

**MHRA**  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

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## **Decision Cover Letter**

### **Decision of the licensing authority to:**

agree a paediatric investigation plan and grant a deferral

MHRA-100966-PIP01-23

### **Scope of the Application**

#### **Active Substance(s)**

COVID-19 Vaccine (recombinant, adjuvanted)

#### **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 04/04/2023 12:53 BST an application for a Paediatric Investigation Plan

The procedure started on 11/04/2023 11:36 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 agree a paediatric investigation plan and grant a 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

Of 17/05/2023 15:41 BST

On the adopted decision for COVID-19 Vaccine (recombinant, adjuvanted) (MHRA-100966-PIP01-23) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for COVID-19 Vaccine (recombinant, adjuvanted), 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:

<b>Study Type</b>	<b>Number of Studies</b>	<b>Study Description</b>
<b>Quality Measures</b>	1	Study 1 Development of lower strength emulsion for injection formulation for paediatric use.
<b>Non-Clinical Studies</b>	0	Not applicable.
<b>Clinical Studies</b>	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-1V) 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-1V) for the prevention of Coronavirus disease 2019 (COVID-19) in children from birth to less than 5 years of age.
<b>Extrapolation, Modeling &amp; Simulation Studies</b>	0	Not applicable.
<b>Other Studies</b>	0	Not applicable.
<b>Other Measures</b>	1	Commitment to submit a study proposal in the immunocompromised paediatric population.

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

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	No
<b>Date of completion of the paediatric investigation plan:</b>	31/12/2026
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes