Thursday, 23rd October 2008

IMB CONFIRMS SUSPENSION OF ACOMPLIA
(20mg film-coated tablets)

The Irish Medicines Board (IMB) today confirms that in line with the European Medicines Agency (EMEA) recommended suspension of Acomplia (rimonabant) marketed by Sanofi-Aventis, this product will no longer be available on the Irish market. The IMB was a national participant in the decision making process at European level which concluded today* that the benefits of Acomplia no longer outweigh the risks. In the interest of patient safety, the recommendation is that the marketing authorisation for this product should be suspended across the European Union.

Acomplia is a prescription only medicine containing the active substance rimonabant used as an adjunct to diet and exercise in the treatment of obesity in adult patients or overweight patients with other risk factors such as diabetes or dyslipidaemia (abnormal levels of fat in their blood). It has been approved for use throughout the EU since 2006 and at that the time the potential for psychiatric side effects, in particular depression, were identified. Warnings about these side effects have been included in Acomplia's product information since it was first licenced and have been continuously updated and strengthened over time to include new warnings and contraindications in line with emerging data.

According to Dr. Joan Gilvarry, Director of Human Medicines, IMB, this product has been monitored closely and continually evaluated at European level since it was first licensed by the European Commission for use in Europe.

"Following assessment of the most recent data on Acomplia, an increased risk of psychiatric disorders for patients was confirmed. As a precautionary measure to protect patient health, this product will no longer be available. In Ireland, there are a relatively small number of patients on this product for whom alternative treatments are available. Patients currently taking Acomplia should stop their treatment and visit their GP at their convenience for further advice. No further prescriptions for Acomplia should be prescribed or dispensed by doctors and pharmacists," she stated.

Further information is available from the IMB and EMEA websites at www.imb.ie and www.emea.europa.eu

ENDS

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**The recommendation by European Medicines Agency was issued at 4pm today, 23rd October 2008.*

ABOUT THE IRISH MEDICINES BOARD
The Irish Medicines Board (IMB) is the regulatory body responsible for the regulation of medicines, medical devices and healthcare products available in Ireland.