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QSM/MC/IEA.119 25 October 2008

Information Exchange System

Alert No. 119

Marketing authorization for rimonabant to be suspended across the European Union since the benefits of the medicine do not outweigh its risks

The European Medicines Agency (EMEA) has recommended the suspension of the marketing authorization for rimonabant (Accomplia) from Sanofi-Aventis. Rimonabant was authorized in 2006 in the European Union as an adjunct to diet and exercise, for the treatment of obese patients or overweight patients with associated risk factors. Psychiatric side effects were included in rimonabant's Product Information when it was first authorized. Additional related warnings and contraindications were added later, to strengthen the product information and to manage the risks associated with its use.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) has now assessed all available information on the benefits and risks of rimonabant, including data from studies completed since it was granted marketing authorization, and has concluded that the benefits no longer outweigh the risks of psychiatric side effects with rimonabant; the current data suggest that serious psychiatric disorders may be more common than was observed in the clinical trials used in initial assessment of the medicine. The CHMP has confirmed that there is an approximate doubling of the risk of psychiatric disorders in obese or overweight patients taking rimonabant compared to those taking placebo. The CHMP also notes that these psychiatric side effects cannot be adequately addressed by further risk minimization measures.

Prescribers are advised not to issue any prescriptions for rimonabant. Patients who are currently taking rimonabant are advised to consult their doctor or their pharmacist to discuss their treatment.

Reference:

European Medicines Agency recommends suspension of the marketing authorization of Accomplia. EMEA Press Office, 23 October 2008 (www.emea.europa.eu).