sanofi aventis

Because health matters

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

IMPORTANT SAFETY INFORMATION

Acomplia® (rimonabant) 20mg Film Coated Tablets
MA: EU/1/06/344/002

Prescribers should not issue or renew any prescription for ACOMPLIA

Patients who are currently taking ACOMPLIA should consult their doctor or pharmacist at a convenient time to discuss their treatment.

24th October 2008

Dear Healthcare Professional,

Following discussions with EU regulatory agencies including the Irish Medicines Board (IMB), sanofi-aventis would like to inform you that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has recommended the suspension of the marketing authorisation for Acomplia (rimonabant). In line with this recommendation, sanofi-aventis is requesting you to not prescribe or dispense Acomplia.

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 such as type 2 diabetes and dyslipidaemia.

At the time of approval warnings of psychiatric side effects, in particular depression, were included in the product information and identified as the main area for further monitoring. There was approximately a doubling of the risk of psychiatric disorders in patients taking Acomplia in completed clinical studies versus placebo. The product information 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, the CHMP at its October 2008 meeting, considered that in clinical practice the serious psychiatric disorders such as depression, anxiety, sleep disorders and aggressiveness may be more common compared to what was foreseen at the time of approval. Furthermore, the CHMP was concerned that depression could lead to suicidal ideation or even suicide attempts.

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Registered in Dublin, Ireland No. 166500. Directors: T.J. McLaughlin, P. Cuneo (BE), T.G. Coul

In line with the IMB recommendations:

- No further prescriptions for Acomplia should be written or dispensed and a recall has been initiated to patient level.

- Patients are being advised via media statements that they should discontinue treatment with Acomplia and should consult their doctor or pharmacist at a convenient time to discuss treatment options.

- Ongoing clinical trials in Ireland with Acomplia have been voluntarily suspended and further communications will be issued to clinical trial investigators.

Call for reporting

Any suspected adverse reactions experienced by your patients should be reported to the company and /or the IMB in the usual way.

Communication information

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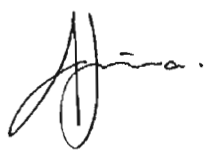
Email address: iemedinfo@sanofi-aventis.com

We remain at your disposal for any further information you may need.

Yours sincerely,



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