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Developing regional guidelines on minimum requirements for the registration of herbal medicinal products

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1. Background

Use of herbal medicines has steadily increased in countries of the WHO Eastern Mediterranean Region. In some countries of the Region, herbal medicines are produced locally and a large population depends on them for primary health care, but in other countries the majority of herbal products are obtained from the United States, Europe or Asia. A major problem in the evaluation of imported herbal products is that many products contain more than 10 plants and it is very difficult to conduct testing and quality control. Another problem is the fact that classificatory categories for herbal products vary from country to country; some categories include functioning foods, dietary supplements and traditional herbal medicines.

Governments need to establish their national regulations on the control of imported herbal medicines through sharing experiences and harmonizing standards on safety and quality control across national boundaries. Previous Eastern Mediterranean Drug Regulatory Authorities Conferences (EMDRAC) in 1999 and 2001 provided general guidance to drug regulatory authorities in the development and implementation of preliminary regulatory systems for herbal medicines. Specific guidance is needed, however, to meet the needs of both countries that are primarily producers and those that are primarily importers of herbal medicines. In 2002, the Forty-ninth Session of the WHO Regional Committee for the Eastern Mediterranean adopted a resolution on traditional medicine (EM/RC49/R.9) in which it requested the Regional Director to take necessary action to develop guidelines for the preparation of national policies and regulations on traditional/complementary/alternative medicine.

In order to develop the regional guidelines on the regulation of herbal medicines, WHO organized two regional workshops on the regulation of herbal medicines for national drug authorities. The first workshop took place in Teheran, Islamic Republic of Iran, from 14 to 17 December 2002. A total of 18 national drug authorities from 8 countries (Afghanistan, Egypt, Islamic Republic of Iran, Morocco, Pakistan, Syrian Arab Republic, Sudan and United Arab Emirates), most of which were producers of herbal medicines, attended the workshop. The workshop focused on controlling the safety, quality and efficacy of local herbal products, and developed draft regional guidelines on how to regulate and control local herbal medicines. The workshop strongly recommended that WHO organize a second regional workshop to review and discuss the draft guidelines developed by the first workshop, focusing on quality control of herbal medicines imported from other countries.

2. Introduction

The second regional workshop on developing regional guidelines on minimum requirements for the registration of herbal medicines was held in Abu Dhabi, United Arab Emirates, from 7 to 9 June 2003, to finalize regional guidelines on the registration of herbal medicines with the main emphasis on quality, safety and efficacy. The workshop was attended by a total of 17 participants from 6 countries of the Eastern Mediterranean Region, Bahrain, Jordan, Qatar, Saudi Arabia, United Arab Emirates and Yemen, most of whom are importers of herbal medicines.

During the inaugural session Mr Mohamed Bin Shahna, Technical Officer, Essential Drugs and Biologicals, WHO/EMRO, delivered a message from Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean. In his message, Dr Gezairy thanked the Ministry of Health and noted that the United Arab Emirates had been chosen as the venue for the workshop because it had a long history in the use of traditional medicines, which was also reflected in the establishment of the Sheikh Zayed Complex for Herbal Research and Traditional Medicine.

Dr Gezairy emphasized that traditional medicine was and would continue to be an important component of health care provision around the globe and in the Region. As much as 80% of rural

people in the Region relied on traditional medicine. The use of herbal medicine was increasing, as in the Islamic Republic of Iran, where sales of herbal medicines increased from US$ 3 million in 1999 to US$ 3.5 million in 2001. In many countries, especially those of the Gulf Cooperation Council, herbal products were imported from other countries and therefore the evaluation of safety, quality and efficacy was essential. In some countries herbal medicine and food were in the same category, hence regulation and quality standards of herbal medicine were important. In 2002, he noted, the Forty-ninth session of the Regional Committee for the Eastern Mediterranean had adopted resolution EM/RC49.R9, which urged Member States to develop and implement national policies and regulations on traditional and complementary medicines, to ensure not only that they were used appropriately, but also optimally, as a means of increasing access to primary health care. The resolution had also requested the Regional Office to take the necessary action to develop guidelines on the preparation of national policies and regulations concerning traditional and complementary medicines.

A message from Dr Hamad Abdel Rahman Al Madfaa, Minister of Health, United Arab Emirates, was read by Dr Abdul Ghaffar Abdul Ghaffour, Assistant Undersecretary for Curative Medicine. In his message Dr Al Madfaa welcomed the participants and stressed that the Ministry of Health was seriously following up all the factors that guarantee the quality safety and efficacy of herbal medicines. He also emphasized the growing need to protect and preserve traditional medicine knowledge and natural resources.

Mr Bin Shahna then briefed the participants on the agenda and methodology of the workshop. During the workshop, experts from countries that are primarily importers of herbal medicines would share experiences in the development and implementation of national regulatory policies, within and outside the Region. The workshop participants would review the draft regional guidelines for the registration of herbal medicines to address specific regional requirements, based on existing WHO guidelines and the issues raised during the workshop.

Dr Abdul Ghaffar Abdul Ghaffour, (United Arab Emirates) and Dr Abdullah Al Bedah (Saudi Arabia) were elected as Chairmen of the workshop. Dr Ahmad Ali Al Nomani (Yemen) and Dr Waleed R. Marji (Jordan) served as rapporteurs. The agenda, programme and list of participants of the workshop are included as Annexes 1, 2 and 3. Minimum requirements for the registration of herbal medicines, finalized during the workshop, are attached in Annex 4.

3. Technical presentations

3.1 Regional overview: the current situation and challenges facing countries of the Eastern Mediterranean Region

Mr Mohamed Bin Shahna, Technical Officer, Essential Drugs and Biologicals, WHO/EMRO

The global, regional and national sales of herbal medicines have shown rapid growth during the last decade. According to the Secretariat of the Convention on Biological Diversity (CBD) report, the global medicines market in 2000 was estimated at US$ 60 000 million. In Japan, the herbal medicines market was worth US$ 1000 million in 1991, US$ 2000 million in 1994, US$ 2200 million in 1996 and US$ 2400 million in 2000. In the United Kingdom, this market was worth US$ 92 million in 1994, US$ 134 million in 1998, and US$ 159 million in 2000 and it was expected to reach US$184 million in 2002. For the United States, the figures are US$ 1600 million in 1994, US$ 3000 million in 1997, US$ 4400 million in 1999 and US$ 5400 million in 2000.

In Member States of the Eastern Mediterranean Region, use of herbal medicines also shows a steady increase. For example, according to the estimate of the Ministry of Health and Medical Education of the Islamic Republic of Iran, annual sales of herbal medicines were US$ 3 million in 1999. This

number increased to US$ 3.1 million in 2002 and 3.5 million in 2001. In Pakistan, the sales of herbal medicines reached US$ 52 million in 1999, and were up to US$ 63 million in 2000 and US$ 70 million in 2001. In 2002 the United Arab Emirates imported 2500 tablets, 699 100 capsules and 6100 bottles of herbal medicine; corresponding figures for 2001 were 257 500 tablets, 2 454 160 capsules and 10 122 bottles. The total number of items of imported herbal medicine increased by 385% between 2000 and 2001.

One of the challenges in many Eastern Mediterranean Region countries, particularly in the countries of the Gulf Cooperation Council, is that the majority of herbal products are imported from the United States and European and Asian countries. A major problem in the evaluation of imported herbal products is that many products contain more than 10 plant parts and therefore it is difficult to conduct testing and quality control on these products. Many national authorities have not yet developed the knowledge and technical skill for evaluation of the quality, safety, and efficacy of the majority of herbal products imported into their countries. Classification for herbal products varies from country to country; in some countries traditional herbal medicines are included in the same category as food and dietary supplements.

Overall, there is a lack of cooperation and information-sharing regarding market control between the ministries of health of different countries of the Region. Important data related to safety, efficacy and quality control are often either insufficient or not available. In most countries, either no safety monitoring system exists or the existing system excludes herbal medicines.

3.2 Global and national review of the regulatory status of herbal medicine

Dr Xiaorui Zhang, Essential Drugs and Medicines Policy, WHO/HQ

Dr Zhang presented the situation on the use of herbal medicines, national policy, regulation, registration of herbal medicines, quality control and good manufacturing practices (GMP), national pharmacopoeia and safety monitoring in the Region, based on information from the Global Survey forms received from 10 countries of the Eastern Mediterranean Region.

4. Country presentations

4.1 Bahrain

Medicines derived from herbal, animal and mineral sources and the accepted topical preparations were described. The documents to be submitted for the registration of a health product were explained and labelling was discussed. Additional requirements, such as the content of herbal product and maximum number of herbal components were described. The general rules were also described in detail; the licences to import and sell health products, for example, are given to pharmacies and special outlets. Annual fees and renewal of product licences were also discussed in detail.

4.2 Jordan

The main features described were harmonizing with WHO guidelines on herbal medicine and the formation of a committee for market authorization. The legal status of herbal preparations was classified into three groups: 1) herbs with local knowledge and traditional use; 2) herbs with international knowledge and traditional use; and 3) herbs without the support of international experience. The requirements for these three groups were discussed further. The total programme up to market authorization was shown in a flow diagram.

4.3 Qatar

The first laws and regulations for medicinal plants were formulated in 1983, followed by laws in 1986 and 2002. Functions and tasks of the Professional Committee of Herbal Medicine and Complementary

Products were described. The establishment of the Herbal Medicines, Food Preparations and Cosmetics Sections and their functions and tasks were also described. The main contents of new regulation for registration of herbal medicine, dietary supplements and cosmetics were discussed. Six useful examples of the regulations for TM/HM/CAM in Qatar were given.

4.4 Saudi Arabia

This presentation comprised a briefing on the current situation of the practice of traditional medicine (TRM) and complementary and alternative medicine (CAM), the availability of two kinds of herbal products, from local and imported crude medicinal plants, and the history of traditional medicine in Saudi Arabian culture. The formation of a registration committee for imported and locally produced herbal medicines at the Ministry of Health was discussed.

4.5 United Arab Emirates

There is a long history of the use of traditional medicine. This is reflected in the establishment of the Sheikh Zayed Complex for Herbal Research and Traditional Medicine as an acknowledged centre in this important area, which after many years is seeing a well deserved revival, both regionally and globally. Traditional, complementary and alternative medicine (TCAM) is regulated in the United Arab Emirates jointly by two departments at the Ministry of Health. The Drug Control Department regulates the registration of non-conventional medicines such as herbal, homeopathic, ayurvedic and Chinese medicine, as well as natural products drugstores and pharmacies, while the Complementary and Alternative Medicine Unit coordinates the licensing and regulation of TCAM practitioners. About 53 herbal medicines are registered and another 120 are under the registration process. Approximately 112 traditional, complementary and alternative medicine practitioners including homeopaths, herbalists, acupuncturists, chiropractors and chiropodists, have passed the TCAM qualifying examinations that are held four times a year.

4.6 Yemen

Traditional medicine was described, including herbal medicines, honey and herbal materials and traditional medical practices. Regulations of the Supreme Board of Drugs and Medical Appliances were also described, along with ongoing activities such as the essential herbal medicine list and data collection.

Seventy-five herbal products have been classified and 59 herbal products have been authorized. Regional harmonization of regulations is needed, along with a standardized list of categories, access to international literature and databases, and qualified ministry of health staff with international experience.

5. Use and regulation of herbal medicine in Europe: Global survey on