



Brussels, 18.8.2016
C(2016) 5439 final

COMMISSION IMPLEMENTING DECISION

of 18.8.2016

**amending the marketing authorisation granted by Decision C(2005)456 for “Truvada -
emtricitabine / tenofovir disoproxil fumarate”, a medicinal product for human use**

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 18.8.2016

amending the marketing authorisation granted by Decision C(2005)456 for “Truvada - emtricitabine / tenofovir disoproxil fumarate”, a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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 Agency¹,

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 products², and in particular Articles 17(2) and 20(7)(a) thereof,

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

Having regard to the opinions of the European Medicines Agency, formulated on 28 January 2016, on 1 April 2016 and on 21 July 2016 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(2005)456 should therefore be amended accordingly. The Community 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(2005)456 should therefore be replaced.

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(2005)456 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 Gilead Sciences International Ltd., Cambridge CB21 6GT, United Kingdom.

Done at Brussels, 18.8.2016

For the Commission

Xavier PRATS MONNÉ

Director-General

