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-100038-PIP01-21

Scope of the Application

Active Substance(s)

Recombinant protein derived from the SARS CoV2 prefusion Spike delta TM protein adjuvanted with AS03

Condition(s)

Prevention of Covid-19

Pharmaceutical Form(s)

Emulsion for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

Sanofi Pasteur

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Pasteur submitted to the licensing authority on 16/02/2021 13:43 GMT an application for a

The procedure started on 15/03/2021 13:43 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:

The agreement of a paediatric investigation plan and on the granting of 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-100038-PIP01-21

Of 24/05/2021 11:47 BST

On the adopted decision for Recombinant protein derived from the SARS CoV2 prefusion Spike delta TM protein adjuvanted with AS03 (MHRA-100038-PIP01-21) 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 for Recombinant protein derived from the SARS CoV2 prefusion Spike delta TM protein adjuvanted with AS03, Emulsion for injection , Intramuscular use .

This decision is addressed to Sanofi Pasteur, 14 Espace Henry Vallée, Lyon, France, 69007

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of COVID-19

2.2 Indication(s) targeted by the PIP:

Active immunization for the prevention of SARS-CoV-2 infection and/or associated disease in children from birth to less than 18 years of age.

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

All paediatric subsets 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	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1 Randomised, modified double-blind, controlled immunogenicity and safety Phase II/ III trial of CoV-2 preS dTM vaccine versus active vaccine comparator or placebo in children from birth to less than 18 years Study 2 Open label, noncomparative, safety and immunogenicity study of CoV-2 preS dTM-AS03 vaccine in immunocompromised children and adolescents from birth to less than 18 years of age for prevention of COVID-19.
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:	31/03/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes