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-100657-PIP01-22-M01

Scope of the Application

Active Substance(s)

BULEVIRTIDE

Condition(s)

Treatment of chronic hepatitis D infection

Pharmaceutical Form(s)

Powder for solution for injection

Route(s) of Administration

SUBCUTANEOUS 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 19/08/2022 19:51 BST an application for a Modification

The procedure started on 07/02/2023 13:31 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

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-100657-PIP01-22-M01

Of 20/02/2023 15:18 GMT

On the adopted decision for BULEVIRTIDE (MHRA-100657-PIP01-22-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 BULEVIRTIDE, Powder for solution for injection , SUBCUTANEOUS 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 hepatitis D infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 3 years of age Pharmaceutical form(s): Powder for solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic hepatitis D infection

2.2 Indication(s) targeted by the PIP:

Treatment of chronic hepatitis D infection

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

The paediatric population from 3 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for solution 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	0	Study 1 Deleted in procedure MHRA-100657-PIP01-22-M01.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Modelling and simulation study to evaluate the use of bulevirtide in the treatment of chronic hepatitis D infection in children from 3 years to less than 18 years of age. Study 3 Extrapolation study to evaluate the use of bulevirtide in the treatment of chronic hepatitis D infection in children from 3 years to less than 18 years of age.
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:	31/12/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes