European Medicines Agency

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PUBLIC STATEMENT ON

Zimulti
(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 Zimulti (rimonabant), indicated as an adjunct to diet and exercise for the treatment of obese patients (BMI ≥ 30 kg/m^2), or overweight patients (BMI > 27 kg/m^2) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia.

Zimulti had not been marketed anywhere in the European Union (EU) since its initial marketing authorisation.

On 5 December 2008, the marketing authorisation holder (MAH) responsible for Zimulti, 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 Zimulti 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 Zimulti. Pursuant to this decision the European Public Assessment Report for Zimulti will be updated to reflect that the marketing authorisation is no longer valid.

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