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-100669-PIP01-22-M01

Scope of the Application

Active Substance(s)

EMTRICITABINE; RILPIVIRINE; TENOFOVIR ALAFENAMIDE FUMARATE

Condition(s)

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Film-coated tablet Age-appropriate oral formulation

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Gilead Sciences Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Gilead Sciences Ltd submitted to the licensing authority on 31/08/2022 17:27 BST an application for a Modification

The procedure started on 07/02/2023 13:10 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-100669-PIP01-22-M01

Of 20/02/2023 10:27 GMT

On the adopted decision for EMTRICITABINE; RILPIVIRINE; TENOFOVIR ALAFENAMIDE FUMARATE (MHRA-100669-PIP01-22-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 EMTRICITABINE; RILPIVIRINE; TENOFOVIR ALAFENAMIDE FUMARATE, Film-coated tablet Age-appropriate oral formulation , ORAL USE .

This decision is addressed to Gilead Sciences Ltd , 280 High Holborn, London, UNITED KINGDOM, WC1V7EE

ANNEX I

1. Waiver

1.1 Condition:

Treatment of human immunodeficiency virus (HIV-1) infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 4 weeks of age Pharmaceutical form(s): Film-coated tablet Age-appropriate oral formulation Route(s) of administration: ORAL USE Reason for granting waiver: 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):

Treatment of human immunodeficiency virus (HIV-1) infection

2.2 Indication(s) targeted by the PIP:

Treatment of human immunodeficiency virus (HIV-1) infection

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

The paediatric population from 4 weeks to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Development of film-coated tablets for use in children from 6 years to less than 12 years of age. Study 2 Development of an age-appropriate oral formulation for use in children from 4 weeks to less than 6 years of age, and in children above 6 years of age unable to swallow tablets.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 3 Open-label, randomised study in healthy adult volunteers to determine the bioequivalence of the age-appropriate oral formulation developed in Study 2 relative to the adult film-coated tablet.
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:	Yes
Date of completion of the paediatric investigation plan:	31/03/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes