WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

REPORT

WORKING GROUP ON HARMONIZATION OF STANDARDS AND REGULATORY FRAMEWORK OF HERBAL MEDICINES

Seoul, Republic of Korea
27-30 November 2001

Manila, Philippines
January 2002

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NOTE

The views expressed in this report are those of the participants in the Working Group on Harmonization of Standards and Regulatory Framework of Herbal Medicines and do not necessarily reflect the policy of the World Health Organization.

This report has been prepared by the Regional Office for the Western Pacific of the World Health Organization for governments of Member States in the Region and for the participants in the Working Group on Harmonization of Standards and Regulatory Framework of Herbal Medicines held in Seoul, Republic of Korea from 27-30 November 2001.

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Keywords

Medicine, Herbal – standards / Drug and quality control / Korea

SUMMARY

The Working Group on Harmonization of Standards and Regulatory Framework of Herbal Medicines met in Seoul, Republic of Korea, from 27 to 30 November 2001. The main objectives of the meeting were: (1) to share experiences of regulatory measures to control the quality of herbal medicines; (2) to identify issues relating to collaboration within and among participating countries on quality and standards of herbal medicine; (3) to identify practical mechanisms for harmonizing herbal medicines, particularly regulatory requirements, quality and standard of herbal medicines; (4) to define the areas of collaboration and the role of each of the participating countries; and medicine; and (5) to develop a plan on harmonizing herbal medicines among participating and other interested countries in the Region.

The meeting was attended by 20 temporary advisers, a consultant, and a member of the Secretariat from the WHO Western Pacific Region. There were also a number of observers from the People's Republic of China, Japan, and the Republic of Korea in attendance.

Country reports on the status, quality control, and regulatory aspects were presented by temporary advisers from Australia, China, Hong Kong (China), Japan, the Republic of Korea, Singapore and Viet Nam.

Subsequently, the Working Group was divided into two groups to examine the issues of quality standards and technical requirements of herbal medicines. Given the increased use and trade of herbal medicine and some reports of adverse reactions and the lack of common standards and regulations among the Member States, the Working Group concluded that in order to ensure the uniformity of quality, safety and efficacy of the same herbal medicines in these and other Member States in the Region, there is a need for cooperation and harmonization of the standards and regulatory requirements. As a step toward harmonization, the Working Group identified issues, priorities, activities and mechanisms for harmonization, and proposed the formation of an organization to facilitate this work. The Working Group recommended that:

(1) a Forum in the WHO Western Pacific Region be formed with the aims of:

- promoting health by recognizing and developing common regulatory requirements and guidelines that aim to ensure the quality, safety and efficacy of herbal medicines in the Region; and

- harmonizing regulatory requirements and guidelines to lead to a greater mutual acceptance of herbal medicines;

(2) the Forum be known as the "Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)";

(3) the Forum consist of representatives of regulatory authorities and research institutes. Later, industry associations from interested Member States will also be invited;

(4) the first priorities of the Forum shall consist of the following items:

- harmonization of nomenclature related to herbal medicines (plants, preparation and use);
- harmonization of methods and guidelines for the registration and regulation of herbal medicines, including the development of standards and monographs;
- harmonization of agricultural (GAP) and field collection practice (GFCP) procedures, including standard operating procedures (SOPs) on the use of pesticides, harvest, storage, and other protocols to insure consistent quality of the starting source materials; and
- establishment of a system for dissemination and communication of information relating to the regulation of herbal medicine;

(5) the appointed Preparation Committee, in collaboration with the WHO Western Pacific Regional Office, convene a further meeting in 2002 to establish the Forum and the organizational structure to fulfill the above aims and priorities;

(6) funding in support of the Forum be sought from interested Member States, industry associations and other organizations;

(7) the Working Group participants, wherever possible, brief the appropriate government policy and decision makers and other interested parties and stake holders on the deliberations and recommendations of this Working Group and initiate activities to implement the above priorities; and

(8) to facilitate the above identified tasks, and to provide immediate contact, two representatives, one each from the regulatory authority and a research institute from each of the participating Member States are to be nominated from among the participants of the present Working Group as temporary focal points.

1. INTRODUCTION

Over the past decade, there has been increased global interest in the use of traditional systems of medicine, especially herbal medicinal products. In developing countries, they are most often used in primary healthcare, whereas, in developed countries, these medical modalities, designated as complementary and alternative medicine (CAM), are often used concomitantly with conventional medicine in medical treatments. The use of CAM in the United States of America increased from 34% in 1990 to 42% of adults in 1997, and American consumers spent an estimated US$5.1 billion on herbal medicines in 1997.[1] In the same year, the global market for herbal products was estimated to be approximately US$20 billion.[2,3] More recently, the global trade in herbal medicine has been estimated to total US$ 43 billion.[4] Regionally, there has been an increased production, use and international trade of herbal medicine among the Member States of the Western Pacific Region. Herbal medicine production in China amounted to US$ 2.3 billion in 1995; total annual sales of herbal medicine in the Republic of Korea exceeded US$ 500 million in 1996; annual herbal medicine products sales in Japan approximate US$ 1.5 billion (according to data available in 1992); and the import of Chinese herbal medicine into Australia has increased four-fold in as many years.[5]

Despite the dramatic increase in the use and commerce of herbal medicine, the quality of these products, which can affect their efficacy and/or safety, vary greatly from product to product, and from country to country. The factors contributing to these quality variations may be due to the lack or inconsistent use of good agricultural or field collection practices; intentional or unintentional substitution adulteration with other plant or pharmaceutical materials; the contamination by microbes, microtoxins, synthetic drugs and/or other noxious chemicals; the lack of good manufacturing and laboratory practices; the lack of pharmaco-toxicological evaluations; and the absence of, or lack of uniform regulatory requirements among the producer and/or user nations.[6] The prescribing, sale and use of inferior or questionable quality herbal medicines could represent a public heath problem.

Historically, the production, and registration of pharmaceutical products containing single active chemical compounds also varied from country to country. In 1990, interested parties in the European Community, Japan, and the United States of America initiated an International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which has since harmonized many guidelines to insure the production of the drugs having the same quality, safety and efficacy for registration in these countries.[7] Theoretically, harmonization of the production and regulation of herbal medicines would bring forth similar beneficial effects to public health. To date, except for some proposed guidelines on the quality control of single herb products by the European Agency for the Evaluation of Medicinal Products, there have been no concerted effort in the harmonization of herbal medicines, especially multi-component herbal formulae commonly found in

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