IRISH MEDICINES BOARD

Notice Information: - Advisory
18 December 2009

Part 1. Product Information

a)	Title:	European Medicines Agency issues interim safety advice on risks associated with sibutramine
b)	Product Name/Type:	Reductil
c)	Active Substance:	Sibutramine

Part 2. Problem/Issue

a)	Problem/Issue:	The European Medicines Agency is reviewing data that indicate an increased risk of serious cardiovascular events, such as stroke or heart attack, with medicines containing sibutramine. The data come from the Sibutramine Cardiovascular OUTcomes (SCOUT) trial, which included nearly 10,000 patients enrolled for up to six years. Because of the seriousness of the findings of the SCOUT study, the Agency's Committee for Medicinal Products for Human Use (CHMP) is currently assessing the implications of these findings for the use of sibutramine in normal clinical practice.

Part 3. Background Information

a)	Background Information:	Sibutramine containing medicines (authorised as Reductil in Ireland) are indicated for use in obese patients and in overweight patients who also have other risk factors such as type-2 diabetes or dyslipidaemia. The European Medicines Agency has issued interim safety notice advising healthcare professionals (in particular prescribers) and patients to be aware of the potential risks associated with the use of sibutramine-containing medicines following receipt of new trial data. Advice to Healthcare Professionals and Patients: Healthcare professionals (in particular prescribers) and patients are reminded to prescribe and use sibutramine-containing medicines with caution, and only in accordance with the currently approved product information; 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 treated with sibutramine should be regularly monitored for increases in blood pressure and heart rate because sibutramine is known to increase 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 IMB will provide updated information when available.

Part 4. Enquiries

a)	All enquiries should be made to:	For more information go to the Agency's Press Release (18/12/09)