National policy on traditional medicine

and

regulation of herbal medicines

Report of a WHO global survey

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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.

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