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for the
Appropriate
Use of
Herbal
Medicines



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FOREWORD

Herbal medicines form an important part of most traditional systems of medicine in the Western Pacific Region. They play an important role particularly in primary health care.

The significant contribution made by herbal medicines to human health has led to increased popular, official and commercial interest. More and more governments are considering policies on the appropriate use of herbal medicines.

In 1989, the World Health Assembly adopted a resolution on traditional medicine and modern health care. This resolution urges Member States to introduce measures for the regulation and control of medicinal plant products.

Government policy on herbal medicines requires a clear statement on the role of herbal medicines in health care. The extent of the government's involvement and the relationship between herbal medicine and general health services need to be clearly defined. At the same time, mechanisms need to be established to ensure the safety and quality of herbal medicines and traditional methods of care.

To support Member States that are engaged in these issues, the WHO Regional Office for the Western Pacific Region organized a Working Group on Herbal Medicines in December 1997. This meeting prepared a set of *Guidelines for the appropriate use of herbal medicines*.

The guidelines cover a broad range of topics in relation to herbal medicines, with particular emphasis on national policy development, regulation of practice and registration of herbal products.

In some countries, a significant percentage of the population still relies heavily on locally produced herbal medicines for their health care. It may not, therefore, be possible to implement some aspects of the guidelines immediately. A schedule could be set up so the guidelines are implemented step by step. These guidelines represent a set of generic principles which can be flexibly implemented by individual countries.

It is hoped that these guidelines will prove a useful technical, managerial and administrative tool for countries intending to initiate or continue promoting the appropriate use of herbal medicines in their health care systems.



S. T. Han, MD, Ph.D.
Regional Director

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1 INTRODUCTION

1.1 The role of herbal medicines

Plants have been used for health and medical purposes for several thousands of years. The number of higher plant species on earth is about 250 000. It is estimated that 35 000 to 70 000 species have, at one time or another, been used in some cultures for medicinal purposes. A majority of the world's population in developing countries still relies on herbal medicines to meet its health needs. Herbal medicines are often used to provide first-line and basic health service, both to people living in remote areas where it is the only available health service, and to people living in poor areas where it offers the only affordable remedy. Even in areas where modern medicine is available, the interest on herbal medicines and their utilization have been increasing rapidly in recent years.

Medicinal plants are important sources for pharmaceutical manufacturing. Medicinal plants and herbal medicines account for a significant percentage of the pharmaceutical market. For example, in China, medicinal plants and their products had a 33.1% share of the pharmaceutical market in 1995. In Malaysia, the market for traditional medicine is estimated at about 1 billion Malaysia ringgit annually.

1.2 WHO's policy on herbal medicines

The World Health Organization is fully aware of the importance of herbal medicines to many of its Member States and supports the use of medicinal plants and their products. In early 1978, the World Health Assembly, the WHO governing body, adopted a resolution on drug policies and management of medicinal plants, which

recognized the importance of medicinal plants in the health care system. The World Health Assembly proposed coordinating efforts through the preparation of an inventory of medicinal plants, the development of criteria and methods for proving the safety and efficacy of medicinal plant products, and the dissemination of relevant information. In 1987, 1988 and 1989, three more resolutions were adopted covering the identification, evaluation, preparation, cultivation, utilization, regulation and conservation of medicinal plants.

Based on those resolutions, WHO's policy on herbal medicine may be summarized as follows:

- (1) WHO is fully aware of the importance of herbal medicines for the health of a large number of the population in today's world. Herbal medicines are recognized as valuable and readily available resources, and their appropriate use is encouraged;
- (2) To promote the proper use of medicinal plants, a comprehensive programme for their identification, evaluation, preparation, cultivation, recognition as valuable and readily available resources, and their appropriate use is encouraged;
- (3) It is necessary to make a systematic inventory and assessment (pre-clinical and clinical) of medicinal plants; to introduce measures on the regulation of herbal medicines to ensure quality control of herbal products by using modern techniques, applying suitable standards and good manufacturing practices; and to include herbal medicines in the national standard or pharmacopoeia.

- (4) As many of the plants that provide traditional and modern drugs are threatened with extinction, WHO endorses the call for international cooperation and coordination to establish programmes for the conservation of medicinal plants, to ensure that adequate quantities are available for future generations.

1.3 The need for the guidelines on appropriate use of herbal medicines

Herbal medicines, particularly those applied by traditional systems of medicine, have been used for thousands of years. Clinical experience built over many centuries provides a substantial basis for the safe and effective use of herbal medicines, not just as a main form of therapy, but as a complement to the main stream of Western medical treatment in certain diseases. In developing countries, herbal medicines are considered to be more readily available, accessible, affordable, culturally acceptable and sustainable than Western medicines. In developed countries, the popularity of herbal medicines is continuing to grow, particularly for the treatment of certain categories of disease.

Herbal medicines, however, are not necessarily always safe simply because they are natural. Some have given rise to serious adverse reactions and some contain chemicals that may produce long-term side effects such as carcinogenicity and hepatotoxicity. Herbal medicines will only benefit the health of human beings when they are used appropriately. Thus, good quality control and standardization of herbal medicines are essential. Furthermore, with the increased use of both herbal medicines and modern western pharmaceutical drugs, there is a need to monitor interactions.

With the growing popularity of herbal medicines worldwide, many countries will be interested in receiving technical support and guidance in developing a framework for the promotion, development and regulation of herbal medicines. This framework will lay a strong

foundation for the future development of herbal medicines in the health care systems of individual countries.

The management of herbal medicine practices and the use of herbal medicinal plants differ from country to country and are at different stages of development. These guidelines for the appropriate use of herbal medicines, general enough to be comprehensive and yet flexible enough to be modified for each individual country's needs, will, therefore, be helpful.

2 GOALS AND OBJECTIVES OF THE GUIDELINES

2.1 Goals

- To promote the appropriate use of herbal medicines; and
- to encourage the integration of herbal medicines into the mainstream health service delivery system.

2.2 Objectives

- To provide basic principles and applicable standards for interested countries and areas in the Region to develop a national policy and programmes on herbal medicines;
- to guide interested countries and areas in the Region to develop measures for promoting the appropriate use of herbal medicines, appropriate to their own situations;
- to facilitate information exchange on the appropriate use of herbal medicines among policy-makers, researchers and drug administrators; and
- to ensure the safe and effective use of herbal medicines by practitioners and consumers.

3 DEFINITIONS

The following terms are used as working definitions in this document:

Characterizing compound or marker a natural constituent of a plant part that may be used to assure the identity or quality of a plant material or preparation, but is not necessarily responsible for the plant's biological or therapeutic activity.

Herbal medicines plant-derived materials or products with therapeutic or other human health benefits which contain either raw or processed ingredients from one or more plants. In some traditions, materials of inorganic or animal origin may also be present, although for the purpose of this document, the focus will be on plant materials only.

Under this definition, there are three kinds of herbal medicines: raw plant materials, processed plant materials and medicinal herbal products. The definition does not apply where the active component has been identified, and either isolated or synthesized as a chemical component of a drug product.

- Ingredient*** the substance in the herbal formulation which may not be a purified chemical component.
- Medicinal herbal products*** finished, labelled pharmaceutical products in dosage forms that contain one or more of the following: powdered plant materials, extracts, purified extracts, or partially purified active substances isolated from plant materials. Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines.
- Medicinal plant*** a plant which has been used for medical purposes at one time or another, and which, although not necessarily a product or available for marketing, is the original material of herbal medicines.
- Processed plant materials*** plant materials treated according to traditional procedures to improve their safety and efficacy, to facilitate their clinical use, or to make medicinal preparations.
- Raw plant materials*** fresh or dry plant materials which are marketed whole or simply cut into small pieces.

Therapeutic compound

a constituent which is responsible for the intervention of a plant, that results in the amelioration of the manifestations of human disease.

Traditional use

the use of herbal medicines by practitioners of a traditional system of medicine, where:

- (a) the use is well-established and widely acknowledged, i.e., the use represents the accumulated experience of many practitioners over an extended period of time;
- (b) the use of the herbal medicine, including dosage, indication, and administration route is well-established and documented; and
- (c) the use is generally and currently regarded as safe.

4 NATIONAL POLICY DEVELOPMENT

A national policy is a statement of the Government. It should clearly indicate the view of the Government on the role of herbal medicines in promoting and maintaining health and the Government's position on their development, appropriate use and relationship to the national drug policy.

4.1 Process for the development of a policy on herbal medicine

A systematic review of the current status of herbal medicine in individual countries and its role in maintaining health will be necessary for policy development.

The national health authority is the most appropriate body to take the lead in developing the national policy. It can be assisted by a national advisory committee, supported by subcommittees to advise on specific aspects, if required. Where necessary, expert opinions can be obtained from international agencies and other countries. In formulating the policy, consideration should be given to the existing health care system, socioeconomic situation, local tradition and culture. The approach should be practical.

A strategic plan should be developed as part of overall planning. Following identification of problems and benefits, priorities can be set and objectives better defined. The adoption of a strategy is very important as it may involve a choice between several approaches to address the issues. Consultation with the communities and interested parties concerned is essential.

The contents of the draft policy document should be discussed with institutions within and outside government and with the private sector before it is finalized and submitted for formal endorsement.

4.2 Issues to be included in the policy

A number of components will be important in the development of an effective policy on herbal medicine. The policy should recognise the contribution herbal medicine can make to the overall health care system of the country.

4.2.1 Recognizing the role of herbal medicine in the health care system

It is noted that herbal medicine has been used by traditional systems of medicine for a long time. Prolonged and apparently uneventful use of herbal medicine is highly suggestive of its safety and efficacy. Traditional use of herbal medicine is usually an integral part of the culture, which developed within an ethnic group before the spread of modern science. The principles of the traditional system of medicine must be respected when a policy on herbal medicine is prepared. As a general rule, traditional experience should be taken into account along with the medical, historical and ethnological background of the medicine.

4.2.2 Supporting the appropriate use of herbal medicine

The policy should address the importance of herbal medicines in the health care system by identifying the health, economic, social and other benefits of their use. The policy may need to make reference to specific strategies for promoting and incorporating the use of herbal medicines.

4.2.3 Developing appropriate human resources

To ensure the safe and effective use of herbal medicines, the training requirements of practitioners and regulators need to be addressed. This should include reference to quality training programmes for practitioners, and consideration of the educational requirements of regulatory and other personnel.

The policy should also address the education of medical practitioners, pharmacists and the community to facilitate the safe and effective use of herbal medicines as an integral part of the total health care system.

4.2.4 Establishing suitable management and regulatory measures

The needs of consumers and industry, the role of practitioners, and the responsibilities of government should be clearly established in this regard. Policies should be responsive to these identified needs and be designed to ensure they best serve the public in terms of the delivery of safe and effective herbal medicines. The policy should consider the regulatory framework necessary to oversee the manufacture, processing, storage, distribution, sale, import, export and use of these products.

4.2.5 Planning for research and development

The direction and priorities for research and development should be identified. These should take into account such matters as the nature of the country's health care system, the economic and social situation, the availability of health and research personnel, and the degree of access to orthodox and herbal medicines. Account should also be taken of associated research activities occurring in the Region and globally.

4.2.6 Supply of herbal medicines

Where appropriate, the policy should address the need for, and mechanisms to ensure reliable supply of quality herbal medicines. These measures may include policies to manage the utilization of local natural resources, and cultivation and trading with attention to minimizing contamination.

4.2.7 Subscribing to the conservation of medicinal plants

The policy should address the need to preserve endangered species, particularly those identified as requiring conservation nationally and internationally. Practical measures for conservation may need to be identified, particularly for those plants identified as having significant therapeutic use and other benefits to the country.

4.2.8 Provisions of funds

For a national policy to be realised, the policy should identify the costs associated with any national programme and the expected sources of funding. The cost-benefit of the national herbal medicine policy and programme may need to be identified.

4.2.9 Technical cooperation among countries

The importance and benefits of cooperation with other countries, particularly on technical issues, should be recognized. Mechanisms to facilitate this cooperation should be included in the policy.

4.2.10 Monitoring and evaluation of national herbal medicine policies

A process for monitoring and evaluating of the progress and success of the policy should be an integral part of the herbal medicine policy. This will provide the basis for any adjustment to the policy as it evolves, and support for ongoing funding.

5 DEVELOPMENT OF A NATIONAL PROGRAMME ON HERBAL MEDICINES

During the forty-second World Health Assembly, Member States were urged to initiate comprehensive programmes on medicinal plants used in traditional medicine for their identification, evaluation, preparation, cultivation and conservation. The approach to the adoption and development of these programmes should take into consideration the socioeconomic situation of the country and availability of resources to support these programmes. The countries should take a phased approach taking into consideration the priorities of each country.

5.1 National management body for the herbal medicine programme

A national body of appropriate size to coordinate the development of the herbal medicine programme should be established. This body should be responsible for defining the national policy and strategy and translating them into an action plan. It should work closely with other related agencies such as the national drug policy body.

The national management body for herbal medicine should coordinate the implementation of multisectoral and interdisciplinary activities related to herbal medicine. It should also provide advice, suggestions and references to policy-makers. It should ensure that the adopted policy, strategy and action plans are translated into operational activities at different levels.

Advisory committees should be set up to provide suggestions and recommendations to the national body. A national network for implementation of the national herbal medicine programme should be established to support the work of the national body.

5.2 Use of herbal medicines in health care

In many communities and families in the Region, herbal medicine is an available, affordable, effective and culturally-acceptable health care modality. The use of herbal medicine can meet certain primary health care requirements of the people, particularly in less developed, rural and remote areas. The existing community-based traditional medicine projects in several countries have demonstrated the vital role that can be played by herbal medicine in primary health care. In more developed countries, it can complement modern pharmaceutical medicines.

The knowledge available in communities about the use of medicinal plants should be collected and collated, preferably with the participation of the communities themselves. Medicinal plants commonly used in the communities should be selected. The basic criteria in the selection of plants should be: (1) locally available; (2) useful for common health problems; and (3) availability of references on their safety and efficacy. Educational and training materials on these selected plants should be prepared and disseminated. Community health workers should be trained in the identification, collection, processing, storage and utilization of the plants. Villagers should be encouraged to plant medicinal plants in their gardens or backyards.

The herbal medicine practices should be coordinated and integrated into the country's health care system. They can be components of health care establishments at the primary, secondary and tertiary levels or can stand alone. Countries are encouraged to be aware of recent developments in herbal medicine throughout the world and to adopt such treatments into their health care services as and when appropriate if it is beneficial to the community.

5.3 Research on herbal medicines

Although herbal medicines used by traditional systems of medicine have been tested through long historical practice, scientific research on herbal medicines will provide additional evidence of their safety and efficacy. Research will also provide data on herbal medicines to meet regulatory requirements. However, respect of the principles of the traditional system of medicine under study must be an important consideration when the research project is prepared, conducted and evaluated. The *Research guidelines for evaluating the safety and efficacy of herbal medicines*, prepared by the WHO Regional Office for the Western Pacific, provide suggestions and guidance on research methodology on pharmacodynamic and general pharmacological studies, toxicity investigations and clinical trials.

Efforts should be made to upgrade research capability in the field of herbal medicines. Research should initially be utilization-based and preferably include the participation of practitioners and consumers to ensure maximum support from the community.

Whenever necessary, research projects should be conducted in collaboration, involving various research agencies.

5.4 Preparation of information on medicinal plants

A monograph on medicinal plants is a technical document which provides scientific information on the safety, efficacy and quality control of medicinal plants to promote their proper use as herbal medicines. It can serve as a document for official endorsement as well as assist the appropriate use of herbal medicine. It will also facilitate information exchange among Member States.

The information contained in the monographs includes botanical features, quality control standard and test methods, major chemical constituents, clinical applications, pharmacology, posology and possible contraindications and precautions. The format of monographs for medicinal plants, prepared by a WHO collaborating

centre for traditional medicine at the University of Illinois in Chicago, United States of America, could be used as a model for interested countries.

Each country should prepare informative publications from the monographs as a reference for the health care workers and the public.

5.5 Conservation of medicinal plants

The use of plants as medicines has been taken for granted on the assumption that the plants will be available on a continuing basis. However, many medicinal plants face extinction or severe genetic loss. The forty-first World Health Assembly (1988) adopted a resolution which endorsed the call for international cooperation and coordination to establish a basis for the conservation of medicinal plants to ensure that adequate quantities are available for future generations. Each individual country is encouraged to develop programmes to preserve the continuing existence of local medicinal plants and, if applicable, to introduce additional plants through appropriate processes.

Guidelines on the conservation of medicinal plants prepared by WHO, IUCN (The World Conservation Union) and WWF (World Wide Fund for Nature) should be followed by Member States when a national programme on herbal medicine is prepared.

Medicinal plants are valuable natural and genetic resources and an inventory and survey of medicinal plants should be conducted in each country regularly. A list of endangered species of medicinal plant in each country should be prepared and actions for their protection and conservation should be taken, preferably by the Government, including the establishment of seed banks.

The cultivation of plants needed for medicinal purposes should be encouraged to ensure adequate local supply. Incentive schemes could be devised to support this.

5.6 Training and education

Proper plans should be made concerning the education and training of practitioners and related health workers, and, where appropriate, examination, continuing education, and registration or licensing of the appropriate groups.

A human resource development plan should also be prepared to ensure that there will be adequate types and numbers of health care personnel to support this programme. External support and expertise may be required at various stages.

It is desirable to include knowledge on traditional and herbal medicine in the curricula for students in medical and pharmaceutical schools.

5.7 Collection and exchange of information on herbal medicines

Collection and exchange of information on herbal medicines, including the preparation of monographs on medicinal plants and evaluation of their safety, efficacy and quality, should be encouraged. For collected information, the construction of various databases is desirable to promote information exchange. Utilization of available databases and distribution of information from existing databases should be given high priority.

6 REGULATION OF PRACTITIONERS

Herbal medicines may be used as self-medication for many conditions. However, in most cases, the use of herbal medicines needs to be guided by qualified practitioners.

The type of regulatory framework deemed appropriate for herbal medicine will thus depend on the nature of the problems identified as arising from its practice.

Regulation of practitioners who provide service to others, particularly practitioners whose practice brings economic benefit, should ensure quality of herbal medicine services and thus protect the public. The regulation of herbal medicine practitioners may also protect the qualified practitioners.

6.1 Options

There are many regulatory options which can be adopted. These range from professional organizations imposing standards on their own members, to a recognition of these standards, either directly or indirectly, by the government, including statutory support for bodies which impose standards or formal government registration of practitioners by law.

6.2 Examination

To facilitate the process for registration of practitioners, a national examination system could be created. The examination could be organized by health authorities or an independent body under the

supervision of the Government. The establishment of a national examination system will promote efforts in upgrading the training on herbal medicine and ensuring that certain standards of practice are met.

7 REGULATION OF THE MANUFACTURE AND DISTRIBUTION OF MEDICINAL HERBAL PRODUCTS

7.1 General considerations

Medicinal herbal products are prepared from material of plant origin which may be subject to contamination and deterioration, and may vary in composition and properties. This is in contrast to conventional pharmaceutical products, which are usually prepared from synthetic materials by means of reproducible manufacturing techniques and procedures. Furthermore, in the manufacture and quality control of medicinal herbal products, procedures and techniques are often used which are substantially different from those employed for conventional pharmaceutical products and from traditional methods of preparation.

The control of the starting materials, storage and processing assumes particular importance because of the complexity, variability and perishable natures of any medicinal herbal products and the number of potentially active ingredients present in small quantities. It is advisable that medicinal herbal products that may be widely used in the marketplace are adequately regulated so as to ensure quality, efficacy and safety of the products.

In recognition of the various legislative, socioeconomic and cultural contexts, the degree and form of management or regulation should be consistent with the specific circumstances of that country, yet adequate to ensure safety and quality of herbal medicines. In

some countries different regulatory requirements for herbal medicines have been applied.

A regulatory system should be developed for manufacturers and distributors of medicinal herbal products at all levels including importers, exporters, wholesalers or retailers by licensing, registration or other means. The system should allow for periodic review.

7.2. Good manufacturing practices (GMP)

Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to quality standards appropriate to their intended use and as required by the marketing authority. GMP rules are directed primarily at diminishing the risks inherent in any pharmaceutical production that cannot be prevented completely through the testing of final products.

All procedures for the manufacture of herbal medicine under regulation should be in accordance with GMP. WHO *Good manufacturing practices for pharmaceutical products* and *Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicinal products* may be consulted when the GMP for an individual country is prepared.

A phased approach to the implementation of GMP may be required.

7.3 Training of regulatory staff

The agency administering the regulatory system should develop appropriately qualified staff resources, capable of making informed decisions in the area of herbal medicines. This may involve the provision of specific training programmes.

7.4 WHO certification scheme on the quality of pharmaceutical products moving in international commerce

Countries that do not have professional staff or laboratories to evaluate and handle extensive documentation for registration, may wish to take into account regulatory decisions made in other countries. The WHO certification scheme on the quality of pharmaceutical products moving in international commerce could be applied.

The aim of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce is to assure the quality of imported drugs, especially in small countries that have no drug registration system or no facilities for the systematic evaluation of the quality, efficacy and safety of pharmaceutical products.

A certificate is issued by drug regulatory authorities in exporting countries on request from drug regulatory authorities in importing countries. The certificate issued under the scheme confirms that:

- (1) the pharmaceutical product mentioned in the certificate has been: evaluated for quality, safety and efficacy; registered in the country of origin; and approved for sale in that country. An explanation is required if any of these three criteria are not met;
- (2) the pharmaceutical product has been manufactured according to Good Manufacturing Practices and that the manufacturing plant in the country of origin has been regularly inspected by the drug regulatory authorities to confirm compliance with GMP;
- (3) the labelling and any other written information accompanying the product has been approved by the drug regulatory authority in the country of origin.

A similar system could be used for herbal medicines available for the international market.

8 REGULATION OF HERBAL MEDICINES

8.1 General considerations

8.1.1 Each country or area should adopt a regulatory system to manage the appropriate use of herbal medicines. Adopting a regulatory mechanism will help ensure that herbal medicines have acceptable quality, safety and efficacy. The WHO *Guidelines for the assessment of herbal medicines* should be consulted when assessment processes for herbal medicines are being prepared.

Legislation should act as clear guidelines to industry and in its formation should draw on the expertise of a wide range of stakeholders (industry, consumers, practitioners, etc).

Legislation on herbal medicines should also recognise specific issues such as traditional history of use and/or level of current (unregulated) usage in the community. As a general principle, the history of use of a substance should in most cases be adequate evidence of its basic safety, provided its proposed application appropriately reflects its historical use.

8.1.2 Characteristics of herbal medicines

Herbal medicines have several attributes which differ from chemical synthetic drugs.

Herbal medicines are major remedies used by traditional systems of medicine which were developed based on different concepts from those of modern medicine.

Herbal medicines, as defined above, are usually mixed chemical compounds. Often not all active components of herbal medicines have been isolated, characterized or quantified. Efficacy is a result of the summation of pharmacological activity of an undefined blend of active components from one or more species of herb. Even a single plant material is not a purified single chemical compound. Standard techniques for the control of individual purified components may not be applicable for evaluating the quality of herbal medicines. In most cases it may not be appropriate to transfer the existing controls on chemical drugs to herbal medicines.

Where herbal medicines are not prepared by traditional methods it would need to be established that the processes have not changed the safety and therapeutic activity of the herbal medicines.

8.1.3 The regulatory process is a mechanism for evaluating the safety, efficacy and quality of medicinal products. The levels of evaluation may vary depending on the product. A comprehensive regulatory system for pharmaceutical products would require adequate data on pharmaceutical chemistry, pharmacological and toxicological studies, clinical investigations and therapeutic applications. However, for herbal medicines some modifications to the regulatory system are necessary. The registration requirement for herbal medicines would most likely be different from that for purified chemical drugs.

8.1.4 Various assessment procedures can be established with consideration of the categories of herbal medicine and different country situations.

(a) Notification procedure (listing): This involves obtaining information on herbal medicines which are being sold in a certain country. The amount of

information requested in a notification may vary. It may initially be restricted to the names of herbal medicines and of manufacturers or importers if the medicine is imported from other countries. It may then be expanded to require notification of the composition, the pharmacological action, and the therapeutic classification. The assessment of listed herbal medicines may focus solely on the safety and quality for each intended use.

The listed herbal medicines may include those used traditionally, which are well-established, and those only used for simple, self-limiting conditions, without therapeutic claims having been assessed.

- (b) **Registration procedure (licensing):** This comprises detailed evaluation of data submitted in support of the safety, efficacy, and quality of pharmaceutical products. It also determines the indications for its use. The procedure includes an assessment of both the herbal medicinal product, manufacturing procedures and facilities.

8.1.5 All manufacturing procedures should be in accordance with Good Manufacturing Practices (GMP). However, for many developing countries, medicinal herbal products are manufactured by factories, small workshops or traditional medical practitioners which may not meet GMP requirements. Countries should establish a process for manufacturers to acquire GMP status within an established timeframe.

8.1.6 Different regulatory procedures may be applied to raw plant materials, processed plant materials and medicinal herbal products. In some countries, raw plant materials may not be required to be regulated.

- 8.1.7 For toxic plant materials, the regulatory authority may issue a list of controlled toxic plant materials to guide manufacturers, wholesalers or importers and the public. The use of listed toxic medicinal substances may need special regulations.
- 8.1.8 For countries where a mechanism for the regulation of herbal medicines has not yet been established, the regulation procedure could be initiated step by step. A first stage notification (listing) procedure will provide useful data on medicinal herbal products available on the market. Depending on human resource and laboratory facilities, more comprehensive regulatory procedures could be implemented in order to achieve an acceptable level of safety, quality and efficacy.

8.2 Requirements for raw plant materials

While a regulatory system for raw plant materials used in individual dispensing would be difficult and impractical to implement, plant materials identified as toxic should be subjected to specific regulatory procedures. Plant materials classified as toxic should be dispensed only by appropriately qualified practitioners.

At all levels of handling of raw plant materials, clear and accurate identification and labelling is paramount. Countries should also give consideration to mechanisms for controlling contamination of raw plant materials with pests, microorganisms, aflatoxins and other mycotoxins, pesticides, heavy metals and other foreign matters.

8.3 Requirements for processed plant materials

8.3.1 Processed plant materials may be supplied as ingredients to practitioners or as starting materials to product manufacturers. In these cases, the following information should be supplied:

- (a) taxonomical classification of the plant including genus, species and family;
- (b) common names;
- (c) expected countries of origin;
- (d) part of the plant used and its condition (such as fresh aerial part; dried root and rhizome, sliced or decorticated);
- (e) year, season, preliminary preparation and drying and methods of collection, if necessary;
- (f) the method of preparation, including details of new processing techniques; and
- (g) the excipients used (where relevant) for commercial reasons.

8.3.2 Where, for commercial reasons, the supplier/manufacturer of processed medicinal materials does not wish to provide details of the extraction methodology or excipients used to the manufacturer or practitioner, a notification (listing) or registration procedure could be implemented. In this case, particularly if using new processing methods, in addition to the information required under 8.3.1, the following information, may also be required, if relevant:

- (h) characterizing compounds of the processed medicinal material and the chromatogram of the characterizing compounds;
- (i) data on long-term toxicity tests, if appropriate;
- (j) data on mutagenicity tests;
- (k) data on carcinogenicity tests, if appropriate;
- (k) data on reproductive and developmental toxicity tests when necessary;
- (l) stability tests;
- (m) quality standard, including the assay or limit of toxic ingredients, microorganisms, mycotoxins, heavy metals and pesticide, insecticide and herbicide residues; and
- (n) reports on clinical trials, when necessary.

8.4 Requirements for medicinal herbal products

For medicinal herbal products a notification (listing) or registration procedure should be used in most cases. The manufacturers, distributors or importers should provide information on items listed below in relation to the product. In general, the requirements for medicinal herbal products would be pertaining to the product, however, data on individual components may in some circumstances be required. Efforts should be made to achieve high standards of practice in this area wherever possible.

- (1) For traditionally used medicinal herbal products the following are needed:
 - (a) name of the product;
 - (b) list of ingredient(s) (active and inactive) of the product with scientific name(s), part of the plant used, and quantity; and with reference to the source text for the prescription, if available;
 - (c) the list of plant ingredient(s) of the product with taxonomic classification, including species, genus, and family;
 - (d) methods and technology used in manufacture;
 - (e) physical and chemical identification tests;
 - (f) quality standards for the ingredients when necessary (which may include the limit of residue of heavy metals and pesticides, insecticide and herbicide);
 - (g) quality standards for the products;
 - (h) stability tests;
 - (i) therapeutic uses and dosage;
 - (j) evidence of traditional use or recent clinical experience with the product in the form proposed, to support the safety and efficacy of the product;
 - (k) package and packaging materials; and
 - (l) content on label or package insert.

For those traditionally used herbal medicines with new dosage forms or new administration routes, the following additional data may be needed:

- (m) comparative data on bioavailability.

For special dosage forms, such as injections and nebulisers, additional data may be required.

For those traditionally used herbal medicines with new indications, the following data, additional to items (a) to (l) may be needed:

- (n) reports on clinical trials.

- (2) For new medicinal herbal products which contain herbs with no traditional history of use, the following data should be submitted, in addition to the data on items (a) to (l) listed above:

- (a) data on pharmacodynamic, bioavailability tests, and general pharmacological studies;
- (b) data on acute toxicity tests;
- (c) data on long-term toxicity tests, if necessary;
- (d) data on mutagenicity tests, if necessary;
- (e) data on carcinogenicity tests, if necessary;
- (f) data on reproductive and developmental toxicity tests, if necessary; and
- (g) reports on clinical trials.

- (3) For importing countries, confirmation of the regulatory status in the country of origin should be required. Countries should consider extending the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce to cover medicinal herbal products. Where countries and areas have not yet adopted this scheme, the importers should submit a certificate of free sale and certificates of Good Manufacturing Practice (GMP) for the country of origin. Those certificates should be issued by the drug regulatory authority of the country of origin. After reviewing all the documents, a registration or notification (listing) may be given to medicinal herbal products imported by individual importers and the registration or listing number must appear on the labels of medicine.

8.5 Label requirements

It is recommended that the following is printed on the product label in the official language(s) used by the countries or areas:

- (a) name of product;
- (b) name and quantity (in dry weight when relevant) of active ingredient(s);
- (c) dosage form;
- (d) directions for use including indications, dosage, mode of administration, duration of use, age group limitations, and use during pregnancy and lactation;
- (e) warning statements and relevant contraindications, adverse effects, if any, and overdose information when relevant;
- (f) batch number;

- (g) expiry date;
- (h) storage conditions;
- (i) name and address of manufacturers and/or importers;
and
- (j) registration or notification (listing) number.

The scientific name of active ingredient(s), in addition to the common name in the language of preference of the national regulatory authority, should be used.

The label and package insert should be “user-friendly”. Easy and understandable information should be provided.

The drug regulatory authority may provide to industry directions on labelling and on allowable indications and claims.

8.6 Responsible government agency for regulation

The responsible government agency could be the Drug Regulatory Authority or other government agencies with similar responsibilities. It is recommended that a special unit for herbal medicines should be created under the responsible agency for the regulation of medicines.

The responsible agency should review and evaluate all the data received from manufacturers or wholesalers. The applicants should be informed on time whether or not their products have been accepted for notification (listing) or registration.

The responsible agency should keep all the records for registration or notification of herbal medicines.

A registration or notification number should be given when an herbal medicine has been accepted with the drug regulatory authority. A certificate of registration or notification will be issued to each herbal medicine accepted by the relevant authority.

The regulatory authority should provide information to medical practitioners, pharmacists, owners of herbal drug stores and the public on the regulatory process and should have available a list of accepted medicinal herbal products.

8.7 Promotion and advertisement of herbal medicines

Advertisements and other promotional activities aimed at health personnel and the public should be fully consistent with the accepted product information. Restrictions may be placed on some advertising claims consistent with public health and safety.

8.8 Monitoring of adverse reactions to herbal medicines

The regulatory authority should establish a system for monitoring or surveillance of adverse reactions to herbal medicine. In the first instance, manufacturers should be encouraged to submit reports of adverse reactions. Ultimately, post-marketing surveillance should be required for medicinal herbal products which contain either toxic ingredients or present with new indications, new processing methods or routes of administration. Practitioners and consumers should be encouraged to report any adverse effects related to the use of medicinal herbal products. The regulatory authorities should investigate reported cases of adverse effects and, if necessary, issue relevant warnings or impose further restrictions on the use of the medicinal herbal product. Regulatory authorities are encouraged to maintain accurate records of reported adverse reactions to herbal medicines and to make available that information to other Member States on request.

9 USE OF THE GUIDELINES

These guidelines for the appropriate use of herbal medicines are intended to facilitate the work of national health authorities. It is hoped that they can cover a wide range of issues and meet the different situations of countries and areas in the Region. These guidelines can be modified by each Member State to suit their own specific needs. It is hoped that each interested country will eventually develop its own management and regulatory system for herbal medicine which will best suit its own situation. A phased approach to the adoption of the guidelines should be considered by Member States.

These guidelines also provide reference points for researchers, manufacturers and traders.

ANNEX 1

REPORT OF THE MEETING OF THE WORKING GROUP ON HERBAL MEDICINES

SUMMARY

The Working Group on Herbal Medicines met in Manila, Philippines, from 8 to 12 December 1997. The main objective of the meeting was to develop guidelines for the appropriate use of herbal medicines for interested countries in the Region which would assist in the development of national policies and programmes on herbal medicines.

The meeting was attended by 17 temporary advisers, two consultants, two secretariat staff from the WHO Regional Office for the Western Pacific and three observers. Dr Wong Kum Leng was elected Chairman, Mrs Napsah binti Mahmud, the Vice-Chairman and Dr Nelia Cortes-Maramba and Dr Boun Hoong Southavong were the two Rapporteurs.

The meeting commenced with presentations from the two consultants and one secretariat member. These presentations briefly summarized:

- (1) the Regional growth of herbal medicine and relevant WHO policies and programmes;
- (2) the regulation of herbal medicine in the Region; and

- (3) progress in herbal medicine research.

Dr S.T. Han, WHO's Regional Director for the Western Pacific, delivered a speech during the opening ceremony. Country reports on the status and activity of herbal medicine were then presented by the temporary advisers.

On subsequent days, significant focus was given to identifying the essential principles behind the development of any national policy and programme in herbal medicine, and key issues relevant to the regulation of herbal medicines and herbal medicine practitioners. In the course of these discussions, the Working Group developed the guidelines for the appropriate use of herbal medicines.

A summary of the principal conclusions and recommendations follows:

- (1) With the growing use of herbal medicines in the Region, it is becoming important for Member States to formulate their own national policy and programme on herbal medicine.
- (2) The guidelines for the appropriate use of herbal medicines, developed by the Working Group, are to be utilized fully or partially by Member States, depending on each country's own situation and distinct needs.
- (3) Herbal medicines, especially traditional herbal medicines, will increasingly need to meet basic standards of quality control and safety. Member States are encouraged to work towards this as part of their national programme on herbal medicine.
- (4) Bilateral and multilateral cooperation among Member States and with WHO are essential to harmonize regulatory standards across Member States and to facilitate exchange of information.

1. Introduction

Herbal medicine in traditional medical practice is an important resource which can be mobilized for the attainment of the common goal of health for all. These herbal medicines have contributed significantly to man's struggle against diseases and maintenance of health. In recent years, interest in the use of herbal preparations has increased. Herbal medicines are used in most countries in the Region either within the state health care system or in communities and private practices outside the state system. The growing interest in, and the increased consumption of herbal preparations as herbal medicines have also raised considerations about the need for regulation. Special attention to the nature and characteristics of herbal medicines is warranted in forming regulatory provisions and procedures.

The consumption of herbal medicines is significant and appears to be steadily increasing for a number of countries in the Region. In rural China, 35% of outpatients and 22% of inpatients are treated with traditional medicines. Herbal medicine sales accounted for 33.1% of the drug market in 1995, and represented a greater than 200% increase on production levels of 1990. In Hong Kong, 60% of the population have consulted traditional medicine practitioners. Japan saw a 15-fold increase in herbal medicine sales between 1979 and 1989 in contrast to a 2.6 fold increase in sales of pharmaceutical drugs during the same period. In Australia, a recent survey identified 48.5% of Australians as using alternative medicines, including herbal medicine. The consumption of herbal medicines does not appear to be abating.

WHO's policy on herbal medicines acknowledges their important role for the health of a large number of people. For particular cultural and socioeconomic groups, they form a significant part of their health services. WHO promotes the safe and effective use of herbal medicines and encourages their integration, wherever possible, into the delivery of mainstream health care services.

1.1 Objectives

The objectives of the meeting were to:

- (1) review the current status of the appropriate use of herbal medicines in the Region;
- (2) present and discuss various issues and models for the appropriate use of herbal preparations as herbal medicines;
- (3) develop draft guidelines for the appropriate use of herbal medicines; and
- (4) recommend future directions for the implementation of these guidelines.

1.2 Participants

The Working Group was composed of 17 temporary advisers, two consultants, two secretariat staff from the WHO Regional Office for the Western Pacific and three observers. The list of participants is attached as Annex 2.

1.3 Organization

Dr Wong Kum Leng and Mrs Napsah binti Mahmud were elected Chairman and Vice-Chairman of the Working Group. Dr Nelia Cortes-Maramba and Dr Boun Hoong Southavong were the two Rapporteurs.

1.4 Opening ceremony

Dr S.T. Han, Regional Director for the Western Pacific, opened the meeting by pointing out that WHO recognizes the very significant contribution which traditional medicine, and in particular herbal

medicine, can make to public health in the Region. He reported on the high usage figures for herbal medicines in the Region, the capacity of plant materials to offer new drugs and successful medical treatment, and the degree of integration into the official health care system of herbal medicine by some Member States. Dr Han indicated that WHO fully supports Member States in their efforts to integrate traditional medicine into their health care delivery systems. He noted that the Working Group, in preparing guidelines for the appropriate use of herbal medicines, should include technical suggestions for Member States interested in promoting the proper use of herbal medicine, which are flexible, feasible and practical.

Dr S.T. Han's opening speech is attached as Annex 4.

2. Proceedings

The agenda of the Working Group is shown in Annex 3.

2.1 Initial presentations

The meeting commenced with presentations from the two consultants and one secretariat member. These presentations briefly summarized:

- the Regional growth of herbal medicine and relevant WHO policies and programmes;
- the regulation of herbal medicine in the Region; and
- progress in herbal medicine research.

Dr Chen Ken, WHO Medical Officer for Traditional Medicine, outlined the current status of herbal medicines in the WHO Western Pacific Region and drew the Working Group's attention to growth statistics from a number of countries and areas. It was identified that:

- A great number of people in the Region still use herbal medicine for various reasons.
- A major part of traditional therapies involves the use of herbal medicines.
- Herbal medicines have a substantial share of the drug market.
- Medicinal plants are important sources of pharmaceutical products.
- Medicinal plants are important sources for the development of new drugs.

WHO's policy and programme on herbal medicines was also outlined. WHO's policy describes a high level of awareness of the importance of herbal medicines and the need to promote the proper use of medicinal substances. WHO's programme objectives are to:

- promote the safe and effective use of traditional medicine; and
- encourage the integration of traditional medicine into the general health services system, where applicable.

WHO will continue efforts to promote the proper use of herbal medicine through policy development, training, research and information exchange.

Mr Alan Bensoussan, Senior Lecturer, Faculty of Health, and Head, Research Unit for Complementary Medicine, University of Western Sydney, Campbelltown, Australia, summarized the essential policy elements and trends within a number of regional jurisdictions to do with the practice of herbal medicine. Legislative structures governing the practice of herbal medicine vary significantly between neighbouring jurisdictions. Regulatory approaches to herbal

medicine in different countries may be seen as a continuum, from a highly regulated model where practitioners are licensed and supervising boards are established to maintain standards and oversee qualifications; to a virtual absence of regulation, where any person may set up in practice of herbal medicine, constrained only by the prospect of personal liability for negligence and breach of contract, and general provisions relating to poisons and therapeutic goods. More extreme legislation in some jurisdictions may result in the complete exclusion of herbal medicine practitioners from the health care marketplace.

Regional and overseas trends indicate that increasing numbers of jurisdictions are contemplating the introduction of occupational regulation of herbal medicine practitioners to supplement the various forms of regulation on the materials and the conduct of herbal practice.

Professor Il-Moo Chang, Director, Natural Products Research Institute, Seoul National University, Seoul, Republic of Korea, summarized herbal medicine research activities in the Region. The major areas of activity include the following:

- There is a significant current focus on quality control methods to achieve standardization. Where a herb has unknown active ingredients, indicative constituents and/or fingerprint analysis (usually high pressure liquid chromatography patterns) have been used for the purpose of standardization and quality control.
- Classical animal cell culture, as well as gene manipulation techniques, are being applied to produce active ingredients of CITES-subjected (Convention on International Trade in Endangered Species) animal species.

- Where it is not easy to understand the efficacy of herbal medicine in terms of modern pharmacology, animal models are being developed to test the efficacy of specific herbs.
- Because of the difficulty in assessing an extensive range of herbal prescriptions (est. 100 000), efforts have been made to establish minimum safety assessment requirements. These include assessment of acute toxicity and some systematic toxicity tests. If abnormalities arise then more detailed toxicological studies are undertaken.
- Information databases and exchange mechanisms are being established.
- A coding system for nomenclature of traditional Chinese medicine prescriptions is being established.

2.2 Country reports

Country reports on the status and activity of herbal medicine were presented by the temporary advisers and are summarized below.

Australia

Ms Laurayne Bowler communicated that responsibility for the regulation of medicine is split between States and Territories on the one hand, who deal with practitioners, and the Commonwealth on the other hand, with whom the responsibility for proprietary medicines largely lies. However, there is only limited control on the dispensing of raw herbal material. The Therapeutic Goods Act, which was passed in 1989, set out for the first time in Australia a system for the regulation of herbal proprietary medicines. Approximately 1500

herbal substances are contained in some of the medicinal products entered on the Australian Register of Therapeutic Goods. A recent government review of the Therapeutic Goods Act in 1997 has made a number of further recommendations to improve regulations on advertising, herbal standards, the regulatory process and the food/drug interface, while imposing the minimum regulatory burden on industry necessary to protect public health and safety.

The regulation of Chinese herbal medicine practitioners is due for consideration by State and Territory health ministers early in 1998.

Cambodia

Mr Seng Lim Neou reported that many valuable traditional medicine documents and skilled practitioners were lost during the time of Polpot-Khmer Rouge. In 1979, the Government officially integrated traditional medicine into the national health system and it has played a significant role in Cambodian health care. However, since 1990 and the Government's adoption of a free market policy, its importance has gradually diminished. Currently, approximately 230 traditional healers are registered with the Health Department of the Municipality of Phnom Penh. They all work in the private sector and perform all tasks - from manufacturing and sales to patient treatment. There is no quality control of their products.

The national policy on traditional medicine is to increase the importance of Cambodian traditional medicine and encourage traditional practice as a complement to modern medicine.

China

Mr Shen Yu Long indicated that the administration of Chinese herbal medicine in China has two important aspects. The first is the policy of government support, (mutual development and promotion of modern and traditional Chinese medicine), which is signified in China's constitution. The second consists of the substantial infrastructure of research, education and training in herbal medicine existent in China. There are 170 Chinese medicine research institutes with about 15 000 professional researchers. There are 30 universities and colleges with a total of 37 000 Chinese medicine students.

Both aspects are symbolic of the substantial degree of recognition, support and integration of Chinese herbal medicine as part of the mainstream health care system in China.

Hong Kong

Dr Ting-hung Leung reported that, although Chinese medicine is very much an integral part of the health care system in the Hong Kong Special Administrative Region (SAR), China, there has been no specific legal control and recognition of Chinese medicine practitioners or medicines. There are an estimated 7000 Chinese medicine practitioners in Hong Kong. Following recommendations of a Working Group report (1989), a Preparatory Committee on Chinese Medicine (PCCM) was appointed by the Secretary of Health and Welfare in 1995. Recent recommendations from the PCCM include the establishment of a statutory framework to regulate the practice, the use of and trading in Chinese medicine. The Hong Kong Government would commence statutory registration of Chinese medicine practitioners by the year 2000 and

regulation of Chinese medicines would occur in phases from that date. The Basic Law of the Hong Kong SAR provides that the Government shall formulate appropriate policies to develop both western and traditional Chinese medicine.

Japan

Dr Motoyoshi Satake stated that, in Japan, the practice of herbal medicine is restricted to western medicine doctors and pharmacists. In 1976, Kampo (traditional Chinese) medicines were introduced by the National Health Insurance System and have been used in hospitals and pharmacies. Herbal medicines sold in the market are estimated to be worth about US\$1.5 billion, which is about 3.5% of the total medicine market. The Japanese pharmacopoeia contains over 100 monographs on traditional Chinese herbs.

A re-evaluation process is now occurring for some of the 210 Kampo products currently available under the Pharmaceutical Affairs Law. Some debate ensued as to what was driving this new evaluation of Kampo herbal formulae for which approval was already granted. The question was raised as to whether political, economic or social reasons were behind this re-evaluation.

Republic of Korea

Dr Soo-Myung Oh and Dr Dong-Suk Park reported that oriental medicine has a long history in the Republic of Korea and plays a significant role in the health care system. A particular form of traditional medicine developed from the combination of Korean and Chinese medicines. In 1952, a national medical law was passed establishing oriental medicine and modern medicine as

parallels within the health care system. There are now 11 colleges providing six-year programmes in oriental medicine. There are now more than 9000 licensed oriental medicine doctors.

So far as herbal medicines are concerned, there are specialized guidelines for manufacturers and traders, and the Government is currently standardizing the commonly used proprietary herbal medicines. In 1996, the Department of Oriental Medicine within the Ministry of Health and Welfare was opened, employing experts in herbal medicine. Previously, western medicine pharmacists were readily permitted to dispense some herbal medicines, but now western pharmacists, in order to be authorized to dispense herbal medicines, are required to take a national examination spanning some 100 traditional Chinese prescriptions. A parallel system of oriental pharmacists is also being created which will provide experts capable of dispensing the full range of herbal prescriptions. The increasing public demand for herbal medicines requires further substantial national support at Government level.

Dr Park Sang-Pyo also provided a paper entitled, "Current status of herbal medicine in Korea".

Lao People's Democratic Republic

Dr Boun Hoong Southavong reported that in rural areas, more than 90% of communities use traditional Lao medicine to prevent and cure disease. The Government of Laos has in place a national policy which actively promotes the use of traditional medicine and has set up the Research Institute of Medicinal Plants (RIMP). The development of Lao infrastructure for traditional medicine (including the RIMP) depends very much on WHO support and is currently quite fractured across the country. There is a significant effort in

progress for the revival of traditional medicine. No clear regulatory mechanisms currently exist for traditional medicine practitioners or herbal medicines.

Macao

Dr Cheong Tai stated that the majority of Macao people believe in and rely on indigenous traditional medicines to satisfy their primary health care needs. In 1994, a law came into effect to ensure control of a number of aspects of traditional Chinese medicines, including their safety, efficacy and quality, and the regulation of trade and marketing. Importers, exporters and wholesalers and traditional Chinese pharmacies are required to hold licences. There are currently 100 licensed traditional Chinese medicine pharmacies in Macao. A form of defacto registration exists which requires that all products imported into Macao be registered and sold freely in their countries of origin. Where proprietary herbal medicines are exempt from registration controls in their own countries, then Macao importers are required to produce an analysis certificate for each individual batch. All traditional medicine products must comply with general labelling requirements. Over 400 herbs, including 31 classified as toxic herbs, are restricted for sale by licensed Chinese pharmacies. The list of toxic herbs is currently being updated and perfected.

Malaysia

Mrs Napsah binti Mahmud reported that implementation of registration and licensing of traditional medicines in 1992 marked the systematic regulatory control of traditional medicines in Malaysia. The registration exercise, while ensuring safety and quality of imported and locally manufactured traditional

medicines, could also be considered a starting point for the upgrade of local herbal medicine manufacture. Manufacturing methods will need to comply with the basic elements of GMP by the end of 1997.

The Ministry of Health has recently set up committees to review the possibility of traditional medicines playing a formal role in the health care system. The three main areas of focus should be:

- registration of traditional medicine practitioners;
- education and training of practitioners; and
- the identification of products with proven safety, quality and efficacy.

A National Committee on Herbal Medicines was also established in 1995 to look into such aspects as research and development on herbal medicinal plants, the establishment of a series of Malaysian herbal monographs, and developing strategies to ensure conservation of medicinal plants and to promote the herbal medicines industry.

Mongolia

Dr Miaegombo Ambaga reported that Mongolia has an abundant diversity of plant species and a rich tradition of utilization. There have been recent increases in the usage of traditional medicine and in the number of new plant preparations. A government drug agency monitors quality control of herbal medicines. Full registration of herbal medicine practitioners includes reference to three groups: western medical practitioners with little traditional herbal training, graduates from the new schools of traditional medicine, and a number of older private practitioners for whom examinations are available.

New Zealand

Dr Paratene Ngata shared with the Working Group the distinct nature of the Maori indigenous traditional healing practices. So far as the regulation of herbal medicine practitioners is concerned, Common Law principals operate in New Zealand, as they do in Australia. Herbal medicines are listable under New Zealand law (Medicines Act 1981 and Medicines Regulations 1984) and fall under the category of 'dietary supplements'. Dr Ngata indicated that the inclusion of traditional healing in the health system may occur through a system of Government 'purchasing' services for consumers. This would impose some formalization of healing activities to develop acceptable standards, which may in turn risk autonomy or compromise certain essential characteristics of healing.

Philippines

Dr Alfonso T. Lagaya summarized that the Philippine government is very supportive of activities related to the research, education and production of traditional herbal medicines and, for these purposes, has recently approved the establishment of the Philippine Institute of Traditional and Alternative Health Care.

There are two groups of practising herbalists in the Philippines - a handful of licensed modern medicine physicians and approximately 250 000 unregulated traditional herbalists. While the integration of traditional medicine into the current health care delivery system is intended, and the plans for the future regulation of the large unregulated traditional medicine workforce will be fully implemented until the establishment of the Philippines Institute of Traditional and Alternative Health Care.

The production and sale of herbal medicines are regulated by the Department of Health. A listing system is established for local herbal and traditional drugs but imported proprietary medicines are currently exempted. Government policy is that herbal medicines will be used nationwide within a primary health care context.

Professor Nelia Cortes-Maramba added that there are new and substantial levels of evaluation of herbal medicines commencing from point of growth to the provision of the finished product.

Singapore

Dr Wong Kum Leng stated that while western medicine is the main form of health care in Singapore, herbal medicine continues to enjoy considerable popularity. In 1994, the Ministry of Health appointed a committee to review the practice of Chinese medicine. The Committee advocated the need to regulate the more than 2000 Chinese medicine practitioners in Singapore and also recommended steps to upgrade the standard of training. In 1995, the Ministry established a departmental Chinese Medicine Unit.

Singapore has adopted a phased approach, initial self-regulation is to be followed by statutory regulation. Statutory regulation for acupuncturists will be implemented by the year 2000, while that for Chinese herbalists is intended to be in place several years later. At present, herbal medicines are exempted from product registration unless they contain controlled substances - essentially, no licences are required for their manufacture, sale or importation. However, various aspects of herbal medicines are required to comply with the various legislations. No product registration for

Chinese proprietary medicines is anticipated although products will be listed by the Government. Manufacturers will be licensed on the basis of GMP standards.

There is a prohibition on labelling and advertising claims for 19 diseases. There was some discussion as to the basis upon which the 19 prescribed diseases were selected.

Viet Nam

Professor Le Van Truyen reported that, since 1955, traditional medicine has played a formal role in Viet Nam. This has involved the re-establishment of traditional medicine as a component of public health care, the establishment of an appropriate network from central government to the local level, the training of traditional medical personnel, and the introduction of a programme of scientific research and international cooperation. A number of laws have been passed on the regulation of practitioners and medicines. The Vietnamese pharmacopoeia, which was compiled in the 1970s, is now being rewritten to include herbal medicine monographs.

However, despite these efforts, some problems still exist. There are two colleges in Viet Nam specializing in training personnel in traditional medicine, but the system of training needs reorganization. Nineteen out of 63 provinces are without traditional medicine hospitals and many other hospitals do not have traditional medicine departments. The demand for this form of medical care cannot currently be met. Presently, 30% of all patients are being treated by traditional medicine and an estimated 50% of the population want to be treated by traditional medicine.

2.3 Principles and format for the development of the guidelines

Dr Chen Ken led the Working Group discussion by clarifying the purposes of the guidelines and the context of their development. One role of WHO is to provide technical advice to Member States. Furthermore, WHO has already received requests from Member States for support in this area. In the context of herbal medicine practice, Member States generally face one of three difficulties: a lack of awareness within government of the role of herbal medicines; a gap between government interest and significant support; or, finally, a lack of relevant expertise in dealing with herbal medicines.

Many different countries and regional jurisdictions are grappling with a range of issues related to the practice of herbal medicine, its widespread and increasing usage and how best to ensure it is delivered safely and effectively to consumers. Preparing informed guidelines on the appropriate use of herbal medicine will support all nations in developing an appropriate national programme which reflects their specific requirements and cultural context. The guidelines are designed to act as foundation principles for all interested countries and jurisdictions.

These guidelines are designed to assist government determine policy and practice in herbal medicine. A series of principles for the formation of the guidelines emerged during discussion. These include that the guidelines:

- promote the practice and development of the appropriate use of herbal medicines;
- represent a set of generic principles able to be flexibly implemented by different jurisdictions according to their domestic contexts;
- are able to meet the needs and different situations of countries in the Region;

- support the harmonization of the promotion, management and regulation of herbal medicine without making significant impositions on individual countries;
- respect traditional knowledge in the formation of these guidelines;
- facilitate communication and information exchange between Member States, including the development of bilateral and regional cooperation;
- act as a reference point for government and health authorities; and
- may be used by manufacturers, researchers, academics and practitioners.

The Working Group was then organized into two discussion groups. The focus of the first discussion group was to develop draft guidelines on national policy and programme formation, and the regulation of herbal medicine practitioners. The second discussion group focused on issues related to the management and regulation of herbal medicines. These groups met independently for one and a half days each and developed draft guidelines which were then debated more comprehensively in plenary sessions.

2.4 Discussions on national policy and programme development

Discussion group members agreed unanimously that the formation of a national policy and programme for herbal medicine is a critical first step in giving support to and promoting the use of herbal medicine. A national policy will support the implementation of the practice of herbal medicine into the health care services of the country. It will also aid in the national and international coordination of regulatory structures, the establishment of suitable research

programmes and the ability to undertake effective international collaboration.

2.5 Discussions on regulation of herbal medicines

The second discussion group focused on issues related to the regulation of herbal medicines. The group acknowledged that some form of regulation was required of manufacturers and distributors in that their products may be used widely by consumers. However, Good Manufacturing Practice (GMP) may not be able to be implemented in some developing nations that are heavily reliant on herbal medicines. The group agreed that phased implementation of regulatory requirements was important. The appropriate training of staff involved in regulatory matters was also raised and discussed. The WHO certification scheme on the quality of pharmaceutical products was identified as a scheme that may be of help in small countries where there are no facilities or mechanisms for the systematic evaluation of the safety of herbal products.

During the one and a half days of discussion that followed, a number of areas were considered and debated, including:

- the distinct regulatory requirements for raw plant materials, processed plant materials, and medicinal herbal products;
- marketing, labelling and advertising issues;
- regulatory measures consistent with the conservation of species;
- general aspects of safety assessment (toxicity studies, safety based on experience);
- general aspects of assessment of efficacy and intended usage; and
- monitoring of adverse reactions to herbal medicines.

2.6 Final discussion on the guidelines

After one and a half days of group discussion, the Working Group resumed activity in a plenary session, providing opportunity for further discussion. One of the principal concerns was the way in which guidelines may be interpreted by regulatory authorities. The Working Group, while wishing to provide some direction on the kind of safety data that may be required of some herbal medicines, did not wish this to result in significant impositions for some countries who might have substantial difficulties in implementing stringent regulatory measures. Furthermore, there was a strong feeling among some members of the Working Group that regulatory guidelines with long lists of potential data requirements may inappropriately encourage regulatory authorities to require more rather than less. This may overlook the fact that herbal medicines by definition have been used extensively and over long periods of time and that some modifications, such as dosage forms or indications, may not fundamentally affect the herb's safety. The history of use of a substance should in most cases be adequate evidence of its basic safety.

The regulation of practitioners was discussed at some length and it was agreed that only limited review of this area would be provided in the guidelines. Forms of professional regulation vary significantly within and between nations, reflecting the varying legislative structures, and the Working Group deemed it appropriate only to make general recommendations in this regard.

2.7 Closing ceremony

In his closing remarks, Dr S.T. Han, Regional Director of the WHO Regional Office for the Western Pacific, stated that he accepted the recommendations of the expert Working Group and that he would ask his operational staff to prepare a plan for their implementation. He commented that he was most impressed by the focused and detailed discussions and the productiveness of the Working Group

in developing the guidelines. Dr Han communicated his reservations, however, that imposing GMP on the herbal medicines industry, particularly in developing countries, may not at this stage be a realistic goal. Each country will need to determine the appropriate times for the implementation of various parts of the guidelines. Dr Han expressed confidence that the final guidelines accurately reflected the substantial expertise contained within the membership of the Working Group.

Dr S.T. Han's closing remarks is attached as Annex 5.

On behalf of all participants, Dr Wong acknowledged the effort and support of the WHO Regional Office for the Western Pacific in holding the Working Group meeting and thanked all temporary advisers and the two consultants for their continued efforts throughout the week in devising the final guidelines based on the discussions of the Working Group.

3. Conclusions and recommendations

3.1 Conclusions

The Working Group recognizes the significant growth that has occurred in the use of herbal medicines in the Region and the major health care role they play in many countries. Major advances have also occurred in research on herbal medicines, confirming their value and significant contribution to health care services. Their increasing use also raises the need for appropriate monitoring and evaluation of herbal medicines.

The Working Group recognizes that the work of WHO is important in providing direct guidance and support to countries and areas in the development of national herbal medicine policies and programmes. WHO can continue to make a major contribution to public health through supporting the development of policies that generate better access to quality herbal medicines.

The Working Group recommends that the WHO Regional Office for the Western Pacific continues to develop, expand and adjust as necessary the technical, managerial and administrative tools needed for the formulation and implementation of national herbal medicine policies in accordance with these proposed guidelines. It further recommends that WHO continues to strengthen its support to countries in developing and implementing national herbal medicine policies.

It is highly desirable that the WHO Regional Office for the Western Pacific plays a role in stimulating collaboration among Member States for purposes such as general information exchange, standardizing nomenclatures, and sharing research knowledge and experience.

These guidelines, which were formally adopted by the Working Group, represent a milestone in that they signal a common direction for the appropriate use of herbal medicines that, in turn, can be either adopted or adapted by Member States in the Region.

One immediate outcome of this Working Group meeting is that the Working Group volunteers to form an informal network to facilitate information exchange on herbal medicines and to collaborate in other areas with a view to expanding the networking as appropriate. This reflects the priority given by members of the Working Group to these issues.

3.2 Recommendations

The Working Group's main recommendations are reflected in the Guidelines for the Appropriate Use of Herbal Medicines. In addition, the members of the Working Group provide the following recommendations which are focused on the implementation of the Guidelines:

- (1) **WHO should promote the use of the Guidelines for the Appropriate Use of Herbal Medicines among Member States by:**
 - reporting the contents of these Guidelines to Member States;
 - helping Member States to organize training courses, seminars and national workshops on the appropriate use of herbal medicines;
 - helping Member States to set up an action plan for the development of a national policy on the appropriate use of herbal medicines; and
 - encouraging Member States to translate the Guidelines into national official languages.
- (2) **Member States should be urged to develop national policies and programmes to promote the appropriate use of herbal medicines as part of the national health care services. WHO Guidelines for the Appropriate Use of Herbal Medicines could be used as a basis for developing a national policy and programme on herbal medicines. As an initial step, each Member State should assess the need and extent of regulatory mechanisms required to promote safe and effective use of herbal medicines. Attention should be directed to the regulation of herbal medicine practitioners and related workers, regulatory provisions related to manufacturing and distribution, and evaluation mechanisms for herbal medicines.**
- (3) **A collaborative framework among countries and areas in the Region to support the appropriate use of herbal medicines should be established. The framework should include mechanisms to facilitate the exchange of information, the preparation of monographs on medicinal plants and the development of training and education resources and**

programmes. The WHO Regional Office for the Western Pacific should coordinate the development of the collaborative framework. To facilitate this activity, Member States should advise WHO of:

- progress on implementation of their national policies and provide copies to WHO for distribution, including regulating structures that have been adopted;
- proposals to develop resources, such as monographs and training programmes and provide to WHO copies of these resources; and
- adverse effects or particular problems which may be of importance or interest to Member States.

The WHO Collaborating Centres for Traditional Medicine and other interested institutions could play an active role in supporting the coordinating activities of WHO. Members of the Working Group will form an informal network to facilitate information exchange and collaboration on herbal medicine matters among them and to support WHO programme activities in the area of herbal medicines.

- (4) Medicinal plants represent valuable natural resources. There is an increasing concern surrounding the issue of endangered species of plants with significant therapeutic benefits. Member States are therefore urged to:

- document endangered species in their countries;
- develop a sustainable conservation plan which may include ex-situ, in-situ and on-farm conservation, natural parks, botanical gardens, and seed banks for medicinal plants; and

implement appropriate regulation for the sustainable development and management of these endangered species.

- (5) In consultation with indigenous people and with their involvement, Member States should actively encourage.
- the identification of indigenous plants with significant therapeutic activity;
 - research into their safety and efficacy; and
 - applied research on their use.

The private sector and industry should be encouraged to participate in these efforts.

- (6) The Working Group notes the recommendations made by the WHO Working Group on the Safety and Efficacy of Herbal Medicines in 1992 encouraging research on herbal medicine. The Working Group reaffirms these recommendations and encourages WHO and Member States to maintain their efforts in promoting scientific research on herbal medicine.
- (7) It is noted that several computer databases on medicinal plants and herbal medicines are available and a new database on toxicity of herbal medicines will be developed. An active programme of promotion and education should be developed to ensure that existing databases are used and information from these databases is disseminated.

ANNEX 2

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ANNEX 3

AGENDA

1. Opening ceremony
2. Herbal medicines in the Western Pacific Region and the WHO programme on herbal medicines
3. Regulation of herbal medicine - a regional review
4. A review of herbal medicine research in the Region
5. Country reports
6. Introduction: Preparation of guidelines for the appropriate use of herbal medicine
7. Discussion: Principles and format for the development of guidelines
8. Group I discussion: National policy and programme development (including utilization, research, education and other programme areas)
9. Group II discussion: Regulation and registration of herbal medicine
10. Plenary session: Reports and comments on group discussions
11. Group preparation of draft guidelines
12. Plenary session: Presentation and discussions on the draft guidelines prepared by the groups
13. Discussion: Recommendations of the Working Group

14. **Final discussions on the guidelines**
15. **Adoption of guidelines**
16. **Final discussions on the recommendations of the Working Group**
17. **Adoption of the recommendations of the Working Group**
18. **Closing ceremony**

14. **Final discussions on the guidelines**
15. **Adoption of guidelines**
16. **Final discussions on the recommendations of the Working Group**
17. **Adoption of the recommendations of the Working Group**
18. **Closing ceremony**

ANNEX 4

OPENING SPEECH OF DR S.T. HAN, WHO REGIONAL DIRECTOR FOR THE WESTERN PACIFIC REGION WORKING GROUP ON HERBAL MEDICINES 8 December 1997, Manila, Philippines

DISTINGUISHED PARTICIPANTS, COLLEAGUES, LADIES
AND GENTLEMEN,

I am very pleased to welcome you all to this meeting.

Herbal medicine is the main component of the traditional system of medicine. It has been used for thousands of years and has made a significant contribution to human health. Today, people still attach considerable importance to herbal medicine, particularly in this Region.

For its part, WHO recognizes the very significant contribution which traditional medicine can make to public health in the Region. We fully support Member States in their efforts to integrate traditional medicine into their health delivery systems, particularly in extending the coverage of primary health care.

Accurate figures on regional expenditure on herbal medicine are not available. However, in Australia for example, expenditure on alternative medicine, including herbal medicine, is estimated at about US\$438 million annually. In China, herbal medicine represents about one-third of the drug market. In Hong Kong, herbal medicines worth over US\$260 million are imported annually and over 900

raw and processed herbal medicines are generally available in herbal shops. In Malaysia, sales of traditional medicines are estimated at about US\$315 million annually.

Herbal medicine holds great but still largely unexplored potential for the development of new drugs to combat major health problems. Artemisinin and its derivatives, for example, extracted from *Artemisia annua*, have become the most effective remedy for multi-drug-resistant malaria cases.

In China, Japan, the Republic of Korea and Viet Nam, the use of herbal medicine is an integral part of the formal health service system. In other countries, herbal medicine is usually used only in the community or in private practice. However, increasing public interest, as demonstrated by herbal medicine's share of the drug market, has raised government awareness in the Region. Health authorities in several countries and areas are reviewing the current status of herbal medicine and the possibility of bringing it into the mainstream of the health service.

Mechanisms for ensuring the safety and control of herbal medicine need to be introduced as part of its formal incorporation into the health service system. In Australia, Macao and Malaysia, for example, systems for the registration of herbal medicine products have been implemented. The regulation of the use of herbal medicine in medical practice is being considered in Australia, Hong Kong, Malaysia and Singapore.

Recognition of the value of herbal medicine is not always accompanied by strong support and the development of vigorous programmes at national level and below. Implementation of government policy is often slowed down by the lack of experience of health authorities. The different philosophical backgrounds of traditional and modern medicine make it difficult for one system to judge the other. Despite these difficulties, there have recently been some significant developments regarding the promotion of traditional medicine in the Region. For example, the meeting of the Ministers of Health of the Pacific island countries in Rarotonga in August 1997 agreed that the use of traditional medicine, including

herbal medicine, should be encouraged where appropriate, and steps should be taken to incorporate its use in the health care system. At the forty-eighth session of the WHO Regional Committee for the Western Pacific it was decided that a technical briefing on traditional medicine should be included during the forty-ninth session of the Regional Committee in 1998.

The major task of this Working Group is to prepare guidelines for the appropriate use of herbal medicine. These guidelines will include technical suggestions for Member States interested in promoting the proper use of herbal medicine. They will include recommendations on how to develop a comprehensive national programme, regulate the practice of herbal medicines and introduce measures for registration. Guidelines on education and research and information exchange will also be prepared.

There is no single model for promoting the proper use of herbal medicine. The guidelines you recommend should be flexible enough to provide various options to Member States to enable them to identify the most appropriate approach to suit their own needs. The guidelines you provide should be both feasible and practical.

I am fully aware that it will not be an easy task to prepare such guidelines. This will be a challenge to all of you. The Working Group is a good mixture of policy-makers, administrators, researchers and practitioners. With your broad experience of herbal medicine, I am sure that you will be able to provide extremely valuable recommendations for further steps to promote the proper use of herbal medicine in the Region. I look forward very much to hearing the outcome of your deliberations.

I like to inform you that the meeting is held with support from the Republic of Korea Government.

I wish you a successful and fruitful meeting and an enjoyable stay in Manila.

ANNEX 5

CLOSING REMARKS OF DR S.T. HAN, WHO REGIONAL DIRECTOR FOR THE WESTERN PACIFIC WORKING GROUP ON HERBAL MEDICINES 12 December 1997, Manila, Philippines

THANK YOU MR CHAIRMAN AND DISTINGUISHED DELEGATES,

Traditional medicine, including herbal medicine, is a very important area that may need to be more exploited in future. The Western Pacific Region has established a lead in the theory and practice of herbal medicine and we intend to consolidate it. For example, only two days ago in the Philippines, the President signed the alternative medicine act, "R.A. 8423 - an act creating the Philippine Institute of Traditional and Alternative Health Care to accelerate the development of traditional and alternative health care in the Philippines, providing for a traditional and alternative health care development fund and for other purposes". This working group is a good example of how seriously traditional medicine is taken in the Region. In fact, I think this was one of the liveliest and most productive meetings we have ever held in the Regional Office, and I congratulate you for that.

Although I can assure you that we shall continue to pay serious attention to traditional medicine, I do not think we should attempt to cover all aspects. I would like to focus our efforts on two areas: medicinal plants or herbal medicine and acupuncture. We have

already been very active in these two areas. For example, I have just signed the preface of *Medicinal plants in the Republic of Korea*, which will be published next year. This is the fourth in a series of books. *Medicinal plants in China* and *Medicinal plants in Viet Nam* have already been published and *Medicinal plants in the South Pacific* is being printed.

During your discussions you have discussed policy development with regard to herbal medicine. You have drawn up some draft guidelines for Member States which I think are excellent, as good if not better than those governing pharmaceutical management in Western medicine. Of course these are guidelines and it is up to governments whether they adopt or adapt them, according to their needs. For example, I am a little concerned that some countries may not be able to implement GMP, good manufacturing practice, in herbal medicine when they already have problems implementing GMP with regard to Western medicine. Nevertheless, I think the guidelines are very important because they enable Member States to see what can be done at the national level. Here at WHO we shall do our best to implement those parts of the guidelines that relate to the work of WHO.

Please allow me to make some specific points about the guidelines. First of all, let me assure you that they will be widely disseminated and that we shall be promoting their use. Second, using these guidelines I shall try to ensure that all countries will be able to develop their own national policies and programmes in the field of herbal medicine. Third, I would like to emphasize the importance of the networking aspect, in particular making use of collaborating centres within and outside the Region. This is in conformity with one of the 47 recommendations made to the Executive Board with regard to reforming the work of WHO. This recommendation advocated that greater use be made of WHO collaborating centres. Fourth, the issue of endangered species was mentioned frequently in your discussions. I think we have to preserve as many species of plants as possible. Fifth, we need better databases, they should be expanded and the information they contain analysed closely. In particular, databases should record

not only the beneficial effects and availability of herbal medicinal plants but also the toxicity and adverse effects of certain herbal medicines.

With regard to following-up this meeting, I would like to suggest that the next meeting on this subject be held in about three years. We have to give Member States time to implement the recommendations. If we are to have a meeting annually, we shall simply repeat what was said at this meeting.

In closing, let me thank you Mr Chairman and also the Vice-Chairman and two rapporteurs who must have worked very hard to write these excellent guidelines. I would like to thank the temporary advisers and others who have also guided or helped guide the meeting, especially Professor Il-Moo Chang and Mr Alan Bensoussan.

With these few words, I would like to wish you a pleasant journey back home. I am sure we shall meet again sometime in the future. Thank you very much.

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