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 waiver

MHRA-101392-PIP01-24

Scope of the Application

Active Substance(s)

Influenza Virus Type A, H1N1; Influenza Virus Type A, H3N2; Influenza Virus Type B, Victoria lineage

Condition(s)

Prevention of influenza infection

Pharmaceutical Form(s)

Nasal spray, suspension

Route(s) of Administration

NASAL USE

Name / Corporate name of the PIP applicant

ASTRAZENECA UK LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ASTRAZENECA UK LIMITED submitted to the licensing authority on 11/03/2024 18:20 GMT an application for a Paediatric Investigation Plan

The procedure started on 12/03/2024 08:25 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 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-101392-PIP01-24

Of 20/03/2024 06:42 GMT

On the adopted decision for Influenza Virus Type A, H1N1; Influenza Virus Type A, H3N2; Influenza Virus Type B, Victoria lineage (MHRA-101392-PIP01-24) 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 Influenza Virus Type A, H1N1; Influenza Virus Type A, H3N2; Influenza Virus Type B, Victoria lineage, Nasal spray, suspension , NASAL USE .

This decision is addressed to ASTRAZENECA UK LIMITED, 2 Pancras Square, 8th Floor, London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Prevention of influenza infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Nasal spray, suspension Route(s) of administration: NASAL USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of influenza infection

2.2 Indication(s) targeted by the PIP:

Prevention of influenza infection

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Nasal spray, suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Randomised, double-blind, active controlled, multicentre study to assess the safety and immunogenicity of Q/LAIV in comparison with two formulations of FluMist in children from 2 years 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:	30/06/2011
Deferral of one or more studies contained in the paediatric investigation plan:	No