Malta, 22 January 2010

Circular No. P01/2010

Dear Healthcare Professional,

Re: European Medicines Agency recommends suspension of marketing authorisations for sibutramine

The European Medicines Agency (EMA) has finalised a safety review of medicines containing sibutramine. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the risks of these medicines are greater than their benefits and recommended the suspension of marketing authorisations for these medicines across the European Union.

Sibutramine (available in Malta as Reductil) is used to promote weight-loss 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), together with diet and exercise.

Doctors should no longer prescribe, and pharmacists should no longer dispense the medicine. Patients currently taking sibutramine should make an appointment with their doctor at the next convenient time to discuss alternative measures to lose weight. Patients who wish to stop treatment before seeing their doctor can do so at any time.

The review was initiated because data from the Sibutramine Cardiovascular Outcome Trial (SCOUT) showed an increased risk of serious, non-fatal cardiovascular events, such as stroke or heart attack, with sibutramine compared with placebo. The SCOUT trial was designed to determine the impact of weight loss with sibutramine on cardiovascular problems in a large group of overweight and obese subjects with known or high risk for cardiovascular disease. The CHMP noted that the use of sibutramine was not in accordance with the prescribing information for most of the patients enrolled in the SCOUT study, as sibutramine is contra-indicated in patients with known cardiovascular disease. The treatment duration in the study was also longer than normally recommended. However, because obese and overweight patients are likely to have a higher risk of cardiovascular events, the Committee was of the opinion that the data from SCOUT are relevant for the use of the medicine in clinical practice.

The Committee also noted that the data from available studies show that the weight loss achieved with sibutramine is modest and may not be maintained after stopping. The CHMP was therefore of the opinion that the benefits of sibutramine as a weight-loss aid do not outweigh the cardiovascular risks.

The Committee's recommendation for the suspension of the marketing authorisations has now been forwarded to the European Commission for the adoption of a decision.

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full **press release** and **Q&A document** 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