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-100029-PIP01-21) and to grant a product specific waiver

MHRA-100029-PIP01-21-M01

Scope of the Application

Active Substance(s)

RECOMBINANT REPLICATION-INCOMPETENT ADENOVIRUS SEROTYPE 26 VECTOR ENCODING THE SARS-COV-2 SPIKE PROTEIN PER.C6 CELL LINE; 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 17/03/2023 13:18 GMT an application for a Modification

The procedure started on 27/03/2023 09:22 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 grant a product specific waiver

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-100029-PIP01-21-M01

Of 14/04/2023 14:27 BST

On the adopted decision for RECOMBINANT REPLICATION-INCOMPETENT ADENOVIRUS SEROTYPE 26 VECTOR ENCODING THE SARS-COV-2 SPIKE PROTEIN PER.C6 CELL LINE; COVID-19 vaccine (Ad26.COV2-S [recombinant]) (MHRA-100029-PIP01-21-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 to grant of a waiver in all age groups for the listed condition(s).

This decision applies to a Modification for RECOMBINANT REPLICATION-INCOMPETENT ADENOVIRUS SEROTYPE 26 VECTOR ENCODING THE SARS-COV-2 SPIKE PROTEIN PER.C6 CELL LINE; 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:

Prevention of coronavirus disease-2019 (COVID-19) The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Studies 1, 2 and 3 were deleted during procedure MHRA-100029-PIP01-21-M01 and replaced by a full product specific waiver.

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not Applicable
Non-Clinical Studies	0	Not Applicable
Clinical Studies	0	Not Applicable
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	