EUROPEAN
COMMISSION

Bruxelles, 7.1.2015
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COMMISSION IMPLEMENTING DECISION

of 7.1.2015

amending the marketing authorisation granted by Decision C(2009)4049 for "ellaOne - ulipristal acetate", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE FRENCH 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 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[2], and in particular Article 74a thereof,

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

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

Having regard to the opinions of the European Medicines Agency, formulated on 23 October 2014 and on 20 November 2014 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) The review of the data submitted by Laboratoire HRA Pharma, on 24 February 2013 has shown that the change of classification of the medicinal product "ellaOne - ulipristal acetate" is based on significant pre-clinical tests or clinical trials. Therefore, the one-year

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.
[3] OJ L 334, 12.12.2008, p. 7.

period of data exclusivity in accordance with Article 74a of directive 2001/83/EC should be granted.

(3) Decision C(2009)4049 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(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(2009)4049 should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2009)4049 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

Based on the conclusions set out in annex IV to this decision, the one-year period of data exclusivity is granted in accordance with Article 74a of Directive 2001/83/EC.

Article 3

This Decision is addressed to Laboratoire HRA Pharma, 15 rue Béranger, F-75003 Paris, France.

Done at Brussels, 7.1.2015

For the Commission

Ladislav MIKO
Acting Director-General