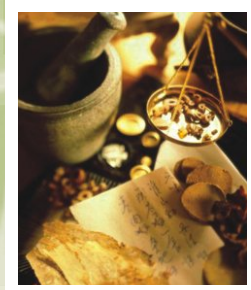

Guidelines for the regulation of herbal medicines in the South-East Asia Region

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

SEA-Trad. Med.-82
Distribution: General

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

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Acknowledgements

These guidelines were developed by participants attending the regional workshop on the Regulation of Herbal Medicines, organized by the WHO Regional Office for South-East Asia and hosted by the Ministry of Public Health, Royal Thai Government, in Bangkok in June 2003. The workshop was supported by the Grand Duchy of Luxembourg.

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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Contents

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

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

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

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