MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101471-PIP01-24

Scope of the Application

Active Substance(s)

Respiratory syncytial virus, prefusion F protein, virus-like particle; Human metapneumovirus, prefusion F protein, virus-like particle ; IVX-A12

Condition(s)

Prevention of lower respiratory tract disease caused by respiratory syncytial virus, Prevention of lower respiratory tract disease caused by human metapneumovirus

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAMUSCULAR 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 08/05/2024 10:33 BST an application for a Paediatric Investigation Plan

The procedure started on 04/06/2024 17:03 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 agree a paediatric investigation plan and grant a deferral 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-101471-PIP01-24

Of 08/07/2025 07:22 BST

On the adopted decision for Respiratory syncytial virus, prefusion F protein, virus-like particle; Human metapneumovirus, prefusion F protein, virus-like particle ; IVX-A12 (MHRA-101471-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 Respiratory syncytial virus, prefusion F protein, virus-like particle; Human metapneumovirus, prefusion F protein, virus-like particle ; IVX-A12 , Solution for injection , INTRAMUSCULAR 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 lower respiratory tract disease caused by respiratory syncytial virus Prevention of lower respiratory tract disease caused by human metapneumovirus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 weeks of age Pharmaceutical form(s): Solution 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):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus Prevention of lower respiratory tract disease caused by human metapneumovirus

2.2 Indication(s) targeted by the PIP:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus or human metapneumovirus

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

The paediatric population from 6 weeks to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	1	Study 1 Non-clinical study in naïve cotton rats to evaluate the risk of vaccine associated enhanced respiratory disease (VAERD).
Clinical Studies	5	Study 2 Modified double-blind, randomised, placebo-controlled trial to evaluate safety and immunogenicity of IVX-A12 in children from 6 weeks to less than 18 years of age. Study 3 Modified double-blind, randomised, placebo-controlled study to evaluate efficacy, safety, and immunogenicity of IVX-A12 in children from 6 weeks to less than 2 years of age. Study 4 Modified double-blind, randomised, placebo-controlled study to assess the immunogenicity and safety of IVX-A12 in children 2 years to less than 5 years of age, and 5 years to less than 18 years of age (at increased risk) when compared to children 6 weeks to less than 2 years of age. Study 5 Randomised, controlled, open-label study to assess the immunogenicity and safety of IVX-A12 in children

		from 6 weeks to less than 13 months of age when co-administered or sequentially administered with routine paediatric immunisations. Study 6 Open-label study to evaluate the safety and immunogenicity of IVX-A12 in immunocompromised children from 6 weeks to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	1	Extrapolation Plan Studies 3 and 4 are part of an extrapolation plan to immuno- bridge efficacy from the children aged 6 weeks to less than 2 years to an older paediatric population.
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:	31/03/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes