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-101053-PIP01-23-M01

Scope of the Application

Active Substance(s)

DOLUTEGRAVIR; ABACAVIR; LAMIVUDINE

Condition(s)

Treatment of Human Immunodeficiency Virus (HIV-1) infection

Pharmaceutical Form(s)

Film-coated tablet, Dispersible tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

ViiV Healthcare UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ViiV Healthcare UK Limited submitted to the licensing authority on 07/07/2023 12:21 BST an application for a Modification

The procedure started on 09/11/2023 10:52 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-101053-PIP01-23-M01

Of 27/11/2023 11:03 GMT

On the adopted decision for DOLUTEGRAVIR; ABACAVIR; LAMIVUDINE (MHRA-101053-PIP01-23-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 DOLUTEGRAVIR; ABACAVIR; LAMIVUDINE, Film-coated tablet, Dispersible tablet , ORAL USE .

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

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 24 months of age. Pharmaceutical form(s): Film-coated tablet, Dispersible tablet Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds 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 (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 2 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Film-coated tablet Dispersible tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a dispersible tablet.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 (This study is the same as Study 1 of procedure EMEA-000409-PIP01-08-M03.) Multicentre, open-label, non-comparative study to evaluate pharmacokinetics, safety, tolerability and antiviral activity of dolutegravir in HIV-1 infected infants, children and adolescents from 4 weeks to less than 18 years of age. Study 3 Open-label, multicentre, multiple dose, trial to evaluate pharmacokinetics and safety of DTG/3TC/ABC in children less than 12 years of age with Human Immunodeficiency Virus Infection.
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:	No
Date of completion of the paediatric investigation plan:	30/09/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes