

**National policy on traditional
medicine**

and

regulation of herbal medicines

Report of a WHO global survey



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National policy on traditional medicine and regulation of herbal medicines
Report of a WHO global survey

Executive summary

Background

Traditional medicine (TM) has always maintained its popularity worldwide. In addition, over the last decade, we have seen an increasing use of complementary and alternative medicines (CAM) in many developed and developing countries. The safety and efficacy of traditional medicine and complementary and alternative medicines, as well as quality control, have become important concerns for both health authorities and the public.

Various traditional medicine practices have been developed in different cultures in different regions, but without a parallel development of international standards and appropriate methods for evaluating traditional medicine. Therefore, sharing national experience and information is crucial.

Challenges

Countries face major challenges in the development and implementation of the regulation of traditional, complementary/alternative and herbal medicines. These challenges are related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring and lack of knowledge about TM/CAM within national drug regulatory authorities.

Challenges related to the regulatory status of herbal medicines: Before manufactured drugs came into widespread use, herbal medicines played an important role in human health. There are great differences between Member States in the definition and categorization of herbal medicines. A single medicinal plant may be defined as a food, a functional food, a dietary supplement or a herbal medicine in different countries, depending on the regulations applying to foods and medicines in each country. This makes it difficult to define the concept of herbal medicines for the purposes of national drug regulation, and also confuses patients and consumers.

Challenges related to the assessment of safety and efficacy: Requirements and methods for research and evaluation of the safety and efficacy of herbal medicines are more complex than those for conventional pharmaceuticals. A single medicinal plant may contain hundreds of natural constituents, and a mixed herbal medicinal product may contain several times that number. If every active ingredient were to be isolated from every herb, the time and resources required would be tremendous. Such an analysis may actually be impossible in practice, particularly in the case of mixed herbal medicines.

Challenges related to quality control of herbal medicines: The safety and efficacy of herbal medicines is closely correlated with the quality of the source materials used in their production. The quality of source materials is, in its turn, determined by intrinsic factors (genetic) and extrinsic factors (environmental conditions, cultivation and harvesting, field collection and post-harvest/collection transport and storage). Therefore, it is very difficult to perform quality controls on the raw materials of herbal medicines.

Good Manufacturing Practice (GMP) specifies many requirements for quality control of starting materials, including correct identification of species of medicinal plants, special storage and special sanitation and cleaning methods for various materials. In

the quality control of finished herbal medicinal products, particularly mixed herbal products, it is more difficult to determine whether all the plants or starting materials have been included.

Challenges related to safety monitoring of herbal medicines: Adverse events arising from consumption of herbal medicines may be due to any one of a number of factors. These include the use of the wrong species of plant by mistake, adulteration of herbal products with other, undeclared medicines, contamination with toxic or hazardous substances, overdosage, misuse of herbal medicines by either health-care providers or consumers and use of herbal medicines concomitantly with other medicines. Therefore, analysis of adverse events related to the use of herbal medicines is more complicated than in the case of conventional pharmaceuticals. Furthermore, herbal medicines are often used for self-care; thus, there is a great need to educate consumers and public in their proper use.

Lack of knowledge about herbal medicines within national drug authorities: The general lack of knowledge about herbal medicines within national drug authorities and the lack of appropriate evaluation methods are factors that delay the creation or updating of national policies, laws and regulations for traditional medicines, contemporary/alternative medicines and herbal medicines.

In order to meet these challenges, the WHO Traditional Medicine Strategy was developed, with its four primary objectives: framing policy; enhancing safety, efficacy and quality; ensuring access; and promoting rational use. Resolution WHA56.31 on traditional medicine was adopted at the Fifty-sixth World Health Assembly in May 2003. The resolution requested WHO to support Member States by providing internationally acceptable guidelines and technical standards and also evidence-based information to assist Member States in formulating policy and regulations to control the safety, efficacy and quality of traditional medicines.

Global Survey and Database

WHO decided to conduct a global survey on national policies on TM/CAM and regulation of herbal medicines and store the results in a global database. In 2001, WHO developed the Global Survey questionnaire, which focused on the main challenges listed above. The questionnaire was divided into three main parts:

- general review of policy and regulation of TM/CAM
- regulation of herbal medicines
- countries' needs for future WHO support and technical guidance.

We received responses from 141 countries, representing 74% of the 191 Member States of WHO at that time. The data were entered into the WHO Global Database developed for the survey. The information in the database is listed under 21 qualitative and quantitative structural indicators, which are intended to assess the situation of TM/CAM policies and herbal medicine regulation. Analysis of the survey results will provide the basis for further development of a comprehensive set of indicators, including background and process indicators for the monitoring of national TM/CAM policies and herbal medicine regulation.

Structure of report

This report is in four parts, covering national policy on traditional medicine and complementary/alternative medicine; regulation of herbal medicines; difficulties encountered by Member States and their needs for WHO support; summary of each country profile, classified by WHO region.

National policy on traditional medicine and complementary/alternative medicine: A national policy on TM/CAM may include some of the following key elements: a definition of TM/CAM, provision for the creation of laws and regulations, consideration of intellectual property issues. The policy may further describe the main strategies proposed by the government for achieving the objectives of the policy. Forty-five (32%) of the responding Member States reported having a policy on TM/CAM. Of those Member States which currently do not have a national policy, 51 (56%) indicate that such policies are currently being developed. Most Member States with a national policy established it recently, since only five States reported having a national policy before 1990. Forty Member States (28%) reported that they had issued a national programme on TM/CAM. Seventy-five countries (53% of the responding Member States) reported having a national office in charge of TM/CAM. In most of these countries, the national office is located within the Ministry of Health. Sixty-one countries (43% of the responding Member States) reported that they have expert committees for TM/CAM. In all, 58 Member States indicated that they had at least one national institute on TM, CAM or herbal medicines.

Regulation of herbal medicines: This section is the central part of the Global Survey. It contains a great deal of detailed information related to regulation of herbal medicines, e.g. regulatory status of herbal medicines, regulation requirements, number of registered herbal medicine products and quality control requirements such as GMP, monographs, etc.

Before 1988, there were only 14 Member States with regulations relating to herbal medicines, but the figure increased to 53 Member States (37%) having laws and regulations in 2003. Of those Member States without current laws or regulations, 42 (49%) declared that these regulations were in the process of being developed. Such results show that Member States are increasingly involved in developing the regulation of herbal medicines.

The questions about the regulatory status of herbal medicines also show, interestingly, that in most Member States (97 out of 142 respondents) herbal medicines are sold as over-the-counter medicines, in contrast to 50 Member States where herbal medicines are also sold as prescription medicines. Medical claims, health claims and nutrients contents claims are the most common types of claims with which herbal medicines may legally be sold (90 Member States allow medical claims, 62 allow health claims and 49 allow nutrient content claims).

The collected information about herbal medicines also shows that 86 Member States (61%) have a registration system for herbal medicines and 17 have 1 000 or more registered herbal medicines. Judging from these data, many Member States are giving the regulation of herbal medicines careful consideration.

Difficulties encountered by Member States and needs for WHO support: This survey demonstrates that Member States have made progress over recent years. However, there are still difficulties in the regulation and harmonization of TM/CAM worldwide. The survey also identifies the main difficulties regarding regulatory issues for herbal medicines – lack of research data, lack of appropriate control mechanisms, lack of education and training and lack of expertise. In this regard, Member States requested WHO to continue providing support for those countries endeavouring to develop a national policy and regulations on TM/CAM.

National policy on traditional medicine and regulation of herbal medicines
Report of a WHO global survey

Summary of each country profile classified by WHO region: The country summaries follow a generalized template, including the status and year of establishment of the following: policy on TM/CAM (national policy, law/regulation, national programme, national office, and national institutes) and the regulation of herbal medicine (law/regulation, regulatory status types, claim types, pharmacopoeia and monographs used, manufacturing requirements and control mechanisms, safety requirements and control mechanisms, registration system, essential drug list, post-marketing surveillance, marketing site and annual sales). These summaries are available for all 141 countries that responded to the survey.

Table 1. Survey return on selected topics, with regional breakdown

	Survey response	Survey % (141)	Global % (191)	AFRO ¹	AMRO	EMRO	EURO	SEARO	WPRO
National policy on TM/CAM	135	96%	71%	35	18	16	36	10	20
Law or regulation on TM/CAM	138	98%	72%	36	18	16	36	10	22
National programme on TM/CAM	133	94%	70%	35	18	16	35	9	20
National office for TM/CAM	136	96%	71%	35	18	16	36	10	21
Expert committee on TM/CAM	133	94%	70%	35	18	15	35	9	21
National research institute on TM, CAM or herbal medicines	135	96%	71%	34	18	16	35	10	22
Law or regulation on herbal medicines	140	99%	73%	36	18	16	38	10	22
Registration of herbal medicines	139	99%	73%	36	18	16	38	10	21

¹ AFRO: WHO Regional Office for Africa; AMRO: Regional Office for the Americas; EMRO: Regional Office for the Eastern Mediterranean; EURO: Regional Office for Europe; SEARO: Regional Office for South-East Asia; WPRO: Regional Office for the Western Pacific.

Table 2. Regional breakdown of responding countries

African Region	Region of the Americas	Eastern Mediterranean Region	European Region	South-East Asia Region	Western Pacific Region
Angola	Antigua & Barbuda	Afghanistan	Armenia	Bangladesh	Australia
Benin	Argentina	Bahrain	Austria	Bhutan	Cambodia
Botswana	Bolivia	Djibouti	Azerbaijan	Dem. People's Rep. of Korea	China
Burkina Faso	Brazil	Egypt	Belarus	India	Cook Islands
Burundi	Canada	Iran (Islamic Rep. of)	Belgium	Indonesia	Fiji
Cameroon	Chile	Jordan	Bulgaria	Maldives	Japan
Central African Rep.	Colombia	Kuwait	Czech Republic	Myanmar	Kiribati
Chad	Costa Rica	Libyan Arab Jamahiriya	Denmark	Nepal	Lao People's Democratic Rep.
Comoros	Dominica	Oman	Estonia	Sri Lanka	Malaysia
Congo	Dominican Republic	Pakistan	France	Thailand	Micronesia (Federated States of)
Côte d'Ivoire	Ecuador	Qatar	Georgia		Mongolia
Democratic Rep. of the Congo	El Salvador	Saudi Arabia	Germany		Nauru
Equatorial Guinea	Guatemala	Sudan	Hungary		New Zealand
Ethiopia	Jamaica	Syrian Arab Republic	Iceland		Niue
Gabon	Mexico	United Arab Emirates	Ireland		Papua New Guinea
Gambia	Nicaragua	Yemen	Israel		Philippines
Ghana	Peru		Kazakhstan		Rep. of Korea
Guinea	Suriname		Kyrgyzstan		Singapore
Guinea-Bissau			Latvia		Solomon Islands
Kenya			Lithuania		Tuvalu
Madagascar			Netherlands		Vanuatu
Malawi			Norway		Viet Nam
Mali			Portugal		
Mauritania			Rep. of Moldova		
Mozambique			Romania		
Niger			Russian Fed.		
Nigeria			Serbia & Montenegro		
Rwanda			Slovakia		
Sao Tome & Principe			Slovenia		
Senegal			Spain		
Seychelles			Sweden		
Sierra Leone			Switzerland		
South Africa			Tajikistan		
Togo			The former Yugoslav Rep. of Macedonia		
United Rep. of Tanzania			Turkey		
Uganda			Ukraine		
Zambia			United Kingdom of Great Britain & Northern Ireland		
			Uzbekistan		
37	18	16	38	10	22
Member States (80% of 46)	Member States (51% of 35)	Member States (76% of 21)	Member States (73% of 52)	Member States (100% of 10)	Member States (81% of 27)

Total respondents: 141

Contents

Acknowledgements	i
Executive summary	iii
Contents	ix
Acronyms, abbreviations and definitions	1
WHO Regions	3
1. Introduction.....	5
1.1 Background.....	5
1.2 WHO Global Survey.....	6
1.3 Global database	8
2. National policy on traditional medicine and complementary/ alternative medicine	11
2.1 National policy on TM/CAM	11
2.2 Laws or regulations on TM/CAM.....	12
2.3 National programme on TM/CAM	16
2.4 National office for TM/CAM.....	19
2.5 Expert committee on TM/CAM	20
2.6 National research institutes.....	22
3. The regulatory situation of herbal medicines.....	25
3.1 Law or regulation on herbal medicines	25
3.2 Regulatory status of herbal medicines.....	29
3.3 Claims	30
3.4 Pharmacopoeias	32
3.5 Monographs on herbal medicines	35
3.6 Manufacture of herbal medicines	37
3.7 Safety and herbal medicines.....	39
3.8 Registration system for herbal medicines	42
3.9 Herbal medicines and the essential drug list.....	44
3.10 Post-marketing surveillance of herbal medicines	46
3.11 The sale of herbal medicines	48
3.12 Annual market sales of herbal medicines.....	49
4. Member States, WHO and herbal medicines.....	51
4.1 Main difficulties faced by countries	51
4.2 WHO support	52
4.3 Survey results	53
5. Country summaries.....	55
5.1 WHO African Region	55
5.2 WHO Region of the Americas.....	74
5.3 WHO Eastern Mediterranean Region	85
5.4 WHO European Region	95
5.5 WHO South-East Asia Region	119
5.6 WHO Western Pacific Region	127
References.....	141
Annex 1. Text of survey instrument.....	143

Acronyms, abbreviations and definitions

CAM	complementary and alternative medicine
GMP	Good Manufacturing Practice
INN	International Nonproprietary Names
TM	traditional medicine

Complementary/alternative medicine (CAM): often refers to a broad set of health-care practices that are not part of a country's own tradition and are not integrated into the dominant health-care system. Other terms sometimes used to describe these health-care practices include "natural medicine", "nonconventional medicine" and "holistic medicine" (1).

Herbal medicine: plant-derived material or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. In some traditions, material of inorganic or animal origin may also be present.

Traditional medicine (TM): is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses (1).

WHO Regions

WHO African Region: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome & Principe, Senegal, Seychelles, Sierra Leone, South Africa, Swaziland, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.

WHO Region of the Americas: Antigua & Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saint Kitts & Nevis, Saint Lucia, Saint Vincent & Grenadines, Suriname, Trinidad & Tobago, United States of America, Uruguay, Venezuela.

WHO Eastern Mediterranean Region: Afghanistan, Bahrain, Cyprus,¹ Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, Yemen.

WHO European Region: Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, San Marino, Serbia and Montenegro, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, The former Yugoslav Republic of Macedonia, Turkey, Turkmenistan, Ukraine, United Kingdom of Great Britain and Northern Ireland, Uzbekistan.

WHO South-East Asia Region: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste².

WHO Western Pacific Region: Australia, Brunei Darussalam, Cambodia, China, Cook Islands, Fiji, Japan, Kiribati, Lao People's Democratic Republic, Malaysia, Marshall Islands, Micronesia, Mongolia, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Philippines, Republic of Korea, Samoa, Singapore, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu, Viet Nam.

¹ Now in the European Region.

² Not a WHO Member State at the time of distribution of the questionnaire, and therefore not included in the Global Survey.

