



EUROPEAN COMMISSION

Brussels, 9.12.2011
C(2011)9437 final

COMMISSION IMPLEMENTING DECISION

of 9.12.2011

amending the marketing authorisation granted by Decision C(2008)5680 for “Xarelto - rivaroxaban”, a medicinal product for human use

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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“Xarelto - rivaroxaban”, a medicinal product for human use**

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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, submitted by Bayer Pharma AG on 15 December 2010 under Article 4(1) of Regulation (EC) No 726/2004,

Having regard 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, and in particular Article 17(2) thereof,

Having regard to the application submitted on 15 December 2010 by Bayer Pharma AG under Article 16 of Regulation (EC) No 1234/2008,

Having regard to the notifications submitted by Bayer Pharma AG, under the first subparagraph of Article 14(1) of Regulation (EC) No 1234/2008,

Having regard to the notification submitted by Bayer Pharma AG, under Article 15(1) of Regulation (EC) No 1234/2008,

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 334, 12.12.2008, p. 7.

³ OJ L 334, 12.12.2008, p. 7.

Having regard to the opinion of the European Medicines Agency, formulated on 22 September 2011 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) The medicinal product “Xarelto - rivaroxaban”, entered in the Community register of medicinal products under numbers EU/1/08/472/001-010 and authorised by Commission Decision C(2008)5680 of 30 September 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 extension requested should therefore be granted.
- (3) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the major variation type II and of the need to amend the marketing authorisation for the medicinal product "Xarelto - rivaroxaban" which is entered in the Community Register of Medicinal Products under numbers EU/1/08/472/001-010.
- (4) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on minor variations notified between 22 February 2011 and 22 September 2011.
- (5) 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)9758final of 14.12.2011 is simultaneously being addressed to the Member States.
- (6) The amendments requested should therefore be granted.
- (7) The marketing authorisation should be updated and Decision C(2008)5680 of 30 September 2008 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.
- (8) 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

Decision C(2008)5680 is amended as follows:

⁴ OJ L 311, 28.11.2001, p. 67.

1) The following notifications for minor variations are added to the marketing authorisation:

Application number	Scope (EU numbers affected)
EMA/H/C/944/IA/14/G	A.1, A.5.a) (EU/1/08/472/001-010)
EMA/H/C/944/IB/13/G	B.II.b.2.b).2 (EU/1/08/472/001-010)

2) The following numbers are added to Article 1 and entered in the Community Register of Medicinal Products:

EU/1/08/472/011	Xarelto - 15 mg - Film-coated tablet - Oral use - blister (PP/alu) - 14 tablets
EU/1/08/472/012	Xarelto - 15 mg - Film-coated tablet - Oral use - blister (PP/alu) - 28 tablets
EU/1/08/472/013	Xarelto - 15 mg - Film-coated tablet - Oral use - blister (PP/alu) - 42 tablets
EU/1/08/472/014	Xarelto - 15 mg - Film-coated tablet - Oral use - blister (PP/alu) - 98 tablets
EU/1/08/472/015	Xarelto - 15 mg - Film-coated tablet - Oral use - blister (PP/alu) - 10 x 1 tablet
EU/1/08/472/016	Xarelto - 15 mg - Film-coated tablet - Oral use - blister (PP/alu) - 100 x 1 tablet
EU/1/08/472/017	Xarelto - 20 mg - Film-coated tablet - Oral use - blister (PP/alu) - 14 tablets
EU/1/08/472/018	Xarelto - 20 mg - Film-coated tablet - Oral use - blister (PP/alu) - 28 tablets
EU/1/08/472/019	Xarelto - 20 mg - Film-coated tablet - Oral use - blister (PP/alu) - 98 tablets
EU/1/08/472/020	Xarelto - 20 mg - Film-coated tablet - Oral use - blister (PP/alu) - 10 x 1 tablet
EU/1/08/472/021	Xarelto - 20 mg - Film-coated tablet - Oral use - blister (PP/alu) - 100 x 1 tablet

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 Bayer Pharma AG, 13342 Berlin, Deutschland.

Done at Brussels, on 9.12.2011.

*For the Commission
Paola TESTORI COGGI
Director-General*