European Medicines Agency

29 March 2005
CHMP/187488/2004

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
OPINION FOLLOWING AN ARTICLE 31 REFERRAL

Paroxetine

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

BACKGROUND INFORMATION*

Paroxetine is a phenylpiperidine derivative and is a selective inhibitor of the presynaptic 5-hydroxytryptamine (5-HT) reuptake. Paroxetine inhibits the neuronal uptake of serotonin and thereby facilitates serotonergic transmission. Paroxetine was first approved in 1990 as an antidepressant in the U.K. Subsequently national Marketing Authorisations have been granted in all EU Member States for the treatment of various psychiatric disorders.

On 13 June 2003, UK referred the matter to the EMEA under Article Article 31 of Directive 2001/83/EC, as amended, for paroxetine containing medicinal products. The reasons for referral concerned the risk of emotional lability, including hostility and suicidal behaviour in children and adolescents and withdrawal reactions with paroxetine.

The referral procedure started on 26 June 2003. The Rapporteur and Co-Rapporteur appointed were: Dr. F. Lekkerkerker and Dr. P. Arlett, respectively. During the referral procedure Dr. B. van Zwieten Boot took over the Rapporteurship from Dr. F. Lekkerkerker and Dr. F. Rotblat took over from Dr. P. Arlett. Written explanations were provided by the Marketing Authorisation Holder by 1 September 2003, 13 February 2004, 2 April 2004 and 16 April 2004. Oral explanations were given on 20 April 2004.

Based on evaluation of the available data and the Rapporteurs' assessment reports, the CHMP considered that the benefit/risk profile of paroxetine containing medicinal products remains favourable. The CHMP adopted an opinion on 22 April 2004. The final CHMP opinion was adopted on 8 December 2004 recommending

> *the variation of the Marketing Authorisations in accordance with the Summary of Product Characteristics for paroxetine containing medicinal products.*

Paroxetine containing medicinal products are approved for the treatment of:

- Major depressive episode
- Obsessive compulsive disorder
- Panic disorder with and without agoraphobia
- Social anxiety disorders / social phobia
- Generalised anxiety disorder
- Post-traumatic stress disorder

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

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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 Summary of Product Characteristics 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 29 March 2005.

Notes: The information given in this document and Annexes reflect only the CHMP Opinion dated 8 December 2004.

Following the adoption of the CHMP Opinion for paroxetine, the CHMP further reviewed the risk of suicidal behaviour in children and adolescents treated with this type of medicines. An updated warning in relation to children and adolescents was recommended to be included in the Product Information. For more information please refer to:
http://www.emea.eu.int/pdfs/human/referral/SSRIs/29783705en.pdf
http://www.emea.eu.int/pdfs/human/referral/SSRIs/EMEA-H-A-31-651-SSRIs-en.pdf

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