

## **PLACING A HERBAL MEDICINAL PRODUCT ON THE MALTESE MARKET**

**This section outlines the two possible regulatory routes by which you can legally supply herbal medicines now or in the near future.**

### **Is your herbal product a medicine?**

Not all herbal products are medicines. Many herbal products can legally be sold as food or cosmetics for example. It is therefore important that you begin by establishing whether your product is classified as a medicine. If it isn't, you don't have to comply with medicines legislation (although you will have to comply with other legislation relevant to your product).

Guidance on what is a medicine is available in our [Borderline Classification Committee](#) section, which helps you determine whether your product is medicinal. Advice from the Authority's Borderline Classification Committee on whether your product is likely to be medicinal can be obtained by completing a [BCC application form](#) and submitting it to the committee together with the labelling, packaging and patient information.

### **How herbal medicines can be authorised to be placed on the Market**

If a herbal product is classified as a medicine, there are two possible regulatory routes by which you can legally supply your herbal medicine. You will need to ensure that your product complies with the following necessary requirements.

#### **1) Traditional herbal medicinal products registration**

30 October 2005 marked the introduction of a new registration procedure, the Traditional Herbal Medicinal Product Registration Procedure which will help protect public health by requiring specific standards of safety and quality for traditional herbal medicinal products. This procedure is based on the requirements of the European Directive on Traditional Herbal Medicinal Products (2004/24/EC), transposed into Maltese legislation by [Legal Notice 379 of 2005](#).

Manufactured herbal medicines placed on the Maltese market after 30<sup>th</sup> April 2004 will need to comply with the requirements of this procedure or, alternatively obtain a marketing authorisation according to Medicines (Marketing Authorisation) Regulations, 2005. Manufactured herbal medicinal products placed on the market before 30 April 2004, will need to comply with the requirements of this procedure by **April 2011** or obtain a marketing authorisation as set out in (2).

The Medicines Authority had requested importers, wholesale dealers and other companies placing herbal products on the Maltese market to notify the Herbal Products section about any products containing herbal substances and to provide evidence, when required, to demonstrate that a product was on the market on 30 April 2004. The

products for which notifications have been received and which satisfy the criteria for traditional herbal products will be able to benefit from the 7-year transition.

Those that have been placed on the market after 30 April 2004 cannot benefit from the transition and need registration or authorisation to be further placed on the market.

Registration requirements for a simplified registration procedure are being set up and an application form based on these requirements will be made available.

Some of the documents that will be required for simplified registration include:

- ✓ SmPC (Summary of Product Characteristics)
- ✓ Quality dossier covering the quality of the herbal ingredients and the finished product
- ✓ Bibliographic review of safety data
- ✓ Expert report/s on non-clinical and clinical aspects of safety
- ✓ Expert report/s including bibliographic or expert evidence that the medicinal product or corresponding product has been in medicinal use throughout a period of 30 years
- ✓ Draft patient information leaflet
- ✓ Draft labelling

More information on registration requirements can be obtained from Chapter 1 Marketing Authorisation (November 2005) on the Commission website <http://pharmacos.eudra.org/F2/eudralex/vol-1/home.htm> where other guidelines on the format of the dossier, SmPC etc can also be found.

## **2) Herbal medicinal products Marketing Authorisation**

Currently around 15 herbal medicines hold a provisional marketing authorisation after meeting safety, quality and efficacy (or effectiveness) criteria in a similar manner to any other licensed medicine, for example, paracetamol.

When applying for a licence for herbal medicines, many companies have difficulty meeting conventional requirements to prove efficacy. However, after the introduction of the Traditional Herbal Medicinal Product Registration Procedure, it will continue to be possible to obtain a marketing authorisation for herbal medicines where the required levels of safety, quality and efficacy can be demonstrated. That is that the existing arrangements will continue under which herbal medicinal products (like any other medicines) may be eligible for a full marketing authorisation based on demonstration of safety, quality and efficacy. Registration requirements for this type of authorisation are similar to those of other medicinal products and are subject to all the requirements of the regulations under the Medicines Act, 2003.

## **Further information contact details**

Guidance on whether your herbal product is a medicine contact:

Borderline Classification Committee,  
Medicines Authority, 198,  
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Information on the regulation of herbal medicines in Malta contact e-mail  
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Information of manufacturing, wholesale dealing, importing of herbal medicinal products  
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