EUROPEAN
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COMMISSION IMPLEMENTING DECISION

of 18.4.2016

renewing and amending the marketing authorisation for the medicinal product for human use "Tysabri - Natalizumab", granted by Decision C(2006)3046

(Text with EEA relevance)

(ONLY THE ENGLISH 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 Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Biogen Idec Limited, on 27 August 2015, under Article 14(2) of Regulation (EC) No 726/2004 with a view to the renewal of the marketing authorisation for the medicinal product "Tysabri - Natalizumab",

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 products[2],

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Biogen Idec Limited in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinions of the European Medicines Agency, formulated on 21 May 2015, on 24 September 2015, on 19 November 2015 and on 25 February 2016 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "Tysabri - Natalizumab", entered in the Community register of medicinal products under number(s) EU/1/06/346 and authorised by Commission Decision C(2006)3046 of 27 June 2006, complies 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 use[3].

[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.

(2) The marketing authorisation which expires on 30 June 2016 should therefore be renewed.

(3) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(4) Decision C(2006)3046 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(5) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2006)3046 should therefore be replaced.

(6) 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 marketing authorisation granted by Decision C(2006)3046 of 27 June 2006 which expires on 30 June 2016 is renewed.

Article 2

Decision C(2006)3046 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Biogen Idec Limited, Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom.

Done at Brussels, 18.4.2016

For the Commission

Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION