IRISH MEDICINES BOARD

Notice Information: Human Medicines - Recall 23 October 2008

Part 1. Product Information

a)	Title:	Acomplia Suspension
b)	Product Name/Type:	Acomplia (rimonabant) 20mg Film Coated Tablets
c)	Active Substance:	Rimonabant
d)	Product Classification:	Weight-reducing / anti-obesity medicine
e)	Prescription Required:	Yes

Part 2. Problem/Issue

a) Problem/Issue:

IMMEDIATE SUSPENSION OF THE MARKETING OF ACOMPLIA
The Irish Medicines Board [IMB] today announced the suspension of Acomplia 20mg Film Coated Tablets in Ireland, with immediate effect, based on a recommendation by the European Medicines Agency (EMEA). Acomplia is a prescription only medicine containing the active substance rimonabant, and is used as an adjunct to diet and exercise in the treatment of obesity in adult patients or overweight patients with associated risk factors. It has been authorised in the EU since 2006. The EMEA's Committee for Medicinal Products for Human Use (CHMP) has concluded, based on evaluation of new data from post-marketing experience regarding psychiatric side effects, that the benefits of Acomplia no longer outweigh its risks and that the marketing authorisation should be suspended across the European Union (EU).

Part 3. Action to be taken

a)	Action to be taken:	Advice to patients/consumers: - Stop taking the medicine. - Return to your doctor when convenient for a review of your condition and further advice. - Return any remaining packs (unused or partially used) of the above products to your pharmacist. Advice to Doctors: - Do not issue any prescriptions for Acomplia and review the treatment of patients currently taking the medicine. Advice to Pharmacists: - Do not dispense any Acomplia and quarantine existing stocks. The IMB is working to inform all patients and healthcare professionals of this issue and has instructed the relevant company to recall their products from all patients / consumers, pharmacies, hospitals and wholesalers immediately.

Part 4. Enquiries

a)	All enquiries should be made to:	The Press Release is available for download. Further information, including a Questions and Answers document, is available from the EMEA Website . Patients and healthcare professionals who have any queries can contact the IMB on 01-6764971 Media Queries: Siobhan Molloy / Angie Grant (Weber Shandwick) Tel: (01) 676 01 68 or 086 817 50 66 / 086 377 2791

Part 5. Keywords

a)	Keywords:	Acomplia (rimonabant) recall warning suspension