COMMISSION IMPLEMENTING DECISION

of 1.8.2011


(Text with EEA relevance)
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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency1, and in particular Article 9(4)(c) thereof,

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 use2, and in particular Articles 33, 34 and 127a thereof,

Having regard to the application for an extension within the meaning of Annex I to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products3, grouped with a variation not falling within the meaning of Annex I to that Regulation, submitted by Boehringer Ingelheim International GmbH on 21 January 2010 under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 10 June 2011,

Whereas:

(1) The medicinal product "Pradaxa - dabigatran etexilate mesilate" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and

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of the Council of 6 November 2001 on the Community code relating to medicinal
products for human use⁴.

(2) It is therefore appropriate to authorise the amendment, for the purposes of its
extension, of the marketing authorisation. To this effect, Commission Decision
C(2011)5694 of 1.8.2011 amending, for the purposes of its extension, the
marketing authorisation to the medicinal product "Pradaxa - dabigatran etexilate
mesilate" is simultaneously being addressed to Boehringer Ingelheim
International GmbH.

(3) The marketing authorisation is subject to conditions or restrictions with regard to
the safe and effective use of the medicinal product. It is appropriate that
implementation of these conditions is ensured by the Member States.

(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 shall ensure implementation of the conditions or restrictions with
regard to the safe and effective use of the medicinal product set out in the Annex.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, on 1.8.2011.

For the Commission
Paola TESTORI COGGI
Director-General