

4.00pm Thursday, 21<sup>st</sup> January 2010

## **IMB SUSPENDS SIBUTRAMINE (REDUCTIL) ON IRISH MARKET**

The Irish Medicines Board (IMB) today confirms that in line with the European Medicines Agency (EMA) recommendation, medicines containing sibutramine are no longer authorised for use in Ireland. The IMB was a national participant in a decision making process at European level which concluded today\* that the risks of sibutramine-containing medicines outweigh their benefits. In the interest of patient safety, the recommendation is that the marketing authorisation for sibutramine-containing medicines should be suspended across the European Union.

Sibutramine is a prescription medicine used to assist weight loss in the treatment of obesity in adult patients or overweight patients with other risk factors such as type-2 diabetes or dyslipidaemia (abnormal levels of fat in the blood). It has been authorised for use in Ireland since 2001. The decision to recommend a suspension of these products follows a pan European review and assessment of data from a Sibutramine Cardiovascular OUTcomes (SCOUT) trial which showed an increased risk of serious cardiovascular events such as heart attack or stroke in patients with cardiovascular disease treated with this medicine. The risk is also considered to be applicable to patients without a diagnosis of cardiovascular disease as obesity is a risk factor for cardiovascular disease. In addition, when all available study data were considered, it was noted that the weight loss achieved with sibutramine treatment is modest in comparison with that obtained with placebo.

According to Dr. Joan Gilvarry, IMB Director of Safety Monitoring, patients currently taking sibutramine-containing medicines (marketed as Reductil) should stop taking this medicine and should consult with their doctor for advice on alternative measures to lose weight.

“The safety of this product has been monitored at European and national level since it was first licensed. Sibutramine-containing medicines have always been contraindicated for patients with known cardiovascular disease. However, following assessment of the recently available data from the SCOUT study, which involved 10,000 people, the increased risk of serious cardiovascular events observed in patients with cardiovascular disease was also considered to apply to those without cardiovascular disease. As a precautionary measure to protect patient health, sibutramine-containing medicines will no longer be authorised for use in Ireland.

“We have a relatively small number of patients using these products in Ireland and there are alternative treatments available if considered necessary. We are recommending to patients who are currently taking Reductil, or any other sibutramine-containing medicines, to stop taking this medicine and to visit their GP at their convenience for further advice. No further prescriptions for these products should be prescribed or dispensed by doctors and pharmacists,” she states.

Further information is available from the IMB and EMA websites at [www.imb.ie](http://www.imb.ie) and [www.ema.europa.eu](http://www.ema.europa.eu)

**ENDS**

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**NOTE TO EDITORS**

*\*The recommendation by European Medicines Agency was issued at 4pm today, 21<sup>st</sup> January 2010.*

Please note the following advice which has been issued by the Irish Medicines Board in relation to the suspension of all authorisations for medicines containing sibutramine.

**Advice to patients/consumers:**

- Stop taking the medicine.
- Return to your doctor when convenient for a review of your condition and further advice.

**Advice to Doctors:**

- Do not issue any new prescriptions for sibutramine containing medicines and review the treatment of patients currently taking these medicines.

**Advice to Pharmacists:**

- Do not continue to dispense any sibutramine-containing medicines and quarantine all existing stocks. Further information regarding recall arrangements will be issued shortly.
- If patients decide to return unused or partially used packs to you, please accept this stock back from patients and place it in quarantine. Please then follow the recall instructions that you will receive shortly from the IMB.

**ABOUT THE IRISH MEDICINES BOARD**

The Irish Medicines Board (IMB) is the competent authority for the licensing of human and veterinary medicines and medical devices in Ireland. Its role is to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products.