

20th September 2004

Implementation of Legislation regarding Traditional Herbal Medicinal Products

Introduction

Directive 2004/24/EC of the European Parliament and of the Council, amending, as regards Traditional Herbal Medicinal Products, Directive 2001/83/EC on the Community Code relating to Medicinal Products for Human Use, was published on the 31st March 2004 in the *Official Journal of the European Union*. This directive came into force on the 30th April 2004 throughout the 25 member states of the European Union, thus harmonizing the regulation of traditional herbal medicinal products throughout the EU. As a member state, Malta is obliged to comply with this Directive. The process will involve its transposition into Maltese legislation, as a regulation under the Medicines Act, 2003, and ultimately its implementation and enforcement by the Licensing Authority from the 30th October 2005.

This Directive sets out specific standards for safety, quality and consumer information for Over-The-Counter *traditional herbal medicinal products*, giving specific provisions applicable to these medicines.

At present in Malta, herbal products do not require a marketing authorization, unless they fall under the definition of a “medicinal product” (Medicines Act, 2003, Article 2), for example if they make medicinal claims, therefore requiring an application for a marketing authorisation under Directive 2001/83/EC. Once the legislation on Traditional Herbal Medicinal products comes into force on the 30th October 2005, a product registration issued by the Licensing Authority will be required prior to placing the product on the Maltese market. The directive provides an appropriate system for the regulation of these products taking into account their tradition of use and their complex composition.

The Herbal Medicinal Products Working Party, which meets at the EMEA (Agency for the Evaluation of Medicinal Products), is working on a list of Herbal Medicinal Products that may be considered as “traditional”. It is planned that this list will be finalized in November 2004 during the next committee meeting, and will relate to Community Herbal monographs relevant to the registration and authorization of traditional herbal medicinal products throughout Europe. These monographs will provide guidance as to the properties of these products, including therapeutic uses, pharmaceutical forms and strengths that would classify them as medicinal products. An applicant seeking to register a product containing a substance on the list in the form and for the indications as specified on the list could then refer to this list rather than have to demonstrate traditional use and safety. The applicant would still need to demonstrate quality.

Practical Implications for products on the local market

- For products that were on the market in Malta on 30 April, 2004, when the directive was published, there is a transitional period of seven years that will end on the 30 April 2011. This means that for traditional herbal medicinal products that are covered by the Traditional Herbal Medicinal Products Directive and were already on the market on entry into force, 30 April 2004, the Medicines Authority shall apply the provisions of the Directive within seven years after its entry into force. These products will be included in a transition list.
- As from November 2003, the Medicines Authority had contacted local importers and wholesale dealers of herbal products to submit lists of herbal products that were currently on the Maltese market. The Medicines Authority, whilst acknowledging the lists of products each importer/wholesale dealer has submitted, kindly asks the parties concerned to officially confirm that they agree with the lists.
- These lists are being sent back to the importers/wholesale dealers for confirmation. Other importers/wholesale dealers that have not been contacted or have not already supplied these lists are asked to supply them to the Medicines Authority by 31 October 2004. Failure to comply will confirm that the distributor is not interested in having his products on the transition list, thus not intending to apply for a product registration and therefore, does not intend to benefit from the seven year derogation for these products. These lists should cover the product(s) for which a company intends to seek Traditional Use registration and which should be in line with the Directive by the end of the derogation (30 April 2011).
- These lists will be used to compile the transitional list including all the products that will benefit from the 7-year derogation. The products will be verified by comparing to notification information kept by Port Health and Malta Standards Authority. For the Herbal Medicinal Products included, in the absence of safety concerns, it is envisaged that they can remain on the market until April 2011.

By November 2005, products that fall within the definition of a traditional herbal medicine, they are not on the transition list and do not have a marketing authorisation, should be removed from the market until a product registration under the simplified registration scheme or a full marketing authorisation is granted. This means that for herbal products placed on the Maltese market for the first time after 30 April 2004 there is no derogation and after 1 November 2005 cannot be placed on the market without a market authorization or a product registration under the simplified registration scheme.

Manufactured, finished, over-the-counter traditional herbal medicines will be covered by the simplified registration. It is a common situation to find products containing the same ingredients that can be regarded either as medicines or as foods or cosmetics, depending on presentation. There are a number of herbal ingredients that have accepted usage in a range of different categories besides medicines, including food, cosmetics or general consumer products. If a product is currently sold legally as a food, cosmetic or general consumer product, companies can continue to sell their products under these categories. The registration only covers products that are classified as medicines. While many herbal products are

medicines, others are not, and so do not require a registration under the Traditional Herbal Medicines Registration Procedure or a Marketing Authorisation.

Any herbal products that will not be considered as traditional herbal medicinal products and therefore not requiring registration, that make specific medicinal claims, would still need to be registered as a medicinal product as laid out in the definition of a medicinal product in the Medicines Act, 2003, with immediate effect by applying for a Marketing Authorisation.

Registration and Licensing of Herbal Medicinal Products

Each company placing herbal medicinal products on the market will be required to hold a manufacturer's or a wholesale dealer's license issued by the Licensing Authority as well as an authorization/product registration for each individual Herbal Medicinal Product on the market, as is the case with other medicinal products (as specified in the Medicines Act, 2003, Articles 54-65).

A herbal medicinal product can be placed on the Maltese market by a Marketing Authorization Holder/Manufacturer in one of the following procedures:

1. With a marketing authorization as for other medicinal products, i.e. with an application form accompanied by a dossier containing particulars and documents proving its quality, safety and efficacy as specified in the Medicines Act, 2003 and any regulations made there under. The Marketing Authorisation Holder must be established in the Community.
2. By demonstrating that the constituent(s) of the herbal medicinal product has(ve) a well-established medicinal use with recognized efficacy and an acceptable level of safety, with references to published scientific literature.
3. By using the Simplified Registration Procedure for products that despite their long tradition do not fulfill the requirements of a well established medicinal use and are not eligible for a marketing authorization. The products eligible for this simplified procedure should be listed in the community list of Herbal substances and should satisfy the criteria set out in the directive. This procedure should be limited to products where an authorization cannot be obtained as per 1 and 2 above, in particular because of a lack of sufficient scientific literature demonstrating a Well-Established Use with recognized efficacy and an acceptable level of safety. The quality aspect of the medicinal product is independent of its traditional use; therefore documents regarding the necessary physico-chemical, biological and microbiological tests have no derogation and should be supplied.

The Simplified Registration Procedure can also be used for products containing herbal medicinal products in combination with vitamins/minerals, provided that the action of the vitamins and minerals is ancillary to that of the herbal active ingredient(s) regarding the specified claimed indication. The Simplified Registration cannot be used for Homeopathic Products (regulated by Directive 2001/83/EC). Herbal substances confined to prescription control are not eligible for the simplified procedure, and should apply for a marketing authorization. Registrations will be permitted for herbal medicines that are taken orally, for external use or inhalation.

Herbal medicinal products intended for injection will not be granted a registration under the Simplified Procedure.

For this Simplified Registration Procedure, several criteria must be met, including evidence that the medicinal product, or a corresponding product (having the same active ingredient and a similar intended purpose) has been in medicinal use throughout a period of at least 30 years preceding the date of application, including at least 15 years within the Community.

Other requirements include specific additional information on any labeling and patient information leaflet (PIL).

The Simplified Registration Procedure has to be effective from the 30th October 2005. The Medicines Authority will be issuing the relevant application forms, documentation requirements and fees for simplified registration. If you have any queries or would like more information, please send an e-mail to herbals.adm@gov.mt.

Any legislation mentioned in this text can be accessed through: “Legislation” section in “Links” section of the Medicines Authority website.