Press Release

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International Ayurveda Foundation

Traditional Herbal Medicinal Products Directive 2004/24/EC
Executive Summary of the Legal Advice

Introduction

The International Ayurveda Foundation (IAF) - UK, Switzerland and India, is concerned about the impact of new regulations and laws in the European Union on the practice and products of Ayurveda in Europe after 1st May 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. IAF had conducted a wide-ranging research survey during 2010 by circulating a Questionnaire to Ayurveda practitioners, manufacturers, exporters/importers. The Questionnaire can be viewed on our website: www.iaf-ngo.org under Publications page. The results of this survey were analysed by Dr. Yogendra Yadav, a well-known social scientist/psephologist and Dr. Madhulika Banerjee, a political scientist and author of "Power, Knowledge, Medicine – Ayurvedic Pharmaceuticals at Home and in the World" (published by Orient BlackSwan). The findings of this extensive survey will be put in public domain later. However, IAF fully understands how a range of people associated with Ayurveda in Europe are affected due to the impact of THMPD on Ayurveda and Traditional Systems of Medicine. An academic legal team, headed by Mr. Jonathan Butterworth, conducted a legal research on the impact of THMPD. IAF has now decided to release the Executive Summary of this academic Legal Advice. IAF is currently discussing various legal options and remedies available with eminent experts at the Bar on European and Human Rights Laws. We need to build a sound base for legal action to lift the burden of the EU's THMPD. In this regard, IAF has served a formal notice to European Union President His Excellency Mr. Jose Manuel Barroso on 19 October 2009. A copy of this notice is attached to this Executive Summary of Legal Advice. IAF is planning to hold a colloquium amongst its active advisors on Ayurveda soon before taking a final decision in the matter of the legal challenge.

Executive Summary of the Legal Advice

Directive 2001/83/EC requires that no medicinal products may be placed on the European market unless a Marketing Authorisation is obtained. In order to do so a product must satisfy a positive risk-benefit balance meeting the requisite 'quality, safety and efficacy' criteria. There are three types of marketing authorisation. Firstly, normal marketing application grants and secondly, well established marketing application grants, both of which are regulated by Directive 2001/83/EC. Thirdly, simplified registration grants for 'a traditional use registration' which are regulated by the Traditional Herbal Medicinal Product Directive 2004/24 EC (THMPD). This Executive Summary addresses Traditional use registration under the THMPD.

Traditional Herbal Medicinal Products are classified as medicinal products containing exclusively one or more herbal substances, provided that any extra vitamins or minerals are ancillary to those substances. Traditional herbal medicinal products may obtain marketing authorization through the simplified registration procedure if the product:

a) is intended and designed for use without the supervision of a medicinal practitioner,
b) is exclusively for administration in accordance with a specified strength and posology,
c) is for oral or external use and/or inhalation preparation,
d) has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community (the 15 year rule),

e) proves not to be harmful in the specified conditions of use, and
f) the pharmacological effects or efficacy of the product are plausible on the basis of long-standing use and experience.

Moreover, medicinal products may still satisfy the THMPD 15 year rule if they have been used for 15 years within the Community despite not having obtained registration or authorisation as a medicinal product. If a traditional herbal medicinal product has been used for less than 15 years within the Community but satisfies all the other criteria required by the simplified registration procedure then the Member State where the registration application was submitted shall refer the product to the Committee for Herbal Medicinal Products who have a discretionary power to provide the medicinal product with a 'traditional use registration'.

There are several concerns relating to the THMPD.

Key concerns:

- **OTC products:** Under the THMPD medicines applying for traditional long standing use exemption should have indications appropriate for traditional herbal medicine products that are designed to be used without the intervention of a medical practitioner for diagnosis, treatment or monitoring purposes. This will only cover purely herbal Over The Counter (OTC) products. However, all Ayurvedic medicines essentially need the presence of a qualified Ayurveda practitioner to supervise and monitor the various physiological and pathological changes in the patient during the various stages of therapeutic action of the concerned drug or therapy. As a result, the THMPD may be incompatible with the EU principle of proportionality as well as freedom of establishment enumerated within Article 49 Treaty on the Functioning of the European Union (TFEU) and the Article 56 TFEU freedom to provide and receive services.

- **Excessive cost:** The THMPD in certain circumstances may amount to a substantial interference with the enjoyment of possessions contrary to law due to the significant monetary loss caused denial of market access, and estimated fee for registration under the THMPD. In particular, the registration of one product with four ingredients could cost as much as £75,000-100,000. Much of this high cost is due to excessive and inappropriate quality control requirements. As a result the THMPD may be incompatible with Article 114 of the TFEU, Article 28 TFEU free Movement of Goods and Article 17 Charter of Fundamental Rights of the European Union, read in light of Article 1 of the First Protocol to the European Convention on Human Rights (ECHR). Moreover, the THMPD may also violate the General Agreement on Tariffs and Trade (GATT) prohibition on import and export restrictions as a result of excessive cost.

- **Herbal products:** the THMPD only regulates market authorisation for 'herbal products' and the inclusion of other non-herbal biological and non-biological active ingredients are not covered. However, its worth noting that IAF exhausted all the local remedies by corresponding extensively over seven years with UK Government and EU. The UK Government conceded to IAF *"We fully accept that Ayurveda is a distinct discipline in its own right - we would not challenge this. We also accept that the practice of Ayurveda extends beyond the use of herbs."* The THMPD, however, may not allow for products that are combinations of otherwise legal ingredients. Moreover, the word 'ancillary' in the THMPD is unclear and inappropriate, since there is nothing like an ancillary action for an Ayurvedic medicine. Even though the therapeutic action of a drug is the combined effect of the total ingredients, Ayurveda identifies many drugs that have a supportive role in enhancing the action of other drugs in the specific combination. They may not have a direct pharmacological action, but their presence is very important in catalysing the therapeutic action of the drug. As a result, the THMPD may be incompatible with the EU principles of good administration, subsidiarity and proportionality.

- **Traditional use:** the Traditional Use requirement of the THMPD requires that in order for a product to apply for traditional use registration, it should provide sufficient data to prove that it

has been in use for a minimum period of 30 years of which 15 years should be within the European Community. This will exclude all the Ayurveda products, which do not have a documented usage history for 15 years in EU. Most of the purely herbal Ayurveda medicines that were used by practitioners for their treatments will also not meet this requirement. Moreover, it may be the case that no new products can be brought to market if they had been available for many years in another non-EU country with a good safety record. Even those, which have been in use in the EU for over 15 years, are required to produce bibliographic and expert evidence of Traditional use. In the case of Ayurveda it is difficult to collect these forms of evidence from reliable sources because there was no statutory regulation for the practice. As a result, the THMPD may be incompatible with the GATT prohibition on import and export restrictions, Article 114 of the TFEU, Article 28 TFEU free Movement of Goods and the EU principles of good administration, subsidiarity and proportionality.

- **Route of administration:** the THMPD excludes medicines that take any route for administration other than oral, external application or inhalation. Therefore, all medicines that should be used for treatments like Vasthi (Medication through anal route); Utharavasthi (Medication through urethral and vaginal routes) may be excluded and denied entry into the EU. As a result, the THMPD may be incompatible with the EU principles of proportionality, good administration and subsidiarity as well as Articles 2 and 8 of the Agreement on the Application of Sanitary and Phytosanitary Measures ('SPS Agreement').

- **Least restrictive means:** it may be possible to assess quality, safety and efficacy of Ayurvedic medicines on the basis other less restrictive means, such as evidence of sustained usage in countries where such medicinal products have been in use. For instance, bibliographical or expert evidence from the country of origin of any Traditional System of Medicine could be considered plausible for the pharmacological effects or efficacy of the product. Moreover, the following methods may be more appropriate when used both individually and collectively, to assess quality, safety and efficacy: classical texts with their modern interpretations decided by experts, Ayurvedic pharamcoepia and standard formulary. Finally, reverse pharmacology is strongly advocated as a method of assessing safety, quality and efficacy for traditional systems of medicines which is appropriate to their form and nature. As a result, the THMPD may be incompatible with the EU principles of proportionality, good administration and subsidiarity as well as Articles 2 and 8 of the SPS Agreement.

- **Consultation:** The THMPD consultation process performed by the Medicines and Healthcare products Regulatory Agency (MHRA) may not have been compatible with the obligation to give reasons. In particular, the IAF has substantial evidence to suggest that the MHRA did not provide an adequate degree of information in order to satisfy the obligation to provide reasons and to enable persons taking part in the consultation process to ascertain the reasons for the adoption of the THMPD framework. In particular, the MHRA responded to numerous consultation contributions by stating: "having considered the comments made in response to MLX 318, the Ministers have decided to make no further changes in response to this latest consultation." As a result, the THMPD may be incompatible with Article 296 TFEU and/or the duty to give reasons.

- **Freedom of religion and belief:** Article 9 of the ECHR provides everyone with 'the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief and freedom, either alone or in community with others and in public or private, to manifest his religion or belief, in worship, teaching, practice and observance.' However, the THMPD significantly restricts the freedom of Ayurveda stakeholders to access Ayurvedic medicinal products. The stakeholders represented by the IAF believe that Ayurvedic practices, including the use of Ayurvedic medicines, are ***required*** by their belief system and are not merely acts which are ***permitted*** or ***encouraged.*** Moreover, numerous stakeholders represented by the IAF regard adherence to these practices as mandatory. As a result, the THMPD may be incompatible with the Article 9 ECHR right to freedom of religion and belief.

- **Right to privacy:** Article 8 ECHR provides everyone with 'the right to respect for his private and family life, his home and his correspondence'. Article 8 also protects the establishment and development of relationships with others in the public, employment and business context. The THMPD may amount to a disproportionate violation of the right to private life provided by Article 8 ECHR to the extent that it prevents and limits the freedom of Ayurveda stakeholders to establish and develop relationships in this public, business and business context.

- **Safety data:** Applicants under the THMPD system are often incapable of supplying the requisite safety data. In particular, applicants are required to present Bibliographic review of safety data, together with an expert report. Traditional medicinal products are prepared on the basis of documented or undocumented traditional knowledge being passed down from generation to generation, and are not necessarily a result of chemical reactions under laboratory conditions. Therefore, it may not be feasible to provide the same level of documentary evidence as applicable to modern medicinal products. As a result, the THMPD may be incompatible with the EU principles of proportionality, good administration and subsidiarity.

- **Good Manufacturing Practice:** an applicant must furnish all the quality requirements applicable to licensed medicines in the EU, Good Manufacturing Practice (GMP) requirements are compulsory for manufacturers and importers, and licensing is required for manufacturers, importers and distributors. However, it is, in some circumstances, not possible for products to comply with the quality requirements laid down by the GMP requirements because traditional herbal medicines do not operate on the same medicinal basis as allopathic modern medicines. To this extent it is questionable whether standards of scientific objectivity and excellence are satisfied by a framework which fails to recognise the significant differences between modern and traditional medicines and imposes the same quality requirements. As a result, this clause may be incompatible with the EU principles of proportionality, good administration and subsidiarity as well as Articles 2 and 8 of the SPS Agreement. Moreover, the THMPD may be incompatible the freedom of establishment enumerated within Article 49 TFEU and the Article 56 TFEU freedom to provide and receive services as a result of inappropriate GMP requirements.

- **Discrimination:** The THMPD may violate the GATT prohibition on discrimination due to the disadvantages and obstacles faced by traditional medicinal products originating in or destined for other member states outside of the EU caused by the traditional use clause required for market authorisation. Many products from non-EU countries have yet to be used in the European Union and may thereby be excluded. They would then only be permitted if they were able to successfully pass through a full drugs regime, likely to be prohibitively expensive for most non-pharmaceutical manufacturers or suppliers. Furthermore, the advantages accorded to products originating in the EU, are not necessarily immediately and unconditionally accorded to all other like products originating for other Member states outside of the EU. In particular, products originating outside the EU may be less capable of demonstrating long standing use within the EU, because while they have produced and provided traditional medicinal products outside of the EU to adequate standards of safety, efficacy and quality, they have not previously imported products into the EU. Therefore, country of origin may accord a significant advantage to Members of the EU in contrast with Members outside of the EU. As a result, the THMPD may be incompatible with the GATT Article 3(4) prohibition on discrimination and the GATT Article 1 Most Favoured Nation Principle as well as the Article 14 ECHR prohibition of discrimination.

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An Appeal for Contribution
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For **the International Ayurveda Foundation** to truly make a difference, both in the lives of exceptional individuals and in India as a whole, we need your help.

The IAF in the UK is a non-profit UK Company, limited by guarantee, having no share capital and registered Charity No. 1105162.

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Your donations in the UK and India towards promoting Ayurveda will be significant for us in our mission. You will be helping India as well as the whole world to have a healthy possible future.

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