EMA/296812/2024

European Medicines Agency decision

P/0253/2024

of 19 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for SARS-CoV-2 virus recombinant spike protein receptor binding domain fusion homodimer – XBB.1.16-XBB.1.16 variant / SARS-CoV-2 virus recombinant spike protein receptor binding domain fusion heterodimer (B.1.351 and B.1.1.7 strains) (beta-alpha variants) (Bimervax), (EMEA-003191-PIP01-22-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

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[2],

Having regard to the European Medicines Agency's decision P/0465/2022 issued on 4 November 2022,

Having regard to the application submitted by HIPRA Human Health S.L.U. on 23 February 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 May 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for SARS-CoV-2 virus recombinant spike protein receptor binding domain fusion homodimer – XBB.1.16-XBB.1.16 variant / SARS-CoV-2 virus recombinant spike protein receptor binding domain fusion heterodimer (B.1.351 and B.1.1.7 strains) (beta-alpha variants) (Bimervax), emulsion for injection, intramuscular use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to HIPRA Human Health S.L.U., 135 Avinguda Selva, 17170 – Amer, Spain.

EMA/PDCO/91797/2024
Amsterdam, 31 May 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-003191-PIP01-22-M01

Scope of the application

Active substance(s):

SARS-CoV-2 virus recombinant spike protein receptor binding domain fusion homodimer – XBB.1.16-XBB.1.16 variant / SARS-CoV-2 virus recombinant spike protein receptor binding domain fusion heterodimer (B.1.351 and B.1.1.7 strains) (beta-alpha variants)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Emulsion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

HIPRA Human Health S.L.U.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, HIPRA Human Health S.L.U. submitted to the European Medicines Agency on 23 February 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0465/2022 issued on 4 November 2022.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 2 April 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

    - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Prevention of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Prevention of coronavirus disease 2019 (COVID-19)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Emulsion for injection

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of lower strength emulsion for injection formulation for paediatric use
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (HIPRA-HH-3)** Open label uncontrolled study of safety and immunogenicity COVID-19 Vaccine (recombinant, adjuvanted) (PHH-1V) as heterologous booster for the prevention of coronavirus disease 2019 (COVID-19) in adolescents from 12 years to less than 18 years of age. **Study 3 (HIPRA-HH-6)** Open label study of safety and immunogenicity of adapted COVID-19 Vaccine (recombinant, adjuvanted) (PHH-1V81) as heterologous booster for the prevention of coronavirus disease 2019 (COVID-19) in children from 5 years to less than 12 years of age. **Study 4 (HIPRA-HH-8)** Randomised, double blind, active controlled study of safety and immunogenicity and open label safety expansion of a primary series, and open label study of a booster dose of adapted COVID-19 Vaccine (recombinant, adjuvanted) (PHH-1V81) for the prevention of coronavirus disease 2019 (COVID-19) in children from birth to less than 5 years of age.

Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

- BIMERVAX is indicated as a booster for active immunisation to prevent COVID-19 in individuals 16 years of age and older who have previously received a mRNA COVID-19 vaccine.
  - Invented name(s): BIMERVAX
  - Authorised pharmaceutical form(s): Emulsion for injection (injection)
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure