

EMEA/CHMP/266022/2008 EMEA/H/A-5.3

## OPINION OF THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE PURSUANT TO ARTICLE 5(3) OF REGULATION (EC) No 726/2004, ON ANTIDEPRESSANTS

## **Basis for opinion**

On 26 March 2008, the European Commission presented to the EMEA a request for a CHMP opinion under Article 5(3) of Regulation (EC) No 726/2004 on antidepressants, as a result of a published meta-analysis that questioned the efficacy and clinical relevant effects of antidepressants approved for the treatment of patients with major depression. The grounds for this request are appended to this opinion (Appendix 1).

The procedure started on 24 April 2007.

## **Opinion**

The CHMP, having considered the matter as set out in the appended assessment report (Appendix 2), is of the opinion that no public health concerns have been identified that are considered as being of Community interest. Therefore, the CHMP recommends that no further action should be taken at Community level.

The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

This opinion is forwarded to the European Commission, all other Member States, Iceland and Norway, together with its appendices.

The opinion will be published on the EMEA website.

London, 30 May 2008

On behalf of the CHMP Dr Eric Abadie, Chairman