

Guidelines on minimum requirements for the registration of herbal medicinal products in the Eastern Mediterranean Region



World Health Organization
Regional Office for the Eastern Mediterranean

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Introduction

Global sales of herbal medicines have increased rapidly during the past decade. The Secretariat of the Convention on Biological Diversity estimated the global herbal medicines market at US\$ 60 billion in 2000. In Japan, the herbal medicines market more than doubled between 1991 and 2000. In the United States, the market expanded from US\$ 1.6 billion in 1994 to US\$ 5.4 billion in 2000.

Use of herbal medicines has also increased steadily in countries of the WHO Eastern Mediterranean Region. In some countries, for example the Islamic Republic of Iran, herbal medicines are produced locally and a large population depends on them for primary health care. In other countries, such as the United Arab Emirates, 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 they often contain more than 10 plants, and it is very difficult to conduct testing and quality control. Another problem is that classification categories for herbal products vary from country to country; some categories include functional foods, dietary supplements and traditional medicines.

Overall, there is a lack of cooperation and information sharing regarding market control between the ministries of health of different countries in 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.

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. Eastern Mediterranean Drug Regulatory Authorities Conferences 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 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

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