

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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100865-PIP01-23-M01) and to the deferral.

MHRA-100865-PIP01-23-M02

Scope of the Application

Active Substance(s)

RILPIVIRINE

Condition(s)

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Prolonged-release suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 10/10/2025 19:55 BST an application for a Modification

The procedure started on 31/10/2025 09:47 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100865-PIP01-23-M02

Of 28/11/2025 10:07 GMT

On the adopted decision for RILPIVIRINE (MHRA-100865-PIP01-23-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 (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for RILPIVIRINE, Prolonged-release suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, UNITED KINGDOM, HP12 4EG

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 2 years of age. Pharmaceutical form(s): Prolonged-release suspension for injection. Route(s) of administration: INTRAMUSCULAR 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 (HIV-1) infection.

2.2 Indication(s) targeted by the PIP:

Treatment of human immunodeficiency virus (HIV-1) infection, in combination with long-acting cabotegravir.

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):

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	2	Study 1 (Same as study 3 of the cabotegravir adopted UK-PIP EMEA-001418-PIP01-13-M01 and subsequent MHRA modifications thereof.) Multi-centre, open-label, non-comparative trial to evaluate the pharmacokinetics, safety, tolerability and acceptability of oral and long-acting (LA) formulations of rilpivirine and cabotegravir in virologically suppressed adolescents from 12 years to less than 18 years of age with HIV-1 infection. Study 2 (This is the same as Study 6 in the adopted UK-PIP EMEA-001418-PIP01-13-M02 and subsequent MHRA modifications thereof, for cabotegravir in condition: Treatment of human immunodeficiency virus (HIV-1) infection.) Multi-centre open-label, non-comparative study to evaluate pharmacokinetics (PK), safety and tolerability of cabotegravir and rilpivirine [oral and long acting (LA) formulations] in children from 2 years to less than 12 years of age with HIV-1 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:	Yes
Date of completion of the paediatric investigation plan:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes