MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-102391-PIP01-26

Scope of the Application

Active Substance(s)

CABOTEGRAVIR

Condition(s)

Prevention of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Powder for prolonged-release suspension for injection

Route(s) of Administration

INTRAMUSCULAR

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 23/04/2026 14:55 BST an application for a Paediatric Investigation Plan

The procedure started on 30/04/2026 17:39 BST

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 agree a paediatric investigation plan and grant a deferral and grant a 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-102391-PIP01-26

Of 19/06/2026 12:37 BST

On the adopted decision for CABOTEGRAVIR (MHRA-102391-PIP01-26) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for CABOTEGRAVIR, Powder for prolonged-release suspension for injection , INTRAMUSCULAR .

This decision is addressed to ViiV Healthcare UK Limited, 79 New Oxford Street, London, UNITED KINGDOM, WC1A 1DG

ANNEX I

1. Waiver

1.1 Condition:

Prevention of human immunodeficiency virus (HIV-1) infection The waiver applies to: • the paediatric population from birth to less than 12 years of age; • powder for prolonged-release suspension for injection, intramuscular use; • on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of human immunodeficiency virus (HIV-1) infection.

2.2 Indication(s) targeted by the PIP:

In combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high- risk adolescents, from 12 years to less than 18 years of age, weighing at least 35 kg.

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

From 12 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Powder for prolonged-release suspension for injection.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Open label, single arm, repeat dose study to investigate the safety, tolerability and pharmacokinetics (PK) of CAB ultra-long-acting (ULA) administered intramuscularly in the gluteus medius in participants at risk of HIV-1 acquisition.
Extrapolation, Modeling & Simulation Studies	1	Study 2 PopPK study to support extrapolation of efficacy from adults based on exposure matching and to determine the final paediatric posology for use in adolescents from 12 years to less than 18 years of age. Study 1, 2 are part of an extrapolation plan covering the paediatric population from 12 years to less than 18 years of age, as agreed by the PDCO.
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:	30/04/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes