European Medicines Agency
Evaluation of Medicines for Human Use

London, 13 December 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Glucomed and associated names

International Non-Proprietary Name (INN): glucosamine hydrochloride

BACKGROUND INFORMATION

Glucomed and associated names, 625 mg, tablet, contains glucosamine which is an endogenous substance, a normal constituent of the polysaccharide chains of cartilage matrix and synovial fluid glucosaminoglycans. Glucosamine was mainly introduced on the world-wide market as a food-supplement but with the aim to improve symptoms in patients with osteoarthritis or joint pain or function.

Navamedic ASA submitted applications for mutual recognition of Glucomed and associated names, 625 mg, tablet on the basis of the marketing authorisation granted by Sweden on 4 August 2005. The Mutual Recognition Procedure started on 18 October 2005.
The Reference Member State was Sweden and the Concerned Member States were Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Germany, Greece, Spain, Finland, France, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, The Netherlands, Poland, Portugal, Slovakia and United Kingdom and Norway and Iceland.
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. Sweden referred the reasons for disagreement to the EMEA on 31 March 2006.

The applicant was asked to demonstrate efficacy of glucosamine in the intended indication “relief of symptoms in mild to moderate osteoarthritis of the knee”. In addition the applicant was asked to justify the proposed dose and posology, to characterise the safety profile, including a discussion of reported adverse drug reactions, to justify the relevance of literature considering that the formulations of glucosamine sulphate (as the sodium chloride complex) used in the cited literature differ from the concerned application formulation and whether the differences in formulation will alter the efficacy and safety of the product, to elucidate the possibility of interactions with other medicinal products, and finally to show a positive risk/benefit profile of glucosamine hydrochloride in the intended indication.

The arbitration procedure started on 27 April 2006 with the adoption of a list of questions. The Rapporteur was Dr. Salmonson and the Co-Rapporteur was Dr Abadie. The Marketing Authorisation Holder provided written explanations on 21 July 2006.

During their September 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 Glucomed and associated names for the relief of symptoms in mild to moderate osteoarthritis of the knee, that there was no objection for the granting of a Marketing Authorisation and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State

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

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should be amended. A positive opinion was adopted by y a majority of 19 out of 27 votes on 21 September 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, labelling and package leaflet in Annex III.

The final opinion was converted into a Decision by the European Commission on 13 December 2006.