EUROPEAN
COMMISSION

Brussels, 12.1.2022
C(2022) 291 final

COMMISSION IMPLEMENTING DECISION

of 12.1.2022

correcting Decision C(2021)9893 final of 20.12.2021 granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Nuvaxovid - COVID-19 Vaccine (recombinant, adjuvanted)", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH 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) 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 Novavax CZ, a.s., on 17 November 2021, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinions of the European Medicines Agency, formulated on 20 December 2021 and on 4 January 2022 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The Commission has been made aware of the fact that Annex II of Decision C(2021)9893 final of 20.12.2021 requires amendment due to adaptations to the requirements and specifications with regard to manufacturing.

(2) This Decision rectifies Decision C(2021)9893 final by correcting Annex II and adapting Article 2 accordingly. It should apply retroactively from the date of notification of that Decision.

(3) 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 92, 30.3.2006, p. 6.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2021)9893 final is corrected as follows:

(1) Article 2 shall be replaced by the following Article 2:

"The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the requirements and specifications set out in Annex II, including with regard to manufacturing. Those requirements shall be reviewed annually."

(2) Annex II shall be replaced by the text set out in Annex II to this Decision.

Article 2

This Decision applies from 20 December 2021.

Article 3

This Decision is addressed to Novavax CZ, a.s., Bohumil 138, 281 63 Jevany, Česká republika.

Done at Brussels, 12.1.2022

For the Commission

Sandra GALLINA
Director-General

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION