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:

agree a paediatric investigation plan and grant a deferral

MHRA-100473-PIP01-22

Scope of the Application

Active Substance(s)

Recombinant COVID-19 subunit nanoparticle

Condition(s)

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Emulsion and suspension for emulsion for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

SK Chemicals GmBH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SK Chemicals GmBH submitted to the licensing authority on 10/03/2022 14:41 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/03/2022 17:22 GMT

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-100473-PIP01-22

Of 05/07/2022 13:20 BST

On the adopted decision for Recombinant COVID-19 subunit nanoparticle (MHRA-100473-PIP01-22) 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 Recombinant COVID-19 subunit nanoparticle , Emulsion and suspension for emulsion for injection , Intramuscular use .

This decision is addressed to SK Chemicals GmbH, Mergenthalerallee 77, Eschborn, GERMANY, 65760

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 and suspension for emulsion for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	3	Study 1 Randomised, placebo-controlled, 2-stage, observer-blind study to assess the immunogenicity and safety of SK SARS-CoV-2 recombinant protein nanoparticle vaccine adjuvanted with AS03 (GBP510) in adolescents aged 12 years to less than 18 years. Study 2 Randomised, placebo-controlled, observer-blind, dose-escalating, age de-escalating study to assess the immunogenicity and safety of SK SARS-CoV-2 recombinant protein nanoparticle vaccine adjuvanted with AS03 (GBP510) in children from birth to less than 12 years of age. Study 3 Open-label, uncontrolled study to assess the immunogenicity and safety of SK SARS-CoV-2 recombinant protein nanoparticle vaccine (GBP510) adjuvanted with AS03 in immunocompromised children and adolescents from birth to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

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:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes