IRISH MEDICINES BOARD

Notice Information: Human Medicines - Warning 19 July 2007

Part 1. Product Information

a)	Title:	Acomplia must not be used inpatients on antidepressants or with major depression
b)	Product Name/Type:	Acomplia
c)	Active Substance:	Rimonabant
d)	Authorisation Holder:	Sanofi-Aventis
e)	Prescription Required:	Yes

Part 2. Problem/Issue

a) Problem/Issue:

European Medicines Agency recommends Acomplia must not be used in patients on antidepressants or with major depression The European Medicines Agency (EMEA) today recommended contraindicating Acomplia (rimonabant) from sanofi-aventis, in patients with ongoing major depression or who are being treated with antidepressants, because of the risk of psychiatric side effects. Doctors in the EU have already been warned about this since June 2006 but the Agency's Committee for Medicinal Products for Human Use (CHMP) has now recommended upgrading this warning. Acomplia has been authorised in the EU since June 2006 as an adjunct to diet and exercise for the treatment of obese or overweight adult patients. Psychiatric side effects, in particular depression, were identified as the main safety issue at the time of approval. They were reflected in the medicine's product information as a warning that doctors should not prescribe Acomplia in patients with uncontrolled serious psychiatric conditions such as major depression. As part of its continuous monitoring of the safety of medicines, the CHMP requested sanofi-aventis in June 2007 to submit all available information on the psychiatric side effects of Acomplia. Finalising the assessment of the available data at its 16-19 July 2007 meeting, the CHMP concluded that the benefits of Acomplia continue to outweigh its risks, except in patients with ongoing major depression or taking antidepressants. The CHMP also recommended adding a warning that treatment with Acomplia should be stopped if a patient develops depression, as well as the inclusion of additional information on the psychiatric safety of Acomplia. Doctors will be sent a letter to inform them about the updated prescribing information. Patients and their carers should be aware of the risk of depression in patients taking Acomplia. The CHMP recommendation will now be forwarded to the European Commission for adoption of a Decision. (The above has been taken from the EMEA Press Release)

Part 3. Enquiries

a) All enquiries should be made to:

Notes: 1. For more information, see the accompanying question-and-answer document , which also includes the recommended updated product information (in Annex 1). 2. Acomplia is authorised in the European Union/European Economic Area, and is marketed in 13 European countries. Rimonabant is also authorised as Zimulti, but this product is not marketed in the European Union. 3. The European Public Assessment Report for Acomplia can be found here: http://www.emea.europa.eu/humandocs/Humans/EPAR/acomplia/acomplia.htm 4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu Media enquiries only to: Martin Harvey Allchurch or Monika Benstetter Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu

Part 4. Keywords

a)	Keywords:	Acomplia rimonabant