Malta, 24 July 2007

Circular No. P10/2007

Dear Healthcare Professional,

Re: Withdrawal of Veralipride-containing Medicinal Products

Following assessment of all available data on the safety and efficacy of veralipride, the Committee for Medicinal Products for Human Use (CHMP) has concluded that it is associated with side effects, including depression, anxiety and tardive dyskinesia (a movement disorder which may be long-lasting or irreversible), both during and after treatment. Due to its limited efficacy, the CHMP further concluded that the risks of veralipride in the treatment of hot flushes associated with the menopause in women are greater than its benefits and therefore recommended that the medicine should be taken off the market. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is of the opinion that the advice provided in the EMEA's press release and Q & A document is appropriate and opportune. These documents are being made available for information only since there are no veralipride-containing medicinal products authorised for marketing in Malta.

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