MHRA
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Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

Accept of change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-100351-PIP01-21-M01

Scope of the Application

Active Substance(s)

DOLUTEGRAVIR; RILPIVIRINE

Condition(s)

Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection.

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Ltd submitted to the licensing authority on 13/04/2022 08:10 BST an application for a Modification

The procedure started on 15/02/2023 13:45 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-100351-PIP01-21-M01

Of 12/04/2023 13:44 BST

On the adopted decision for DOLUTEGRAVIR; RILPIVIRINE (MHRA-100351-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 deferral included in that paediatric investigation plan)

This decision applies to a Modification for DOLUTEGRAVIR; RILPIVIRINE, Film-coated tablet , ORAL USE .

This decision is addressed to GlaxoSmithKline UK Ltd , 980 Great West Road, Brentford, United Kingdom, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Film-coated tablet Route(s) of administration: ORAL 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):

Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection.

2.2 Indication(s) targeted by the PIP:

Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection.

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

The paediatric population from 6 years of age and weighing at least 25 kg to less than 18 years.

2.4 Pharmaceutical Form(s):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 was deleted in MHRA-100351-PIP01-21-M01.
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 (201676) Single dose, crossover pivotal bioequivalence evaluation of up to 2 fixed dose combination tablets of dolutegravir/ rilpivirine compared to the co-administered reference formulations TIVICAY (dolutegravir) 50mg and EDURANT (rilpivirine) 25mg in healthy male and female adult volunteers. Study 3 Multicentre, single-arm study to evaluate the pharmacokinetics, safety, tolerability and antiviral efficacy of switching to dual therapy, dolutegravir (DTG) plus rilpivirine (RPV), in anti-retroviral therapy (ART)-experienced HIV-1-infected children, from 6 to less than 12 years of age who are virologically suppressed on their current anti-retroviral (ARV) regimen.
Extrapolation, Modeling & Simulation Studies	2	Study 4 DTG paediatric PopPK model for determination of paediatric dose. Study 5 RPV paediatric PopPK model for determination of paediatric dose.
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:	30/06/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes