European Medicines Agency
Evaluation of Medicines for Human Use

London, 13 April 2007
EMEA/CHMP/75285/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(4)[1] REFERRAL FOR

Alendronate HEXAL and associated names

International Non-Proprietary Name (INN): alendronic acid (as sodium alendronate trihydrate)

BACKGROUND INFORMATION

Alendronate HEXAL and associated names, 10 mg tablets, contains alendronic acid as sodium alendronate trihydrate, which is a bisphosphonate indicated in the treatment of post-menopausal osteoporosis.

Hexal A/S submitted applications for mutual recognition of Alendronate HEXAL and associated names, 10 mg tablets on the basis of the marketing authorisation granted by Sweden on 3 December 2004. The Reference Member State was Sweden and in the first wave of the mutual recognition procedure, the concerned Member States which have already granted the marketing authorisation were Germany and Poland. In the repeat use of the Mutual Recognition procedure, which started on 11 October 2005, the application was submitted to the Concerned Member States (CMS): Belgium, Greece and Denmark. These Member States were not able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. Sweden referred the reasons for disagreement to the EMEA on 10 July 2006.

Significant difference has been identified with regard to the indication for treatment of osteoporosis in men and this was considered to be of serious public health concern.

The arbitration procedure started on 27 July 2006 with the adoption of a list of questions. The Rapporteur was Dr. Tomas Salmonson and Co-Rapporteur(s) was Dr. Frits Lekkerkerker. The Marketing Authorisation Holder provided written explanations on 19 October 2006.

During their January 2007 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the objections that triggered the Article 29 Referral, should not prevent the granting of a Marketing Authorisation for Alendronate HEXAL and associated names. The CHMP considered that the benefit/risk ratio was considered to be favourable in the following indication: "Treatment of osteoporosis in men at increased risk of fracture. A reduction in the incidence of vertebral, but not of non-vertebral fractures has been demonstrated". Therefore the CHMP issued a positive opinion on 24 January 2007 recommending the granting of the Marketing Authorisation and the amendments of the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State.

The list of the product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the Summary of Product Characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 13 April 2007.

[1] Article 29(4) of Directive 2001/83/EC, as amended.

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