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Traditional Herbal Medicines in the European Union: Is the Herbal Directive a Benefit or Obstacle?



Since May 1, 2011 new rules on marketing authorization apply to certain herbal medicinal products. These rules may have important effects for manufacturers and importers of such products.

EU Directive 2004/24 (the Herbal Directive) amends EU Directive 2001/83 on the Community Code relating to medicinal products for human use as regards traditional medicinal products. Under that directive, herbal medicinal products required an authorization before they could be marketed as such in the EU. Application for a marketing authorization required the submission of an extensive dossier and demonstration of a well-established medicinal use with recognized efficacy. Many traditional herbal medicinal products could not satisfy these requirements and could not therefore be marketed as medicinal products in the EU. Instead, Member States often took the view that they were not “medicinal products” within the meaning of the EU legislation and permitted them to be marketed as food supplements, which are subject to EU legislation on food and can be marketed without registration.

The Herbal Directive introduces a uniform regime for the new category of “traditional herbal medicinal products.” This regime is less onerous than that applicable under EU Directive 2001/83 to conventional medicinal products.

What are Traditional Herbal Medicinal Products?

Herbal medicinal products are defined as products which contain exclusively herbal substances or preparations (although vitamins and minerals having an ancillary action may be added). Traditional herbal medicinal products are defined as those that have been in medicinal use for at least 30 years, including at least 15 years in the EU, provided that data demonstrate that use is harmless and efficacy is plausible, are intended and designed to be used without the supervision of a medical practitioner, are exclusively for administration in accordance with a specified strength

and dosage, and are prepared for administration orally, externally or by inhalation (rather than by injection).

The Herbal Directive

The Herbal Directive establishes a simplified registration procedure for traditional herbal medicinal products. In contrast to other medicinal products for which a marketing authorization is sought, the application for registration does not need to include pre-clinical tests, clinical trials, a pharmacovigilance summary, or a risk management plan. The applicant must, however, demonstrate that its product satisfies the definition of a traditional herbal medicinal product [see above] and submit:

- bibliographical or expert evidence that the product (or a corresponding product) has been in medicinal use for the requisite period
- a bibliographic review of safety data
- an expert report

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- evidence that the product was manufactured in compliance with the principles and guidelines of good manufacturing practice as laid down by the commission in EU Directive 2003/94.

The simplified registration procedure is a national procedure. This means that an application must be submitted in each EU member state where the applicant intends to market the product. However, the relevant national authorities will recognize registrations granted by other member states in certain circumstances.

The Herbal Directive also requires that any labeling of a registered traditional herbal medicinal product must state that the product is a traditional herbal medicine and that the user should seek medical advice if the symptoms persist.

Benefits or Obstacles?

Now that traditional herbal medicinal products are tightly defined and regulated in the Herbal Directive, it will be more difficult for Member States to take the view that products falling within that definition can continue to be marketed as food supplements (although herbal products making no medical claims may still be marketed as such). Compared to the formalities for obtaining a marketing authorization for “normal” medicinal products, the new registration procedure for traditional herbal medicinal products will be simpler, quicker and, therefore, less expensive. It is nonetheless expected that some manufacturers and importers will take their traditional herbal medicinal products off the EU market rather than incur the costs of registration. This is likely to be the case in particular for

multiple herbal products and for herbal medicinal products that are not based on European traditions, such as Chinese and Ayurvedic medicinal products. Such products often do not have the long history of use within the EU which is necessary for simplified registration under the Herbal Directive. They will therefore require a standard marketing authorization as for all other medicines, including costly and time-consuming tests and clinical trials. Manufacturers will have to calculate from potential sales figures in the EU market whether this is worth the investment and effort.

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