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

London, 20 August 2003
EMEA/CPMP/4260/03/en

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP) SUMMARY INFORMATION ON REFERRAL OPINION FOLLOWING ARBITRATION PURSUANT TO ARTICLE 29 OF COUNCIL DIRECTIVE 2001/83/EC FOR

BOTOX

Active substance: **Clostridium botulinum type A neurotoxin complex**

BACKGROUND INFORMATION

Botox [Clostridium botulinum toxin type A neurotoxin complex] inhibits the release of acetylcholine at the presynaptic membrane on cholinergic neurons. Botox was first licensed in the European Union in 1994 for neuromuscular disorders via intramuscular route.

In June 2002, the Marketing Authorisation Holder, Allergan Pharmaceuticals (Ireland) Ltd applied for a new indication through Mutual Recognition Procedure (MRP), for Botox for the treatment of axillary hyperhidrosis. Primary hyperhydrosis is a chronic idiopathic disorder of excessive and uncontrolled sweating. The mechanism of action of Botox in hyperhidrosis is thought to be the inhibition of cholinergically-induced excessive sweating by blockage of autonomic sympathetic nerve fibres innervating sweat glands.

The Reference Member State for this MRP was Ireland with Austria, Belgium, Denmark, Germany, Greece, Finland, Iceland, Italy, Luxembourg, Norway, Portugal, Spain, and Sweden as Concerned Member States. On September 3rd 2002 a referral for arbitration according to article 29 of Directive 2001/83/EC was triggered by Germany and Italy regarding the major objections on the clinical safety and efficacy of this new indication for the medicinal product Botox.

The procedure started on 17 October 2002. Supplementary information was provided by the Marketing Authorisation Holder on 11 November 2002 and further written explanations on 5 February 2003.

The CPMP, having considered the points of disagreement and the responses provided by the Marketing Authorisation Holder, was of the opinion that the objections raised by Germany and Italy should not prevent the granting of a Marketing Authorisation for the new indication “persistent severe primary hyperhidrosis of the axillae, which interferes with the activities of daily living and is resistant to topical treatment” subject to certain essential conditions for the safe and effective use of the medicinal product. The CPMP adopted a positive opinion on 20 February 2003.

The scientific conclusions and the grounds for the amendment of the Summary of Product Characteristics are set out in Annex II.

The final opinion was converted into a decision by the European Commission on 25 June 2003.

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