

15 April 2010

Dear Sir/Madam,

RE: IMPLEMENTATION OF LEGISLATION REGARDING HERBAL MEDICINAL PRODUCTS

1 European Directive 2004/24/EC on traditional herbal medicinal products was published in 2004. This directive allows for simplified registration for herbal medicinal products which fall into the definition of a 'traditional herbal medicinal product'.

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Many herbal medicinal products are still being placed on the market in Malta without the required authorisation. According to the legislation, manufactured herbal medicines placed on the market in Malta are required to have either a Traditional Herbal Licence (THL) or a Marketing Authorisation (MA). Some products currently placed on the market as foods, food supplements and cosmetics may fall within the definition of a 'traditional herbal medicinal product', and would therefore require registration.

An information session on the regulatory requirements for registration of herbal medicinal products is being organised by the Medicines Authority for all herbal product importers, health food shop owners, wholesale distributors and other stakeholders.

You are invited to attend this information session, which will be held on 29 April 2010 at The Palace Hotel, High Street, Sliema at 7.15pm. Complementary parking will be available subject to availability. You are kindly requested to confirm your attendance by sending an e-mail to herbals.adm@gov.mt with your name and the number of persons attending.

Yours faithfully,



Helen Vella
Director
Licensing Directorate