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

Efexor depot and associated names

International Non-Proprietary Name (INN): venlafaxine

BACKGROUND INFORMATION

Efexor depot, 37.5 mg, 75 mg, 150 mg, hard prolonged-release capsules, is an antidepressant, indicated for the treatment of major depressive episodes, for the prevention of recurrence of major depressive episodes, for the treatment of social anxiety disorder, panic disorders with or without agoraphobia, and generalized anxiety disorder.

On 3 May 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 Efexor depot.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) of Efexor depot approved across EU Member States, with respect to the treatment of major depressive episodes, the prevention of recurrence of major depressive episodes, the treatment of social anxiety disorder, panic disorders with or without agoraphobia, and generalized anxiety disorder.

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

The procedure started on 24 May 2007. The Marketing Authorisation Holder provided supplementary information on 26 September 2007.

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 with a subsequent revision on 25 September 2008 recommending the harmonisation of the SPC, Labelling and Package Leaflet for Efexor depot**.**

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 28 November 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