EUROPEAN
COMMISSION

Brussels, 20.12.2013
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COMMISSION IMPLEMENTING DECISION

of 20.12.2013

amending the marketing authorisation granted by Decision C(2008)159 for "Abraxane - paclitaxel", a medicinal product for human use

(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],

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], and in particular Article 17(2) thereof,

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

Having regard to the opinion of the European Medicines Agency, formulated on 21 November 2013 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) 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.

(2) Decision C(2008)159 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(3) The review of the data submitted by Celgene Europe Limited on 26 April 2013 has shown that the new therapeutic indication proposed for the medicinal product "Abraxane - paclitaxel" brings significant clinical benefit in comparison with existing therapies. Therefore, an additional year of marketing protection in accordance with Article 14(11) of Regulation (EC) No 726/2004 should be granted.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 334, 12.12.2008, p. 7.

(4) 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(2008)159 should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2008)159 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 2

On the basis of Annex IV to this Decision, the marketing protection is extended to eleven years in accordance with Article 14(11) of Regulation (EC) No 726/2004.

Article 3

This Decision is addressed to Celgene Europe Limited, 1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom.

Done at Brussels, 20.12.2013

For the Commission
Paola TESTORI COGGI
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION