



European Medicines Agency
Evaluation of Medicines for Human Use

London, 16 September 2008
EMA/CHMP/500252/2008

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
(CHMP)**

**OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR
Remeron and associated names**

International Non-Proprietary Name (INN): mirtazapine

BACKGROUND INFORMATION

Remeron and associated names, 15, 30 and 45 mg tablets, 15, 30 and 45 mg orodispersible tablets, 15 mg/ml oral solution, is a noradrenergic and specific serotonergic antidepressant indicated for the treatment of episodes of major depression.

On 11 October 2007, N.V. Organon presented to the EMA a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the nationally authorised Summaries of Product Characteristics (SPC), Labelling and Package Leaflet, including quality aspects of the medicinal product **Remeron** and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) including quality aspects of **Remeron** and associated names approved across EU Member States, with respect to treatment of major depressive episodes.

The procedure started on 15 November 2007. The Marketing Authorisation Holder provided supplementary information on 19 March 2008

During its June 2008 meeting, the CHMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the proposal for the harmonisation of the SPC, Labelling and Package Leaflet including the quality aspects was acceptable and that they should be amended.

The CHMP gave a positive opinion on 26 June 2008 recommending the harmonisation of the SPC, Labelling and Package Leaflet including quality aspects for **Remeron** and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC, Labelling and Package Leaflet in Annex III.

A Decision was issued by the European Commission on 15 September 2008.