

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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Contents

Acknowledgements	4
Introduction.....	5
Guidelines on minimum requirements for the registration of herbal medicinal products.....	7
Categorization of herbal medicines	7
Requirements for safety of “new herbal medicines”	8
Requirements for safety of traditional herbal medicines	8
Minimum requirements for efficacy of herbal medicinal products	9
Quality control of herbal medicinal products	10
Pharmacovigilance of herbal medicinal products	14
Control of advertisements of herbal medicinal products	16
Annex 1. List of participants at the first workshop	17
Annex 2. List of participants at the second workshop	21
Annex 3. Work of the Regional Office in the area of traditional, alternative and complementary medicine	26

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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 traditional, complementary and alternative medicine.

In order to develop regional guidelines on the regulation of herbal medicines, WHO organized two regional workshops for national drug authorities. The first workshop took place in Teheran, Islamic Republic of Iran, from 14 to 17 December 2002. Representatives of national drug authorities from eight countries (Afghanistan, Egypt, Islamic Republic of Iran, Morocco, Pakistan, Syrian Arab Republic, Sudan and United Arab Emirates), most of which are producers of herbal medicines, attended the workshop. The workshop focused on controlling the safety, quality and efficacy of herbal products, and developed draft regional guidelines on regulation of herbal medicines. It was strongly recommended that a second regional workshop be organized to focus on quality control of herbal medicines imported from other countries.

The second regional workshop was held in Abu Dhabi, United Arab Emirates, from 7 to 9 June 2003. It was attended by representatives of national drug authorities from six countries of the Region (Bahrain, Jordan, Qatar, Saudi Arabia, United Arab Emirates and Yemen), who reviewed the draft guidelines developed in the first workshop. Lists of participants in each workshop are included as Annexes 1 and 2. At the end of this process, after intensive discussion and review by national drug authorities from 13 countries of the Eastern Mediterranean Region, regional guidelines on minimum requirements for the registration of herbal medicinal products were finalized. The guidelines are intended to be used for the assessment of crude botanical drugs and for industrially-prepared finished products. A list of traditional herbal substances and combinations of herbal substances would facilitate both tasks. WHO monographs are available for more detailed information.

The WHO Regional Office for the Eastern Mediterranean has been involved in the area of traditional medicine since the early 1980s. A number of important regional meetings have been held and publications produced, including a model Herbal Remedies Act which was developed in 1986 and has inspired national regulation of herbal medicines in some countries of the Region. A chronology of the work of the Regional Office in the area of traditional, complementary and alternative medicine is included as Annex 3.

Guidelines on minimum requirements for the registration of herbal medicinal products

Categorization of herbal medicines

Traditional herbal medicines

These are defined as herbal medicines (single or mixture of herbs) that have been widely used, supported by well-established safety and efficacy data, or have been used within the local community for a minimum period of 15 years. This category would also include traditional medicine formulations to which minor changes have been made. Herbal medicines that are not indigenous to the Eastern Mediterranean Region, e.g. ginseng, could also be included if they have been widely used within the Region and if sufficient knowledge about their safety and efficacy exists.

New herbal medicines

Herbal medicines (single or mixture of herbs) can be considered “new herbal medicines” if never used within the community or region, used for only a short period of time, used to a very small extent (few uses in a small number of patients), or used in a new combination of herbal substances never combined before.

In order to promote a harmonized assessment, a regional list of traditional herbal substances/combination of substances is proposed. This list should originate from proposals submitted by countries to the WHO Regional Office for the Eastern Mediterranean. The list should contain the following items:

- scientific botanical name of the plant (Latin binominal nomenclature)
- common/English name of the plant
- common names of the plant in regional languages
- plant part used
- name of the herbal medicine
- common name(s) of the herbal medicine
- dosage form (e.g. powder, herbal tea, extract)
- mode of administration (e.g. oral, external use, inhalation)

- range of safe dosages (daily dose) as found in literature
- safety category
 - Class I: safety established by use over long time.
 - Class II: safe under specific conditions of use (should preferably be covered by well-established documentation)
 - Class III: herbal medicines of uncertain safety.

Requirements for safety of “new herbal medicines”

The safety data required for registration of new herbal medicines will be identical for any new substance:

- single-dose toxicity
- repeated-dose toxicity
- chronic toxicity
- organ-targeted toxicity, if necessary
- immunotoxicity
- embryo/foetal and prenatal toxicity, if necessary
- mutagenicity/genotoxicity, if necessary
- carcinogenicity, if necessary
- local tolerance.

In special circumstances, such as new combinations of well-known substances, some of these studies may not be necessary.

Requirements for safety of traditional herbal medicines

Any assessment of traditional herbal medicines must be based on an unambiguous identification and characterization of the constituents. A literature search must be performed. This should include general literature such as traditional 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, if available, database searches in online or offline databases, e.g. the WHO adverse drug reaction database, National Library of Medicine’s Medline, etc. Searches should focus not only on the specific herbal drug 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.

Countries of the Eastern Mediterranean Region should share information on reliable sources of such information in the proposals submitted to the WHO Regional Office. In assessing these bibliographic data, particular attention should be given to the characteristics and type of preparation described in the literature:

- does the literature refer to the same herbal preparation?
- can the data be extrapolated, e.g. extract prepared with ethanol 40% vs. extract prepared with ethanol 60%?
- the duration and extent of use of the herbal medicine; can the use have generated sufficient experience on safety?
- is it plausible that risks would have been recognized empirically?

The need for additional data or additional new tests should be considered in light of the information requirements for new herbal medicines. Many of the tests required for these new medicines may be replaced by documented experience. However, it should be carefully considered whether all questions on toxicology raised can be answered adequately and in a plausible way by the available knowledge. Particular attention should be given to effects that cannot be readily detected 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 small children. In assessing safety in pregnancy, information on traditional misuse, e.g. as an agent to induce abortion, should be assessed.

Minimum requirements for efficacy of herbal medicinal products

Efficacy claims for herbal medicinal products are made with respect to:

- acute diseases, which have a rapid onset and are of relatively short duration;
- chronic diseases, which have a slow onset and last for a long period of time;
- health enhancing effects.

In most cases, acute disease refers to a life-threatening disease, or one in which delayed treatment will lead to the deterioration of health or to loss of capacity to cure the disease, for example, severe cardiovascular diseases, gastrointestinal diseases, endocrine diseases, haematological diseases and immune disorders and diseases.

Patients suffering from certain health conditions, e.g. loss of appetite, hay fever, menopause, sometimes recover without any medical intervention. Efficacy of herbal medicinal products in this area could be supported by data from well-established documentation including national pharmacopoeias and monographs, as well as other authoritative documents such as WHO monographs. Pre-clinical data of efficacy may not be necessary, but clinical data are required. If traditional use of products with well-established documentation reflects changes in medicinal indication, dosage form or mode of administration, the efficacy data and clinical data could be consulted (see Tables 1 and 2). The efficacy should be proven by pre-clinical data and clinical trials or well-established documentation. If the changes could have an impact on the pharmacodynamics of the medicine, pre-clinical study is needed.

Quality control of herbal medicinal products

Approaches to quality assurance

Quality assurance is the shared responsibility of manufacturers and regulatory bodies. Manufacturers must adhere to good agricultural and collection practice (GACP), good manufacturing practice (GMP) and good laboratory practice (GLP) standards, establish appropriate specifications for their products, intermediates and starting materials and compile well-structured comprehensive documentation on pharmaceutical development and testing. The producer should make a continuous effort to improve standards and to adapt them to the present state of knowledge. A cooperative approach between manufacturers, e.g. by establishing medicines master files for specifications and quality controls, is encouraged.

National health regulatory authorities should establish guidance 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 producer. Regulatory authorities should facilitate access of good-quality herbal medicines to the market by providing monographs in pharmacopoeias and by providing training and advice to small producers.

Implementation of such requirements is possible only if the production and marketing of herbal medicines is subject to an adequate registration scheme.

Table 1. Summary of efficacy data requirements

Category	Pre-clinical data of efficacy	Clinical data of efficacy	Other data or information required
Acute diseases	Needed	Control trial needed	
Chronic diseases	May be needed	May or may not be needed	
Health enhancing effects	May not be needed	May not be needed	Supported by well-established documents such as national pharmacopoeias and monographs

Table 2. Proposed requirements for efficacy data for the evaluation of traditional herbal medicines with various changes

Traditional herbal medicines with well-established documentation	Pre-clinical data of efficacy ^a	Clinical data of efficacy ^b
No change, according to well-established documentation	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
Medicinal indication	Needed	Needed
Herbal medicinal ingredients:		
Addition ^c	Needed	Needed
Deletion ^d	May or may not be needed	May or may not be needed
New combination ^e	Needed	Needed
Medicinal plant part used	Needed	Needed
Methods of preparation	Needed	Needed

^a Pre-clinical data include laboratory tests and data on the standard dose and dosage form

^b Clinical data refer to clinical research in WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine

^c Addition of one or more plants into traditionally used formulas

^d Deletion of one or more plants from traditionally used formulas

^e New combination of two or more traditionally used formulas

Quality control of imported herbal medicinal products

All imported herbal medicinal products need to meet requirements of safety and efficacy and quality control regulation in importing countries. In order to control the quality of imported herbal medicinal products, the following requirements should be taken into account:

- licenses for importers, wholesalers and manufacturers of imported herbal medicine products should be issued by the national health regulatory authority;
- dealers in imported herbal medicinal products need to apply for one or more of the licences depending on the type of business involved, such as wholesale, and manufacture;
- the onus of applying for an import licence is on the local company wishing to import and sell herbal medicinal products in countries.

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

- details of company;
- particulars of person making application on behalf of company;
- certificate of company/business registration;
- store layout plan.

Importers are required to provide information on each imported herbal medicinal product handled by them and will be allowed to deal only in products which are approved in the exporting countries. Detailed requirements for each imported herbal medicinal product comprise:

- full product formula (in languages of the importing and exporting countries);
- a set of labels, pamphlet, carton and specimen sales pack;
- particulars of manufacturer and assembler(s);
- manufacturer's licence or certificate from health authority of manufacturing country/origin. An export certificate for the herbal medicinal product if the product is imported.

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

Guidelines related to GACP and GMP

All parties involved in the production of herbal medicinal products should adhere to the principles set out in the WHO GACP guidelines for medicinal plants and GMP. Manufacturers of herbal medicines should be licensed and registered. The quality assurance system should be adequate and proportionate to the type of production and the regional situation, e.g. agricultural production or industrial production. The implementation of a credible concept of quality assurance, e.g. identifying and eliminating potential sources of contamination, rather than implementing all individual technical aspects, should be the primary goal.

In order to encourage implementation of GACP practices, incentives should be offered to producers of botanical raw material. Examples of incentives could be: technical and logistical support in the selection of appropriate sites for agricultural production; providing seeds and seedlings; selecting fertilizers and pesticides; and providing or giving advice on machinery for harvesting and primary processing. The government should honour efforts by issuing certificates to those producers that adhere to GACP standards based on the country situation.

Guidelines related to quality control

The basis for quality control is the establishment of appropriate specifications and standards. Information on appropriate standards can be found in official pharmacopoeias and monographs.

In choosing analytical methods, the availability and robustness of the method must be considered. It may be preferable to use simple methods such as microscopic identification, thin-layer chromatography or titration of active substance if a full validation of more sophisticated methods such as high-performance liquid chromatography, gas chromatography and gas chromatography/mass spectrometry is not possible. If such advanced methods are used, a full validation for each test will be necessary.

Product information

The product information should include all necessary information on proper use of the product. The following elements of information will usually be included:

- brand name of product;
- quantitative list of active ingredients, including plant names, part of plants used (i.e. Latin name);
- dosage form;

- indications;
- the minimum, maximum and average dosage levels must be stated (if appropriate, specified for children and pregnant women);
- mode of administration;
- duration of use;
- adverse effects, where applicable;
- over-dosage information;
- contraindications, warnings, precautions;
- drug interactions, where applicable;
- date of issue;
- expiry date of product;
- lot number;
- name of manufacturer or company with full address.

Pharmacovigilance of herbal medicinal products

Adverse drug reaction (ADR) reporting

Pharmacovigilance units are necessary to collect and assess information on herbal and traditional medicines. Where such units exist they should include information on traditional and herbal medicines.

Each ADR report should be checked for a possible association with traditional or herbal medicines. Health professionals should be encouraged to ask their patients about the use of herbal and traditional medicines, including medicinal foods, and to include information on concomitant use in their ADR report.

Each herbal medicine must be identified clearly by its composition, brand name (if applicable) and dosage. If such information is missing in the ADR report, the pharmacovigilance unit should try to gather complete information, e.g. by asking the reporting health professional.

In analysing ADR reports, the following points should be considered.

- A literature search on the herbal product, its constituents and any co-medication should be performed.
- 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 medicine?

- did the ADR occur when the co-medication was added to the herbal treatment?
- did the ADR stop when the herbal medicine was withdrawn?
- was the ADR reversible?
- did the ADR reappear after re-exposure?
- The dosage used should be compared with the dosage specified in the literature:
 - did the patient use a higher dose than recommended? Could it be intoxication rather than an ADR?
 - is the dosage so low compared with the traditional dose that a link is not plausible? However, be aware of allergic reactions;
 - were there any signs of allergic reactions, such as asthma, eosinophilia or angio-oedema?
- 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 virus markers or ethanol misuse in hepatitis?
- Databases should be searched for similar case reports for association with the same or similar herbal medicines or combination products. In the case of suspicion, go to original reports because the database file may not be complete and additional information may be found in the original report.
- If no association is found in the literature, or if an association is not plausible because of the low dose, there could be a problem related to product quality. Check for possible adulteration, substitution, contamination, e.g. by mycotoxins, heavy metals, etc.

The assessment should be conducted in cooperation with a panel of experts in pharmacognosy and toxicology and other health professionals, including traditional healers.

A clear conclusion on the causality should be made using the terms proposed by WHO guidelines related to drug safety monitoring.

Strengthening the reporting system to include safety monitoring for herbal medicinal products

- Promote education and awareness for the public and professionals.
- Establish a proper regulatory system for herbal medicine.
- Activate medicines information centres in health authorities to set up a special section and system for ADR of herbal medicines and any other possible medicines-related problems.

- Use existing tools (for conventional drugs) to collect and analyse data supported by a computerized system.
- Emphasize the scientific use of herbal medicines.
- Attempt to solve problems with the existing reporting system by using advanced databases.
- Request WHO assistance in developing ADR reporting systems.
- Encourage manufacturers and professionals who produce and/or prescribe herbal medicines to report ADRs to the relevant authorities.

Control of advertisements of herbal medicinal products

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

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

Sharing information on advertisements of herbal medicinal products and cooperation among the countries of the Region should be encouraged.

Annex 1

List of participants in the first regional workshop on regulation of herbal medicines

Teheran, Islamic Republic of Iran, 14–17 December 2002

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Annex 2

List of participants in the second regional workshop on regulation of herbal medicines

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Annex 3

Work of the Regional Office in the area of traditional, complementary and alternative medicine

The list below provides a chronological perspective on the work of the WHO Regional Office for the Eastern Mediterranean in the area of traditional, complementary and alternative medicine. It covers meetings, important presentations, Regional Committee resolutions and relevant documents produced by WHO. These documents, as well as the reports of the meetings, are available from the Regional Office upon request.

- 1983** Intercountry Meeting on Traditional Medicines held in Khartoum, Sudan, 5–10 March
- 1986** Model Herbal Remedies Act (WHO-EM/Pharm/119-E) developed for regulation of herbal medicines
- 1991** Intercountry Expert Meeting on Traditional Medicine and Primary Health Care held in Cairo, Egypt, 30 November to 3 December
- 1993** Regional Consultation on Development of Guidelines for National Policy on Traditional Medicine held in Alexandria, Egypt, 21–23 December
- 1996** Regional Consultation on Better Traditional Healers and Traditional Birth Attendants in National Health Services held in Islamabad, Pakistan, 11–14 October
- Paper on Regulation and Assessment of Herbal Medicines presented by WHO to the Eastern Mediterranean Drug Regulatory Authorities Conference in Manama, Bahrain, 4–8 November
- 2000** Survey on regulation of herbal medicines conducted in 22 countries of the Region, with feedback received from 13 countries. Out of these, 5 countries reported having a national policy on traditional medicine. Results of the survey were included in the WHO publication *National Policy on Traditional Medicine and Regulation of Herbal Medicine* (May 2005)

- 2002** International Seminar on Integration of Traditional Medicine and Modern Science held jointly with the Islamic Organization for Medical Sciences in Cairo, Egypt, 12–15 October
- A paper on the WHO Strategy for Traditional Medicine (EM/RC49/13) presented to the 49th Session of the Regional Committee for the Eastern Mediterranean, 30 September – 3 October
- Resolution EM/RC49/R.9 on Traditional Medicine adopted by the 49th Session of the Regional Committee for the Eastern Mediterranean
- Regional Workshop on Regulation of Herbal Medicines held in Teheran, Islamic Republic of Iran, 14–17 December, for national drug authorities to develop regional guidelines on the regulation of herbal medicines
- 2003** Second Regional Workshop on Regulation of Herbal Medicines held in Abu Dhabi, United Arab Emirates, 7–9 June to review the draft guidelines developed in the first workshop
- 2005** International Workshop on Consultation on Quality Control of Herbal Medicine held in Abu Dhabi, United Arab Emirates on 13–15 June, hosted by the Zayed Complex for Herbal Research and Traditional Medicine
- Consultation on Development of Regional Guidelines for National Policies on Traditional Medicine and Complementary and Alternative Medicine held in Abu Dhabi, United Arab Emirates, 22–24 November