EUROPEAN
COMMISSION

Brussels, 26.7.2018
C(2018)5101 (final)

COMMISSION IMPLEMENTING DECISION

of 26.7.2018

amending, under Article 20 of Regulation (EC) No 726/2004 of the European Parliament and of the Council, the marketing authorisation, granted by Decision C(2012)1335(final), for "Esmya - ulipristal", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE HUNGARIAN 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 20(3) and (8) thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 31 May 2018 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The placing on the market of the medicinal product "Esmya - ulipristal" was authorised by Commission Decision C(2012)1335(final) of 23 February 2012.

(2) The Commission initiated a procedure in accordance with Article 20(2) of Regulation (EC) No 726/2004 and requested the opinion of the European Medicines Agency as to whether the marketing authorisation should be maintained, varied, suspended or withdrawn.

(3) In accordance with Article 20(8) of Regulation (EC) No 726/2004 the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency issued a recommendation on 17 May 2018.

(4) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex IV to this Decision, shows that a decision should be taken amending the marketing authorisation for the medicinal product concerned.

(5) Decision C(2012)1335(final) should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(6) 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(2012)1335(final) should therefore be replaced.

[1] OJ L 136, 30.4.2004, p. 1.

(7) 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(2012)1335(final) of 23 February 2012 for the medicinal product "Esmya - ulipristal" is amended, on the basis of the scientific conclusions set out in the Annex IV to this Decision.

Article 2

Decision C(2012)1335(final) 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 Gedeon Richter Plc., Gyömrői út 19-21., 1103 Budapest, Magyarország.

Done at Brussels, 26.7.2018

For the Commission

Xavier PRATS MONNÉ
Director-General