

Malta, 23 October 2008

Circular No. P11/2008

Re: The EMEA recommends the suspension of the marketing authorisation of Acomplia

The European Medicines Agency (EMA) has recommended the suspension of the marketing authorisation for Acomplia (rimonabant) from Sanofi-Aventis. The EMA's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Acomplia no longer outweigh its risks and that the marketing authorization should be suspended across the European Union (EU).

Acomplia has been authorised in the EU since June 2006 as an adjunct to diet and exercise for the treatment of obese patients or overweight patients with associated risk factors. Warnings about psychiatric side effects, in particular depression, have been included in the product information since Acomplia was first authorised. The product information for Acomplia has been continuously updated and strengthened to include further contraindications and upgraded warnings on these concerns to manage the risks associated with the use of Acomplia.

Following the assessment of the available information on the benefits and risks of Acomplia including data from studies completed since it was granted marketing authorisation, the CHMP confirmed at its 20-23 October meeting, that there is an approximate doubling of the risk of psychiatric disorders in obese or overweight patients taking Acomplia compared to those taking placebo.

The CHMP considered that the new data from post-marketing experience and ongoing clinical trials indicated that serious psychiatric disorders may be more common than in the clinical trials used in the initial assessment of the medicine. The CHMP was also of the opinion that these psychiatric side effects could not be adequately addressed by further risk minimisation measures.

In addition, the CHMP noted, that the effectiveness of Acomplia in clinical practice is more limited than was expected on the basis of the clinical trials, because available data indicate that patients generally take Acomplia only for a short period.

Prescribers should not issue any prescriptions for Acomplia and should review the treatment of patients currently taking the medicine. Patients who are currently taking Acomplia should consult their doctor or pharmacist at a convenient time to discuss their treatment. There is no need for patients to stop treatment with Acomplia immediately, but patients who wish to stop can do so at any time.

The CHMP opinion will now be sent to the European Commission for the adoption of a decision, applicable in all EU countries.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the full [press release](#) and [Q&A document](#) issued by the EMEA, attached here for your perusal.