The European Agency for the Evaluation of Medicinal Products
Pre-authorisation Evaluation of Medicines for Human Use

London, 1 December 2003
EMEA/CPMP/3258/03/en/Final

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

SUMMARY INFORMATION ON REFERRAL OPINION FOLLOWING ARBITRATION

PURSUANT TO ARTICLE 30 OF COUNCIL DIRECTIVE 2001/83/EC FOR

Calcichew-D3 mite and associated names

International NonProprietary Name (INN): Calcium 500 mg / cholecalciferol 5 µg

BACKGROUND INFORMATION

Cholecalciferol (vit D3), undergoes a biotransformation into 1,25 dihydroxycholecalciferol, a main active metabolite of vitamine D, which is necessary to promote the intestinal absorption of calcium. Calcium is essential for a number of physiological functions and particularly bone mineralization.

Medicinal products containing cholecalciferol and/or calcium carbonate have been nationally authorised in EU Member States, resulting in different Summaries of Product Characteristics based on individual national decisions.

Nycomed Pharma AS presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, in order to harmonise the national SPCs of the medicinal product Calcichew-D_3 mite and associated names and additionally to harmonise the pharmaceutical documentation . A dossier in CTD format and a proposal for a harmonised SPC were submitted by the MAH on 20 September 2002. The referral procedure started on 27 September 2002.

The CPMP having considered the Rapporteur and the Co-Rapporteur assessment reports, and scientific discussion within the Committee was of the opinion that the benefit/risk ratio of calcium carbonate is considered to be favourable. The CPMP issued a positive opinion, on 26 June 2003, recommending the harmonisation of the SPC for Calcichew-D3 mite and associated names for the following agreed therapeutic indications: prevention and treatment of vitamine D and calcium deficiency; vitamin D and calcium supplement as an adjunct to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency.

An overall summary of the scientific evaluation is provided in Annex II together with the amended summary of product characteristics in Annex III.

A Decision was issued by the European Commission on 1 December 2003.

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