ANH BRIEFING PAPER
TRADITIONAL HERBAL MEDICINAL PRODUCTS DIRECTIVE (THMPD)
2010 update

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Traditional Herbal Medicinal Products Directive (Directive 2004/24/EC)

Background

- The Traditional Herbal Medicinal Products Directive (THMPD) exists as a sub-Directive of the Human Medicinal Products Directive (2001/83/EC, amended by 2004/24/EC). This Directive essentially offers a simplified ('fast-track') medicinal licensing scheme for herbal medicinal products that are able to demonstrate, using a bibliographic review of safety data together with an expert report, 30 years continuous safe usage, of which at least 15 are within the EU (Article 16(c)1(c)).

- This simplified scheme avoids the need to demonstrate safety and efficacy, which are typically the most costly aspects of applying for a full medicinal license (market authorisation).

- Applications for a THMPD license are made via particular Member States, with data being considered by the Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency (EMEA), which has also been given responsibility to establish monographs for herbal substances. (http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC.html). At the time of writing, 22 monographs are complete, around 100 have been submitted and not more than a total of between 200-300 are expected.

- Licensed THMPD products are intended for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment. This creates a major constraint since many traditional medicinal products are typically used in conjunction with advice by a practitioner, for minor but also for more serious ailments, including cancer, psychiatric diseases, infectious diseases (e.g., hepatitis, influenza), cardiovascular diseases or metabolic diseases such as diabetes, none of which would be acceptable by the licensing authority.

- The full provisions of THMPD come into force in April 2011. The provisions, however, provide particular obstacles for many small to medium-sized enterprises (SMEs) in the natural health sector which are manufacturing and/or retailing traditional herbal products. There are a number of reasons for this:

  - Cost of compiling a dossier and applying for a license. SMEs generally manufacture or sell a diverse range of products, each with relatively small turnover, as compared with large corporations, which are typically reliant on fewer products, each with high sales volumes. High costs for licensing therefore impact SMEs disproportionately compared with large corporations;

- The requirement by the HMPC for high quality genotoxic data. For many herbal substances used in traditional cultures these data are not available, while in others they are viewed as being of insufficient quality by HMPC/ EMEA. This requirement has been one of the major reasons for the small number of applications to the registration scheme (around 110 in total from 25 Member States, at the time of writing);

- The requirement to meet pharmaceutical Good Manufacturing Practices (GMPs), which considerably exceed the standards for food manufacture and are sometimes inappropriate for certain categories of ingredient or product (e.g., some botanicals). Additionally manufacturers are required to retain the services of a 'Qualified Person' to ensure compliance with pharmaceutical standards;

- Difficulty in compliance with the pharmaceutical criteria stipulated under the Directive, which, for example, require identification of marker compounds in order to meet stability requirements. While these criteria can be met in the case of single or two-herb combinations, they cannot generally be met in the case of poly-herbal products which are typical of many traditional medicinal cultures;

- Many traditional cultures utilise non-herbal products, including in particular ingredients of animal origin and minerals. These are presently disallowed by the Directive.

- The European Commission has published an important report entitled 'Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal product' on 29 September 2008 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0584:FIN:en:PDF). The report recognises some of the difficulties that companies have had with the registration scheme, but indicates there is likely to be little future flexibility with regard to altering the provisions, with the primary exception of expanding the scope to include non-herbal substances. More hopeful, however, is the conclusion by the Commission that a new legal framework may be considered for particular traditional medical systems, e.g., Ayurveda, Traditional Chinese Medicine, anthroposophic medicine, etc.

Key Concerns

1. **Discrimination against non-European Herbal Traditions** by requiring at least 15 out of 30 years of usage within the EU, as the basis for proving long established, traditional usage. The basis for this requirement is the supposedly varying pharmavigilance standards in different regions, implying that standards outside of Europe may be lower than those within Europe. This provision seriously disadvantages Ayurveda, Traditional Chinese Medicine, South East Asian, Tibetan, Amazonian and southern African traditions, which are among the longest and most developed botanically-based healthcare traditions worldwide.

2. **Particular combinations of herbal products may be disallowed**. 'Traditional use' under the THMPD is based on use of an individual herb or specific combination of herbs. It therefore prevents use of new or innovative combinations that might be supported by

emerging science. An amendment to remedy this constraint is under consideration by the European Commission, but will require the support of the European Parliament.

3. **Products are subject to pharmaceutical criteria and GMPs**. Under the THMPD, manufacturers must meet pharmaceutical GMPs, including stringent purity, stability and genotoxicity criteria that are identical to those used for conventional pharmaceuticals, under the provisions of the same base Directive (2001/83/EC). These criteria cannot be met in the case of many poly-herbal products owing to the complexity of mixtures, the masking of known markers and, in other cases, the lack of standards for identification of markers.

4. **Traditional medicines are eligible for registration only if they are intended for minor ailments**, while traditional medical systems generally have developed to cater for the full range of ailments and diseases encountered in their indigenous environments. Accordingly, the registration scheme may be discriminatory against ethnic minorities within the EU who might wish to benefit from products associated with their traditional medical system. While food supplements are able to be sold legally within the EU containing ingredients that support the health (or reduce the disease risk) of, for example, cardiovascular or neurological systems, these are disallowed under the THMPD scheme.

5. **Excessive cost of accessing the THMPD regime**. The cost of meeting the data requirements for the THMPD, including the assembly of dossiers of bibliographic and expert evidence, as well as the requirements for genotoxicity data (which typically have to be commissioned as existing data are not available) is prohibitive for many SMEs.

6. **Herbal Products containing significant levels of vitamins and minerals will be prohibited,** and allowed only if the action of those nutrients is considered 'ancillary' to that of the herbal ingredients.

7. **Herbal products containing non-herbal ingredients other than vitamins and minerals are currently disallowed**. However, the Directive may in the future be amended to allow such ingredients, although verifying their safety to the satisfaction of the HMPC is likely to be challenging and very expensive.

8. **Increased cost to consumer and restriction of freedom of choice** given that significant compliance costs will apply, which will be passed on to the end user, making the cost of products uneconomic for some and limiting their right to make their own health choice.

9. **Committee control**. Authorisations are controlled by the HMPC, which is weighted strongly towards drug pharmacologists/cognosists, as opposed to practicing medical herbalists and others with specific expertise on traditional medical practices.

10. **Impact on non-European herbal suppliers**. Many herbs potentially eligible under the THMPD scheme are hand-collected or produced by small-holder farmers and communities in non-EU countries. If products containing such herbs are disallowed as botanical-containing food supplements, and are also unable to be licenced under the THMPD scheme, these rural communities could be impacted very seriously.–