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CPMP/2325/99

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held an extraordinary meeting on 31 August 1999 in order to finalise the scientific review of anorectic agents for which referral procedures had been initiated in accordance with Article 15a of Council Directive 75/319/EEC, as amended, and to adopt final opinions for such medicinal products.

The attention is called to the fact that such CPMP opinions constitute a recommendation which is transmitted to the European Commission. The final decision is taken by the European Commission after consultation with the Member States and is subsequently addressed to such Member States for implementation at national level.

The outcome of the above referral procedures can be summarised as follows:

- The CPMP adopted final opinions by majority vote recommending the withdrawal of the marketing authorisations for medicinal products containing the following active substances:
 - amfepramone
 - phentermine
 - clobenzorex, fenproporex, mefenorex, norpseudoephedrine and phendimetrazine.

A minority of CPMP members was in favour of a suspension of such marketing authorisations.

Such recommendation was based on a lack of therapeutic efficacy, leading to an unfavourable benefit/risk balance.

The CPMP took into account that at this point in time, there are no marketing authorisations in the EU for fenbutrazate, mazindol, phenmetrazine and propylhexedrine containing medicinal products.

- The CPMP adopted a final opinion by consensus, recommending the withdrawal of the marketing authorisations for fenfluramine and dexfenfluramine containing medicinal products. Such recommendation was based on an unacceptable safety profile under normal conditions of use and limited therapeutic efficacy, leading to an unfavourable benefit/risk balance.

It should be noted that fenfluramine and dexfenfluramine containing medicinal products are no longer available in the European Union since 1997.

On behalf of Prof. Rolf Bass
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Head of Sector New Chemical Substances

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