EUROPEAN
COMMISSION

Brussels, 15.2.2023
C(2023) 1214 final

COMMISSION IMPLEMENTING DECISION

of 15.2.2023

on the annual renewal of the conditional marketing authorisation for the medicinal product for human use "JEMPERLI - dostarlimab", granted by Decision C(2021)2913(final), and amending that Decision

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 15.2.2023

on the annual renewal of the conditional marketing authorisation for the medicinal product for human use "JEMPERLI - dostarlimab", granted by Decision C(2021)2913(final), and amending that Decision

(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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[1], and in particular Article 10(2) and 14-a thereof,

Having regard to Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[2],

Having regard to the application submitted by GlaxoSmithKline (Ireland) Limited, on 27 September 2022, under Article 6(2) of Regulation (EC) No 507/2006 with a view to the annual renewal of the conditional marketing authorisation for the medicinal product "JEMPERLI - dostarlimab",

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],

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

Having regard to the opinions of the European Medicines Agency, formulated on 15 December 2022 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "JEMPERLI - dostarlimab", entered in the Union Register of Medicinal Products under the number EU/1/21/1538 and authorised by Commission Decision C(2021)2913(final) of 21 April 2021, remains in compliance with the

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 92, 30.3.2006, p. 6.
[3] OJ L 334, 12.12.2008, p. 7.

requirements of Article 14-a of Regulation (EC) No 726/2004 of the European Parliament and of the Council, and Regulation (EC) No 507/2006,

(2) The conditional marketing authorisation should therefore be renewed.

(3) 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.

(4) Decision C(2021)2913(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(5) 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(2021)2913(final) should therefore be replaced.

(6) 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 conditional marketing authorisation granted by Decision C(2021)2913(final) of 21 April 2021 is renewed.

Article 2

Decision C(2021)2913(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

The period of validity of the renewed authorisation shall be one year from 22 April 2023.

Article 4

This Decision is addressed to GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Done at Brussels, 15.2.2023

For the Commission

Sandra GALLINA
Director-General

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION

Signed by / Podpisano przez:

Ewa Anna Gemza

Date / Data:
2024-04-05
13:29