EUROPEAN
COMMISSION

Brussels, 30.3.2023
C(2023) 2354 final

COMMISSION IMPLEMENTING DECISION

of 30.3.2023

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "BIMERVAX - 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 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) thereof,

Having regard to the application submitted by Hipra Human Health, S.L.U., on 22 March 2023, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 30 March 2023 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "BIMERVAX - 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[2].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The Committee for Medicinal Products for Human Use considered that "SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion heterodimer – B.1.351-B.1.1.7 strains" is a new active substance.

(4) 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 "BIMERVAX - COVID-19 Vaccine (recombinant,

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.

adjuvanted)", the characteristics of which are summarised in Annex I to this Decision. "BIMERVAX - COVID-19 Vaccine (recombinant, adjuvanted)" shall be registered in the Union Register of Medicinal Products under number EU/1/22/1709.

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 period of validity of the marketing authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Hipra Human Health, S.L.U., Avda. la Selva, 135, 17170 Amer (Girona), España.

Done at Brussels, 30.3.2023

For the Commission

Stella KYRIAKIDES
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION