

# Prescribing and Clinical Effectiveness Bulletin

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## **RIMONABANT (ACOMPLIA): MARKETING AUTHORISATION SUSPENDED**

The European Medicines Agency (EMA) has recommended the suspension of the marketing authorisation of rimonabant (Acomplia) across the European Union following an assessment of the latest safety data. Prescribers will already be aware of existing concerns related to the use of rimonabant in patients at risk of depression or suicide and those taking antidepressant drugs or suffering from major depression (see *PACE Bulletins*, Vol 2, Nos 10 and 13). A review of recent data at the October meeting of the EMA's Committee for Medicinal Products for Human Use (CHMP) identified an approximate doubling of the risk of psychiatric disorders in obese or overweight patients taking rimonabant compared to placebo. In addition, between June and August 2008, five cases of suicide were reported in patients taking rimonabant in ongoing studies compared to one suicide linked to placebo. The CHMP have also reviewed the data on effectiveness and have concluded that rimonabant is probably less effective than originally thought because most patients take the drug for much shorter periods than the duration of the early trials.

EMA advice to patients and prescribers is as follows:

- Prescribers should not issue any further prescriptions for rimonabant (Acomplia) and should review the treatment of all patients currently taking this medicine.
- Patients currently taking rimonabant (Acomplia) should be encouraged to consult their doctor as soon as convenient to review their treatment and discuss alternative options.
- There is no need for patients to stop treatment with rimonabant (Acomplia) immediately, although patients who wish to stop treatment can do so at any time.

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