Q&A: Registration of Traditional Herbal Medicinal Products

What are Traditional Herbal Medicinal Products?

Some plants contain substances that may be used to treat diseases. Medicinal products that are made from these substances are known as "herbal medicinal products". Even though they are natural, a number of these products may be dangerous for patients. This is why they are covered by pharmaceutical legislation, which aims to protect public health by ensuring the safety, efficacy and quality of medicinal products.

Within the group of herbal medicinal products, some have a long tradition of use. European Union legislation classifies as **traditional** herbal medicinal products those herbal medicinal products that have been used for at least 30 years, including at least 15 years within the EU, are intended to be used without the supervision of a medical practitioner and are not administered by injection.

Some examples of herbals used in traditional herbal medicinal products are: Calendula officinalis L; Echinacea purpurea L., Moench; Eleutherococcus senticosus (Rupr. et Maxim.) Maxi; Foeniculum vulgare Miller subsp. vulgare var. vulgare; Foeniculum vulgare Miller subsp. vulgare var. dulce (Miller) Thellung; Hamamelis virginiana L; Mentha x piperita L. and Pimpinella anisum L.

Why did the EU decide to adopt specific legislation on traditional herbal medicinal products?

All medicinal products, including herbal medicinal products, need a marketing authorisation to be placed on the EU market.

However, traditional herbal medicinal products have particular characteristics, notably their long tradition of use. To take account of this, the EU has introduced a lighter, simpler and less costly registration procedure for them, while providing the necessary guarantees of quality, safety and efficacy.

The Herbal Directive (Directive 2004/24/EC) was adopted to facilitate the placing on the EU market of traditional herbal medicinal products.

The simplified procedure allows the registration of traditional herbal medicinal products without requiring safety tests and clinical trials, which the applicant is obliged to provide under the full marketing authorisation procedure.

The long tradition of the medicinal product makes it possible to reduce the need for these tests and trials that can be replaced by documentation which indicates that the product is not harmful in specified conditions of use and that its efficacy is plausible on the basis of long-standing use and experience.

However, even a long tradition of use does not exclude concerns about the product's safety. Therefore competent authorities of the Member States are entitled to ask for additional data, if they deem it necessary, to assess the safety of the medicinal product.

In summary, the Herbal Directive introduces a simplified procedure compared with the requirements of a full marketing authorisation.

What does the deadline of 30 April 2011 represent for manufacturers of traditional herbal medicinal products?

The Herbal Directive was adopted by the European Parliament and the Council on 31 March 2004. It gave an exceptionally long transitional period of 7 years to register traditional herbal medicinal products that were already on the market on the date of entry into force of the Directive. This 7 years transitional period ends on 30 April 2011.

Traditional herbal medicinal products that were legally on the market before 30 April 2004 were allowed to remain on the market until the end of the transitional period. This has given applicants 7 years to register. It is up to the applicants to submit the corresponding application to the competent authorities in the Member States where they want to market, in time for their registration by the end of the transitional period.

Does the Herbal Directive impose new requirements for the placing on the market of traditional herbal medicinal products? Would these requirements be too burdensome for small and medium-sized enterprises and reduce access for Chinese and Ayurvedic medicinal products?

Before 2004, herbal medicinal products were covered by the same requirements as other medicinal products. The Herbal Directive amends those requirements and provides for a simplified registration procedure introduced to facilitate the placing on the market of traditional herbal medicinal products for all companies, including small and medium-sized enterprises (SMEs).

The simplified procedure allows the registration of traditional herbal medicinal products, including Chinese or Ayurvedic herbal medicinal products or herbal medicinal products from any other tradition, without requiring tests and trials on safety and efficacy, which the applicant is normally obliged to provide. Instead for registration of traditional herbal medicinal products, the applicant has to only provide sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the European Union.

This procedure is less burdensome than the full marketing authorisation and therefore facilitates the access of these products to the market in the EU. Consequently, it does not reduce access for Chinese or Indian Ayurvedic medicinal products or the products of companies with reduced financial means.

What is the role of the European Medicines Agency for the registration of traditional herbal medicinal products after 30 April 2011?

The European Medicines Agency (EMA) does not have a role in the registration of traditional herbal medicinal products. The simplified procedure is a national one. This means that applications for registration need to be submitted in each Member State where the product is to be marketed. These applications are handled by the competent authority in each Member State.

However, a Committee for Herbal Medicinal Products (HMPC) was set up at the European Medicines Agency in September 2004 in view of the establishment of an EU list of herbal preparations or herbal substances by the European Commission. This means that Member States shall recognise registration of traditional herbal medicinal products granted by another Member State whenever it is based on the EU list.

The tasks of the HMPC are not linked to the existence of the transitional period. Applications for registration of traditional herbal medicinal products can be submitted even if the substance or preparation is not included in the EU list.

Are herbal products allowed to remain on the market as food or food supplements after 30 April 2011?

Herbal substances can be used to manufacture medicinal products or food.

A herbal product will be considered a medicinal product where presented as having properties for treating or preventing disease in human beings or where it has a pharmacological, immunological or metabolic action. It is the competence and responsibility of national authorities to decide, on a case-by-case basis, whether a herbal product fulfils the definition of medicinal product.

Where a herbal medicinal product is not registered or authorised by 1 May 2011, the product may not be on the EU market.

However, herbal products may be classified and placed on the market as food provided that they do not fulfil the definition of medicinal products and that they do comply with the applicable food law. In particular, herbal products marketed in the form of food supplements should comply with Directive 2002/46/EC on food supplements and Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

Will all alternative therapies, plants and books on plants be banned after 30 April 2011 in the European Union?

No. The Herbal Directive regulates traditional herbal medicinal products by allowing a simple and light registration procedure. It does not apply to alternative therapies and does not ban any specific substances, practitioners, books or the plants as such.