EUROPEAN
COMMISSION

Brussels, 29.8.2024
C(2024)6262 (final)

COMMISSION IMPLEMENTING DECISION

of 29.8.2024

amending the marketing authorisation granted by Decision C(2015)5144(final) for "KEYTRUDA - pembrolizumab", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[1],

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[2], and in particular Article 17(2) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Merck Sharp & Dohme B.V. in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinions of the European Medicines Agency, formulated on 14 March 2024, on 2 May 2024 and on 25 July 2024 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(2015)5144(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(2015)5144(final) 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(2015)5144(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 Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, Nederland.

Done at Brussels, 29.8.2024

For the Commission

Sandra GALLINA
Director-General