European Medicines Agency
Evaluation of Medicines for Human Use

London, 03 April 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(2)[1] REFERRAL FOR

Nifedipine Pharmamatch 30 and 60 mg

International Non-Proprietary Name (INN): Nifedipine

BACKGROUND INFORMATION

Nifedipine Pharmamatch 30 and 60 mg prolonged release tablets (nifedipine) is 1,4 – dihydropyridine calcium antagonist used for symptomatic treatment of chronic stable angina pectoris as monotherapy or in combination with a beta-blocker and in the treatment of patients with light to moderate essential hypertension.

Pharmamatch BV submitted applications for mutual recognition of Nifedipine Pharmamatch retard 30 and 60 mg tablets on the basis of the marketing authorisation granted by the Netherlands on 29 November 2004. The Mutual Recognition Procedure started on 25 May 2005. The Reference Member State was Netherlands and the Concerned Member States were Belgium and the United Kingdom. These Member States were not been able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. The United Kingdom referred the reasons for disagreement to the EMEA on 23 August 2005.

Significant differences have been identified with regard to the proposed SPC compared to the SPC of the reference product in the UK. The differences in section 4.3 and 4.6 were considered to be of serious public health concern. Section 4.3 and 4.6 of the SPC of the reference product in the UK contains the information that the product is contraindicated in pregnancy, for women capable of child-bearing or for nursing mothers.

The arbitration procedure started on 15 September 2005. The Rapporteur and Co-Rapporteur appointed were Tomas Salmonson and Eric Abadie, respectively. The Marketing Authorisation Holder provided written explanations on 13 October 2005.

During the January 2006 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for Nifedipine Pharmamatch retard 30 and 60 mg tablets, that the objections raised by United Kingdom should not prevent the granting of a Marketing Authorisation and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be amended. A positive opinion was adopted 26 January 2006.

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 03 April 2006.

[1] Article 29(2) of Directive 2001/83/EC, as amended.

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