EUROPEAN
COMMISSION

Brussels, 20.12.2021
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COMMISSION IMPLEMENTING DECISION

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 opinion of the European Medicines Agency, formulated on 20 December 2021 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Nuvaxovid - COVID-19 Vaccine (recombinant, adjuvanted)" 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 use[3].

(2) "Nuvaxovid - COVID-19 Vaccine (recombinant, adjuvanted)" falls within the scope of Regulation (EC) No 507/2006, in particular Article 2(1). In addition, as set out in Annex IV, the medicinal product meets the requirements of Article 4 of this Regulation for the granting of a conditional marketing authorisation.

(3) Authorisation for the placing on the market of "Nuvaxovid - COVID-19 Vaccine (recombinant, adjuvanted)" should therefore be granted 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 92, 30.3.2006, p. 6.
3 OJ L 311, 28.11.2001, p. 67.

(4) The Committee for Medicinal Products for Human Use considered that "SARS-CoV-2 recombinant spike protein" is a new active substance.

(5) 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 provided for in Article 3 and 14-a of Regulation (EC) No 726/2004 is granted for the medicinal product "Nuvaxovid - COVID-19 Vaccine (recombinant, adjuvanted)", the characteristics of which are summarised in Annex I to this Decision. "Nuvaxovid - COVID-19 Vaccine (recombinant, adjuvanted)" shall be registered in the Union Register of Medicinal Products under number EU/1/21/1618.

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the requirements set out in Annex II. Those requirements shall be reviewed annually.

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 period of validity of the authorisation shall be one year from the date of notification of this Decision.

Article 5

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

Done at Brussels, 20.12.2021

For the Commission

Margaritis SCHINAS
Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION