

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27.5.2009
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NOT FOR PUBLICATION

COMMISSION DECISION

of 27.5.2009

concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisation of medicinal products for human use which contain the active substance "methylphenidate"

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 34(1) thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 22 January 2009 by the Committee for Medicinal Products for Human Use,

Whereas:

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

(2) On 22 June 2007, the European Commission referred a question to the Committee for Medicinal Products for Human Use under Article 31(1) of Directive 2001/83/EC, pursuant to which, in specific cases where the interests of the Community are involved, a matter may be referred to that Committee before a decision is reached on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variation to the terms of a marketing authorisation which appears necessary.

(3) The scientific assessment by the Committee, the conclusions of which are set out in Annex II to this Decision, shows that, in the interests of the Community, a decision should be taken amending the marketing authorisation for the medicinal products 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,

HAS ADOPTED THIS DECISION:

Article 1

The Member States concerned shall amend national marketing authorisations for the medicinal products referred to in Annex I on the basis of the scientific conclusions set out in Annex II.

[1] OJ L311, 28.11.2001, P. 67

Article 2

The national marketing authorisations referred to in Article 1 shall be based on the amendments of the summary of the product characteristics and the package leaflet set out in Annex III and, in accordance with Article 32(4) of Directive 2001/83/EC, shall be subject to the conditions set out in Annex IV to this Decision.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 27.5.2009

For the Commission
Heinz Zourek
Director-General