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 (MHRA-100669-PIP01-22-M01) and to grant a product specific waiver.

MHRA-100669-PIP01-22-M02

Scope of the Application

Active Substance(s)

RILPIVIRINE; TENOFOVIR ALAFENAMIDE FUMARATE; EMTRICITABINE

Condition(s)

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Film-coated tablet

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 03/07/2023 10:20 BST an application for a Modification

The procedure started on 14/11/2023 18:15 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 grant a product specific 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-100669-PIP01-22-M02

Of 20/11/2023 14:08 GMT

On the adopted decision for RILPIVIRINE; EMTRICITABINE; TENOFOVIR ALAFENAMIDE (MHRA-100669-PIP01-22-M02) 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 and granting a waiver in all age groups for the listed condition(s).

This decision applies to a Modification for RILPIVIRINE; EMTRICITABINE; TENOFOVIR ALAFENAMIDE, 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 18 years of age. Pharmaceutical form(s): Film-coated tablet Age-appropriate oral formulation Route(s) of administration: ORAL USE Reason for granting waiver: For the paediatric population from birth to less than 4 weeks 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). For the paediatric population from 4 weeks to less than 2 years of age: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible. For the paediatric population from 2 years to less than 18 years of age: 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):

Studies 1, 2 and 3 were deleted during procedure MHRA-100669-PIP01-22-M02 and replaced with a full product specific waiver.

2.2 Indication(s) targeted by the PIP:

Not applicable.

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

Not applicable.

2.4 Pharmaceutical Form(s):

Not applicable.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	