MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100966-PIP01-23) and to the deferral

MHRA-100966-PIP01-23-M01

Scope of the Application

Active Substance(s)

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

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 the Decision

Pursuant to the Human Medicines Regulations 2012, HIPRA Human Health S.L.U. submitted to the licensing authority on 27/06/2024 21:32 BST an application for a Modification

The procedure started on 03/09/2024 08:27 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

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

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100966-PIP01-23-M01

Of 04/11/2024 14:32 GMT

On the adopted decision for Selvacovatein (INN) - SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion heterodimer (B.1.351 and B.1.1.7 strains) (beta-alpha variants); SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion homodimer – XBB.1.16-XBB.1.16 variant (MHRA-100966-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Selvacovatein (INN) - SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion heterodimer (B.1.351 and B.1.1.7 strains) (beta-alpha variants); SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion homodimer – XBB.1.16-XBB.1.16 variant, Emulsion for injection , INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Prevention of Coronavirus disease 2019 (COVID-19)

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Emulsion for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of lower strength emulsion for injection formulation for paediatric use.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	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 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 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.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	1	Commitment to submit a study proposal in the immunocompromised paediatric population.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/09/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes