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 and to the deferral

MHRA-100147-PIP01-21-M01

Scope of the Application

Active Substance(s)

OSELTAMIVIR PHOSPHATE

Condition(s)

Treatment and prevention of influenza

Pharmaceutical Form(s)

Capsule hard; Powder for oral suspension

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

Roche Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 17/06/2021 15:28 BST an application for a Modification

The procedure started on 23/11/2021 15:51 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-100147-PIP01-21-M01

Of 01/12/2021 10:51 GMT

On the adopted decision for OSELTAMIVIR PHOSPHATE (MHRA-100147-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 (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for OSELTAMIVIR PHOSPHATE, Capsule hard; Powder for oral suspension , Oral use .

This decision is addressed to Roche Products Limited, Hexagon Place, 6 Falcon Way, Shire Park , Welwyn Garden City,, United Kingdom, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment and prevention of influenza

2.2 Indication(s) targeted by the PIP:

Treatment and prevention of influenza in healthy and immunocompromised patients 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):

Capsule hard; Powder for oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	4	Study 1 Open-label, non-randomised, PK / PD and safety trial to evaluate oseltamivir in children less than 24 months of age with confirmed influenza infection. (NIH Study CASG 114); Study 2 Randomized, double-blind, multi-centre, stratified trial to evaluate efficacy, safety, tolerability and resistance of oseltamivir conventional and high dose for the treatment of in immunocompromised paediatric patients from 1 year to less than 18 years of age (and in adults) with influenza. (NV20234 [treatment]); Study 4 Open label, non-randomized, multiple dose PK / PD and safety trial of oseltamivir in the treatment of infants from birth to less than 12 months of age with confirmed influenza infection. (WP22849); Study 5 Open label, randomized, two-arm multi-centre trial to evaluate pharmacokinetics and pharmacodynamics of two doses of oseltamivir in the treatment of influenza in immunocompromised paediatric patients from birth to less than 13 years of age. (NV25719); Study 6 Deleted in procedure EMEA-000365-PIP01-08-M11
Extrapolation, Modeling & Simulation Studies	1	Study 3 To simulate multi-dose administration of oseltamivir in immunocompromised children from birth to less than 18 year of age

		for treatment and prophylaxis of influenza.
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:	31/05/2019
Deferral of one or more studies contained in the paediatric investigation plan:	Yes