



London, 23 October 2008
Doc. Ref. EMEA/CHMP/537777/2008

PRESS RELEASE

The European Medicines Agency recommends 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 the marketing authorisation 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. Patients currently included in clinical trials with Acomplia should contact the investigator, who will be able to provide more information.

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

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Notes:

1. More information is available in a [question and answer document](#)
2. The suspension of a marketing authorisation is a precautionary measure, during which time a medicinal product is not available. The lifting of the suspension is conditional on the marketing authorisation holder resolving the issues identified by the Agency

3. Acomplia is marketed in 18 Member States (Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Lithuania, Malta, the Netherlands, Slovakia, Spain, Sweden and the United Kingdom). Rimonabant is also authorised as Zimulti. Zimulti is not marketed in the EU.
4. In July 2007, the CHMP recommended contraindicating Acomplia in patients with ongoing major depression or who are being treated with antidepressants. Furthermore, in May 2008, the CHMP recommended updating the product information to reflect the fact that depression may occur as a side effect of Acomplia in patients who have no obvious risk factors apart from obesity itself, and to advise prescribers to monitor patients for signs and symptoms of psychiatric disorders, particularly depression, after the start of treatment.
5. The review of Acomplia was initiated under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated when there are public health concerns with a centrally authorised medicine. The European Commission asked the CHMP to assess all aspects of safety of the centrally authorised medicines containing rimonabant and to give its opinion on the measures deemed necessary to ensure the safe use of rimonabant and on whether the marketing authorisation for these products should be maintained, varied, suspended or withdrawn.
6. More information on Acomplia is available in the European Public Assessment Report (EPAR) on the Agency's website:
<http://www.emea.europa.eu/humandocs/Humans/EPAR/acomplia/acomplia.htm>
7. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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