Malta, 18 December 2009

Circular No. P14/2009

Dear Healthcare Professional,

Re: European Medicines Agency updates on ongoing safety review of sibutramine

The European Medicines Agency (EMA) is reviewing data that indicate an increased risk of serious cardiovascular events, such as stroke or heart attack, with medicines containing sibutramine. Sibutramine (Reductil) is indicated for use in obese patients and in overweight patients who also have other risk factors such as type-2 diabetes or dyslipidaemia (abnormal levels of fat in the blood).

Due to the seriousness of these findings, the Agency's Committee for Medicinal Products for Human Use (CHMP) is currently assessing the implications for use of sibutramine in normal clinical practice.

In the meantime, doctors and patients are reminded to use sibutramine-containing medicines with caution, and only in accordance with the currently approved product information. In particular, these medicines should not be used in patients with coronary artery disease, congestive heart failure, peripheral arterial occlusive disease, arrhythmia and cerebrovascular disease (stroke or transient ischemic attack). All patients should be regularly monitored for increases in blood pressure and heart rate. Patients who do not lose at least 5% of their body weight within 3 months should stop treatment. The maximum treatment duration should not exceed one year.

The Committee will conclude its review at its January 2010 meeting. Further information will be provided about the outcome at that stage.

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full press release issued by the EMA, attached here for your perusal.

Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt