MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-100473-PIP01-22) and to the deferral

MHRA-100473-PIP01-22-M01

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 09/02/2023 10:36 GMT an application for a Modification

The procedure started on 27/03/2023 13:22 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-100473-PIP01-22-M01

Of 06/10/2023 10:19 BST

On the adopted decision for Recombinant COVID-19 subunit nanoparticle (MHRA-100473-PIP01-22-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 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:	31/03/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes