

**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 |

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 Member States (80% of 46) | 18 Member States (51% of 35) | 16 Member States (76% of 21) | 38 Member States (73% of 52) | 10 Member States (100% of 10) | 22 Member States (81% of 27) |

Total respondents: 141

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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.

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:

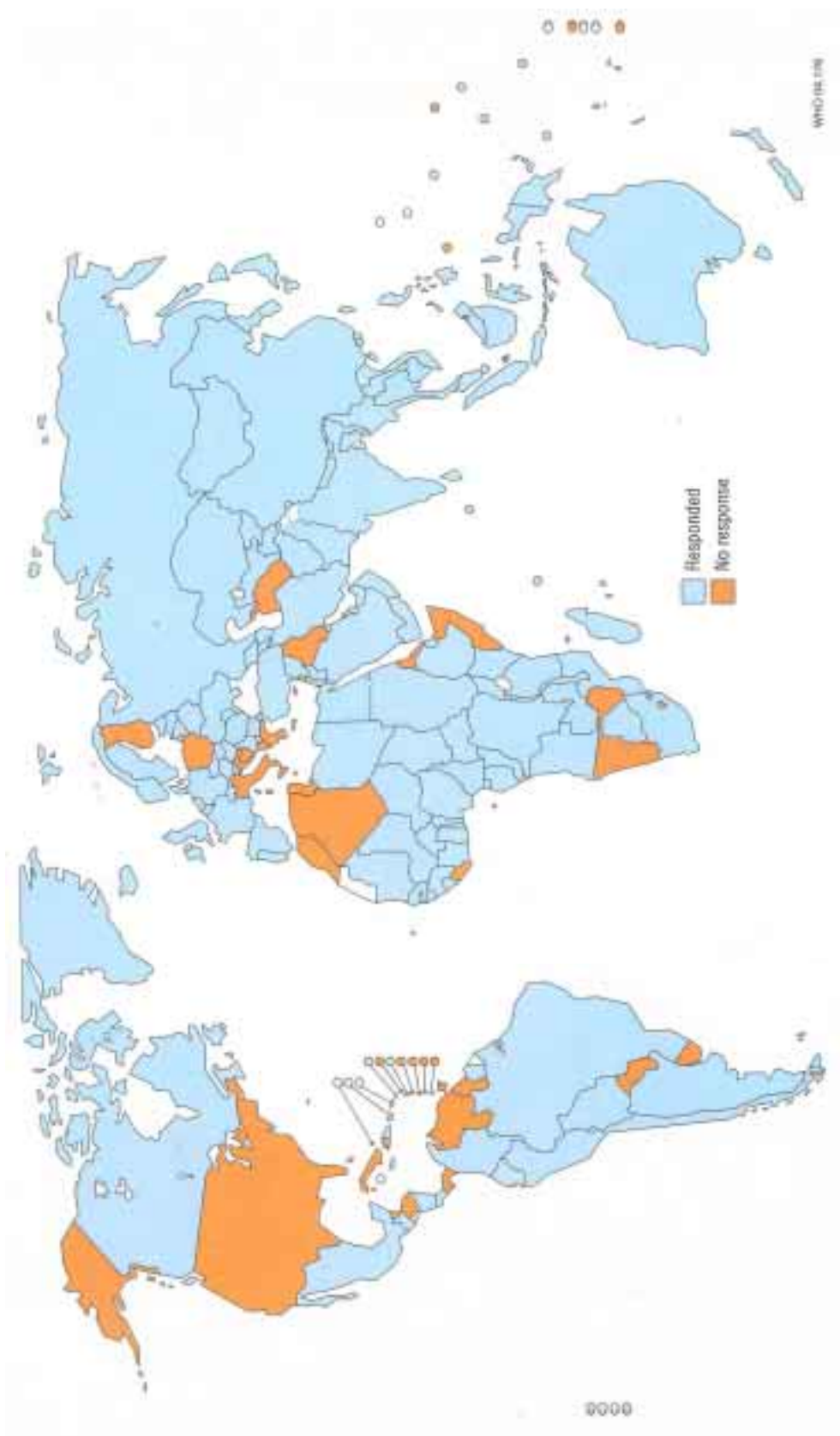
- general review of policy and regulation on TM/CAM
- regulation of herbal medicines
- countries' needs for future WHO support and technical guidance.

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).¹ 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

¹ 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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2. National policy on traditional medicine and complementary/alternative medicine

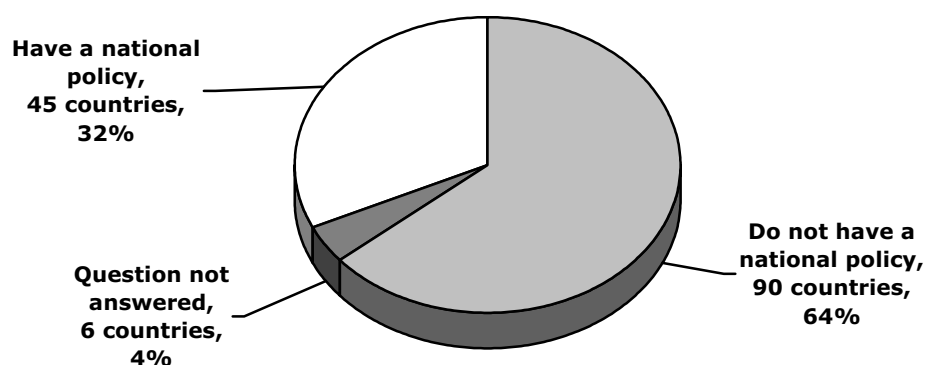
2.1 National policy on TM/CAM

As defined in the survey form and based on the WHO publication *WHO traditional medicine strategy 2002-2005* (2), the concept of a national policy on TM/CAM involves some of the following key elements: a definition of TM/CAM, provision for the creation of laws and regulations, and consideration of intellectual property issues. National policy also can reflect the main strategies proposed by the government for achieving the objectives of the policy. National policy may include laws and regulations on TM/CAM in the same document.

In the survey form, Member States were asked the following question: “Is there a national policy on TM/CAM?” and were given the choice yes/no. If responding yes, Member States were further asked for the year of issue of the national policy. If responding no, they were asked if such a policy is in the process of being established.

The survey results from the 141 Member States responding to the Global Survey demonstrate that 32% (45) of these have issued national policies on TM/CAM (see Figure 1).

Figure 1. National policy on TM/CAM

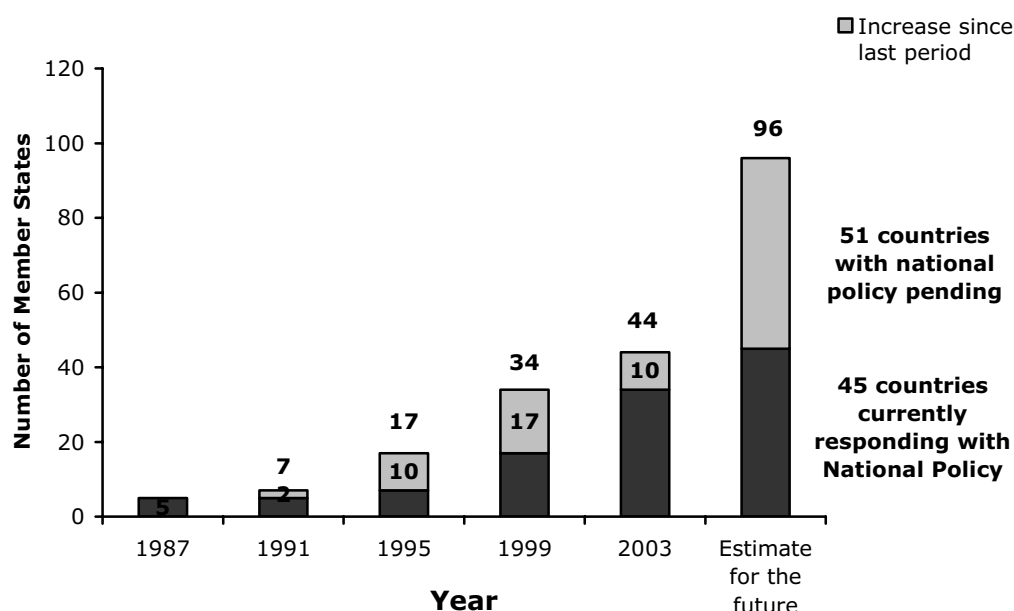


Furthermore, of those Member States that do not currently have a national policy on TM/CAM, a significant percentage (56%, 51 countries) have indicated that such policies are in the process of development.

Of those countries with national policies, 44 provided the year in which the policy was issued. The number of Member States with national policies on TM/CAM has increased significantly overall in the last decade. It is also apparent that a majority of Member States that responded (59%, 27 States) have issued such policies since 1996. It implies a growing trend in the recent past for Member States to establish national policies on

TM/CAM. This trend will continue since, as noted above, 51 countries are currently developing their national policy on TM/CAM (Figure 2).

Figure 2. Number of Member States with national policies on TM/CAM, by year



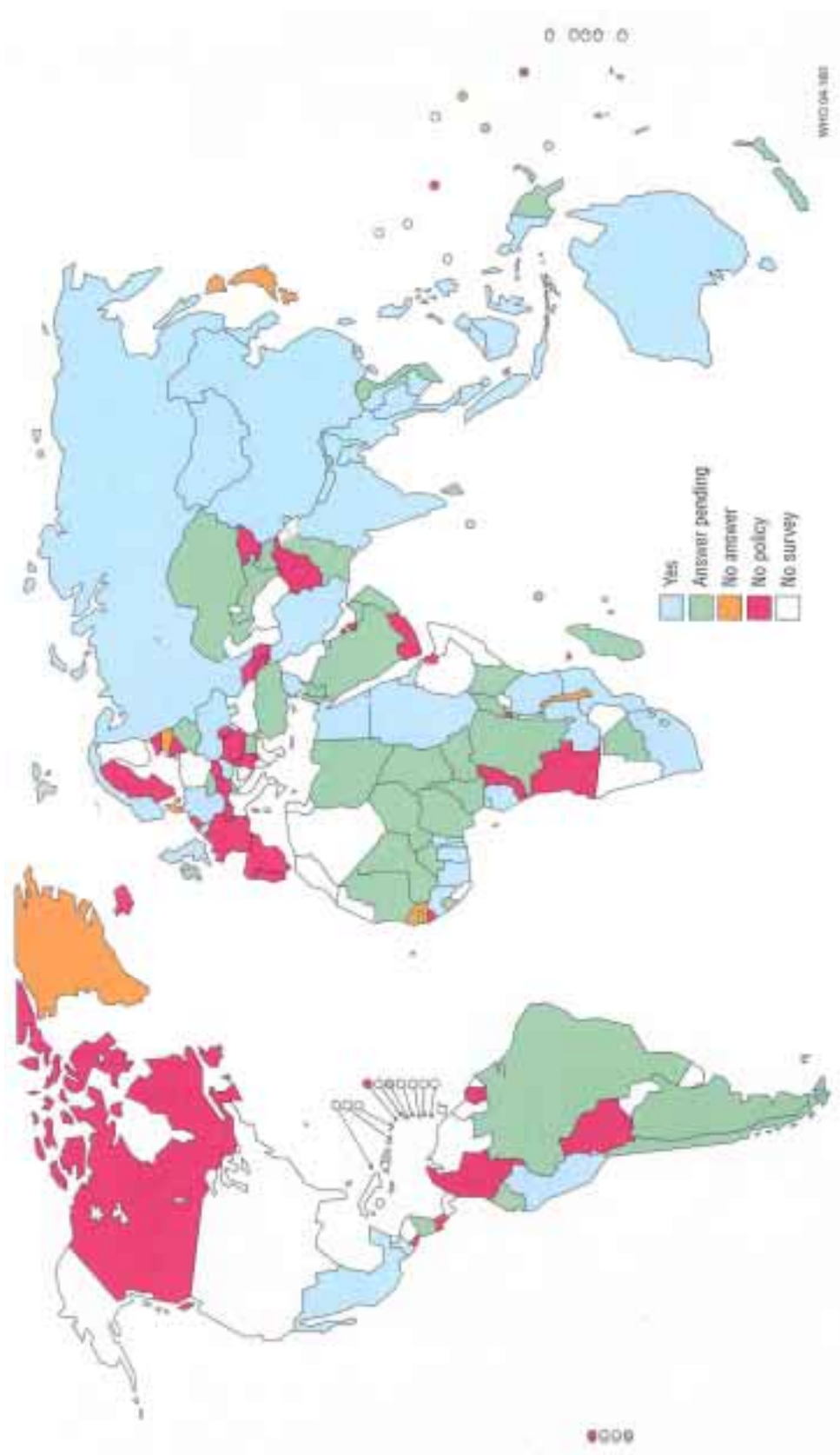
Finally, Map 2 indicates those countries with national policies on TM/CAM, and those countries indicating that such policies are in the process of development.

2.2 Laws or regulations on TM/CAM

A question about laws and regulations on TM/CAM was included on the survey form, following the definitions established in the WHO publication *Indicators for monitoring national drug policies* (5). The structure and comprehensiveness of laws and regulations on TM/CAM varies from country to country; furthermore, in some Member States, while no national policy exists, laws and regulations cover different areas in TM/CAM regulation.

A law on TM/CAM was defined as the first stage of legislative procedure. It is the rule of conduct imposed by the authority. A law establishes the legal conditions under which TM/CAM should be organized in line with a national TM/CAM policy or other relevant policies. The law may cover various areas in the TM/CAM field, including education of professionals, licensing of practitioners and manufacturers, manufacture of products used in TM/CAM, sales practices, etc. Both the public and the private sector may be covered.

A regulation on TM/CAM was defined as the second stage of legislative procedure, specifically designed to provide the legal machinery required to achieve the administrative and technical goals of the law. Many activities in the field of TM/CAM may be covered by regulations, such as a description of obligations and responsibilities of licensed practitioners, the penal sanctions if these are not respected, the obligations incumbent on manufacturers of TM/CAM products, etc.

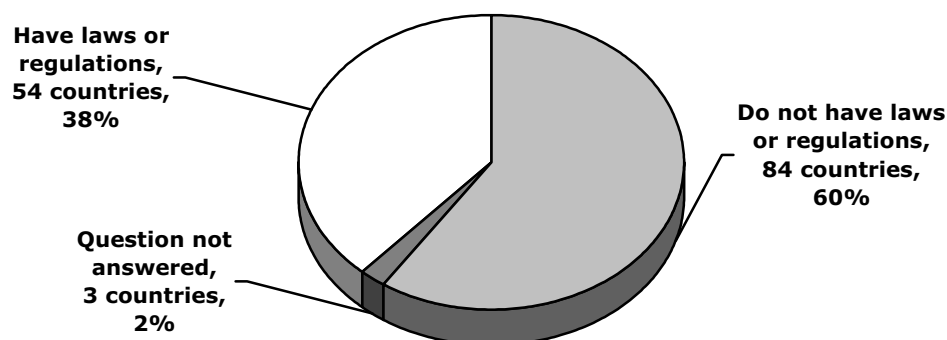


Map 2. Member States with national policies and those pending

Member States were asked whether they had a national law or regulation on TM/CAM; if the respondents replied “yes”, they were asked for the date it was issued, and if they replied “no”, they were asked whether such a law or regulation is in the process of being developed.

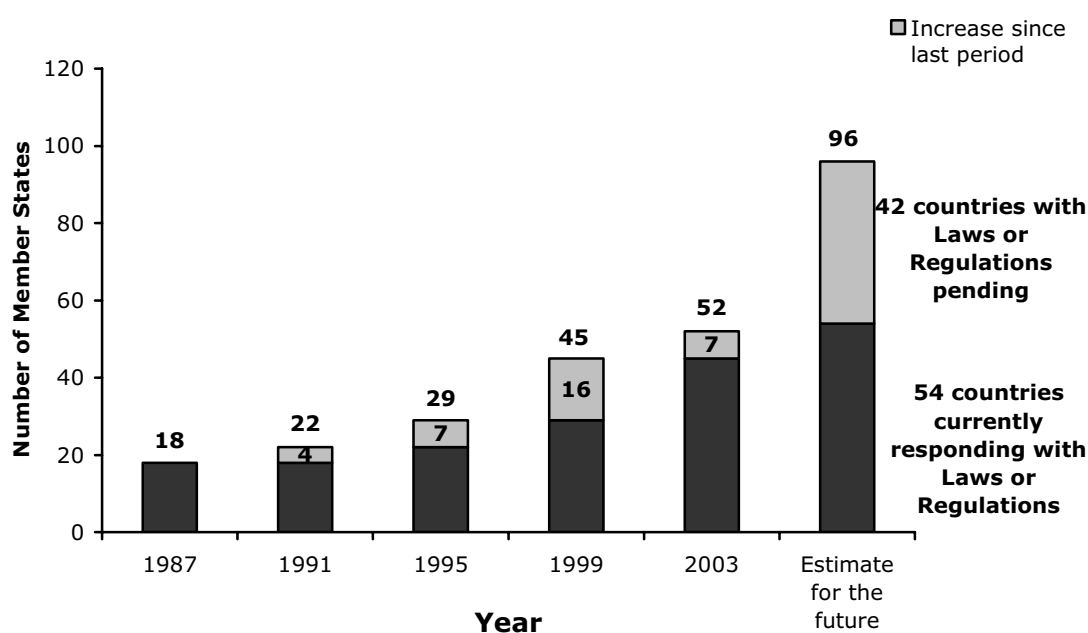
A minority of countries reported having laws or regulations on TM/CAM (38%, 54 countries, see Figure 3).

Figure 3. National laws or regulations on TM/CAM

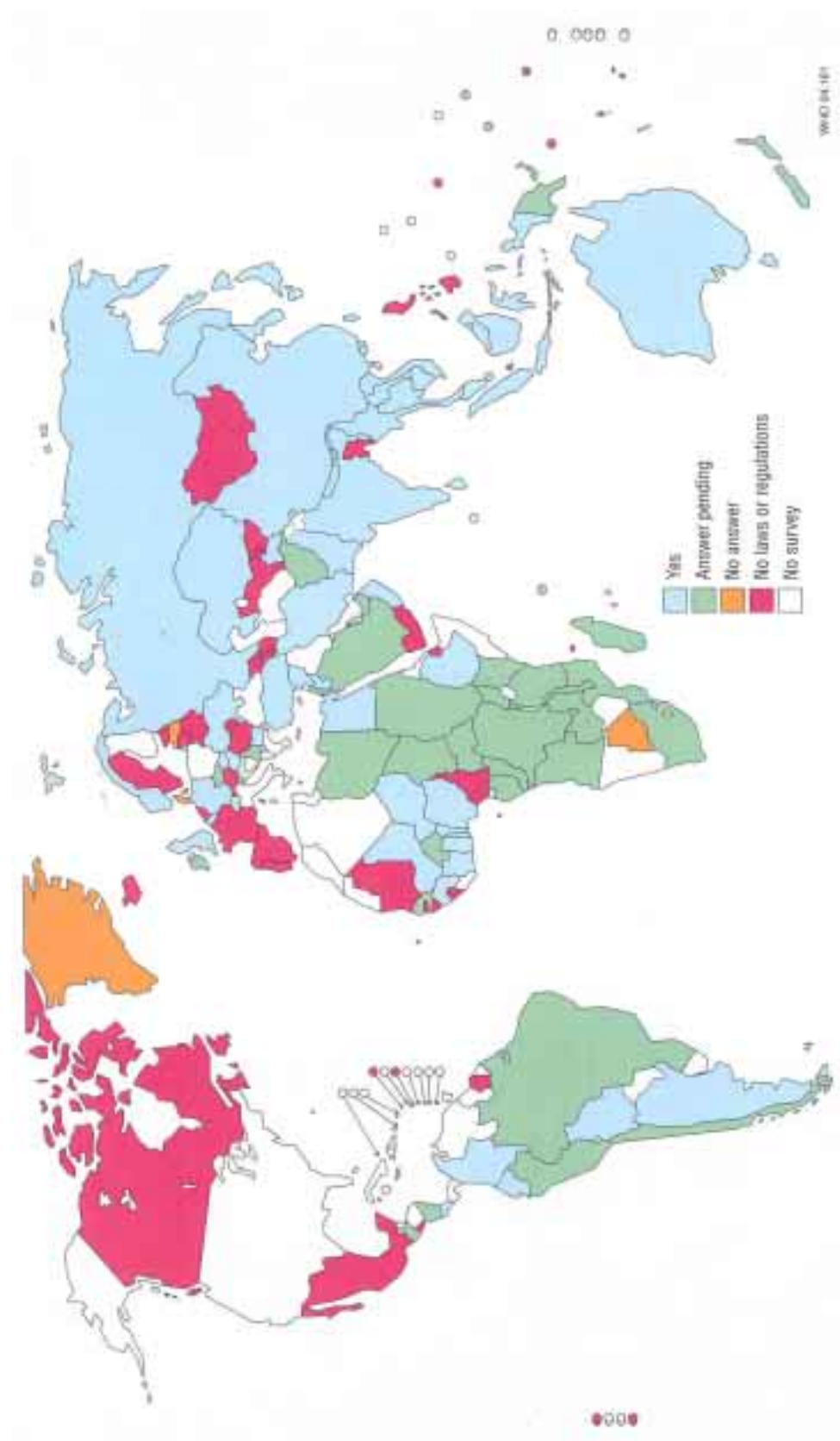


Fifty-two Member States supplied the year of issue for laws or regulations on TM/CAM. While many Member States had developed such laws or regulations by 1987, the majority of these laws or regulations were created in the period 1988-2003 (Figure 4).

Figure 4. Number of Member States with laws or regulations on TM/CAM, by year



Map 3 indicates those Member States in which a law or regulation on TM/CAM is in place and those in which a law or regulation is in development.



Map 3. Member States with laws or regulations on TM/CAM

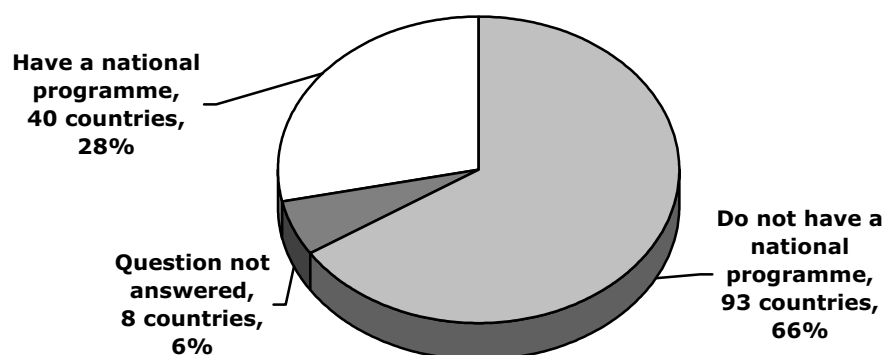
2.3 National programme on TM/CAM

A national programme on TM/CAM, as defined in the survey form, is any programme performed at local or national level by the Ministry of Health, other ministries or local bodies, whose mandate is to take specific action in order to achieve objectives in line with national policy or legislation.

Member States were asked whether a national programme exists and if so, when it was created. If they answered “no”, they were asked to indicate whether such a programme is in the process of being established.

Forty Member States (28%) reported that they had created a national programme on TM/CAM (Figure 5).

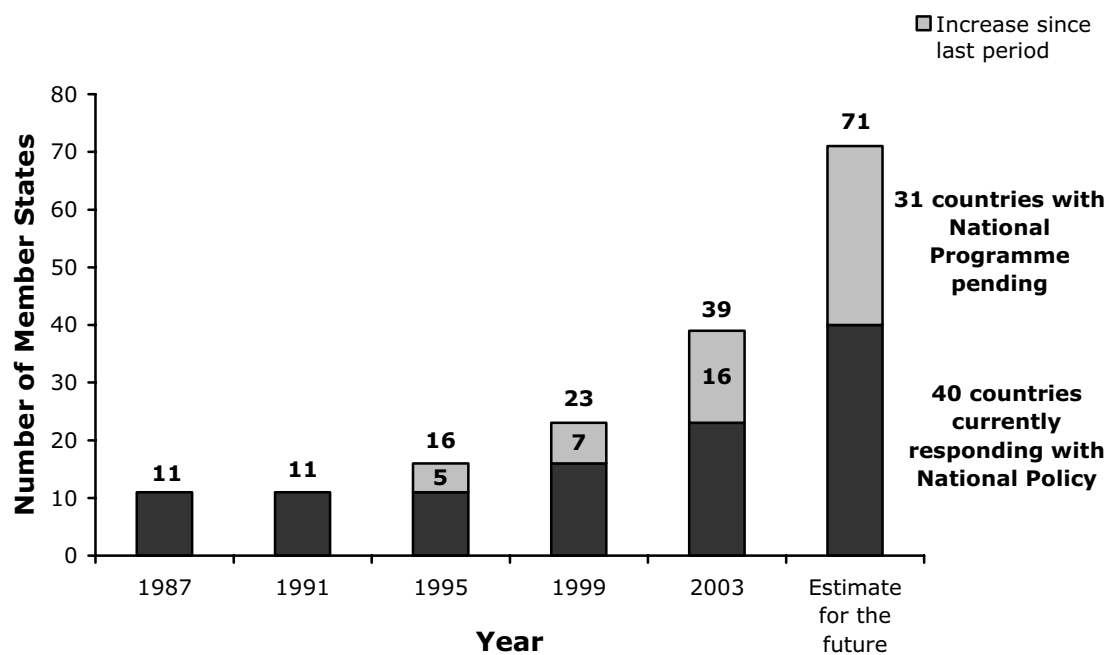
Figure 5. National programmes on TM/CAM



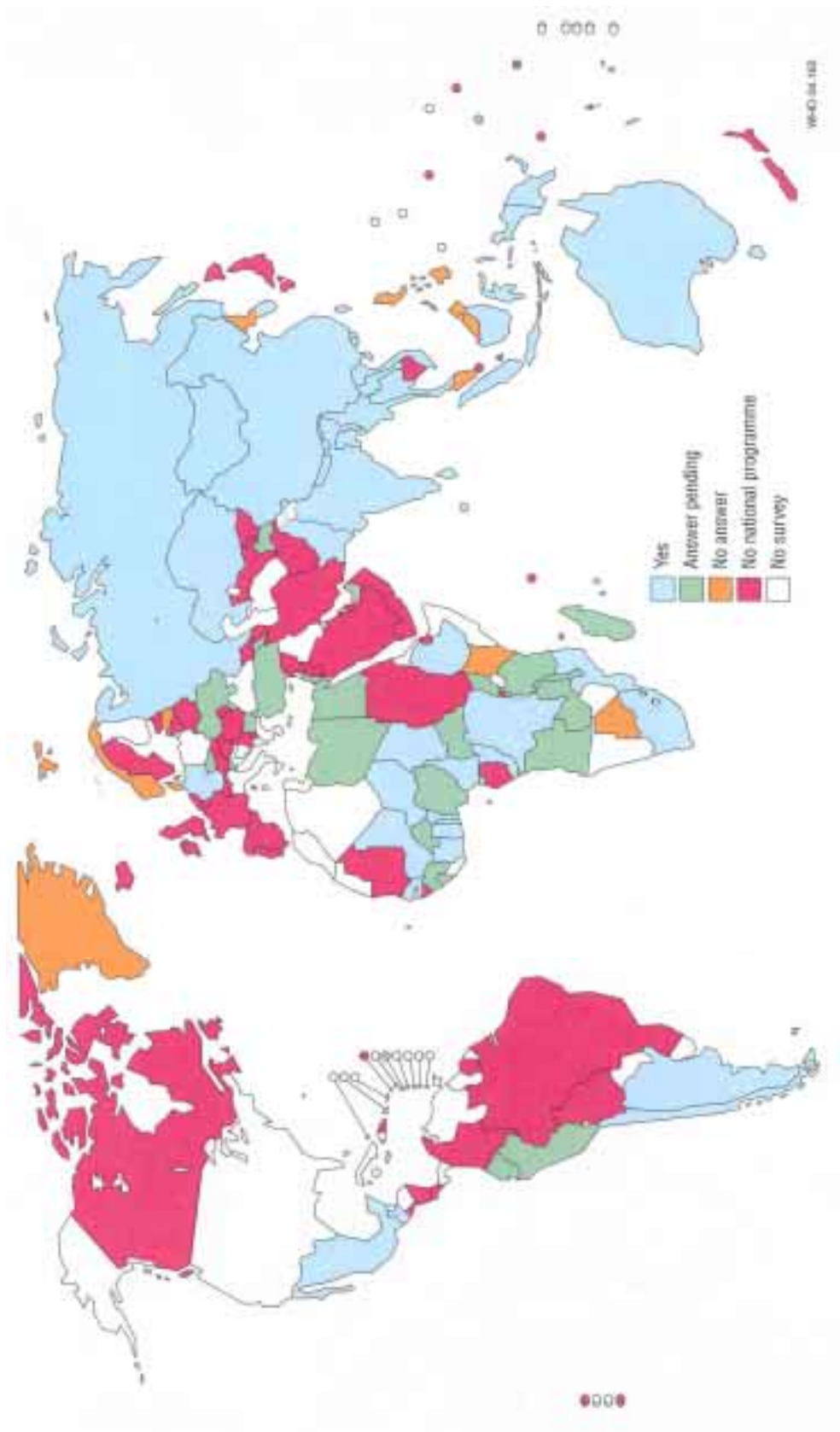
Further, of those Member States lacking such a programme, 33% (31 countries) indicated that such a programme was in the process of being established.

Of the 40 countries having a national programme on TM/CAM, 39 stated the year of issue. It can be seen that the number of national programmes on TM/CAM has more than doubled in the last decade (Figure 6). Furthermore, the greatest numbers of national programmes on TM/CAM were issued in the period 2000-03 compared with other periods, signalling an increased trend in establishing national programmes.

Figure 6. Number of Member States with national programmes on TM/CAM, by year



Finally, Map 4 indicates those Member States with national programmes on TM/CAM, and those Member States indicating that a national programme is in development.



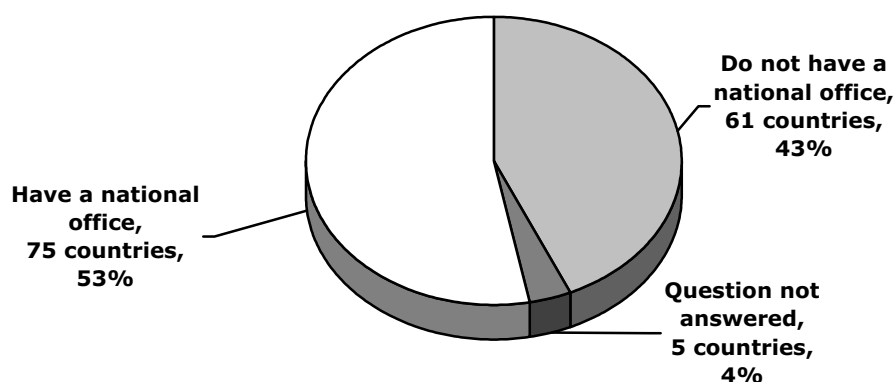
Map 4. Member States with a national programme

2.4 National office for TM/CAM

Member States were asked whether a national office for TM/CAM existed. If one did, they were asked to provide the date of establishment and the ministry responsible for it. Although the term “national office” was not defined, the working definition is an office or department which forms part of the national authority and is responsible for TM/CAM issues. If countries replied “no”, they were asked to indicate whether such an institution is being planned.

Compared with other categories of national policy, the survey results reveal that more Member States have national offices for TM/CAM than national policies, laws or regulations and national programmes. More than half (75 countries, 53%, Figure 7) of responding Member States reported having such an office.

Figure 7. National offices for TM/CAM

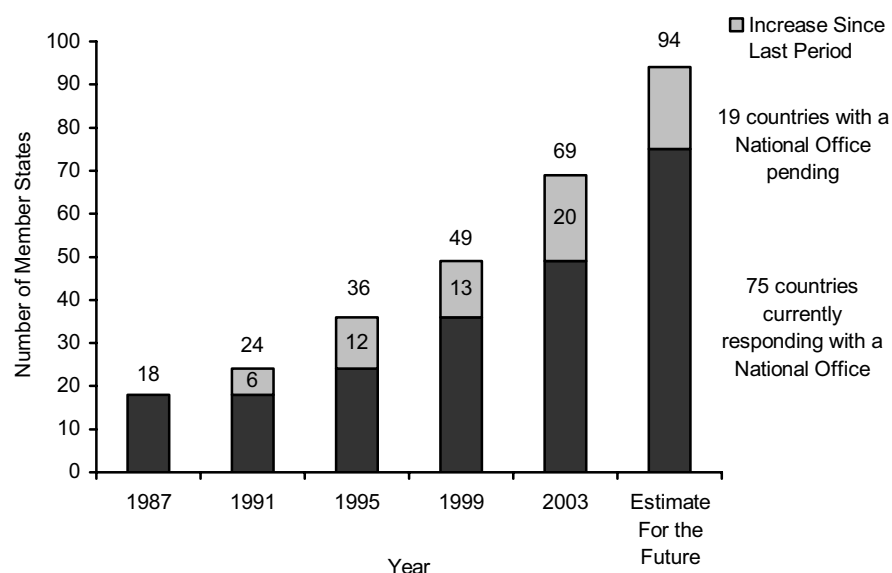


Nearly all (92%) of those countries with national offices report that they are run by the Ministry of Health.

Of the 57 countries reporting that a national office does not exist, only 19 (31%) indicated that such an institution is being planned.

A study of the years of establishment for national offices on TM/CAM supports the idea that such institutions are a more recent development. As outlined in Figure 8, from 1987 to 2003, the number of national offices throughout the world nearly quadrupled. During the period from 2000 to 2003, almost twice as many national offices were established as in any other period.

Figure 8. Number of Member States with a national office on TM/CAM, by year



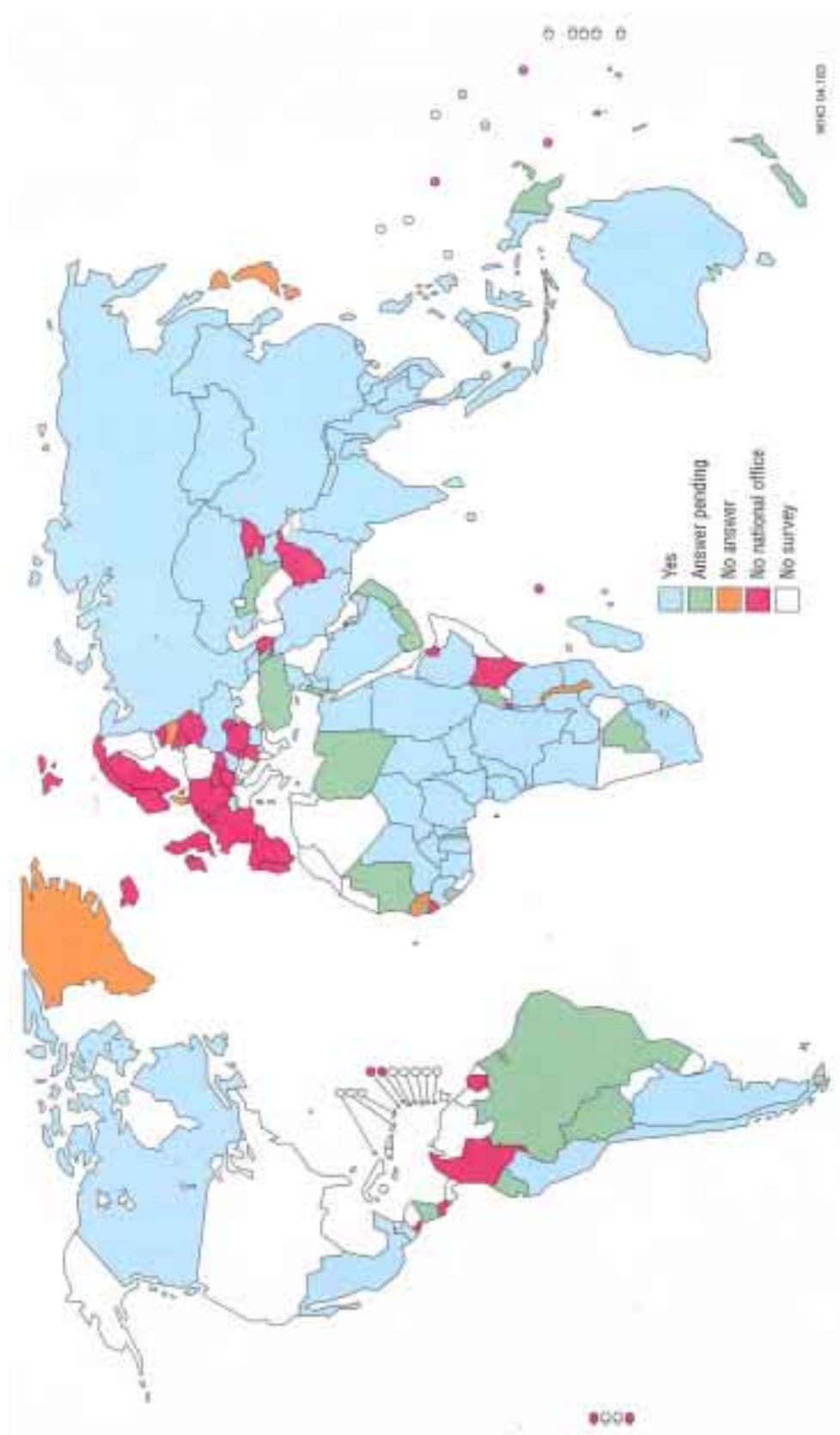
Finally, Map 5 below shows those Member States that have a national TM/CAM office, and those that indicated that such an office is in development.

2.5 Expert committee on TM/CAM

Although not specified in the survey form, the working definition of an expert committee on TM/CAM is a group convened by the national government for the purpose of reviewing and making policy and technical recommendations on TM/CAM topics.

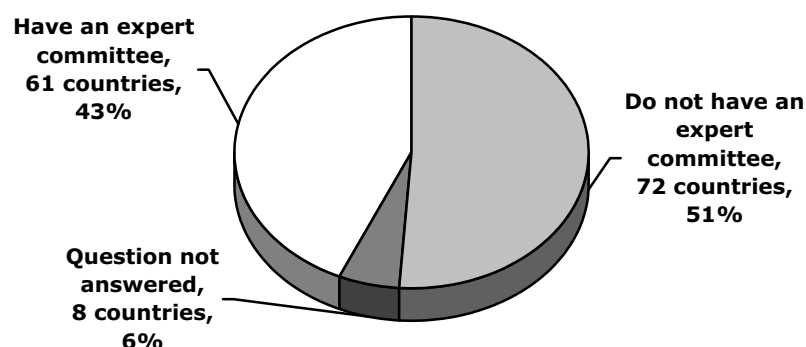
Member States were asked to indicate whether such a group exists and, if so, the date of its establishment.

The survey response indicates that 43% (61 countries) of the responding Member States have expert committees for TM/CAM (Figure 9).



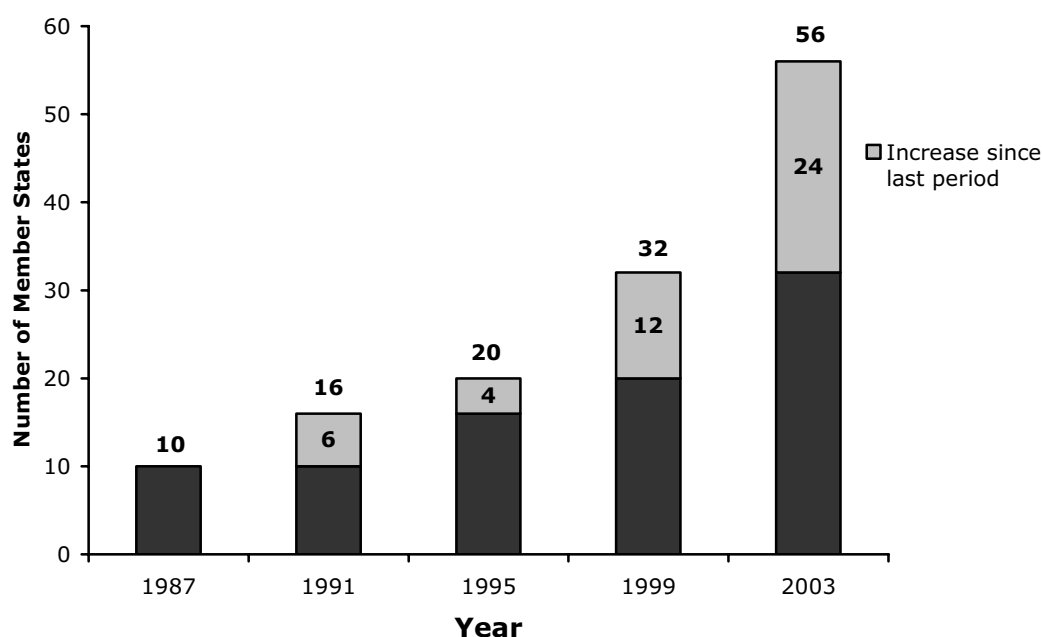
Map 5. Member States with a national office on TM/CAM

Figure 9. Expert committee on TM/CAM



Of those Member States having expert committees, 53 provided the date of establishment of their national group. Analysis of these data indicates a recent surge in the establishment of these committees. The number of expert committees more than quadrupled during the period 1988-2003 compared with all of the years prior to 1988 (see Figure 10).

Figure 10. Number of Member States with expert committees, by year



2.6 National research institutes

As defined in the survey instrument, a national research institute for TM, CAM or herbal medicines is a research institute that performs research on TM, CAM or herbal medicines, and is funded partially or fully by the government.

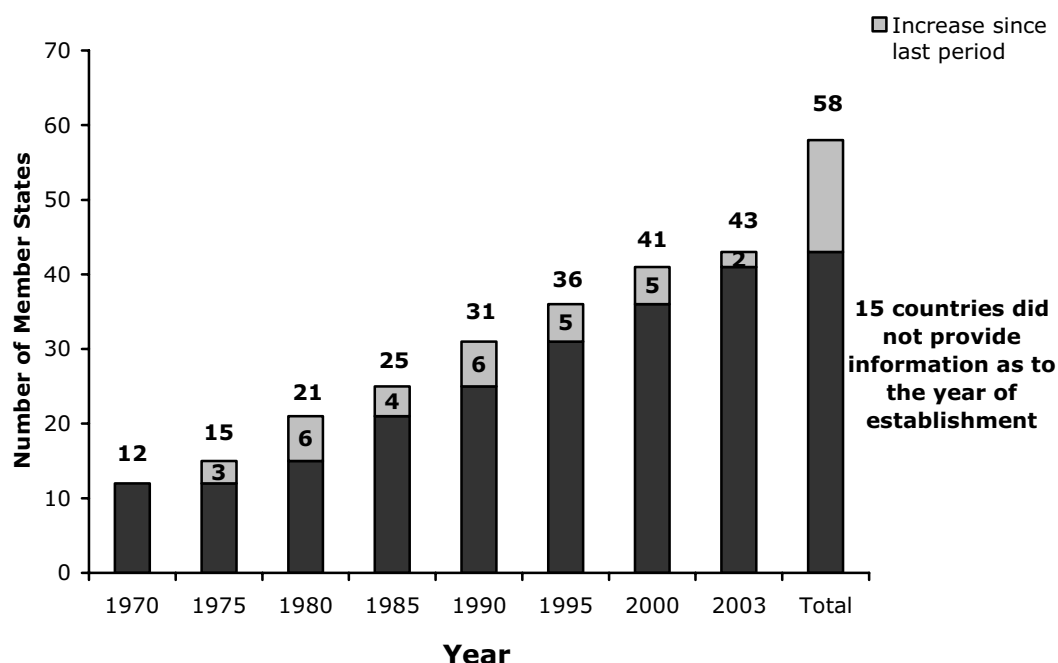
Member States were asked if they had research institutes on traditional medicine, complementary/alternative medicine and herbal medicines. They were also asked for the year of establishment of each research institute.

Results for this section were decidedly mixed. In all, 58 Member States indicated that they had at least one national institute on TM, CAM or herbal medicines. Only seven countries had all three types of research institute, and 28 countries had two kinds of institute.

The survey results further indicate that 27% (38) of responding Member States have a research institute on TM and 33% (46 countries) had one on herbal medicines, but only 6% (9 countries) had a research institute on CAM.

Data on the date of establishment of national research institutes on TM, CAM or herbal medicines were also requested. Forty-three countries supplied the dates of establishment, showing consistent growth in the establishment of these institutes (Figure 11).

Figure 11. Number of Member States with a national research institute on TM, CAM or herbal medicines, by year



3. The regulatory situation of herbal medicines

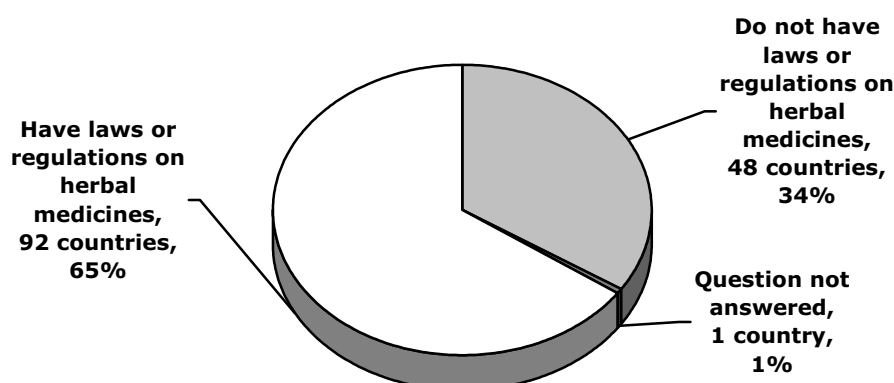
3.1 Law or regulation on herbal medicines

In the survey form, reference was made to the previous definitions of laws and regulations provided for TM/CAM. Herbal medicines have been defined above in the Introduction. In addition, in some countries, animal and mineral materials may be present in herbal medicines.

Member States were asked whether laws or regulations existed for herbal medicines; if they replied yes, follow-up questions asked for the year of issue of such laws or regulations, and the type of law or regulation. The options for the type of law or regulation included the same law or regulation as for conventional pharmaceuticals, a separate law or regulation for herbal medicines, or a law or regulation partly the same as for conventional pharmaceuticals.

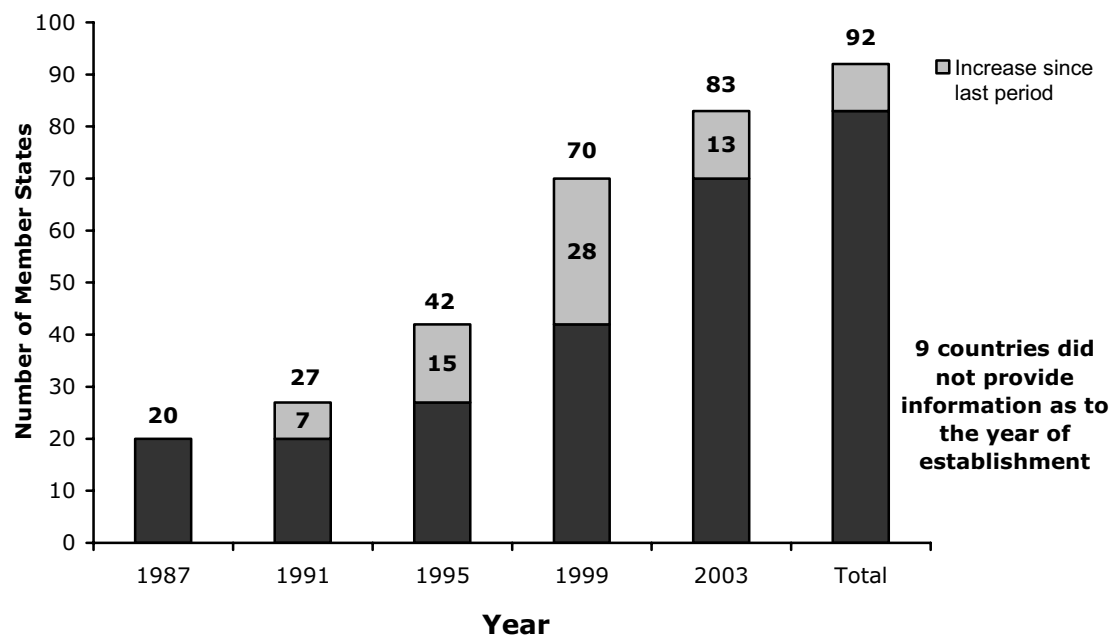
Survey responses indicate that a majority of responding Member States (92 countries, 65%, Figure 12) have laws or regulations on herbal medicines.

Figure 12. Laws or regulations on herbal medicines



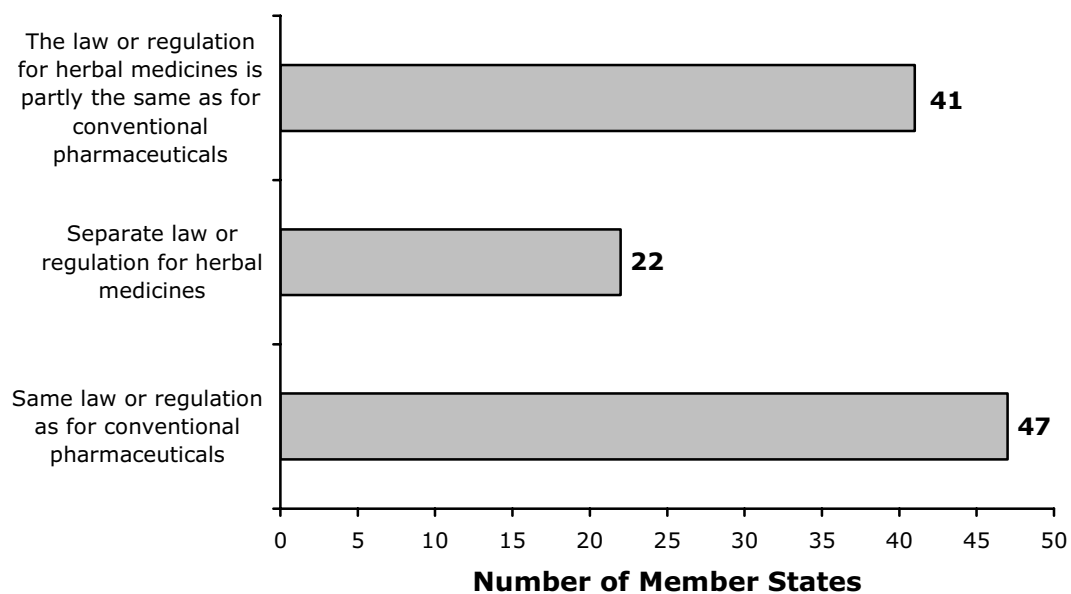
Information provided by 77 of the responding Member States about the year of issue of the law or regulation indicates clearly that the development of laws and regulations on herbal medicine is a recent phenomenon (Figure 13). Over the last 15 years, the number of Member States with laws and regulations on herbal medicines has increased dramatically. The highest number of laws and regulations on herbal medicine were issued between 1996 and 1999.

Figure 13. Number of Member States with laws or regulations on herbal medicines, by year

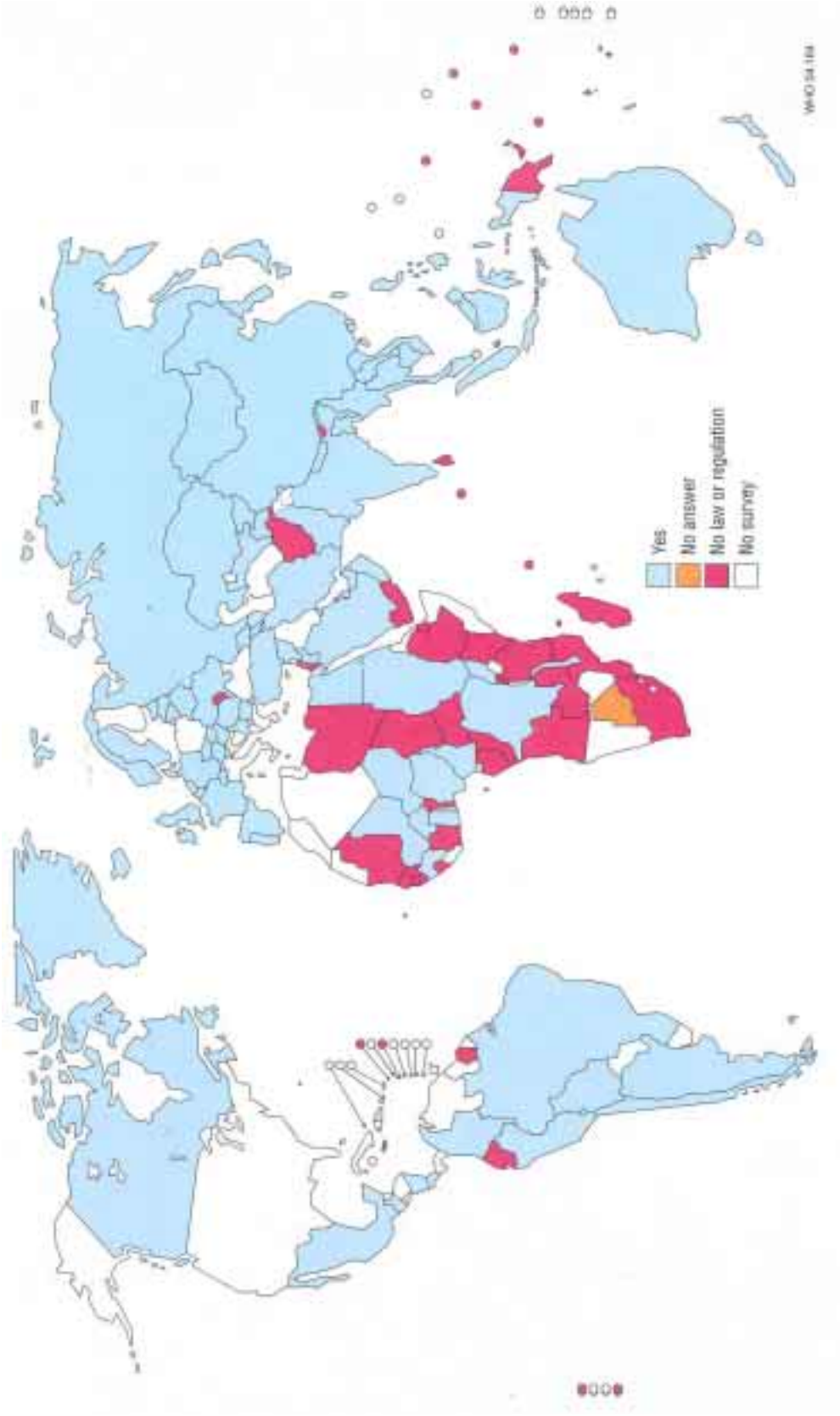


Responses from those Member States having laws or regulations governing herbal medicine largely indicate that these are similar to laws or regulations on conventional medicine (see Figure 14). As responding Member States were able to choose all categories of law or regulation as required, the total number of answers in the chart below exceeds the number of respondents. As many Member States have more than one law or regulation pertaining to herbal medicines, many Member States indicated more than one category for the type of law or regulation. The total number of Member States which responded to this question was 91.

Figure 14. Type of law or regulation on herbal medicines



Finally, Map 6 below illustrates the Member States responding to the Global Survey which have laws or regulations on herbal medicines.



Map 6. Member States with law or regulation on herbal medicines

3.2 Regulatory status of herbal medicines

Member States were asked about the regulatory status or statuses that are used for herbal medicines in their regulatory frameworks. Detailed descriptions of seven possible regulatory categories for herbal medicines were given on the survey form. The options were the following: prescription medicines, over-the-counter medicines, self-medication only, herbal medicines as a separate regulatory category, dietary supplements, health foods, functional foods and other status. These definitions are presented below.

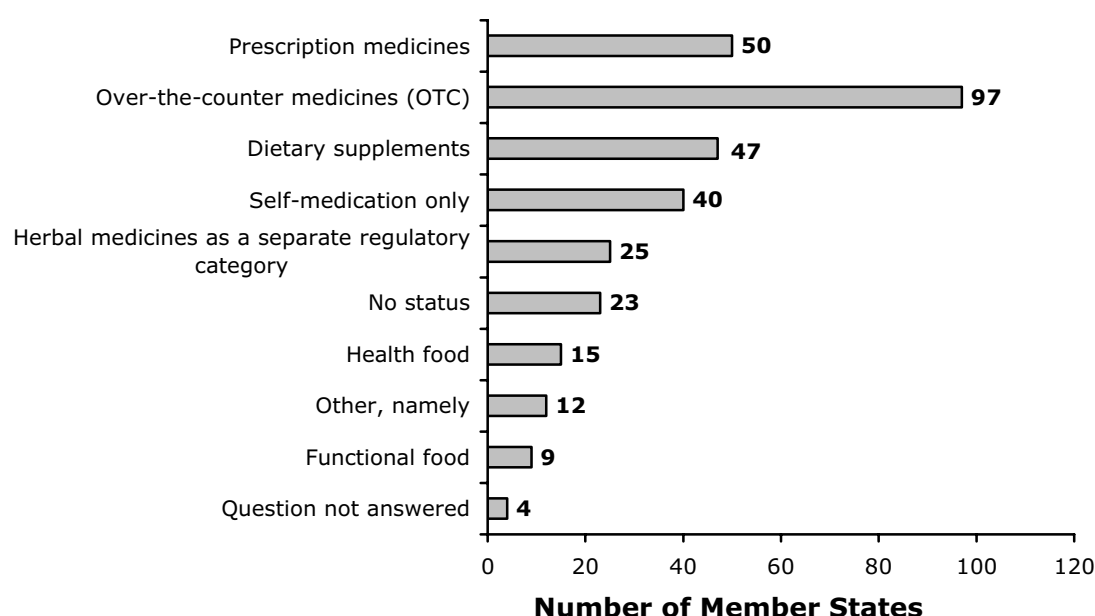
- **Prescription medicines:** medicines/drugs that can only be purchased with a prescription (i.e. a physician's order) (6).¹
- **Over-the-counter medicines:** medicines/drugs that can be purchased without a prescription from a physician (6).
- **Self-medication only:** medicines/drugs permitted for self-medication purposes only.
- **Dietary supplements:** a dietary supplement is a substance which contains, for instance, a vitamin, a mineral, a herb or other botanical or an amino acid. A dietary supplement may be intended to increase the total daily intake of a concentrate, metabolite, constituent, extract or combination of these ingredients (7).
- **Health food:** health foods could be products that are presented with specific health claims and therefore regulated differently from other foods (8).
- **Functional foods:** like health foods, functional foods may be products which are offered with specific health claims and therefore regulated differently from other foods (8).
- **Other:** products classified differently from the above-mentioned categories.

Responses were provided by 131 Member States; as each was able to choose more than one category, the total number of responses exceeds the number of respondents. The regulatory category most often chosen was that of over-the-counter medicine, accounting for 97 responses (see Figure 15 below). The next most popular responses accounted for 23-38% of the total, and included the following categories: prescription medicines, dietary supplements and self-medication only. A total of 23 countries indicated that there was no regulatory status established for herbal medicines.

Countries also had the option of describing other regulatory categories defined by their legislation; 13 countries provided this information. The other regulatory categories applied to herbal medicine include the following: health products, cosmetics, traditional medicines, herbal remedies, supportive medicines, homeopathic, bioactive and probiotic substances, and complementary products.

¹ In some countries, the legal framework allows traditional practitioners to prescribe medicines.

Figure 15. Regulatory status of herbal medicines



3.3 Claims

These questions focused on the types of claims that may be made about herbal medicines under laws or regulations. Definitions of the different types of claims were provided on the survey form. The possible categories of claims were medical claims, health claims, nutrient content claims, structure/function claims, no claims or other claims.

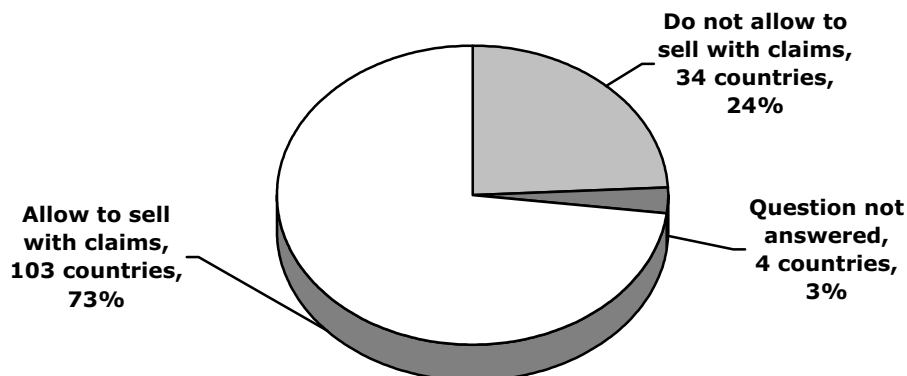
For the purposes of this study, medical claims are defined as those claims specified to treat, cure or prevent a disease or restore, correct or modify physiological functions. Most often products with medical claims have to be registered by the medical products agency before they may be placed on the market (9).

A definition for health claims was given in the survey, based on the one developed by the Swedish Food Administration (10), which states that health claims include any statement, suggestion or implication in labelling or advertising that a product carries a specific health benefit, but not nutritional claims nor medicinal claims. The term health claim further includes claims that refer to nutrient function and recommended dietary practice.

Nutrient content claims involve the indication that a particular product is rich or low in a nutritional component, such as fibre or fat (10). Structure/function claims link a substance to an effect on a structure or function of the body (8).

Member States were first asked whether claims could be made about herbal medicines in their country; if they answered “yes”, they were then asked to choose those categories of claims that could be made in accordance with the law or regulation for herbal medicines. An overwhelming majority of responding countries indicated that herbal medicines are sold with claims (73%, 103 countries, see Figure 16).

Figure 16. Number of Member States that allow the sale of herbal medicines with claims



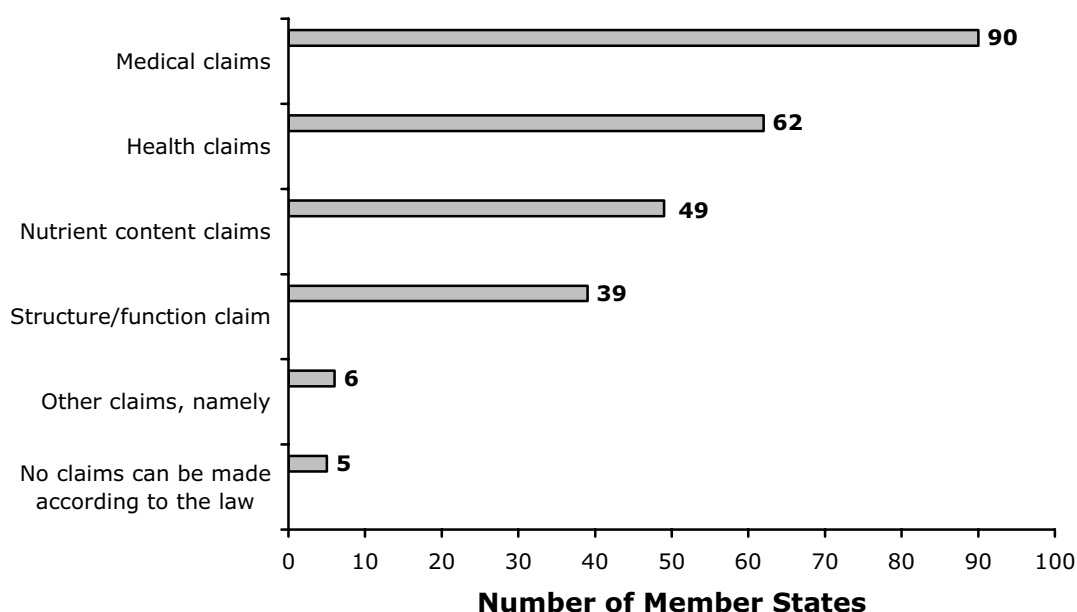
Of those countries indicating that herbal medicines are sold with claims, all 103 provided details about the categories of claims that are allowed by law or regulation (Figure 17). The most common claims made are medical claims, which was chosen by 87% of the responding countries. Health claims were indicated by 60% of the countries, followed by nutrient content claims and structure/function claims, chosen by 48% and 38% of the countries, respectively.

Six countries choose the option of including other claim categories; those given include the following: cultural use claims, effects against bewitchment, sorcery and accidents, cosmetic claims and traditional use claims.

While the results clearly indicate a tendency for medical and health claims to be made for herbal medicines, there is also a clearly a problem with the way the question was worded and interpreted. The form of the question clearly indicates that the claims chosen should represent only those allowable by law or regulation, yet several countries chose claim categories as well as the category “No claim can be made according to the law”.

The meaning of these responses is complex. As five countries who chose “no claim” and other claim categories have more than one regulatory category, it would seem that different regulatory statuses could have specific claims which may be made by law. However, there is a chance that the question may have been misinterpreted, with countries selecting claims that are made about herbal medicines that are not necessarily regulated or sanctioned by law, but rather represent claims made without regulatory oversight or requirements.

Figure 17. Types of claims legally allowed



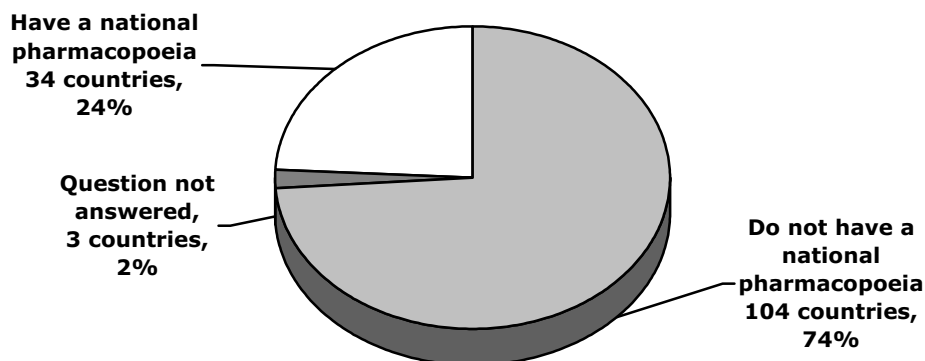
3.4 Pharmacopoeias

Member States were asked a series of questions concerning the existence of a national pharmacopoeia that includes herbal medicines. A pharmacopoeia is a formulary, especially an official one and usually one having legal force in all pharmacies of a given country, containing a description of drugs used in current medical practice and noting their formulae, analytical composition if known, physical constants, main chemical properties useful for identification and mode of preparation of compound preparations/combination products. Details may also be included of assay methods to regulate purity, content of active principle, preservation of quality and, where appropriate, biological potency (11).

If Member States indicated that a national pharmacopoeia existed, the survey asked for bibliographical information about it and asked about its legal status. If Member States indicated that they lacked a national pharmacopoeia, they were asked whether one was being developed and, further, whether another pharmacopoeia was in use. If indicated, the bibliographical details and legal status of other pharmacopoeias used were solicited.

As illustrated in Figure 18, only 24% (34 countries) of the responding countries indicated that a national pharmacopoeia existed and was in use. Of the 104 countries lacking such a national pharmacopoeia, 25% (26 countries) indicated that such a document was in preparation.

Figure 18. Number of Member States with a national pharmacopoeia



As shown in Figure 19, of those 104 Member States lacking a national pharmacopoeia, 56% (58 countries) indicated that another pharmacopoeia was in use. Detailed information about the pharmacopoeia which was used in the absence of a national pharmacopoeia was provided by 52 Member States and listed below in Figure 20. Many countries reported the use of several different pharmacopoeias, the sum of all the responses in Figure 20 therefore exceeds the number of respondents. Finally, 31 countries (30%) reported not using any pharmacopoeia.

Figure 19. Other pharmacopoeias used in the absence of a national one

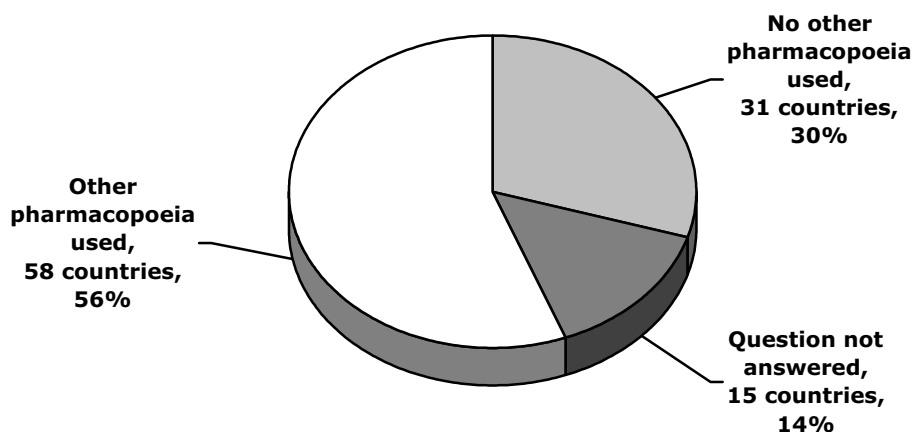
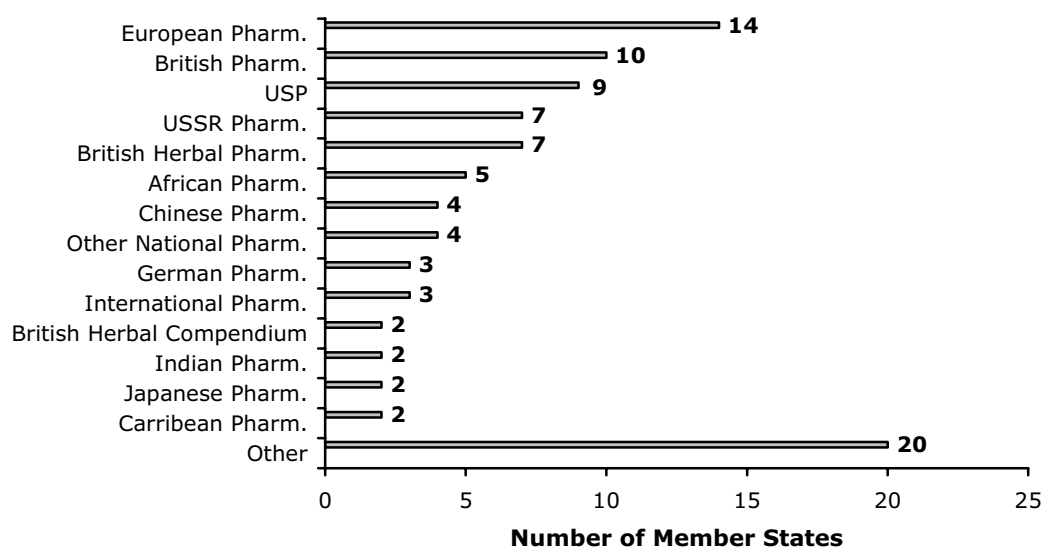


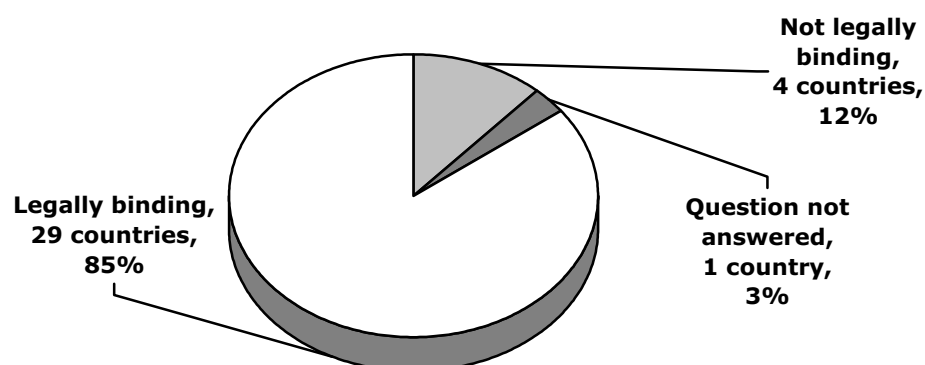
Figure 20. Details of other pharmacopoeias used



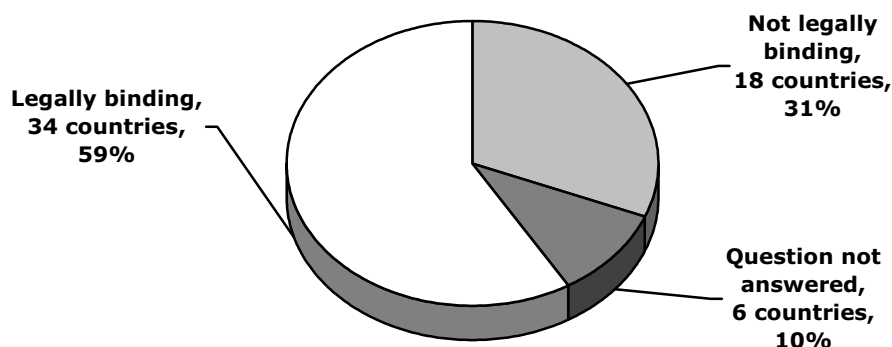
The survey results indicate that the *European pharmacopoeia* is used most frequently (by 14 countries) where no national pharmacopoeia is available, followed by the *British pharmacopoeia* and the *United States pharmacopoeia*. However, these figures are inflated by the fact that the *European pharmacopoeia* has been adopted by the European Union as its official guide; as many of those countries reporting use of the *European pharmacopoeia* are in the European Union, their survey replies tend to overemphasize the global use of this pharmacopoeia. If the official signatories to the *European pharmacopoeia* are excluded, six other countries use this pharmacopoeia.¹

Finally, countries were asked about the legal status of the national or other pharmacopoeia used (Figure 21 and Figure 22). In 85% of the 34 countries with a national pharmacopoeia, the information it contains is legally binding. In 59% of the 58 countries using another pharmacopoeia, the information contained in the other pharmacopoeia is legally binding.

Figure 21. Legal status of national pharmacopoeias



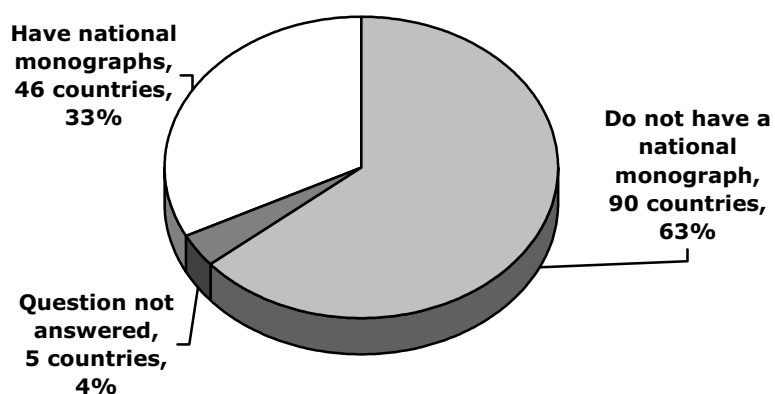
¹ Based on the list of parties in the *European pharmacopoeia*, 4th ed., 2002. However, four of these countries were observers at the time and may have joined the European Pharmacopoeia Commission since.

Figure 22. Legal status of other pharmacopoeias

3.5 Monographs on herbal medicines

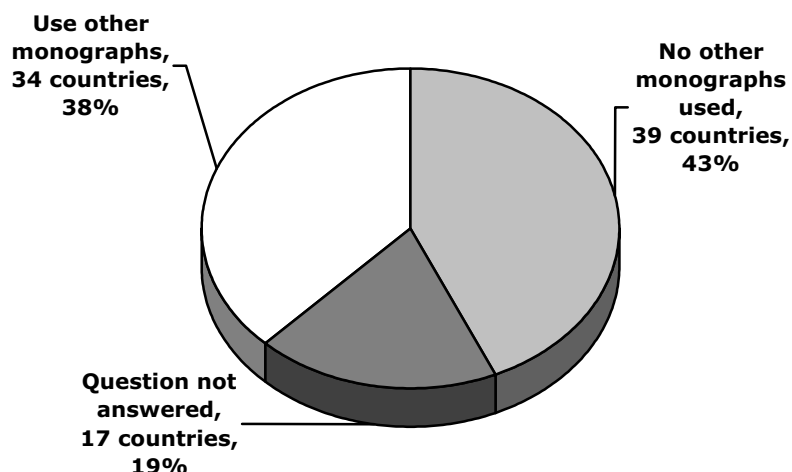
Member States were asked a series of questions concerning the existence of national monographs on herbal medicines. As defined in the survey form, monographs on herbal medicines are descriptions of different herbal medicinal formulae, which either are included in a pharmacopoeia or exist separately (12). If Member States indicated that national monographs existed, the bibliographical information was solicited and the question of the legal status of the national monographs was posed. If Member States indicated that they lacked national monographs, they were asked whether such monographs were in the process of development and, further, if other monographs were in use. If indicated, the bibliographical and legal status of other monographs used was solicited.

Of the responding Member States, 46 (33%) reported that they had national monographs on herbal medicines (Figure 23): furthermore, of the 84 countries that reported not having national monographs, 25 (28%) indicated that national monographs were in development.

Figure 23. National monographs on herbal medicines

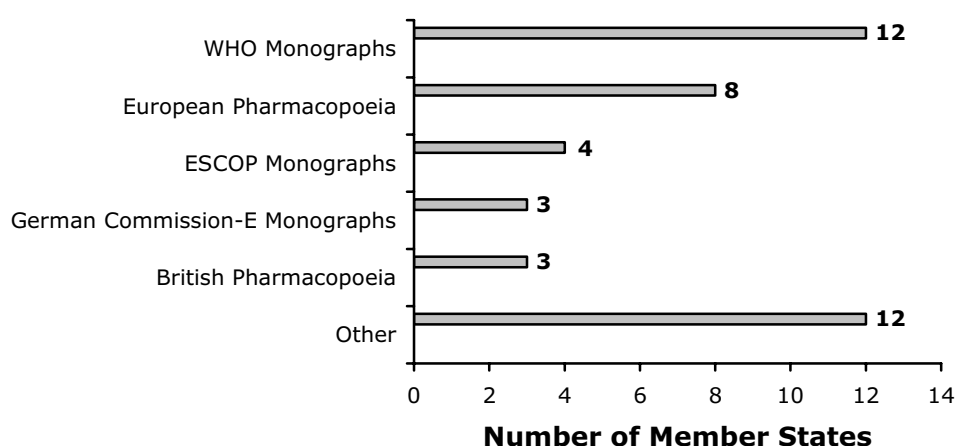
Of the 84 countries which lack national monographs, 38% (34 countries) reported the use of other monographs, as illustrated in Figure 24.

Figure 24. Other monographs used in the absence of a national monograph



In place of national monographs on herbal medicines, many countries reported the use of multiple monographs. Detailed information on the major categories of monographs used was given by 30 countries and is presented in Figure 25. These figures are based on the responses given by 27 countries; however, as many countries used multiple monographs, the total numbers presented in Figure 25 exceeds the number of responding countries.

Figure 25. Other monographs used



As presented in Figure 25, the *WHO monographs* series was reported as being used by the largest number of countries, followed by the *European pharmacopoeia* and the European Scientific Cooperative on Phytotherapy monographs (*ESCOP monographs*). Almost all the monographs reported by responding countries are included in the various pharmacopoeias.

Finally, countries which reported having national monographs and those reporting their use of other monographs were asked about the legal status of the monographs (see Figure 26 and Figure 27). Of the 46 countries with national monographs, 52% (24 countries) reported that their monographs were legally binding. Of the 34 countries that reported using other monographs, 44% (15 countries) reported that such texts are legally binding.

Figure 26. Legal status of national monographs

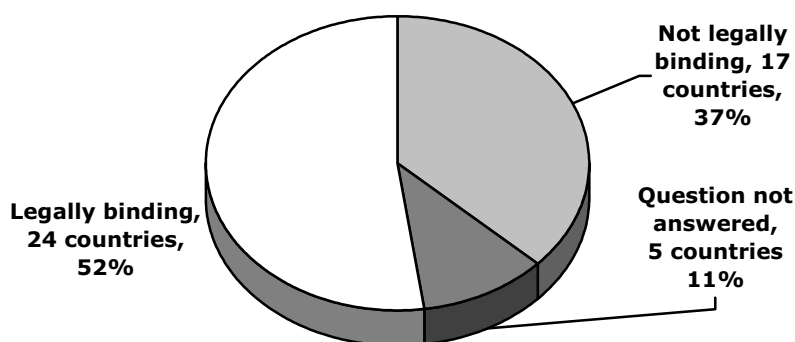
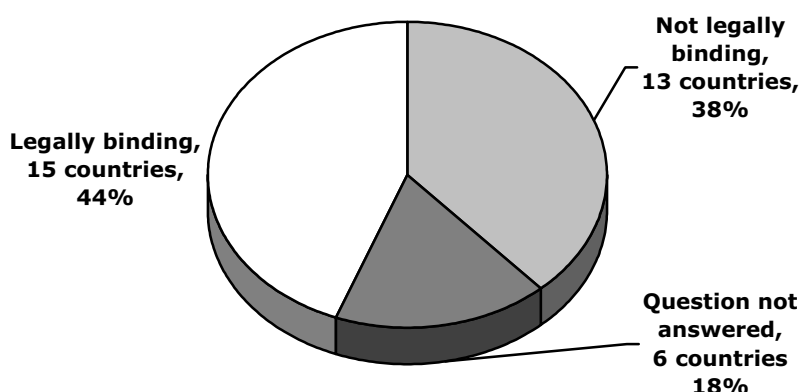


Figure 27. Legal status of other monographs



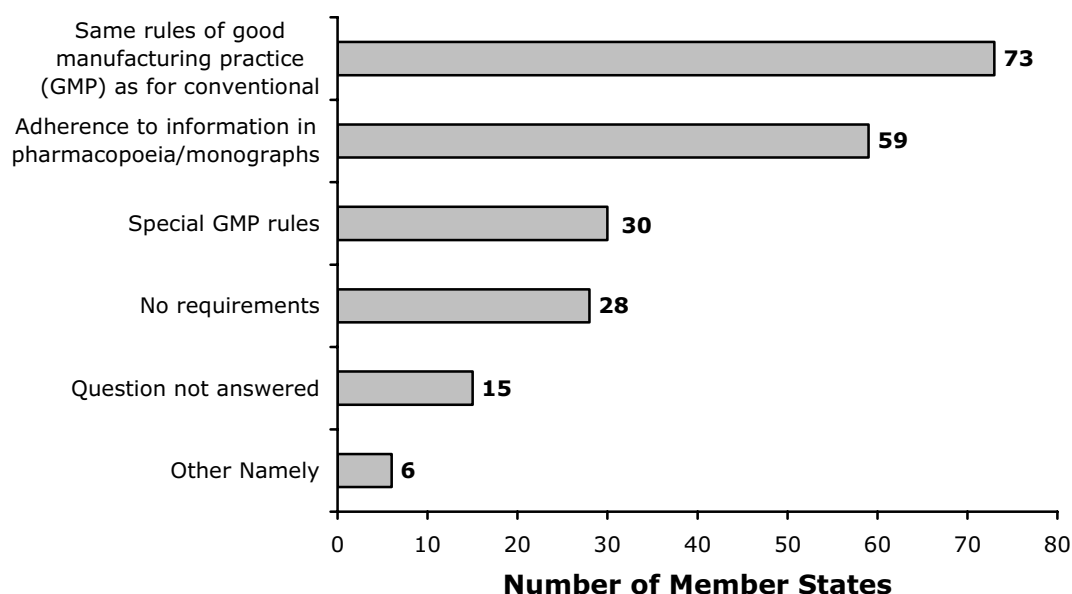
3.6 Manufacture of herbal medicines

Member States were next asked about regulatory requirements for the manufacture of herbal medicines. Possible answers included the following options: adherence to information in pharmacopoeias or monographs, the same GMP rules as for conventional pharmaceuticals, special GMP rules, no requirements and other requirements. Countries were able to choose all that applied. For clarification purposes, GMP was described as requirements in areas such as quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacture and analysis, complaints and product recall and self-inspection (13).

A total of 126 countries responded to this set of questions (see Figure 28). Most countries indicated that the same GMP rules as used for conventional pharmaceuticals were required for herbal medicines. The next largest number was reports of adherence

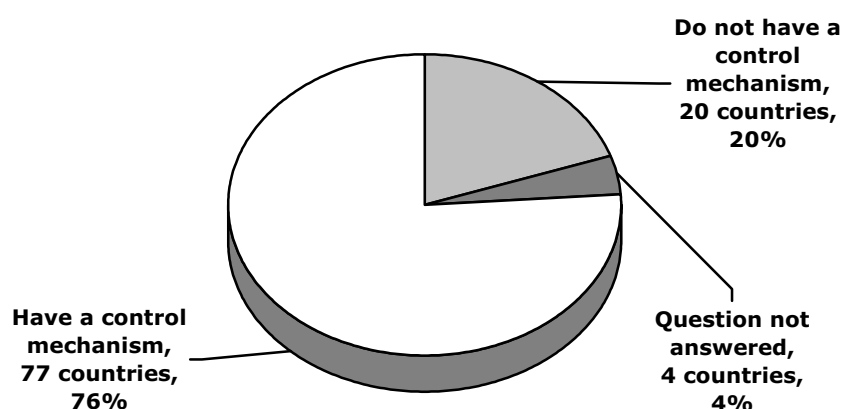
to information in pharmacopoeias or monographs. Six countries provided additional regulatory requirements for manufacturing; these included the following: good hygienic practices, some elements of GMP (requirements about documentation, licensing of manufacture, packing, marking, design of pharmaceuticals), according to the United States Food and Drug Administration (FDA) regulations, and domestic and family practices.

Figure 28. Manufacturing: regulatory requirements



Member States were further asked whether the implementation of the regulatory requirements selected in the previous question was monitored by a control mechanism. If they answered affirmatively, the countries were asked to describe the type of control mechanism. Though 126 countries responded to this question, the figure below represents only the 101 countries that reported having some sort of regulatory requirements (i.e. excluding those countries which responded only “no requirements” or did not answer the previous question). As illustrated in Figure 29, 76%, or 77 countries, indicated that they have control mechanisms for manufacturing regulatory requirements.

Figure 29. Existence of control mechanisms for manufacturing requirements



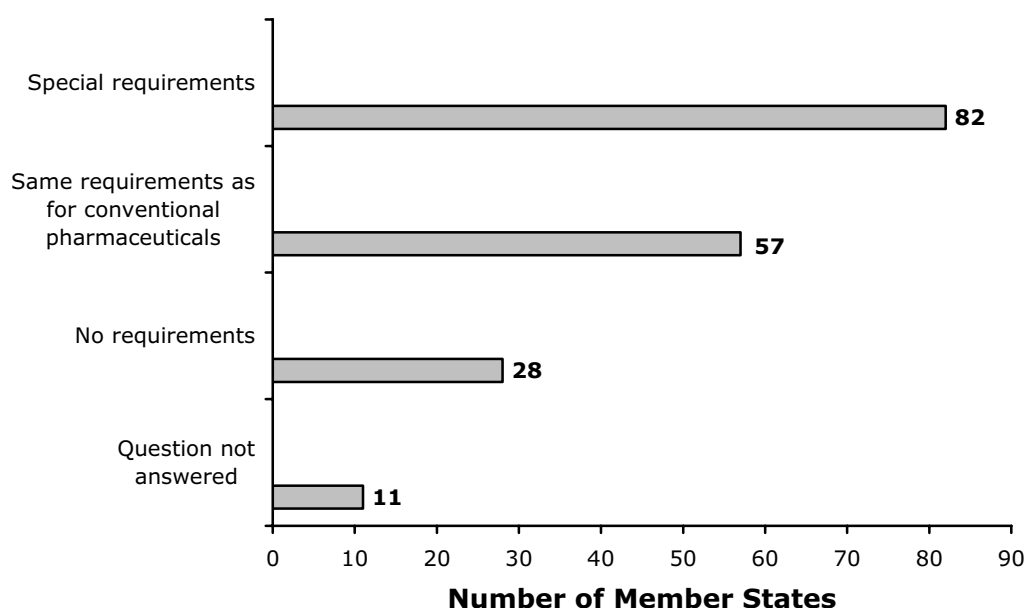
Many responding countries provided details on the type of control mechanism used to ensure implementation of manufacturing regulatory requirements. Out of these, the most commonly cited control mechanisms were inspection and licensing of products or manufacturers.

3.7 Safety and herbal medicines

Member States were next asked a series of questions related to safety and herbal medicines. The first question asked countries to describe those regulatory requirements used for the safety assessment of herbal medicines. The following options were given: same requirements as for conventional pharmaceuticals, special requirements or no requirements. If Member States chose the option “special requirements”, they were further asked to choose all that applied from the following options: traditional use without demonstrated harmful effects, reference to documented scientific research on similar products, and other requirements. If other requirements were selected, the respondents were asked to describe the requirement.

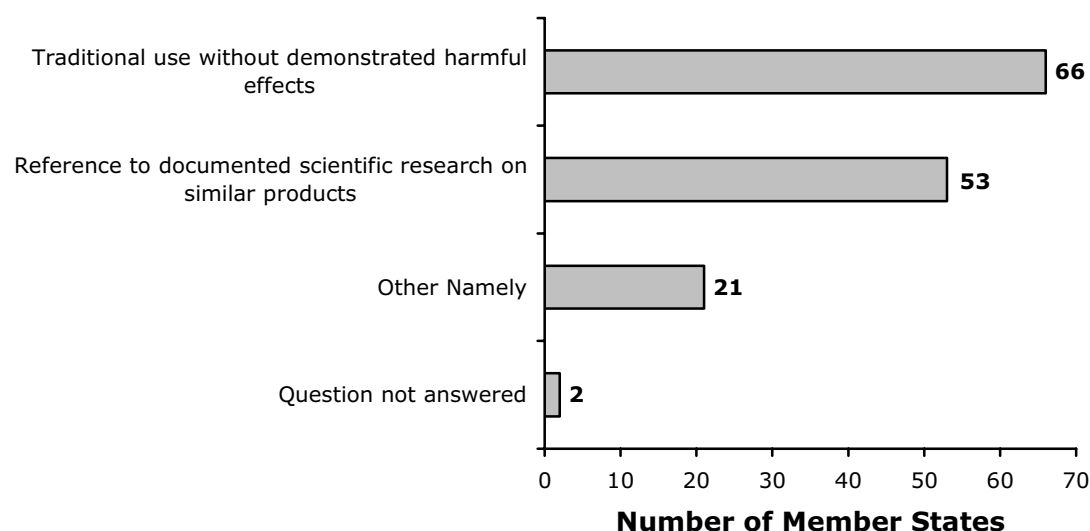
A total of 130 Member States responded to this question: however, as respondents were asked to choose all that applied, there are more responses than respondents for this question (Figure 30). Eighty-two countries indicated that special regulatory requirements exist for herbal medicine. Of the remaining responses, 57 countries indicated that the same regulatory requirements for safety assessment apply to herbal medicines as to conventional pharmaceuticals. Finally, 28 countries indicated that no regulatory requirements for safety assessment exist in their country.

Figure 30. Regulatory requirements for safety assessment of herbal medicines



When selecting the category “special requirements”, countries were further asked to choose the relevant categories of special requirement, or to describe other special requirements. Sixty-six countries of the 82 that chose the category of special requirements indicated that their laws and regulations employ the regulatory requirement of traditional use without demonstrated harmful effects, while 53 countries indicated that they had a regulatory requirement for reference to documented scientific research (Figure 31). Please note that, as countries were able to choose all options that apply, the number of responses exceeds the number of responding countries.

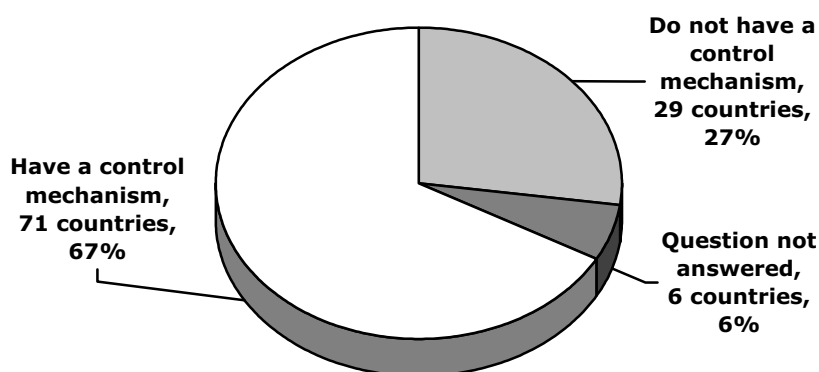
Figure 31. Special regulatory requirements for safety assessment of herbal medicines



Twenty-one countries chose the option “other” and provided details on other regulatory requirements for safety assessment. These included the following: clinical studies, bibliographical documents, screening of herbs not suitable for food use, screening for toxic elements, radioactivity and heavy metals, well-established use, traditional literature documentation and toxicological studies.

Finally, countries were asked whether control mechanisms exist for the regulatory requirements for safety assessment detailed above and, if so, a brief description was requested. Though 125 Member States responded, the figure below only includes 106 since it excludes those that did not respond to the previous question, or responded solely that there are no requirements. Of the responding countries, 67%, or 71 countries, indicated that such control mechanisms exist (Figure 32). The control mechanisms were also specified in some cases, of which licensing and registration, laboratory testing and pharmacovigilance centres were among the most frequently cited.

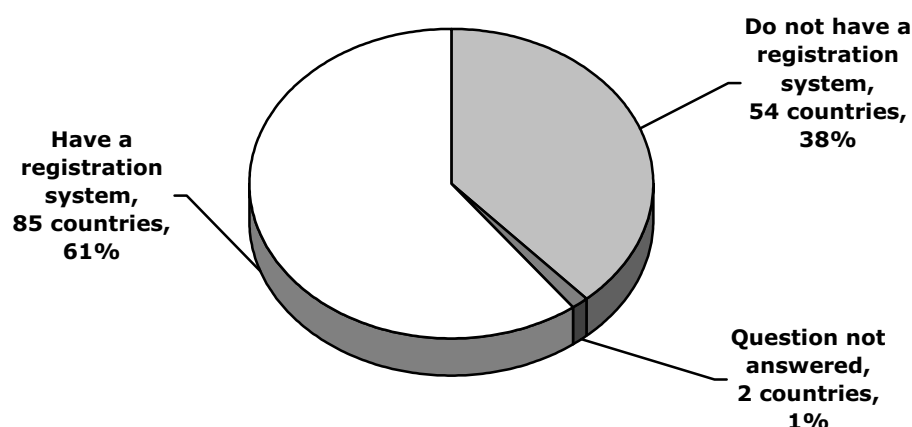
Figure 32. Existence of a control mechanism for safety requirements



3.8 Registration system for herbal medicines

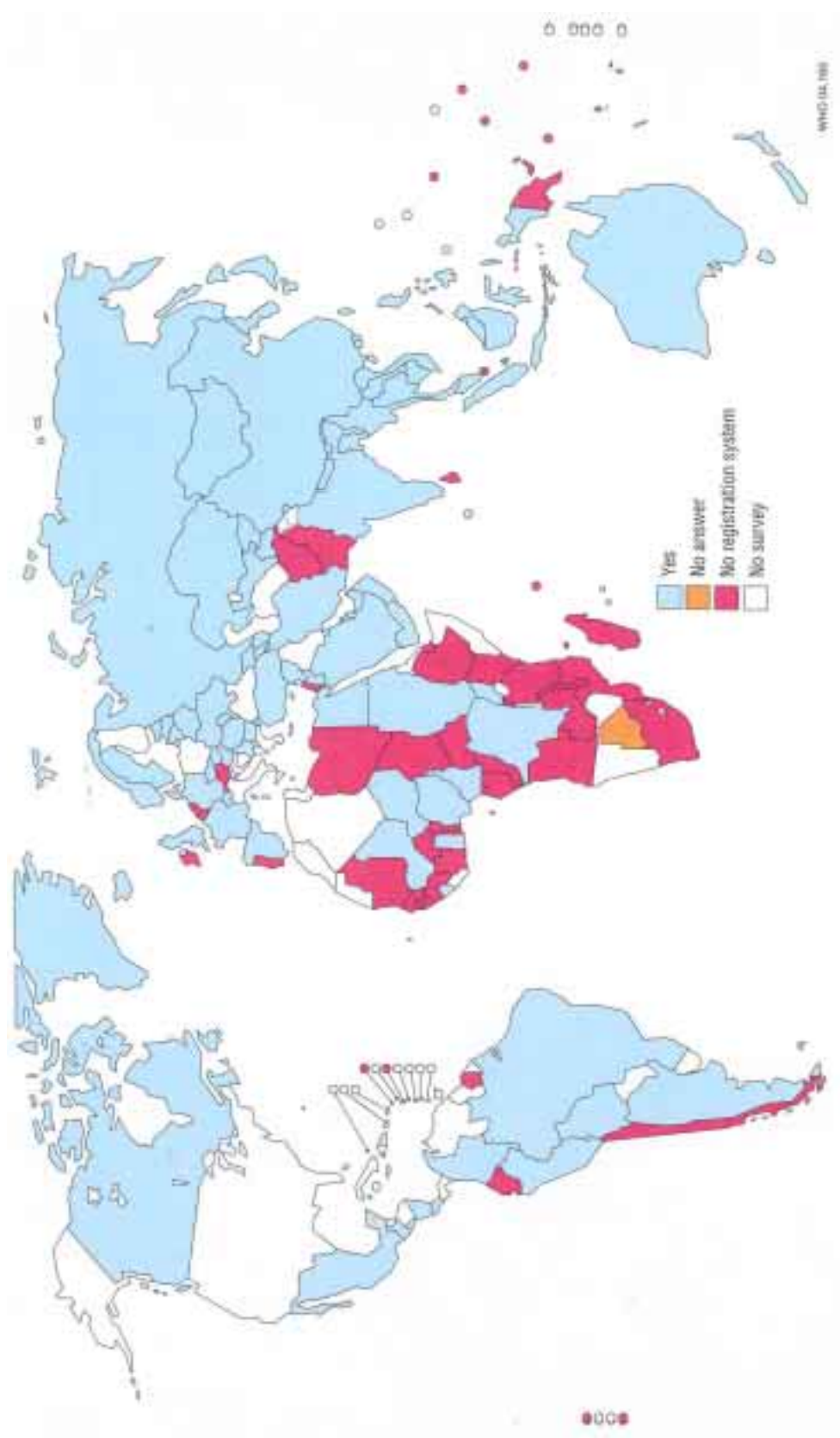
Countries were asked whether a registration system exists for herbal medicines; 139 countries answered the question. Eighty-five countries (61%) reported that they have registration systems for herbal medicines (Figure 33).

Figure 33. Registration system for herbal medicines



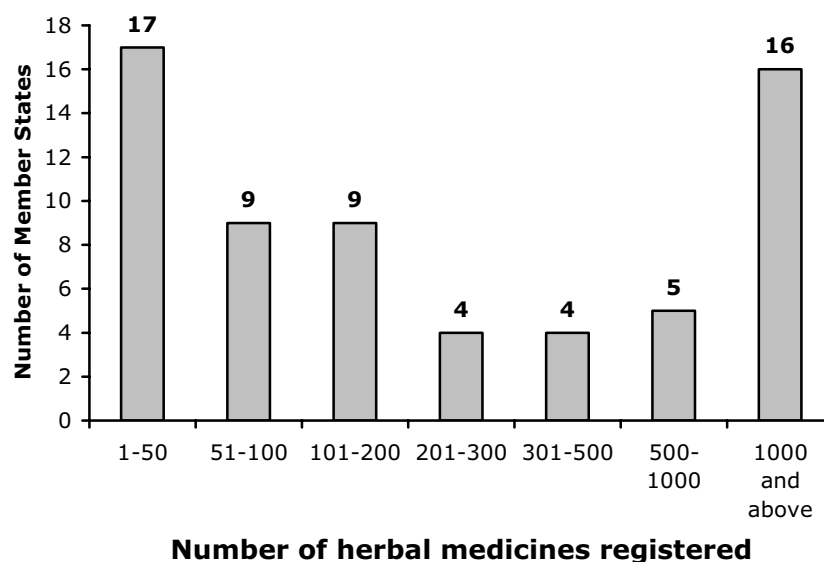
The countries with registration systems for herbal medicines are indicated on the map below (Map 7).

If countries reported having a registration system for herbal medicines, they were asked to provide the number of herbal medicines registered. Sixty-four countries provided a number for registered herbal medicines (Figure 34). The reported number of registered herbal medicines ranged from 0 to 10 000. Several countries could not provide a number of registered medicines or indicated that no medicines were yet registered, as the systems had recently been implemented.



Map 7. Member States with herbal medicine registration

Figure 34. Number of herbal medicines registered

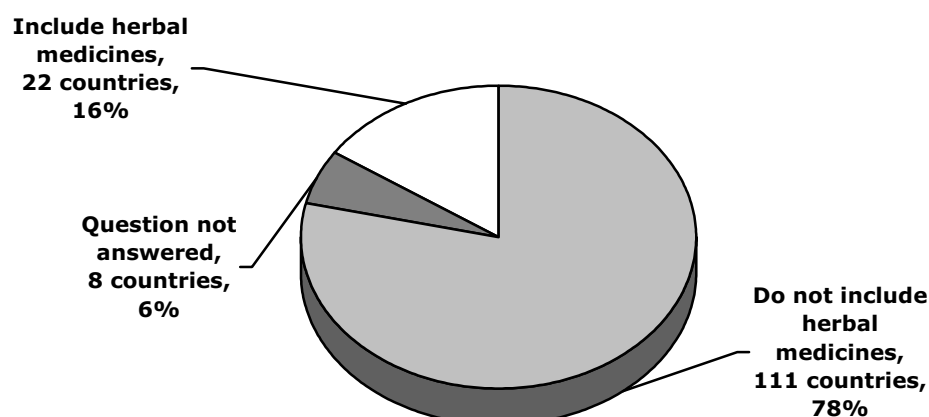


3.9 Herbal medicines and the essential drug list

An essential drug list, as defined by the WHO document *Indicators for monitoring national drug policies* (5) is “a booklet containing all the drugs approved for use in the public sector. In certain cases, there is one booklet, which contains all the drugs agreed for all health-care levels. In others, there are lists/booklets by level of use (tertiary, secondary, primary care). The booklet may contain additional information on each of the drugs. In certain countries the essential drug list may also apply to the private sector ... the list should be officially approved by the ministry of health, should be written using INN and distributed widely in the public sector. The international nonproprietary name (INN) is the shortened scientific name based on the active ingredient; WHO is responsible for assigning INN to pharmaceutical substances.”

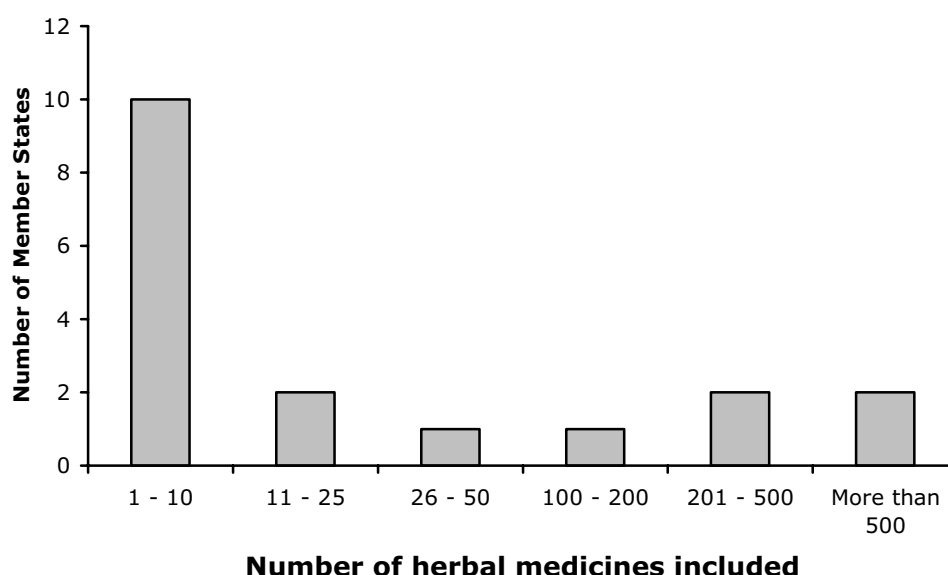
Member States were asked whether herbal medicines are included in the national essential drug list. One hundred and thirty-three countries answered this question, with 22 countries (16%) indicating that herbal medicines are included on the essential drug list (Figure 35). However, Member States were not asked whether they have a national essential drug list at all, therefore some Member States that answered no herbal medicines were included did so because they have no existing national essential drug list for any medicines. Follow-up information was requested about the number of herbal medicines included on the list and the year of issue of the essential drug list (Figure 36 and Figure 37).

Figure 35. Herbal medicines included on a national essential drug list



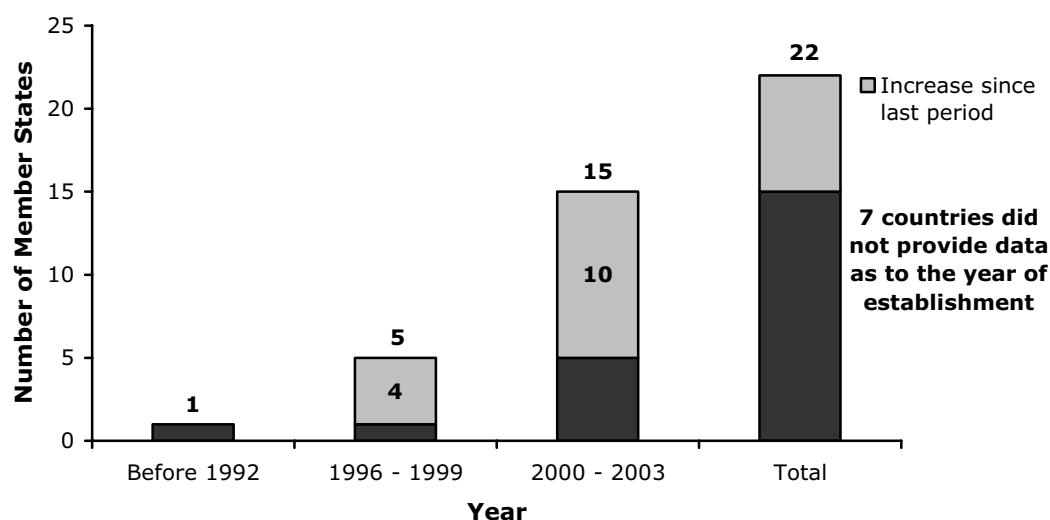
Of the 22 countries reporting the inclusion of herbal medicines on their essential drug list, 18 provided the number of herbal medicines listed (see Figure 35). The majority of countries had listed between one and 10 herbal medicines; however, a number of countries reported including more than 100 medicines. At the extreme end, China reported 1 242 herbal medicines listed on its essential drug list. An average of 165 herbal medicines was listed.

Figure 36. Number of herbal medicines included on essential drug list



Fifteen countries reported the year of issue for the essential drug list; 12 countries provided a copy of the list (Figure 37). The clear trend is for essential drug lists that include herbal medicines to have been issued in the most recent period, from 2000 to 2003. It is not clear, however, whether herbal medicines represent as recent an inclusion as such figures may suggest.

Figure 37. Number of Member States with herbal medicines on essential drug list, by year

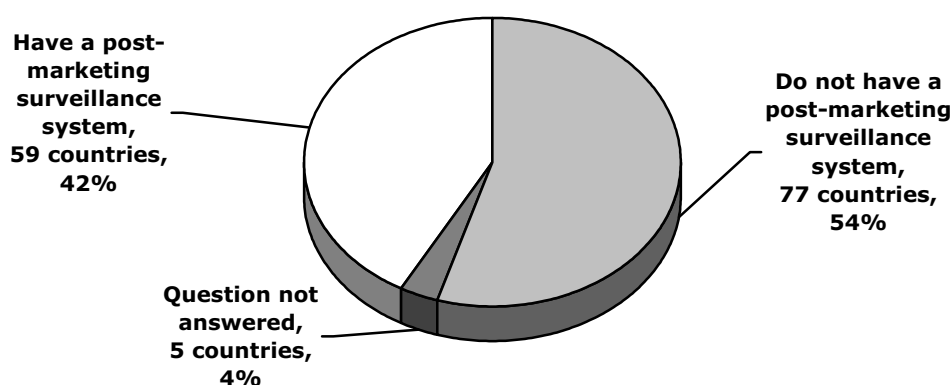


3.10 Post-marketing surveillance of herbal medicines

Countries were first asked whether they had a post-marketing surveillance system for herbal medicines. If countries responded “yes”, the next question asked whether there is a national system to monitor adverse effects of herbal medicines. If such a system exists, the date of establishment was requested. If the Member State reported that a post-marketing surveillance system for herbal medicines did not exist, the next question asked if there are plans to establish such a system.

A total of 114 countries answered the first question regarding the existence of a post-marketing surveillance system for herbal medicines. Fifty-nine countries, or 42%, reported that they had such a system (Figure 38), with many indicating in a comment that the surveillance system is the same as for conventional pharmaceuticals.

Figure 38. Post-marketing surveillance system for herbal medicines



Of the 77 countries that reported the absence of a post-marketing surveillance system for herbal medicines, 44 countries, or 58%, reported that such a system was in development.

Of those countries that reported the existence of a post-marketing surveillance system, 53, or 90%, reported that they also had a national system to monitor adverse effects of herbal medicines (Figure 39). Of these 53 countries, 37 provided information on the year of establishment of national systems to monitor adverse effects of herbal medicines. The majority have been founded in the last 15 years (Figure 40).

Figure 39. National system to monitor adverse effects relating to herbal medicines

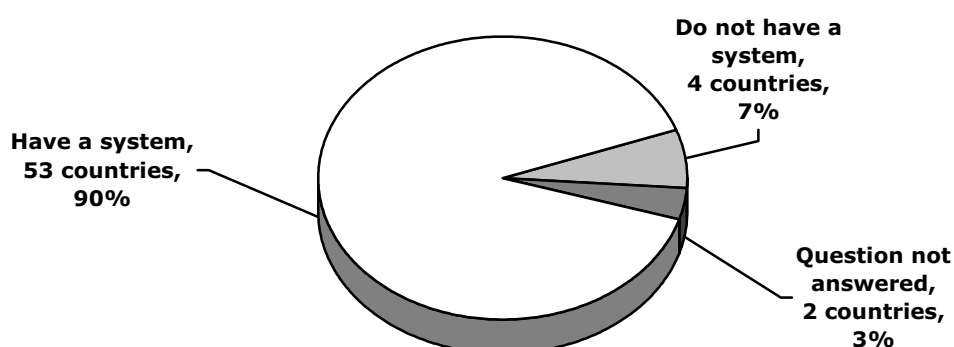
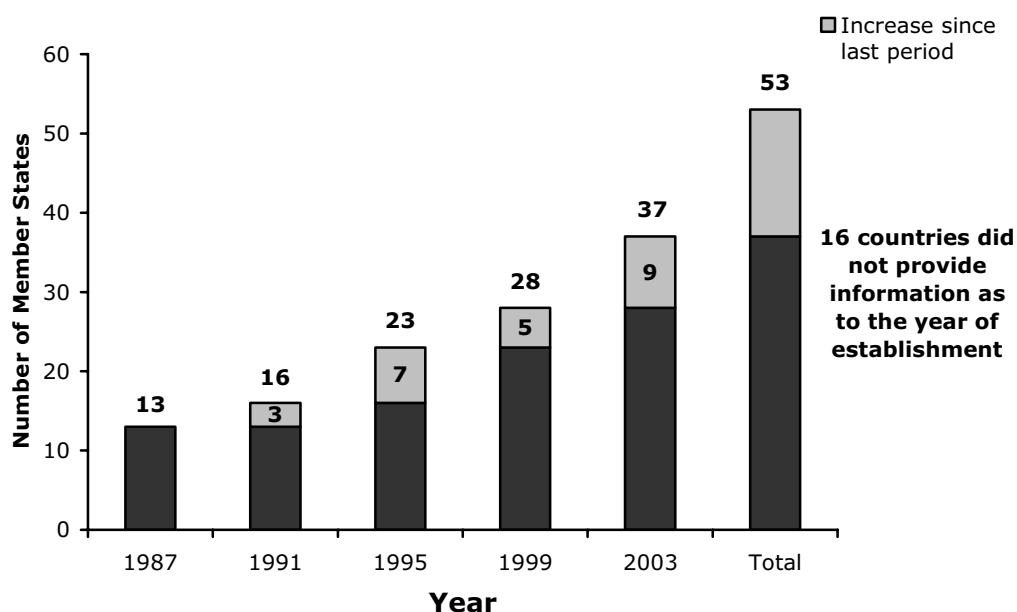


Figure 40. Number of Member States with a national system to monitor adverse effects relating to herbal medicines, by year



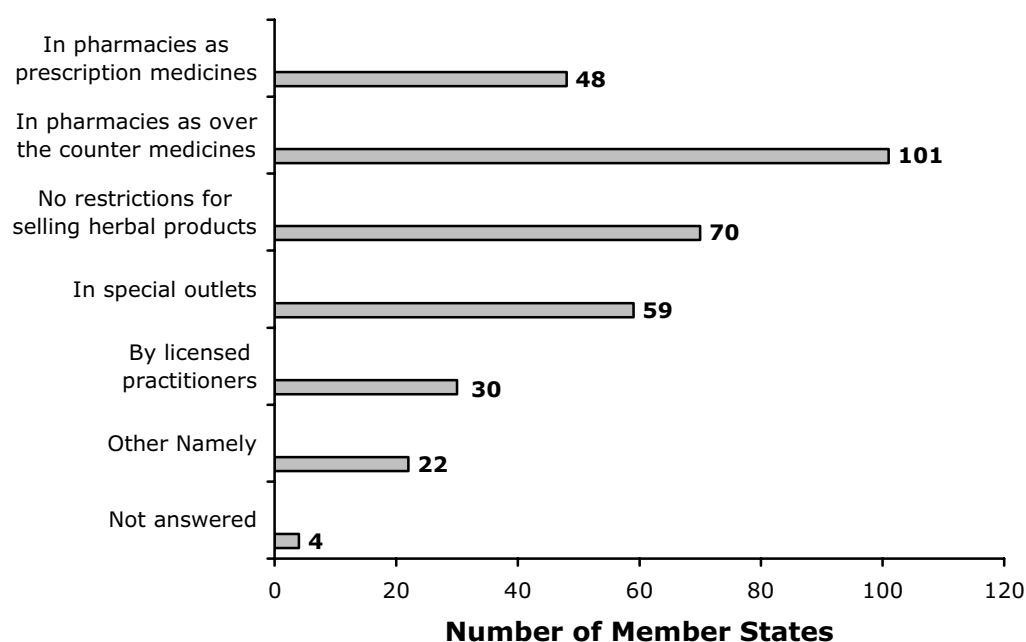
3.11 The sale of herbal medicines

In this question, countries were asked about the methods of sale of herbal medicine. Countries were requested to select all methods of sale employed on their territory from the following options: in pharmacies as prescription drugs; in pharmacies as over-the-counter drugs; in special outlets; by licensed practitioners; no restrictions on selling herbal medicines; and other ways. If “other ways” was selected, a description was requested.

A total of 137 countries reported on the location and methods of sale of herbal medicines. Figure 41 provides details of how countries responded. By far the most commonly selected category is that of sale in pharmacies as over-the-counter drugs, with 101 countries reporting this method of sale. Interestingly, the next most popular selection is that which states that there are no restrictions on the sale of herbal medicines, selected by 70 countries. The next most popular method of sale is in special outlets, chosen by 59 countries, followed by sale in pharmacies as prescription medicines (48 countries) and finally by licensed practitioners (30 countries).

Twenty-two countries selected the option “other ways”, including the following: peddling in markets and in ambulatory sales (e.g. selling door-to-door); by unlicensed practitioners; in indigenous communities; in herbal clinics and traditional healers; in health shops, supermarkets and food markets; and through mail order and multilevel marketing systems.

Figure 41. Sale of herbal medicines



3.12 Annual market sales of herbal medicines

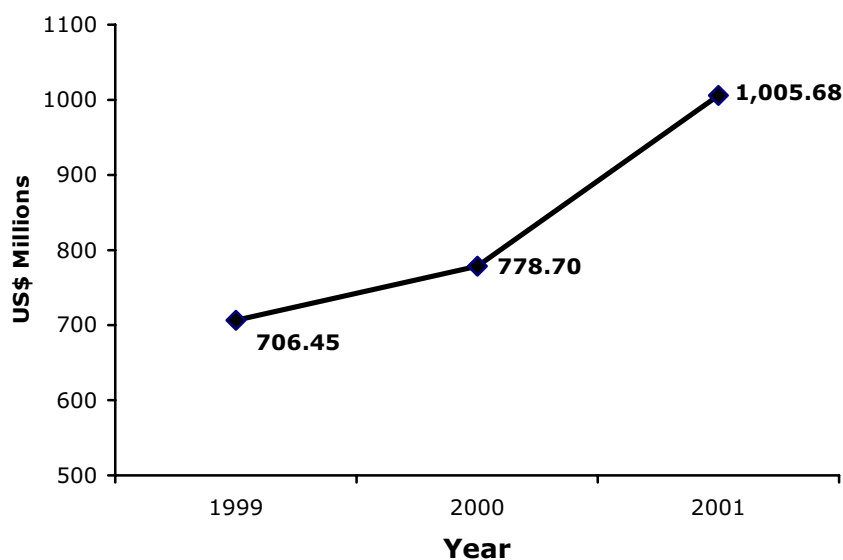
In the final question in this section related to the regulation of herbal medicines, countries were asked to provide data about annual market sales for herbal medicine for the most recent three years. The question also asked for clarification of the source of the figures provided.

Thirty countries provided some data on annual market sales of herbal medicines. However, as the data were largely fragmentary, the compiled results represent the nine Member States that included data for the period 1999-2001. It includes Member States from all six WHO Regions, with varying levels of economic development. The data which were excluded from the compilation were not complete, or were not provided for the chosen period. Finally, some countries provided figures in terms of packs of tablets or bottles of tonics, but such figures are not comparable between countries.

The nine States included in the results below (Figure 42) are Bhutan, Canada, Czech Republic, Islamic Republic of Iran, Madagascar, Malaysia, Pakistan, Sudan and Sweden. When figures were given in local currency, they were converted to United States dollars, using the exchange rates published by the United Nations on 1 November 2003.

The data excluded from the compilation above provide further evidence of the rise in annual market sales of herbal medicine globally.

Figure 42. Annual market sales of herbal medicines in nine countries, 1999-2001



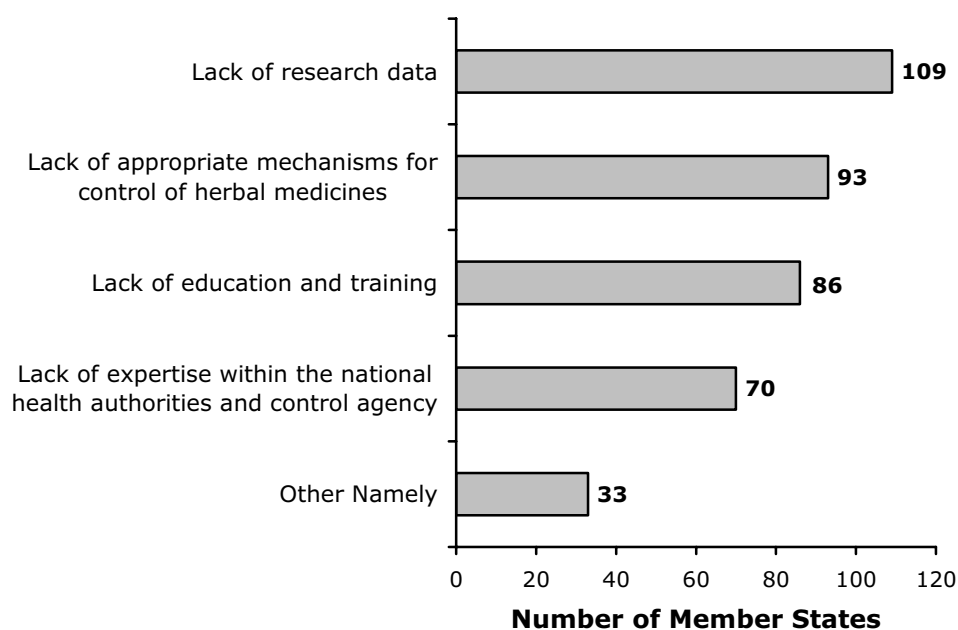
4. Member States, WHO and herbal medicines

4.1 Main difficulties faced by countries

In this section, countries were asked about their specific needs and given the opportunity to provide feedback on the types of support they most needed from WHO. The first question asked about the main difficulties faced by each Member State regarding regulatory issues for herbal medicines. The options, from which the countries could select all that applied, included the following: lack of research data; lack of expertise within the national health authorities and drug control agency; lack of appropriate mechanisms for control of herbal medicines; lack of education and training; other.

A total of 129 countries answered this question; for the detailed responses, see Figure 43 below. The category chosen by the most countries was that of a lack of research data (109 countries), followed by lack of appropriate mechanisms for the control of herbal medicines (93 countries), lack of education and training (86 countries), lack of expertise within the national health authorities and control agency (70 countries) and other (33 countries).

Figure 43. Main difficulties regarding regulatory issues for herbal medicines



Of those countries selecting “other”, the following were the responses which were included as major difficulties regarding regulatory issues on herbal medicines: lack of funding for research, lack or inadequacy of literature, lack of support, insufficient personnel, no national quality control laboratory, herbal medicines placed on the market as food, lack of awareness of the importance of the topic, adulteration of herbal medicines and lack of support for an accreditation system for practitioners.

4.2 WHO support

Next, countries were asked to rate the types of support offered by WHO related to herbal medicines according to their needs and interests. They were asked to rate the following categories as “not needed”, “needed” or “much needed”: information-sharing on regulatory issues; training workshops about national capacity to establish regulations on herbal medicine; general guidelines for research and evaluation of traditional medicines; training workshops about national capacity-building on safety monitoring of herbal medicines; provision of databases; arrangement of global meetings; other types of support.

Figure 44 provides a detailed breakdown of the rating of each category of WHO support; as different numbers of countries ranked each category, the figures are given below for clarification purposes (Table 3). While a majority of countries ranked every category as “much needed”, the category cited by the most countries and the one most often ranked “much needed” was the category of information-sharing on regulatory issues.

Figure 44. Member States' needs for WHO support

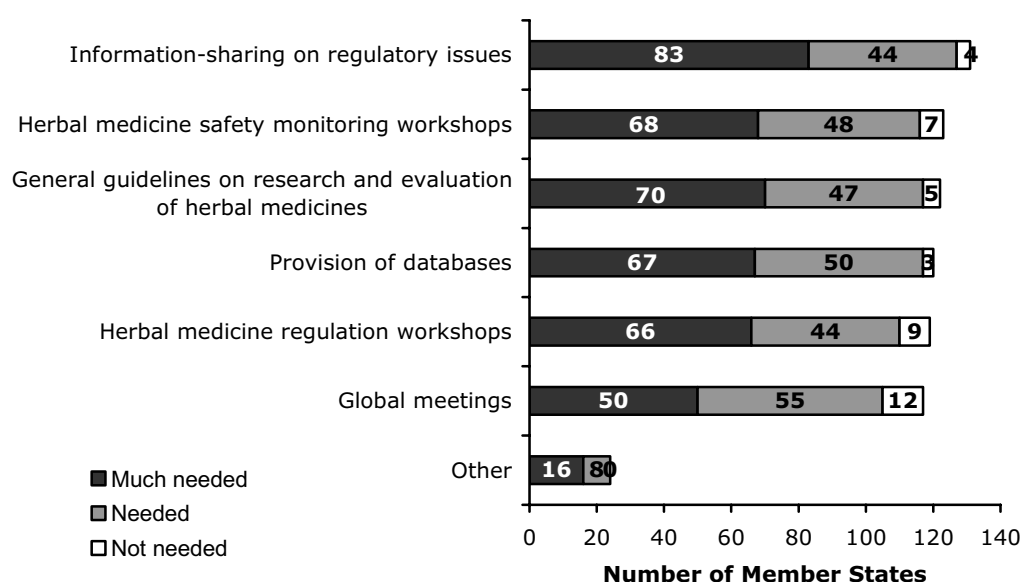


Table 3. Types of support requested by Member States, by level of preference

| | Much needed | Needed | Not needed | Total answers |
|---|-------------|--------|------------|---------------|
| Information-sharing on regulatory issues | 83 | 44 | 4 | 131 |
| Herbal medicine regulation workshops | 66 | 44 | 9 | 119 |
| General guidelines on research and evaluation of herbal medicines | 70 | 47 | 5 | 122 |
| Herbal medicine safety monitoring workshops | 68 | 48 | 7 | 123 |
| Provision of databases | 67 | 50 | 3 | 120 |
| Global meetings | 50 | 55 | 12 | 117 |
| Other | 16 | 8 | 0 | 24 |

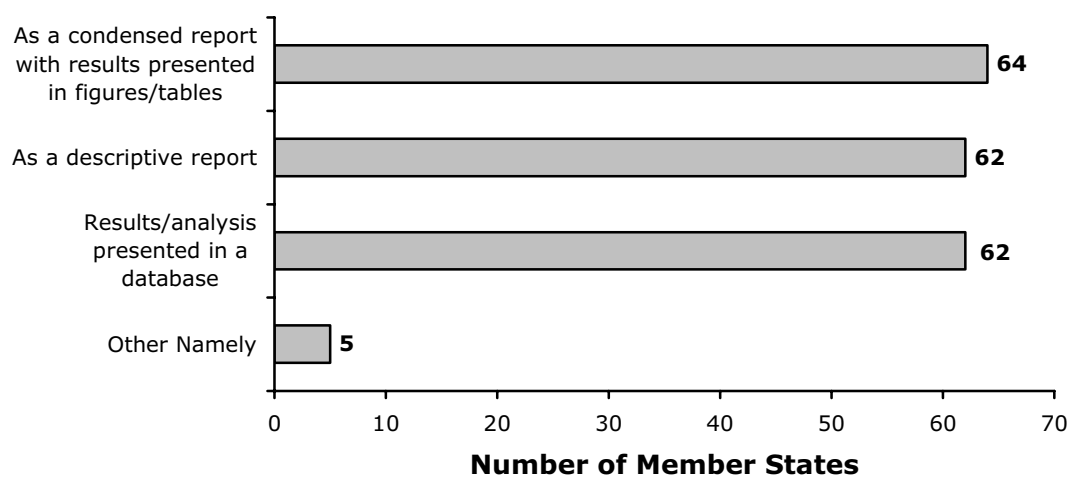
Of the 24 countries selecting other forms of support, the following were the suggestions reported: assistance with registration of traditional medicine; intellectual property issues; funding to develop a national database of traditional medicine and herbs; scientific references and research; equipment, facilities and funding for research; support and funding for the development of national pharmacopoeias and monographs; support for the development of regional monographs; standard normative system for herbal medicine; a workshop on adverse-effect reporting, monitoring and analysis; periodic consultant visits; visit by WHO technical advisors to assess the national situation of medicinal plants; pharmacovigilance and assistance with policy development.

4.3 Survey results

Finally, countries were asked to indicate preferences for the format of the report summarizing the survey results. Many countries chose more than one option, so the figures presented below in Figure 45 exceed the number of responding countries.

The five countries that chose the option “Other” expressed a preference for an electronic format available over the Internet.

Figure 45. Member States' preference for the format of report on survey results



5. Country summaries

The country summaries included in this chapter follow a generalized template that includes 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, site of marketing and annual sales). These summaries are provided for all 134 countries that responded to the survey. In some cases, complete information was never provided, therefore data is incomplete for some countries. In other cases, relevant health focal points provided additional information at some point during the working procedure. When the information was directly relevant to the subjects listed above, it was incorporated into the summary.

5.1 WHO African Region

Countries that responded to the survey: African Region



Thirty-seven of the 46 countries in the WHO African Region responded to the Global Survey. Table 4 summarizes the development of national policy and regulation of TM/CAM and herbal medicines in the African Region, with comparative figures for all of the responding countries and the global percentages. The figures and percentages represent those countries responding positively to the questions. The survey response figures represent all of the responding countries, either in the region or globally as indicated.

Table 4. WHO African Region: positive responses

| | Member States in the African Region which responded positively | Regional survey % that responded positively (37) | Global survey % that responded positively (141) |
|---|--|--|---|
| National policy on TM/CAM | 12 | 32% | 32% |
| Law or regulation on TM/CAM | 10 | 27% | 38% |
| National programme on TM/CAM | 15 | 41% | 28% |
| National office for TM/CAM | 25 | 68% | 53% |
| Expert committee on TM/CAM | 16 | 43% | 43% |
| National research institute on TM, CAM or herbal medicines | 18 | 48% | 41% |
| Law or regulation on herbal medicines | 12 | 32% | 65% |
| Registration of herbal medicines | 8 | 21% | 61% |

The data clearly indicate that significant progress has been made in the WHO African Region regarding the development of national policies and regulations on traditional and complementary/alternative medicines. In particular, the high number of countries with national programmes, national offices and national research institutes on TM/CAM demonstrates an expanding commitment among African Region countries to promote and develop the scientific basis of African traditional medicines. In this region, however, the development of national policies and regulation, particularly for herbal medicines, is much more limited, especially in comparison with the Global Survey response figures.

Angola

There is no national policy on TM/CAM in the Republic of Angola. Laws and regulations are currently being developed, as is a national programme. The national office on TM/CAM was established in 1998 under the direction of the Ministry of Health. The expert committee was established in the same year. There are no national research institutes on TM, CAM or herbal medicines.

There is no regulation of herbal medicines in Angola. Herbal medicines are classified as over-the-counter medicines. By law, no claims may be made about herbal medicines.

A national pharmacopoeia is currently in development, as are national monographs on herbal medicines. There is no information available on manufacturing requirements or safety requirements for herbal medicines. There is no registration system for herbal medicines; no herbal medicines are included on a national essential drug list. There is no information on a post-marketing surveillance system for herbal medicines. Herbal medicines in Angola are sold in special outlets, by licensed practitioners and in markets.

Benin

The Republic of Benin established a national policy in 2002, a law or regulation concerning TM/CAM was adopted in 2001, and a national programme on TM/CAM was put in place in 1999. A TM/CAM office has existed since 1997 under the Ministry of Health. The expert committee was established later in 2001. No national research institute exists for the study of TM/CAM and herbal medicines.

Benin does not regulate herbal medicines; herbal medicines are classified only as over-the-counter medicines and for self-medication and can be sold with medical, health, nutrient content, and structure/function claims. No national pharmacopoeia or national monograph exists, although both are currently being developed. In the meantime, nothing is used. There are no regulatory requirements for manufacturing or safety assessment of herbal medicines. There is no system of registration and herbal medicines are not included on the essential drug list. No post-marketing surveillance exists, though a system is being established. Herbal medicines are sold either as over-the-counter drugs in pharmacies, or without regulation.

Botswana

The Republic of Botswana does not currently have a national policy on TM/CAM, although this is in the process of development. Data were lacking on the existence of laws or regulations and a national programme on TM/CAM. Although Botswana does not currently have a national office, it was reported that such a national office is in development. Botswana does have an expert committee on TM/CAM, established in 2001 – the Health Education Unit in Gaborone. There are no national research institutes on TM, CAM or herbal medicines.

Information is not available on the regulation of herbal medicine, but in Botswana, no herbal medicine has any regulatory status. Again, no information is available about claims made for the sale of herbal medicine, nor about the claims that are allowed by law or regulation. Botswana does not have a national pharmacopoeia, nor is one in the process of development.

No information was provided regarding the existence of national monographs or the regulatory requirements for the manufacture of herbal medicine. Botswana does not have any control mechanism for the manufacture of herbal medicine. No regulatory requirements exist regarding safety; unprocessed herbal medicines without clinical claims are exempt from regulation as a medicine. Therefore, safety and regulation issues do not apply. Data are likewise incomplete regarding registration, inclusion on the essential drug list, post-marketing surveillance system and market sale information.

Burkina Faso

Burkina Faso currently has no national policy, laws or regulations, nor a national programme on TM/CAM, but has reported that all three are being developed. A national office on TM/CAM exists; the *Service de médecine et pharmacopée traditionnelles* (Traditional Medicine and Pharmacopoeia Service) was established in 1987 and is administered by the Ministry of Health in Ouagadougou. The expert committee on TM/CAM in Burkina Faso was founded in 2000. Burkina Faso does not have research institutes on TM or CAM, but does have one on herbal medicine, founded in 1983, called the *Institut de recherche en sciences de la santé* (Institute for Health Sciences Research).

Burkina Faso has a national regulation on herbal medicine, which is partly the same type as for conventional medicine. The national regulation on herbal medicine is part of the public health code, No. 23/94/ADP, established in 1994. The relevant regulatory categories of herbal medicine are over-the-counter drug and dietary supplements. Herbal medicines are sold with claims in Burkina Faso; by law or regulation, herbal medicines can be sold with medical and nutrient content claims. Burkina Faso does not have a national pharmacopoeia, and uses the *Senegalese pharmacopoeia* (1974), but it is not legally binding. Likewise, Burkina Faso does not have national monographs, but

uses those in the *African pharmacopoeia* (1985), which contains 261 monographs. It is not legally binding.

Regarding the regulatory requirements for manufacturing, the rules of GMP used for conventional pharmaceuticals also apply to herbal medicines. There is no control mechanism for the application of these requirements. The regulatory requirements for safety are limited to special requirements that include traditional use without demonstrated harmful effects and references to documented scientific research on similar products; no control mechanism exists for these requirements.

No registration system for herbal medicines exists, and herbal medicines are not included on a national essential drug list. A post-marketing surveillance system exists, but no system yet exists for monitoring adverse effects of herbal medicines. In Burkina Faso, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets and by licensed practitioners. Burkina Faso reported annual market sales figures for 1998-2000, estimated by the National Traders Network. In 1998, the annual market sales for herbal medicines were 1.5 billion CFA francs (US\$ 2.68 million), in 1999 sales were 1.8 billion CFA francs (US\$ 3.22 million) and in 2000, sales were 3 billion CFA francs (US\$ 5.37 million).

Burundi

The Republic of Burundi does not currently have national policy or laws and regulations on TM/CAM, but they are currently in development. Burundi has a national office on TM/CAM, administered under the Ministry of Health and established in 2002. A national expert committee was established in 2002 as well. National research institutes exist for traditional medicine and for herbal medicines; however, the dates of establishment and names of the institutes are not available.

Burundi does not regulate herbal medicine, but it was reported that herbal medicines have the regulatory statuses of over-the-counter sale medicines and for self-medication only. Herbal medicines in Burundi are not sold with claims. Burundi does not have a national pharmacopoeia, nor is one pending, but uses other pharmacopoeias that are not legally binding. No national monographs exist, nor are any used in their place.

The relevant regulatory requirements for manufacturing are the same GMP rules as for conventional medicines, but these are not enforced by any control mechanism. No regulatory requirements for safety assessment exist. Burundi does not have a registration system for herbal medicines, nor are herbal medicines included on the national essential drug list. A post-marketing surveillance system is currently in development. Herbal medicines in Burundi are sold in special outlets and by licensed practitioners with no restrictions.

Cameroon

The Republic of Cameroon currently does not have national policy or laws and regulations on TM/CAM, but a national policy is being developed. A national programme was established in 2001 called the *Etude de la médecine traditionnelle* (School of Traditional Medicine). A national office was established in 1995, and is administered by the Ministry of Health. No expert committee exists. National research institutes on traditional medicine and herbal medicine have been established.

In Cameroon, national regulation of herbal medicine was introduced in 1998 in Decree No. 98/405/PM. The regulation is partly the same for herbal medicines as for conventional pharmaceuticals. Herbal medicines in Cameroon have regulatory status

as prescription medicines, over-the-counter medicines and for self-medication. Health and medical claims may be made about herbal medicines. Cameroon does not have a national pharmacopoeia, but uses the *European pharmacopoeia*. No national monographs exist, nor are other monographs used in their place.

Regulatory requirements for manufacturing of herbal medicines are the same GMP rules required for conventional medicines; the implementation of these requirements is controlled through inspection. Requirements for safety assessment of herbal medicines include special requirements of traditional use without demonstrated harmful effects and references to documented scientific literature on similar products, but no control mechanism exists for these.

A registration system for herbal medicines exists in Cameroon, and currently 10 medicines are registered. One herbal medicine is included on the national essential drug list established in 1999. A post-marketing surveillance system is in development. Finally, sales of herbal medicines in Cameroon include sales in pharmacies as prescription medicines and over-the-counter medicines, in special outlets and by travelling pedlars.

Central African Republic

In the Central African Republic, a national policy and laws and regulations and a national programme on TM/CAM are in development. The national office on TM/CAM was established in 1997 under the administration of the Ministry of Health. An expert committee on TM/CAM was created in 1995. No national research institutes on TM/CAM and herbal medicines exist.

There is no regulation of herbal medicines in the Central African Republic and there is no regulatory status applied to herbal medicines. No claims may be made about herbal medicines. A national pharmacopoeia and national monographs are the process of being developed.

There are no manufacturing or safety assessment regulatory requirements. In the Central African Republic, there is also no registration of herbal medicines, nor are herbal medicines included on the essential drug list. A post-marketing surveillance system is currently in development. No restrictions exist on the sale of herbal medicines in the Central African Republic.

Chad

In the Republic of Chad, a national policy, laws and regulations on TM/CAM are currently in development. The national programme on TM/CAM was established in 2002, while the national office on TM/CAM was created in 2001 under the Ministry of Health. No committee of experts exists; however, national research institutes on traditional medicine and on herbal medicine were founded in 1993.

Chad does not regulate herbal medicines, therefore there is no regulatory status for herbal medicines, nor can claims be made by law. There is no national pharmacopoeia, nor are there national monographs, and no other instruments are used in their place. There are no manufacturing or safety assessment requirements, nor is a registration system in place. Herbal medicines are not listed on the essential drug list. A post-marketing surveillance system is being developed. There are no restrictions on the sale of herbal medicines.

Comoros

In the Islamic Federal Republic of the Comoros (now the Union of the Comoros), there are no national policy, laws or regulations, and none is in development. A national office was established in 2002 under the Ministry of Health. There is no expert committee on TM/CAM. A national research institute on traditional medicine was founded in 1979, called the *Centre national de documentation et de recherche scientifique* (National Documentation and Scientific Research Centre – NDRS).

Comoros does not regulate herbal medicines, although herbal medicines have a regulatory status of over-the-counter medicines. No claims can legally be made about herbal medicines. There is no national pharmacopoeia, nor are there national monographs, and none are used in their place. There are no manufacturing or safety assessment requirements, nor is a registration system in place. Herbal medicines are not listed on the essential drug list. No post-marketing surveillance system exists. Herbal medicines are on free sale in the Comoros.

Congo

The Republic of the Congo does not have a national policy on TM/CAM, and is not currently establishing one. However, a bill on traditional medicine has been presented to the Parliament and is awaiting approval. The national programme was issued in 1982. Decree No. 82-228 also established the national office on TM/CAM. The national office, the *Service de la médecine traditionnelle* (Traditional Medicine Department) is administered by the Ministry of Health. There is no expert committee on TM or CAM, nor are there national research institutes on TM/CAM or herbal medicine.

Congo does not regulate herbal medicines; there is no regulatory status given to herbal medicines and no claims can legally be made. A national pharmacopoeia is currently being developed: at present, the *African pharmacopoeia* (1985) is used. No national monographs exist, and no others are used in their place.

The relevant manufacturing regulatory requirements include adherence to the information contained in pharmacopoeias and monographs. Special GMP rules apply to herbal medicines, but no control mechanism exists to ensure implementation of these requirements. The regulatory requirements for safety assessment include all of the following: the same requirements as for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. No control mechanism exists for these requirements for safety assessment of herbal medicines.

No registration system exists, and herbal medicines are not included on an essential drug list. The post-marketing surveillance system is being developed. No restrictions are made on the sale of herbal medicines. Estimates of market sales for 2001-2003 about the growth of the market are 25%, 30% and 20%, respectively.

Côte d'Ivoire

In the Republic of Côte d'Ivoire, the national policy on TM/CAM was established in 1996. The laws or regulations about TM/CAM were established in 1999 by the Council of Ministers. The national programme on TM/CAM was issued through the Ministerial Decree of 28/12/2002. The national office, established in 2002, is called the *Programme national de promotion de la médecine traditionnelle* (National Programme for the Promotion of Traditional Medicine) and is located in Abidjan, Côte d'Ivoire. The expert committee on TM/CAM was also established in 2002. No national research institutes on TM, CAM or herbal medicines have been established in Côte d'Ivoire.

Herbal medicines are not regulated in Côte d'Ivoire; no regulatory status is given to herbal medicines and no claims can be legally made. Neither a national pharmacopoeia nor national monographs exist, although the latter are in development. No regulatory requirements exist for manufacturing or safety assessment, since the programme has only recently been established. No registration system exists, and herbal medicines are not included on an essential drug list. The post-marketing surveillance system is being developed. Herbal medicines are freely sold by their makers in Côte d'Ivoire.

Democratic Republic of the Congo

In the Democratic Republic of the Congo, a national policy and laws and regulations on TM/CAM are currently being developed. The national programme was issued in 2002 through ministerial decree No. 1250, on the Organization of the Exercise of the Profession of Practitioner of Traditional Medicine. The national office was also established in 2002 as the *Programme national de promotion de la médecine traditionnelle et des plantes médicinales* (National Programme for the Promotion of Traditional Medicine and Medicinal Plants), administered by the Ministry of Health. The expert committee was created in 1997. The national research institute, the *Institut de recherche en sciences de santé* (Institute for Health Sciences Research), founded in 1976, conducts research on traditional medicine and herbal medicine.

Regulation of herbal medicines was established in 2001 through ministerial decree. The regulation is the same as that for conventional pharmaceuticals. In the Democratic Republic of the Congo, herbal medicines have regulatory status as prescription medicines and over-the-counter medicines. Herbal medicines are sold with claims; according to law, medical, health, nutrient content and structure/function claims are possible.

There is no national pharmacopoeia, nor is one being developed; the *African pharmacopoeia* (1985) is used and is legally binding. Likewise, there are no national monographs, nor are they in development; the *WHO monographs* are used and are legally binding. The relevant regulatory requirements for manufacturing are adherence to information in pharmacopoeias and monographs and the same GMP rules as for conventional pharmaceuticals; however, there is no control mechanism for these requirements. Regulatory requirements for safety assessment include the following: the same requirements as for conventional pharmaceuticals as well as special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. The implementation of these requirements for safety assessment is ensured through compulsory submission of the results of toxicological assays.

There is a registration system for herbal medicines; 15 medicines are registered. The essential drug list includes six herbal medicines and was issued in 2001. A post-marketing surveillance system exists and includes adverse-effect monitoring, established in 1982. In the Democratic Republic of the Congo, herbal medicines are sold in pharmacies as prescription medicines and over-the-counter medicines.

Equatorial Guinea

In the Republic of Equatorial Guinea, a national policy on TM/CAM was issued in 1999 and laws and regulations on TM/CAM were issued in 1985. There is no national programme; however, one is in development. The national office, *Service médecine traditionnelle* (Traditional Medicine Department), administered by the Ministry of Health and Social Welfare, was established in 1995. There is no expert committee. The

national research institute, *Conseil pour la recherche scientifique et technique* (Council for Scientific and Technical Research), was established in 1989 and covers both traditional and herbal-medicine research.

Regulation of herbal medicines in Equatorial Guinea was established in 1985 through special legislation applying only to herbal medicines, through Law No. 4/1985, which also created the Traditional Medicine Department. Herbal medicines have the regulatory status of over-the-counter medicines and self-administered medications. By law, medical, nutrient content and structure/function claims may be made about herbal medicines.

No national pharmacopoeia exists, nor is one planned; furthermore, no pharmacopoeia is used in its place. National monographs exist in the *Recetario plantas medicinales de Equatorial Guinea* (1996), which contains 18 monographs. The information is not legally binding. No requirements exist for manufacturing; however, special requirements of traditional use without demonstrated harmful effects exist for safety assessment, and these are enforced by supervision visits to the traditional practitioners.

There is no system of registration, and herbal medicines are not included on the essential drug list. No post-marketing surveillance exists or is in preparation. There are no restrictions on the sale of herbal medicines: however, they are sold through special outlets and licensed practitioners.

Ethiopia

In the Federal Democratic Republic of Ethiopia, the national policy on TM/CAM was issued in the Health, Drug, Science and Technology Policy of 1999. Laws and regulations on TM/CAM were issued in the Drug Administration and Control Proclamation No. 176/99 of 1999. The national programme is one of the responsibilities of the Drug Administration and Control Authority (DACA) established by Proclamation No. 176. DACA, administered by the Ministry of Health, was established as the focal point for the national office on TM/CAM in 2000. The expert committee is also part of DACA. Finally, the national research institute covering both traditional and herbal medicines is the Drug Research Department of the Ethiopian Health and Nutrition Institute.

Ethiopia does not regulate herbal medicine and no regulatory status exists for herbal medicine: however, herbal medicines are sold with medical claims. There is no national pharmacopoeia or national monographs. No regulatory requirements exist for manufacturing or for safety assessment. There is no registration system, herbal medicines are not included on an essential medicines list, nor is there a post-marketing surveillance system. There are no restrictions on the sale of herbal medicines in Ethiopia.

Gabon

The Gabonese Republic issued its national policy in 1995 in Ordinance No. 001/95, which officially recognizes traditional medicine in the overall Gabon health policy. No laws or regulations on TM/CAM have been issued, but these are in the process of development, as is the national programme. The national office, administered by the Ministry of Health, was established in 2000. No expert committee exists. A research institute on traditional medicine and herbal medicine has been established.

However, Gabon does not regulate herbal medicine. No regulatory status is given to herbal medicines and no claims can legally be made. Neither a national pharmacopoeia

nor national monographs exist. There are no regulatory requirements for manufacturing or safety assessment. No registration system exists, and herbal medicines are not included on an essential drug list. The post-marketing surveillance system is being developed. Herbal medicines are sold in special outlets without any restrictions.

The Gambia

In the Republic of the Gambia, national policy is in the process of being developed. Laws and regulations on TM/CAM do not exist, nor are they currently in development. A national programme exists, but no information was provided as to when it was established. The national office, administered by the Ministry of Health, was established in 2000 as part of the national acute respiratory infection control programme. The expert committee on TM/CAM was established in 2002. No national research institutes exist for study of TM/CAM or herbal medicines.

The Gambia does not currently regulate herbal medicines. No regulatory status is given to herbal medicines, and no claims can legally be made. Neither a national pharmacopoeia nor national monographs exist. There are no regulatory requirements for manufacturing or safety assessment. No registration system exists, and herbal medicines are not included on an essential drug list. There are no restrictions on sale of herbal medicines in the Gambia.

Ghana

In the Republic of Ghana, the national policy on TM/CAM was issued in 2002. Laws and regulations on TM/CAM were issued in 1992, and the national programme in 2000. The national office on TM/CAM was established in 1999 under the direction of the Ministry of Health. The expert committee was also established in the same year. A national research institute on herbal medicines was established in 1975.

Herbal regulation in Ghana began in 1992 through the Food and Drugs Law, which also establishes regulations on conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines and as a separate regulatory category. By law, medical, health and nutrient content claims may be made. The *Ghana herbal pharmacopoeia* was published in 1992; it is not considered to be legally binding. The national pharmacopoeia also contains monographs on herbal medicines.

Regulatory requirements for manufacturing of herbal medicines include the same GMP rules that apply to conventional pharmaceuticals and special GMP rules. While a large proportion of manufacturers of herbal medicines in Ghana are small-scale industries, efforts have been made to provide training in GMP compliance. Implementation of the manufacturing requirements is ensured through annual inspections. Safety assessment requirements include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products and phytochemical analysis. Compliance with these requirements is ensured through the pharmacovigilance centre.

There are 340 registered herbal medicines in Ghana; however, none is included on the national essential drug list. The national post-marketing surveillance system has included adverse-effect monitoring of herbal medicines since 2000. In Ghana, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets and by licensed practitioners.

Guinea

The Republic of Guinea established its national policy on TM/CAM in 1994; laws and regulations on TM/CAM followed in 1997. No national programme exists, but one is in development. The national office was established in 1977, is administered by the Ministry of Health and is called the *Division de médecine traditionnelle* (Traditional Medicine Division). An expert committee called the Thematic Group on TM/CAM was created in 1999. A national institute on herbal medicines was established in 2001.

Regulation of herbal medicines in Guinea began in 1994, and is characterized as being partly the same laws and regulations as for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines, self-medication and as herbal medicines as a separate regulatory category. No claims may be made according to law. No national pharmacopoeia exists, but one is in development; other pharmacopoeias are used, but details were not given, and they are not legally binding. National monographs exist in the *Plantes médicinales guinéennes* (1997), but they are not legally binding.

Regulatory requirements for manufacturing include adherence to the information contained in pharmacopoeias and monographs and special GMP for herbal medicines; however, there is no control mechanism to ensure implementation. The regulatory requirements for safety assessment include the special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Again, there is no control mechanism for these requirements.

There is no registration system for herbal medicines and they are not included on the essential drug list. A post-marketing surveillance system is in development. Herbal medicines in Guinea are sold in pharmacies as prescription and over-the-counter medicines without restriction.

Guinea-Bissau

The Republic of Guinea-Bissau has no national policy, laws or regulations, national programme, national office, expert committee or research institutes related to TM/CAM.

Guinea-Bissau does not regulate herbal medicines, and they are treated as over-the-counter medicines, about which claims cannot be made. Neither a national pharmacopoeia nor national monographs exist; however, they are in the process of development. No other materials are used in their place. There are no regulatory requirements for manufacturing or safety assessment. No registration system exists, and herbal medicines are not included on an essential drug list. There are no restrictions on sale of herbal medicines in Guinea-Bissau.

Kenya

In the Republic of Kenya, a national policy, laws and regulations on TM/CAM are being developed. No national programme has been issued, and no national office or expert committee have been established. A national research institute that conducts research on traditional medicine was established in 1984, called the Kenya Medical Research Institute.

Herbal medicines are not regulated in Kenya. Neither a national pharmacopoeia nor national monographs exist or are being developed. No other pharmacopoeias or monographs are used in their place.

No information was provided on manufacturing requirements, but special regulatory requirements for safety assessment of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products apply to herbal medicines. These have been established by the Kenya Medical Research Institute, but no control mechanism exists to ensure their implementation.

There is no registration system for herbal medicines and they are not included on the essential drug list. A post-marketing surveillance system is in development. Herbal medicines in Kenya are sold without restriction.

Madagascar

The Republic of Madagascar has a national policy, laws and regulations and a national programme on TM/CAM in development. The national office was established under the Ministry of Health in 2002 and is called the *Service de la médecine et pharmacopées traditionnelles* (Department of Traditional Medicine and Pharmacopoeias). There is no expert committee. Two national research institutes on herbal medicine exist: the *Institut malgache de recherche appliquée* (Malagasy Institute of Applied Research – IMRA) was founded in 1958 and the *Centre national d'application des recherches pharmaceutiques* (National Centre for the Application of Pharmaceutical Research – CNARP) in 1971.

Madagascar does not regulate herbal medicines; they are classified as over-the-counter medicines. By law, medical, health, nutrient content and structure/function claims may be made. Neither a national pharmacopoeia nor national monographs exist; however, they are in the process of development. No other materials are used in their place.

Manufacturing regulatory requirements include adherence to the information contained in pharmacopoeias and monographs, GMP rules for conventional pharmaceuticals and special GMP rules. There is no control mechanism for these requirements. Safety assessment regulatory requirements include those required for conventional pharmaceuticals, and special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products apply to herbal medicines. There is, however, no control mechanism for these requirements.

There is no registration system for herbal medicines and they are not included on the essential drug list. A post-marketing surveillance system is in development. Herbal medicines in Madagascar are sold without restriction in pharmacies as over-the-counter medicines and in special outlets.

Madagascar provided annual market sales data for the period 1999-2001. In 1999, sales were 15.71 million Malagasy francs (US\$ 2 million) and involved 417 051 kg of herbal medicines; in 2000, sales were 18.28 million francs (US\$3.15 million) and involved 580 401 kg of herbal medicines; and in 2001, 20.78 million francs (US\$ 3.59 million) and 320 609 kg of herbal medicines. These figures are from the *Institut national de la statistique* (National Statistics Institute – INSTAT).

Malawi

In the Republic of Malawi, no information is available about the national policy on TM/CAM. Laws and regulations on TM/CAM are pending, as is the national programme. No information is available about a national office, expert committee or national research institute.

Herbal medicines are regulated by the same laws that are used for conventional pharmaceuticals. No information is available on their regulatory status. Herbal medicines may be sold by law with medical and structure/function claims.

No information is available about the existence or development of a national pharmacopoeia, or whether other pharmacopoeias are used. No national monographs exist. No information is available about regulatory requirements for manufacturing or safety assessment. There is no registration system for herbal medicines and they are not included on the essential drug list. A post-marketing surveillance system is in development. There is no market information for Malawi on the methods of sale of herbal medicines.

Mali

While the Republic of Mali does not currently have a national policy on TM/CAM, such a policy is in development. Laws, regulations and the national programme on TM/CAM were issued in 1973. In 1968, the national office was established as the *Département médecine traditionnelle* (Traditional Medicine Department) under the Ministry of Health. No expert committee for TM/CAM exists: however, national research institutes were established in 1968 as part of the Traditional Medicine Department.

Regulations on herbal medicines were issued in 1994 which are partly the same as those governing conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines and may, by law, be sold with medical claims. No national pharmacopoeia exists; in its place the *African pharmacopoeia* (1985) is used, but is not legally binding. National monographs exist in the *Formulaire thérapeutique* (1998), which contains seven monographs, but those are not legally binding.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs, as well as good conditions for harvest, drying, extraction and packaging and quality control. Implementation of these requirements is ensured by laboratory testing for content and foreign substances and by ensuring correct identification of plants and standardized extracts. Safety assessment regulatory requirements include special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Implementation is ensured by means of toxicity testing.

The registration system for herbal medicines includes seven medicines, as does the essential drug list. A post-marketing surveillance system exists that includes adverse-effect monitoring of herbal medicines; it was established in 1990. Herbal medicines in Mali are sold in pharmacies as over-the-counter medicines and in herb shops.

Mauritania

Although the Islamic Republic of Mauritania does not currently have a national policy on TM/CAM, one is in the process of development. No laws or regulations yet exist on TM/CAM; a national programme has also not been issued. No national office exists, although one is being planned. No expert committee exists, nor do research institutes on TM/CAM or herbal medicine.

Mauritania does not regulate herbal medicines; they are categorized as over-the-counter medicines, self-medication, herbal medicines, dietary supplements or health foods. No claims can legally be made about them. A national pharmacopoeia and

national monographs are in development; no other materials are used in their place at present.

Regulatory requirements for manufacturing are restricted to adherence to information in pharmacopoeias and monographs. Requirements for safety assessment are restricted to the special requirement of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. No information is available on the control mechanisms for these regulatory requirements. No registration system exists for herbal medicines. A post-marketing surveillance system is in development. There are no restrictions on the sale of herbal medicines in Mauritania.

Mozambique

The Republic of Mozambique currently has a national policy which was approved recently, while laws and regulation on TM/CAM are being developed. There is a national programme on TM/CAM, and a national office was established in 1977, which is administered by the Ministry of Health. The expert committee for TM/CAM was created in 2000. While no national research institutes on TM, CAM or herbal medicines exist separately, there is a Department of Studies of Medicinal Plants and Traditional Medicine in the National Institute of Health.

Herbal medicine is not regulated in Mozambique, so no regulatory status exists for herbal medicines and no claims may be made by law. In place of a national pharmacopoeia, the *African pharmacopoeia* (1985) is used and is legally binding. The national monographs are contained in the series *Plantas Medicinais e seu uso tradicional em Mocambique* (1983-1991, five volumes). The information in this series is legally binding.

As there is no manufacture of herbal medicine in the country, no regulatory requirements or safety assessment requirements exist. There is no registration system for herbal medicines, and they are not included on the essential drug list. A post-marketing surveillance system is in development. Herbal medicines are sold in pharmacies as over-the-counter medicines with no restrictions.

Niger

The Republic of the Niger is currently developing its national policy on TM/CAM, but laws and regulations were issued in 1997, and the national programme on traditional medicine was issued in 2001. The national office was established in 1995 under the administration of the Ministry of Health; however, no expert committee has been established, nor have any national research institutes on TM, CAM or herbal medicines.

Niger began regulation of herbal medicines in 1997, using legislation that is partly the same as that which regulates conventional pharmaceuticals. Under this regulation, herbal medicines are classified in the following regulatory categories: over-the-counter medicines, self-medication, dietary supplements and functional foods. No claims may be made under these laws. Niger's national pharmacopoeia is in development, and those pharmacopoeias used in its place are legally binding. National monographs are contained in the *Inventaire des plantes medecinales* (2000), which contains 339 monographs. It is not legally binding.

The relevant regulatory requirements for manufacturing include the use of the same GMP rules as for conventional pharmaceuticals and special GMP rules. The implementation of these requirements is ensured by the *Laboratoire national de santé publique et d'expertise* (National Laboratory of Public Health and Expert Evaluation –

LANSPEX). Special requirements for safety assessment, including traditional use without demonstrated harmful effects and reference to documented scientific research on similar products, apply to herbal medicines; the implementation of these requirements are also ensured by LANSPEX.

There is a registration system for herbal medicines, and currently one product is registered. The national essential drug list includes one herbal medicine; it was issued in 2000. A post-marketing surveillance system is in development. Herbal medicines in Niger are sold in pharmacies as over-the-counter medicines, in special outlets and by licensed practitioners.

Nigeria

The Federal Republic of Nigeria is currently developing a national policy on TM/CAM. Laws and regulations were issued in 1993 and revised in 1999. A national programme is also pending. The national office was established in 1997, and is administered by the Federal Ministry of Health. The expert committee on TM/CAM was created in 1978. Nigeria has two national research institutes on TM/CAM and herbal medicines, founded in 1988 and 1992. They are the Nigeria Natural Medicines Development Agency in Lagos, Nigeria and the National Institute for Pharmaceutical Research and Development.

Regulation of herbal medicines was introduced in Nigeria in 1993 in Decree No. 15, and was revised in 1999. Herbal medicines are regulated as dietary supplements, health foods, functional foods and as an independent regulatory category. Claims that may be made about herbal medicines include health, nutrient content and structure/function claims in accordance with the law. The Nigerian national pharmacopoeia and national monographs are in development, but no other materials are used in their place at present.

Manufacturing regulatory requirements are restricted to good hygienic practices and are enforced through checklists drawn up by the regulatory agency. Special requirements for safety assessment exist, including traditional use without demonstrated harmful effects; compliance with these requirements is ensured through animal studies to assess acute toxicity. There are currently 107 registered herbal medicines in Nigeria, but none is listed on the essential drug list. A post-marketing surveillance system is in development. In Nigeria, herbal medicines are sold without restriction by licensed practitioners.

Rwanda

The Rwandese Republic is currently developing laws and regulations on TM/CAM, but neither a national policy nor a national programme are planned. No national office exists, nor are there plans to develop one. There is no expert committee. The national research institute on traditional medicine and herbal medicines, the *Institut de recherche scientifique et technologique* (Scientific and Technological Research Institute – IRST) was established in 1982 (*Pharmacopée traditionnelle*).

Herbal medicines are not currently regulated in Rwanda; they are categorized as over-the-counter medicines, self-medication and dietary supplements. By law, medical claims may be about herbal medicines. No national pharmacopoeia exists; however the *Pharmacopée belge* (IV. ed.), the *Pharmacopée française* (IX. ed.) and the *Pharmacopée japonaise* (XI. ed.) are used, but are not legally binding. National monographs are being developed.

Regulatory requirements for herbal medicines include adherence to information in pharmacopoeias and monographs and the same rules of GMP as are used for conventional pharmaceuticals. Implementation of these requirements involves internal controls and consultation with the *International pharmacopoeia* and *European pharmacopoeia*. Safety assessment requirements are the same as those for conventional pharmaceuticals, and implementation is ensured through quality control of raw materials and manufactured products.

There is no registration system for herbal medicines, and no herbal medicines are included on the national essential drug list. A post-marketing surveillance system is in development. Herbal medicines in Rwanda are sold in pharmacies as prescription and over-the-counter medicines. Estimates by a researcher of the annual market sales of seven herbal medicines were provided for 2000 and 2001; however, the units of measurement used (whether currency or units sold) are unclear.

Sao Tome and Principe

Currently the Democratic Republic of Sao Tome and Principe is developing a national policy, laws, regulations and a national programme on TM/CAM. No national office exists, or is currently planned. No expert committee exists, nor any national research institutes on TM/CAM or herbal medicines.

Herbal medicines are not regulated in Sao Tome and Principe. No national pharmacopoeias or national monographs exist or are in development. No formal written regulatory requirements for manufacturing exist; for safety assessment, requirements are restricted to traditional use without demonstrated harmful effects. No control mechanism exists for this requirement.

No registration system exists, nor are herbal medicines included on the national essential drug list. There is no post-marketing surveillance system for herbal medicines, nor are there plans to develop one. Herbal medicines in Sao Tome and Principe are sold in special outlets.

Senegal

In the Republic of Senegal, information on the status of a national policy on TM/CAM is not available. Laws and regulations on TM/CAM are pending, and a national programme has been set up. No information is available about a national office, expert committee or national research institutes.

Herbal medicines in Senegal are not regulated. No information is available about regulatory status. Herbal medicines are sold with medical claims. No information is available on a national pharmacopoeia. No national monographs exist, nor are any in development.

Regulatory requirements for manufacturing consist of the same GMP rules as for conventional pharmaceuticals. There is no information about control mechanisms for these requirements, or about safety assessment requirements.

There is no registration system for herbal medicines and they are not included on the essential drug list. No post-marketing surveillance system exists, and none is in development. There is no market information available for Senegal.

Seychelles

In the Republic of Seychelles, national policy, laws and regulations on TM/CAM are currently in development. There is currently no national programme, national office or expert committee for TM/CAM. No national research institutes exist for the study of TM/CAM and herbal medicines.

Seychelles does not regulate herbal medicines, but herbal medicines are given the status of self-medication only. Neither a national pharmacopoeia nor a national herbal monograph exist or are being developed; the *British pharmacopoeia* is currently used, though the information is not considered legally binding. No requirements currently exist for the manufacturing or safety assessment of herbal medicines. There is no registration system for herbal medicines, and none are listed on the essential drug list. No post-marketing surveillance system exists and there are no plans to establish such a system. In the Republic of Seychelles, herbal medicines are mainly sold on the premises of herbalists.

Sierra Leone

The Republic of Sierra Leone is in the process of establishing a national policy, a national programme and a national office for TM/CAM. There is no national law or regulation on TM/CAM and there are no plans to develop one. An expert committee for TM/CAM was established in 2003 at the University of Sierra Leone. No national research institutes exist for the study of TM/CAM or herbal medicines.

Sierra Leone does not regulate herbal medicines; however, they are classified as over-the-counter medicines and as dietary supplements. By law, no claims may be made about herbal medicines. There are no plans to develop a national pharmacopoeia or national monographs, and nothing else is used in their place. No regulatory requirements apply to the manufacturing of herbal medicines. The regulatory requirements for the safety assessment of herbal medicines are the same as for conventional pharmaceuticals, but there is no control mechanism to ensure implementation. There is a registration system for herbal medicines, but there are no available data on the number of herbal medicines registered. No herbal medicines are included on the national essential drug list. There are currently plans to establish a system for post-marketing surveillance of herbal medicines, which are sold either in pharmacies as over-the-counter drugs or without any restrictions.

South Africa

The national policy on TM/CAM of the Republic of South Africa was issued in 1996 as part of the National Drug Policy. Laws and regulations are currently in development. The national programme on TM/CAM was issued in 2002. The national office was established in 2001 under the Ministry of Health. The Medicines Control Council serves as the expert committee for TM/CAM; it was established in 2001. While no national research institutes exist for TM, CAM or herbal medicines independently, other national research institutes have departments that cover traditional and herbal medicines.

In South Africa, herbal medicines are not currently regulated, although the laws and regulations are currently being finalized. No regulatory status yet exists for herbal medicines; however, currently they are sold for self-medication only. By law, health and nutrient content claims may be made about herbal medicines.

The national pharmacopoeia is in development, as are national monographs on herbal medicines. In place of national monographs, the *WHO monographs* are used; however, they are not legally binding.

The manufacturing requirements for herbal medicines are the same GMP rules as those used for conventional pharmaceuticals. Compliance with these requirements is ensured through GMP inspections of herbal medicine manufacturing centres and a manufacturing licensing system. Safety assessment requirements include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products and clinical data. Compliance is ensured through adherence to at least one of these requirements.

There is currently no national registration system for herbal medicines, although one is in development. No herbal medicines are included on the national essential drug list. A national post-marketing surveillance system for herbal medicines is in development. In South Africa, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed practitioners and without restriction.

Togo

In the Togolese Republic, the national policy on TM/CAM was issued in 1996, and laws and regulations were issued in 2001. The national programme on TM/CAM was issued in 1996. Although there is no national office, there is a programme head for traditional medicine at the Ministry of Health, and a national office is being set up. No expert committee exists, nor any national research institutes on TM/CAM or herbal medicines.

In Togo, herbal medicine regulations were passed in 2001; this legislation is partly the same as for conventional pharmaceuticals. Herbal medicines have the regulatory status of over-the-counter medicines or self-medication, with herbal medicines as an independent regulatory category. Claims are made for herbal medicines; these include medical and health claims as well as effects against bewitchment, sorcery and accidents.

No national pharmacopoeia exists or is being developed; in its place, the following resources are used but are not legally binding *Codex français*, *Pharmacopée africaine* (1985) and *Médecine traditionnelle et pharmacopée: contributions aux études ethnobotaniques et floristiques au Togo* (1986). No national monographs exist or are being developed; instead, the monographs contained in the annual periodical *Revue de médecines et pharmacopées africaines* are used.

There are no regulatory requirements for manufacturing of herbal medicines. Safety assessment requirements include use without demonstrated harmful effects and reference to documented scientific research on similar products, but there is no control mechanism to ensure implementation.

There is no registration of herbal medicines and they are not included on the essential drug list. There is no post-marketing surveillance system, and none is planned. In Togo, herbal medicines are sold without restriction in special outlets and as over-the-counter medicines in pharmacies.

Uganda

In the Republic of Uganda, a national policy, laws and regulations, a national programme and a national office on TM/CAM are all currently being developed. No expert committee has yet been set up. A national research institute on herbal medicines was established in 1963; it is the Natural Chemotherapeutics Research Laboratory.

Herbal medicine regulation in Uganda was established by the National Drug Authority Statute and Policy of 1993. The law for herbal medicines is the same as for conventional pharmaceuticals. There is no specific regulatory status given to herbal medicines. Claims which may be made by law include health, medical, nutrient content and cultural use claims.

The national pharmacopoeia is entitled *A contribution of the traditional medicine pharmacopoeia of Uganda* (1993); the information is not legally binding. No national monographs exist; however, the regional monographs of the Scientific, Technical and Research Commission of the Organization of African Unity are used.

There are no manufacturing regulatory requirements for herbal medicines: however, if they are produced for commercial use, then the medical safety and hygiene rules of the National Drug Authority inspectorate apply. There are no safety assessment requirements, and it is noted that issues of safety generally arise from the misuse of herbal medicines.

A registration system for herbal medicines was established in 2002; however no medicines are yet registered. Herbal medicines are not included on the essential drug list. No post-marketing surveillance system is in place, nor is one planned. In Uganda, herbal medicines are sold in pharmacies as over-the-counter medicines, by pedlars and in food markets, without restriction.

United Republic of Tanzania

In the United Republic of Tanzania, a national policy was issued in 2000; laws and regulations and a national programme on TM/CAM are being developed. The national office was established in 1989 as the Traditional Medicine Section of the Department of Curative Services, administered by the Ministry of Health. No expert committee exists. The national research institute on traditional medicine, the Institute of Traditional Medicine of the Muhimbili University College of Health Sciences, was founded in 1974.

Herbal medicines are currently not regulated in the United Republic of Tanzania. Herbal medicines have no regulatory status and are chiefly used for self-medication purposes. No claims may be made about herbal medicines by law. There is no national pharmacopoeia, nor are there national monographs; furthermore, none are in development and nothing is used in their places.

There are no manufacturing requirements; safety assessment requirements are limited to traditional use without demonstrated harmful effects; however, no control mechanism guarantees this requirement. There is no registration system for herbal medicines, nor are herbal medicines included on the essential drug list. A post-marketing surveillance system is being planned. There are no restrictions on the sale of herbal medicines in the United Republic of Tanzania.

Zambia

In the Republic of Zambia, the national policy on TM/CAM is part of the National Drug Policy, approved in 1997. National laws and regulations and a national programme on TM/CAM are being planned. The national office on TM/CAM is split between a desk for traditional medicine practices and a component of the National Drug Policy Analysis office on traditional and herbal medicines. An expert committee and national research institutes on TM/CAM are being planned.

While Zambia does not currently regulate herbal medicines, a bill has been proposed to do so; as the bill has not yet been passed, there is no regulatory status for herbal medicines at present. Herbal medicines are sold with claims, including medical, health nutrient content and structure/function claims; however, as the regulations are still pending, these are not yet legally recognized. There is no national pharmacopoeia and there are no national monographs in existence or in preparation. There are no manufacturing or safety assessment regulatory requirements as yet.

Likewise, there is not yet a registration system for herbal medicines, nor are herbal medicines included on the essential drug list. There are currently no plans to establish a post-marketing surveillance system for herbal medicines. There are no restrictions on the sale of herbal medicines in Zambia.

5.2 WHO Region of the Americas

Countries that responded to the survey: Region of the Americas



Eighteen of the 35 countries of the WHO Region of the Americas responded to the Global Survey. Table 5 summarizes the development of national policy and regulation of TM/CAM and herbal medicines in the Region of the Americas, with comparative figures for all the responding countries and the global percentages. The figures and percentages represent those countries responding positively to the questions. The survey response figures represent all of the responding countries, either in the region or globally as indicated.

Table 5. Region of the Americas: positive responses

| | Member States in the Americas Region responding positively with the following | Regional survey % that responded positively (18) | Global survey % that responded positively (141) |
|---|--|--|---|
| National policy on TM/CAM | 3 | 17% | 32% |
| Law or regulation on TM/CAM | 6 | 33% | 38% |
| National programme on TM/CAM | 4 | 22% | 28% |
| National office for TM/CAM | 8 | 44% | 53% |
| Expert committee on TM/CAM | 9 | 50% | 43% |
| National research institute on TM, CAM or herbal medicines | 7 | 39% | 41% |
| Law or regulation on herbal medicines | 13 | 72% | 65% |
| Registration of herbal medicines | 13 | 72% | 61% |

In the WHO Region of the Americas, there are considerable differences in the kinds of policies and regulations that have been developed. Many countries have regulation and registration systems for herbal medicines, yet the number of countries developing similar laws, regulations or national policies on TM/CAM is relatively small. However, the number of countries having expert committees, national research institutes and national offices is much higher, which may mean that such policies and regulations are being developed, or will be in the future.

Antigua and Barbuda

In Antigua and Barbuda, none of the following have been issued or established for TM/CAM: national policy, laws and regulations, a national programme, a national office, expert committee or national research institutes. None of these are in development.

Antigua and Barbuda does not regulate herbal medicines, and herbal medicines have no regulatory status. No claims can legally be made about herbal medicines. There is neither a national pharmacopoeia nor national monographs, and no other materials are used in their place.

There are no manufacturing or safety assessment regulatory requirements, nor is a registration system in place. Herbal medicines are not included on an essential drug list. No post-marketing surveillance system exists or is planned. In Antigua and Barbuda, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets and without restriction.

Argentina

The national policy on TM/CAM in the Argentine Republic is currently in development. In 1998, Resolution 144/98 established laws and regulations on TM/CAM, specifically on phytotherapeutic medicines and vegetable drugs. Under this same resolution, a national programme was established. The national office on TM/CAM is administered by the Ministry of Health, and is called the Committee on Harmonization of Vegetable Drugs; it was founded in 1992. An expert committee on TM/CAM was created in 1999. No national research institutes on TM/CAM currently exist.

Herbal regulation in Argentina was introduced in 1998 in Resolution 144/98. It established regulations that were partly the same as, but separate from, those used for conventional pharmaceuticals. In Argentina, herbal medicines are regulated as prescription medicines, over-the-counter medicines and dietary supplements. By law, medical claims may be made about herbal medicines.

The national pharmacopoeia is called the *Farmacopea nacional argentina* (1965); in addition, other pharmacopoeias used include the *United States pharmacopoeia*, *European pharmacopoeia* and *British pharmacopoeia*. The information in these pharmacopoeias is legally binding. National monographs are in preparation; however, the following materials are currently used and are legally binding: *United States pharmacopoeia*, *European pharmacopoeia*, *British pharmacopoeia*, *European Scientific Cooperative on Phytotherapy (ESCOP) monographs* and the *WHO monographs*.

The relevant regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and special GMP rules. The safety assessment requirements include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products, toxicological studies when traditional use cannot be demonstrated and submission of a full toxicological and pharmacological dossier. Compliance with these requirements is ensured by the requirement for a formal registration process submitted to the *Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* (National Administration of Drugs, Foods and Medical Devices – ANMAT), which ensures full compliance with the manufacturing and safety assessment requirements.

There is a registration system for herbal medicines, but the number of registered medicines is not currently available. No herbal medicines are included on an essential drug list. Argentina has a post-marketing surveillance system that includes a national

system to monitor adverse effects of all medicines, including herbal medicines, which was established in 1993. In Argentina, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, in special outlets and by licensed practitioners.

Bolivia

In the Republic of Bolivia, there is not currently a national policy on TM/CAM, nor is any policy being developed. There are laws and regulations on TM/CAM that were issued in 1987. There is no national programme on TM/CAM in existence or in preparation. A national office is being planned. No committee of experts exists. Research on herbal medicines is undertaken at the *Instituto de Investigaciones Farmacobiológicas de la Facultad de Farmacia y Bioquímica de la Universidad Mayor de San Andrés* (Institute of Pharmacobiochemical Research, Faculty of Pharmacy and Biochemistry, UMSA) and the Cochabamba Laboratory, acting as national research institutes.

Herbal regulation in Bolivia was introduced in 1996 in Law No. 1737; this legislation is partly the same as that which regulates conventional pharmaceuticals. Herbal medicines are regulated in Bolivia as over-the-counter medicines and in their own independent regulatory category. Claims that may be made by law are limited to medical claims. There is no national pharmacopoeia, nor is one in preparation; however, the *British herbal compendium* (1992) is used in its place. No information is available on national monographs or other monographs used.

Special GMP rules apply to herbal medicines, yet there is no mechanism for ensuring their implementation. Safety assessment requirements are limited to traditional use without demonstrated harmful effects; again, there is no existing control mechanism. There are currently 52 registered herbal medicines. No herbal medicines are included on the essential drug list. A post-marketing surveillance system is being planned. In Bolivia, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets with no restrictions.

Brazil

In the Federative Republic of Brazil, there is currently no national policy on TM/CAM, but the Ministry of Health is elaborating the Natural Medicine and Complementary Practices National Policy, which includes phytotherapy, acupuncture, homeopathy and anthroposophic medicine. A standardization proposal for the use of medicinal plants and phytotherapeutic medicines in the *Sistema Único de Salud* (Unified Health System – SUS) is being drafted. Laws and regulations and a national programme are in preparation. There is no national office or expert committee, nor are there national research institutes.

Regulation of herbal medicine has existed in Brazil since 1967, and the fourth version of the regulations, RDC 48/2004, was put in place in 2004. It is partly the same as the legislation on conventional pharmaceuticals. Herbal medicines are regulated in the following categories: herbal drugs (both prescription medicines and over-the-counter medicines), functional foods, probiotics, bioactive substances and cosmetics. Medical claims can only be made if the product is registered as a herbal drug. The national pharmacopoeia is the *Farmacopéia brasileira* (4th ed., 1988); the information it contains is legally binding. The national pharmacopoeia also contains the national monographs.

The regulatory requirements for manufacturing include adherence to the information contained in pharmacopoeias and monographs, and the same rules of good

manufacturing practice as for conventional pharmaceuticals, as well as special rules. These requirements are ensured through certification of GMP for the production and pharmaceutical areas. Safety assessment requirements include the same requirements as for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects; again, there is no existing control mechanism, but reference is made to documented scientific research on similar products. The implementation of these requirements is ensured through annual inspections.

There are more than 1000 herbal medicines registered in Brazil; none is included on the national essential drug list; however, a list of phytotherapeutic medicines is currently being prepared for inclusion. There is a post-marketing surveillance system that includes adverse-effect monitoring, established in 2001. Herbal medicines in Brazil are sold in pharmacies as prescription and over-the-counter medicines. In 2001, the total sales of herbal medicines reached an estimated US\$ 400 million.

Canada

Canada has no national policy, laws or regulations or national programme on TM/CAM. No national laws or regulations apply to any health disciplines, as power in these areas lies entirely with the provinces and territories. A national office exists, the Natural Health Products Directorate of the Health Product and Food Branch. It was established in 1999, and is administered by the Ministry of Health. The office also serves as the expert committee and national research institute.

Regulation of herbal medicines was introduced in Canada in 2003 in separate laws within the Food and Drugs Act. Herbal medicines are regulated as over-the-counter medicines, self-medication, dietary supplements and as natural health products. By law, medical, health, nutrient content and structure/function claims may be made about herbal medicines.

No national pharmacopoeia exists. National monographs are in development. In place of a national pharmacopoeia and national monographs, the following materials are used: *Compendium of pharmaceuticals and specialties*, *Canadian drug reference for health professionals*, *Compendium of nonprescription products (CNP)*, *United States pharmacopoeia*, *Herbal medicines*, *Expanded Commission E monographs*, *ESCOP monographs*, *WHO monographs*, *Pharmacopoeia of the People's Republic of China*, *PDR for herbal medicines*, *British herbal compendium* and *British herbal pharmacopoeia*.

Special GMP rules are required for manufacturing of herbal medicines; these are enforced by submitting to inspection to ensure the granting of a site licence to manufacturers, importers and labellers. To market a herbal product, the manufacturer, importer or labeller must have both a site licence and a product licence. Special requirements for safety assessment include special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Requirements for safety assessment are enforced by the need for a product licence that is conditional on providing satisfactory evidence of compliance with the safety requirements laid down in the regulations.

Under the current system of herbal registration, over 10 000 herbal medicines were registered. A new system was due to come into effect during 2004. No herbal medicines are included on an essential drug list. A post-marketing surveillance system that includes monitoring of adverse effects of herbal medicines was established in 1965 and is the same as for conventional pharmaceuticals.

In Canada, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed and unlicensed practitioners and in multi-level marketing.

Annual market sales based on a market survey of herbal medicines for Canada in 1999 was US\$ 380 million, in 2000 US\$ 400 million and in 2001 US\$ 400 million. In 1999, sales of herbs and vitamins were estimated at 937 million Canadian dollars (US\$ 715 million).

Chile

A national policy on TM/CAM is in development in the Republic of Chile, as are laws and regulations. In 1992, a national programme was established, and in the same year the national office, *Unidad de Medicina Tradicional y Otras Practicas Médicas Alternativas* (Unit for Traditional Medicine and Other Alternative Medical Practices) was established within the Ministry of Health. No national research institutes on TM/CAM or herbal medicines have been established.

In 2002, Chile began regulation of herbal medicines, with a separate, specialized law. Herbal medicines are regulated as over-the-counter medicines, as dietary supplements and as an independent regulatory category. By law, medical and health claims may be made about herbal medicines. In place of an outdated national pharmacopoeia, alternatives are used, including the following: *International pharmacopoeia*, *United States pharmacopoeia*, *British pharmacopoeia*, *German pharmacopoeia* and *German homeopathic pharmacopoeia*. National monographs are in production.

Regulatory requirements for manufacturing include observation of information in pharmacopoeias and monographs and special GMP rules for herbal medicines. These requirements are guaranteed through authorization and control of packaging establishments. Special rules for safety assessment include traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Implementation of these requirements is ensured by an official listing system and hygienic controls placed on packaging establishments and on the medicines themselves.

There is no registration system, nor are herbal medicines included on an essential drug list. There is a national post-marketing surveillance system that includes adverse-effect monitoring for herbal medicines. In Chile, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets.

Colombia

In the Republic of Colombia, a national policy on TM/CAM neither exists nor is pending. Laws and regulations on TM/CAM were first issued in 1964 in Decree 1950, and were updated and expanded in 1995, 1997, 1998 and 2001. No national programme has been issued, nor has a national office been established, and neither is planned. An expert committee on TM/CAM was established in 1976. The *Instituto Humboldt*, founded in 1900, serves as a national research institute in CAM.

Herbal medicine is regulated in Colombia by means of Decree 677 of 1995 and Decree 337 of 1998. The regulations established are partly the same as those for conventional pharmaceuticals, while some are separate for herbal medicines. Herbal medicines are regulated as over-the-counter medicines and as an independent regulatory category. Claims that are made about herbal medicines include medical, health and structure/function claims, but none are recognized by law.

No national pharmacopoeia exists, nor is one planned; in lieu of this, the *United States pharmacopoeia*, *Codex francés* and *British herbal pharmacopoeia* are used. The information is

considered legally binding. National monographs exist, but they are not legally binding.

Regulatory requirements for manufacturing include adherence to the information contained in pharmacopoeias and monographs, the same rules of GMP as for conventional pharmaceuticals, and special rules. No information on control mechanisms is available. Safety assessment requirements include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products and clinical studies. Compliance with these requirements is ensured by a health registry.

There is a registration system for herbal medicines; the number of registered medicines is not available. Herbal medicines are not included on the essential drug list. No system of post-marketing surveillance exists or is being planned. Herbal medicines in Colombia are sold in pharmacies as over-the-counter medicines and special outlets without restriction.

Costa Rica

In the Republic of Costa Rica, a national policy on TM/CAM and a national programme have not been issued and are not currently being developed. Laws and regulations on TM/CAM currently exist. A national office solely for TM/CAM does not exist; however, the Ministry of Health includes units responsible for the regulation of TM/CAM, including an expert committee that controls and registers products. National institutes of herbal medicines exist at the *Escuela de las Ciencias de la Tierra y el Mar* (School of Earth and Marine Sciences, established 1980) and *Centro de Investigaciones de Productos Naturales* (Centre for Research into Natural Products, established 1988).

In Costa Rica, regulation of herbal medicines involves separate regulations that are partly the same as those for conventional pharmaceuticals and cover the registration, importation, marketing and advertising of herbal medicines. They are not classified in any regulatory category. By law, statements may be made regarding medical, health, nutrient content and structure/function claims; however, medical claims must be supported by the scientific literature.

No national pharmacopoeia exists. None is planned, and no others are used instead. No national monographs exist, but instead the following, among others, are used, although they are not legally binding: *Complete German Commission E monographs* and *WHO monographs on selected medicinal plants*.

The same GMP rules are required for the manufacture of herbal medicines as are used for conventional pharmaceuticals; compliance with these is guaranteed by means of routine inspections and an initial inspection for permission to begin manufacturing. Special GMP rules are currently being developed especially for herbal medicines. The same requirements for safety assessment apply to herbal medicines as to conventional pharmaceuticals; implementation is ensured by laboratory analysis and user reports and complaints.

A total of 359 herbal medicines are registered; there is no national essential drug list. There is a national post-marketing surveillance system that includes herbal medicines. In Costa Rica, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets without restriction.

Dominica

A national policy on TM/CAM is being developed in the Commonwealth of Dominica, as is a national programme. There are, however, currently no plans to develop laws or regulations. No national office exists, and information is unavailable about any plans to develop one. An expert committee has been created. No national research institutes currently exist.

Herbal medicines are not regulated in Dominica; however, they are sold with health claims. In place of a national pharmacopoeia, the *British pharmacopoeia* is used and is legally binding. No national monographs exist.

There are no manufacturing requirements and safety requirements are limited to traditional use without demonstrated harmful effects. There is no quality control mechanism for this requirement. There is no registration system, nor are herbal medicines included on the essential drug list. A post-marketing surveillance system is planned. In Dominica, herbal medicines are sold as over-the-counter medicines and in special outlets without restriction.

Dominican Republic

In the Dominican Republic, national policy on TM/CAM is in development; in 2001, laws and regulations were adopted. No national programme has been issued. In 1993, the national office on TM/CAM was established under the Ministry of Health. No expert committee currently exists. There are no national research programmes.

Herbal medicine regulation was introduced in 2001; the regulation is partly the same as for conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines, self-medication and dietary supplements. By law, medical, health, nutrient content and structure/function claims may be made about herbal medicines. No national pharmacopoeia or monographs exist and none are being developed.

The same GMP requirements apply to herbal medicines as to conventional pharmaceuticals. No information is available on the control mechanism for these manufacturing requirements. There are no safety assessment regulatory requirements. The registrations system includes 3 000 herbal medicines; there are no herbal medicines on the essential drug list. A post-marketing surveillance system is being planned. In the Dominican Republic, herbal medicines are sold as over-the-counter medicines and in special outlets without restriction.

Ecuador

In the Republic of Ecuador, national policy on TM/CAM is currently at the development stage; however, laws and regulations were issued in 1998. A national programme is currently being planned, as is a national office. No expert committee exists, nor do any national research institutes.

Ecuador does not currently regulate herbal medicines; the regulatory status given to herbal medicines includes prescription and over-the-counter medicines, self-medication, dietary supplements, health foods and cosmetics. Medical and health claims may be made by law. A national pharmacopoeia is being developed; no information is available on national monographs.

Likewise, there is no information on manufacturing requirements for herbal medicines; there are no safety requirements. Herbal medicines are not registered or included on an essential drug list. No post-marketing surveillance system exists. In Ecuador, herbal medicines are sold in special outlets without restriction.

El Salvador

The Republic of El Salvador has no national policy, laws, regulations, national programme, national office, expert committee or national research institute for TM/CAM. None of these is currently being developed.

El Salvador established regulation of herbal medicines in 1988 through Decree No. 55; this is the same law that regulates conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. Medical, health and nutrient content claims are made about herbal medicines. There is no national pharmacopoeia, nor is one in development. Instead, the following pharmaceuticals are used: *German pharmacopoeia*, *Pharmacopoeia argentina*, *British pharmacopoeia*, *United States pharmacopoeia*, *Spanish pharmacopoeia*, *European pharmacopoeia*, *Swiss pharmacopoeia*, *International pharmacopoeia*, *Japanese pharmacopoeia* and *Mexican pharmacopoeia*. The information contained in these pharmacopoeias is legally binding. No national monographs have been, or are being, developed; no others are used in their place.

Manufacturing regulatory requirements consist of special GMP rules for herbal medicines; compliance with these rules is ensured through inspection and a manufacturing licensing system. Safety assessment regulatory requirements consist of special requirements including traditional use without demonstrated harmful effects and reference to scientific research on similar products. No control mechanism exists to ensure compliance with these safety requirements.

There is a registration system, and 51 herbal medicines are registered. No herbal medicines are included on the national essential drug list. No post-marketing surveillance system exists; however, one is being planned. In El Salvador, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, and in special outlets.

Guatemala

The national policy of the Republic of Guatemala on TM/CAM was established in 2000 in the *Políticas del Plan Nacional de Salud, 2000-2004* (Policies of the National Health Plan, 2000-2004). Laws and regulations are currently being developed. The national programme and national office were established in 2001; the office is called the *Programa Nacional de Medicina Popular Tradicional* (National Programme of Popular Traditional Medicine). The Ministry of Health and Social Assistance administers the office. There is no expert committee. National research institutes on traditional medicine are part of the Universidad de San Carlos de Guatemala, including the *Centro de Estudios Folklóricos* (Centre for Folklore Studies, established in 1981), the Faculty of Chemical Sciences and Pharmacy and the Faculty of Agronomy.

Guatemala has issued a number of regulations related to herbal medicines, which are partly the same as those for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. By law, medical and structure/function claims may be made. A national pharmacopoeia and national monographs are being developed; the *WHO monographs* are used in place of the national ones.

The manufacturing regulatory requirements are the same GMP rules applied to conventional pharmaceuticals; implementation is enforced through annual self-inspections. Special safety requirements include traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. There are control mechanisms for these safety requirements, but no specific information is available.

The registration system is currently under revision, so the number of registered herbal medicines is not known. There are no herbal medicines on the essential drug list. There is no post-marketing surveillance system, nor is one currently being planned. In Guatemala, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Jamaica

In Jamaica, a national policy, laws and regulations and a national programme are being developed. The national office was established in 2000 as part of the Ministry of Health. An expert committee also exists, as does a national research institute on herbal medicines.

The policy to regulate herbal medicines in Jamaica is currently being developed by amending the previous policy to incorporate herbal medicines. Herbal medicines are classified as prescription and over-the-counter medicines, dietary supplements, health foods, functional foods and homeopathic products. Claims may be made about herbal medicines; for medical claims, a product must be registered, while for health, nutrient content and structure/function claims, product registration may be required, depending on the nature of the claims and the product components.

In place of a national pharmacopoeia, the *British herbal pharmacopoeia* (1983) is used. In place of national monographs, the *Complete German Commission E monographs* and *Herbal drugs and phytochemicals* (1994, Wichtl and Grainger, eds.) are used. The latter contains 181 monographs. Neither is considered legally binding.

The same manufacturing requirements apply to herbal medicines as to conventional pharmaceuticals; they are enforced by means of herbal product registration. Special safety assessment requirements apply to herbal medicines, including traditional use without demonstrated harmful effects, reference to documented scientific research on similar products and proof of safety from the regulatory authority of the country of origin. The registration system also enforces implementation of these requirements.

There is a national herbal medicines registration system; however, the number of registered medicines is not known. Herbal medicines are not included on an essential drug list. Jamaica has a post-marketing surveillance system that includes adverse-effect monitoring. Consumers and health professionals are encouraged to report to the authorities using an adverse drug report form. In Jamaica, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, in special outlets and by licensed practitioners.

Mexico

The national policy of the United Mexican States was introduced in 2001; however, no laws or regulations have been issued or are being planned. The national programme was issued in 2001 in the Work Plan of the National Office, the *Dirección de Medicina Tradicional* (Traditional Medicine Directorate) for 2001-2006. The office is part of the Ministry of Health. In 2001, an expert committee on TM/CAM was created. National research institutes for traditional medicine include the National Institute of Anthropology and History and for herbal medicine the Herbarium of the Mexican Institute of Social Security.

In Mexico, regulation of herbal medicines was established in 1997; the law is partly the same as for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines, dietary supplements, health foods and

herbal remedies. By law, medical, health and structure/function claims may be made. The national pharmacopoeia, *Farmacopea Herbolaria de los Estados Unidos de Mexico* (2001), is legally binding. The national pharmacopoeia also includes monographs.

Manufacturing requirements include the same GMP rules as for conventional pharmaceuticals, but also include adherence to information in pharmacopoeias and monographs and special GMP rules for herbal medicines. Implementation of these requirements is enforced through inspections. Safety assessment regulatory requirements are the same as for conventional pharmaceuticals, but also include references to documented scientific research on similar products, as well as the results of microbiological analysis and the absence of toxic residues. Inspections also serve as the control mechanism for safety requirements.

There is a registration system, but it is not known how many herbal medicines are registered. Two herbal medicines are listed on the national essential drug list. There is a system of post-marketing surveillance, which includes a national adverse-effect monitoring system established in 2000. In Mexico, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines and in special outlets.

Nicaragua

Although Nicaragua does not have a national policy, laws or regulations on TM/CAM, they are currently being developed. No national programme has been introduced. The national office is being established. The national expert committee on TM/CAM was established in 2003. No national research institutes have been established for TM, CAM or herbal medicines.

The regulation of herbal medicines was introduced in 1998 through Law 292, the national pharmaceuticals law. This law also regulates conventional pharmaceuticals; however, there are also special rules that apply only to herbal medicines. Herbal medicines are regulated as prescription medicines, over-the-counter medicines, dietary supplements, health foods and functional foods. By law, herbal medicines may be sold with medical, health, nutrient content and structure/function claims.

Although no national pharmacopoeia currently exists, one is being developed. No information is available on the other pharmacopoeias currently used and legally binding. Sixty-three national monographs on herbal medicines may be found in the *Compendia de Plantas Medicinales* (2000). In addition, monographs in the *Farmacopoeia caribeña* are used; both are considered to be legally binding.

Regulatory requirements for manufacturing include the same GMP rules as for conventional pharmaceuticals and special GMP rules. No control mechanism exists to ensure compliance with these requirements. Safety assessment requirements include those used for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. No control mechanism has been established for safety assessment requirements.

There is a registration system for herbal medicines; however, the number of registered herbal medicines is not available. No herbal medicines are included on the national essential drug list. A post-marketing surveillance system is currently being planned for herbal medicines. In Nicaragua, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed practitioners, without restriction and in indigenous communities.

Peru

In 1990, in Legislative Decree No. 584 and Supreme Decree No. 002-92-SA, the Republic of Peru established a national policy on TM/CAM laws. Regulations and a national programme are being developed. The national office, the *Instituto Nacional de Medicina Tradicional* (National Institute of Traditional Medicine, INMETRA) was established in 1990. In 2002, in Law No. 27657, INMETRA was included in the *Instituto Nacional de Salud* (National Institute of Health), changing its name to *Centro Nacional de Salud Intercultural* (National Centre for Intercultural Health, CENSI). CENSI leads national research efforts in TM/CAM. CENSI also promotes the implementation of TM services, as well as CAM within the National Health Coordinated and Decentralized System.

In 1997, Peru established regulations on herbal drugs and medicines through the same law used for conventional medicines. Herbal medicines are regulated as over-the-counter medicines and dietary supplements. According to the law, herbal medicines may be sold, depending on their health and nutritional content. A technical committee led by CENSI has been formed for the regulation of Law No. 27399 on Sustainable Utilization of Medicinal Plants, and Law No. 27821 on Promotion of Nutritional Complements for Alternative Development.

There is no national pharmacopoeia. There are no national monographs. No information is available on manufacturing requirements or their enforcement. Safety requirements are limited to the stipulation of traditional use without demonstrated harmful effects; there is no control mechanism for this regulatory requirement. Currently CENSI is developing the Peruvian Medicinal and Related Plants Pharmacopoeia Project, the Medicinal Plants National Herbarium and biogardens and botanical gardens nationwide.

There is a registration system for herbal medicines, but there is no information as to the number of herbal medicines registered. None are on the list of essential drugs. The establishment of a post-marketing surveillance system is being considered. Herbal medicines in Peru are sold as over-the-counter medicines without restriction.

Suriname

In the Republic of Suriname, no national policy, laws, regulations, national programme or national office on TM/CAM exist, nor are they in the process of being developed. There is also no expert committee and there are no national research institutes on TM/CAM or herbal medicines.

Herbal medicines are not regulated in Suriname and consequently have no regulatory status, nor can claims be legally made about them. Neither a national pharmacopoeia nor national monographs exist, and no information is available on other materials used in their place.

No information is available on manufacturing regulatory requirements or any control mechanism to ensure compliance. Safety regulations are limited to reference to scientific research on similar products; no information is available on a control mechanism for this requirement. No registration system exists for herbal medicines, nor are they included on a national essential drug list. No post-marketing surveillance system for herbal medicines exists, nor is one being planned. In Suriname, there are no restrictions on the sale of herbal medicines.

5.3 WHO Eastern Mediterranean Region

Countries that responded to the survey: Eastern Mediterranean Region



Sixteen of the 22 countries of the WHO Eastern Mediterranean Region responded to the Global Survey. Table 6 summarizes the development of national policy and regulation of TM/CAM and herbal medicines in the region, with comparative figures for all the responding countries and the global percentages. The figures and percentages represent those countries responding positively to the questions. The survey response figures represent all the responding countries, either in the region or globally, as indicated.

Table 6. WHO Eastern Mediterranean Region: positive responses

| | Member States in the Eastern Mediterranean Region responding positively with the following | Regional survey % that responded positively (16) | Global survey % that responded positively (141) |
|---|--|--|---|
| National policy on TM/CAM | 5 | 31% | 32% |
| Law or regulation on TM/CAM | 8 | 50% | 38% |
| National programme on TM/CAM | 2 | 13% | 28% |
| National office for TM/CAM | 10 | 63% | 53% |
| Expert committee on TM/CAM | 8 | 50% | 43% |
| National research institute on TM, CAM or herbal medicines | 8 | 50% | 41% |
| Law or regulation on herbal medicines | 12 | 75% | 65% |
| Registration of herbal medicines | 12 | 75% | 61% |

Countries in the Eastern Mediterranean Region demonstrate a strong commitment to research in TM/CAM and herbal medicines. There is also a high level of commitment to developing national policies on TM/CAM, especially for the regulation and registration of herbal medicines.

Afghanistan

In the Islamic State of Afghanistan, there is no national policy, law or regulation, national programme or national office for TM/CAM. Though there are currently no plans to establish a national policy or national programme, a law or regulation on TM/CAM is being developed. An expert committee for TM/CAM was established in 2002. No national research institutes exist for the study of TM/CAM or herbal medicines.

Afghanistan does not regulate herbal medicines. Herbal medicines are sold with claims; however, there is no information regarding the types of claims that may be made by law. Neither a national pharmacopoeia nor a national herbal monograph exist, and there are currently none in development. At present, no other monographs or pharmacopoeias are used in their place. The same GMP regulatory requirements apply to the manufacturing of herbal medicines as to conventional pharmaceuticals. Safety requirements include the same requirements as for conventional pharmaceuticals and special requirements, namely traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Neither the manufacturing nor the safety requirements are assured by any control mechanism. There is no registration system for herbal medicines and no herbal medicines are included in the national essential drug list. There is currently no post-marketing surveillance system for herbal medicines; however, there are plans to establish one. In the Islamic State of Afghanistan, there are no restrictions on the sale of herbal products.

Bahrain

The Kingdom of Bahrain has not issued or established any of the following for TM/CAM: national policy, laws or regulations, a national programme, a national office, an expert committee or national research institutes.

Bahrain regulates herbal medicines using the same, or partly the same, legal framework as is used for conventional pharmaceuticals. Herbal medicines are regulated as dietary supplements, health foods and health products. Health and nutrient content claims are made about herbal medicines. The *PDR for herbal medicines* is used in place of a national pharmacopoeia, and is legally binding. No national monographs exist and no others are used.

Manufacturing regulatory requirements include adherence to information in pharmacopoeias and monographs and the same rules of GMP as for conventional pharmaceuticals. No control mechanism exists. Safety assessment requirements are those used for conventional pharmaceuticals and reference to documented scientific research on similar products. Again, no control mechanism is in place to ensure implementation of these requirements.

The registration system has registered 600 herbal medicines; herbal medicines are not included on an essential drug list. No post-marketing surveillance system exists, or is being planned. In Bahrain, herbal medicine is sold in pharmacies as over-the-counter medicines and in special outlets.

Djibouti

There is currently no national policy, law or regulation, national programme or national office for TM/CAM in the Republic of Djibouti, nor are there any plans to establish these. Neither is there an expert committee or national research institute for the study of TM/CAM or herbal medicines. Herbal medicines are not regulated in Djibouti and have the regulatory status of self-medication only. Herbal medicines are

not sold with claims. There is neither a national pharmacopoeia nor a national monograph on herbal medicines, and neither is being developed. No other pharmacopoeia is currently being used. There is no information regarding the regulatory requirements for the manufacture or safety assessment of herbal medicines. There is no registration system for herbal medicines, and none are included on the national essential drug list. Currently, there is also no post-marketing surveillance system for herbal medicines, nor any plans to establish one. There are no restrictions on the sale of herbal products in the Republic of Djibouti.

Egypt

In the Arab Republic of Egypt, national policy on TM/CAM is part of the national drug policy issued in 2001. Laws and regulations were first developed in 1955. A national programme is being developed. The National Centre for Medicinal Plants was established in 1995, and serves as the national office under the Ministry of Health. An expert committee on TM/CAM was established in 1992. National research institutes were established in 1994, including the National Applied Research Centre for Medicinal Plants established by the Ministry of Health in 1995 (Ministerial Decree No.212) and operating within the National Organization for Drug Control and Research (NODCAR).

Herbal medicine regulation in Egypt began in 1955, and is achieved through the same laws as are used for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines, self-medication and dietary supplements. Medical, health and nutrient content claims may be made by law. The *Egyptian pharmacopoeia* (1972, 1980) is the national pharmacopoeia, and contains monographs on herbal medicines; it is legally binding.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs, the same rules of GMP as for conventional pharmaceuticals and special GMP rules. Regulatory requirements for safety assessment are limited to reference to documented scientific research on similar products. Control mechanisms exist for both manufacturing and safety assessment requirements.

There are 600 registered herbal medicines. No herbal medicines are included on the national essential drug list. There is a post-marketing surveillance system and a national system to monitor adverse events for herbal medicines. Both registration and quality control of herbal drugs must be performed in the laboratories of NODCAR.

In Egypt, herbal medicines are sold in pharmacies as over-the-counter and prescription medicines and by licensed practitioners. Annual market sales data (including local and export sales) were provided. In 2000, sales amounted to 34 million Egyptian pounds (US\$ 5.54 million), in 2001 38 million Egyptian pounds (US\$ 6.2 million), and in 2002, 44 million Egyptian pounds (US\$ 7.2 million).

Islamic Republic of Iran

The Islamic Republic of Iran established its national policy on TM/CAM in 1996, and in that year laws and regulations were developed. No national programme currently exists. A national office for TM/CAM was established within the Ministry of Health in 1981 as the part of the Department of Pharmaceutical Affairs. An expert committee was established in 1995. A national research institute on herbal medicines was founded in 1999.

Regulation of herbal medicines was revised in 1996. Herbal medicines are regulated as prescription and over-the-counter medicines and as dietary supplements. Medical, health and nutrient content claims may be made by law. The *British pharmacopoeia* and the *Pharmacopoeia of the People's Republic of China* are used in lieu of a national pharmacopoeia, but are not legally binding. The *National formulary of Iran* (2nd ed. 2000) contains the 70 national monographs; it is not legally binding.

Special GMP rules apply to the manufacture of herbal medicines; the implementation of these requirements is ensured by GMP inspection and national laboratory testing. Safety assessment requirements are traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Implementation of these requirements is ensured by the adverse-drug-reaction centre.

The registration system has registered 170 herbal medicines. No herbal medicines are included on an essential drug list. A post-marketing surveillance system that includes adverse-effect monitoring exists. In the Islamic Republic of Iran, herbal medicines are sold in pharmacies as over-the-counter and prescription medicines and in special outlets. Estimated annual market sales data for herbal sales was provided. In 1999, sales totalled US\$ 3 million, in 2000, US\$ 3.1 million and in 2001, US\$ 3.5 million.

Jordan

Although the Hashemite Kingdom of Jordan does not currently have a national policy on TM/CAM, one is currently being developed. Laws and regulations were established in 2001. No national programme is currently being planned. The national office on TM/CAM is part of the Drug Directorate of the Ministry of Health; it was established in 1999. An expert committee was created in 1991. No independent national research institutes on TM/CAM or herbal medicines have been established.

Herbal regulations in Jordan were developed in 2001, and are partly the same as for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines and for self-medication. By law, medical, health, nutrient content and structure/function claims may be made. In lieu of a national pharmacopoeia, the *United States pharmacopoeia* is used. The *WHO monographs* are used in place of national monographs, and they are legally binding.

In Jordan, the regulatory requirements for the manufacture of herbal medicines are the same GMP rules that apply to conventional pharmaceuticals; implementation is ensured by a control mechanism. Safety assessment requirements are the same as for conventional pharmaceuticals, but also include special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products; a control mechanism also exists for these requirements, involving toxicological studies.

The herbal medicines registry contains 35 medicines. No herbal medicines are included on the national essential drug list. A post-marketing surveillance system that includes adverse-effect monitoring was established in 2002. In Jordan, herbal medicines are sold in pharmacies as over-the-counter and prescription medicines without restriction.

Kuwait

The State of Kuwait established a national policy on TM/CAM through the creation of the Islamic Medicine Centre in 1978. Laws and regulations on TM/CAM were issued in 1989, and a national programme was created in 1984. The national office, the Islamic

Medicine Centre, is part of the Ministry of Health; the Centre also serves as the expert committee and national research institute on herbal medicine.

Kuwait began regulation of herbal medicine in 1989 with the introduction of a separate law on herbal medicines. Herbal medicines are regulated as over-the-counter medicines, self-medication, dietary supplements, health foods and functional foods. Medical and health claims may legally be made. In lieu of a national pharmacopoeia and national monographs, the *European pharmacopoeia*, *British pharmacopoeia*, *United States pharmacopoeia* and *International pharmacopoeia* are used and are legally binding.

Regulatory requirements for the manufacture of herbal medicines include the same GMP rules as for conventional pharmaceuticals, as well as adherence to information in pharmacopoeias and monographs. Implementation of these requirements is enforced through quality control of raw materials, manufacturing and finished products. Safety assessment requirements include the same requirements as for conventional pharmaceuticals and traditional use without demonstrated harmful effects. The control mechanism is the same as for manufacturing requirements, in which random samples are tested for quality-control purposes.

The registry for herbal medicines contains 30 herbal medicines. No herbal medicines are included on a national essential drug list. A post-marketing surveillance system is being planned.

In Kuwait, herbal medicines are sold in pharmacies as over-the-counter medicines without restriction; however, herbal medicines manufactured by the Islamic Medicine Centre are given to patients free of charge. Data were provided on the quantity of herbs used in manufacture and distributed: in 1999, it was 4 573 kg, in 2000, 3 755 kg and in 2001, 3 355 kg.

Libyan Arab Jamahiriya

In the Great Socialist People's Libyan Arab Jamahiriya, there are plans to establish a national policy, law or regulation, national programme and national office for TM/CAM. No expert committee currently exists; however, there is a national research institute for TM/CAM and herbal medicines. There is no national law or regulation on herbal medicines; therefore, they have no status and are not sold with claims. Though no national pharmacopoeia or monograph currently exists or is being developed, the *British herbal pharmacopoeia* and *European pharmacopoeia* are used, although they are not legally binding. No regulatory requirements apply to the manufacturing or safety assessment of herbal medicines. There is no registration system for herbal medicines, and consequently no herbal medicines are included on the national essential drug list. There are no available data about any post-marketing surveillance system in Libya. Herbal medicines are either sold in pharmacies as over-the-counter drugs or sold without restriction.

Oman

A national policy on TM/CAM in the Sultanate of Oman is currently being established. In 2001, national laws and regulations on TM/CAM were introduced. No national programme has been issued or is being developed. There is also no national office, expert committee or research institute.

Herbal regulation in Oman began in 2001; it is similar to legislation for conventional pharmaceuticals. Herbal medicines have no regulatory status. Medical claims may

legally be made. No national pharmacopoeia or national monographs exist, nor are they in development.

The same rules of GMP apply to herbal medicines as to conventional pharmaceuticals; no control mechanism ensures their implementation. Safety assessment requirements include the same requirements as for conventional pharmaceuticals, as well as special requirements consisting of use without demonstrated harmful effects and reference to documented scientific research on similar products; again, no control mechanism exists.

A registration system for herbal medicines has been established in Oman, but currently no figures are available on the number of registered herbal medicines. Herbal medicines are not included on an essential drug list. A post-marketing surveillance system is being planned. In Oman, herbal medicines are sold by licensed practitioners.

Pakistan

In the Islamic Republic of Pakistan, a national policy on TM/CAM is being developed. Laws and regulations were developed in 1965 and amended in 1970 and 2002. A national programme was issued in 1965 and the national office was established in the same year; the office is part of the Ministry of Health. An expert committee on TM/CAM was established in 2001. The Drugs Control and Traditional Medicines Division of the National Institute of Health serves as the national institute on traditional medicine and was established in 1991.

The Drugs Act of 1962 controls the regulation of herbal medicines as regards advertising and prevention of misuse. Herbal medicines are regulated as over-the-counter medicines and dietary supplements. No claims may legally be made about herbal medicines. The national pharmacopoeia is the *Tibbi pharmacopoeia* (1967); the information is not legally binding. The *Monographs of unani medicines* (Vol. 1) has been prepared and published.

The Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and Any Other Non-Allopathic Medicine Act has been prepared to regulate the manufacture, sale, storage, import and export of medicines from these systems. The Act has been approved by the Federal Cabinet and Prime Minister of Pakistan; however, there are currently no regulatory requirements for either manufacture or safety assessment of herbal medicines. There is no registration system. Herbal medicines are not included on an essential drug list. A post-marketing surveillance system is being developed. In Pakistan, herbal medicines are sold in pharmacies as over-the-counter drugs, by licensed practitioners, and in special outlets without any restrictions. Annual market sales data are 3.8 billion Pakistani rupees (US\$ 49 million) for 1999, 4.5 billion rupees (US\$ 78 million) for 2000 and, 5 billion rupees (US\$ 87 million) for 2001.

Qatar

The State of Qatar does not have a national policy on TM/CAM, nor is one currently in development. Regulations on TM/CAM were issued in 1990 and in 2002. No national programme exists, nor is one currently being developed. The national office was formed in 2002 as part of the Ministry of Public Health; it is called the Herbal Medicines, Food Supplements and Medicated Cosmetic Section. An expert committee for TM/CAM was created in 1990. There are no national research institutes on TM/CAM.

Herbal regulations in Qatar were issued in 1990 and updated in 2002; these laws are separate from those dealing with conventional pharmaceuticals. Herbal medicines are

regulated as over-the-counter medicines, dietary supplements, complementary products and as an independent regulatory category. By law, medical, health, nutrient content and structure/function claims may be made about herbal medicines.

There is no national pharmacopoeia; instead, the *German herbal pharmacopoeia* and the *British herbal pharmacopoeia* are used, and are legally binding. Five national monographs exist; they were published by the University of Qatar. They are *Ecology and flora of Qatar* (1981), *Environment and plant life in Qatar* (1986), *Phytochemistry of the flora of Qatar* (1986), *Phytochemistry of the historical and cultural plants of Qatar* (1989) and *Medicinal and poisonous plants of Qatar* (1995).

Regulatory requirements for the manufacture of herbal medicines are limited to adherence to information in pharmacopoeias and monographs; there is no mechanism for control of this requirement. Safety assessment requirements involve research into safety and local uses of current products and new products, use in other States in the region and information from other agencies regulating the product.

The registration system has accepted 2 134 herbal medicines; it was established in 1996. There are no herbal medicines included on a national essential drug list. A post-marketing surveillance system is being planned. Herbal medicines in Qatar are sold in pharmacies as over-the-counter medicines without restriction.

Saudi Arabia

The Kingdom of Saudi Arabia is currently developing a national policy, laws and regulations on TM/CAM. No national programme has been issued. A national office was established within the Ministry of Health in 1995. There is no expert committee on TM/CAM. A national research institute on herbal medicines is part of King Saud University.

Herbal-medicine regulation in Saudi Arabia was established in 1996 with the issue of a separate law specifically for herbal medicines. The regulatory categories for herbal medicines include over-the-counter medicines, self-medication, dietary supplements, health foods and functional foods. By law, medical, health, nutrient content and structure/function claims may be made.

No national pharmacopoeia exists; however, the *German pharmacopoeia*, *British pharmacopoeia* and *WHO monographs* are used instead. They are not legally binding. In place of national monographs the *WHO monographs* are used, although they are not legally binding.

Regulatory requirements for manufacturing include some of the same GMP rules as for conventional pharmaceuticals, as well as special GMP rules. Implementation of these requirements is enforced through plant and factory inspections. Safety assessment requirements include some of the same requirements as for conventional pharmaceuticals, as well as reference to documented scientific research on similar products. Laboratory testing and analysis serve as the control mechanisms for these requirements.

In Saudi Arabia, there are 450 registered herbal medicines; however, none are included on an essential drug list. No plans have currently been made to establish a national post-marketing surveillance system. In Saudi Arabia, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, and in special outlets without restriction.

Sudan

In the Republic of the Sudan, the Department of Medicinal Plants and Traditional Medicines was established in 1995 under the National Board of Pharmacy. The national policy on TM/CAM has been drawn up since the establishment of this department. Laws and regulations are currently at the development stage. There is no national programme on TM/CAM. The national office was established within the Federal Ministry of Health under the name Medicinal Plants and Traditional Medicine Directorate. The National Research Institute conducts research on traditional medicine and herbal medicine; it was established in 1975.

Sudan first issued regulations on herbal medicines in 1996 and renewed them in 1998 and 2002. These regulations are separate from those for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, self-medication and dietary supplements. By law, medical and nutrient content claims may be made about herbal medicines.

In lieu of a national pharmacopoeia, the *British herbal pharmacopoeia* is used, and is considered to be legally binding. In place of national monographs, the *WHO monographs* are used.

The regulatory requirements for manufacturing include adherence to information in the *British herbal pharmacopoeia* and the *WHO monographs*, as well as the GMP rules for conventional pharmaceuticals and special GMP rules for herbal medicines. The implementation of these requirements involves evaluation of quality-control data submitted by the manufacturer, GMP inspection and documentation of the raw material supply. Requirements for safety assessment include traditional use without demonstrated harmful effects and biosafety studies. To ensure adherence to these requirements, the biosafety study protocols are strictly followed.

There are eight herbal medicines currently registered. Sudan is planning to create an independent list of essential Sudanese medicinal plants. A post-marketing surveillance system is currently being developed.

Herbal medicines in Sudan are sold in pharmacies as over-the-counter medicines and in special outlets. Annual market data was included for one registered herbal product, senna tablets, which is the only herbal product cultivated in Sudan and locally manufactured in tablet form by a local manufacturer. In 2001, total sales were 7.404 million Sudanese dinars (US\$ 28 000 – 17 433 600 tablets), and in 2002 sales were worth 8.123 million dinars (US\$ 31 000 – 19 148 500 tablets). In 2003, sales totalled 8.861 million dinars (US\$ 34 000 – 20 889 270 tablets). Crude senna, gum arabic, gum acacia and hibiscus are marketed locally and internationally in commercial quantities. Digoxin and diosmin are registered as imported items.

Syrian Arab Republic

A national policy on TM/CAM was issued in the Syrian Arab Republic in 1998, along with laws and regulations. No national programme currently exists. The national office was established in 2000 as part of the Ministry of Health. An expert committee was founded in 2000. No national research institutes on TM, CAM or herbal medicines have been established.

In the Syrian Arab Republic, regulation of herbal medicines was introduced in 1998 as part of the same law that regulates conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, health foods and as an independent regulatory category. Medical and herbal claims may be made by law.

In place of a national pharmacopoeia, the *United States pharmacopoeia* is used and is legally binding. No national monographs exist, but the *Physician's desk reference* is used and is also legally binding.

The regulatory requirements for manufacture of herbal medicines include adherence to information in pharmacopoeias and monographs and the GMP guidelines for herbal medicines that were established in 2004. Implementation of these requirements is enforced by a control mechanism. Safety assessment requirements include clinical trials submitted during registration and product licences. Clinical trials are required for preparations intended to be used for specific indications (e.g. diabetes, hypertension, etc.), and are assessed by the Ministry of Health's high-level technical committee. There is no control mechanism for these requirements.

There are currently 44 herbal medicines registered in the Syrian Arab Republic. There are no herbal medicines included on the national essential drug list. No post-marketing surveillance system exists. Herbal medicines are sold in pharmacies as prescription medicines.

United Arab Emirates

Currently, no national policy exists for TM/CAM in the United Arab Emirates; however, such a policy is being developed. Laws, regulations and a national programme on TM/CAM are also in development. The national office, which comes under the Ministry of Health, was established in 2001. There is currently no expert committee; however, TM/CAM applicants are examined and evaluated for their licence to practice by a specialized committee called the "Committee for Evaluation of Qualifications of Doctors and Specialists in Complementary and Alternative Medicine". The Zayed Complex for Herbal Research and Traditional Medicine was established in 1996 and serves as the national research institute for traditional and herbal medicine.

The national laws and regulations on herbal medicines were established in 1995, as separate laws and regulations that are partially the same as those for conventional medicines. Herbal medicines are regulated as prescription and over-the-counter medicines, and as a separate regulatory category. By law, medical, health, nutrient content and structure/function claims may be made about herbal medicine. While the national pharmacopoeia is in the process of being developed, others are used, but are not legally binding. No national monographs yet exist, but they are in development. In their place, a number of others, including the *WHO monographs*, are used, but are not legally binding.

The regulatory requirements for the manufacture of herbal medicines include adherence to information in pharmacopoeias and monographs, as well as modified GMP rules. Compliance with these regulations is ensured through inspection and certification. The safety requirements for herbal medicines are special requirements, including demonstrated traditional use without harmful effects and reference to documented scientific research on similar products, in addition to the report of the Ministry of Health's quality control laboratory.

A registration system exists, which includes about 70 herbal medicines and a number of single and combination homeopathic medicines, as well as a few proprietary traditional Chinese medicines, yet none are included on a national essential drug list. Many herbal and other products from natural sources are registered using a simpler criterion, namely registration of general-sale pharmaceutical products. A post-marketing surveillance system has been established, and an adverse-effect monitoring system is being developed.

In the United Arab Emirates, herbal medicines are generally sold in pharmacies as prescription and over-the-counter medicines and in special outlets. However, many herbal products and food supplements are also imported under special permits from the municipalities and sold in health food outlets licensed by them. Annual sales figures are based on estimates of imports through the Ministry of Health for 2001 and 2002. In 2001, US\$ 1.358 million of herbal medicines were imported. These imports consisted of 1 842 160 caplets and tablets and 10 122 bottles. In 2002, such imports had a value of US\$ 1.264 million and involved 2 495 760 caplets and tablets and 14 440 bottles.

Yemen

In the Republic of Yemen, no national policy, laws, regulations or national programme for TM/CAM have been established, nor are any in the process of development. A national office for TM/CAM is being planned. No expert committee exists, nor do any national research institutes currently exist for TM/CAM or herbal medicines.

No laws or regulations on herbal medicines have yet been established in Yemen. Herbal medicines are classified as over-the-counter medicines, dietary supplements and health foods, for self-medication only. Herbal medicines are sold with medical, health and nutrient content claims. No national pharmacopoeia exists, and there is no further information about whether one is in preparation or whether other pharmacopoeias are used in its place. National monographs neither exist nor are being developed, nor are any others used in their place.

No information is available on the manufacturing regulatory requirements for herbal medicines, but a control mechanism exists to ensure compliance. Information is also not available about safety requirements for herbal medicines or control mechanisms for compliance.

A registration system exists; however, the number of registered herbal medicines is not known. No herbal medicines are included on a national essential drug list. No information is available on the existence of a post-marketing surveillance system. In Yemen, herbal medicines are sold in pharmacies as over-the-counter medicines without restriction.

5.4 WHO European Region

Countries that responded to the survey: European Region



Thirty-nine of the 51 countries of the WHO European Region responded to the Global Survey. Table 7 summarizes the development of national policy and regulation of TM/CAM and herbal medicines in the European Region, with comparative figures for all of the responding countries and the global percentages. The figures and percentages represent those countries responding positively to the questions. The survey response figures represent all of the responding countries either in the region or globally as indicated.

Table 7. WHO European Region: positive responses

| | Member States in the European Region responding positively with the following | Regional survey % that responded positively (38) | Global survey % that responded positively (141) |
|---|--|---|---|
| National policy on TM/CAM | 7 | 18% | 32% |
| Law or regulation on TM/CAM | 14 | 37% | 38% |
| National programme on TM/CAM | 3 | 8% | 28% |
| National office for TM/CAM | 9 | 24% | 53% |
| Expert committee on TM/CAM | 10 | 26% | 43% |
| National research institute on TM, CAM or herbal medicines | 10 | 26% | 41% |
| Law or regulation on herbal medicines | 36 | 98% | 65% |
| Registration of herbal medicines | 32 | 84% | 61% |

While a large number of countries in the WHO European Region have developed national policies and regulations on TM/CAM through different mechanisms, it is in the area of herbal-medicine regulation and registration that the commitment of the countries of the Region to these issues is most evident. The high percentage of countries with herbal-medicine regulation and herbal-medicine registration systems demonstrates a high level of commitment to ensuring the safety, quality and efficacy of herbal medicines through strong regulatory and policy systems.

Armenia

In the Republic of Armenia, no national policy, laws or regulations on TM/CAM exist, nor are there currently plans to establish them. There is neither a national programme nor an office for TM/CAM, although there are plans to establish them. There are no expert committees set up or national research institutes on TM, CAM or herbal medicine, but research on TM takes place within a department of the National Institute of Health.

Regulation of herbal medicines in Armenia began in 1998 through the national drug law that also regulates conventional pharmaceuticals. Herbal medicines are regulated as a separate category and as dietary supplements. By law, herbal medicines may be sold with medical claims. No national pharmacopoeia exists, nor is one in the process of being developed. In its place, the *British herbal pharmacopoeia* is used and is legally binding. National monographs are found in the *Armenian national formulary for herbal medicines* (2001), which is legally binding. The *WHO monographs* are also used and are legally binding as well.

Regulatory requirements for herbal medicines are limited to adherence to information in pharmacopoeias and monographs; compliance is ensured through inspection by the Drug and Medical Technology Agency. Safety regulatory requirements include the same requirements as for conventional pharmaceuticals and reference to scientific research on similar products. The control mechanism for this requirement is an expert report on safety at the time of registration.

There are 130 registered herbal medicines and 60 herbal dietary supplements. The national essential drug list contains three herbal medicines, and there is a national essential herbs list. The national centre for post-marketing monitoring of adverse drug reactions (including those of herbal medicinal products) was established within the Drug and Medical Technology Agency in 1997. The centre participates in the WHO Programme for International Drug Monitoring. In Armenia, herbal medicines are sold in pharmacies as over-the-counter medicines and by licensed practitioners without restriction. National sales of herbal medicines in 2001 were estimated to be between US\$ 50 000 and US\$ 60 000, based on data provided by local herbal-medicine producers.

Austria

The Republic of Austria has not developed, and has no plans to develop, national policy, laws, regulations, a national programme or a national office on TM/CAM. There are no expert committees or national research institutes on TM/CAM or herbal medicines.

Herbal medicine regulation was introduced in Austria in 1989 in Law No. 541. The regulation is partly the same for herbal medicines as for conventional medicines. In Austria, herbal medicines are regulated as prescription and over-the-counter medicines. Medical claims may be made by law about herbal medicines.

The national pharmacopoeia, the *Austrian pharmacopoeia*, and the *European pharmacopoeia* are used and are both legally binding. The *Austrian pharmacopoeia* contains monographs, which are also legally binding.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and the same rules of GMP as for conventional pharmaceuticals. Inspections ensure compliance with these requirements. Safety regulatory requirements are the same as for conventional pharmaceuticals, and compliance is ensured through the pharmacovigilance reporting system.

There is no registration system for herbal medicines, nor are any included on a national essential drug list. No national post-marketing surveillance system explicitly exists for herbal medicines, nor is one being planned. In Austria, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines and in special outlets.

Azerbaijan

The Republic of Azerbaijan does not have a national policy, laws, regulations, a national programme, a national office, or an expert committee on TM/CAM, nor are there currently any plans to establish these. No information is available about the existence of national research institutes on TM, CAM or herbal medicines.

The same laws and regulations that apply to conventional pharmaceuticals apply to herbal medicines. Herbal medicines are regulated as over-the-counter medicines, self-medication, dietary supplements, health foods and as a separate regulatory category. By law, medical, health nutrient content and structure/function claims may be made about herbal medicines.

No national pharmacopoeia exists, and no information is available about the other pharmacopoeia that is used and considered to be legally binding. National herbal monographs are in development. Other monographs are used in their place and are considered to be legally binding; however, no information was provided about which monographs are used.

Manufacturing regulatory requirements include adherence to information in pharmacopoeias and monographs, the same GMP rules as for conventional pharmaceuticals and special GMP rules. No control mechanism exists to ensure compliance with these requirements. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals; however, no control mechanism exists to ensure compliance.

There is a registration system for herbal medicines; however, the number of registered herbal medicines is not known. Herbal medicines are included on the national essential drug list; however, the number included is not known. A post-marketing surveillance system for herbal medicines is being planned. In Azerbaijan, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed practitioners and without restriction.

Belarus

The Republic of Belarus is currently developing a national policy on TM/CAM. Currently, no laws, regulations, national programme, national office, or expert committee on TM/CAM have been established, nor are there currently any plans to establish these. No national research institutes on TM, CAM or herbal medicines have been set up.

The same laws and regulations that apply to conventional pharmaceuticals also apply to herbal medicines. Herbal medicines are regulated as over-the-counter medicines and as dietary supplements. By law, medical claims may be made about herbal medicines.

In place of a national pharmacopoeia, the *State pharmacopoeia of the USSR* is used and is considered to be legally binding. No national monographs exist or are in development, and no others are used in their place.

Manufacturing requirements in Belarus include adherence to information in pharmacopoeias and monographs and the same GMP rules as for conventional pharmaceuticals. A control mechanism exists to ensure compliance with these

requirements; however, no details are available. Safety regulatory requirements include the same requirements as for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. To ensure compliance with these requirements, the registration procedures require reports on safety.

There are 300 registered herbal medicines in Belarus; however, none is included on a national essential drug list. The post-marketing surveillance system includes a national system to monitor adverse effects of herbal medicines, which was established in 1999. In Belarus, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Belgium

National policy on TM/CAM in the Kingdom of Belgium was established in 1999, as were laws and regulations. No national programme has been issued, nor has national office have been established. However, a national office under the direction of the Ministry of Health is being planned. No expert committee exists, nor do national research institutes on TM/CAM or herbal medicines.

Regulation of herbal medicines was introduced in 1969; the regulations are partly the same as for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines and as dietary supplements. Medical and nutrient content claims may be made by law.

The *European pharmacopoeia* serves as the national pharmacopoeia, and is considered to be legally binding. No national monographs exist.

Regulatory requirements for manufacturing of herbal medicines include adherence to the information in pharmacopoeias and monographs and the same GMP rules as for conventional pharmaceuticals. Compliance with these requirements is ensured through inspections of the manufacturing and packaging sites. Safety requirements are the same as for conventional pharmaceuticals, and are ensured through the pharmacovigilance centre and general pharmacy inspections.

There is no registration system, nor are herbal medicines included on a national essential drug list. The national post-marketing surveillance system established in 1990 includes adverse-effect monitoring of herbal medicines. In Belgium, herbal medicines are sold in pharmacies as conventional and over-the-counter medicines without restriction.

Bulgaria

In the Republic of Bulgaria, national policy on TM/CAM is being developed. Laws and regulations on TM/CAM were established in 1995 and amended in 2000. A national programme is being planned. The national office, established in 1988 – the Department of Traditional Medicine – is administered by the Ministry of Health. An expert committee was established in 1998 as part of the Bulgarian Drug Agency. No national research institutes have yet been established to investigate TM, CAM or herbal medicines.

Herbal medicines are regulated through laws and regulations which are partly the same as for conventional pharmaceuticals; these were issued in 1995 and amended in 2001. The relevant law is Regulation No.17 of 19 May 2001 on documentation requirements for marketing authorization for medicinal products. Herbal medicines are regulated as prescription medicines and over-the-counter medicines and as dietary

supplements. By law, medical, health and structure/function claims may be made about herbal medicines.

No national pharmacopoeia yet exists, although one is in development. Instead, the *European pharmacopoeia* is used, and is considered legally binding. No national monographs yet exist, although they are also in development; in their place, the *ESCOP monographs* are used, although they are not legally binding.

Regulatory requirements for manufacturing are the same rules of GMP as for conventional pharmaceuticals, and are controlled through manufacturing authorization inspections. Safety requirements include those required for conventional pharmaceuticals and traditional use without demonstrated harmful effects. No control mechanism exists for these safety requirements.

A total of 113 herbal medicines have been registered, but none is included on a national essential drug list. There is a post-marketing surveillance system that includes adverse-effect monitoring, which was introduced in 1975.

In Bulgaria, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines and in special outlets. Estimates of the volume of annual sales of packs of four of the most popular herbal medicines sold were provided for 1999, 2000 and 2001. In 1999, 48 814 packs were sold (figures only given for two medicines); in 2000, 134 548 packs were sold and in 2001, 127 996 packs were sold. Although the total volume decreased between 2000 and 2001, this is due to a drop in sales of one of the four medicines: sales of the other three medicines increased in the same period.

Czech Republic

Although national policy, laws, regulations and a national programme on TM/CAM do not currently exist in the Czech Republic, they are being developed. No national office exists, nor is one being planned. There is also no expert committee or national research institute on TM, CAM or herbal medicines.

National laws and regulations on herbal medicines were introduced in 1997 in Law No. 79, which is also the same law that regulates conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. Legally, medical claims may be made about them.

The *Cesky lekopis 2002 (Pharmacopoeia bohémica MMII)* is the national pharmacopoeia containing two legally binding parts: the *European pharmacopoeia* in translation and national monographs.

Regulatory requirements for manufacturing include adherence to information contained in pharmacopoeias and monographs and the same GMP rules that are used for conventional pharmaceuticals. Compliance with these requirements is ensured by means of GMP standards. The safety requirements for herbal medicines are the same as for conventional pharmaceuticals and assessment during the registration process is guaranteed. As of November 2003, there were 230 registered herbal medicines.

No herbal medicines are included on a national essential drug list. A national post-marketing surveillance system that includes adverse-effect monitoring exists. Herbal medicines are sold in the Czech Republic in pharmacies as prescription and over-the-counter medicines and in special outlets. Data for volume and value of national market sales of herbal medicines was provided, based on reporting from herbal medicines wholesalers.

In 1999, the national sales volume was 6.17 million packs of herbal medicines, with a value of 246.6 million Czech koruna (US\$ 9 million). In 2000, the volume reached 6.62 million packs, with a value of 256.55 million koruna (US\$ 9.363 million). Finally, in 2001, annual sales involved 8.14 million packs with a value of 315.76 million koruna (US\$ 11.524 million).

Denmark

No information is available for the Kingdom of Denmark about national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM.

Regulation of herbal medicines in Denmark began in 1992, through laws and regulations separate from, but similar to, those for conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines and as a separate regulatory category. By law, herbal medicines may be sold with medical claims.

No national pharmacopoeia exists: the *European pharmacopoeia* is used instead and is legally binding. No national monographs exist; however, the monographs in the *European pharmacopoeia* are used instead, and are considered to be legally binding.

The same GMP rules used for conventional pharmaceuticals apply to herbal medicines, and compliance is ensured through inspection by the Danish Medicines Agency. Safety requirements include reference to documented scientific research on similar products and bibliographical documents; these documents are part of the application process for marketing authorization.

There are 170 registered herbal medicines; there are no herbal medicines included on a national essential drug list. A post-marketing surveillance system that includes adverse-effect monitoring of herbal medicines exists. In Denmark, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets without restriction.

Estonia

The Republic of Estonia does not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM, nor are there currently any plans to establish these.

Regulation of herbal medicines began in 1998 in Estonia; herbal medicines are regulated as prescription and over-the-counter medicines and as dietary supplements. By law, medical, health and nutrient content claims may be made for herbal medicines.

The *European pharmacopoeia* is used in lieu of a national pharmacopoeia and national monographs, and is considered legally binding. In addition, the monographs in the *British herbal pharmacopoeia* and the *WHO monographs* are used.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and the same GMP rules as are used for conventional pharmaceuticals. Compliance is ensured by inspection by the State Agency of Medicines, but only for those herbal medicines regulated as prescription medicines. Safety requirements vary according to the regulatory status of the herbal medicines; however, requirements include those laid down for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. The control mechanism of inspection ensures compliance.

There are currently 85 registered herbal medicines in Estonia; however, none is listed on the essential drug list. A post-marketing surveillance system for herbal medicines that includes a national monitoring system for adverse effects was established in 1995. Herbal medicines in Estonia are sold in pharmacies as prescription and over-the-counter medicines.

France

The French Republic does not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM, nor are there currently any plans to establish these.

Regulation of herbal medicines in France began in 1985, using the same laws and regulations as are used for conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines, and by law, medical claims may be made about them.

No national pharmacopoeia is currently used, and there is no information available about national monographs. The same GMP rules are required for the manufacture of herbal medicines as for conventional pharmaceuticals. Compliance with these requirements is ensured through inspections. Safety requirements are the same as for conventional pharmaceuticals, but also include the special requirement of traditional use without demonstrated harmful effects.

In France, 787 herbal medicines are registered; none is listed on a national essential drug list. A post-marketing surveillance system that includes pharmacovigilance for herbal medicines has been established. Herbal medicines are sold in pharmacies as over-the-counter medicines in France.

Georgia

Georgia does not have a national policy, laws, regulations, a national programme or an expert committee on TM/CAM, nor are there currently any plans to establish these. A national office was established in 2001, and is administered by the Ministry of Health. No information is available on national research institutes on TM, CAM or herbal medicines.

In Georgia, regulation of herbal medicines was introduced in 2002 in laws and regulations similar to those that regulate conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines and as a separate regulatory category. By law, medical claims may be made about herbal medicines.

A national pharmacopoeia was published in two volumes, in 2000 and 2003; it is legally binding. National monographs on herbal medicines are being developed.

Manufacturing regulatory requirements for herbal medicines are adherence to pharmacopoeias and monographs; no information is available on the control mechanism used to ensure compliance with this requirement, if any. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals; no control mechanism exists to ensure compliance.

There are 181 registered herbal medicines in Georgia; however, none is included on a national essential drug list. No post-marketing surveillance system for herbal medicines exists, nor is one currently being planned. In Georgia, herbal medicines are sold in pharmacies as over-the-counter medicines.

Germany

In the Federal Republic of Germany, a national policy on TM/CAM was issued in 1976. In that year, laws and regulations on TM/CAM were also issued. A national programme for TM/CAM was introduced in 1978. There is not currently a national office for TM/CAM, although there is a relevant department in the Federal Institute for Drugs and Medical Devices. The national expert committee was established in 1978. There are currently no national research institutes for TM/CAM or herbal medicines.

The national laws and regulations on herbal medicines in Germany were issued in 1976, and have been updated, for instance by several amendments to the Medicines Act. Herbal medicines are regulated as prescription medicines, over-the-counter medicines and as medicines for self-care purposes, which are sold outside pharmacies. By law, medical claims and claims about traditional use may be made about herbal medicines.

A national pharmacopoeia, the *Deutsches Arzneibuch* (German pharmacopoeia, DAB) and the *European pharmacopoeia* are used and are considered to be legally binding. A number of additional national monographs have been issued, such as the *Deutscher Arzneimittel-Codex* (DAC), but they are not legally binding.

Regulatory requirements for the manufacture of herbal medicines include adherence to the information in pharmacopoeias and, in the absence of pharmacopoeias, monographs, other monographs, the GMP rules for conventional pharmaceuticals and special GMP rules, the German Medicines Act, and Eudralex (the European Union rules relating to medicinal products). Compliance with these requirements is ensured through inspection and marketing authorization. Safety regulatory requirements include those required for conventional pharmaceuticals. Implementation of these requirements is ensured through pharmacovigilance and literature reviews.

There are approximately 3500 herbal medicines registered in Germany. The post-marketing surveillance system, established in 1978, includes monitoring for adverse effects of herbal medicines. Herbal medicines are sold in Germany in pharmacies as prescription and over-the-counter medicines, in special outlets and in supermarkets. According to industry data for 2002, annual sales of herbal medicines in Germany had a value of 2.072 billion euros (US\$ 2.432 billion).

Hungary

A national policy on TM/CAM was introduced in the Republic of Hungary in 1997 as part of the Law on Public Health, Chapter IV, Section 104. Laws and regulations were issued on naturopathic activities in 1987 and 1997. There is no national programme on TM/CAM. The National Institute of Pharmacy, which was established in 1962 under the Ministry of Health, has dealt with the evaluation and registration of traditional herbal medicines since about 1982. Two scientific societies and an association on TM/CAM have been established. The Research Institute for Medicinal Plants was founded in 1915.

In Hungary, herbal medicinal products may be sold as traditional herbal products, called "healing products or paramedicine" (having therapeutic effects but not considered to be medicaments), or as herbal medicines, which are considered to be conventional pharmaceutical products. Both are regulated as over-the-counter medicines for self-medication purposes and by law, medical claims and health claims may be made.

The regulation for traditional herbal products ("healing products or paramedicine") was issued in 1987. According to this decree, a traditional herbal product may be

approved if: its composition or components are known; the quality of the components and product is determined and constantly ensured; its safety in the doses to be administered is proven; the conditions of its production meet the public health regulations; the prescribed technology for its production can be ensured; its established effect is proven through evaluation or based on scientific knowledge.

The regulations for herbal medicines (conventional pharmaceutical products which contain herbal drug(s) or herbal drug preparation(s)) were laid down in a law of 1998 and regulations, in 2000 and 2001, which refer to medicines in general. These regulations include some special quality requirements for herbal medicines.

The seventh edition of the *Hungarian pharmacopoeia* (1986) is the national pharmacopoeia in force. However, Hungary has signed the Convention on the Elaboration of a European Pharmacopoeia, so the standards of the *European pharmacopoeia*, which are included in the eighth edition of the *Hungarian pharmacopoeia*, are also legally binding.

The GMP rules used for conventional pharmaceuticals are also requirements for the manufacture of herbal medicines; compliance is ensured through regular GMP inspections of herbal preparation manufacturers. The safety and efficacy of a herbal medicinal product may be proved using the same requirements as those for conventional pharmaceuticals, including preclinical and clinical trials or by referring to documented scientific research on similar products. Safety and efficacy requirements are ensured through the controlled production of the product and quality-assurance data.

There are currently 40 authorized herbal medicinal products and about 700 registered traditional herbal medicinal products (healing products) in Hungary. Though none of these is included on the essential drug list, there is also a traditional herbal drugs list containing 98 drugs without indication (decree 81/2003(XII.23) of Minister of Health). A post-marketing surveillance system including adverse-effect monitoring was established in 1970. Herbal medicines are sold in pharmacies as over-the-counter medicines; traditional herbal medicines are sold in pharmacies and in special shops for healing products.

Iceland

The Republic of Iceland does not have a national policy, laws, regulations, a national programme, a national office, or national research institutes on TM/CAM, nor are there currently any plans to establish these. An expert committee on TM/CAM was established in 2000 as part of the Icelandic Medicines Control Agency.

Regulation of herbal medicines in Iceland began in 1997 with the issue of Regulation No. 684, the regulation concerning marketing authorization for herbal medicinal products. This is a separate regulation for herbal medicines and is similar to the regulations on conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines, dietary supplements, health foods and as a separate regulatory category. Medical claims may be made by law only for those herbal medicines that have marketing authorization under the 1997 regulation.

No national pharmacopoeias or national monographs are used; instead, the *European pharmacopoeia* is used, and is considered to be legally binding. Regulatory requirements for manufacturing include the same GMP rules as for conventional pharmaceuticals, as well as adherence to the information in pharmacopoeias and monographs. Implementation of these requirements is ensured through the submission of GMP approval documents for manufacturers of herbal products authorized under

Regulation No. 684. For other products, no control mechanism exists. Safety regulatory requirements include traditional use without demonstrated harmful effects and reference to documented scientific research on similar products, provided by manufacturers.

Eleven herbal medicines are currently registered in Iceland; none is included on a national essential drug list. The same post-marketing surveillance system used for conventional pharmaceuticals, which includes adverse-effect monitoring, is used for herbal medicines. In Iceland, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets. The value of annual market sales of herbal medicines in 2002 was estimated at 1 billion Icelandic krona (US\$ 13.175 million).

Ireland

Ireland is currently developing its national policy on TM/CAM, as well as laws and regulations. No national programme is currently being developed. There is no national office or national research institute focusing on TM, CAM or herbal medicines.

The regulation of herbal medicines was introduced in 1998 with the passage of the Medicinal Products (Licensing and Sale) Regulations, which regulate conventional and herbal medicines. Herbal medicines are regulated as prescription medicines, over-the-counter medicines, dietary supplements and medicines for self-medication purposes. By law, medical, health, nutrient content and structure/function claims may be made.

In Ireland, the *European pharmacopoeia* is used in lieu of a national pharmacopoeia; it is legally binding. The monographs contained in it are also used in place of national ones.

Regulatory requirements for the manufacture of herbal medicines include adherence to the information contained in pharmacopoeias and monographs, the GMP rules for conventional pharmaceuticals and special GMP rules. Implementation of these requirements is ensured through the licensing of manufacturers and authorization of herbal products. Regarding safety, the same regulatory requirements that apply to conventional pharmaceuticals also apply to herbal medicines; compliance is likewise ensured by the same means.

There is no registration system, nor are herbal medicines included on a national essential drug list. The same post-marketing surveillance system used for conventional medicines is used to monitor herbal medicines. In Ireland, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines and in special outlets without restriction.

Israel

The State of Israel is currently developing a national policy, laws and regulations, a national programme and a national office for TM/CAM. There is currently no expert committee or national research institute on TM/CAM or herbal medicines.

There is currently no specific regulation of herbal medicines in Israel. Herbal medicines may be considered as dietary supplements, and by law no medicinal claims may be made for them. No national pharmacopoeia exists; instead, the *Homeopathic pharmacopoeia*, *British pharmacopoeia*, *French pharmacopoeia* and *United States pharmacopoeia* are used and are considered legally binding. In the place of national monographs, the *ESCOP monographs*, *Commission-E monographs* and *WHO monographs* are used, but these are not considered legally binding.

The regulatory requirements for the manufacture of herbal medicines are the same as those for conventional pharmaceuticals, including the control mechanism to ensure

compliance. As for safety, herbal medicines are screened to restrict those that are not suitable for food use. Furthermore, a list of those herbs which may be used in dietary supplements has been drawn up.

There is currently no registration system, nor are herbal medicines included on a national essential drug list. The same post-marketing surveillance system used for conventional medicines, which includes adverse-effect monitoring, is used for herbal medicines. There are no restrictions on the sale of herbal medicines.

Kazakhstan

In the Republic of Kazakhstan, a national policy on TM/CAM is currently being developed. Laws and regulations were issued in 1997 and 2003. The national programme was introduced in 2001. The national office is administered by the Ministry of Health. No national expert committee for TM/CAM has been established. Several national research institutes focus on the study of herbal medicines.

Regulation of herbal medicines in Kazakhstan began in 1995 with Article 8 of President's Decree No. 2655, the same one that regulates conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines, self-medication and dietary supplements. By law, medical and structure/function claims may be made about herbal medicines.

In lieu of a national pharmacopoeia, the *State pharmacopoeia of the USSR* is used, as well as the *United States pharmacopoeia*, *British pharmacopoeia* and *European pharmacopoeia*. The information in these is legally binding. National monographs have been published; however, these are not legally binding.

Manufacturing regulatory requirements are limited to adherence to information in pharmacopoeias and monographs. To ensure compliance, inspection by regional departments is required. Safety regulatory requirements are the same as for conventional pharmaceuticals; compliance is ensured through laboratory testing for radioactivity, microbiological purity and pesticides.

There are 134 registered herbal medicines in Kazakhstan; five were included on the national essential drug list issued in 2003. The post-marketing surveillance system includes a national system to monitor adverse effects of herbal medicines, which was established in 2003. Herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Kyrgyzstan

The Kyrgyz Republic does not have a national policy, laws, regulations, a national programme or a national office on TM/CAM, nor are there currently any plans to establish these. There is no national expert committee. The National Scientific Research and Processing Centre of Balneology and Traditional Medicine of the Ministry of Health of Kyrgyzstan was founded in 1990.

The National Law on Pharmaceuticals of 1997 establishes regulations on herbal medicines that are partly the same as those for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines, dietary supplements and herbal raw materials. By law, herbal medicines must be sold with medical claims.

No national pharmacopoeia yet exists, and there are no immediate plans to develop one; meanwhile, the pharmacopoeia of the former Soviet Union is used, and is considered to be legally binding. National monographs are contained in the *National*

medicinal remedy (1985) and the *Scientific research basis of Kyrgyz national medicine* (1985). Together, the two monographs contain 1 500 monographs, but they are not legally binding.

Manufacturing regulatory requirements include adherence to information contained in the pharmacopoeia and temporary instructions, such as some elements of GMP, which include instructions for the licensing and inspection of herbal-medicine manufacture, as well as requirements for documentation, product marketing authorization and design of labels for herbal medicines. While a control mechanism exists to assure compliance with these requirements, details were not provided. Safety requirements for herbal medicines are the same as for conventional pharmaceuticals, which include testing for toxic elements, radioactivity and heavy metals.

There are currently 95 herbal medicines registered in Kyrgyzstan; however, none are included on the national essential drug list. A post-marketing surveillance system has been established. In Kyrgyzstan, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines. Marketing research on annual sales of herbal medicines provide details of the value and volume of herbal medicines sold in Kyrgyzstan in 2000 and 2001. In 2000, 299 892 packs of herbal medicines were sold for a value of US\$ 39 495. In 2001, 247 538 packs were sold for a total value of US\$ 31 862.

Latvia

Information is not available on the status of national policy, laws and regulations, national programme, national office, or expert committee on TM/CAM in the Republic of Latvia. There are no national research institutes on TM, CAM or herbal medicines.

The national laws and regulations for herbal medicines in Latvia are partly the same as those for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines, dietary supplements and health foods. By law, medical, health and nutrient content claims may be made about herbal medicines.

In place of a national pharmacopoeia, the *European pharmacopoeia*, *British herbal pharmacopoeia*, *German pharmacopoeia* and *German homeopathic pharmacopoeia*. In place of national monographs, *Hagers Handbuch der pharmazeutischen Praxis* is used.

Manufacturing regulatory requirements include adherence to information in pharmacopoeias and monographs and the same rules of GMP that apply to conventional pharmaceuticals. Implementation of these requirements is ensured through state pharmacy inspections. Safety regulatory requirements include the same requirements as for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Implementation of these requirements is not ensured by any control mechanism.

In Latvia, over 100 herbal medicines are registered; however, none is included on a national essential drug list. The post-marketing surveillance system, which includes adverse-effect monitoring, was established in 2000. In Latvia, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Lithuania

The Republic of Lithuania does not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM, nor are there currently any plans to establish these.

Lithuania regulates herbal medicine through laws and regulations, either the same as, or partly the same as, those used for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines and dietary supplements. No information is available about the claims made for herbal medicines.

In place of a national pharmacopoeia, the *European pharmacopoeia* is used and is considered to be legally binding. In place of national monographs, the *WHO monographs* are used, and are considered to be legally binding. There are no plans to develop national versions.

Manufacturing regulatory requirements are limited to adherence to information in pharmacopoeias and monographs; compliance is ensured through the manufacturer's laboratories and the quality-control laboratory of the State Drug Control Agency. Safety regulatory requirements are limited to traditional use without demonstrated harmful effects, but no control mechanism exists for this requirement.

There is a registration system, but no data are available on the number of registered herbal medicines. No information is available about the inclusion of herbal medicines on an essential drug list. No post-marketing surveillance system yet exists, and none is planned. In Lithuania, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Netherlands

The Kingdom of the Netherlands does not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM, nor are there currently any plans to establish these.

In the Netherlands, herbal medicines are regulated under the same laws as conventional pharmaceuticals. Herbal medicines have the regulatory status of prescription or over-the-counter medicines. According to law, health and nutrient content claims may be made.

In place of a national pharmacopoeia, the *European pharmacopoeia* is used and is considered legally binding. No national monographs exist, nor are any others used in their place.

Regulatory requirements for herbal medicines are the same GMP rules used for conventional pharmaceuticals. Implementation of these requirements is ensured through inspection of nonregistered medicines and pharmaceutical inspections. Safety requirements are the same as for conventional pharmaceuticals; no control mechanism exists for these requirements.

In the Netherlands, there is no registration system for herbal medicines, nor are they included on a national essential drug list. There is no post-marketing surveillance system for unregistered herbal medicines, and none is being planned. Herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, *droggeries* and health shops.

Norway

The Kingdom of Norway issued a national policy on TM/CAM in 2002 that included a national programme. A national law or regulation on TM/CAM entered into force in January 2004. No TM/CAM national office exists, nor is the establishment of such an office being planned. There is also no expert committee for TM/CAM. At the University of Tromsø, the National Research Institute on Complementary and Alternative Medicine (NAFKAM) conducts research on TM/CAM and herbal medicines.

Regulation of herbal medicine was introduced as part of the Regulation on Medicinal Products of 22 December 1999 and is partly the same as for conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines and for self-medication only. Herbal medicines may be sold by law with medical claims, if they are registered. There is no national pharmacopoeia, nor is one being developed; the *European pharmacopoeia* is used and considered legally binding. Monographs contained in the *European pharmacopoeia* are also considered legally binding, since there is no national herbal monograph and one is not currently being developed.

Regulatory requirements for the manufacturing of herbal medicines involve adherence to information in pharmacopoeias and monographs and the same rules of GMP as for conventional pharmaceuticals. Inspections are performed in order to ensure that these requirements are implemented. In order to assess the safety of herbal medicines, there are special regulatory requirements, namely traditional use without demonstrated harmful effects. If herbal medicines meet these requirements, they are then approved by the health authorities. This serves as the control mechanism to ensure implementation of the safety requirements.

There are 28 registered herbal medicines in Norway, none of which are included on the national essential drug list. The documentation required for the quality of natural remedies is essentially the same as for other proprietary medicinal products, whereas the requirements for the documentation of safety and efficacy are much less comprehensive and based on bibliographical documentation on traditional uses in folk medicine. The post-marketing surveillance system for herbal medicines includes a system to monitor adverse effects of herbal medicines; however, there is no information about when it was established. Herbal medicines in Norway are sold in both pharmacies and health food stores and may also be sold in ordinary food stores.

Portugal

The Portuguese Republic does not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM, nor are there currently any plans to establish these.

Portugal has introduced regulation of herbal medicines in the same laws as those covering conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. Medical claims may be made about herbal medicines.

There is a national pharmacopoeia, *Farmacopeia portuguesa*; however, no national monographs exist, or are being planned. The same GMP rules used for conventional pharmaceuticals are used for herbal medicines; although a control mechanism exists for these requirements, no detailed information is available. Safety requirements for herbal medicines are also the same as for conventional medicines; a control mechanism exists, but again, no detailed information is available.

There is no registration system for herbal medicines, and none is included on a national essential drug list. The post-marketing surveillance system, which includes adverse-effect monitoring, was established in 1995. In Portugal, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Republic of Moldova

The Republic of Moldova does not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM; information is not available about whether there are currently any plans to establish these.

Herbal medicines are not regulated in the Republic of Moldova; they have the status of over-the-counter medicines. Medical claims may be made about herbal medicines. The *State pharmacopoeia of the USSR* is used and is considered legally binding while the Moldovan national pharmacopoeia is in preparation. There are also national monographs that are considered legally binding.

Regulatory requirements for the manufacture of herbal medicines are limited to adherence to the information in pharmacopoeias and monographs; implementation is ensured through analysis of samples by the State Pharmaceutical Inspectorate. Safety requirements are limited to traditional use without demonstrated harmful effects; implementation is ensured by laboratory testing requirements for certification by the State Pharmaceutical Inspectorate.

There are currently 58 herbal medicines registered in the Republic of Moldova; none is included on a national essential drug list. The post-marketing surveillance system, including adverse-effect monitoring, was established in 1999. In the Republic of Moldova, herbal medicines are sold in pharmacies as over-the-counter medicines.

Romania

Romania does not have a national policy, laws, regulations, a national programme, a national office or an expert committee on TM/CAM, nor are there currently any plans to establish these. A national institute on herbal medicines has been established.

Regulation of herbal medicines was introduced in 2002 in the same law governing the regulation of conventional pharmaceuticals. Herbal medicines are regulated as prescription medicines, over-the-counter medicines and dietary supplements. By law, medical and health claims may be made concerning herbal medicines.

The national pharmacopoeia, the *Romanian pharmacopoeia*, was published in 1993; it is considered to be legally binding. It also contains 85 monographs that are legally binding.

The regulatory requirements for herbal medicines are the same GMP rules as for conventional pharmaceuticals; implementation is ensured through pharmaceutical inspections in the production and distribution channels. Herbal medicines have the same safety requirements as conventional pharmaceuticals. Implementation of these safety requirements is ensured by means of assessment of the safety aspects included in the product dossier and by monitoring the safety of the product on the market through the pharmacovigilance network.

In Romania, 96 herbal medicines have been registered; none is included on the national essential drug list. The post-marketing surveillance system, which includes adverse-effect monitoring, was established in 1976. Herbal medicines are sold in Romania in pharmacies as prescription and over-the-counter medicines.

Russian Federation

In the Russian Federation, the national policy on TM/CAM was issued in 1991 and national laws and regulations in 1993. Development of the national programme began in 2001 and is currently scheduled for completion in 2005. A TM/CAM national office was established in 1991, but there is no information about the ministry which administers it. The expert committee was established in 2001. A national research institute on TM was established in 1991.

The law or regulation on herbal medicines is the same as for conventional pharmaceuticals, but the year of issue is unknown. The regulatory status used for herbal medicines is prescription medicines, over-the-counter medicines or dietary supplements. Herbal medicines are legally sold with medical, nutrient content, and structure/function claims in the Russian Federation.

Eleven editions of the *State pharmacopoeia of the USSR* have been published, the most recent dating from 1990. The information in the pharmacopoeia is legally binding. The previous edition that was published in 1968 is also used to supplement the current edition. The title of the national monograph is translated as *Pharmacopoeia monograph, technical requirements*, and is considered legally binding.

Manufacturing regulatory requirements include adherence to information in pharmacopoeias and monographs and the same GMP rules as those required for conventional pharmaceuticals. The implementation of manufacturing requirements is ensured through licensing of the manufacturing process, compliance with established regulations and certification of products. The requirements for the assessment of safety of herbal medicines are same as for conventional pharmaceuticals, with additional requirements, namely radioactivity control.

There are approximately 260 herbal medicines registered in the Russian Federation and they are almost all included in the essential drug list, which is issued annually. There is a post-marketing surveillance system and a national system to monitor adverse effects of herbal medicines. Herbal medicines are sold in pharmacies as over-the-counter drugs, in special outlets as biologically active supplements or without restriction.

Serbia and Montenegro

In Serbia and Montenegro, no national policies, national programmes, national office or expert committee on TM/CAM have been established, nor are there currently any plans to establish them. Laws and regulations on TM/CAM are in development. A national institute on herbal medicines has been set up.

Regulation of herbal medicines was established in 1993 in a law partly the same as that used to regulate conventional pharmaceuticals. Herbal medicines are regulated as dietary supplements and as supportive medicines, a category similar to over-the-counter medicines. Herbal medicines may be sold with nutrient content and structure/function claims according to law.

The *European pharmacopoeia* is used as a national pharmacopoeia and is considered to be legally binding. Regulatory requirements for the manufacture of herbal medicines include adherence to information in pharmacopoeias and monographs and the same rules of GMP that apply to conventional pharmaceuticals. Implementation is ensured by inspection. Safety requirements for herbal medicines are the same as for conventional pharmaceuticals and involve laboratory testing; no details of the control mechanism used are available.

There is a registration system for herbal medicines in Serbia and Montenegro, but no information about the number of registered medicines is available. No herbal medicines are included on a national essential drug list. A post-marketing surveillance system is being planned. In Serbia and Montenegro, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets.

Slovakia

In the Slovak Republic, there is no national policy on TM/CAM, and there are currently no plans to establish one. The national medicines law that applies to TM/CAM was issued in 1998. No national programme has been issued and no national office, expert committee or national research institutes on TM/CAM have been established.

The regulation of herbal medicines was introduced in 1997, with a separate law or regulation for herbal medicines. Herbal medicines are regulated as prescription medicines, over-the-counter medicines, self-medication, dietary supplements and as a separate regulatory category. By law, medical, health and nutrient content claims may be made about herbal medicines.

The national pharmacopoeia, *Pharmacopoea slovacica*, was published in 1997; it is legally binding. The *Codex pharmaceuticus slovacus*, published in 1997, contains 110 national monographs; these are legally binding.

Manufacturing regulatory requirements include adherence to information in pharmacopoeias and monographs and the same GMP rules as for conventional pharmaceuticals. If the product is registered, compliance with these requirements is part of the procedure including national inspection and GMP requirements. Safety requirements include those used for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects, reference to documented scientific research on similar products and laboratory testing for heavy metals, radioactivity and microbiological contamination. The implementation of these safety requirements is ensured through manufacturing requirements, standards and in-process controls.

There are nine national registered herbal medicines in Slovakia; however, none is included on a national essential drug list. The post-marketing surveillance system includes monitoring of adverse effects of herbal medicines. In Slovakia, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines and in special outlets.

Slovenia

The Republic of Slovenia does not have a national policy, laws, regulations, a national programme or a national office; however, all are currently in the process of being established. There is no expert committee on TM/CAM. No national research institutes on TM/CAM or herbal medicine have been established.

The regulation of herbal medicines is part of the Medicinal Products and Medical Devices Act of 1999, which regulates conventional pharmaceuticals. Before a herbal medicine is placed on the market, there should be a marketing authorization issued by the Agency for Medicinal Products and Medical Devices. Herbal products are regulated as over-the-counter medicines, foods and cosmetics. The claims allowed by law vary according to the regulatory status under which a product is classified. By law, herbal medicinal products may make medical claims; however, other herbal products

such as cosmetics and foods may only make cosmetic and nutritional claims, respectively.

The official pharmacopoeia in Slovenia is the *European pharmacopoeia*. The *Formularium slovenicum* is the national addendum to the *European pharmacopoeia* and contains national monographs that are not included in the *European pharmacopoeia*. Both are considered legally binding.

Regulatory requirements for the manufacture of herbal medicines include adherence to the *European pharmacopoeia* and *Formularium slovenicum* and the same GMP rules as for conventional pharmaceuticals. Implementation of these requirements is ensured by means of GMP inspections. Safety requirements for herbal medicines include those used for conventional pharmaceuticals. Implementation of these requirements is ensured through toxicopharmacological documentation that is required as part of the application for marketing authorization.

There are 69 herbal medicines registered in Slovenia. None are included on the essential drug list. The post-marketing surveillance system, which includes adverse-effect monitoring, was established in 2000. In Slovenia, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets; for those products classified as foods and cosmetics, there are no restrictions. In 2000, the value of herbal medicines sold over-the-counter in Slovenia was US\$ 2 301 000; in 2001, the value of these sales was US\$ 2 158 000. First-quarter sales in 2002 were US\$ 594 000. These values are estimated to be 20% below the actual sales of herbal medicinal products.

Spain

The Kingdom of Spain does not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM, nor are there currently any plans to establish these.

The Spanish Medicinal Products Act No. 25 of 1990 regulates both herbal medicines and conventional pharmaceuticals. Herbal products are regulated as prescription and over-the-counter medicines, self-medication and health foods. By law, medical and health claims may be made, but only for products authorized as medicines.

The *Royal Spanish pharmacopoeia* was published in 2003, and is considered legally binding. National monographs also exist, and are considered legally binding.

Regulatory requirements for the manufacture of herbal medicines include adherence to information in pharmacopoeias and monographs, the same GMP rules as for conventional pharmaceuticals and special GMP rules. Implementation of these requirements is ensured through quality control of manufacturers and systematic campaigns of market control. Safety requirements include those used for conventional pharmaceuticals as well as special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. If the product has a history of traditional safe use, the requirements are less strict. Compliance with requirements is ensured through the national pharmacovigilance system.

In Spain, there are 2 277 registered herbal medicines; however, none is included in an essential drug list. The same post-marketing surveillance system used for conventional pharmaceuticals, including adverse-effect monitoring, is used for herbal medicines; it was established in 1985. In Spain, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Sweden

The Kingdom of Sweden does not have a national policy, laws, regulations or a national programme on TM/CAM and there are no plans to establish them. There is also currently no national office, expert committee or national research institute for TM/CAM.

Regulation of herbal medicine was first introduced in 1978. In 1993, a new act was put into force in Sweden. As part of this regulation, the product group "natural remedy" was defined. It includes herbal medicinal products and medicinal products where the active constituent is a bacterial culture, mineral, salt or salt solution. Furthermore, under the act, the Medical Products Agency should assess the chemical-pharmaceutical, safety and efficacy documentation and decide to approve or reject the product. The requirements for the chemical-pharmaceutical documentation are partly the same as for conventional medicinal products, with due consideration of the special characteristics of herbal material. Concerning safety and efficacy, applications including bibliographical documentation are more common with natural remedies than conventional medicinal products. Natural remedies are regulated as over-the-counter medicines for self-medication, but only for certain approved medical indications. Herbal medicines may be sold, by law, with medical claims for the approved indications only. With the new directive on traditional herbal medicine products, 2004/24/EC, the legislation in Sweden and the rest of the European Union will be revised during 2005.

A national pharmacopoeia exists, but monographs contained in the *European pharmacopoeia* are legally binding and take precedence over national monographs. If there is no monograph in the *European pharmacopoeia*, adherence to national pharmacopoeias is accepted.

Regulatory requirements for the manufacture of herbal medicines involve adherence to information in the *European pharmacopoeia*, where applicable, and to the same GMP rules as those used for conventional pharmaceuticals. Implementation of these requirements is ensured through inspection of the manufacturing site by the competent medical authority. Safety requirements pertain to the active constituent or the finished product, and include special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research. Implementation of these requirements is ensured as part of the pharmacovigilance system for conventional medicines. In this regard, the number of defined daily dosages of the product sold is taken into account.

There are 103 approved natural remedies in Sweden; none is included on a national essential drug list. The post-marketing surveillance system, which includes adverse-effect monitoring, was first applied to natural remedies in 1980.

In Sweden, natural remedies may be sold by anyone with a wholesale trade certificate, i.e. they may be sold not only in pharmacies but also in supermarkets, by mail order, etc. In 1999, annual sales of natural remedies were 980 million Swedish krona (US\$ 127 million), in 2000 and 2001 1.1 billion krona (US\$ 143 million) and in 2002 and 2003 close to 1 billion krona (US\$130 million).

Switzerland

There is no official national policy on TM/CAM in the Swiss Federation. A new law on therapeutic products, specifically mentioning regulations for conventional medicine and TM/CAM, was adopted in December 2000. No national programme has been issued, nor is there information about any such programme in preparation. The Swiss

Agency for Therapeutic Products (Swissmedic) serves as the national office for TM/CAM. It is administered by the Federal Department of Home Affairs; it was established in 2002. No national research institutes on TM, CAM or herbal medicines have been established.

Herbal medicines had already been authorized as medicinal products before the Federal Law on Medicinal Products and Medical Devices, which also regulates conventional pharmaceuticals and technologies, was adopted in 2000. In some cases, simplified procedures for marketing authorizations for TM/CAM apply; but only when the procedures are compatible with quality, safety and efficacy requirements. New regulations for some TM/CAM (for example homeopathic, anthroposophic and traditional Chinese medicines) are currently in elaboration. Therefore expert committees, including medical doctors, therapists, quality experts and members of CAM industry associations, were set up in 2000 to advise in these matters. Herbal medicines are regulated as prescription and over-the-counter medicines. Medical, health, nutrient content and structure/function claims may be made by law.

The *Swiss pharmacopoeia* and the *European pharmacopoeia* are used. The *Swiss pharmacopoeia* also contains monographs on herbal medicines, which are legally binding.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and the same GMP rules used for conventional pharmaceuticals. Implementation of these requirements is ensured by licensing of manufacturing firms for production and wholesale trade. Periodic inspections are also made at these sites. Safety requirements, which are part of the licensing system, include those used for conventional pharmaceuticals and special requirements of traditional use without demonstrated harmful effects and with reference to documented scientific research on comparable products. The licensing system is overseen by Swissmedic.

There are 1 000 registered herbal medicines in Switzerland; there is no essential drug list. The post-marketing surveillance system includes adverse-effect monitoring and was established in 1990. In Switzerland, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, by licensed practitioners and *drogueries*. Data on annual national sales was provided for 1998-2000. In 1998, sales were 227 million Swiss francs (US\$ 171 million), in 1999, they were 228 million francs (US\$ 172 million) and in 2000, they were 227 million francs (US\$ 171 million).

Tajikistan

In the Republic of Tajikistan, a national policy on TM/CAM is in development. Laws and regulations were issued in 1997. A national programme on TM/CAM is being developed. In the Ministry of Health, the Centre for Oriental Medicine was established in 1995. The Attestation Commission of the Ministry of Health serves as the expert committee on TM/CAM. No national research institutes on TM, CAM or herbal medicines have been founded.

Regulation of herbal medicines was introduced in 2001 in Tajikistan; it comprises the same laws and regulations as for conventional pharmaceuticals. Herbal medicines have no regulatory status. Structure/function claims may be made about herbal medicines.

No national pharmacopoeia is being developed; in its place, the *State pharmacopoeia of the USSR* is used. The information contained therein is legally binding. Several national monographs exist, although they are not legally binding.

Manufacturing regulatory requirements in Tajikistan are limited to adherence to information in pharmacopoeias and monographs; no specific details of the structure of the control mechanism are available. Safety requirements for herbal medicines are the same as for conventional pharmaceuticals; again, no specific details are available about the specifics of the control mechanism.

There are 12 registered herbal medicines; two herbal medicines are included on the national essential drug list issued in 2003. A post-marketing surveillance system is being developed. In Tajikistan, herbal medicines are sold in pharmacies as over-the-counter medicines.

The former Yugoslav Republic of Macedonia

In the former Yugoslav Republic of Macedonia, no national policy on TM/CAM has been issued or is in preparation. Laws and regulations on TM/CAM were issued in 1998. No national programme has been issued, nor is one currently being planned. The national office is the Pharmaceutical Agency and is administered by the Ministry of Health; it was founded in 1998. The expert committee on TM/CAM was established in 1992. The Institute for Pharmacology serves as the national research institute for TM/CAM and herbal medicines; it was founded in 1977.

The law establishing regulation of herbal medicines and conventional pharmaceuticals in The former Yugoslav Republic of Macedonia was issued in 1998. Herbal medicines are regulated as over-the-counter medicines. By law, medical claims may be made about herbal medicines.

In place of a national pharmacopoeia and national monographs, the *European pharmacopoeia* is used and is considered legally binding. Manufacturing requirements for herbal medicines are the same GMP rules required for conventional pharmaceuticals; implementation is ensured by regular routine inspections. Safety requirements for herbal medicines include reference to documented scientific research on similar products. Implementation of these requirements is ensured by renewal of registration status every five years.

There are 300 registered herbal medicines; none is included on a national essential drug list. The post-marketing surveillance system, which also includes adverse-effect monitoring, was established in 1992. Herbal medicines are sold in pharmacies as over-the-counter medicines.

Turkey

In the Republic of Turkey, a national policy on TM/CAM is being developed. Laws and regulations on TM/CAM were issued in 1985 in the "Permanent Notice concerning Shops, Spice Shops and Similar Stores". The national programme on TM/CAM is being planned, as is the national office. The expert committee was established in 1985. There are no national research institutes on TM/CAM or herbal medicines.

National regulation of herbal medicines in Turkey was introduced in 1986 and was updated in 1999. The law or regulation for herbal medicine is partly the same as for conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines; by law, health claims may be made about them.

The *Turkish pharmacopoeia* was published in 1974 in its second edition; however, the *European pharmacopoeia* is legally binding. The *Turkish pharmacopoeia* also contains legally binding monographs.

The regulatory requirements for manufacturing are special GMP rules; the specific details of the control mechanism for these requirements are not available. Safety regulatory requirements for herbal medicines are the same as those for conventional pharmaceuticals. Again, details of the control mechanism for these requirements are not available.

There are 41 registered herbal medicines in Turkey; none is included on a national essential drug list. The post-marketing surveillance system was established in 1985 and includes adverse-effect monitoring of herbal medicines. Herbal medicines in Turkey are sold in pharmacies as over-the-counter medicines.

Ukraine

The national policy on TM/CAM in Ukraine was established in 1992; laws and regulations were issued in 1998. A national programme is currently in development. The national office, the Committee on National and Nontraditional Medicine, is administered by the Ministry of Health; it was established in 1998. The expert committee was established in 2001. There are national research institutes focused on traditional medicine and herbal medicine; they were established in 1992.

The regulation of herbal medicines in Ukraine was introduced in 1992; these laws and regulations are partly the same as those governing conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. According to the law, medical, health and structure/function claims may be made.

In lieu of a national pharmacopoeia, which is in development, the *State pharmacopoeia of the USSR* is used and is considered legally binding. National monographs are currently in development.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and the same GMP rules required for conventional pharmaceuticals. No specific information is available about the control mechanisms used. Safety requirements are the same as for conventional pharmaceuticals; again, although a control mechanism is reported to exist, no details are available.

There is a registration system for herbal medicines; however, no information is available on the number of registered medicines. Herbal medicines are included on the essential drug list, but the number is not known. A post-marketing surveillance system, which includes adverse-effect monitoring, was established in 1992. In Ukraine, herbal medicines are sold in pharmacies as over-the-counter and prescription medicines.

United Kingdom of Great Britain and Northern Ireland

The Osteopaths Act 1993 and Chiropractors Act 1994 provided a legal framework for self-regulation of the practice of osteopathy and chiropractic. Although the United Kingdom has no single national office, the Medicines and Healthcare Products Regulatory Agency and the Department of Health in England have several teams to develop policy on the safe use and practice of CAM, working with representatives of the Government offices of Scotland, Wales and Northern Ireland. As is often the case in the United Kingdom, the voluntary sector plays an important facilitating role, and for CAM, this is done by the Prince of Wales's Foundation for Integrated Health. The Department of Health in England has a programme to develop research expertise in CAM and to strengthen the evidence base. It also commissions periodic surveys of the use of CAM in the United Kingdom.

Herbal medicines are regulated under the Medicines Act 1968 (2001/83/EC also applies). This currently provides two regulatory routes for herbal medicines to reach the United Kingdom market. The first is the category of "licensed herbal medicines": to receive a marketing authorization, herbal medicines are required to meet safety, quality and efficacy criteria in a similar manner to any other licensed medicines. Medicinal claims are permitted. The second category is "herbal remedies exempt from licensing requirements": the exemption applies where herbal remedies meet the conditions set out in Section 12 of the Medicines Act 1968. Medicinal claims are not permitted.

Regulatory requirements for licensed herbal medicines include the same GMP rules required for conventional pharmaceuticals. This is enforced through the licensing of herbal medicines and manufacturers and inspections by the Medicines and Healthcare Regulatory Agency. Safety requirements for licensed herbal medicines are the same as for conventional pharmaceuticals and are enforced by the same control mechanisms mentioned above. Unlicensed herbal remedies do not currently have to meet any specific requirements of safety or quality. In accordance with the new European Union directive on traditional herbal medicinal products (2004/24/EC), the legislation will be revised by the end of 2004. This will coincide with the introduction of a simplified registration scheme, under which traditional herbal medicines will have to meet the same specific standards of safety and quality as licensed products. The normal requirement for medicines to demonstrate efficacy will be replaced by evidence of traditional use.

The latest edition of the *British pharmacopoeia* was published in 2002; it is legally binding. The pharmacopoeia contains 124 national monographs.

There are between 300 and 500 licensed herbal medicines in the United Kingdom; however none are included on a national essential drug list. The post-marketing surveillance system, which includes adverse-effect monitoring, was established in 1964. It was expanded to cover unlicensed herbal medicines in 1996.

In the United Kingdom, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, by practitioners (who are not currently licensed) and without restriction. Although the unregulated nature of the herbal medicines market makes estimation of sales figures difficult, an Office of Fair Trading publication indicates the 2000 sales figure to be about 72.7 million pounds sterling (US\$ 123 million).

Uzbekistan

In the Republic of Uzbekistan, a national policy on TM/CAM is being developed. No national laws, regulations or programme have been issued, nor are they currently being planned. A national office is being planned; however, no expert committee or national research institutes have yet been established.

The regulation of herbal medicines began in 1997; it is governed by the same laws and regulations as for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. By law, medical, health, nutrient content and structure/function claims may be made.

A national pharmacopoeia and national monographs are in development; however, no information is available about any others currently being used.

Regulatory requirements for the manufacture of herbal medicine are limited to adherence to information in pharmacopoeias and monographs. No specific information is available about the control mechanism in use to enforce these requirements. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals; pharmaceutical inspections of laboratories for quality control are used to ensure the implementation of these requirements.

Currently, there are 45 registered herbal medicines in Uzbekistan; 20 herbal medicines are included on the national essential drug list. No post-marketing surveillance system has yet been established. Herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, by licensed practitioners and without restriction.

5.5 WHO South-East Asia Region

Countries that responded to the survey: South-East Asia Region



All 10 countries of the WHO South-East Asia Region responded to the Global Survey. Table 8 summarizes the development of national policy and regulation of TM/CAM and herbal medicines in the South-East Asia Region, with comparative figures for all of the responding countries and the global percentages. The figures and percentages represent those countries responding positively to the questions. The survey response figures represent all of the responding countries either in the region or globally as indicated.

Table 8. WHO South-East Asia Region: positive responses

| | Member States in the South- East Region responding positively with the following | Regional survey % that responded positively (10) | Global survey % that responded positively (141) |
|---|--|--|---|
| National policy on TM/CAM | 8 | 80% | 32% |
| Law or regulation on TM/CAM | 7 | 70% | 38% |
| National programme on TM/CAM | 9 | 90% | 28% |
| National office for TM/CAM | 10 | 100% | 53% |
| Expert committee on TM/CAM | 9 | 90% | 43% |
| National research institute on TM, CAM or herbal medicines | 7 | 70% | 41% |
| Law or regulation on herbal medicines | 7 | 70% | 65% |
| Registration of herbal medicines | 9 | 90% | 61% |

There is a strong commitment among the countries of the region to developing research and national policies on TM/CAM. With over 70% of these countries having every level of policy and regulation as well as research bodies and institutes, this region clearly leads the world in TM/CAM and herbal-medicine research and policy development.

Bangladesh

In the People's Republic of Bangladesh, a national policy on TM/CAM was issued in 1995. National laws and regulations are currently in development. The national programme was issued in 1998. The national office was established in 1990 as part of the Ministry of Health. An expert committee was established in 2003. No national research institutes on TM, CAM or herbal medicines have yet been established.

Regulation of herbal medicines was introduced in 1992; the same laws and regulations apply to herbal medicines and conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. They may be sold with medical, nutrient content and structure/function claims.

The *Bangladesh national formularies on unani and ayurvedic medicine* are legally binding. No national herbal monographs are in development.

Regulatory requirements for herbal medicine include adherence to information contained in pharmacopoeias and monographs, GMP rules for conventional pharmaceuticals and special GMP rules. The Drug Administration is in charge of ensuring the implementation of these requirements; however, no detailed information about the specific mechanisms is available. Safety requirements are the same as for conventional medicines, with the addition of traditional use without demonstrated harmful effects. No specific information about the type of control mechanism for these requirements is available.

There is a registration system for herbal medicines; however, the number of registered products is not available. No post-marketing surveillance system exists or is currently being planned. Herbal medicines are sold in pharmacies as prescription and over-the-counter medicines and by licensed practitioners.

Bhutan

The national policy on TM/CAM of the Kingdom of Bhutan is currently being developed, as are laws, regulations and a national programme. The Institute of Traditional Medicine Sciences is part of the Ministry of Health; it was established in 1967. The Pharmaceutical and Research Unit of that Institute has served as the expert committee and the national research institute on traditional medicine since 1998.

Bhutan does not currently have laws or regulations on herbal medicines. Herbal medicines are classified as prescription medicines. Medical, health and structure function claims are made about herbal medicines. No national pharmacopoeia exists, nor is one currently being developed. National herbal monographs are currently in development.

The regulations regarding the manufacture of herbal medicines are the same GMP rules that apply to conventional pharmaceuticals; however, no control mechanism exists for these requirements. There are no safety assessment requirements. There is also no registration system for herbal medicines. As of 1998, there were 103 herbal medicines listed on the national essential drug list. A national post-marketing surveillance system is currently being developed. There are no restrictions on the sale of herbal medicines.

Annual sales data for Bhutan was provided for the period 1999-2001. In 1999, national sales were estimated at 2 579 098 ngultrum (US\$ 57 415). In 2000, the figures rose to 3 185 848 ngultrum (US\$ 70 923) and for 2001, sales reached 4 064 439 ngultrum (US\$ 90 482).

Democratic People's Republic of Korea

The national policy on TM/CAM in the Democratic People's Republic of Korea was issued in 1980, as were laws and regulations. No information is available about the existence of a national programme. The Department of Traditional Koryo Medicine of the Ministry of Public Health was established in 1956. An expert committee on TM/CAM was created in 1961, as were national research institutes on traditional and herbal medicines.

The Law on Medical Product Management was issued in 1999, covering both herbal medicines and conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. By law, medical claims may be made for herbal medicines.

The most recent edition of the *Pharmacopoeia of the Democratic People's Republic of Korea* was published in 1996; it is legally binding. The *Korean herbal medicine monographs* are used, although they are not legally binding. They were published in 1986.

Manufacturing requirements for herbal medicines include adherence to information in pharmacopoeias and monographs and the same GMP rules as those required for conventional pharmaceuticals. A licensing system administered by the drug control group serves as the control mechanism for these requirements. Manufacturers require one of these licences in order to operate. Safety requirements for herbal medicines are identical to those for conventional pharmaceuticals. No detailed information is available about the control mechanism used to ensure that these requirements are met.

There are 1 195 registered herbal medicines in the Democratic People's Republic of Korea. No information is available about the inclusion of herbal medicines on a national essential drug list. The post-marketing surveillance system, including adverse reaction monitoring for herbal medicines, was set up in 1947. Herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

India

In the Republic of India, the national policy on TM/CAM was introduced in 1940. National laws and regulations were also issued in 1940, and updated in 1964, 1970 and 1982. The national programme was issued in 1964. The national office, the Department of Medicine and Homeopathy, was established in 1995 as part of the Ministry of Health and Family Welfare. There are a number of expert committees for different forms of TM/CAM; the earliest was established in 1962. There are also a number of national research institutes; the first was the Central Council of Indian Medicine, established in 1970.

National regulation of herbal medicine began in 1940 with the publication of the Drugs and Cosmetics Act; the laws and regulations on herbal medicines are partly the same as those for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines and dietary supplements. Herbal medicines may be sold with medical, health and nutrient content claims.

India has two multivolume national pharmacopoeias, the *Ayurvedic pharmacopoeia of India* and the *Unani pharmacopoeia of India*. Both are considered to be legally binding. Regarding national monographs, several sources are used, including a national database on medical plants used in ayurvedic medicine and monographs contained in the national pharmacopoeias.

Manufacturing regulatory requirements include adherence to information contained in pharmacopoeias and monographs and the same GMP rules required for conventional

pharmaceuticals. Drug licensing, inspection and testing are employed to ensure compliance with these requirements. Safety requirements include those required for conventional pharmaceuticals, as well as special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. No control mechanism is used for these requirements, as the long-standing use of herbal medicines in the ayurveda, unani and siddha systems demonstrates their safety for human use.

There are 4 246 registered herbal medicines. Essential drug lists exist separately for the three systems of traditional medicine in India; the ayurveda list has 315 herbal medicines on its essential drug list, the unani list has 244 herbal medicines and the siddha list has 98. These lists were issued in 2001, 2000 and 2001, respectively. There are currently plans to establish a post-marketing surveillance system. In India, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, in special outlets, by licensed practitioners and without restriction. Annual herb sales figures, based on sales of 162 medicinal plants between 1999 and 2000, were estimated at 6 705 million Indian rupees (US\$ 149 million).

Indonesia

In the Republic of Indonesia, the “National Policy on Development of Traditional Medicine” was issued in 2000. Laws and regulations on TM/CAM were first issued in 1993. The national programme on TM/CAM was established in 2003. The national office on TM/CAM is administered by the National Agency of Drug and Food Control; it was established in 2001. The expert committee was established in 1977. National research institutes on traditional medicine and herbal medicine were established in 1976.

Through a separate law for herbal medicines, regulation was established in 1993, and updated in 1994 and 1995. Herbal medicines are regulated as over-the-counter medicines, as a separate regulatory category and as traditional medicines. By law, medical, health and structure/function claims may be made.

Three editions of the *Farmakope indonesia* have been published, the most recent dating from 1979. The national pharmacopoeia is legally binding. The *Materia medica indonesia* contains 246 of the national monographs, which are legally binding. It was published between 1977 and 1995.

Special GMP rules are required for the manufacture of herbal medicines; the implementation of these requirements is ensured through inspection and certification. Safety requirements include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products, toxicity data and laboratory testing. Compliance with these requirements is ensured through post-marketing surveillance, inspection, sampling, laboratory testing, investigation, monitoring of adverse effects and law enforcement.

There are 8 632 registered herbal medicines in Indonesia. No herbal medicines are included on a national essential drug list. The post-marketing surveillance system was established in 2002, including adverse-effect monitoring. Herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed practitioners and without restriction. Herbal medicines annual sales data were provided for 2000-02. Sales in 2000 totalled US\$ 144 million, in 2001 sales reached US\$ 167 million and in 2002, sales reached US\$ 189 million.

Maldives

In the Republic of Maldives, the national policy was issued in 1999. National laws and regulations are being developed. The national programme was issued in 1980. In 1932, the national office for TM/CAM was established within the Ministry of Health. The expert committee was formed in 1980. No national research institutes on TM, CAM or herbal medicines have been established.

Maldives does not regulate herbal medicines; herbal medicines are classified as over-the-counter medicines and for self-medication only. No claims may be made by law. No national pharmacopoeia or monographs exist, and none are being developed.

There are no regulatory requirements for manufacturing. Safety requirements are limited to references to documented scientific research on similar products. Ten herbal medicines are registered; none is included on a national drug list. A national post-marketing surveillance system is being planned. In Maldives, herbal medicines are sold in pharmacies as over-the-counter medicines.

Myanmar

In the Union of Myanmar, the national policy on TM/CAM was issued in 1993. The Myanmar Indigenous Medicine Act was adopted in 1953, and updated and renamed the Traditional Medicine Council Law, which serves to ensure that traditional medicine practitioners abide by established rules of conduct and discipline. The Department of Traditional Medicine was established in 1989 under the Ministry of Health and expanded, together with the research division, in 1997. It serves as both the national office and the expert committee.

In Myanmar, the Traditional Medicine Drug Law was enacted in 1996 to ensure the quality, safety and efficacy of traditional medicines. It is a separate law, solely for the regulation of traditional and herbal medicines. The regulatory statuses used for herbal medicine are over-the-counter medicines and herbal medicine as a separate category. By law, herbal medicines may be sold with medical and health claims. Development of a national pharmacopoeia is in progress. The *Monograph of Myanmar medicinal plants* was published in 2000.

Regulatory requirements for herbal medicines are limited to special GMP rules; implementation of these requirements is ensured by inspection and laboratory analysis of quality control. Safety requirements include traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. These requirements are enforced through inspection, laboratory analysis for safety and market surveys.

There are 3 678 registered traditional medicines in Myanmar. The development of national essential traditional medicines drug lists is in progress. The national post-marketing surveillance system does not include adverse-effect monitoring, but such a system is being planned. Herbal medicines are sold in pharmacies as over-the-counter medicines and without restriction.

Nepal

In the Kingdom of Nepal, the national policy on TM/CAM, the “National Ayurveda Health Policy”, was issued in 1996. Laws and regulations were issued in 1978. The national programme, the Second Long-Term Health Plan, 1997-2017, was issued in 1997. The Department of Ayurveda was established within the Ministry of Health in

1981. The expert committee was formed in 2001. No national research institutes on TM, CAM or herbal medicines have been established.

The Drug Act of 1978 established regulations on both herbal medicines and conventional medicines. Further laws and regulations were issued in 1981, 1983 and 1986. Herbal medicines are regulated as prescription and over-the-counter medicines. Medical, health, nutrient content and structure/function claims may be made by law.

No national pharmacopoeias or national monographs yet exist, but they are in development. A number of other texts are used while the national pharmacopoeia and monographs are being prepared, and they are considered legally binding.

Regulatory requirements for herbal medicines include adherence to information in pharmacopoeias and monographs and the same GMP rules as for conventional pharmaceuticals. However, there are no manufacturing requirements for domestic manufacture. The details of the control mechanisms used to ensure compliance are not available. Safety requirements include the same requirements as for conventional pharmaceuticals and the special requirements of traditional use without demonstrated harmful effects, reference to documented scientific research on similar products and reference to the traditional literature. Implementation of these requirements is enforced in the same way as with conventional pharmaceuticals, with special emphasis on evidence from the ancient literature.

There is a registration system in Nepal; however, the number of registered herbal medicines is not available. There is an essential drug list for ayurvedic medicine; however, the number of listed items is not available. A national post-marketing surveillance system is being planned. In Nepal, herbal medicines are sold in pharmacies as over-the-counter and prescription medicines, in special outlets, by licensed practitioners, by street hawkers and without restriction.

Sri Lanka

In the Democratic Socialist Republic of Sri Lanka, the national policy on TM/CAM is currently in development. Laws and regulations on TM/CAM were issued in 1961, and the national programme in 1982. The Department of Ayurveda in the Ministry of Health was established in 1961. There is a national expert committee, and a national research institute on traditional medicine, complementary medicine and herbal medicines was established in 1962.

No national laws or regulations on herbal medicines have been issued. Herbal medicines do not have any regulatory status; they are sold with medical, health, nutrient content and structure/function claims.

The national pharmacopoeia, the *Ayurveda pharmacopoeia*, was published in 1979. The *Compendium of medicinal plants* contains 100 national monographs; it was published in 2002. The information contained therein is considered to be legally binding.

Regulatory requirements for manufacturing include adherence to information in the pharmacopoeia and monographs and the same GMP rules that apply to conventional pharmaceuticals. No control mechanism exists for these requirements. There are no safety requirements.

There is no national registration system, nor are herbal medicines included on a national essential drug list. A post-marketing surveillance system is being planned. In Sri Lanka, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Thailand

The national policy and programme on traditional medicine of the Kingdom of Thailand was issued in 1993, when the Institute of Thai Traditional Medicine was officially established under the Department of Medical Services. In 2002, the institute was placed under the newly established Department for Development of Thai Traditional and Alternative Medicine, Ministry of Public Health. Meanwhile, the national policy on CAM was issued in 2002, when the Division of Complementary and Alternative Medicine was established under the Department for Development of Thai Traditional and Alternative Medicine. Medicinal Plant Research Institute, The Department of Medical Sciences is one of the national research institutes conducting complete-cycled research on medicinal plants to develop into single herbal medicines and setting up standard specifications of medicinal plant materials. Meanwhile, the Institute of Thai Traditional Medicine is responsible for research on the body of knowledge of Thai traditional medicine and evaluation of the therapeutic efficacy of certain practices and recipes.

National laws and regulations on traditional medicines were issued in 1967 under the Drug Act B.E. 2510, which is divided into two parts covering modern and traditional medicines, and was later amended four times in 1975, 1979, 1984 and 1987. There are national expert committees on traditional medicine that oversee the registration of different types of traditional medicines. Certain aspects of the law and regulation of herbal medicines are similar to those for conventional medicines, i.e. the licensing of manufacturers, vendors and importers of TM. Registered traditional medicines can be divided into prescription medicines or over-the-counter medicines (household traditional medicines). Medical, health and structure/function claims may be made about herbal medicines.

As of 2003, the *Thai herbal pharmacopoeia*, published by the Department of Medical Sciences, comprises two volumes containing 21 monographs; however, the information is not considered legally binding. There are five other traditional formularies of herbal medicines that the Food and Drug Administration of Thailand uses as standard references for herbal medicine registration. The information in these formularies is considered legally binding.

Manufacturing regulatory requirements include adherence to information in pharmacopoeias and monographs, special GMP rules (only on a voluntary basis) and other Food and Drug Administration regulations. Control mechanisms for these requirements include pre-marketing control using the Food and Drug Administration's licensing and registration process, and post-marketing control by quality-control analysis of randomly sampled herbal medicines from the market. Safety requirements include traditional use without demonstrated harmful effects, references to documented scientific research on similar products, and toxicity studies. Control mechanisms for these safety requirements are pre-marketing control through the licensing and registration process and post-marketing control by means of adverse reaction reports.

There are over 2 000 herbal medicines registered in Thailand; a total of 16 herbal preparations (three traditional recipes and 13 preparations from five single herbs) are included in the national list of essential drugs, A.D. 1999. A post-marketing surveillance system with adverse-reaction monitoring was established in 2001. General herbal medicines are sold in pharmacies as over-the-counter drugs, or licensed practitioners may make their own herbal preparations and sell them to patients. For registered household herbal medicines, there are no restrictions on sales.

Sales figures for imported and locally produced herbal medicines were provided by Thailand for the period 1997-99. In 1997, herbal imports totalled 177 million baht (US\$ 4.46 million); locally made product sales were 252 million baht (US\$ 6.35 million), making a total of 429 million baht (US\$ 10.81 million). In 1998, imports fell to 100 million baht (US\$ 2.52 million), and sales of locally made products rose to 486 million baht (US\$ 12.2 million), making a total of 586 million baht (US\$ 14.8 million). In 1999, import sales rose to 114 million baht (US\$ 2.87 million) and sales of locally made products reached 550 million baht (US\$ 13.9 million), making a total of 664 million baht (US\$ 16.7 million). The total figures were only 1.8%, 2.0% and 1.2%, respectively, of the annual sales of modern medicines in 1997-99.

5.6 WHO Western Pacific Region

Countries that responded to the survey: Western Pacific Region



Twenty-one of the 27 countries of the WHO Western Pacific Region responded to the Global Survey. Table 9 summarizes the development of national policy and regulation of TM/CAM and herbal medicines in the Western Pacific Region, with comparative figures for all the responding countries and the global percentages. The figures and percentages represent those countries responding positively to the questions. The regional percentage figure is a percentage of the total number of WHO Member States in that region. The survey response figures represent all of the responding countries. The survey response figures represent all the responding countries, either in the region or globally, as indicated.

Table 9. WHO Western Pacific Region: positive responses

| | Member States in the Western Pacific Region responding positively with the following | Regional survey % that responded positively (22) | Global survey % that responded positively (141) |
|---|---|--|---|
| National policy on TM/CAM | 10 | 45% | 32% |
| Law or regulation on TM/CAM | 9 | 41% | 38% |
| National programme on TM/CAM | 7 | 32% | 28% |
| National office for TM/CAM | 13 | 59% | 53% |
| Expert committee on TM/CAM | 9 | 41% | 43% |
| National research institute on TM, CAM or herbal medicines | 8 | 36% | 41% |
| Law or regulation on herbal medicines | 12 | 55% | 65% |
| Registration of herbal medicines | 11 | 50% | 61% |

The countries of the region demonstrate a high level of political commitment to TM/CAM policy and research, which is similar to the total survey response percentages. Almost one third of all the countries responding to the survey have each of the different forms of policy and regulation for TM/CAM and herbal medicines.

Australia

In Australia, the national policy on TM/CAM was issued in 1999. Regulations on TM/CAM in the form of the Therapeutic Goods Act were issued in 1989. The national programme and national office on TM/CAM, the Office of Complementary Medicines, was established in 1999; the office is administered by the Ministry of Health. In 1997, the Complementary Medicines Evaluation Committee was established as the expert committee. No national research institutes have yet been established for TM, CAM or herbal medicines.

In 1989, Australia began regulating herbal medicines by means of the Therapeutic Goods Act, which contains partly the same regulations as those issued for conventional medicines. Herbal medicines are regulated as over-the-counter medicines for self-medication; the specific categories are “registered goods” and “listed goods” and form part of the Australian Register of Therapeutic Goods. Medical, health, nutrient content and structure/function claims may be made for herbal medicines by law.

In place of a national pharmacopoeia, the *British pharmacopoeia* is used, and is considered legally binding in those cases when a herbal medicine is listed in the pharmacopoeia. A number of monographs are used in place of national ones; however, they are not considered legally binding.

Regulatory requirements for herbal medicines include adherence to information in pharmacopoeias and monographs and the same GMP rules as those used for conventional pharmaceuticals. Implementation of these requirements is ensured through GMP licensing for finished-goods manufacturers. Safety requirements for herbal medicines include the same requirements as for conventional pharmaceuticals, as well as special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Compliance with these requirements is ensured through “compositional guidelines” for approved complementary medicine substances that describe the identity tests and limits for contaminants and residues, although these are not legally binding on manufacturers. Other control mechanisms include post-market reviews, evaluation of toxicological data on new proposed herbal substances and history-of-use data.

There are 1 500 herbal medicines registered in Australia; none is included on the national essential drug list. The post-marketing surveillance system has included adverse-effect monitoring since 1970. In Australia, herbal medicines are sold in pharmacies as over-the-counter drugs, in special outlets, by licensed practitioners and without restriction.

Cambodia

In the Kingdom of Cambodia, the national policy on TM/CAM was issued in 1996 and regulations were issued in 1998. There is currently no national programme, and no information available about any plans to issue one. The national office was established in 1982 under the direction of the Ministry of Health. The establishment of an expert committee is currently being planned. The National Center of Traditional Medicine has established a committee with 11 members (Committee for Researching Traditional Medicine), and submitted the proposal (No. 023 MCSVB dated 21 March 2003) to the

Ministry of Health, but it has not yet been formally adopted. There are no national research institutes on TM, CAM or herbal medicines.

Regulation of herbal medicines in Cambodia was introduced in 1998. Herbal medicines are regulated as over-the-counter medicines and for self-medication only. By law, no claims may be made about herbal medicines.

No national pharmacopoeia exists, and one is not currently being prepared. National monographs are found in *Cambodia's medicinal plants, Vol. 1*, approved by the Ministry of Health in 1996, and *Cambodia's medicinal plants, Vol. 2*, approved in 1997, and in *Your medicines in your garden*, which was approved in 2000. Vol. 3 of *Cambodia's medicinal plants* is currently in development. No information is available about the legal status of these monographs. The regulatory requirements for manufacturing or safety assessment, and the control mechanisms established to ensure compliance, come under the Department of Drugs and Food.

There are currently 48 registered herbal medicines; however, none of them are included on a national essential drug list. The regulation of herbal medicines, registration and licence of herbal medicines currently comes under the Department of Drugs and Food. No information is available about post-marketing surveillance or adverse-effect monitoring. Herbal medicines in Cambodia are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed practitioners and without restriction.

China

In the People's Republic of China, the national policy on TM/CAM was issued in 1949 and regulations were issued in 1963. The national programme was issued in 1954. The national office was established in 1949 under the Ministry of Health, but in 1998, the State Drug Administration became responsible for regulatory issues relating to traditional medicine. It is independent of the Ministry of Health. The expert committee on TM/CAM was established in 1963. National research institutes on TM, CAM and herbal medicines have been established, but the dates of establishment are not available.

The national regulations on herbal medicine were issued in 1963 in the same laws as for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines, self-medication, dietary supplements, health foods and functional foods and as a separate regulatory category. By law, medical, health and nutrient content claims may be made.

The *Chinese pharmacopoeia* was first published in 1963, and is considered to be legally binding; it contains 992 national herbal monographs. Regulatory requirements for herbal medicines include adherence to information contained in pharmacopoeias and monographs, the same GMP rules that apply to conventional pharmaceuticals and special GMP rules. No detailed information is available on the control mechanisms used for these requirements. Safety assessment requirements for herbal medicines include the requirements applying to conventional pharmaceuticals as well as special requirements of traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Detailed information about the control mechanisms used to ensure the implementation of these requirements is not available.

There are more than 9 000 registered herbal medicines; by the end of 2002, 1 242 herbal medicines had been included on the national essential drug list. The national post-marketing surveillance system has included adverse-effect monitoring since 1984. In

China, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, in special outlets and by licensed practitioners.

Cook Islands

The Cook Islands do not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on TM/CAM, nor are there currently any plans to establish these.

There are no regulations on herbal medicines, nor do herbal medicines have any regulatory status. No claims may be made by law. No national pharmacopoeia or national monographs exist or are in development. There are no regulatory requirements for manufacturing or safety. No registration system exists; nor are herbal medicines included on a national essential drug list. There is no post-marketing surveillance system for herbal medicines. There are no restrictions on the sale of herbal medicines.

Fiji

In the Republic of Fiji, there is no national policy, law or regulation or national programme for TM/CAM: however, there are plans to establish a national policy and a national programme. There is a TM/CAM national office which is administered under the Ministry of Health. Currently, there is no expert committee or national research institute for the study of TM/CAM or herbal medicines.

Fiji does not regulate herbal medicines, and herbal medicines are not sold with claims. Neither a national pharmacopoeia nor a national herbal monograph exist, and neither is in the process of being prepared. There is no information about the regulatory requirements for the manufacture of herbal medicines. The safety requirement is the special requirement of traditional use without demonstrated harmful effects. There is no information available regarding the registration system for herbal medicines: however, it was reported that no herbal medicines are included on the national essential drug list. There is also no information about any post-marketing surveillance system for herbal medicines. In the Republic of Fiji, there are no restrictions on the sale of herbal products.

Japan

In Japan, no information is available on the existence of a national policy on TM/CAM. National laws and regulations on TM/CAM were issued in 1950 in the Pharmaceutical Affairs Law. No national programme on TM/CAM has been issued, and no programme is in development. No information is available about the establishment of a national office or a national expert committee. The National Institute of Health Sciences conducts research on herbal medicines; it was established in 1874.

National herbal regulations on herbal medicines in Japan were issued in 1960 in the revised Pharmaceutical Affairs Law; these regulations are the same as those for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines, dietary supplements (called “health foods”) and functional foods. By law, medical, nutrient content and structure/function claims may be made for herbal medicines.

The *Japanese pharmacopoeia* was last published in 2001, and is legally binding. No national monographs have been issued, and no others are used in their place. Regulatory requirements for manufacturing are the same GMP rules that apply to

conventional pharmaceuticals; these requirements are part of the following regulations: Pharmaceutical Affairs Law, Regulations for Manufacturing Control and Quality Control of Drugs and Quasi-Drugs and Regulations for Buildings and Facilities for Pharmacies. The control mechanisms used to ensure the implementation of these requirements are the same as those used for conventional pharmaceuticals; however, details are not available. The regulatory requirements for safety are the same requirements that apply to conventional pharmaceuticals. To ensure the implementation of these requirements, the same rules of approval review, GMP and post-marketing surveillance are used for herbal medicines as for conventional pharmaceuticals.

There is an approval system rather than a registration system; at least 1 469 herbal medicines have been approved. No information is available on a national essential drug list, or the inclusion of herbal medicines on it. The post-marketing surveillance system has included adverse-effect monitoring since 1993. In Japan, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines.

Kiribati

No information is available about the existence of plans to issue a national policy on TM/CAM in Kiribati. Laws and regulations are being developed. There is a national programme. The national office of TM/CAM is the Maurin Kiribati Traditional Healers Federation. The national expert committee on TM/CAM was established in 1995. There are no national research institutes on TM/CAM or herbal medicines.

There is currently no regulation of herbal medicine in Kiribati; herbal medicines have no regulatory status and no claims may be made by law. Neither a national pharmacopoeia nor national monographs are in existence or in development.

There are no regulatory requirements for manufacturing or safety. There is no registration system, nor are herbal medicines included on a national essential drug list. A post-marketing surveillance system is currently being developed. There are no restrictions on the sale of herbal medicines.

Lao People's Democratic Republic

In the Lao People's Democratic Republic, the national policy on TM/CAM was included in the National Drug Policy issued in 1998. Regulations were also issued in that year. The national programme on TM/CAM was issued in 2000. The Traditional Medicine Research Centre is the national office of TM/CAM, and is administered by the Ministry of Health; it was established in 1976. There is no expert committee on TM/CAM issues. National research institutes on traditional medicine and herbal medicines were established in 1996 and 1976, respectively.

Regulations on herbal medicine in the Lao People's Democratic Republic were issued in 2002; they are separate from those issued for conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines. By law, no claims may be made. A national pharmacopoeia is neither in existence nor in development. National monographs on herbal medicines are found in *Medicinal plants of ASEAN*; these 10 herbal monographs are considered to be legally binding.

The regulatory requirements for herbal medicines are the same GMP rules used for conventional pharmaceuticals; however, no information is available on any kind of control mechanisms for these requirements. Safety requirements are also the same

requirements as for conventional pharmaceuticals; no control mechanism exists to guarantee these requirements for herbal medicines.

There is a registration system in the Lao People's Democratic Republic; however, the number of registered herbal medicines is not available. Thirty herbal medicines were included on the national essential drug list that was issued in 2002. A post-marketing surveillance system is currently being planned. In the Lao People's Democratic Republic, herbal medicines are sold in pharmacies as over-the-counter medicines and by licensed practitioners.

Malaysia

Malaysia has a national policy on TM/CAM, which was launched in the year 2001. The registration and licensing of TM/CAM is legislated through the Control of Drugs and Cosmetics Regulations 1984. A national programme was established in 2001 along with the policy. The Ministry of Health has recently set up a division for TM/CAM. Several expert committees on TM/CAM have been established to look into specific areas of TM/CAM. A Herbal Medicine Research Centre has also been set up under the Institute for Medical Research.

Regulations for traditional medicines, including herbal medicines and dietary supplements formed part of the Control of Drugs and Cosmetics Regulation in 1984. Traditional medicines are allowed to be sold as over-the-counter medicines. Limited health claims may also be made.

Malaysia does not have any national pharmacopoeia. However, international pharmacopoeias such as The *Chinese pharmacopoeia* and the *Pharmacopoeia of India* are used as references, but are not considered legally binding. Malaysia published the first *Malaysian herbal monograph* in 1999, but this is also not considered to be legally binding.

Traditional manufacturers are required to adhere to the GMP requirements for traditional products, a major part of which has been adapted from the GMP guidelines for pharmaceuticals. Compliance with these requirements is ensured through routine inspection, GMP certification and licensing of manufacturers. Safety requirements for herbal medicines include evidence of traditional use without demonstrated harmful effects, compliance with the limits set for heavy metals (mercury, arsenic, lead), testing for microbial and fungal contamination, other physicochemical tests and screening for adulterants.

As of December 2003, the Drug Control Authority (DCA) has registered approximately 12 000 traditional medicines, including herbal products. However, none of these products are included on the national essential drug list. The post-marketing surveillance programme was introduced for pharmaceuticals in 1987 and was extended to cover traditional medicines in 1997. Adverse drug reaction monitoring of traditional medicines, market sampling and investigation of product complaints have since been included in the programme. In Malaysia, herbal medicines are sold in pharmacies as over-the-counter drugs without any restrictions.

Market sales estimates for imported and locally made medicinal products are currently not available. At the moment, there are no dedicated tariff codes for traditional medicines. However, data have been published for the domestic market in 1999, which gave a value for herbal remedies of 2 billion Malaysian ringgit (US\$ 530.5 million), flavours and fragrances 1.60 billion ringgit (US\$ 424.4 million), pharmaceuticals/nutraceuticals 950 million ringgit (US\$ 252.0 million) which, added together, gives a total value of 4.55 billion ringgit (US\$ 1.2 billion).

Micronesia (Federated States of)

In the Federated States of Micronesia, while there are currently no plans to establish a national policy on TM/CAM, legislation stipulates that no law may be passed against the use of traditional medicine. There are no laws, regulations or national programmes on TM/CAM, nor are there currently any in development. There is no national office, national expert committee or national research institute on TM, CAM or herbal medicines.

There are no regulations on herbal medicines; herbal medicines are classified as prescription and over-the-counter medicines, and as a separate category. Herbal medicines are sold with structure/function claims. No national pharmacopoeia or national herbal monographs exist or are in development. There are no regulatory requirements for manufacturing or safety. There is no registration system for herbal medicines, nor are they included on a national essential drug list. There is no post-marketing surveillance system for herbal medicines. There are no restrictions on the sale of herbal medicines, which are sold when traditional treatment is provided.

Mongolia

In 1999, Mongolia issued its national policy on TM/CAM in the “State Policy for Development of Mongolian Traditional Medicine”. No national laws or regulations specifically for TM/CAM have been issued or are in development; however, all health-related aspects are regulated under the health and drug laws. There have been two national programmes on traditional medicine, 1992-96 and 1997-2000. In 1998, the Traditional Medical Science Technology and Production Corporation was established; it is administered by the Ministry of Health. The national expert committee was established in 1991, and is called the Professional Committee for Traditional Medicine. In 1961, the Institute for Natural Compounds of the Mongolian Academy of Sciences was established and later was transformed into the Institute of Folk Medicine, and finally became the Traditional Medical Science, Technology and Production Corporation in 1998. It serves as the national research institute for traditional medicine.

Regulations on herbal medicines were issued in 1998 and 2001; the laws are the same for herbal medicines as for conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines by the Health Minister's order No. 169 of 2001. By law, herbal medicines may be sold with medical, health and nutrient claims.

In place of a national pharmacopoeia, many reliable resources are used, including the *Chinese pharmacopoeia*, *State pharmacopoeia of the USSR* and *Indian pharmacopoeia*, but they are not considered legally binding. National herbal monographs are found in the *Manual of traditional medicine raw materials and prescriptions control* (2003); the four herbal monographs it contains are considered legally binding.

The regulatory requirements for herbal medicine manufacture are the same GMP rules that apply to conventional pharmaceuticals. Implementation of the requirements is ensured by the State Professional Inspection Agency, which inspects manufacturing processes. The regulatory requirements for safety are the same requirements as those for conventional pharmaceuticals. Compliance with these requirements is ensured by the State Professional Inspection Agency and adverse-reaction monitoring by the Drug Council.

There are 22 registered herbal medicines in Mongolia; however, none are included on the essential drug list. The national post-marketing surveillance system has included adverse-effect monitoring since 1998. Herbal medicines are sold in pharmacies as

prescription and over-the-counter medicines as well as without restriction. Data on national annual sales of herbal medicines were provided for the period 2000 to 2002. In 2000, sales of herbal medicines had a value of 32.4 million tugrik (US\$ 27 835). In 2001, sales reached 44.2 million tugrik (US\$ 37 973). In 2002, sales dropped slightly to 40.2 million tugrik (US\$ 34 536).

Nauru

In the Republic of Nauru, a national policy, laws, regulations and a national programme on TM/CAM are being established. There is a national office administered by the Ministry of Health. No expert committee has been established and there are no national research institutes on TM, CAM or herbal medicines.

There is no regulation of herbal medicines; they are classified for self-medication only. No claims may be made by law. No national pharmacopoeia exists, but one is being developed. The *WHO monographs* are used while the pharmacopoeia is being developed. There are no national herbal monographs, nor are there plans to develop any.

There is no information about the existence of manufacturing requirements; there are no safety requirements for herbal medicine. Likewise, there is no registration system or inclusion of herbal medicines on a national essential drug list. A post-marketing surveillance system is being planned. There are no restrictions on the sale of herbal medicines in Nauru.

New Zealand

In New Zealand, while there is no national policy on TM/CAM currently, such a policy is under consideration. No exclusive laws or regulations on TM/CAM have yet been established; however, several are in development. There is no national programme, nor are there currently plans to issue one. There is no national office for TM/CAM; however, plans for an office of complementary medicine are being discussed. The Ministerial Advisory Committee on Complementary and Alternative Health was established in 2001. No national research institutes on TM/CAM or herbal medicines have been established.

Herbal medicines are regulated under the Medicines Act of 1981, which also regulates conventional pharmaceuticals. Many herbal medicines are regulated under the Dietary Supplements Act of 1985. Herbal medicines are regulated as over-the-counter medicines, dietary supplements and as a separate regulatory category. Herbal medicines classified as extemporaneously prepared herbal medicines are exempt from regulation. Medical and health claims may be made only about those herbal medicines approved under the Medicines Act by law.

There is neither a national pharmacopoeia nor national herbal monographs, and none are being prepared. The same regulatory requirements apply to the manufacture of herbal medicines as apply to conventional pharmaceuticals. Special GMP rules apply to the manufacture of dietary supplements, but they are strictly voluntary. Implementation of these requirements is ensured, when mandatory, by auditing and licensing by the regulatory agency Medsafe. Safety requirements only apply to those herbal medicines not classified as dietary supplements; they are the same that apply to conventional pharmaceuticals. For the herbal medicines that are supplied commercially, implementation of safety requirements is ensured by a pre-market evaluation and approval process.

There is a registration system in New Zealand, which is used only for products sold commercially and not regulated as dietary supplements; the total number of registered herbal medicines is not available. No herbal medicines are included on the national essential drug list. As part of the post-marketing surveillance system, there is adverse-effect monitoring for both conventional pharmaceuticals and herbal medicines. Herbal medicines in New Zealand are sold in pharmacies as prescription and over-the-counter medicines, in special outlets and without restriction. In 2000, sales of complementary medicines and other health-care products were estimated at 70-80 million New Zealand dollars (US\$ 43-49 million).

Niue

In the Republic of Niue, a national policy on TM/CAM is currently being developed. Laws, regulations and national programmes have not been adopted, nor are they in development. There is no national office. The national expert committee was established in 2001. There are no national research institutes.

There are no national laws or regulations on herbal medicines; there is no regulatory status for herbal medicines. Herbal medicines are not sold with claims. There is neither a national pharmacopoeia nor national herbal monographs, nor are there currently plans to develop these. There are no regulatory requirements for manufacturing or safety. There is no national registration system; no herbal medicines are included on a national essential drug list. There is no post-marketing surveillance system for herbal medicines. Herbal medicines are not sold in Niue.

Papua New Guinea

In Papua New Guinea, a national policy, laws and regulations on TM/CAM are currently in development. The national programme was issued in 2001 as part of the National Health Plan, 2001-10. A national office is currently being established. The national expert committee was established in 2001. No national research institutes have yet been established for TM/CAM or herbal medicines.

No national regulations on herbal medicines have been issued. Herbal medicines have no regulatory status, and by law no claims may be made. No national pharmacopoeia exists, none is in the process of development and nothing else is used in its place. No national herbal monographs have been issued or are in the process of development.

There are no regulatory requirements for manufacturing in Papua New Guinea; however, these requirements are being developed. No safety regulatory requirements have yet been established. There is no registration system for herbal medicines, and herbal medicines are not included on a national essential drug list. There is currently no national post-marketing surveillance system for herbal medicines. Herbal medicines are sold without restriction.

Philippines

In the Republic of the Philippines, the national policy on TM/CAM was issued in 1997. No laws or regulations have yet been issued. There is no information available on the existence of a national programme on TM/CAM. The national office, the Philippine Institute of Traditional and Alternative Care, was founded in 1997. It is administered by the Department of Health. There is no national expert committee on TM/CAM. The National Integrated Research Programme on Medicinal Plants of the Philippine Council of Health Research and Development serves as the national research institute on herbal medicines.

The regulations on herbal medicines were issued in 1984; these regulations are separate from those for conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines. By law, medical claims may be made for herbal medicines with supporting scientific proof.

Pending the development of the national pharmacopoeia, the *United States pharmacopoeia*, the *Japanese pharmacopoeia* and the *ESCOP monographs* are used and are considered to be legally binding. Pending the development of national herbal monographs, herbal monographs from a number of foreign pharmacopoeias are used; however, they are not legally binding.

Manufacturing requirements for herbal medicines are the same as the GMP rules for conventional pharmaceuticals. A control mechanism exists to ensure implementation of these requirements; however, specific details are not available. Safety requirements include the same as those required for conventional pharmaceuticals as well as the special requirement of traditional use without demonstrated harmful effects. To ensure compliance with these requirements, preclinical and clinical trials are required.

The Philippines has a registration system for herbal medicines; however, the number of registered herbal medicines is not available. Four herbal medicines are included on the national essential drug list for 2000. The post-marketing surveillance system includes adverse-effect monitoring for herbal medicines, using the same system as for conventional pharmaceuticals. In the Philippines, herbal medicines are sold in pharmacies as over-the-counter medicines and in special outlets. National sales of herbal medicines for January to May 2002 had a value of 11 468 500 Philippine pesos (US\$ 208 024).

Republic of Korea

The national policy of TM/CAM in the Republic of Korea was issued in 1993; in the same year, laws, regulations and a national programme were also issued. The Bureau of Oriental Medicine within the Ministry of Health and Welfare was also established in 1993. Currently, there is no expert committee on TM/CAM. National research institutes on traditional medicine and herbal medicines were established in 1994.

Herbal medicine regulations were first issued in 1986 and were amended in 1994. The regulations on herbal medicine are part of the Pharmaceutical Affairs Law that governs conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. By law, medical, health, nutrient content and structure/function claims may be made for herbal medicines.

The *Korea pharmacopoeia* was issued in 1959, and is considered to be legally binding. No national herbal monographs are currently in development, and no others are used in their place.

Regulatory requirements for manufacturing of herbal medicines in the Republic of Korea are limited to adherence to the information in pharmacopoeias and monographs; no control mechanisms exist for this requirement. Safety requirements are limited to traditional use without demonstrated harmful effects; again, there are no control mechanisms for this safety requirement.

There are about 4 000 registered herbal medicines in the Republic of Korea; 515 herbal medicines are included on the national essential drug list issued in 1959. A post-marketing surveillance system for herbal medicines is being planned. In the Republic of Korea, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets and by licensed practitioners. Annual market sales data were provided

by the Republic of Korea for the period 1998-2001. Sales in 1998 were US\$ 279 million, in 1999, US\$271 million and in 2001, US\$ 291 million.

Singapore

In the Republic of Singapore, the national policy on TM/CAM was issued in 1995. In 2000, the "Traditional Chinese Medicine Practitioners Act" established regulations on TM/CAM. There is no national programme, nor are there currently any plans to issue one. The TM/CAM national office was established in 1995 and is administered by the Ministry of Health. The expert committee was established in 1996. There are currently no national institutes on TM/CAM or herbal medicines.

There are national regulations on herbal medicines in Singapore. A subgroup of herbal remedies is Chinese proprietary medicines (CPM), which are traditional Chinese herbal medicines in finished dosage forms (e.g. tablets, capsules). In 1998, Singapore issued regulations on Chinese proprietary medicines, which are similar to those regulating conventional pharmaceuticals. Herbal medicines are regulated as over-the-counter medicines. By law, medical, health, nutrient content and structure/function claims may be made for herbal remedies, except for 19 serious diseases or medical conditions for which claims are prohibited.

Singapore does not possess a national pharmacopoeia or national herbal monographs. Reputable references, including the *Chinese pharmacopoeia*, are used, but are not considered to be legally binding.

Regulatory requirements for Chinese proprietary medicines are the same GMP rules used for conventional pharmaceuticals. Control mechanisms for CPM requirements include marketing authorization requirements and licensing of manufacturers. Regulatory requirements for safety include traditional use without demonstrated harmful effects, toxic heavy metal content and microbial content testing, and absence of prohibited ingredients. Licensing of dealers and product approval are required for every CPM product imported, manufactured or assembled.

There are currently no registration requirements for herbal medicines and none are included on a national essential drug list; however, a listing system has been established for CPM products. The post-marketing surveillance system for all herbal medicines has included adverse-effect monitoring since 1993. There are no restrictions on the sale of herbal medicines, as long as they comply with the national regulations.

Solomon Islands

In the Solomon Islands, a national policy on TM/CAM was issued in 1994. Laws, regulation and a national programme on TM/CAM have not been issued, nor are they in development. There is also no national office, expert committee or national research institute.

There are no national laws or regulations on herbal medicines; herbal medicines are classified for self-medication only. Herbal medicines are not sold with claims. There is neither a national pharmacopoeia nor national herbal monographs, nor are there currently plans to develop these.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and the same rules of GMP required for conventional pharmaceuticals. There are no control mechanisms for these requirements. Safety requirements are limited to traditional use without demonstrated harmful effects. Again, no control mechanisms exist for this requirement.

There is no national registration system; no herbal medicines are included on the national essential drug list. A post-marketing surveillance system for herbal medicines is in the process of being developed. Herbal medicines are sold without restriction in the Solomon Islands.

Tuvalu

In Tuvalu, no national policy, laws, regulations or national programme on TM/CAM have been issued, nor are they in development. There is also no national office, expert committee or national research institute.

There are no national laws or regulations on herbal medicines; herbal medicines are classified in a separate category. Herbal medicines are not sold with claims. There is neither a national pharmacopoeia nor national herbal monographs, nor are there currently plans to develop these. There are no regulatory requirements for manufacturing or safety. There is no national registration system; no herbal medicines are included on a national essential drug list. There is no post-marketing surveillance system for herbal medicines, nor is one being developed. Herbal medicines in Tuvalu are sold directly by traditional healers.

Vanuatu

In Vanuatu, no national policy, laws, regulations or national programmes have been issued. A national policy is being developed. There is also no national office, expert committee or national research institute.

There are no national laws or regulations on herbal medicines; herbal medicines are classified as a separate category. Herbal medicines are not sold with claims. There is neither a national pharmacopoeia nor national herbal monographs; there are currently no plans to develop them.

Regulatory requirements for manufacturing are the same GMP rules as for conventional pharmaceuticals. No information is available about safety requirements. There is no national registration system; no herbal medicines are included on an essential drug list. There is no post-marketing surveillance system for herbal medicines, nor is one being developed. Herbal medicines in Vanuatu are sold in special outlets.

Viet Nam

In the Socialist Republic of Viet Nam, a national policy on TM/CAM is currently being developed. Laws and regulations were issued in 1989 and a national programme was issued in 1986. The Department of Traditional Medicine is administered by the Ministry of Health, and was established in 1957. There is currently no expert committee. In 1957, the Vietnamese Institute of Traditional Medicine was established, and in 1976 the Hochiminh Institute of Traditional Medicine and Pharmacy was founded.

National laws and regulations on herbal medicines were issued in 1989, separately from the laws governing conventional pharmaceuticals. Herbal medicines are regulated as prescription and over-the-counter medicines. By law, medical, health and nutrient content claims may be made.

The *Vietnam pharmacopoeia* is legally binding, as are the national herbal monographs found in *Vietnam medicinal plants*.

Regulatory requirements for manufacturing include adherence to information in pharmacopoeias and monographs and the same GMP rules used for conventional

pharmaceuticals. Implementation of these requirements is ensured by inspection and visits to manufacturing establishments. Safety requirements for herbal medicines include traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. Classical or traditional remedies are used and promoted without the need to demonstrate the safety of the product. New remedies, indications or uses for herbal medicines must be accompanied by records of clinical trials. Implementation of these requirements is ensured by the registration system.

There are currently 1 573 registered herbal medicines in Viet Nam; 267 herbal medicines are included on the national essential medicines list of 1996. The post-marketing surveillance system includes monitoring of adverse effects for herbal medicines. In Viet Nam, herbal medicines are sold in pharmacies as prescription and over-the-counter medicines, in special outlets and by licensed practitioners.

References

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Annex 1. Text of survey instrument

**A Global Survey on
National Policy on
Traditional/Complementary/Alternative Medicine
&
Regulation of Herbal Medicines**

| |
|-------------------------------|
| Date: |
| Country: |
| Name of Investigator: |
| Title of Investigator: |
| Address: |
| Telephone: |
| Fax: |
| E-mail: |

Introduction

With the widespread use of traditional medicine (TM) as well as complementary/alternative medicine (CAM) and the rapid expansion of international herbal medicine markets, the development of national policies and regulations on TM/CAM has become an important concern for both health authorities and the public. Providers of TM/CAM, other health care professionals and TM/CAM consumers alike are calling for regulations that can ensure the safety of TM/CAM therapies and products, promote recognition of these systems and modalities and further define their role in modern health care systems¹.

National policies and regulations on TM/CAM could ensure the safety, quality and efficacy of these therapies and products, and function as important steps towards integrative health-care systems. However, relatively few countries have developed policies and regulations on TM/CAM so far. Only 25 of WHO's 191 countries have a national policy on TM/CAM and only 64 countries regulate herbal medicines².

To assist countries in the development of TM/CAM policies and regulations of herbal medicines, WHO has published a series of technical guidelines and reviewed regulations on herbal medicines in the document "Regulatory Situation of Herbal Medicines: a Worldwide Review", published in 1998.

With this survey, WHO is taking one step further towards an increased understanding of TM/CAM policies and regulations of herbal medicines in the countries. By using a common approach in the measurement of the regulatory situation in all countries, a comparative analysis of the results will be feasible and major themes and obstacles can be identified. In order to provide continuous valuable support in the future, WHO is also requesting the countries to define their assistance needs.

This survey is based on 21 structural indicators of qualitative and quantitative nature, 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 medicines regulation.

Objectives

The objectives of this survey are:

- To collect updated and comprehensive information on TM/CAM policies and regulations of herbal medicine in countries.
- To identify the specific needs of each Member State regarding capacity building on TM/CAM policies and regulation of herbal medicines, which will enable WHO to accordingly provide appropriate support to the countries.
- To update the document "Regulatory Situation of Herbal Medicines: a Worldwide Review".
- To monitor the impact of the WHO Strategy for Traditional Medicine in relation to present national policy and regulation on TM/CAM/herbal medicines.

The indicators used in this document were developed by the Traditional Medicine/Department of Essential Drug and Medicine Policy in cooperation with the Division of International Health (IHCAR), Department of Public Health at Karolinska Institutet, Sweden.

¹ Stone J. Regulating complementary medicine. *British Medical Journal*, 1996, 312:1492-93.

² WHO traditional medicine strategy 2002-2005 (in press).

1. Traditional/Complementary/Alternative Medicine (TM/CAM)

Useful explanations:

Traditional Medicine (TM): TM is the sum total of the 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.

Complementary and Alternative Medicine (CAM): The term 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', 'non-conventional medicine' and 'holistic medicine'.

Source: *General guidelines for methodologies on research and evaluation of traditional medicine*, WHO/EDM/TRM/2000.1.

Policy

Useful explanations:

National policy on TM/CAM: A national policy on TM/CAM could 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, etc. The policy could further contain main strategies proposed by the government for achieving the objectives of the policy.

Source: *WHO traditional medicine strategy 2002-2005 (in press)*.

1. Is there a national policy on TM/CAM? YES ☐ NO ☐

If yes, year of issue: _____

Please submit a copy of the policy, if available in English, otherwise in original language.

If no, is such a policy in process of being established? YES ☐ NO ☐

Law & Regulation

Useful explanations:

Law on TM/CAM: A law is the first stage of legislative procedures; it is a rule of conduct imposed by the authority. A law establishes the legal conditions under which TM/CAM should be organized in line with a national TM/CAM policy, or other relevant policies. The law could cover different areas in the TM/CAM field, for instance education of professionals, licensing of practitioners and manufacturers, the manufacture of products used in TM/CAM, sales practice, etc. Both public and private sector could be taken into account.

Regulation on TM/CAM: Regulations form the second stage of legislative procedures, specifically designed to provide the legal machinery to achieve the administrative and technical goals of a law. Many activities in the field of TM/CAM could be covered by regulations, such as a description of obligations and responsibilities of licensed practitioners, the penal sanctions if these are not respected, the obligation of manufacturers of TM/CAM products, etc.

Source: *Indicators for monitoring national drug policies*, 2nd ed., WHO/EDM/PAR/99.3.

2. **Is there a national law or regulation on TM/CAM?** YES ☐ NO ☐

If yes, year of issue: _____

Please submit a copy of the law and/or regulation, if available in English, otherwise in original language.

If no, is such a law or regulation in process of being established? YES ☐ NO ☐

National Programme

Useful explanations:

National programme on TM/CAM: A national programme on TM/CAM is defined here as any programme performed on local or national level, by the ministry of health, by other ministries, or by local bodies, whose mandate is to take concrete action in order to achieve objectives in line with the national policy or legislation.

3. **Is there a national programme on TM/CAM?** YES ☐ NO ☐

If yes, year of issue: _____

Please submit a copy of a description of the programme, if available in English, otherwise in original language.

If no, is such a programme in process of being established? YES ☐ NO ☐

National Office

4. Is there a TM/CAM national office? YES ☐ NO ☐

If yes, year of establishment: _____

Please provide the contact address to the national office.

Under which Ministry is it administered?

Ministry of Health ☐

Other, namely _____

If no, is the establishment of such an office being planned? YES ☐ NO ☐

Expert Committee

5. Is there an expert committee for TM/CAM? YES ☐ NO ☐

If yes, year of establishment: _____

Please provide the contact address to the expert committee.

National Research Institute

Useful explanations:

A national research institute for TM/CAM or for herbal medicine is a research institute that performs research on TM/CAM or herbal medicine and is fully or partially funded by the government.

- | 6. Is there a national research institute on: | | | | YEAR OF ESTABLISHMENT |
|---|------------------------------|-----------------------------|--|-----------------------|
| TM? | YES <input type="checkbox"/> | NO <input type="checkbox"/> | | _____ |
| CAM? | YES <input type="checkbox"/> | NO <input type="checkbox"/> | | _____ |
| Herbal medicines?* | YES <input type="checkbox"/> | NO <input type="checkbox"/> | | _____ |

If yes, please provide contact addresses to the respective institutes.

* Please see definition on page 148.

2. The Regulatory Situation of Herbal Medicines

Useful explanations:

Herbal Medicines: Herbal medicines are here defined as 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 present¹.

Conventional Pharmaceuticals: Conventional pharmaceuticals are here defined as medicinal drugs used in conventional systems of medicine with the intention to treat or prevent disease or to restore, correct or modify physiological function².

Source: 1. *General guidelines for methodologies on research and evaluation of traditional medicine*, WHO/EDM/TRM/2000.1. 2. *Dorlands illustrated medical dictionary*, 29th edition, 2000.

Law & Regulation

Useful explanations:

For explanation of law and regulation, please see textbox above.

7. **Is there a national law or regulation on herbal medicines?** YES ☐ NO ☐

If yes, year of issue: _____

Please choose type of law or regulation:

- Same law or regulation as for conventional pharmaceuticals ☐
- Separate law or regulation for herbal medicines ☐
- The law or regulation for herbal medicines is partly the same as for conventional pharmaceuticals ☐

Please write the name of the law and/or regulation above, date of enforcement and submit a copy of the law or regulation, if possible in English, otherwise in original language.

Regulatory Status

Useful explanations:

Prescription Medicines: Medicines/drugs that can only be purchased with a prescription, a physician's order¹.

Over the Counter Medicines: Medicines/drugs that can be purchased without a prescription from a physician¹.

Self-medication only: Medicines/drugs only allowed for self-medication purposes.

Herbal Medicines: see description in textbox above.

Dietary Supplements: A dietary supplement could be intended to supplement the diet that bears or contains for instance a vitamin, a mineral, an herb or other botanical, an amino acid. A dietary substance could be intended to supplement the diet by increasing the total daily intake of a concentrate, metabolite, constituent, extract, or combination of these ingredients².

Health Food: Health foods could be products that are presented with specific health claims and therefore regulated differently than other foods³.

Functional Food: Like health foods, functional foods could be products presented with specific health claims and therefore regulated differently than other foods³.

Other: This group includes products that are classified differently than the above-mentioned categories.

Since many countries define herbal medicines differently, please notice that "herbal medicines" in this questionnaire refer to the WHO definition on page 1.

Source: 1. *Dorlands illustrated medical dictionary*, 29th ed, 2000. 2. Chang J. Scientific evaluation of traditional Chinese medicine under DSHEA: a conundrum. *Journal of Alternative and Complementary Medicine*, 1999, 5:181-189. 3. *CSPI reports: international functional foods: public health boon or 21st century quackery?* Washington, D.C., International Association of Consumer Organizations, 1999 (http://www.cspinet.org/reports/functional_foods/table1.html)

8. Which regulatory status is given to herbal medicines?

Please tick all that apply.

- | | |
|--|--------------------------|
| Prescription Medicines | <input type="checkbox"/> |
| Over-the-counter Medicines (O.T.C.) | <input type="checkbox"/> |
| Self-medication only | <input type="checkbox"/> |
| Herbal Medicines as a separate regulatory category | <input type="checkbox"/> |
| Dietary Supplements | <input type="checkbox"/> |
| Health Food | <input type="checkbox"/> |
| Functional Food | <input type="checkbox"/> |
| Other, namely | <input type="checkbox"/> |
| No status | <input type="checkbox"/> |

* If ticked, please submit the national definition of these terms.

Claims

Useful explanations:

Medical claims: Medical claims are here defined as those claims specified to treat, cure or prevent a disease or restore, correct or modify physiological functions. Most often, products with medical claims have to be registered by the medical products agency before allowed into the market.¹

Health claims: Health claims are here defined as follows: "any statement, suggestion or implication in labelling or advertising that a product carries a specific health benefit, but not nutritional claims nor medicinal claims. The term health claim further includes claims that refer to nutrient function and recommended dietary practice"².

Nutrient content claims: Nutrient content claims are for instance indicating that a certain product is particularly rich or low in a nutritional component such as fibre or fat².

Structure/functional claims: These claims link a substance to an effect on a structure or function of the body³.

Source: 1. Joint Health Claims Initiative Body, www.jhci.co.uk. 2. Swedish Food Administration-
www.slv.se. 3. CSPI reports: international functional foods: public health boon or 21st century
quackery? www.cspinet.org/reports/functional_foods/table1.html

9. Are herbal medicines sold with claims in your country? YES ☐ NO ☐

If yes, by law/regulation, which type of claims can be made for herbal medicines?

Please tick all that apply.

- Medical claims ☐
Health claims ☐
Nutrient content claims ☐
Structure/function claim ☐
No claims can be made according to the law ☐
Other claims, namely _____

Pharmacopoeia

Useful explanations:

Pharmacopoeia: A pharmacopoeia is a formulary, especially an official one and usually one having legal force in all pharmacies of a given country, containing a description of drugs in current medical practices and noting their formulae, analytical composition if known, physical constants, main chemical properties useful in identification, and mode of preparation of compound preparations/combination products. Details may also be included of assay methods to regulate purity, content of active principle, preservation of quality and where appropriate, biological potency.

Source: Churchill medical dictionary, 1989.

10. Is there a national pharmacopoeia including herbal medicines? YES ☐ NO ☐

If yes,

Title: _____
Edition number: _____
Year of issue: _____

Please submit a copy of the pharmacopoeia, if available in English, otherwise in original language.

If several pharmacopoeias exist for herbal products, please submit information about all.

Is the information in the pharmacopoeia legally binding?

YES ☐ NO ☐

If no,

Is a national pharmacopoeia including herbal medicines in process?

YES ☐ NO ☐

Is any other pharmacopoeia used?

YES ☐ NO ☐

If yes,

Title: _____
Edition number: _____
Year of issue: _____

Is the information in the pharmacopoeia legally binding?

YES ☐ NO ☐

Monographs

Useful explanations:

Monographs on herbal products constitute descriptions of different herbal medicinal formulae, which can either be included in a pharmacopoeia or exist separately.

Source: *WHO monographs on selected medicinal plants*, Vol. 1, 1999.

11. Are there national monographs on herbal medicines? YES ☐ NO ☐

If yes,

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

Please submit a copy of the monographs, if available in English, otherwise in original language.

Is the information in the monographs legally binding?

YES ☐ NO ☐

If no,

Are national herbal monographs in process?

YES ☐ NO ☐

Are other monographs used?

YES ☐ NO ☐

If yes,

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

Is the information in the monographs legally binding?

YES ☐ NO ☐

Manufacturing

Useful explanations:

Good Manufacturing Practice (GMP): Basic requirements of GMP include areas such as quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacture and analysis, complaints and product recall and self inspection.

Source: *British pharmacopoeia*, 2000.

12a. What regulatory requirements apply to the manufacturing of herbal medicines?

Please tick all that apply.

- | | |
|---|--------------------------|
| Adherence to information in pharmacopoeia/monographs | <input type="checkbox"/> |
| Same rules of Good Manufacturing Practice (GMP) as for conventional pharmaceuticals | <input type="checkbox"/> |
| Special GMP rules | <input type="checkbox"/> |
| No requirements | <input type="checkbox"/> |
| Others, namely | <input type="checkbox"/> |

Please submit a copy of the rules, if available in English, otherwise in original language.

Comments: _____

12b. Is implementation of the manufacturing requirements of herbal medicines ensured by any control mechanism? YES ☐ NO ☐

If yes,

Please explain the type of control mechanism used.

Safety

13a. What are the regulatory requirements for the safety assessment of herbal medicines?

Please tick all that apply.

- Same requirements as for conventional pharmaceuticals ☐
- Special requirements, namely ☐
- Traditional use without demonstrated harmful effects ☐
- Reference to documented scientific research on similar products ☐
- Other requirements, namely _____ ☐
- No requirements ☐

Comments: _____

13b. Is implementation of the safety requirements for herbal medicines ensured by any control mechanism? YES ☐ NO ☐

If yes,

Please explain the type of control mechanism used.

Registration

14. Is there a registration system for herbal medicines? YES ☐ NO ☐

If yes,

How many herbal medicines are registered? _____

Please submit a list of the registered products.

Essential Drug List

15. Are herbal medicines included in the national essential drug list? YES ☐ NO ☐

If yes,

How many herbal medicines are included? _____

Year of issue of list: _____

Please submit a copy of the essential drug list.

Post-marketing Surveillance

16. Is there a post-marketing surveillance system for herbal medicines? YES ☐ NO ☐

If yes,

Is there a national system to monitor adverse effects of herbal medicines?

YES ☐ NO ☐

Year of establishment: _____

If no,

Are there any plans to establish such a system?

YES ☐ NO ☐

Market

17. How are herbal medicines sold?

Please tick all that apply.

- In pharmacies as prescription drugs
- In pharmacies as over-the-counter drugs
- In special outlets
- By licensed practitioners
- No restrictions for selling herbal products
- Other ways, namely _____

☐
☐
☐
☐
☐

18. What are the annual market sales for herbal medicines? Please fill in statistically verified data or approximate estimates in the table below.

Please fill in data or market estimates from the last three years (for which data are available) and define the type of data/estimates, for instance "data published by ministry of health", "estimate made by investigator", "scientific study".

If data are available for separate categories of herbal medicines, please submit available information from the separate groups in the three empty columns in the table. For example, if a separate estimate is prevalent for herbal medicines sold as functional food, please write "functional food" in one of the grey table-boxes and submit the figures in the column below.

| | HERBAL MEDICINES ANNUAL SALES | | | |
|--------------------------|--|--|--|--|
| YEAR | | | | |
| MARKET SALES | | | | |
| TYPE OF DATA/ESTIMATE | | | | |
| YEAR | | | | |
| MARKET SALES | | | | |
| TYPE OF DATA/ESTIMATE | | | | |
| YEAR | | | | |
| MARKET SALES | | | | |
| TYPE OF DATA/ESTIMATE | | | | |

3. The countries, WHO and Herbal Medicine

Useful explanations:

WHO wants to learn more about the needs of each Member State and the feedback from each country is therefore essential for a future successful support from WHO to the countries.

19. What are the main difficulties faced by your country as regards regulatory issues on herbal medicines?

- | | |
|---|--------------------------|
| Lack of research data | <input type="checkbox"/> |
| Lack of expertise within the national health authorities and control agency | <input type="checkbox"/> |
| Lack of appropriate mechanisms for control of herbal medicines | <input type="checkbox"/> |
| Lack of education and training | <input type="checkbox"/> |
| Other, namely _____ | |

20. What kind of support on herbal products related topics is your country interested to receive from WHO?

Please tick options as prioritised.

| | MUCH NEEDED | NEEDED | NOT NEEDED |
|--|--------------------------|--------------------------|--------------------------|
| Information sharing on regulatory issues | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Training workshops about national capacity to establish regulations on herbal medicine | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| General guidelines for research and evaluation of traditional medicine | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Training workshops about national capacity building on safety monitoring of herbal medicines | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Provision of databases | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Arrangement of global meetings | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other, namely _____ | | | |

21. In which way would you like WHO to present the results from this survey?

- | | |
|--|--------------------------|
| | <input type="checkbox"/> |
| As a descriptive report | <input type="checkbox"/> |
| As a condensed report with results presented in figures/tables | <input type="checkbox"/> |
| Results/analysis presented in a database | <input type="checkbox"/> |

Other suggestions:
