European Medicines Agency
Evaluation of Medicines for Human Use

London, 25 October 2007
EMEA/CHMP/350251/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Xeomin

International Non-Proprietary Name (INN): Clostridium botulinum neurotoxin type A

BACKGROUND INFORMATION

Xeomin, 100 LD_{50} units powder for solution for injection, is indicated for the symptomatic management of blepharospasm and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults.

Merz Pharmaceuticals GmbH submitted applications for mutual recognition of **Xeomin**, 100 LD_{50} units powder for solution for injection, on the basis of the marketing authorisation granted by Germany on 31 May 2005. The Mutual Recognition Procedure started on 24 October 2006. The Reference Member State was Germany and the Concerned Member States were Austria, Denmark, Spain, Finland, France, Italy, Luxembourg, Norway, Poland, Portugal, Sweden and United Kingdom. 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. Germany referred the reasons for disagreement to the EMEA on 29 March 2007.

On the basis of the questions raised by the Member States, the points to be considered by the CHMP concerned the posology, the repeated administration and safety profile in two Phase III studies.

The arbitration procedure started on 26 April 2007 with the adoption of a list of questions. The Rapporteur was Dr Karl Broich and Co-Rapporteur(s) was Dr Pierre Demolis. The Marketing Authorisation Holder provided written explanations on 25 May 2007.

During their 16-19 July 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 benefit/risk ratio is favourable for **Xeomin**, that the objections raised by Finland, France and Italy, 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 by majority on 19 July 2007.

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 24 October 2007.

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

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