The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

19 June 1998
CPMP/1154/98

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

OPINION FOLLOWING AN ARTICLE 10 REFERRAL

FLUOXETIN NM

International Non-Proprietary Name (INN): F**luoxetine**

BACKGROUND INFORMATION

On 20 December 1996 Generics (UK) Ltd submitted an application for Mutual Recognition of the Marketing Authorisation granted by the Danish Competent Authorities for Fluoxetin NM, capsules 20 mg. The Mutual Recognition procedure started on 30 January 1997. The Reference Member State was Denmark and the Concerned Member State was Germany. Finland and Sweden had previously granted Marketing Authorisations under national procedures. The Concerned Member State, Germany not being able to agree with the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State referred the reasons for disagreement to the EMEA on 30 April 1997.

The major reasons concerned bioequivalence and possible therapeutic inefficacy related to the switch from the brand leader.

The Reference Member State sent its report to the EMEA on 12 May 1997. The matter was referred to the CPMP on 14 May 1997. Written explanations and further supplementary information were provided by the Marketing Authorisation Holder on 29 August 1997 and 11 December 1997, respectively.

The CPMP adopted a positive Opinion on 17 December 1997 recommending the granting of the Marketing Authorisation for Fluoxetin NM with amendments to the SPC of the Reference Member State.

A copy of the final opinion for Fluoxetin NM is provided on the Internet, together with Annexes A and B and Annex I, which contains the amended SPC.

The final Opinion was converted into a Decision by the European Commission on 9 June 1998.

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