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

London, 3 April, 1997
CPMP/101-109/96 and CPMP/111-114/96

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
OPINIONS FOLLOWING AN ARTICLE 12 REFERRAL

ANORECTICS

International Non-Proprietary Names (INN):
- Type I Substances: Amfepramone, Clobenzorex, Fenproporex, Mazindol, Mefenorex, Norpseudoephedrine, Phendimetrazine, Phenmetrazine, Phentermine
- Type II Substances: Dexfenfluramine, Fenfluramine
- Type III Substances: Fenbutrazate, Propylhexedrine

BACKGROUND INFORMATION

On 17 May 1995, Germany requested the CPMP, under Article 12 of Council Directive 75/319/EEC, to provide an Opinion "on the risks and benefit of chemically defined, centrally acting anorectics and on their authorisation status" due to concerns about the risk of patients using anorectic agents, in the treatment of obesity, to develop primary pulmonary hypertension. The substances involved in the procedure were classified into three types, Type I-III as listed above.

According to the CPMP Opinions given on 15 February 1996, the SPC's of medicinal products containing these substances required amendment. Recommendations as provided in Annex I of the Opinions proposed amendment to the therapeutic indications, revision of the chapters on posology and method of administration, contra-indications, undesirable effects and implementation of detailed special warnings and precautions for use in a "black box".

The Marketing Authorisation Holders of some of the anorectic agents appealed against the Opinions and grounds for appeal were received on the 15 and 30 April 1996. The grounds were against the wording in the indication, special warnings and undesirable effect sections of the excerpt from the SPC.

On the 20 June 1996, the CPMP considered the grounds for appeal and on the 17 July 1996 adopted final Opinions revising the Opinions given on the 15 February 1996. The excerpt from the SPC was revised by suppressing the word "android" in the indication, and in the special warnings and undesirable effects sections by specifying the Body Mass Index (BMI) level and amending two sentences of the previous text. All other proposals for the SPC by the CPMP remained valid.

A copy of the final Opinions for these products (Type I-III) are provided on the Internet, together with Annex I of the final Opinions which provides the amendments to be introduced into the SPCs of these medicinal products. Translations of the Opinions, with Annex I, are also provided in French, German, and Spanish.

The final Opinions were converted into Decisions by the European Commission on 9 December 1996.

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