

Dear Colleagues

### **Risk of depression and suicidal behaviour with Acomplia (rimonabant)**

I am writing to inform you of new advice on the risk of psychiatric reactions including depression and suicidal behaviour associated with Acomplia (rimonabant). Acomplia should not be prescribed to patients with ongoing major depressive illness and/or ongoing treatment with antidepressants.

Acomplia, a cannabinoid CB1 receptor antagonist, is indicated “As an adjunct to diet and exercise for the treatment of obese patients (BMI $\geq$  30kg/m<sup>2</sup>), or overweight patients (> 27kg/m<sup>2</sup>) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia”

In clinical trials, depressive disorders or mood alterations with depressive symptoms have been reported in up to 10%, and suicidal ideation in up to 1% of patients receiving rimonabant. This risk may be increased in patients with a past history of psychiatric illness. Following assessment of these data, the use of Acomplia has been restricted and the Summary of Product Characteristics (SmPC) has been amended as follows.

#### **Prescribing advice:**

- **Treatment of patients with ongoing major depressive illness and/or ongoing antidepressive treatment is contraindicated.**
- **Acomplia should not be used in patients with current suicidal ideation or with a history of suicidal ideation or depressive disorder unless the benefit of the treatment is considered to outweigh the risk in the individual patient.**
- **Therapy with Acomplia is not recommended in patients with uncontrolled psychiatric illness other than depression**
- **Patients and carers or relatives should be informed about the risk of depression.**
- **Patients should be encouraged to stop treatment and seek medical advice if symptoms of depression occur. Treatment with Acomplia should be stopped if depression occurs.**

Please report any suspected adverse reactions to rimonabant to the Medicines and Healthcare products Regulatory Agency (MHRA) by use of a Yellow Card, which is available from MHRA, CHM Freepost, London SW8 5BR, or electronically via <http://www.mhra.gov.uk>. Further information and a questions and answers document is available on the MHRA website.

Yours sincerely

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