



Brussels, 7.12.2023
C(2023) 8760 final

COMMISSION IMPLEMENTING DECISION

of 7.12.2023

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "JEMPERLI - dostarlimab", a medicinal product for human use and repealing Decision C(2021)2913(final)

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 7.12.2023

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "JEMPERLI - dostarlimab", a medicinal product for human use and repealing Decision C(2021)2913(final)

(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 Agency¹, and in particular Articles 10(2) and 14-a(8) 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 products², and in particular Article 17(2) thereof,

Having regard to the data submitted by GlaxoSmithKline (Ireland) Limited, on 28 March 2023,

Having regard to Commission Delegated Regulation (EU) No 357/2014 of 3 February 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council as regards situations in which post-authorisation efficacy studies may be required, and in particular Article 1(2) thereof³,

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 opinion of the European Medicines Agency, formulated on 12 October 2023 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) On 21 April 2021, authorisation for the placing on the market of "JEMPERLI - dostarlimab" was granted by Decision C(2021)2913(final) subject to certain requirements, in accordance with Article 14-a of Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006.

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 334, 12.12.2008, p. 7.

³ OJ L 107, 10.04.2014, p. 1.

- (2) The specific obligations of the conditional marketing authorisation are fulfilled, in view of the data submitted on 28 March 2023.
- (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(2021)2913(final) should therefore be replaced.
- (4) The medicinal product "JEMPERLI - dostarlimab" complies with the requirements set out in 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 use⁴.
- (5) It is therefore appropriate to replace the conditional marketing authorisation with a marketing authorisation not subject to specific obligations.
- (6) The review of the data submitted by GlaxoSmithKline (Ireland) Limited on 22 April 2023 has shown that the new therapeutic indication proposed for the medicinal product "JEMPERLI - dostarlimab" brings significant clinical benefit in comparison with existing therapies. Therefore, an additional year of marketing protection in accordance with Article 14(11) of Regulation (EC) No 726/2004 should be granted.
- (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 provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "JEMPERLI - dostarlimab", the characteristics of which are summarised in Annex I to this Decision. "JEMPERLI - dostarlimab" is registered in the Union Register of Medicinal Products under number EU/1/21/1538.

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The placing on the market of "JEMPERLI - dostarlimab" shall be subject to this Decision from the date of its notification.

⁴ OJ L 311, 28.11.2001, p. 67.

Article 5

Based on the conclusions set out in Annex IV to this Decision, the additional year of marketing protection is granted in accordance with Article 14(11) of Regulation (EC) No 726/2004.

Article 6

This Decision repeals and replaces Decision C(2021)2913(final) of 21 April 2021.

Article 7

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

Done at Brussels, 7.12.2023

For the Commission

Sandra GALLINA

Director-General

