Malta, 19 October 2007

Circular No. P14/2007

Dear Healthcare Professional,

Re: Benefit-Risk Profile of Clobutinol-containing Medicinal Products

Following the voluntary withdrawal of the marketing authorization of Silomat® in Germany and in all countries where the marketing authorization holder Boehringer Ingelheim had a license on 31st August 2007, as a result of new findings from clinical trials suggesting a potential risk of cardiac arrhythmia, the Committee for Medicinal Products for Human Use (CHMP) had initiated assessment of the benefit risk profile of clobutinol-containing medicinal products. Following the completion of this review, the CHMP has concluded that the benefit risk balance of clobutinol-containing medicinal products is **negative**, and has recommended that all such products should be removed from the market in all Member States. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the attached **press release** and **Q & A document** issued by the EMEA. Further to this, the European Commission will shortly publish a Decision which is legally binding in all Member States and to be implemented by all Marketing Authorisation Holders holding a license for clobutinol-containing medicinal products.

The public is informed that Silomat® has been discontinued in Malta since 2004 and that no other clobutinol-containing medicinal products are authorised for marketing in Malta. Vivian Corporation, the local representatives for Boehringer Ingelheim, has, in collaboration with the Medicines Authority, circulated a communication to all pharmacists informing them about this situation and to remove any remaining stock of this product. It has furthermore issued a press release in local papers on 4th September 2007 to inform the general public about the possible risks associated with this product. The public is reminded that there is no cause for concern for potential late adverse effects. Further questions are addressed in the attached **Q & A document**.

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