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 (EMEA-001318-PIP01-12-M04) and to the deferral

MHRA-101362-PIP01-24-M01

Scope of the Application

Active Substance(s)

ZANAMIVIR; ZANAMIVIR

Condition(s)

Prevention of influenza, Treatment of influenza

Pharmaceutical Form(s)

Solution for infusion, Inhalation powder, pre-dispensed, Solution for infusion, Inhalation powder, pre-dispensed

Route(s) of Administration

INTRAVENOUS USE; INHALATION USE, INTRAVENOUS USE; INHALATION USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 15/02/2024 14:07 GMT an application for a Modification

The procedure started on 15/03/2024 14:43 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:

to accept change(s) to the agreed paediatric investigation plan and to the 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-101362-PIP01-24-M01

Of 03/06/2024 14:11 BST

On the adopted decision for ZANAMIVIR (MHRA-101362-PIP01-24-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 (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for ZANAMIVIR, Solution for infusion; Inhalation powder, pre-dispensed , INTRAVENOUS USE; INHALATION USE .

This decision is addressed to GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of influenza The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Inhalation powder, pre-dispensed Route(s) of administration: INHALATION USE Reason for granting waiver: For the paediatric population from birth to less than 5 years of age - on the grounds that the specific medicinal product is likely to be ineffective. For the paediatric population from 5 years to less than 18 years of age - on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s). Reason for Refusing Waiver: Not Applicable 1.2 Condition: Prevention of influenza The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Inhalation powder, pre-dispensed Route(s) of administration: INHALATION USE Reason for granting waiver: For the paediatric population from birth to less than 5 years of age - on the grounds that the specific medicinal product is likely to be ineffective. For the paediatric population from 5 years to less than 18 years of age - on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Condition 1: Treatment of influenza Condition 2: Prevention of influenza

2.2 Indication(s) targeted by the PIP:

Condition 1: Treatment of influenza A and B virus infection Condition 2: Prevention of influenza A and B virus infection

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

For both Conditions: The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

For both Conditions: Solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Studies for condition: Treatment of influenza only Study 1 (NAI 113678) Open-label, single-arm study to evaluate PK, safety and tolerability of zanamivir in hospitalised children from 6 months to less than 18 years of age with confirmed influenza virus infection. Study 2 Open-label, single-arm study to evaluate PK, safety and tolerability of zanamivir in hospitalised children from 28 weeks post-menstrual age (PMA) to less than 6 months of age with confirmed influenza virus infection.
Extrapolation, Modeling & Simulation Studies	1	Study for condition: Prevention of influenza only Study 3 Extrapolation of efficacy and safety zanamivir IV for the prevention of influenza

		infection from adult data for prevention (challenge study) and from the treatment of influenza program in children.
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:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes