with the adoption and implementation of NCD policies) and consumers (by mobilizing and harnessing popular support against NCD measures such as marketing restrictions, taxes and pricing mechanisms); and
- how cost–benefit analysis could be used to persuade governments to invest in NCD prevention and control policies.

The report below summarizes important issues, themes and topics discussed during the meeting in Moscow, ranging from the design and implementation of legislation, reconciling public health objectives with international trade and investment law commitments, to examples of regional integration, such as the European Union and the Eurasian Economic Union. It also includes the conclusions of discussions with Member States on their current situation, challenges and opportunities identified in using the law to address NCDs. The report could be considered a “primer”, which raises some of the elements to be considered in using the law to address NCD risk factors. It should be read in conjunction with guidance on evidence-based policies from WHO in the areas of tobacco, alcohol and nutrition and obesity.

1. An introduction to law and the prevention of noncommunicable diseases (NCDs)

WHO considers the law to be a powerful policy tool for the prevention and control of NCDs.¹ The adoption and effective implementation of appropriate legislation is central to achieving the vision of a tobacco-free Europe, reducing the harmful use of alcohol and promoting healthy diets – the three main risk factors that were the focus of this meeting.

Of course, law is not the only tool available for addressing NCDs. Other policy interventions include education, support programmes (at population level, targeted at particular populations or for individuals) and health care. Usually, a complementary combination of such interventions will be necessary to address the many, complex causes of NCDs effectively (29).

Decisions about how, when, why, for how long, to what extent and in relation to whom the law can (and should) be used are seldom straightforward. They raise large social, political and economic questions: about how society is ordered (domestically, regionally and globally), how responsibility is allocated, the relative importance of personal autonomy and individual responsibility and what rights, freedoms and powers individuals, corporations and governments are allowed. Different values and approaches may result in very different stances on the role of the state: collective, libertarian, personal autonomy, human rights and free market. Decisions about the use of law should also include the best way to take into account and be informed by public opinion and public participation.

¹ For the purposes of this report, we consider “law and regulations” as referring to norms that are legally binding, which would include statutes (acts of parliament), decrees, regulations and other forms of delegated acts. It would not include self-regulation and other non-legally binding mechanisms.

The public health approach tends to regard the state as having a crucial role in providing supportive environments in which the “healthiest choice is the easiest choice”. This approach is based on a model of “social determinants of health”, endorsed by WHO, in which health is determined by “the conditions in which people are born, grow, work, live and age and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems.” (5).

The three risk factors addressed in this report have some commonalities but are different in many other ways. Policy discussions about the role of law (and the alternatives considered) may depend on the issue at hand and the policy objectives. In deciding whether and how to use law, it may be useful to consider a number of questions.²

1. *What* are we trying to do?

- Eliminate availability, e.g. of food products containing industrially produced trans-fatty acids.
- Stop use or consumption of a product, e.g. tobacco.
- Minimize or moderate use or consumption of e.g. alcohol and foods high in saturated fat, trans-fatty acids, free sugars and/or salt.
- Continue use or consumption but make it safe or safer (or less harmful), e.g. encourage greater availability of foods with better nutritional profiles.

2. At what *level* should we legislate?

- local
- state or provincial
- national
- regional (e.g. supranational legislation by regional integration bodies)
- global (e.g. treaties or other international instruments)

3. What *activities* should we regulate?

- advertising, promotion, sponsorship
- consumer information
- product packaging or labelling
- product content, safety and quality
- product size or volume
- product availability
- product price

4. What *legal tools* should we use? What will be effective and appropriate?

- legislation specific to the risk factor or more general (such as consumer protection, defective products or occupational health and safety)
- regulations
- litigation
- industry self-regulation

² Questions relating to the use of law have been discussed by many authors, but this framing of the questions is adapted from previous work by the McCabe Centre for Law and Cancer.

5. *Upon whom* should we impose legal obligations?

- manufacturers
- retailers and suppliers
- importers and exporters
- broadcasters, publishers, Internet service providers
- employers
- schools
- medical professionals
- individuals

6. What *sanctions* should we impose to ensure compliance and in the case of non-compliance?

- fines
- compensation for harm caused
- imprisonment
- administrative sanctions, such as licence suspension
- professional disciplinary
- negative publicity

7. Which *government authority or agency* should be given powers of monitoring and enforcement?

- health
- consumer protection
- justice, attorney-general
- police, law enforcement
- treasury, finance
- education
- sport and culture
- labour.

There is no single correct answer to these questions. The responses depend on local circumstances, including the nature and scale of the problem; social norms and community attitudes; the political, commercial and social actors involved; the legal culture; and systems of governance more generally. Two particular sets of challenges should be emphasized. Only rarely, if ever, does a single authority have all the relevant power and mandate. Effective use of the law requires genuine collaboration and cooperation across multiple sectors of government and society, which will usually require a combination of formal processes and other forms of interaction. Such collaboration is essential to ensure that laws are implemented in accordance with relevant national and international processes and requirements; that different perspectives and types of knowledge are brought to bear, making it more likely that possible unintended consequences can be identified and avoided; and that practical implementation of the law has been considered and adequately planned.

The enactment of laws will rarely if ever be all that is needed. Considerable attention and effort will usually be required to ensure that the law on the books is that which operates in practice. This may require, for example, public information programmes (or information programmes targeted at groups whose activities are specifically affected) to ensure that their

content and implications are understood, continuous monitoring of implementation, addressing any difficulties identified and clear legal powers and adequate resources for enforcement.

1.1 Example: using the law to control tobacco

The effective use of law plays a central role in tobacco control, as enshrined in the WHO FCTC (16). The Convention is a legally binding treaty under which its Parties commit, as a matter of international law, to undertake a range of activities domestically and internationally, in cooperation with other Parties. The objective of tobacco control measures is clearly set out in WHO FCTC Article 3: “to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke”.

Parties are obliged to take certain legal measures:

- protection of public health policies with respect to tobacco control from the commercial and other vested interests of the tobacco industry (Article 5.3);
- taxation of tobacco products (Article 6);
- protection against exposure to tobacco smoke in workplaces and public places (Article 8);
- tobacco product disclosure and regulation (Articles 9 and 10);
- packaging and labelling, including health warnings, consumer information and bans on misleading packaging (Article 11);
- bans on tobacco advertising, promotion and sponsorship (Article 13);
- measures against illicit trade in tobacco products (Article 15); and
- bans on sales of tobacco products to children (Article 16).

The WHO FCTC underlines the necessity of “comprehensive *multisectoral* national tobacco control strategies, plans and programmes” (Article 5.1).

The governing body of the WHO FCTC, its Conference of the Parties, comprising all the Parties to the treaty, has adopted guidelines for implementing Articles 5.3, 6, 8, 11 and 13 and partial guidelines for implementing Articles 9 and 10, to support Parties in meeting their obligations under these articles (30–32).

Examples of tobacco control legislation are outlined in Box 2.

1.2 Delegates’ views: current state of affairs and national concerns

In the course of plenary and group discussions, the participants noted that countries that have adopted comprehensive laws on tobacco control face challenges to implementation and compliance, including resistance on the part of industry. The group discussion of issues that may arise during implementation of the WHO FCTC revealed limited awareness of what actions fall under the Convention and related laws. For instance, some participants were surprised to learn that scholarships funded by the tobacco industry and various interactions between governments and former employees of tobacco firms may contravene Article 5.3 of the WHO FCTC. As one participant put it, the interpretation and implementation of the WHO FCTC and related legislation should be dynamic and evolving, like measures against seasonal flu: as the industry adapts its advertising and its strategies to resist the legal landscape, national legislators should adapt their strategies to ensure that industry efforts are curbed effectively.

Box 2. Recent examples of tobacco control legislation in Europe

Smoke-free legislation in the Russian Federation

Comprehensive tobacco control came into effect in the Russian Federation on 1 June 2013. The law “On Protecting the Health of Citizens from the Effects of Second Hand Tobacco Smoke and the Consequences of Tobacco Consumption” contains numerous strong tobacco-control provisions, including provisions relating to smoke-free public spaces (33).

The provisions came into force in two stages. The areas required to be 100% smoke-free as of June 2014 were:

- the campuses of educational, cultural, athletic and medical facilities;
- all forms of public transport, including long-distance trains and ships; long-distance passenger ships will be allowed to have designated smoking rooms;
- Government facilities and workplaces;
- lifts and common areas of apartment buildings; however, common areas will be allowed to have designated smoking rooms; and
- children’s playgrounds, public beaches and petrol stations.

Before the smoke-free law came into force, much concern was voiced (actively stimulated by the tobacco industry) about implementation of the law. A particular concern was that the total smoking ban in cafés, bars and restaurants would threaten the owners’ profits. Six months after the law came into force, monitoring was conducted to check compliance with the law. Although good compliance was observed overall, with smoke-free provisions enforced in 93.7% of the cafés and restaurants monitored, violations were identified in 33.9% of hotels, indicating more work to improve compliance in that sector.³

Tobacco Control Law in the Republic of Moldova

In May 2015, the Parliament of the Republic of Moldova endorsed its new Tobacco Control Law, after almost two years of debate in Parliament (34). The provisions of the Law are extensive, advancing the policies and measures in the WHO FCTC and its guidelines. It includes a full ban on smoking in enclosed public spaces and in cars carrying children under the age of 18 and the use of warning labels covering 65% of the front and back of cigarette packages. The Law also includes a full ban on the advertising and promotion of tobacco products and products with a characteristic flavour. Its provisions cover labelling, ingredients, e-cigarettes and cross-border promotion and advertising. It is entering into force gradually. The provisions for a ban on the advertisement and promotion of tobacco products entered into force in January 2016 and a full ban on smoking in enclosed public spaces and cars carrying children under 18 years in May 2016.

The new Law is one of the most robust in the WHO European Region. It represents a major achievement for tobacco control in the Republic of Moldova, as all the provisions were approved by the Government in December 2013 in the format presented, despite strong opposition from the international tobacco industry lobby, local tobacco producers and special interest groups.⁴

³ Based on discussions with the WHO Country Office and the Ministry of Health in the Russian Federation

⁴ Based on discussions with the WHO Country Office and the Ministry of Health in the Republic of Moldova

1.3 Using the law to reduce alcohol consumption and promote good nutrition and healthier diets

Most participants agreed that national policies on alcohol and nutrition, unlike legislation on tobacco control, are still inchoate in many countries in this part of the WHO European Region, despite the considerable burden of disease attributable to these risk factors and strong evidence for the use of law. European strategies and policy documents in the area of alcohol and promoting good nutrition and healthy diets highlight policies that have proven to be effective and cost-effective, including measures to influence the availability, affordability and promotion of alcohol and certain food products (i.e. foods high in saturated fats, trans-fatty acids, free sugars and/or salt) (11, 15). Policy development has, however, been patchy, with a clear tendency to focus on self-regulatory approaches and, in particular, policies to provide information and thereby promote awareness among consumers, even though evidence suggests that they are less effective. Much less has been done to influence price by increasing taxation or introducing comprehensive marketing restrictions, for example (9, 25). Some countries are, however, making progress (see Box 3). To protect breastfeeding, a number of countries have adopted or amended strong legal measures incorporating all of the provisions of the Code. In 2014, Armenia amended its regulations to ensure full adherence to the Code and relevant subsequent World Health Assembly resolutions (see Box 3).

Box 3. Relevant legislative advances across the Region

Alcohol policy in the Russian Federation – action and impact

The Russian Federation has progressively introduced a wide range of legislative measures to reduce alcohol-related harm. Since 2006, the Government has:

- prohibited the sale of all alcoholic beverages at night (including beer);
- banned the selling of beer in small kiosks and shops;
- banned the advertisement of all alcoholic products (including beer) in transport infrastructure;
- introduced a minimum retail price for alcoholic beverages;
- established zero tolerance for drink-driving (0.0% blood alcohol), with fines and revocation of licenses; and
- introduced fines for sales to minors, with progressive fines, administrative measures and criminal proceedings for repeat offenders.

Since 2005, total and alcohol-attributable standardized mortality rates from liver cirrhosis, which are closely related to trends in alcohol consumption, have decreased progressively at a much faster rate than in other European countries (9).

Armenia's law on breastfeeding promotion and marketing of baby food

In 2014, Armenia adopted a law on promoting breastfeeding and regulating the marketing of baby food, which covers all provisions of the Code and relevant World Health Assembly resolutions and goes beyond them in some aspects. The law was formulated to overcome weaknesses in an article of the earlier law on advertising related to the protection of breastfeeding. Inappropriate marketing of breast-milk substitutes had continued, hindering the Government's actions to achieve optimal infant and young child feeding. Civil society groups provided assistance in drafting the new law, and, with support from the Ministry of Health and UNICEF, the draft law was submitted to Parliament. It was later strengthened on the basis of strong evidence. The Armenian experience illustrates the important role that civil society can play when it is accompanied by adequate capacity-building, identification of political allies, patience and persistence (19).

2. The use of law and commercial interests

If states (and ultimately their citizens) are to obtain the benefits that business activity, trade and investment offer, they require legal and regulatory frameworks to promote and protect certain activities. In today's globalized world, such frameworks are needed both domestically and internationally (and often regionally) to protect the interests of states directly and of private entities that conduct business that furthers states' interests.

In the case of states, the interests to be protected include access of goods, services and capital to the markets of other states. The interests of business entities that are often protected include: property (including intellectual property), commercial expression, due process or consultation and other freedom to do business or to conduct enterprise. Conflicts arise, however, in the case of NCD risk factors, when consumption of certain products that business entities have an interest in promoting causes health, social and economic harm, and states have an interest and responsibility in discouraging consumption. The legal interventions described in section 1 inherently involve restrictions on business, trading and investment. Business entities often strongly protect their commercial interests and resist regulation of their activities. Different sectors of government often view competing interests from different perspectives and attach different weight and priority to these different interests. For example, ministers of trade, enterprise and finance may not view a situation in the same light as ministries with responsibility for children, health and welfare. Governments might not always have clear processes for resolving the different points of view of departments and sectors.

In a number of cases, tensions between commercial and public health perspectives have been resulted in domestic litigation or international challenges, in which states or business entities have sought to challenge a country's NCD prevention measures. This has been most prominent in the case of tobacco control. A wide range of measures, including graphic health warnings, plain packaging, bans on advertising, promotion and sponsorship, bans on smoking in workplaces or public places, regulation of product content and product disclosure requirements, have been challenged in domestic, regional and international courts and tribunals. Resolution of such cases often requires consideration of competing rights and interests. Invariably, courts and tribunals attach significant weight to public health interests, for example, by recognizing the sovereign right of states to protect public health by regulation, by recognizing the rights of individuals and communities to life and to the highest attainable standard of health and by recognizing public health as a ground on which the exercise of commercial rights and interests may be limited.

One particular area of tension in tobacco litigation is the protection of intellectual property rights, particularly trademarks. The tobacco industry and states have challenged regulation of tobacco packaging and labelling and particularly tobacco plain packaging (or standardized packaging) laws. Cases based on intellectual property claims are examples of both tensions that arise between competing rights and interests in general and the weight that is attached to public health.

2.1 International trade law and prevention of NCDs

The WTO is the central multilateral body responsible for the rules of international trade between states. WTO agreements include an umbrella agreement (the Agreement Establishing the WTO (28)), agreements for each of the three broad areas of trade covered by the WTO (goods, services and intellectual property), dispute settlement and reviews of government trade policies (35). All WTO agreements are held together as a single undertaking; thus, member states cannot selectively choose which agreement they wish to join. In establishing multilateral rules of trade, the WTO agreements provide a more predictable system of trade, reduce obstacles to international trade in goods and services and provide minimum standards for the protection of intellectual property rights, with the ultimate aim of raising standards of living, levels of employment and real income and expanding trade in goods and services in a sustainable manner. Their aim is to stop countries from enacting measures that constitute arbitrary or unjustifiable discrimination or unnecessary restrictions on trade.

Three WTO agreements are particularly relevant to NCD prevention: *the General Agreement on Tariffs and Trade 1994* (GATT) (36), *the Agreement on Technical Barriers to Trade* (TBT) (37) and *the Agreement on Trade-related Aspects of Intellectual Property Rights* (TRIPS) (38). A dispute may arise when one country adopts measures or takes some action that one or more fellow WTO members consider to be in breach of the WTO agreements (38). For example, a WTO member

seeking to export products to another WTO member may challenge that country's legal and regulatory measures against NCDs on the grounds that they (i) have a detrimental impact on opportunities for competition of imported products with respect to similar domestic products or (ii) unnecessarily restrict trade when alternative measures to achieve the relevant public health objective are available and are less trade restrictive. Only WTO members can access dispute settlement proceedings under WTO law. Over the past few years, a number of NCD prevention measures, including tobacco plain packaging, bans on tobacco additives and flavourings, alcohol labelling measures, nutritional labelling and tax measures, have all been discussed in the WTO's TBT Committee and TRIPS Council, and claims have been brought against WTO Member States under the TBT, GATT and TRIPS agreements. At the time of writing, a WTO challenge to Australia's plain packaging law was pending (39).

2.1.1 *Agreement on Trade-related Aspects of Intellectual Property Rights*

Under the WTO TRIPS Agreement, states commit themselves to minimum standards of intellectual property protection, including for trademarks, geographical indications, copyright, designs and patents. Challenges to NCD prevention measures under TRIPS include claims that the measures do not provide sufficient protection for intellectual property rights, including the purported right of registered trademark owners to use them (Article 16.1), and constitute an unjustifiable encumbrance by "special requirements" (Article 20) on the use of trademarks.

TRIPS explicitly recognizes the importance of public health. One of the Agreement's principles is that (Article 8.1):

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition ... provided that such measures are consistent with the provisions of this Agreement.

In the Doha Declaration on the TRIPS agreement and public health adopted in November 2001, the WTO's Ministerial Conference declared (para 4):

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health (40).

2.1.2 *Agreement on Technical Barriers to Trade and General Agreement on Tariffs and Trade 1994*

Challenges made to NCD prevention measures under the TBT and GATT agreements include claims that the laws are "more trade-restrictive than necessary to fulfil a legitimate objective" and discriminate against imported products in favour of domestically produced "like" products or between imported "like" products (41,42).

2.2 Trade restrictiveness

2.2.1 *Agreement on Technical Barriers to Trade*

Article 2.2 of the TBT Agreement states:

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: ... protection of human health or safety....

A claim under Article 2.2 of the TBT Agreement requires the complainant Member to establish that a regulatory measure for preventing NCDs constitutes a technical regulation⁵ that restricts trade more than necessary to fulfil a legitimate

⁵ A technical regulation is defined in Annex 1 of the TBT Agreement as a "Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method".

objective. Governments seeking to implement bona-fide, non-discriminatory NCD regulatory measures can respond to a challenge to Article 2.2 of the TBT by establishing that the aim of the measure is to achieve a “legitimate” objective (see Box 4). The objective pursued by NCD prevention measures – the protection of human health or safety – is explicitly specified as a “legitimate objective” in Article 2.2 of the TBT. The preamble to the TBT Agreement also states that WTO members recognize that no country should be prevented from taking measures necessary for the protection of human health, provided they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination (37,42).

Box 4. What constitutes a “legitimate objective”

In determining whether a NCD measure pursues a “legitimate objective”, the WTO Appellate Body in the case of *US–Tuna II (Mexico) WT/DS381/AB/R* (16 May 2012) indicated that a panel must assess what a member seeks to achieve through the measure (43). The WTO Appellate Body has stated that WTO decision-making bodies are not bound by a member’s characterization of its objective but must “independently and objectively” assess the objective, taking into account the “texts of statutes, legislative history, and other evidence regarding the structure and operation of the measure”. As mentioned above, the protection of human health or safety is specifically identified as a “legitimate objective” under Article 2.2 of the TBT and referred to in the preamble of the TBT Agreement. A member seeking to adopt a measure for the protection of human health or safety should be supported in establishing that the measure pursues a legitimate objective by robust evidence and in ensuring that the text of the statute, and specifically the objective of the measure, is formulated specifically to reflect such evidence.

The relevant considerations in deciding whether a measure restricts trade more than is necessary to fulfil a legitimate objective include determining the contribution of the measure to fulfilment of the legitimate objective and a comparison with reasonably available alternative measures that make an equal (or greater) contribution to the objective and are less restrictive than the measure at issue, taking into account the risks created by non-fulfilment of the objective (43).

In assessing the contribution of a measure to the achievement of a legitimate objective, the WTO Appellate Body has recognized that the full impact of the measure may be evaluated only “with the benefit of time” (44). The Appellate Body has also recognized that complementary measures may not constitute “alternative” measures:

[C]ertain complex public health or environmental problems may be tackled only with a comprehensive policy comprising a multiplicity of interacting measures....Substituting one element of the comprehensive policy for another would weaken the policy by reducing the synergies between the components, as well as its total effect. (44)

In the *Clove Cigarettes* case (41), Indonesia challenged a law of the USA that prohibits the sale of flavoured cigarettes other than with menthol or tobacco. Indonesia, a producer of clove cigarettes, argued that the law violated Article 2.2 of the TBT on the grounds that it was more trade restrictive than necessary. The WTO Panel examined the evidence on the impact of banning clove cigarettes and/or other flavoured cigarettes on smoking by young people, using the WHO FCTC and Partial Guidelines to reinforce its understanding and support its findings. The WTO Panel noted that the Guidelines draw on the “best available scientific evidence” to support the conclusion that banning clove and other flavoured cigarettes could contribute to reducing smoking by young people (41), which is related to the protection of human health and therefore constitutes a legitimate objective. The Panel ultimately found that the tobacco control measures in question were not more trade restrictive than necessary to fulfil a legitimate objective.

2.2.2 Discrimination

One of the fundamental obligations of the Members of the WTO is to accord each other “most-favoured-nation” and national treatment. This includes an obligation under Article 2.1 of the TBT and Articles III:4 and I:1 of GATT on Members not to discriminate against imported “like” products in favour of domestic products or between imported “like” products by according less favourable treatment.

The concept of discrimination includes both de jure discrimination (discrimination in law) on the face of the measure and de facto discrimination (discrimination in fact), covering measures that appear to be “origin-neutral” and incur application of formally identical legal provisions but that would, in practice, accord less favourable treatment (45).

In the *Clove Cigarettes* case, the WTO Panel found, and the Appellate Body upheld the decision, that measures in the USA that prohibited the sale of certain flavoured cigarettes other than menthol or tobacco were discriminatory on the ground that clove cigarettes and menthol cigarettes were “like” products and that the detrimental impact on competitive opportunities for clove cigarettes constituted discrimination against like products from Indonesia (41). So, even though the measure was found not to restrict trade more than necessary to fulfil a legitimate objective (protection of health), it was found to be discriminatory.

It is important to note that measures to prevent NCDs that are found to effect de facto discrimination do not violate the TBT Agreement or GATT if:

- *TBT*: The de facto detrimental impact on competitive opportunities for imports stems exclusively from a “legitimate regulatory distinction”, including bona-fide measures for the protection of human health. This gives effect to the preambular recognition in the TBT Agreement of Members’ right to regulate. As stated previously, the preamble to the TBT Agreement states that WTO members recognize that no country should be prevented from taking measures necessary for the protection of human health, provided they are not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination (42).
- *GATT*: The measures are necessary to protect human health provided the measure is not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination (Article XX(b)).

WTO panel and Appellate Body decisions confirm the regulatory space available to governments for the protection of human health and confirm that WTO Members have the right to determine the level of protection of health they consider appropriate in a given situation (46). Preservation of human life and health has been described by the WTO Appellate Body as “vital and important in the highest degree” (44,46).

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3. International investment law and prevention of NCDs

3.1 International investment law

International investment agreements include bilateral investment treaties, investment chapters in free trade agreements and investment contracts between states and investors. Their aim is to promote and protect foreign investment and economic development by offering a broad range of protections to investors and their investments on the territory of the other contracting party or parties. While the provisions of international investment agreements vary, they also generally provide a broad range of protections, including protection against expropriation and unfair or inequitable treatment.

Two tobacco control measures have been challenged under international investment agreements, the primary argument being made that the measures breach obligations to investors by states with respect to expropriation and fair and equitable treatment. Both challenges have been unsuccessful (47,48). In December 2015, an arbitral tribunal dismissed a challenge by Philip Morris Asia against Australia’s tobacco plain packaging laws under the 1993 Australia–Hong Kong Bilateral Investment Treaty on jurisdictional grounds, without proceeding to a consideration of merits. The tribunal held that “the initiation of this arbitration constitutes an abuse of rights, as the corporate restructuring by which the Claimant acquired the Australian subsidiaries occurred at a time when there was a reasonable prospect that the dispute would materialise and as it was carried out for the principal, if not sole, purpose of gaining Treaty protection” (paragraph 588) (48). In July 2016, an arbitral tribunal dismissed an investment treaty challenge brought by Philip Morris Switzerland under a 1988 Switzerland–Uruguay bilateral investment treaty against Uruguay’s tobacco packaging laws (graphic health warnings covering 80% of the front and back of their packaging and a single presentation requirement precluding the marketing of more than one brand variant), finding that the measures being challenged did not constitute an expropriation and did not deny fair and equitable treatment.

3.1.1 Expropriation

One of the arguments made under international investment agreements in relation to tobacco control is that measures such as plain packaging, large graphic health warnings and single presentation requirements constitute “indirect” expropriation because of the “effective loss of an investor’s enjoyment or control over their investment” (47–49). This argument was dismissed in the case of *Philip Morris Brands Sàrl v. Uruguay*. In relation to the 80% graphic health warnings, the tribunal held that “there is not even a *prima facie* case of indirect expropriation” (47, paragraph 276). Regarding Uruguay’s single presentation requirement, the tribunal stated that the effects of the requirement were “far from ... causing a substantial deprivation of the value, use or enjoyment of the claimants’ investments”. This was sufficient to dismiss the expropriation claim. Nevertheless, the tribunal went on to find that Uruguay’s measures were bona fide for the purpose of protecting public welfare, were non-discriminatory and proportionate and were therefore a “valid exercise by Uruguay of its police powers for the protection of public health” and could not constitute an expropriation of the claimant’s investment (47, paragraph 287). Other tribunals have similarly found that the “police powers doctrine”, recognized in customary international law, holds that a non-discriminatory regulation for a public purpose such as the protection of health, enacted with due process, will not be deemed to result in indirect expropriation (50).⁶

3.1.2 Fair and equitable treatment

Another argument that has been used to challenge a measure for preventing NCDs is that it breaches international investment agreement provisions in relation to fair and equitable treatment, which have been interpreted to include an obligation to maintain the stability of the regulatory environment and to protect legitimate expectations engendered by the conduct of states toward investors (51). In *Philip Morris Brands Sàrl v. Uruguay*, however, the tribunal found that, in the absence of specific undertakings or representations made to them by Uruguay at the time of the investment or subsequently, “[m]anufacturers and distributors of harmful products such as cigarettes can have no expectation that new and more onerous regulations will not be imposed” (47, paragraph 429).

Governments seeking to enact effective, bona fide regulatory measures to prevent NCDs would argue that investors should be aware that NCD control is customarily subject to “close and extensive regulation”, as highlighted by the tribunal in another tobacco control case, *Grand River* (52). Therefore, in the absence of specific commitments, investors are not entitled to hold a legitimate expectation that the regulatory environment affecting an investment will remain unchanged. This provides critical support for governments seeking to adopt bona fide, non-discriminatory NCD control measures (52).

Fair and equitable treatment is therefore covered by several types of agreement.

- International trade and investment agreements provide regulatory space for bona fide, non-discriminatory public health measures. This has been confirmed by case law interpreting the agreements.
- Specifically in the context of international trade law, the preservation of human life and health has been recognized by the WTO Appellate Body as “vital and important in the highest degree”.
- In relation to international investment law, international investment tribunals have affirmed the sovereign right of states to regulate to protect public health, in accordance with the “police powers” doctrine recognized under customary international law and that, in the absence of specific undertakings or representations, investors cannot legitimately expect that states will not introduce regulation of general application to address public health concerns.

⁶ “In the Tribunal’s view, Methanex is correct that an intentionally discriminatory regulation against a foreign investor fulfils a key requirement for establishing expropriation. But as a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, inter alia, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.”

3.2 Investor–state arbitration: dealing with corporate challenges to policies for preventing NCDs

3.2.1 *What enables industry to challenge NCD prevention and control measures?*

International investment law (in the form of international investment agreements, bilateral investment treaties and various free-trade agreements) provides protection against expropriation and a guarantee of fair and equitable treatment, and most agreements also grant corporate actors the right to bring claims directly against the host government before a neutral arbitration tribunal. Investor–state arbitration is unique in several respects.

- Most investment treaties do not require investors to exhaust national solutions before initiating arbitration; investors can bypass local courts and thus avoid the possibility of biased treatment by the national judiciary.
- Investors can claim monetary remedies. In other areas of international law, such as international trade or human rights law, the right to claim damages is either absent (WTO law) or limited (European Court of Human Rights).
- Arbitral awards are readily enforceable in most jurisdictions under the International Centre for Settlement of Investment Disputes Convention and the 1958 New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards.

3.2.2 *How does investor–state arbitration work?*

The process is voluntary and consensual: both disputing parties must give their consent to arbitration. Host states may offer their consent to arbitration in (i) contracts concluded between the foreign investor and ministries and agencies; (ii) national legislation, such as a law, on foreign investment; (iii) an investment treaty between the host state and the home state of a foreign investor; and (iv) investment chapters in free trade agreements referred to in section 3.3. For instance, in *Philip Morris v Australia* (48), the tobacco firm relied on consent to arbitration enshrined in an investment treaty agreement between Australia and Hong Kong. Consent provided in international investment agreements is usually regarded as a unilateral offer by the state, addressed to a potentially indefinite number of investors covered by the relevant treaty. Once consent is given, it cannot be revoked unilaterally.

3.2.3 *What kind of claims can be resolved by investor–state arbitration?*

The capacity of corporate actors to harness investor–state arbitration effectively in order to challenge NCD prevention measures hinges on the wording of the applicable treaty. Treaties determine what kinds of disputes can be resolved through investment arbitration in a variety of ways. Some international investment agreements allow arbitration in any kind of dispute arising between an investor and the host contracting party, while, in some treaties, the arbitration clause is defined more narrowly and allows only a certain predetermined category of disputes to be referred for investment arbitration.

3.2.4 *Which arbitration forums can be used, and why does it matter?*

Investment treaties usually offer one or more mechanisms for dispute settlement from which claimant-investors can choose. The principal avenues for investor–state arbitration are:

- the International Centre for Settlement of Investment Disputes (ICSID), a system specifically designed for adjudicating investor–state disputes;
- the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules;
- the Arbitration Institute of the Stockholm Chamber of Commerce, the Court of Arbitration of the International Chamber of Commerce, the London Court of International Arbitration and regional and national arbitration centres.

The arbitration forum chosen matters because different arbitral institutions have different rules on enforcement. For instance, arbitral awards rendered by an ICSID tribunal may not be reviewed or set aside by national courts of the seat of arbitration (they are subject only to annulment on limited grounds under the ICSID Convention). The ICSID Convention also provides for “automatic” enforcement of arbitral awards in all states that are parties to the Convention. By contrast, arbitral awards rendered under the UNCITRAL rules may be reviewed and potentially set aside by the competent national court at the seat of arbitration. For instance, if a dispute between Kazakhstan and a German investor was decided in arbitration in The Hague, a competent Dutch court could review the final award. Arbitral awards by an UNCITRAL tribunal are recognized and enforced through national courts, usually in accordance with the New York Convention on the Recognition and

Enforcement of Foreign Arbitral Awards. So, if an award is rendered against the Government of Belarus, a national court in Belarus might refuse to enforce the award.

3.3 Prevention of NCDs and commercial rights under Eurasian regional investment and trade agreements

Many states in Europe have not only signed bilateral investment treaties but also joined regional trade and investment agreements. Such agreements may be invoked by corporate bodies seeking to challenge NCD prevention laws and policies. Of particular relevance to the countries participating in this workshop are Eurasian investment and trade agreements, such as the 1997 Commonwealth of Independent States Investor Rights Convention and the 2014 Treaty on the Eurasian Economic Union. The Commonwealth of Independent States Investor Rights Convention has a narrower protective scope than many usual investment treaties. It includes a limited range of investment protection standards, and its dispute settlement clause has been construed as offering no unilateral consent to investment arbitration. In contrast, the more recent Eurasian Economic Union Agreement has comprehensive provisions on the promotion and protection of investment, including guarantees of national treatment, compensation for expropriation, and transparency. It also safeguards investors' access to investor–state arbitration.

Many of the new investment treaties contain an exception for public health measures or in some cases more specifically for tobacco control. The Eurasian Economic Union Agreement, does not contain such exceptions. A comparison of this Agreement with the Commonwealth of Independent States Investor Rights Convention demonstrates how states can delimit their exposure to investor claims. For instance, a more carefully drafted arbitration clause and the insertion of an exceptions clause for public health measures could restrict the ability of corporations to dispute NCD laws and policies in the future.

3.4 Reconciling investment protection and prevention of NCDs: preserving the regulatory freedom of host states

In its World Investment Report 2015, the United Nations Conference on Trade and Development (UNCTAD) stressed the importance of finding the right balance between investor protections and safeguarding the right to legislate (53). It also offered various policy options for addressing challenges and concerns. For instance, to safeguard the right to legislate, host states can choose to circumscribe (or clearly define) international investment agreement standards of protection, such as the fair and equitable treatment standard and expropriation, and introduce “safety valves”, such as exceptions for public policies (49). To foster a sustainable investment, states may consider including new treaty provisions to prevent the lowering of environmental or social standards, to ensure compliance with domestic laws and to strengthen corporate social responsibility. In reforming existing provisions for investor–state dispute settlement, host states can opt for provisions to enhance transparency, limit investors' access to arbitration and introduce local litigation requirements. States can achieve their reform objectives by choosing the most suitable combination of reform tools (49).

Measures for the prevention of NCDs might therefore be challenged in investment arbitration in various ways.

- Broadly framed provisions on investor–state arbitration offer businesses access to investment arbitration in a wide range of disputes.
- Such clauses enable investors to pursue challenges against NCD-related laws and policies.
- Waiver of local solutions enables investors to bring a claim directly to arbitration, thus bypassing national courts.
- Depending on the forum chosen, arbitral awards may not be reviewed or annulled.

3.5 What states can do to prevent challenges from investors

The UNCTAD World Investment Report 2015 offers various policy options from which states can choose to redesign their investment protection policies.

- Safeguard the right to regulate through clearly defined standards of protection and incorporating “safety valves” such as public policy exceptions.

- Reform investment dispute settlement by adding clauses that increase transparency, delimit investors' access, enhance the control of contracting parties' and introduce requirements for local solutions.
- Promote and facilitate investment by targeting promotion to sustainable development.
- Foster responsible investment by including clauses that prevent the lowering of environmental or social standards, ensure compliance with domestic laws and strengthen corporate social responsibility.
- Enhance systemic consistency by introducing clauses and mechanisms to manage interactions between investment treaty law and other bodies of international law and with domestic investment and other policies.

4. Lessons from the European Union: European law and policies on NCDs

The experience of the European Union may be of particular interest to countries in the east of the WHO European Region, for various reasons. Georgia, the Republic of Moldova and Ukraine have far-reaching associations agreements that envisage harmonization with European Union standards in many fields. These countries and Azerbaijan are also participants in the European Neighbourhood Policy, and Azerbaijan has a partnership and cooperation agreement with the European Union and some commitments to alignment with European Union standards. Furthermore, the countries that participate in the Eurasian Economic Union (Armenia, Belarus, Kazakhstan, Kyrgyzstan and the Russian Federation) may learn from the experience (both successes and challenges) of the European Union model of regional integration in tackling the cross-border effects on public health of the trade in tobacco products, foods high in saturated fats, trans-fatty acids, salt and free sugars and alcoholic beverages.

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During the past decade, the European Union adopted several strategies for reducing the impact of the four main risk factors for NCDs: tobacco use, harmful use of alcohol, unhealthy diets and physical inactivity. In line with WHO recommendations, it is recognized that NCDs can be addressed effectively only with the involvement of a wide range of sectors that affect our daily lives. The strategies differ, however, significantly. The European Union tobacco control policy is characterized by a strong legislative approach based on the adoption of legally binding rules to influence demand for tobacco products (availability, affordability, presentation and promotion), whereas the action of the European Union to reduce alcohol consumption is based mainly on exchange of best practices and adoption of self-regulatory standards by industry. Work in the European Union on nutrition and obesity prevention represents an intermediate approach, with both the adoption of binding rules for food products as consumer goods and calls on the food industry to regulate their practices by adopting self-regulatory standards (54,55).

The main consideration in determining action on obesity in the European Union is its regulatory powers as compared with the domestic competence of its 28 Member States. The European Union's scope for regulatory action is determined (and limited) by the powers that its Member States have conferred on its institutions and the principles of subsidiarity and proportionality. If competence to act has been identified (i.e. European Union power to act for instance to remove a barrier to the free movement of goods in the internal market), it will be necessary to engage with the principles of subsidiarity and proportionality. The principle of subsidiarity is that all proposals for European Union action are scrutinized to determine whether the aim would be better achieved at national or at European Union level. Thus, the European Union can act only when it is deemed that it will better achieve the proposed action than Member States. The principle of proportionality relates to the question of whether the proposed mechanism (or "means") is appropriate to achieve the aims. Again, proposals are scrutinized to determine whether the aims could be achieved by another, less restrictive means. In other words, European Union action (in terms of content and form) should not go beyond what is necessary to achieve the stated aims (56).

4.1 Tobacco

European Union tobacco control has been marked by a strong legislative role, in which it has invoked its duty to ensure strong protection of public health, as demonstrated by the adoption of Directive 2003/33 on tobacco advertising and sponsorship (57) and Directive 2014/40 on tobacco products (58) (which replaces Directive 2001/37). European Union law regulates the composition of tobacco products, bans misleading claims (such as “light” or “mild”), imposes combined textual and graphic warnings and prohibits the advertising, sponsorship and placement of tobacco products when such marketing techniques affect the functioning of the internal market (i.e. when they have a cross-border element). The European Union has also become a Party to the WHO FCTC, thus acting with its Member States in public health at global level.⁷

4.2 Alcohol

The European Union has adopted few supranational regulations on alcohol-related harm. The Alcohol Strategy of 2006 resulted in limited regulatory interventions. For example, Directive 2010/13 on audiovisual media services regulates the content of alcohol promotions in audiovisual media (59); however, the provisions are narrowly defined, and most European Union Member States have adopted stricter measures at national level to better protect the health of their citizens. This has led in turn to extensive fragmentation of the internal market; as much marketing occurs across borders – e.g. via the Internet – it could be argued that cross-border marketing is better regulated at European Union level. Similarly, the European Union has exempted alcoholic beverages from the mandatory disclosures that are required for foods in Regulation 1169/2011 on the information provided to consumers. Thus, the labels on alcoholic beverages containing more than 1.2% by volume of alcohol must indicate the actual alcoholic strength by volume but do not have to list the ingredients or bear a “nutrition declaration” (i.e. calories) (60). The only action of the European Union law with regard to alcoholic beverages is adoption of Regulation 1924/2006 and banning of the use of nutrition and health claims on alcoholic beverages containing more than 1.2% by volume of alcohol (61).

4.3 Nutrition

The European Union approach in the field of nutrition and obesity prevention is intermediate between those it has adopted for tobacco control and the harmful use of alcohol. The Strategy on nutrition, overweight and obesity-related health issues culminated in publication of a White Paper in 2007 (62). The Strategy is an integrated approach to reducing ill health resulting from poor nutrition, overweight and obesity, combining both regulation and self-regulation. In 2014, the High-level Group on Nutrition and Physical Activity, a group of European Union government representatives led by the European Commission, issued a European Union Action Plan on Childhood Obesity, which comprises a series of voluntary initiatives to support a healthy start in life and promote healthier environments (63). The regulations of the European Union ensure that the information provided to consumers is both reliable (by banning *misleading* nutrition and health claims) and sufficient (by introducing a mandatory list of ingredients and a nutrition declaration intended to help consumers make healthier choices). Two pieces of legislation have been adopted (56): the Nutrition and Health Claims Regulation in 2006 (61) and the Food Information to Consumers Regulation in 2011 (60).

4.4 Legal arguments mounted by the tobacco, alcoholic beverages and food industries against European Union rules intended to regulate them

The right to free expression, the right to property (which includes intellectual property) and the right to trade are protected within the European Union; however, they are not absolute and can be limited by restrictions on the grounds of public health, providing that the restrictions are proportionate. This means, first, that they must be legitimate and contribute to the pursuit of a specific objective, i.e. they must be evidence-based, and, secondly, that they do not exceed what is required to achieve the objective, bearing in mind competing interests. Proportionality therefore involves a balancing act, which, in turn, requires complex social, economic and cultural considerations. The Court of Justice of the European Union recognizes the difficulties involved in such assessment and therefore leaves a broad margin of discretion to European Union legislature.

⁷ The European Union recently signed, ratified and implemented the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products, which was opened for signature on 10 January 2013; it is available at <http://www.who.int/fctc/protocol/about/en/>.

Recent case law illustrates how the Court has engaged with the argument. For example, in its September 2012 *Deutsches Weintor* judgement, in which the European Union prohibition on health claims on alcoholic beverages was challenged on the grounds that it violated the right to property and the right to trade, the Court responded that these rights had to be balanced against the European Union's obligation to ensure a high level of public health protection in the development and implementation of all its policies (64). Similarly, in its *Philip Morris et al.* judgement in May 2016, in which tobacco manufacturers challenged the compatibility of the European Union Tobacco Products Directive with their right, among others, to free expression, the Court of Justice unequivocally dismissed the claim and confirmed that it would grant a broad margin of discretion to European Union legislature when determining the extent to which public health concerns should justify restriction to purely economic interests (65).

Governments working individually or collectively within the European Union have a broad margin of discretion to regulate the tobacco, alcohol and food industries to prevent and control NCDs. To do so successfully, they should be aware as early as possible in preparing policy of the arguments that these industries might put forward to challenge their validity in court in order to ensure that they comply with the requirements of proportionality.

Box 5. Eurasian Economic Union and harmonization of legislation

The Eurasian Economic Union is an international organization for regional economic integration and was established by the Treaty on the Eurasian Economic Union (66). Its aims are to ensure the freedom of movement of goods, services, capital and labour and to implement coordinated, coherent, uniform economic policies, with a view to creating a common market within the Union. Health is not listed within the scope of work of the Eurasian Economic Union; however, it is mentioned in several articles of the Treaty. In particular, Article 29 (Exceptions to the Procedure of Functioning of the Internal Goods Market) states that "Member States shall be entitled to apply restrictions in mutual trade (provided that such measures are not a means of unjustifiable discrimination or a disguised restriction on trade) if required for...protection of human life and health...."

As the Eurasian Economic Union is a common market, it will probably enact harmonized technical regulations and standards for products that are traded extensively across borders (e.g. tobacco, alcohol and food). With respect to taxes on products that may affect mutual trade within the Union, it has outlined a policy of harmonization (convergence), including for tobacco products. This was driven by concern about divergences in tax rates and prices for products across the Union (67). In 2015, the Union outlined a framework for harmonizing taxes on tobacco products, which, according to an analysis, would result in significantly lower increases in tax rates in Kazakhstan and the Russian Federation. Economic modelling indicates that such "freezing" of tobacco taxes could stabilize smoking at very high rates or lead to further increases, particularly among women.⁸

5. Key lessons and a way forward

During the concluding discussions, the participants reiterated the importance of fostering intersectoral collaboration and creating legal and policy mechanisms for comprehensive NCD control and prevention, with input from a wide range of government stakeholders. While tobacco control laws have been widely adopted in the region, further action is required, with effective implementation of laws in line with FCTC guidelines, in particular with regard to interactions between governments and industry, and stronger, more effective sanctions and incentives embedded in national legislation. Many states have laws that could form a basis for preventing undue influence by industry on government officials, such as laws on the responsibilities and duties of public officials; however, such legislation is not expressly aligned with laws on tobacco control and other risk factors for NCDs. Furthermore, although much has been done to use the law to reduce smoking, other NCD risk factors, such as alcohol and unhealthy diets, are yet to be adequately addressed with the requisite legal mechanisms at national level.

⁸ The findings of the modelling exercise were presented to the workshop by Polina Kuznetsova.

Participants discussed challenges associated with interactions among trade, foreign investment and NCD policies. They concurred that, while international trade and investment rules are important in promoting trade and ensuring that foreign investors are not treated unfairly by host governments, foreign investors must also be held to strict standards in order to protect health. Delegates reported lack of awareness in their countries about international trade and investment law and its relevance and potential impact on national policy-making for public health and NCD prevention and control. They stressed that experts in trade and investment law should be involved to a greater extent in designing laws and policies relative to NCDs and recognized the importance of building the requisite legal capacity in health ministries and agencies; furthermore, public health experts should be involved in drafting and negotiating investment treaties that are being signed or revised by national governments. Inter-agency cooperation will enable states to continue their investment protection and promotion policies while creating the necessary policy space for regulations to prevent NCDs.

Other activities considered important were:

- mechanisms to enable public health experts to work with legal experts in designing NCD laws and regulations, with input from many sectors of government when drafting and negotiating international trade and investment treaties;
- further courses on public health law, including trade and investment law, so that public health officials could enhance their legal capacity in the health sector;
- comprehensive information and policy “toolkits” on use of enforcement sanctions and penalties to ensure full implementation of NCD laws and regulations; and
- collaboration with nongovernmental organizations and civil society to enlist their support in furthering NCD prevention.

5.1 A toolkit for policy-makers

As demonstrated in this “primer”, public health can be protected within the law. Many laws for NCD prevention have been implemented without challenge or have withstood challenge when unfairly disputed. NCD measures that are evidence-based, well designed and appropriately targeted are less likely to be contested before national and international dispute settlement bodies.

More and more countries are rightly moving towards the use of law to prevent NCDs, such as through regulations to control tobacco, reduce alcohol consumption and promote healthy diets. It will therefore become ever more crucial to ensure consistent use of evidence to target regulations and to build a strong case that the measures are necessary, have a legitimate objective, are non-discriminatory, have followed due process and do not unduly restrict trade or pose a burden in meeting their objectives. In addition, in the context of trade and investment, it will be increasingly important for countries to abstain from making specific representations to investors that the regulatory environment will remain unchanged. Such legislation will be able to withstand challenges from corporations and from other states. Countries could also pre-empt challenges to NCD prevention laws and policies by contextualizing their measures in comprehensive, multisectoral prevention and control strategies and by ensuring greater cooperation between health experts and lawyers from the outset.

5.2 Key activities

- Establish collaboration among health, trade and investment sectors to ensure that public health measures are based on understanding of obligations under international trade and investment law and that investment and trade agreements are negotiated and drafted in such a way as to ensure regulatory space for public health.
- Ensure that public health measures are based on evidence and that the measures, including their objectives, reflect the evidence and, when relevant, states’ international commitments to protect public health.
- Ensure that the measures are proportionate to the objective and level of protection sought by the government.
- Do not draw distinctions between different products in their regulatory treatment, unless the distinctions are based on bona fide, evidenced-based, legitimate regulatory reasons.

- Establish a clear expectation that NCD risk factors will be subject to ongoing regulation. Avoid specific commitments, undertakings or representations that such regulation will remain unchanged.
- The UNCTAD World Investment Report 2015 offers several policy options from which states can choose in designing sustainable investment policies and safeguarding the right to regulate (46).

Useful links

International investment agreements: <http://investmentpolicyhub.unctad.org/IIA>.

Investment arbitration decisions and awards: <http://investmentpolicyhub.unctad.org/ISDS>.

How to reform and modify investment treaties: http://unctad.org/en/PublicationChapters/wir2015ch4_en.pdf.

World Trade Organization agreements: https://www.wto.org/english/docs_e/legal_e/legal_e.htm.

World Trade Organization Dispute Settlement Body reports: https://www.wto.org/english/tratop_e/dispu_e/dispu_by_country_e.htm.

McCabe Centre WHO FCTC knowledge hub: <http://www.mccabecentre.org/knowledge-hub/>.

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The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.



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