

HTA Blog

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[EMEA withdraws antiobesity drug](#)

The antiobesity drug rimonabant (sold under the brand name Acomplia) has had its marketing authorisation suspended across Europe. The European Medicines Agency (EMA) says that the benefits no longer outweigh the risks of psychiatric disorders, particularly depression.

Doctors have been advised not to issue new prescriptions for rimonabant and to review the treatment of any patients taking it. Patients taking rimonabant should see their doctor or pharmacist to discuss their treatment. There is no need for them to stop taking rimonabant immediately, the agency advises, but they can if they wish.

Warnings about psychiatric side effects, in particular depression, have been included in rimonabant's product information ever since it was first approved in Europe in June 2006. In June 2007 use of the drug was contraindicated in anyone with major depressive disorders or who was taking antidepressant drugs. In March this year the product information was updated again, to advise doctors to monitor patients taking rimonabant for signs of depression and other psychiatric disorders.

The US Food and Drug Administration decided not to license rimonabant because of concerns about depression and suicidal ideation and because of lack of evidence about the long term risks.

The European agency's Committee for Medicinal Products for Human Use reviewed all the evidence relating to rimonabant since it was granted marketing authorisation. It found that serious psychiatric disorders may be more common than in the clinical trials considered in the initial assessment of the drug and that the effectiveness in clinical practice is more limited than expected because patients generally take rimonabant for only a short period.

In a letter to healthcare professionals informing them of the European review, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) wrote: "There was approximately a doubling of the risk of psychiatric disorders in patients taking rimonabant compared with patients taking placebo." The letter also said that symptoms such as depression, sleep disturbance, anxiety, and aggression may be more common in clinical practice than in the prelicensing clinical trials.

The committee considered that further restrictions on the use of rimonabant would not be sufficient to reduce the risk of harm. The MHRA said: "The measures and clinical advice implemented to date to try to reduce the frequency of psychiatric reactions (particularly depression) with rimonabant

have not adequately controlled this risk. Patients who may be at highest risk of psychiatric reactions cannot be identified reliably. Therefore, further restrictions on the use of this medicine would be unlikely to reduce the risk to an acceptable level."

By January 2008 the MHRA had received 876 reports of psychiatric reactions to rimonabant, including 52 reports of suicidal or self harming thoughts or behaviour. There was one death by suicide. For comparison, the MHRA said that, by the end of 2007, prescriptions for rimonabant had been issued for the equivalent of 21 000 patient treatment years.

Rimonabant is a cannabinoid receptor antagonist that acts as an appetite suppressant. It was approved by the UK's National Institute for Health and Clinical Excellence in June this year as a second line treatment for obesity after orlistat or sibutramine.

Rimonabant's manufacturer, Sanofi Aventis, said in a statement that it "remained committed" to the drug and expected the suspension of marketing authorisation to be temporary.

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The European Medicines Agency's press release is at www.emea.europa.eu/humandocs/PDFs/EPAR/acomplia/53777708en.pdf.

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