

## References

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2. *WHO traditional medicine strategy, 2002-2005* (document WHO/EDM/TRM/2002.1). Geneva, World Health Organization, 2002).
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4. *Legal status of traditional medicine and complementary/alternative medicine: a worldwide review* (document WHO/EDM/TRM/2001.2). Geneva, World Health Organization, 2001.
5. Brudon-Jakobowicz P, Rainhorn J-D, Reich MR. *Indicators for monitoring national drug policies – a practical manual*, 2<sup>nd</sup> ed. (WHO/EDM/PAR/99.3). Geneva, World Health Organization, 1999 ([http://www.who.int/medicines/library/par/indicators/who\\_edm\\_par\\_993.shtml](http://www.who.int/medicines/library/par/indicators/who_edm_par_993.shtml), accessed 29 December 2004).
6. *Dorlands illustrated medical dictionary*, 29<sup>th</sup> ed. Philadelphia, WB Saunders Company, 2000.
7. Chang J. Scientific evaluation of traditional Chinese medicine under DSHEA: a conundrum. *Journal of Alternative and Complementary Medicine*, 1999, 5:181-189.
8. *CSPI reports: international functional foods: public health boon or 21<sup>st</sup> century quackery?* Washington, D.C., International Association of Consumer Organizations, 1999 ([http://www.cspinet.org/reports/functional\\_foods/index.html](http://www.cspinet.org/reports/functional_foods/index.html), accessed 29 December 2004).
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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**

<b>Date:</b>
<b>Country:</b>
<b>Name of Investigator:</b>
<b>Title of Investigator:</b>
<b>Address:</b>
<b>Telephone:</b>
<b>Fax:</b>
<b>E-mail:</b>

## **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 systems<sup>1</sup>.

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 medicines<sup>2</sup>.

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.

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

<sup>2</sup> 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*, 2<sup>nd</sup> 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 present<sup>1</sup>.

**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 function<sup>2</sup>.

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

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## Law & Regulation

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### 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

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**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 order<sup>1</sup>.

**Over the Counter Medicines:** Medicines/drugs that can be purchased without a prescription from a physician<sup>1</sup>.

**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 ingredients<sup>2</sup>.

**Health Food:** Health foods could be products that are presented with specific health claims and therefore regulated differently than other foods<sup>3</sup>.

**Functional Food:** Like health foods, functional foods could be products presented with specific health claims and therefore regulated differently than other foods<sup>3</sup>.

**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*, 29<sup>th</sup> 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 21<sup>st</sup> century quackery?* Washington, D.C., International Association of Consumer Organizations, 1999 ([http://www.cspinet.org/reports/functional\\_foods/table1.html](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.

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## Claims

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### 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.<sup>1</sup>

**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"<sup>2</sup>.

**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 fat<sup>2</sup>.

**Structure/functional claims:** These claims link a substance to an effect on a structure or function of the body<sup>3</sup>.

**Source:** 1. Joint Health Claims Initiative Body, [www.jhci.co.uk](http://www.jhci.co.uk). 2. Swedish Food Administration-  
[www.slv.se](http://www.slv.se). 3. CSPI reports: international functional foods: public health boon or 21<sup>st</sup> century quackery? [www.cspinet.org/reports/functional\\_foods/table1.html](http://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



### 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:** \_\_\_\_\_

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**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.

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### 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.

	<b>HERBAL MEDICINES ANNUAL SALES</b>			
YEAR				
<b>MARKET SALES</b>				
TYPE OF DATA/ESTIMATE				
YEAR				
<b>MARKET SALES</b>				
TYPE OF DATA/ESTIMATE				
YEAR				
<b>MARKET SALES</b>				
<b>TYPE OF DATA/ESTIMATE</b>				

### **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
- Lack of expertise within the national health authorities and control agency
- Lack of appropriate mechanisms for control of herbal medicines
- Lack of education and training
- 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.

	<b>MUCH NEEDED</b>	<b>NEEDED</b>	<b>NOT NEEDED</b>
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?**

- 
- As a descriptive report
- As a condensed report with results presented in figures/tables
- Results/analysis presented in a database

**Other suggestions:**

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