European Medicines Agency

9 August 2005
EMEA/CHMP/289490/2005

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

SUMMARY INFORMATION ON REFERRAL OPINION FOLLOWING ARBITRATION PURSUANT TO ARTICLE 30 OF COUNCIL DIRECTIVE 2001/83/EC FOR

Calcium Sandoz and associated names

International Non-Proprietary Name (INN): Calcium lactate gluconate, Calcium carbonate

BACKGROUND INFORMATION

Calcium is an essential mineral, necessary for bone formation and maintenance, for electrolyte equilibrium in the body and for the proper functioning of numerous regulatory mechanisms.

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

Novartis Consumer Health SA 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 Calcium Sandoz Effervescent tablets, 500/1000 mg 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 22 September 2004. The referral procedure started on 21 October 2004

The CHMP 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 Sandoz Effervescent tablets, 500/1000 mg and associated names is considered to be favourable. The CHMP issued a positive opinion, on 21 April 2005, recommending the harmonisation of the SPC for Calcium Sandoz Effervescent tablets, 500/1000 mg and associated names for the following agreed therapeutic indications:

- -Prevention and treatment of calcium deficiency
- -Calcium supplement as an adjunct to specific therapy in the prevention and treatment of osteoporosis
- -Rickets and osteomalacia, in addition to vitamin D_3 therapy

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

A Decision was issued by the European Commission on 9 August 2005.

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