INTERNATIONAL AYURVEDA FOUNDATION
(For reply email: prcpatel@vsnl.com)
Questionnaire On the
European Union's Traditional Herbal Medical products Directive (THMPD) and UK Implementing Measures

The International Ayurveda Foundation (IAF) is concerned about the impact new regulations and laws in the European Union on the practice and products of Ayurveda in Europe after April 2011. The most important legal instrument is the EU Directive called the Traditional Herbal Medicinal Products Directive 2004/24/EC (THMPD) and UK Implementing Measures, which is summarized below. The IAF has decided to understand how a range of people associated with Ayurveda in Europe—whether practitioners, manufacturers, exporters/importers conducting this survey of Ayurveda practitioners, manufacturers and traders to build a sound base for legal action to lift the burden of the EU's THMPD on all our work. It is very important to secure your views on how THMPD will impact on you. Your experience will assist us in reforming the Directive. We would therefore be most grateful if you could fill the questionnaire in. We will respect your confidentiality in analysing and making use of the results, and any quotations will be presented according to the choice you indicate

Please state your preference:

a. I consent to be quoted by name.
b. I consent to be quoted anonymously
c. My remarks may not be used, but responses to questions may be used.

Summary of the Directive

Medicinal products are defined under the Directive as medicinal products containing exclusively one or more herbal substances, provided that any extra vitamins or minerals are ancillary to those substances. There are two broad provisions that are relevant.

Provision 1: A traditional medicinal product will receive a traditional use registration if it satisfies the following conditions: that it is:- exclusively for administration in accordance with a specified strength and posology; for oral or external use and/or inhalation preparation; intended and designed for use without the supervision of a medicinal practitioner; has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the European Community (the 15 year rule); proves not to be harmful in the specified conditions of use (this criterion is to be demonstrated by bibliographical or expert evidence); and the pharmacological effects or efficacy of the product are plausible on the basis of long-standing use and experience

Provision 2: In order to demonstrate 'quality, safety and efficacy' under the traditional use registration scheme of the THMPD 2004/24 EC the following criteria must be demonstrated:

Quality: The applicant should furnish all the quality requirements applicable to licensed medicines under Directive 2001/83 EC. Therefore, compliance with Good Manufacturing Practice (GMP) will be required, plus a manufacturer's licence, a wholesale dealer's licence or a wholesale dealer's (import) licence as appropriate. Holders of such licences will need to have available the services of a Qualified Person (QP).

Safety: A bibliographic review of safety data together with an expert report is required. The products, including their indications, must be suitable for over-the-counter sale. Agreed medicinal indications will be permitted, which will be limited to indications adapted for traditional herbal products for use without the advice or intervention of a medical practitioner.

Efficacy: There is no requirement to present data on tests and trials relating to efficacy. The required evidence of the medicine's use for at least 30 years will be indicative that there may well be as least some evidence as to the efficacy of the medicine. The labeling of the product will reflect this position with the wording: 'traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use'.

QUESTIONNAIRE

Please answer all the questions that are relevant to you. If you need extra space, please attach additional information on a separate sheet of paper. Please also provide any information that you think is relevant where we have not asked for it. Your confidentiality, but our case will be stronger if you consent to the use of quotations anonymously. (***Wherever the responses are numbered, or expect to be in numbers (for instance, number of years), please fill in your response number in the box on the left side of the margin of that question.***)

BACKGROUND

1. Name :

2. Designation: (*if you represent an organisation*)

3. Professional degree in Ayurveda (*if any*)

4. Gender: 1 Male 2 Female

5. Age: (*Actual in years*)

6. Address

   Contact Details:
   Telephone (work):

   (cell phone)

   Email address(es)

7. Are you (please fill the box with the correct category)?

a. Manufacturer	2 Yes	1 No (*If yes, please skip to q.9*)
b. Trader	2 Yes	1 No (*If yes, please skip to q.10*)
c. Practitioner	2 Yes	1 No (*If yes, please skip to q.11*)
d. Researcher	2 Yes	1 No (*If yes, please skip to q.12*)
e. Health administrator	2 Yes	1 No (*If yes, please skip to q.13*)

8. What organisation do you work in or for?

01. Individual practice	02. Group practice
03. Manufacturing Company	04. Trading Company
05. Hospital/ Public Health Unit	06. Medical Research
07. NGO	97. Other
98. Don't know	99. N.A.

9. ***If you are a manufacturer:***
   a. How long have you been manufacturing Ayurvedic medicines? (*give actual years*)

b. Please give details of your place(s) of manufacture.

c. What is the product range you manufacture?

d. How long have you been exporting Ayurvedic products to the EU? (*give actual years*)

e. In what forms have you exported them? Please list.

f. Under what rules have you been able to export/import so far?

10. ***If you are a trader:***

a. How long have you been trading in Ayurvedic medicines? (*give actual years*)

b. Which places in India and the EU have you traded between? Please give details.

c. What are the products you have traded in?

d. For how long have you been exporting Ayurvedic products to the EU? (*give actual years*)

e. In what forms have you exported them? Please list.

f. Under what rules have you been able to export/import so far?

11. ***If you are a practitioner,***

a. How long have you been practicing? (*give actual years*)

b. Where do you practice?

c. What forms of treatment do you provide?

d. Under what rules do you practice?

e. Do you have records of your patients? 2 Yes 1 No

f. Have you been following any particular disease entity or kind of patient in your practice?
2 Yes 1 No

g. Is there any other specialty of your practice that you would like to state?
2 Yes 1 No

(*If yes*) Please mention

12. ***If you are engaged in research***

a. Please describe your research on Ayurvedic products

b. Please give details of the relevance of the research to the qualifying criteria of the Directive set out above.

c. How long have you been conducting this research? (*give actual years*)

d. Have any results been published or are about to be published? 2 Yes 1 No

13. ***If public health administrator, background of the public health administrator***

a. For how long have you been involved in this field? (*give actual years*)

b. Which geographical areas have you worked in?

c. What kinds of policy level involvements have you had?

d. What kinds of responsibilities have you shouldered in your job?

AWARENESS AND INFORMATION

On the THMPD regulations themselves:

14. Here are the major clauses of the THMPD regulations for Ayurvedic medicines. Which of these would you say which of these you had heard about before beginning to read this questionnaire? *Please put the relevant numeral in the box on the left.. For example, if you had heard of Provision 1 somewhat, then please put 3 in the box on the left. (The numerals are for coding and for interpretation later purpose-they do not show a grading of your response*)

	Fully	Somewhat	Not heard of	heard of, but not fully understood
a. Provision 1	4	3	2	1
b. Provision 2	4	3	2	1

15. How did you come to know about them?
    1. Through the ADMA
    2. From the newspapers/ special Pharma supplements/
    3. Pharmaceutical industry magazines
    4. From casual conversation amongst people in the industry
    5. Any other source (*please specify*)

16. The last few years have seen a fair amount of discussion in different kinds of media on issues around CAM in general and Ayurveda in particular. We would like to know how you rate these discussions with respect to the issues raised. *Please code the numeral in the relevant box.*

Name of the issue	Coverage			Fairness of coverage		
	Adequate	Inadequate	Generous	Supportive	Objective	Hostile
a. The Robert Saper paper	1	2	3	3	2	1
b. The Walton Committee Report	1	2	3	3	2	1
c. Research on Ayurveda done by the NIH in the US	1	2	3	3	2	1
d. The WHO Policy Document on Traditional Medicine (2002)	1	2	3	3	2	1
e. The Government of India policy document on Traditional Medicine (2002)	1	2	3	3	2	1
f. Research done on Ayurveda in India	1	2	3	3	2	1
g. The setting up of the Traditional Knowledge Digital Library in India	1	2	3	3	2	1

CONSULTATIONS

17. Were you consulted by EU or UK authorities regarding the drafting or implementation of the THMPD 2004/24/EC or UK implementing legislation?

    2 Yes 1 No

    (*If yes*), please specify the agency that consulted you and the nature of consultation

18. Have you or your organisation been directly affected by the THMPD to your detriment in employment related difficulties?

2 Yes 1 No

a. *If yes*, what are the difficulties? (*Please Code in the box as many as are applicable in your case.*)

1. Been unable to move freely within the territory of Member States to accept offers of employment, stay in a Member State for the purpose of employment, or to remain in the territory of a Member State after having been employed in that State
2. Been unable to provide or receive services in another Member State (services defined as Economic/commercial activity on a temporary basis) unable to exercise the right to pursue Self-employed activity,
3. Been unable to move goods freely Suffered a substantial interference with the enjoyment of possessions

19. Have you personally been asked for advice or furnishing of information on your knowledge for the purpose of policy-making? 2 Yes 1 No

20. Have you ever deposed before any Commission of Enquiry in response to queries about your system? 2 Yes 1 No

(*If yes*), Please give instances and we request you to attach a copy of your deposition.

ASSESSMENT OF THE IMPACT OF THMPD ON AYURVEDA PRODUCTS

21. On looking at the THMPD regulations, what do you think would be the implications for the products you export/import to the EU:

a. On safety

i. Do you think that your product may be declared unsafe?
2 Yes 1 No 8 Can't say

ii. Do you think you may be asked to prove safety standards that you are not aware of?
2 Yes 1 No 8 Can't say

iii. Do you think you may be asked to provide safety indicators that are too expensive for your company?
2 Yes 1 No 8 Can't say
(*If no*), then what plans do you have to execute these?

iv. Do you think you may be asked to provide safety indicators that are irrelevant to your products?
2 Yes 1 No 8 Can't say

v. which of the regulatory provisions on safety do you think are irrelevant? Please name these.

vi. Please list why you think these are irrelevant.

b. On Quality

i. Do you think that your product maybe declared below the quality required in Europe?
2 Yes 1 No 8 Can't say

ii. Do you think you may be asked to prove quality standards that you are not aware of?
2 Yes 1 No 8 Can't say

iii. Do you think you may be asked to provide quality indicators that are too expensive for your company? 2 Yes 1 No 8 Can't say

(*If no*), then what plans do you have to execute these?

iv. Do you think you may be asked to provide quality indicators that are irrelevant to your products?

2 Yes 1 No 8 Can't say

v. Which of the regulatory provisions on quality do you think are irrelevant? Please name these.

vi. Please list why you think these are irrelevant.

22. Any other experience that you may have to share that is relevant to this, please state here

ASSESSMENT OF REGULATIONS

23. Do you feel that the THMPD safety, efficacy and quality requirements are appropriate and necessary for regulating the safety, quality and efficacy of Ayurvedic medicinal products and other TSMs?

	Necessary	Appropriate
a. Safety requirements	2	1
b. Efficacy requirements	2	1
c. Quality requirements	2	1

(*Can you please give reasons for your answer? Please use supplementary sheets*).

24. Here are some key points that have come up during the debates concerning THMPD. We would like to have your views on these. Please say if you agree (strongly agree or agree) or disagree (strongly disagree or strongly disagree) with the following. *Please Code the numeral in the relevant box. For example, if you agree, Code 3 (The numerals are for coding and later interpretative purpose-they do not show a grading of your response).*

Statements	Strongly agree	Agree	Disagree	Strongly disagree	Don't know/ Can't Say
a. The long use clause will exclude all Ayurveda products that do not have a documented usage history for 15 years in the EU	4	3	2	1	8
b. The 'traditional use' clause, which only recognizes individual herbal agents, will exclude Ayurvedic medicines because most of them are compound drugs.	4	3	2	1	8
c. The classification of Ayurveda as 'herbal' will mean that all products that use raw materials other than herbs will not be eligible for import.	4	3	2	1	8
d. Ayurvedic medicinal products which are not taken orally, externally or through inhalation will not be eligible for THMPD traditional use registration.	4	3	2	1	8
e. Ayurvedic medicinal products which are not Over the Counter (OTC) medicinal products and must be administered through an Ayurvedic practitioner will not be eligible for THMPD traditional use registration.	4	3	2	1	8
f. Traditional herbal medicinal products originating outside the EU receive less favourable treatment than like products originating within the European Union.	4	3	2	1	8
g. The THMPD was designed to discriminate between EU medical products and those of Ayurveda.	4	3	2	1	8

25. For manufacturers and traders: considering what you already know of the THMPD regulations, what do you think could be the possible impact on each of the products you export/import to the EU? (We *have given space for two products, please add more rows if necessary*).

Products	Possible Impact
1	
2	

SCIENTIFIC OBJECTIVITY OF THE THMPD

26. How would you rate the quality of scientific assessment and advice on which THMPD is based on the basis of criteria below? *Please rate it on a scale of 1-10, where 1 is poor and 10 is excellent.*

a. Transparency

b. Excellence

c. Independence

d. Objectivity

ALTERNATIVES

27. Which of the methods of regulation of the safety of Ayurvedic products in India are you expected to comply with? Please list them here.

28. Are you aware of the following methods of regulation of the safety of Ayurvedic products?

a. Reverse Pharmacology	2 Yes	1 No	8 Can't say
b. Phytopharmacology	2 Yes	1 No	8 Can't say
c. Pharmacovigilance	2 Yes	1 No	8 Can't say
d. Whole systems testing	2 Yes	1 No	8 Can't say

Any other information you would like to provide .....