

FAX



IRISH MEDICINES BOARD

IMPORTANT SAFETY INFORMATION – PLEASE READ

**To: General practitioners,
Pharmacists, Cardiologists,
Endocrinologists**

**From: Dr. Joan Gilvarry
Director of Safety Monitoring**

Fax number: N/A

Date: 21st January, 2010

Re: Sibutramine (Reductil)

Dear Doctor/Pharmacist,

The IMB has **suspended the authorisations for sibutramine containing medicines in Ireland** following the recommendation issued by the European Medicines Agency (EMA) at 4pm today. The EMA's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of sibutramine do not outweigh its risks and that the marketing authorisations should be suspended across the European Union (EU).

Following assessment of the available information on the benefits and risks of sibutramine, including data from the SCOUT study (Sibutramine Cardiovascular OUTcomes Trial) completed in 2009; the CHMP has concluded that there is an increased risk of serious cardiovascular events, such as stroke and myocardial infarction with sibutramine, in patients with cardiovascular disease. The increased risk is considered to be applicable to patients without known cardiovascular disease given that obesity itself is a risk factor. Additionally, looking at all of the studies of sibutramine in the management of obesity, the CHMP noted that the weight loss achieved with sibutramine treatment is modest in comparison with that obtained with placebo.

The IMB has initiated a recall of the product and further information regarding the recall and suspension will be communicated to you separately, as necessary.

In the meantime, the IMB is advising with immediate effect that doctors should stop prescribing sibutramine-containing medicines and that pharmacists should no longer dispense these medicines. The treatment of patients currently taking sibutramine should also be reviewed. Patients are being advised via media statements that they should discontinue treatment with sibutramine and should consult their doctor or pharmacist at a convenient time to discuss alternative measures to lose weight.

Further information on the background to this issue and a Q&A document are available from the IMB/EMA websites (www.imb.ie / www.ema.europa.eu).

Yours sincerely,

Joan Gilvarry

**Dr. Joan Gilvarry, MB., FRCP
Director of Safety Monitoring**