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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral.

MHRA-100029-PIP01-21

Scope of the Application

Active Substance(s)

COVID-19 vaccine (Ad26.COV2-S (recombinant))

Condition(s)

Prevention of coronavirus disease-2019 (COVID-19)

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 29/01/2021 09:25 GMT an application for a

The procedure started on 18/02/2021 07:29 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100029-PIP01-21

Of 09/04/2021 11:48 BST

On the adopted decision for COVID-19 vaccine (Ad26.COV2-S (recombinant)) (MHRA-100029-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 COVID-19 vaccine (Ad26.COV2-S (recombinant)), Suspension for injection , Intramuscular use .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, United Kingdom, HP12 4EG

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:

Active immunisation for the prevention of COVID-19 in the paediatric population from birth to less than 18 years of age

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

All subsets of the paediatric population from birth to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Suspension 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 double-blind controlled study, to evaluate the safety, reactogenicity and immunogenicity of different dose levels of Ad26.COV2-S (recombinant) regimen (1 or more doses) in healthy adolescents from12 years to less than 18 years of age (and adults) for the prevention of COVID-19. (VAC31518COV2001) Study 2 Randomised, double-blind, controlled study to evaluate the safety, reactogenicity and immunogenicity of Ad26.COV2-S (recombinant) in healthy children from birth to less than 18 years of age (and adults) for the prevention of COVID-19 (VAC31518COV3006). Study 3 Open label, single arm study to evaluate the safety, reactogenicity and immunogenicity of Ad26.COV2-S (recombinant) in immunocompromised children 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:	31/03/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes