



European Medicines Agency
Evaluation of Medicines for Human Use

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

**OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR
Risperdal Consta and associated names**

International Non-Proprietary Name (INN): risperidone

BACKGROUND INFORMATION

Risperdal Consta and associated names is an anti-psychotic, indicated for the maintenance treatment of schizophrenia in patients currently stabilised with oral antipsychotics. It is available as prolonged release powder and solvent for suspension for intramuscular use.

On 24 July 2007 the European Commission presented to the EMEA 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 of the medicinal product Risperdal Consta and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) of Risperdal Consta and associated names approved across EU Member States, with respect to the indication, the special warnings and precautions for use and the interaction with other medicinal products and other forms of interaction.

This medicinal product belongs to the list of products identified in 2007 for SPC harmonisation.

The procedure started on 20 September 2007. The Marketing Authorisation Holder provided supplementary information on 28 January 2008 and 28 April 2008.

During its July 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 was acceptable and that they should be amended.

The CHMP gave a positive opinion on 24 July 2008 recommending the harmonisation of the SPC, Labelling and Package Leaflet for Risperdal Consta 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 7 October 2008.