European Medicines Agency
Evaluation of Medicines for Human Use

London, 6 October 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR

Zyrtec and associated names

International Non-Proprietary Name (INN): cetirizine

BACKGROUND INFORMATION

Zyrtec and associated names, 10 mg film coated tablets, 10 mg/ml oral drops, 1 mg/ml oral solution, is an anti-allergic drug indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis and for the relief of chronic idiopathic urticaria.

On 9 October 2007 the 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 **Zyrtec** and associated names.

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

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

The procedure started on 18 October 2007. The Marketing Authorisation Holder provided supplementary information on 28 January 2008.

During its May 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 30 May 2008 recommending the harmonisation of the SPC, Labelling and Package Leaflet for **Zyrtec** 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 6 October 2008.

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