EUROPEAN
COMMISSION

Brussels, 7.4.2021
C(2021)2534 (final)

COMMISSION IMPLEMENTING DECISION

of 7.4.2021

amending the marketing authorisation granted by Decision C(2017)5171(final) for "Trimbow - beclometasone / formoterol / glycopyrronium bromide", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ITALIAN 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 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 products[2], submitted by Chiesi Farmaceutici S.p.A. on 26 March 2020 under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 28 January 2021 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(2017)5171(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(3) 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(2017)5171(final) should therefore be replaced.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2017)5171(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 2

This Decision is addressed to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, 43122 Parma, Italia.

Done at Brussels, 7.4.2021

For the Commission

Sandra GALLINA
Director-General