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 and associated names

International Non-Proprietary Name (INN): risperidone

BACKGROUND INFORMATION

Risperdal and associated names is as an antipsychotic, indicated for the treatment of schizophrenia, manic episodes associated with bipolar disorders, persistent aggression in patients with moderate to severe Alzheimer's dementia and treatment of persistent aggression in conduct disorder in children. It is available as film coated tablets, oro-dispersible tablets (rapidly disintegrating) and oral solution.

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 and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) of Risperdal and associated names approved across EU Member States, with respect to the indications, the posology and method of administration, the contra-indications, 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 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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu