



EUROPEAN COMMISSION

Brussels, 1.8.2011
C(2011)5694 final

COMMISSION IMPLEMENTING DECISION

of 1.8.2011

**amending, for the purposes of its extension, the marketing authorisation granted by
Decision C(2008)1180 for "Pradaxa - dabigatran etexilate mesilate", a medicinal
product for human use**

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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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 10(2) 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 products², grouped with variations 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 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 use³, and in particular Article 61(3) thereof,

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

Whereas:

- (1) The medicinal product "Pradaxa - dabigatran etexilate mesilate", entered in the Community register of medicinal products under numbers EU/1/08/442/001-008

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 334, 12.12.2008, p. 7.

³ OJ L 311, 28.11.2001, p. 67.

and authorised by Commission Decision C(2008)1180 of 18 March 2008, remains in compliance with the requirements set out in 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 use⁴.

- (2) The marketing authorisation should be subject to compliance with conditions, set out in Annex II to this decision. The implementation of certain of these conditions with regard to the safe and effective use of the medicinal product is to be ensured by the Member States, in accordance with Article 127a of Directive 2001/83/EC. To this effect, Commission Decision C(2011)5693 of 1.8.2011 is simultaneously being addressed to the Member States.
- (3) The extension requested should therefore be granted.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,
- (5) Boehringer Ingelheim International GmbH has submitted, under Article 61(3) of Directive 2001/83/EC, a notification for changes to an aspect of the labelling or the package leaflet, which is not yet included in Decision C(2008)1180 of 18 March 2008.
- (6) The marketing authorisation should be updated and Decision C(2008)1180 of 18 March 2008 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2008)1180 is amended as follows:

1) The following notification for a change to an aspect of the labelling or the package leaflet is added to the marketing authorisation:

Application number	Annex (EU numbers affected)
EMEA/H/C/829/N/19	IIIB (EU/1/08/442/001-008)

2) The following numbers are added to Article 1 and entered in the Community register of medicinal products:

EU/1/08/442/009	Pradaxa - 150 mg - Capsule, hard - Oral use - blister (alu/alu) - 10 x 1 capsules
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⁴ OJ L 311, 28.11.2001, p. 67.

- EU/1/08/442/010 Pradaxa - 150 mg - Capsule, hard - Oral use - blister (alu/alu) - 30 x 1 capsules
- EU/1/08/442/011 Pradaxa - 150 mg - Capsule, hard - Oral use - blister (alu/alu) - 60 x 1 capsules
- EU/1/08/442/012 Pradaxa - 150 mg - Capsule, hard - Oral use - blister (alu/alu) multipack - 3 x (60 x 1) capsules, multipack
- EU/1/08/442/013 Pradaxa - 150 mg - Capsule, hard - Oral use - bottle (PP) - 60 capsules
- EU/1/08/442/014 Pradaxa - 110 mg - Capsule, hard - Oral use - blister (alu/alu) multipack - 3 x (60 x 1) capsules, multipack

- 3) Annex I is replaced by the text set out in Annex I to this Decision;
- 4) Annex II is replaced by the text set out in Annex II to this Decision;
- 5) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, on 1.8.2011.

For the Commission
Paola TESTORI COGGI
Director-General