

3. The regulatory situation of herbal medicines

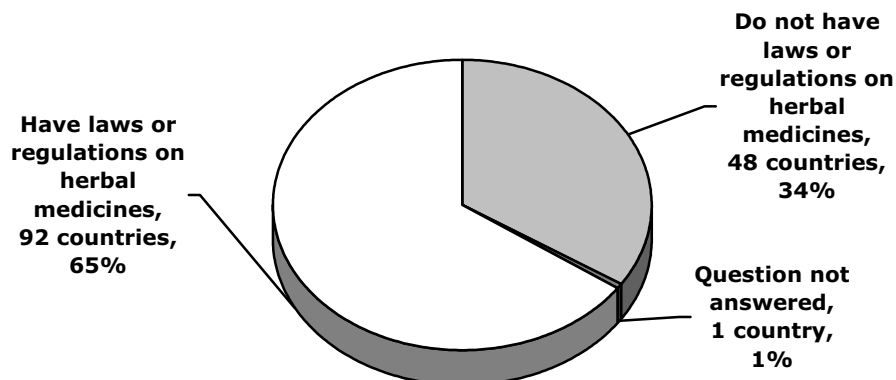
3.1 Law or regulation on herbal medicines

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.

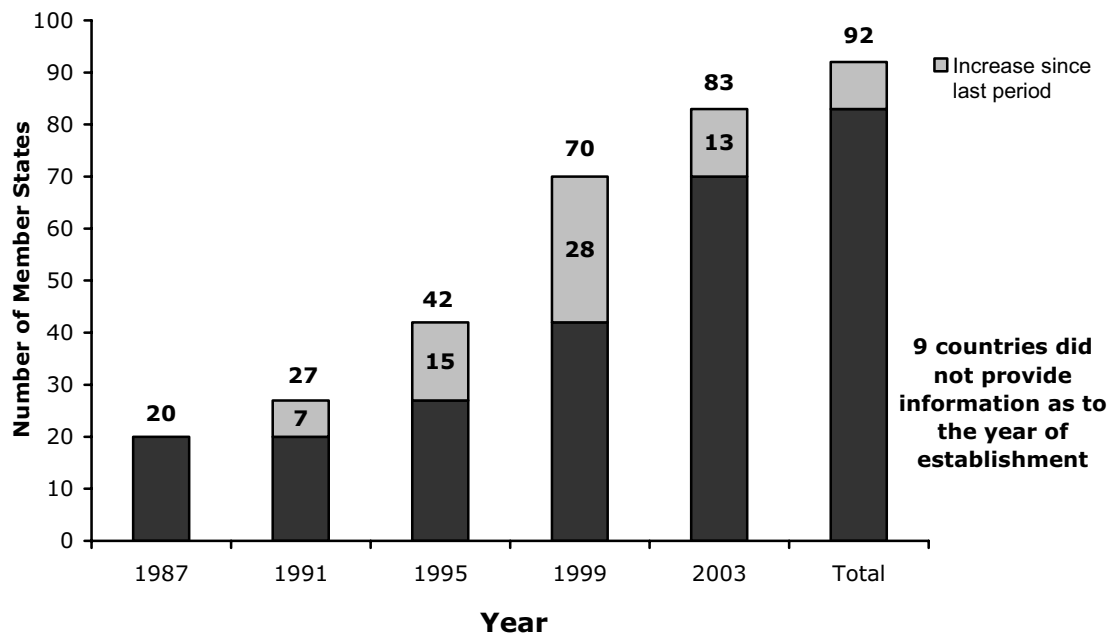
Survey responses indicate that a majority of responding Member States (92 countries, 65%, Figure 12) have laws or regulations on herbal medicines.

Figure 12. Laws or regulations on herbal medicines



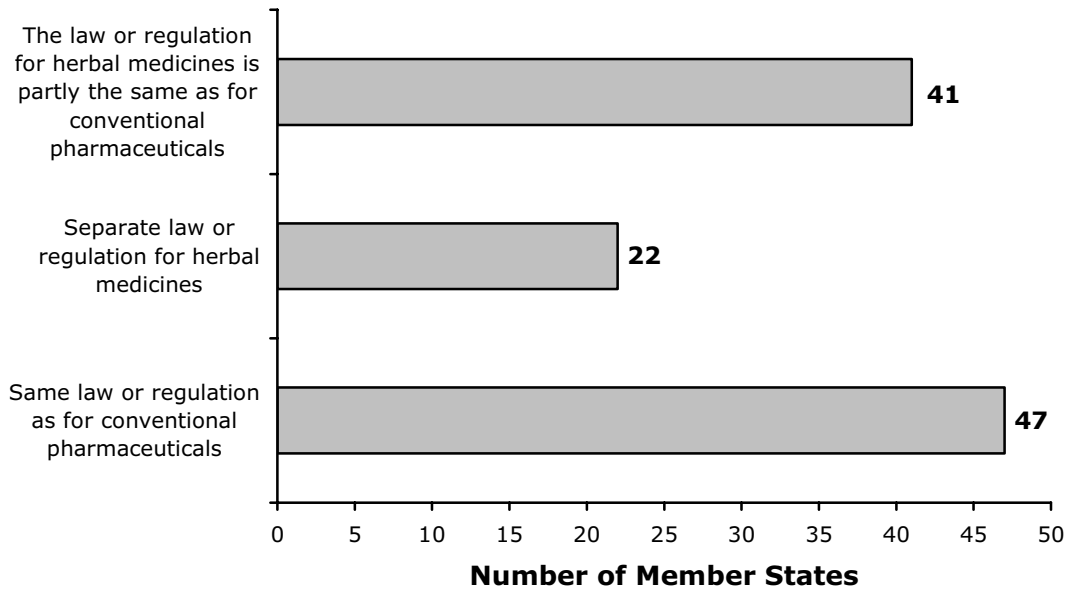
Information provided by 77 of the responding Member States about the year of issue of the law or regulation indicates clearly that the development of laws and regulations on herbal medicine is a recent phenomenon (Figure 13). Over the last 15 years, the number of Member States with laws and regulations 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.

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.

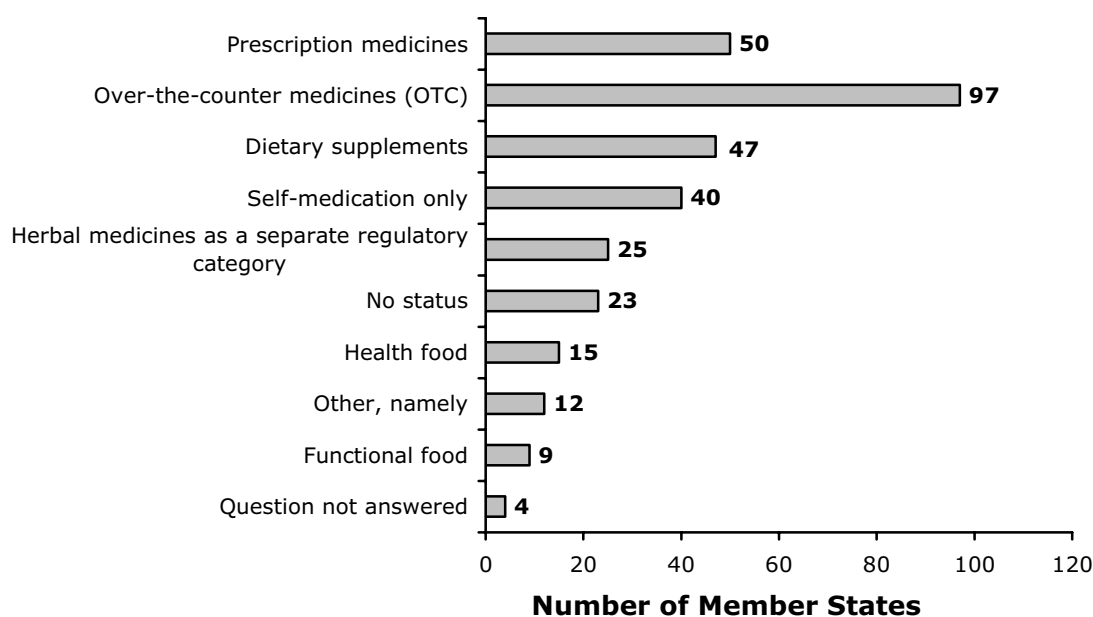
- **Prescription medicines:** medicines/drugs that can only be purchased with a prescription (i.e. a physician's order) (6).¹
- **Over-the-counter medicines:** medicines/drugs that can be purchased without a prescription from a physician (6).
- **Self-medication only:** medicines/drugs permitted for 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.

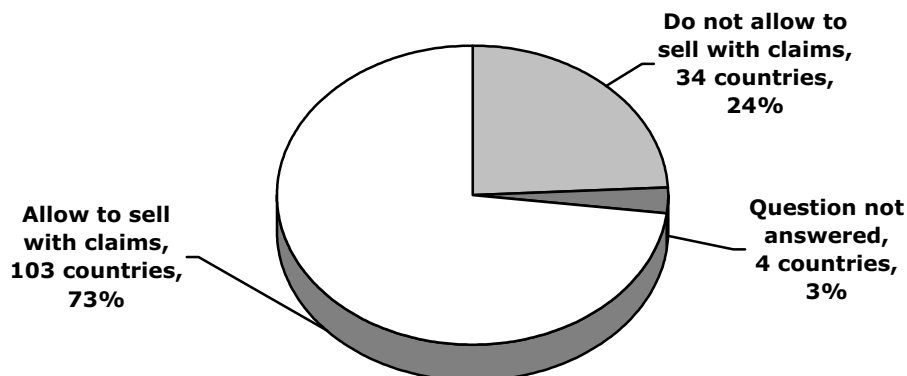
For the purposes of this study, medical claims are defined as those claims specified to treat, cure or prevent a disease or restore, correct or modify physiological functions. Most often products with medical claims have to be registered by the medical products agency before they may be placed on the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



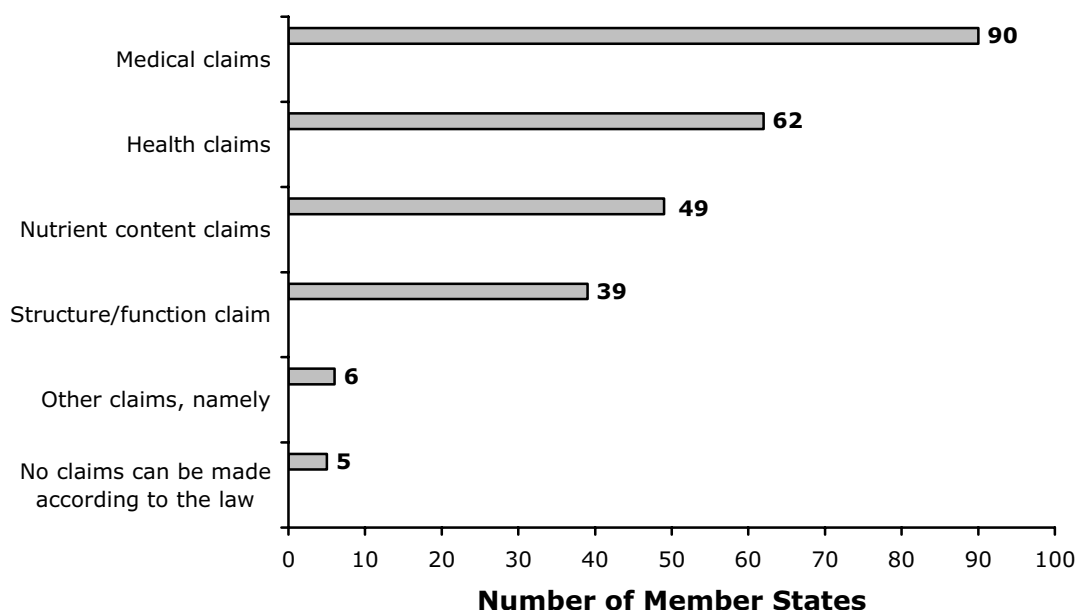
Of those countries indicating that herbal medicines are sold with claims, all 103 provided details about the categories of claims that are allowed by law or regulation (Figure 17). The most common claims made are medical claims, which was chosen by 87% of the responding countries. Health claims were 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



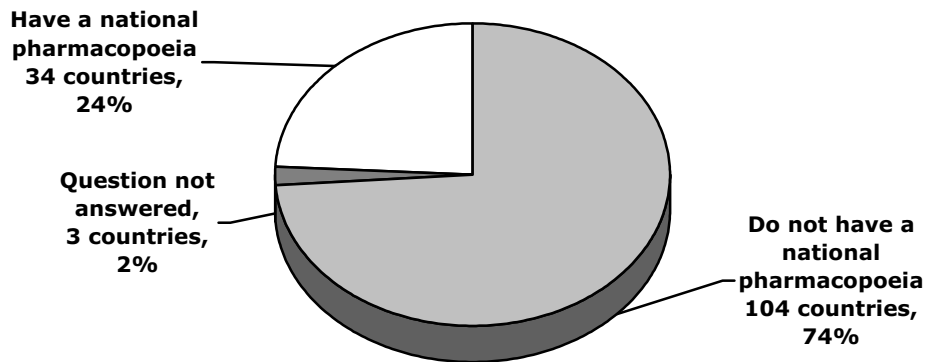
3.4 Pharmacopoeias

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

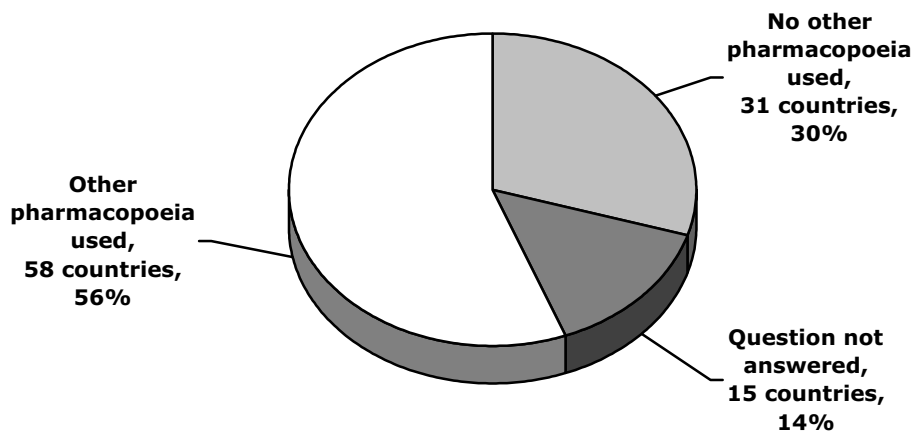
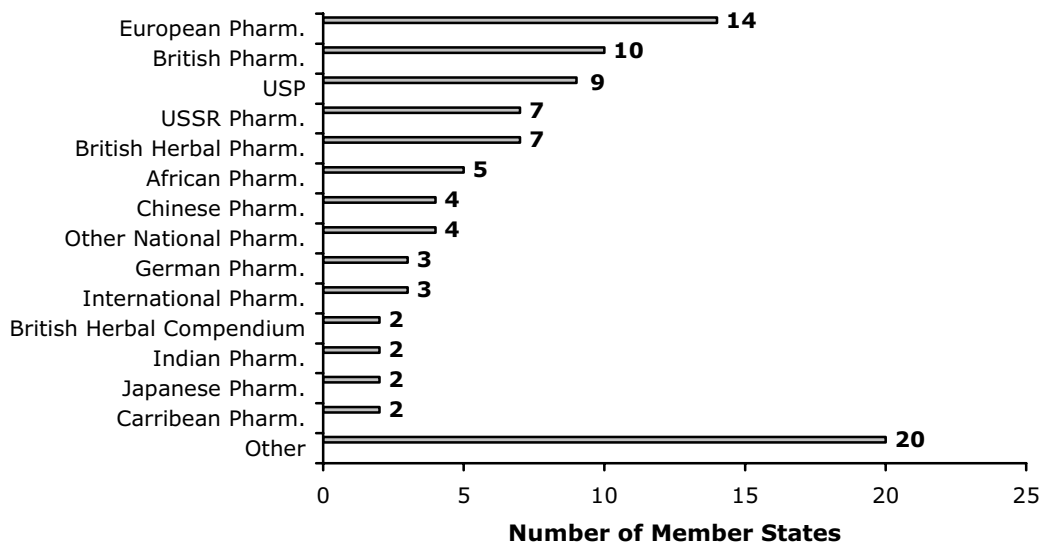


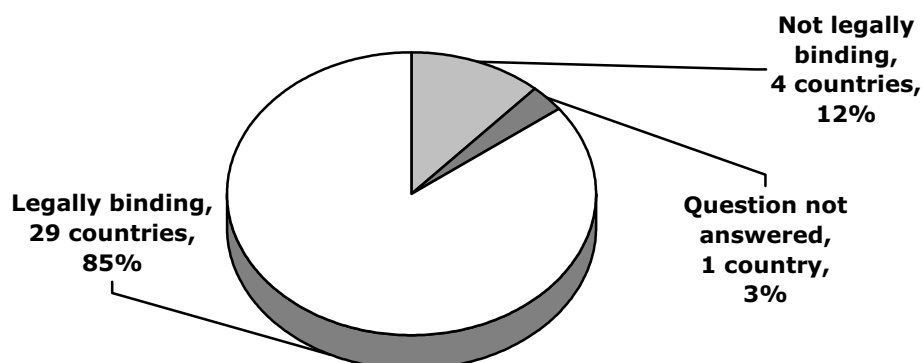
Figure 20. Details of other pharmacopoeias used



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

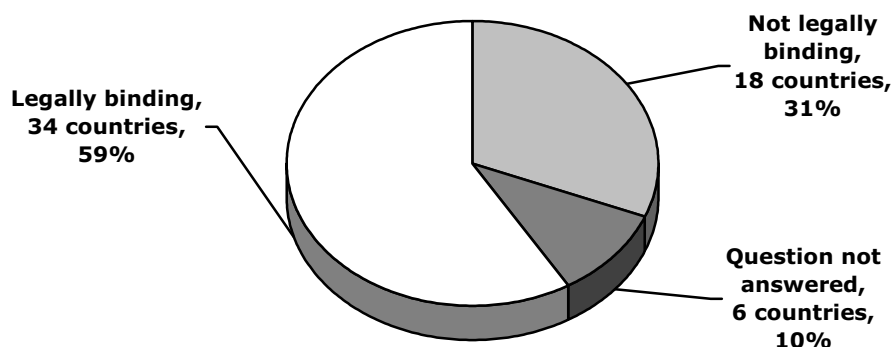
Finally, countries were asked about the legal status of the national or other pharmacopoeia used (Figure 21 and Figure 22). In 85% of the 34 countries with a national pharmacopoeia, the information it contains is legally binding. In 59% of the 58 countries using another pharmacopoeia, the information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

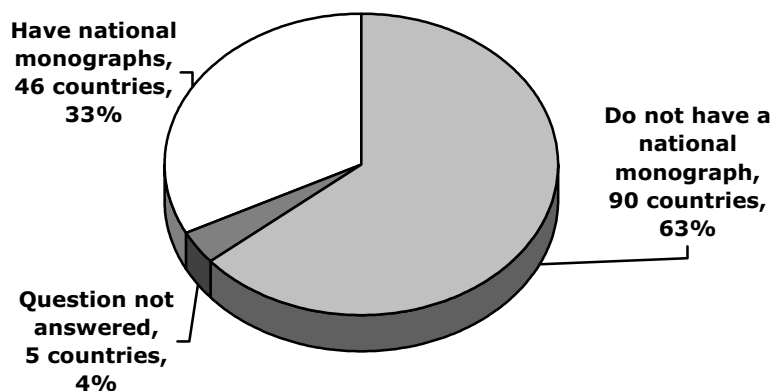


3.5 Monographs on herbal medicines

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.

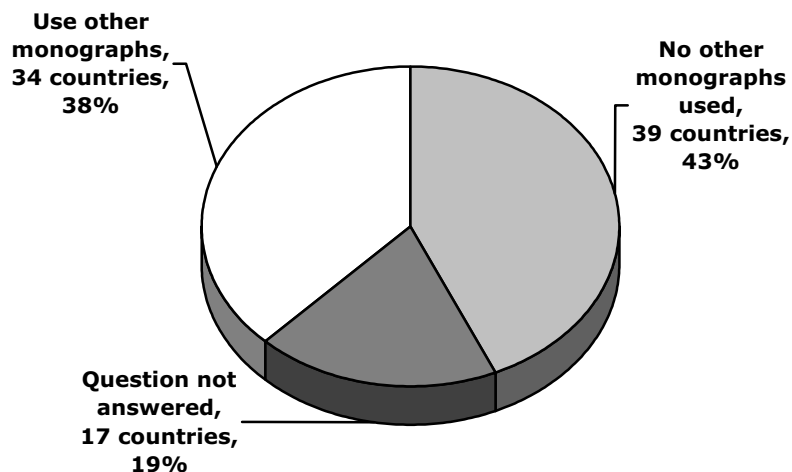
Of the responding Member States, 46 (33%) reported that they had national monographs on herbal medicines (Figure 23): furthermore, of the 84 countries that reported not having national monographs, 25 (28%) indicated that national monographs were in development.

Figure 23. National monographs on herbal medicines



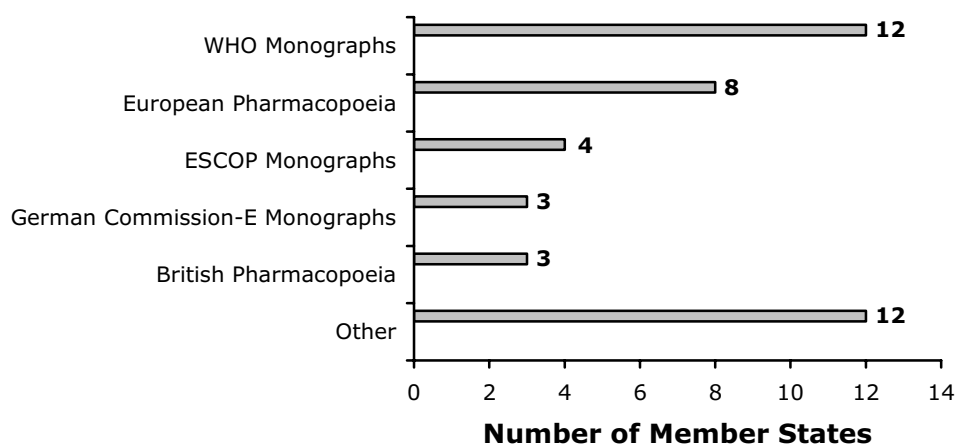
Of the 84 countries which lack national monographs, 38% (34 countries) reported the use of other monographs, as illustrated in Figure 24.

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

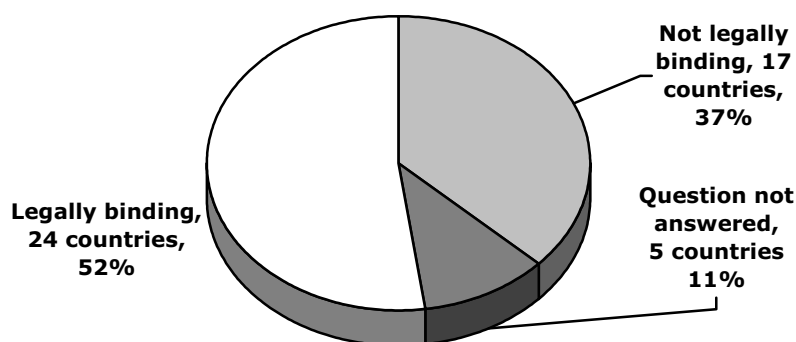
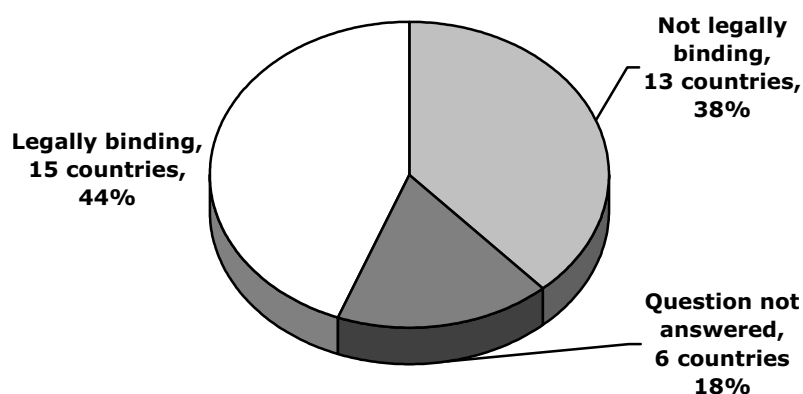


Figure 27. Legal status of other monographs



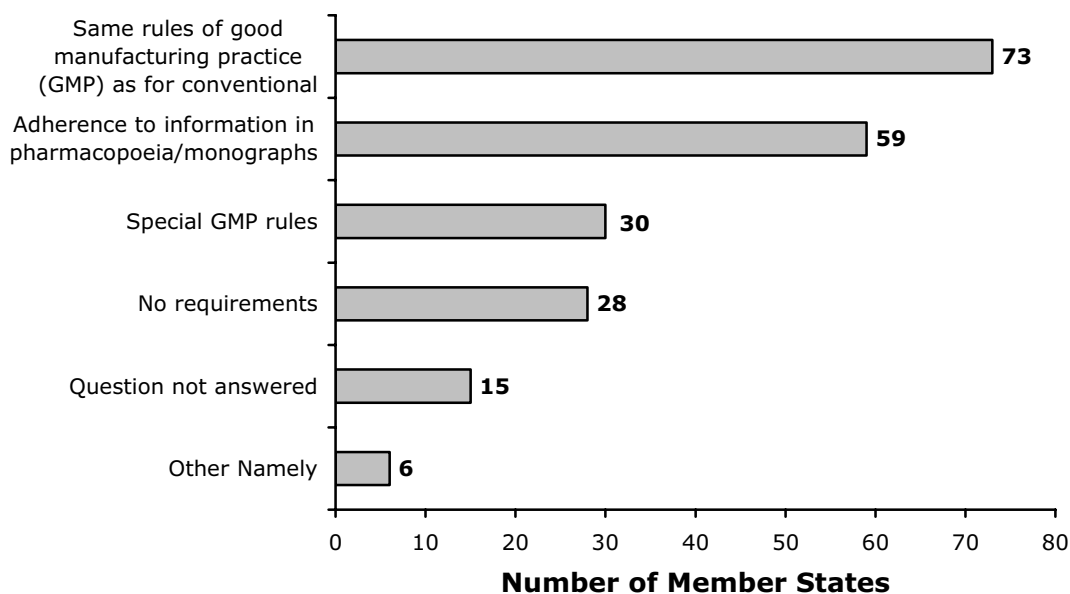
3.6 Manufacture of herbal medicines

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

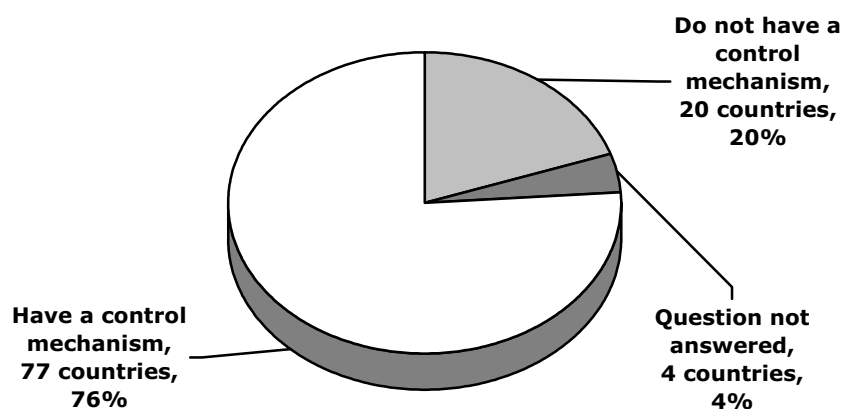
to information in pharmacopoeias or monographs. Six countries provided additional regulatory requirements for manufacturing; these included the following: good hygienic practices, some elements of GMP (requirements about documentation, licensing of manufacture, packing, marking, design of pharmaceuticals), 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



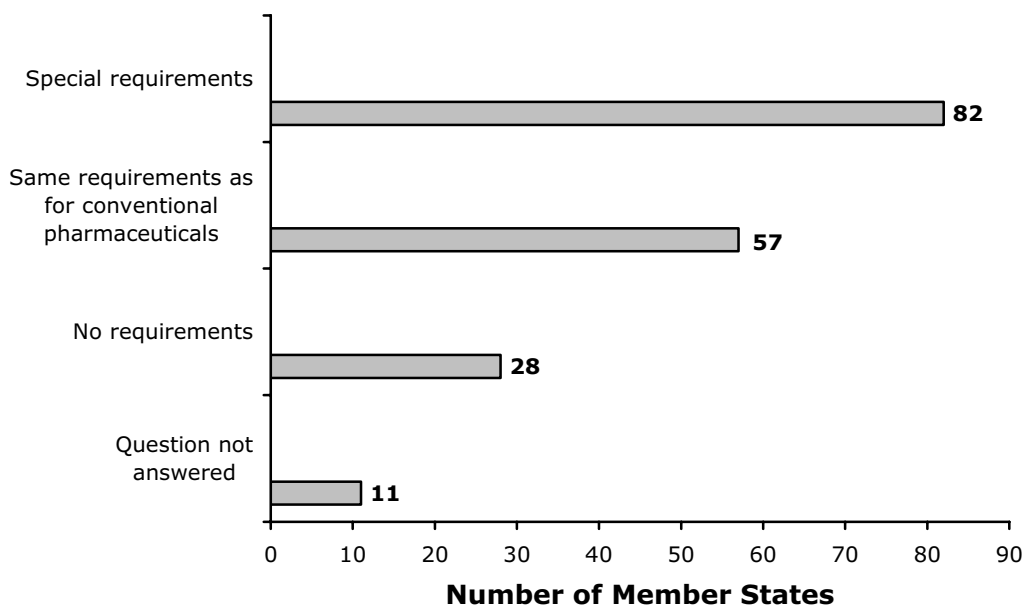
Many responding countries provided details on the type of control mechanism used to ensure implementation of manufacturing regulatory requirements. Out of these, the most commonly cited control mechanisms were inspection and licensing of products or manufacturers.

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.

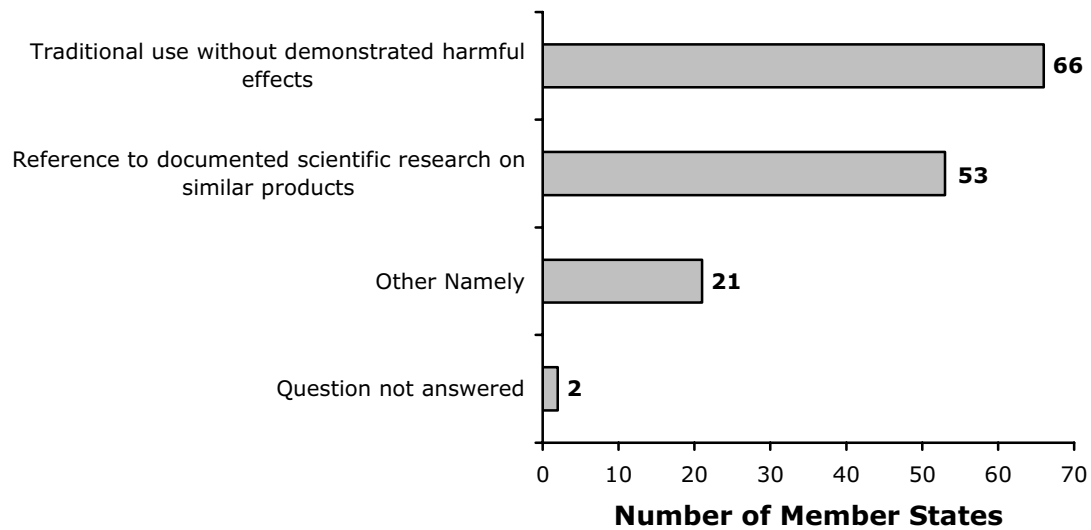
A total of 130 Member States responded to this question: however, as respondents were asked to choose all that applied, there are more responses than respondents for this question (Figure 30). Eighty-two countries indicated that special regulatory requirements exist for herbal medicine. Of the remaining 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.

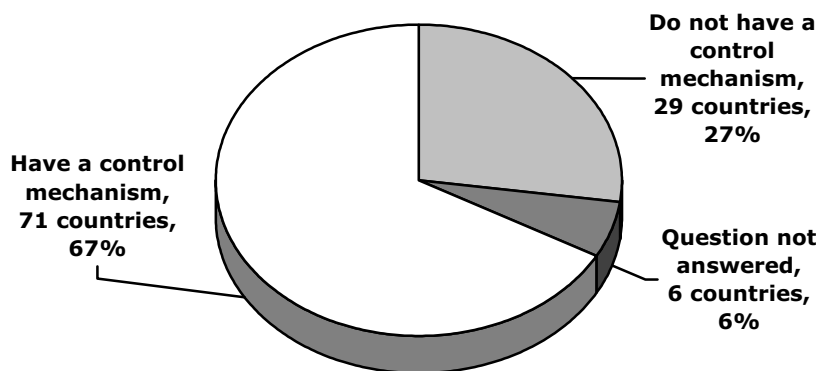
Figure 31. Special regulatory requirements for safety assessment of herbal medicines



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.

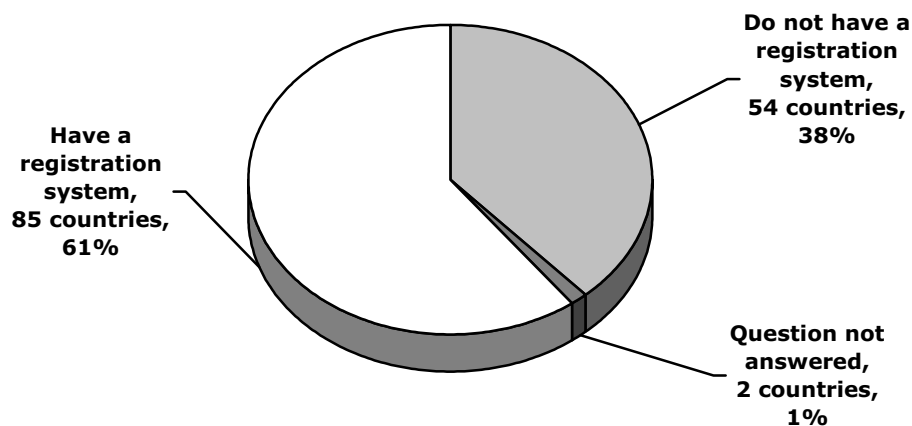
Figure 32. Existence of a control mechanism for safety requirements



3.8 Registration system for herbal medicines

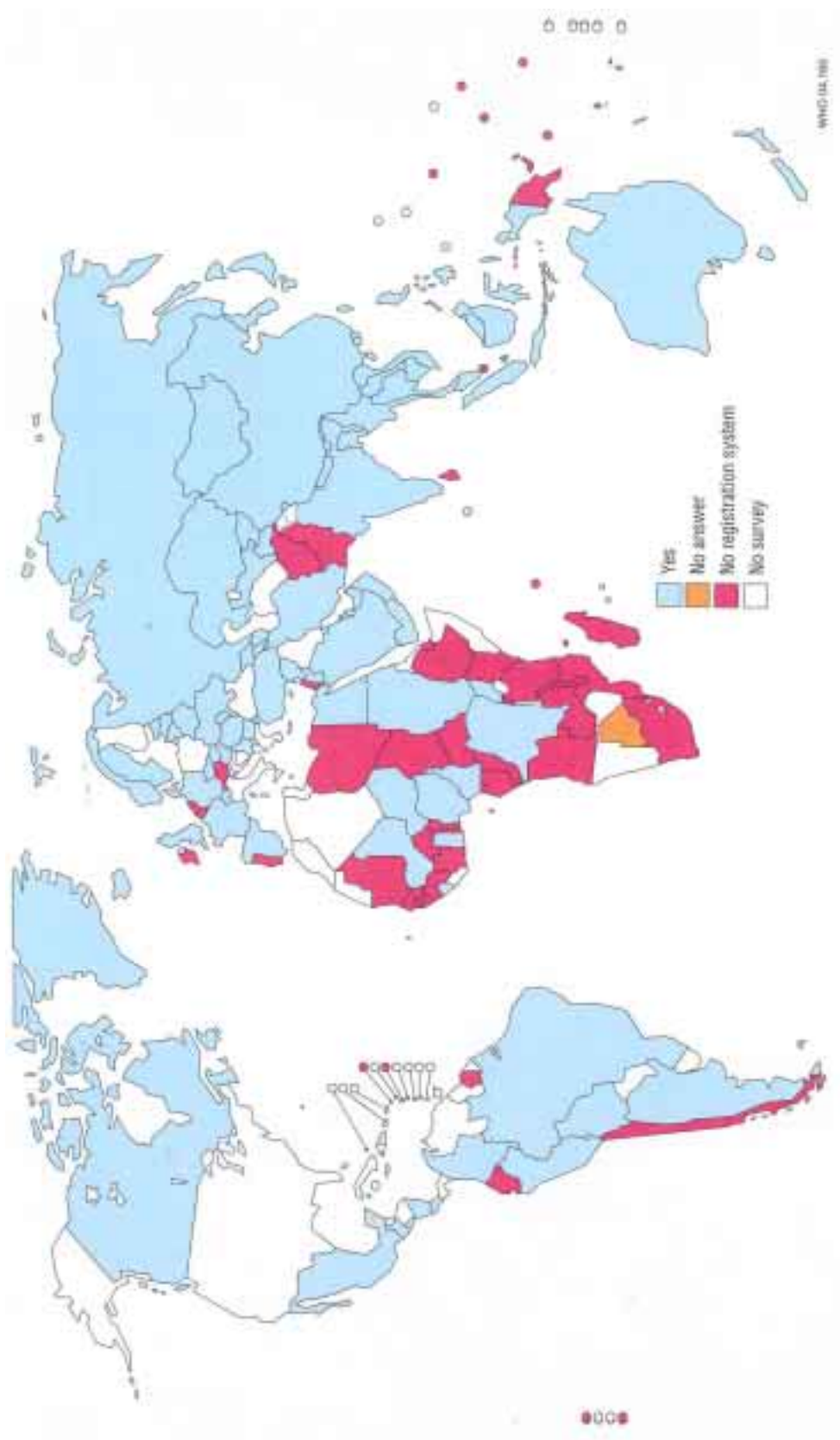
Countries were asked whether a registration system exists for herbal medicines; 139 countries answered the question. Eighty-five countries (61%) reported that they have registration systems for herbal medicines (Figure 33).

Figure 33. Registration system for herbal medicines



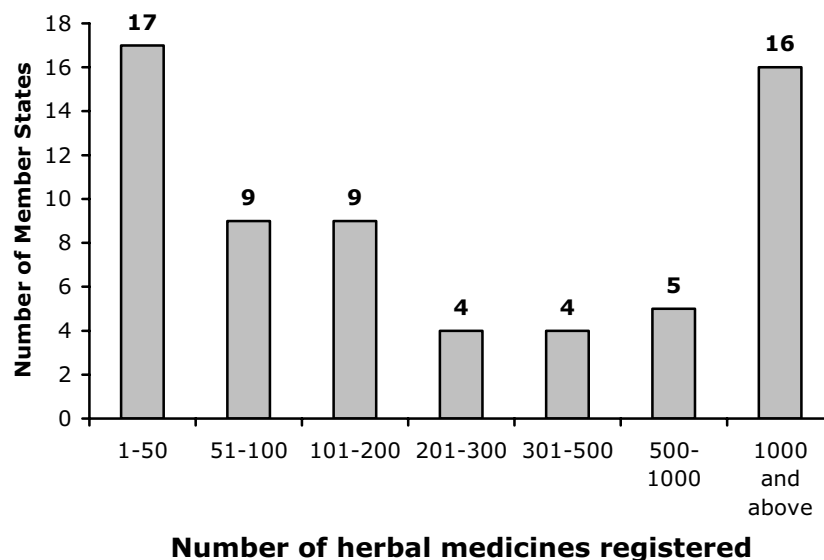
The countries with registration systems for herbal medicines are indicated on the map below (Map 7).

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

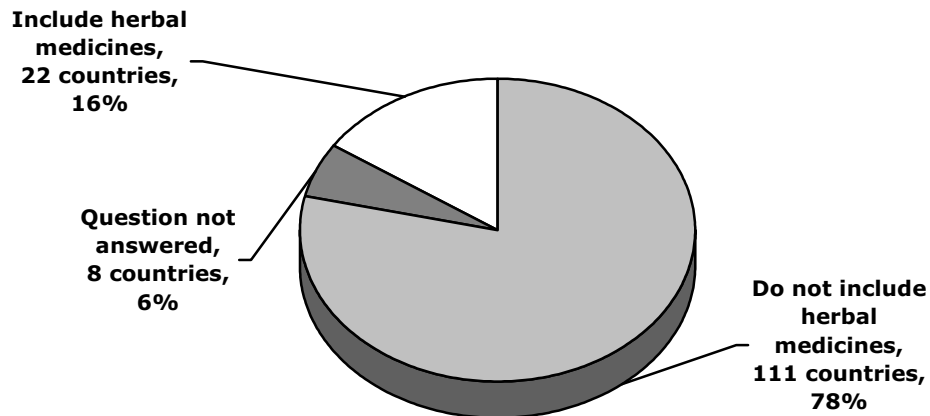


3.9 Herbal medicines and the essential drug list

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.”

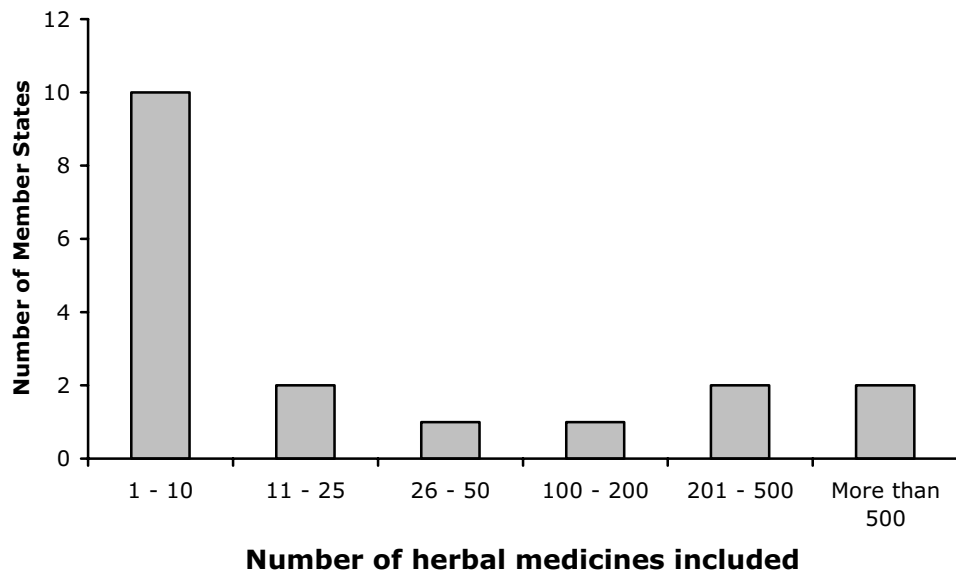
Member States were asked whether herbal medicines are included in the national essential drug list. One hundred and thirty-three countries answered this question, with 22 countries (16%) indicating that herbal medicines are included on the essential drug list (Figure 35). However, Member States were 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



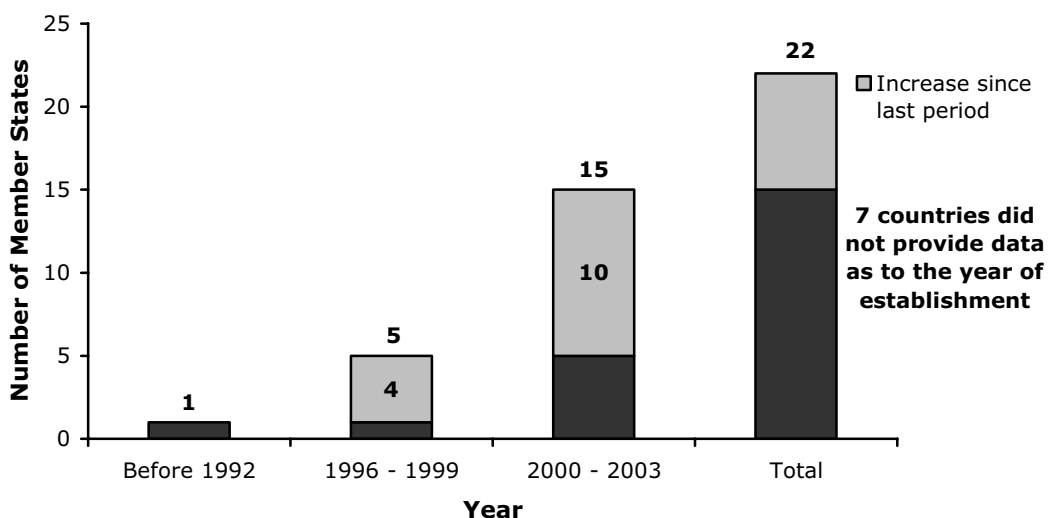
Of the 22 countries reporting the inclusion of herbal medicines on their essential drug list, 18 provided the number of herbal medicines listed (see Figure 35). The majority of countries had listed between one and 10 herbal medicines; however, a number of countries reported including more than 100 medicines. 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

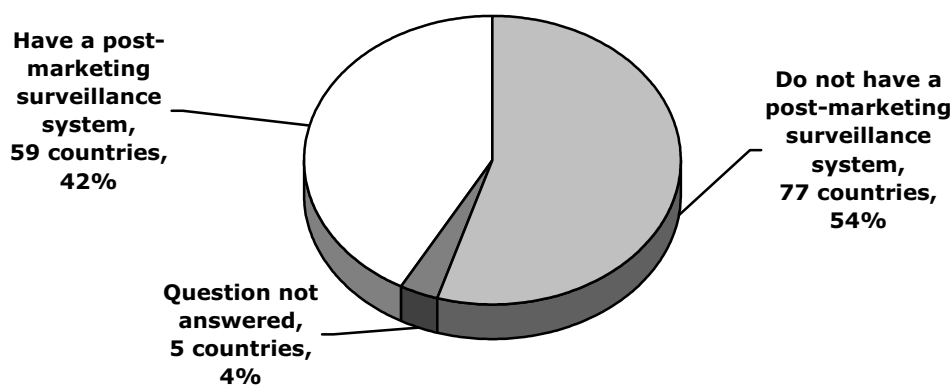


3.10 Post-marketing surveillance of herbal medicines

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

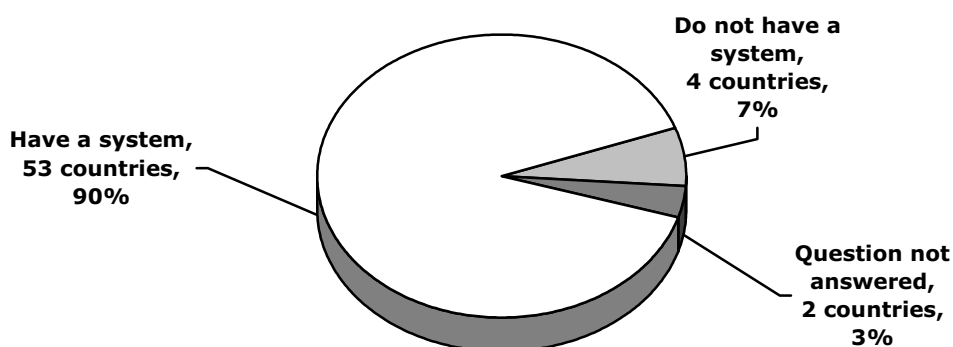
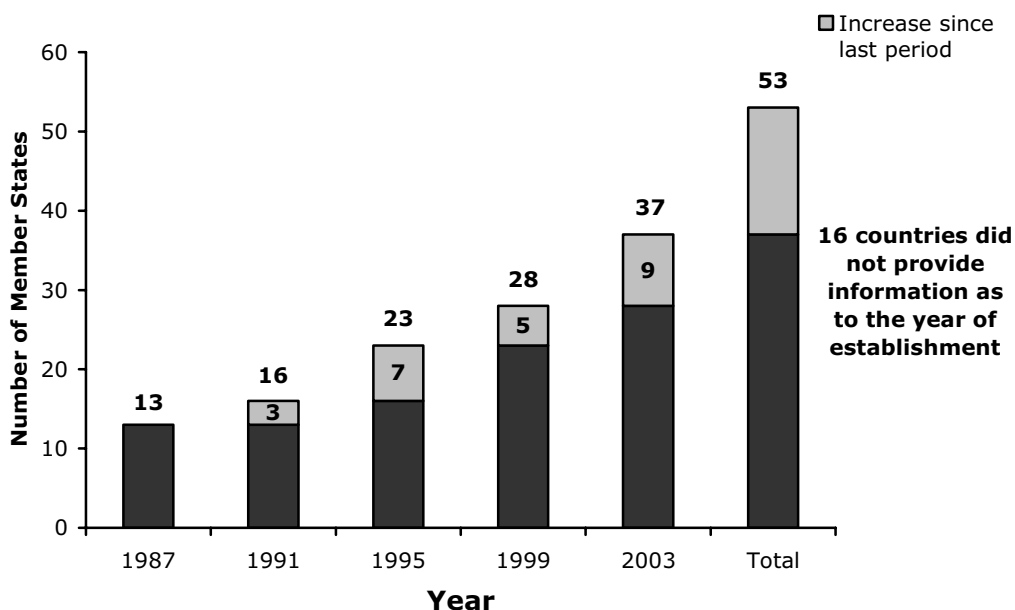


Figure 40. Number of Member States with a national system to monitor adverse effects relating to herbal medicines, by year



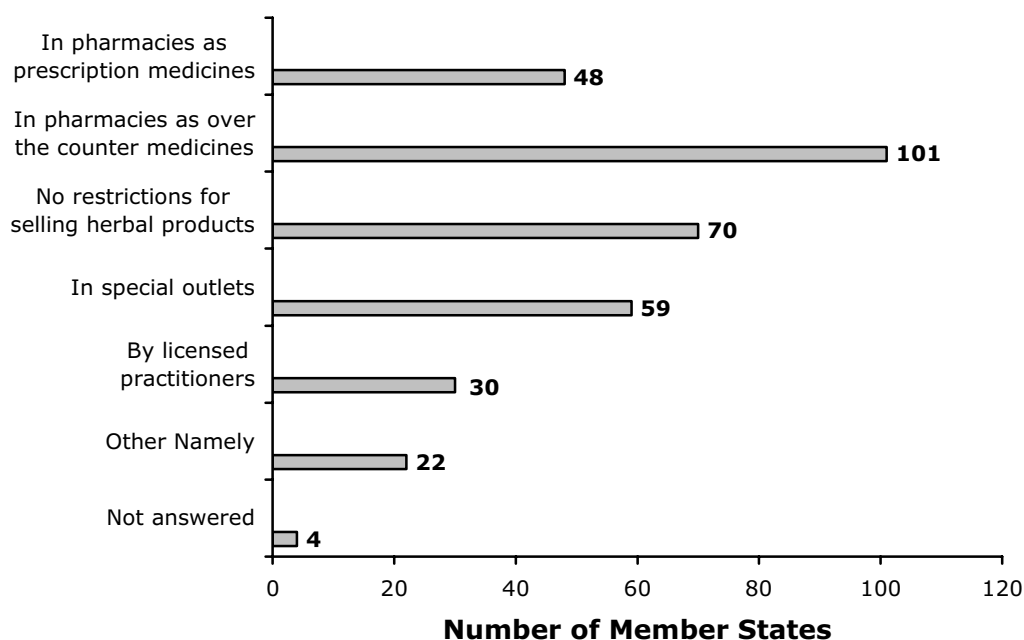
3.11 The sale of herbal medicines

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

