

# 1. Introduction

## 1.1 Background

In the last decade, there has been a global upsurge in the use of traditional medicine (TM) and complementary and alternative medicines (CAM) in both developed and developing countries. Today, therefore, certain forms of traditional, complementary and alternative medicines play an increasingly important role in health care and health sector reform globally. Hence, the safety and efficacy, as well as the quality control, of traditional medicine and complementary and alternative medicines have become important concerns for both health authorities and the public (2).

The development of traditional medicines has been influenced by the different cultural and historic conditions in which they were first developed. Their common basis is a holistic approach to life, equilibrium between the mind, body and environment, and an emphasis on health rather than on disease. Generally, the treatment focuses on the overall condition of the individual patient, rather than on the ailment or disease. This more complex approach makes evaluation highly difficult, since so many factors must be taken into account.

Therefore, therapies and theories of TM/CAM differ from country to country and region to region. The commercial value of herbal medicines on the international market is high and increasing greatly. Unfortunately, there is a lack of common standards and understanding and appropriate methods for evaluating traditional medicine to ensure the safety, efficacy and quality control of TM/CAM. 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.

Before manufactured drugs came into widespread use, herbal medicines played an important role in human health. Reviewing the history of the development of medicines, we see that most herbal medicines were originally derived from foods. Most manufactured drugs were developed from medicinal plants. The influence of culture and history on the use of herbal medicines differs from country to country and region to region, and they still have a major impact on the use of herbal medicines in modern societies. Therefore, 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.

In order to meet these challenges, the WHO Traditional Medicine Strategy (2) 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. Furthermore, the recommendation from the workshop on herbal medicines at the Eleventh International Conference of Drug Regulatory Authorities (ICDRA – Madrid, Spain, 16–19 February 2004) requested that regulatory agencies should work together to make the best use of scientific resources related to herbal medicines, and stated that sharing national experience and information was crucial. It also requested WHO to facilitate these activities, e.g. by providing updated monographs on medicinal plants and technical/regulatory guidance.

## **1.2 WHO Global Survey**

Herbal medicines are the most widely used traditional medicines. The most important challenges are those of safety, efficacy and quality of herbal medicines. These depend on adequate regulation.

In 1994, WHO contacted countries to collect information on the regulation of herbal medicines. Unfortunately, only 52 countries out of 191 responded. A WHO publication entitled *Regulatory situation of herbal medicines: a worldwide review* (3) was produced, including information from those 52 countries. At countries' further request, WHO published *Legal status of traditional medicine and complementary/alternative medicine: a worldwide review* (4) in 2001. However, much of the information in this document was obtained at second hand. Resolution WHA56.31 requests WHO to provide evidence-based information to assist Member States in formulating policy and regulations to control the safety, efficacy and quality of traditional medicines. A global survey to collect primary information from national health authorities was therefore necessary. WHO decided to establish a global database on national policies on TM/CAM and regulation of herbal medicines, using information obtained from a global survey.

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

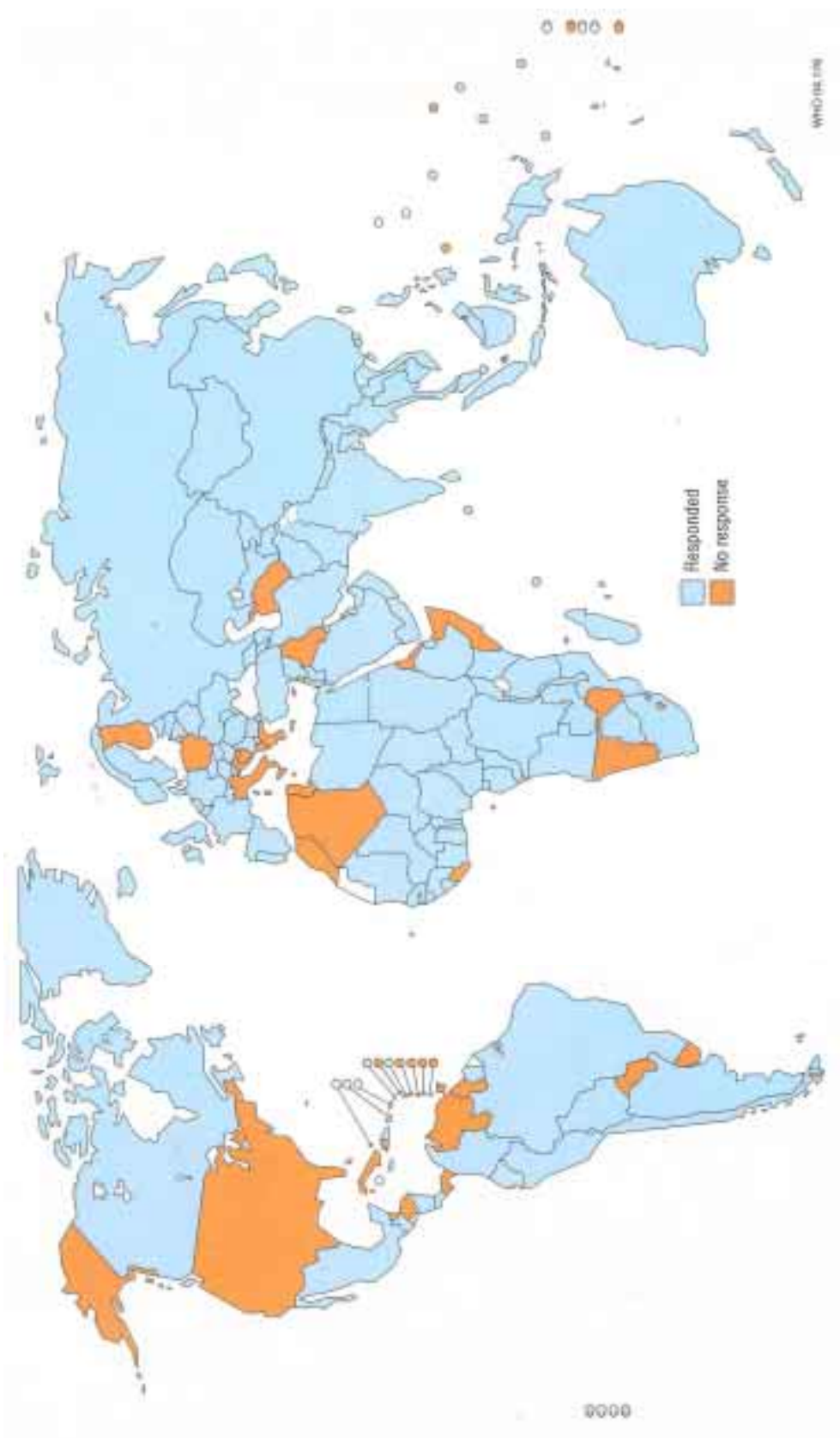
Thanks to our cooperation with the WHO Regional Offices, we received responses from 141 countries, representing 74% of the 191 Member States of WHO at that time (see Map 1).<sup>1</sup> The data were entered into the WHO Global Database developed for this survey. Table 1 and Table 2 above provide a regional breakdown of those countries which responded to the Global Survey.

### **Methods**

WHO initiated the draft survey questionnaire in 1998 and began consulting with national drug authorities to ensure that each part of the questionnaire was easily

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<sup>1</sup> Since Timor-Leste was not a Member State of WHO at the time and consequently was not included in the survey, all global statistics refer to a total of 191 countries.



**Map 1. Member States that responded to the survey**

comprehensible. The questionnaire was designed to focus on priority areas in TM/CAM policy and regulation and herbal medicine regulation in order to facilitate a timely and complete response, in view of the time constraints facing national drug authorities.

Clearly, in each country, the national drug authorities are fully occupied by their considerable volume of routine tasks. In order to minimize the additional burden on them, the information included in the global database covers only national policies on TM/CAM and areas directly related to regulation and registration of herbal medicines. Therefore, other important information which might be of interest to Member States is not included in this survey.

In early 2002, WHO contacted national health authorities, the majority of which were located within national food and drug control agencies, through its Regional Offices and country offices in order to collect data.

The returned surveys were analysed for clarity of the responses, and incomplete and unclear responses were queried. Finally, the draft country profiles featured in Section 5 were distributed to the national authorities of each country for review and correction before this document was finalized. We sincerely thank all the countries that contributed to this report and the Global Survey.

All the data in this document were collected from national drug authorities and clarified where necessary, but there may be still some discrepancies between these primary data and data presented in previous WHO publications on these topics (2, 3, 4). Every effort was made to ensure the clarity and accuracy of the data used in the analysis and presented here, but there may be some mistakes or misinterpretations in the data presented. WHO welcomes any updates, clarifications or corrections.

With this survey, WHO has taken a further step towards an increased understanding of TM/CAM policies and regulation of herbal medicines in countries. By using a common approach to the measurement of the regulatory situation in all countries, it will be feasible to conduct a comparative analysis of the results, and major themes and obstacles can be identified. In order to provide continuous support in the future, WHO also requested countries to define their assistance needs. Additionally, the data provided in response to this survey forms a baseline for future understanding of the implementation and impact of the WHO Traditional Medicine Strategy.

### **1.3 Global database**

Using the collected data and information from the Global Survey, a WHO global database was created. The purposes of the database are to:

- collect and update country information on national TM/CAM policy and regulation of herbal medicines
- share information and experience of national policy on TM/CAM and regulation of herbal medicines to facilitate the establishment of relevant national policy and regulations
- monitor country progress in the field of TM/CAM, particularly that relating to the safe and effective use of herbal medicines
- identify the most difficult areas in countries and the kinds of assistance and support which Member States need from WHO
- continue updating the information in the future.

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.

### **Utilization**

In the database, users will be able to find not only the countries' replies to the questionnaire, but also the detailed information on the laws and regulations themselves, as well as further regulatory requirements, monographs and pharmacopoeias. Unfortunately, these details have not been translated into English because of lack of funds.

Finally, after consultation with national drug authorities, it was decided to open the WHO global database only to the national health authorities at present, not to the general public.

WHO plans to continue to update and expand the database. A second survey will be undertaken in the near future, upon the completion of the WHO Traditional Medicine Strategy.

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