COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 09.03.2000

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NOT FOR PUBLICATION

COMMISSION DECISION

of 09.03.2000

concerning the withdrawal of marketing authorisations of

medicinal products for human use which contain the following substance:

"Phentermine"

COMMISSION DECISION

of 09.03.2000

concerning the withdrawal of marketing authorisations of

medicinal products for human use which contain the following substance:

"Phentermine"

THE COMMISSION OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation and administrative action relating to proprietary medicinal products [1], as last amended by Directive 93/39/EEC [2], and in particular Article 14(1) and (2) and 15a thereof;

Having regard to the final opinion of 31 August 1999 of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products, whose opinion was requested pursuant to Article 15a of Directive 75/319/EEC,

Whereas:

(1) Medicinal products for human use, authorized by the Member States, must comply with the requirements of Council Directives 65/65/EEC [3], 75/318/EEC [4] and 75/319/EEC, as last amended by Directive 93/39/EEC.

(2) Article 15a of Council Directive 75/319/EEC applies where a Member State considers that the variation of the terms of a marketing authorisation which has been granted in accordance with the Chapter III of Council Directive 75/319/EEC, or its suspension, or withdrawal is necessary for the protection of public health,

(3) "Protection of Public Health" must be understood as the assessment and the management of risks to public health, related to the quality, safety or efficacy of medicinal products,

(4) Medicinal products containing **"Phentermine"**, have already undergone a Community Referral under Article 12 of Council Directive 75/319/EEC in 1996, leading to a Community harmonisation of the Marketing Authorisation with regard to this group of medicinal products, cf. Decision C(96)3608 final/1 of 9 December 1996. The same group of medicinal products has subsequently been the subject to further Community Referral started by Belgium on 19 November 1997 under Article 15a of Directive 75/319/EEC. Therefore Article 15a of Council Directive 75/319/EEC is the proper legal basis for the procedure leading to the present Decision,

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[1] OJ No L 147, 9.6.1975, p. 13.

[2] OJ No L 214, 24.8.1993, p. 22.

[3] OJ No 22, 9.2.1965, p. 369/65.

[4] OJ No L 147, 9.6.1975, p. 1.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The Member States shall, in accordance with this Decision, withdraw the national marketing authorizations provided for in the first paragraph of Article 3 of Directive 65/65/EEC concerning the medicinal products listed in Annex I which contain the following substance:

"Phentermine"

Article 2

The national marketing authorizations for these medicinal products shall be withdrawn on the basis of the scientific conclusions summarized in Annex II to this Decision.

Article 3

The Member States shall comply with this Decision within 30 days of its notification. They shall immediately inform the Commission and the European Agency for the Evaluation of Medicinal Products thereof.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 09.03.2000

For the Commission

Erkki LIIKANEN
Member of the Commission