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

3 August 1998
CPMP/1416/98

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

OPINION FOLLOWING AN ARTICLE 10 REFERRAL

AMARYL

International Non-Proprietary Name (INN): **Glimepiride**

BACKGROUND INFORMATION

On 20 June 1995, Hoechst Roussel B.V. (The Netherlands) submitted an application for Mutual Recognition of the Marketing Authorisation, on the basis of the Marketing Authorisation granted by the Dutch Competent Authorities for Amaryl 1 mg, 2 mg, 3 mg, 4 mg and 6 mg tablets. The Mutual Recognition procedure started on 29 September 1995. The Reference Member State was The Netherlands and the Concerned Member States were Austria, Greece, Italy, Portugal and Spain. Sweden and Denmark had previously granted Marketing Authorisations for Amaryl 1 mg, 2 mg and 3 mg tablets under national procedures. The Concerned Member States, Austria and Portugal, 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 21 December 1995 and 28 December 1995, respectively.

The major reasons concerned the possible carcinogenic potential and the less possible glycaemic control with Amaryl.

The Reference Member State sent its report to the EMEA on 28 December 1996. The matter was referred to the CPMP on 18 January 1996. Written explanations were provided by the Marketing Authorisation Holder on 29 February 1996.

The CPMP adopted a positive opinion on 17 April 1996 recommending the granting of the Marketing Authorisation for Amaryl with amendments to the Summary of Product Characteristics of the Reference Member State.

A copy of the final opinion for Amaryl 1 mg as a relevant example is provided on the Internet, together with Annex I and Annex II, which contains an example of the amended Summary of Product Characteristics. Annex III provides an overall summary of the CPMP scientific evaluation.

The final opinion was converted into a Decision by the European Commission on 29 August 1996.

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