EUROPEAN COMMISSION

Brussels, 26.1.2010
C(2010)567

COMMISSION DECISION

of 26.1.2010

concerning, in the framework of Article 107 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisation of "Antiadiposo", a medicinal product for human use which contains the active substance "iodocasein/thiamine nitrate"

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[1], and in particular Article 107 thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 22 October 2009 by the Committee for Medicinal Products for Human Use, whose opinion was requested on 17 September 2009,

Whereas:

(1) Medicinal products for human use authorised by the Member States must meet the requirements of Directive 2001/83/EC.

(2) As a result of the evaluation of the pharmacovigilance data for the medicinal product "Antiadiposo" which contains the active substance "iodocasein/thiamine nitrate", the Italian Republic informed the Agency in accordance with paragraph 1 of Article 107 of Directive 2001/83/EC that the marketing authorisation should be suspended.

(3) The Committee has prepared an opinion, the conclusions of which are set out in Annex II to this Decision, recommending that a decision should be taken revoking the marketing authorisation for the medicinal product concerned.

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

[1] OJ L 311, 28.11.2001, p. 67

HAS ADOPTED THIS DECISION:

Article 1

The Member State concerned shall revoke the national marketing authorisation for the medicinal product referred to in Annex I on the basis of the scientific conclusions set out in Annex II.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 26.1.2010

For the Commission
Heinz ZOUREK
Director-General