

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-100303-PIP01-21-M02) and to the deferral

MHRA-100303-PIP01-21-M03

Scope of the Application

Active Substance(s)

EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE; COBICISTAT; DARUNAVIR ETHANOLATE

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

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 14/10/2024 18:40 BST an application for a Modification

The procedure started on 02/12/2024 12:56 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-100303-PIP01-21-M03

Of 22/01/2025 20:24 GMT

On the adopted decision for EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE; COBICISTAT; DARUNAVIR ETHANOLATE (MHRA-100303-PIP01-21-M03) 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 EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE; COBICISTAT; DARUNAVIR ETHANOLATE, Film-coated tablet , ORAL 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 type-1 (HIV-1) infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population below 6 years of age or weighing less than 25 kg 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 HIV-1 infection in paediatric subjects weighing 25 kg or more from 6 years of age

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

The paediatric population weighing 25 kg or more from 6 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Evaluation of the acceptability for paediatric patients between 12 to less than 18 year olds of the adult tablet of Symtuza. Study 2 Development of a scored film-coated tablet of Symtuza and evaluation of acceptability for patients aged at least 6 years old weighing at least 25 kg.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 3 Study deleted during procedure EMEA-001825-PIP01-15-M02 Study 4 Study deleted during procedure MHRA-100303-PIP01-21-M02 Study 6 (GS-US-216-0128) Study added during procedure MHRA-100303-PIP01-21-M02 Open-label trial to evaluate pharmacokinetics, safety and efficacy of once-daily cobicistat-boosted darunavir administered as part of a combined antiretroviral regimen in HIV-1 infected, treatment-experienced children.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation study for cobicistat-boosted darunavir (D) doses in paediatric subjects 25 kg to less than 40 kg. Extrapolation plan Studies 5 and 6 are part of an extrapolation plan covering the paediatric population

		from 6 years to less than 18 years of age, as agreed by the Regulatory Agency.
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:	31/03/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes