Malta, 20 July 2007

Circular No. P09/2007

Dear Healthcare Professional,

Re: Risk of Psychiatric Side-effects associated with the Use of Acomplia (Rimonabant)

As part of its continuous monitoring on the safety of medicines, the Committee for Medicinal Products for Human Use (CHMP) has assessed all available data to date on psychiatric side-effects associated with the use of Acomplia. The CHMP concluded that the benefit-risk profile of this product remains positive, except in patients with ongoing major depression or taking antidepressants. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is of the opinion that the advice provided in the EMEA's press release and Q & A document is appropriate and opportune, and recommends prescribers to follow this advice when prescribing Acomplia. Furthermore, the Medicines Authority has agreed with Sanofi-Aventis, which is the license holder for this product in the European Union, to circulate a Dear Healthcare Professional Letter to local prescribers, detailing the outcome of the CHMP's discussion. The Medicines Authority will notify healthcare providers and patients in a timely fashion as new information becomes available.

Medicines Authority
198, Rue D'Argens, Gzira, GZR 03 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 email: info.mru@gov.mt