



European Medicines Agency

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PUBLIC STATEMENT ON

Acomplia (rimonabant)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 19 June 2006, the European Commission granted a marketing authorisation valid throughout the European Union for the medicinal product Acomplia (rimonabant), indicated as an adjunct to diet and exercise for the treatment of obese patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} > 27 \text{ kg/m}^2$) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia.

On 13 November 2008, the marketing of Acomplia was suspended in all the Member States in which the product was being marketed.

On 5 December 2008, the marketing authorisation holder (MAH) responsible for Acomplia, sanofi-aventis, notified the European Commission of its decision to voluntarily withdraw its marketing authorisation. The MAH stated that no additional clinical data will now be available to lift the suspension of the marketing authorisation for Acomplia following its decision to discontinue the ongoing rimonabant clinical development program in all indications.

On 16 January 2009, the European Commission issued a decision to withdraw the marketing authorisation for Acomplia. Pursuant to this decision the European Public Assessment Report for Acomplia will be updated to reflect that the marketing authorisation is no longer valid.

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