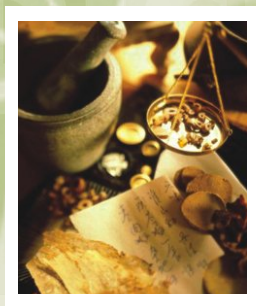


GUIDELINES  
FOR THE  
REGULATION  
OF  
HERBAL  
MEDICINES  
IN THE SOUTH-EAST  
ASIA  
REGION



Guidelines for the regulation  
of herbal medicines  
in the South-East Asia Region



World Health Organization  
Regional Office for South-East Asia  
New Delhi

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# Guidelines for the Regulation of Herbal Medicines in the South-East Asia Region

Developed at the Regional Workshop on  
the Regulation of Herbal Medicines  
Bangkok, 24-26 June 2003



World Health Organization  
Regional Office for South-East Asia  
New Delhi

### Acknowledgements

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This document will not only be used by countries in the SEA Region to positively impact the population, but will also prove to be beneficial to other regions and countries by serving as a reference to facilitate setting up requirements for registration and regulation of herbal medicines.

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# Acronyms and Abbreviations

ADR	Adverse Drug Reaction
CAM	Complementary and Alternative Medicine
GACP	Good Agricultural and Collection Practices
GC	Gas Chromatography
GC-MS	Gas Chromatography-Mass Spectrometry
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
HPLC	High-performance Liquid Chromatography
SEARO	WHO Regional Office for South-East Asia
TLC	Thin Layer Chromatography
TM	Traditional Medicine

# Preface

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Traditional medicine and complementary/alternative medicine (TM/CAM) have been used, through the ages, in all countries of the WHO South-East Asia Region (SEAR). Many countries in this Region have extensive systems of TM within existing health services. In the rural areas of countries such as India, Indonesia, Nepal and Sri Lanka, a large proportion of the population use traditional medicines to meet their primary health care needs. Due to this long history, the roles of TM and its practitioners have been recognized by the governments in this Region, with national policies and regulations on TM being implemented in many of these countries.

Governments in the South-East Asia Region are encouraging medical doctors to work with traditional practitioners at the hospital level, and to support research on TM. For example, in India there are 2860 hospitals providing Ayurvedic medicines. In Bhutan, in the national health centre, patients can receive both conventional and TM treatments based on their needs. Among the 11 Member States in SEAR, there are five with national research institutes of TM.

Used as self-care or as an alternative form of treatment to conventional medicines, there is a large market and demand for medicinal plants and herbal products. Many countries in SEAR need expertise and guidance to develop national regulations and safety monitoring systems. According to the WHO global survey on the national policy and regulation of TM, there are three common difficulties and challenges: lack of information sharing; lack of safety monitoring for herbal medicines; and lack of methods to evaluate their safety and efficacy.

To address the above-mentioned needs and the WHO Regional Office for South-East Asia organized a regional workshop on the 'Regulation of Herbal Medicines' at Bangkok on 24–26 June 2003. The workshop was attended by 24 participants from the national drug authorities of 10 countries and 2 observers each from 9 of the 11 Member Countries of SEAR. Dr Xiaorui Zhang, Coordinator of Traditional Medicine at WHO/HQ and Dr K. Weerasuriya, Regional Adviser, Essential Drugs and Medicines Policy, SEARO also attended the workshop

To support Member States in renewing or updating their regulations on traditional medicines, and to meet technical requirements for evaluating the safety, efficacy and quality control of herbal medicines, these Regional Guidelines for the Regulation of Herbal Medicines in the South-East Asia Region were developed.



# 1. Objectives

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The objective of these guidelines is to propose to Member States a framework for facilitating the regulation of herbal medicines/products used in traditional medicine (TM). The proposed framework, which has a regional perspective, should help accelerate the establishment of appropriate mechanisms for registration and regulation of herbal medicines within SEAR, based on criteria for safety of use, therapeutic efficacy, quality control and pharmacovigilance. Traditional medicine involves not only the use of herbal medicines, but also use of animal parts and minerals. As herbal medicines are the most widely used of the three, and as the other types of materials involve other complex factors, this document will concentrate on herbal medicines.

## 1.1 General objective

This document aims to facilitate the registration and regulation of herbal medicines by establishing the foundation for a harmonized regulatory standard to meet the common demands of the Region.

## 1.2 Specific objectives

- To propose a classification for herbal medicines;
- To propose regulatory requirements for the registration of each category of herbal medicines;
- To set up minimum requirements for registration and regulation of herbal medicines.



## 2. Classification of herbal medicines

For practical purposes, herbal medicines can be classified into four categories, based on their origin, evolution and the forms of current usage. While these are not always mutually exclusive, these categories have sufficient distinguishing features for a constructive examination of the ways in which safety, efficacy and quality can be determined and improved.

### Category 1: Indigenous herbal medicines

This category of herbal medicines is historically used in a local community or region and is very well known through long usage by the local population in terms of its composition, treatment and dosage. Detailed information on this category of TM, which also includes folk medicines, may or may not be available. It can be used freely by the local community or in the local region.

However, if the medicines in this category enter the market or go beyond the local community or region in the country, they have to meet the requirements of safety and efficacy laid down in the national regulations for herbal medicines.

### Category 2: Herbal medicines in systems

Medicines in this category have been used for a long time and are documented with their special theories and concepts, and accepted by the countries. For example, Ayurveda, Unani and Siddha would fall into this category of TM.

### Category 3: Modified herbal medicines

These are herbal medicines as described above in categories 1 and 2, except that they have been modified in some way—either shape, or form including dose, dosage form, mode of administration, herbal medicinal ingredients, methods of preparation and medical indications. They have to meet the national regulatory requirements of safety and efficacy of herbal medicines.

### Category 4: Imported products with a herbal medicine base

This category covers all imported herbal medicines including raw materials and products. Imported herbal medicines must be registered and marketed in the countries of origin. The safety and efficacy data have to be submitted to the national authority of the importing country and need to meet the requirements of safety and efficacy of regulation of herbal medicines in the recipient country.



## 3. Minimum requirements for assessment of safety of herbal medicines \_\_\_\_\_■

### 3.1 Safety category

A drug is defined as being safe if it causes no known or potential harm to users. There are three categories of safety that need to be considered, as these would dictate the nature of the safety requirements that would have to be ensured.

- Category 1: safety established by use over long time
- Category 2: safe under specific conditions of use (such herbal medicines should preferably be covered by well-established documentation)
- Category 3: herbal medicines of uncertain safety (the safety data required for this class of drugs will be identical to that of any new substance)

Data will be required on the following:

- Acute toxicity
- Long-term toxicity

Data may also be necessary on the following:

- Organ-targeted toxicity
- Immunotoxicity
- Embryo/fetal and prenatal toxicity
- Mutagenicity/genotoxicity
- Carcinogenicity

### 3.2 General considerations for assessment of safety of herbal medicines

Any assessment of herbal medicines must be based on unambiguous identification and characterization of the constituents. A literature search must be performed. This should include the general literature such as handbooks specific to the individual form of therapy, modern handbooks on phytotherapy, phytochemistry and pharmacognosy, articles published in scientific journals, official monographs such as WHO monographs, national monographs and other authoritative data related to herbal medicines and, if available, database searches

in online or offline databases, e.g. WHO adverse drug reaction database, National Library of Medicine's Medline, etc. The searches should not only focus on the specific herbal medicinal preparation, but should include different parts of the plant, related plant species and information originating from chemotaxonomy. Toxicological information on single ingredients should be assessed for its relevance to the herbal medicines.

### 3.2.1 Specific requirements for assessment of safety of four categories of herbal medicines

Before any category of herbal medicine listed above is introduced into the market, the relevant safety category needs to be reviewed and the required safety data obtained, based on that particular safety category.

#### Category 1: Indigenous herbal medicines

These can be used freely by the local community or region, and no safety data would be required. However, if the medicines in this category are introduced into the market or moved beyond the local community or region, their safety has to be reviewed by the established national drug control agency.

If the medicines belong to safety category 1, safety data are not needed. If the medicines belong to safety category 2, they have to meet the usual requirements for safety of herbal medicines. Medicines belonging to safety category 3, i.e. 'herbal medicines of uncertain safety', will be identical to that of any new substance.

#### Category 2: Herbal medicines in systems

The medicines in this category have been used for a long time and have been officially documented. Review of the safety category is necessary. If the medicines are in safety categories 1 or 2, safety data would not be needed. If the medicines belong to safety category 3, they have to meet the requirements for safety of 'herbal medicines of uncertain safety'.

#### Category 3: Modified herbal medicines

The medicines in this category can be modified in any way including dose, dosage form, mode of administration, herbal medicinal ingredients, methods of preparation, or medical indications based on categories 1 and 2. The medicines have to meet the requirements of safety of herbal medicines or requirements for the safety of 'herbal medicines of uncertain safety', depending on the modification.

#### Category 4. Imported/exported products with a herbal medicine base

Exported products shall require safety data, which have to meet the requirements for safety of herbal medicines or requirements for safety of 'herbal medicines of uncertain safety', depending on the safety requirement of the importing/recipient countries.

### 3.3 Literature review of herbal medicines

Member States in the South-East Asia Region should share information from reliable sources. In assessing these bibliographic data, particular attention should be paid to the following aspects:

- The characteristics and type of preparation described in the literature: Does the literature refer to the same herbal preparation? Can the data be extrapolated?
- The extent of time and use of the herbal medicines: Can the use have generated sufficient experience on safety? Is it plausible that the risks would have been recognized empirically?

The need for additional data or new tests should be considered in the light of the information requirements for new substances. Many of the tests required for new substances may be replaced by documented experience. However, it should be carefully considered if all the questions on toxicology raised for new substances could be answered sufficiently and in a plausible way by the available general knowledge. A specific focus should be given to effects that cannot be detected or are very difficult to detect empirically, e.g. genotoxicity.

The assessment should determine if there is sufficient information to guarantee safe use in vulnerable populations, such as pregnant or lactating women, and in children. For the assessment of safety in pregnancy, information on misuse, e.g. as an agent to induce abortion, should be assessed.

# 4. Minimum requirements for assessment of the efficacy of herbal medicines

## 4.1 Claims categories

### Disease

- Acute disease: Diseases that have a rapid onset and a relatively short duration.
- Chronic disease: Diseases that have a slow onset and last for long periods of time. Diseases of acute onset could also progress to a chronic state.

In most cases, severe diseases refer to a life-threatening illness or those diseases in which delayed treatment will lead to deterioration of the disease state or loss of capability to cure them. For example, severe cardiovascular, gastrointestinal, endocrine, haematological diseases, and immune disorders and diseases fall into this group.

- Health condition: Problems related to health conditions are those which, with time, could recover spontaneously, even without any medical intervention, e.g. loss of appetite, hay fever, menopause, etc. The efficacy for this category could be supported by data in existing well-established documents such as national pharmacopoeia and monographs as well as other authoritative documents such as WHO monographs. Pre-clinical and clinical data of efficacy may not be necessary.

Table 1. Summary of the efficacy data requirements for the three types of disease and conditions

Type of disease	Pre-clinical data of efficacy	Clinical data of efficacy	Other data or information required
Acute	Needed	Control trial needed	
Chronic	May be needed	Clinical data may or may not be needed	
Health condition	May not be needed	May not be needed	Supported by well-established documents such as national pharmacopoeia and monographs

Table 2. Requirements data for the evaluation of efficacy of traditionally used herbal medicines with limited modifications

Traditionally used herbal medicines with well-established documentation		Pre-clinical data of efficacy	Clinical data of efficacy	
No change based on traditional use		Not needed	May not be needed	
Changes	Dose	May be needed	Needed	
	Dosage form	May be needed	Needed	
	Mode of administration	May or may not be needed	Needed	
	Medical indication	Needed	Needed	
	Herbal medicinal ingredients	Addition	Needed	Needed
		Deletion	May or may not be needed	May or may not be needed
		New combination	Needed	Needed
	Part of medicinal plant used	Needed	Needed	
Methods of preparation	Needed	Needed		

## 4.2 Explanation of terms used in tables

General efficacy data requirements are given in Table 1. The herbal medicines that are used with well-established documents, but with changes in medical indication, dosage form, mode of administration, clinical and pre-clinical efficacy data are given in Table 2. The efficacy should be proven by clinical trials or well established documentation. If the changes will modify the pharmacodynamics, pre-clinical studies are needed. The following are terms related to the tables:

- Pre-clinical data: These include efficacy of laboratory test and data regarding the standard dose and dosage form;
- Clinical data of efficacy: This refers to 'clinical research' in WHO General Guidelines for Methodologies on Research and Evaluation of Herbal Medicines;
- Addition: This means the addition of one or more plants or ingredients into traditionally used formulas;
- Deletion: This refers to the deletion of one or more plants or ingredients from traditionally used formulas;
- New combination: Two or more traditionally used formulas are put together.

### 4.3 Minimum requirements for assessment of the efficacy of herbal medicines

- The assessment of efficacy for herbal medicines in categories 1 and 2 are not required if they are used locally;
- For medicines in category 3, pre-clinical data and clinical data may or may not be required depending on the modification(s), which are given in Table 2;
- For medicines in category 4, efficacy data are required.

# 5. Quality assurance of herbal medicinal products

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Quality assurance of herbal medicinal products is the shared responsibility of manufacturers and regulatory bodies. National drug regulatory authorities have to establish guidelines on all elements of quality assurance, evaluate dossiers and data submitted by the producers, and check post-marketing compliance of products with the specifications set out by the producers as well as compliance with Good Manufacturing Practices (GMP).

The manufacturers have to adhere to Good Agricultural and Collection Practices (GACP), GMP and Good Laboratory Practice (GLP) standards, establish appropriate specifications for their products, intermediates and starting materials and compile a well-structured, comprehensive documentation on pharmaceutical development and testing. The producers should make continued efforts to improve standards and adapt them to the present state of knowledge. A cooperative approach between different manufacturers, e.g. by establishing drug master-files for specifications and quality control, should be encouraged.

## 5.1 Coordinating quality control

A coordinating agency on GACP should be established to facilitate the availability of good-quality herbal medicines to the market by giving training and advice to small producers and farmers. To encourage implementation of GACP, incentives should be given to producers of botanical raw materials. These include giving technical and logistic support in the selection of appropriate sites for agricultural production, providing seeds and seedlings, selecting fertilizers and pesticides, providing or giving advice on machinery for harvesting and primary processing. The government should honour efforts by issuing certificates to producers and farmers who adhere to the GACP, based on the country situation. Implementation of such requirements is only possible if the production and marketing of herbal medicines is subject to an adequate registration scheme by a drug regulatory authority.

## 5.2 Quality assurance

Elements of quality assurance are:

- adherence to GACP, GMP and GLP guidelines;
- setting specifications; and
- quality control measures.

## 5.3 Quality control for herbal medicinal products

All herbal-based medicinal products should meet the requirements for safety, efficacy and quality, as per the Categories of Herbal Medicines (see the section on Minimum requirements for assessment of safety of herbal medicines).

All imported herbal medicinal products need to meet the requirements for safety, efficacy and quality control regulations in the importing countries. To control the quality of imported herbal medicinal products, the following requirements should be taken into consideration.

### 5.3.1 Licensing authority

Licensing for importers, wholesalers, manufacturers and assemblers of herbal medicinal products should be issued by the national drug regulatory authority. Dealers of imported herbal medicinal products need to apply for one or more of the licences depending on the type of business involved, such as licence of importers, wholesalers, manufacturers and assemblers.

### 5.3.2 Import licence

The responsibility of applying for an import licence shall rest with local companies which are approved by the licensing authority to import herbal medicinal products and sell them in the importing countries.

The following information related to the importing company is required for the application of an import licence:

- Particulars of the company;
- Particulars of the person making the application on behalf of the company;
- Certificate of company/business registration;
- Layout plan of the store.

Importers are required to provide information on each imported herbal medicinal product they deal with, and will be allowed to deal in approved products only. Detailed requirements for each imported herbal medicinal product are as follows:

- Full product formula (in the languages of the importing and exporting countries);
- A set containing labels, pamphlet, carton and specimen sales pack (in the languages of the importing and exporting countries, if necessary);
- Particulars of manufacturer(s) and assembler(s);



- Manufacturer's licence or certificate from the drug regulatory authority of the manufacturing country of origin. Pre-export Notification and Certificate of Free Sale of the herbal medicinal product should be obtained from the concerned authority.

Based on the above-mentioned minimum requirements, each national drug regulatory authority could develop its own requirements for quality control of imported herbal medicinal products.

## 5.4 Guidelines related to Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP)

The coordinating agency should adhere to the principles set out in the WHO Guidelines on Good Agricultural and Collection Practices for Medicinal Plants (for GACP) and manufacturers and assemblers should follow WHO Good Manufacturing Practices (for GMP). Manufacturers of herbal medicines should obtain a licence and register their products. The quality control system for production should be in place. The implementation of a credible concept of quality assurance, e.g. identifying and eliminating potential sources of contamination, should be a primary goal of the manufacturers rather than the implementation of all individual technical aspects.

The following areas should be considered while studying the WHO guidelines:

- Control of raw materials (refer to the GACP and Quality Control Methods for Medicinal Plant Products);
- Control of starting materials and intermediate substances;
- In-process control (Standard Operating Procedure for Processing Methods should be mentioned);
- Finished product control (It should be performed with reference to the control of raw materials, starting materials and intermediate substances).

## 5.5 Guidelines related to quality control

The purpose of quality control is to ensure quality of the products by adhering to appropriate specifications and standards. Information on appropriate standards can be found in official pharmacopoeias, monographs, handbooks, etc.

In choosing analytical methods, the availability, robustness and validity of the methods must be considered, such as microscopic identification, thin layer chromatography (TLC), titration of active substance and, if possible, a full validation of more sophisticated methods,



such as high-performance liquid chromatography (HPLC), gas chromatography (GC), and gas chromatography-mass spectrometry (GC-MS). If such advanced methods are used, a full validation for each test would be necessary.

## 5.6 Product information for registration

This should include all necessary information on the proper use of the product. The detailed information of the herbal medicinal products should include the following requirements for registration:

- Quantitative list of ingredients; if this is difficult, it could be replaced by including the plant names and plant parts used (i.e. Latin name);
- Full product formula for imported herbal-based medicinal products (in the language of the importing and exporting countries);
- A set containing labels, pamphlet, carton and specimen sales pack;
- Particulars of manufacturer(s) and assembler(s);
- Manufacturer's licence or certificate from the drug regulatory authority. Pre-export notification and Certificate of Free Sale of the herbal-based medicinal product should be obtained from the concerned authority;
- Brand name of product;
- Dosage form;
- Indications;
- Dosage;
- Mode of administration;
- Duration of use;
- Adverse effects, if any;
- Contraindications, warnings, precautions and major drug interactions, if possible;
- Date of manufacture;
- Expiry date of product;
- Lot/Batch number;
- Storage condition.

## 6. Pharmacovigilance of herbal medicinal products

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Of the 11 Member Countries in the South-East Asia Region, there are only four with national systems for monitoring the safety of traditional medicinal products. There is an urgent need, therefore, to set up national systems for monitoring the safety of medicinal products in the Region. The national system for monitoring safety of medicinal products should include herbal medicinal products in the scope of its activities.

The national government needs to strengthen capacity building in setting up and running such systems through training programmes etc. While developing a national programme to monitor the safety of medicinal products, care should be taken to ensure that this will include:

- Establishing a national pharmacovigilance centre for monitoring the safety of medicinal products including herbal medicinal products;
- Training staff who will be included in the reporting system;
- Setting up necessary equipment;
- Developing the reporting forms;
- Setting up a multidisciplinary advisory committee to review and analyse the collected data.

### 6.1 Adverse drug reaction report

Pharmacovigilance units or national pharmacovigilance centres are necessary to collect and assess information on adverse drug reaction (ADR) relating to medicinal products including herbal medicines. Where such units/centres exist, they should include herbal medicines in the current scope of their activities.

Each ADR report should be evaluated and assessed on the causality with the suspected herbal medicines. Health professionals should be encouraged to ask their patients about the use of herbal products and herbal medicines, including 'medicinal foods/health food/dietary supplement' and any other medicines, and to include information on concomitant use in their ADR.

Each herbal medicine should be clearly identified by its constituents, brand name (if applicable) and dosage. If such information is missing in the ADR, the pharmacovigilance unit/centre should immediately try to gather complete information, e.g. by asking the reporting health professional. To avoid the missing vital information, national drug regulation on herbal

medicines and herbal medicines should include all the necessary information on registered herbal medicinal products and an ADR reporting form.

In analysing ADR reports the following aspects should be considered:

- (1) A literature search on the herbal product, its constituents and any co-medication should be performed;
- (2) The time–ADR relationship must be assessed:
  - When did the ADR occur?
  - Did the symptom occur when the herbal medication was started?
  - Has any co-medication been used before the use of the herbal medicines without side-effect?
  - Did the ADR occur when the co-medication was added to the herbal treatment?
  - Did the ADR stop when the herbal medicines were withdrawn?
  - Was the ADR reversible?
  - Did the ADR reappear after re-exposure?
- (3) The dosage used should be compared with the traditional dosage described in the literature:
  - Did the patient use a higher dose than recommended? Would it be intoxication rather than an ADR?
  - Is the dosage so low compared to the traditional dose that a link is not plausible? However, be aware of allergic reactions!
  - Were there any signs of allergic reactions such as: rashes, asthma, eosinophilia, angio-oedema?
- (4) How common is the symptom with other diseases?
  - What is the prevalence of diseases with the same symptoms, e.g. hepatitis?
  - Can other causes be eliminated, such as viral markers or ethanol misuse in hepatitis?
- (5) Search databases for similar case reports for association with the same or similar herbal medicines or combination products. In the case of suspicious files, go to original reports, because the database file may not be complete and additional information may be found in the original report;
- (6) If no association was found in literature, or if an association is not plausible because of the low dose, there could be a problem related to the product's quality. Check for possible adulteration, substitution or contamination, e.g. by mycotoxins, heavy metals, etc.

The assessment should be done in cooperation with an expert panel comprising experts in pharmacognosy, toxicology and other health professionals including providers of herbal medicines.

A clear conclusion on the causality should be made using the terms proposed by WHO Guidelines Related to Safety Drug Monitoring.

## 6.2 How to set up or expand the reporting system on adverse events relating to herbal medicinal products

To begin with, the report will be voluntary. If possible, the report should be mandatory later. The following actions should be taken into account when setting up a reporting system, or including providers of herbal medicinal products in a pre-existing reporting system:

- Provide education and awareness for the public/consumers and professionals including doctors, pharmacists, herbal medicine practitioners, etc.;
- Establish a proper regulatory system for herbal medicines;
- Activate medicine information centres in health authorities for the establishment of special sections and systems for ADR of herbal medicines and any other possible medicine-related problem;
- Use existing tools (for conventional drugs) to collect and analyse data supported by a computerized system;
- Emphasize the scientific use of herbal medicines;
- Solve existing problems in the reporting systems by using advanced database programmes;
- Ask for WHO assistance in establishing an ADR reporting system;
- Encourage manufacturers, the public/consumers and professionals including doctors, pharmacists, practitioners of herbal medicine, etc. who produce, prescribe or use herbal medicines, to report ADR to relevant authorities.

## 7. Control of advertisements of herbal medicinal products

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The national authorities responsible for the regulation of herbal medicinal products and practices should approve every advertisement before it reaches the public.

The regulatory authority should issue advertisement permits after satisfactory evaluation of the contents of each advertisement to ensure that the public gets the correct information about the product, devoid of ambiguous or fraudulent claims. The print and electronic media should be notified to ensure that every advertiser of herbal medicinal products obtains the permit from the national authority before such an advertisement is published.

It is necessary that information on the advertisement of herbal medicinal products is shared among countries and overall cooperation with different, relevant national authorities is encouraged.

## 8. Recommendations

To Member States

Member States should:

- Develop national regulations on herbal medicines based on the WHO guidelines;
- Establish a national advisory committee for herbal medicines;
- Adopt requirements for the registration of herbal medicines as proposed during this workshop;
- Establish coordination agencies to implement GACP;
- Establish an ADR monitoring centre and system for conventional medicines and herbal medicines, and develop necessary linkages with other ADR monitoring centres in the Region and with WHO collaborating centres;
- Work to strengthen the regional network in all possible aspects of herbal medicines, particularly with regard to their safety, efficacy and ADR;
- Develop and strengthen herbal medicine education and training, practice and research;
- Work at facilitating harmonization among those countries that have common systems of herbal medicine.

To WHO

WHO Should:

- Support Member States in establishing and updating regulations on herbal medicines by providing technical assistance and organizing training workshops on herbal medicine;
- Support Member States to set up and strengthen centres for monitoring safety of medicinal products and systems by training human resources for the regulation of herbal medicines, and providing technical assistance and logistic support; and
- Provide technical guidelines, methodology and training for evaluating the safety, efficacy and quality of herbal medicines.

## Annex I

# List of participants

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## Annex 2

# Summary report of the workshop

The workshop was held in Bangkok, Thailand on 24–26 June 2003, and was attended by 24 participants and 2 observers from 9 countries and WHO Representatives from Headquarters and SEARO. The Democratic People's Republic of Korea and Timor-Leste were unable to join the meeting.

## Opening session

The workshop was opened by Dr Zhang, Coordinator, Traditional Medicine Team, Essential Drugs and Medicines Policy, WHO-HQ.

The opening session was followed by the introduction of the delegations and election of Chairpersons and Rapporteurs. The forum endorsed the nomination of the following:

- Dr Anchalee Chuttaputti, Senior Pharmacist, The Institute of Thai Traditional Medicine, Ministry of Public Health, Thailand, as Chairperson
- Mr L. Prasad, Joint Secretary, Department of Indian Systems of Medicine and Homeopathy, Ministry of Health and Family Welfare, India, as Co-chair
- Mr Sonam Dorji, EDP Coordinator DVED, Health Department, Bhutan, as Rapporteur
- Dr M. Hayatie Amal, Director of Traditional Medicine, Cosmetics and Complementary Products, Inspection and Certification, the National Agency of Drug and Food Control, Jakarta, Indonesia, as Rapporteur.

## Adoption of the agenda

The participants agreed to and adopted the agenda of the meeting.

## Objectives of the workshop

- Introduce a WHO Herbal Medicine Strategy and WHO technical guidelines;
- Share national experiences and models on regulations and evaluation of safety, efficacy and quality control measures for herbal medicines among the countries of SEAR;
- Review existing registration of herbal medicines in the countries of SEAR;
- Set up minimum requirements for the registration of herbal medicines.

## Methods of the workshop

- Plenary discussion
- Country presentation
- Group discussion
- Group reports

## Expected outcome

To establish minimum requirements for the registration of herbal medicines in the WHO South-East Asia Region.

## The sessions

### 1. Global and national review of regulatory status of herbal medicines

- Dr Zhang briefed the participants on the importance of the workshop and apprised them of the World Health Assembly resolution on Herbal/Traditional Medicines and the resolution adopted by the WHO Regional Committee for South-East Asia on Traditional Medicines.

A global review of the use of Traditional Medicine and WHO Traditional Medicine Strategy and a presentation on Traditional Medicine in the Member States of the WHO South-East Asia Region was provided by Dr Zhang.

### 2. Country presentations

Each participant presented the country situation with respect to the regulatory status of herbal medicine including: assessment of quality, safety and efficacy of herbal medicines, registration procedures, presence of national research institutes, national programmes, expert committee, national pharmacopoeia, national herbal monographs, perspectives on harmonization, etc.

### 3. Safety and Efficacy of herbal medicines

- Dr Zhang introduced WHO guidelines for assessment of the safety and efficacy of herbal medicines.
- Thailand and Indonesia presented their experiences in this area.

## 4. Group discussions

The participants were divided into two groups for group discussions.

Group 1

- Major challenges and minimum requirements on safety

Group 2

- Major challenges and minimum requirements on efficacy

The SEAR countries agreed to develop certain categories of herbal medicines by reviewing the experiences and practices of the Member Countries, and by learning from the practices of other Regions. These were:

Category 1 Indigenous Herbal Medicines

Category 2 Herbal Medicines in systems

Category 3 Modified Herbal Medicines

Category 4 Imported Herbal-based Medicinal Products

Three safety categories were also agreed to, as follows:

Category 1 Safety established by long time use

Category 2 Safe under specific conditions of use (herbal medicines should be preferably covered by well-established documentation)

Category 3 Herbal medicines of uncertain safety

## 5. Quality assurance

Dr Zhang introduced WHO-GACP and other guidelines. India and Sri Lanka presented respective country experiences on GACP. Participants agreed to develop certain classifications of herbal medicine by reviewing Member Countries' experiences and practices and learning from the practices of other regions.

## 6. Monitoring safety

Dr Zhang introduced the WHO guidelines and activities on monitoring the safety of herbal medicines. Thailand, Indonesia and Sri Lanka shared their countries' experience on methods of analysis of cases with adverse events of herbal medicines.

## 7. Working group discussions

The participants were divided into two groups for group discussions.

### Group 1

- GMP, GACP and quality control methods of herbal materials

### Group 2

- Reporting systems: How to set up safety monitoring systems, methods for analysis of cases with adverse events

## 8. Working group reports on:

- Developing common requirements for registration of herbal medicines
- Pharmacovigilance of herbal medicinal products