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-100143-PIP01-21-M02) and to the deferral

MHRA-100143-PIP01-21-M03

Scope of the Application

Active Substance(s)

TENOFOVIR ALAFENAMIDE FUMARATE

Condition(s)

Treatment of chronic viral hepatitis B

Pharmaceutical Form(s)

Age-appropriate non-tablet, Film-coated tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Gilead Sciences Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Gilead Sciences Ltd submitted to the licensing authority on 12/12/2025 14:41 GMT an application for a

The procedure started on 08/01/2026 17:15 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-100143-PIP01-21-M03

Of 10/03/2026 14:49 GMT

On the adopted decision for TENOFOVIR ALAFENAMIDE FUMARATE (MHRA-100143-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 for TENOFOVIR ALAFENAMIDE FUMARATE, Age-appropriate non-tablet formulation Film-coated tablet , ORAL USE .

This decision is addressed to Gilead Sciences Ltd, 280 High Holborn , London, UNITED KINGDOM, WC1V 7EE

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic viral hepatitis B. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Age-appropriate non-tablet formulation Film-coated tablet Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic viral hepatitis B

2.2 Indication(s) targeted by the PIP:

Treatment of chronic hepatitis B 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):

Age-appropriate non-tablet formulation Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Deleted during procedure MHRA-100143-PIP01-21-M01 Study 2 Development of an age appropriate oral non-tablet formulation.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 3 Deleted during procedure EMEA-001584-PIP01-13-M02. Study 4 (Cohort 2 of GS-US-320-1092) Double-blind, placebo-controlled, pharmacokinetic, efficacy, safety, tolerability and antiviral activity study of tenofovir alafenamide administered for 24 weeks followed by 24 weeks open label extension phase in treatment naïve and treatment experienced, HBeAg-positive and HBeAg-negative children (2 years to less than 12 years of age) with chronic hepatitis B infection. Study 5 (GSUS-320-1196) Open-label, relative bioavailability study of the proposed age-appropriate paediatric formulation in healthy adult volunteers.
Extrapolation, Modeling & Simulation Studies	1	Study 6 (added in procedure MHRA-100143-PIP01-21-M03) Population PK analysis to inform characterization of tenofovir alafenamide (TAF)/TFV exposure

		based on the TAF program in participants with CHB (across the Phase 1 and Phase 3 studies with TAF in adults and the data collected in the paediatric study GS-US-320-1092) and data from studies in paediatric participants living with HIV-1 receiving TAF.
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:	31/03/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes