European Medicines Agency

London, 21 August 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)
OPINION FOLLOWING AN ARTICLE 6(12) REFERRAL

Prozac and associated names

International Non-Proprietary Name (INN): **Fluoxetine**

BACKGROUND INFORMATION*

Fluoxetine is a selective inhibitor of serotonin reuptake.

Prozac is authorised in most EU Member States for the treatment of major depressive episodes, obsessive-compulsive disorder and bulimia nervosa in adults. The CHMP began an arbitration review for Prozac, following an application by the marketing authorisation holder to extend the indication to include the treatment of major depressive episodes in children and adolescents.

On 2 May 2005, France referred the matter to the EMEA under Article 6(12) of Commission Regulation EC No 1084/2003.

The review was initiated on the basis of unresolved safety and efficacy concerns.

The referral procedure started on 26 May 2005.

The Rapporteur and Co-Rapporteur appointed were: Dr Barbara van Zwieten-Boot and Dr Tomas Salmonson, respectively.

Written explanations were provided by the Marketing Authorisation Holders on 29 August 2005, 6 January 2006, 3 April 2006 and 11 May 2006. Oral explanations were given by the Marketing Authorisation Holders on 26 April 2006.

Based on evaluation of the currently available data and the Rapporteurs' assessment reports, the CHMP considered that the benefits of Prozac are greater than its potential risks in this population and therefore adopted an opinion on 1 June 2006 recommending the following extension of the indication:

Children and adolescents aged 8 years and above: Moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4-6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression only in combination with a concurrent psychological therapy.

The Member States competent authorities will continue to keep the product under regular review.

The list of product names concerned is given in the Annex I. The scientific conclusions are provided in the Annex II, together with the amended product information in the Annex III and the conditions of the marketing authorisations in the Annex IV.

The final opinion was converted into a Decision by the European Commission on 21 August 2006.

* **Notes**: The information given in this document and Annexes reflect only the CHMP Opinion dated 1 June 2006. The Member States competent authorities will continue to keep the product under regular review.

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