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 and to the deferral

MHRA-102445-PIP01-26-M01

Scope of the Application

Active Substance(s)

PRETOMANID

Condition(s)

Treatment of multi-drug-resistant tuberculosis

Pharmaceutical Form(s)

Tablet, Dispersible tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Viatris Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Viatris Products Limited submitted to the licensing authority on 07/04/2026 16:21 BST an application for a Modification

The procedure started on 21/04/2026 12:46 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 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-102445-PIP01-26-M01

Of 05/05/2026 10:40 BST

On the adopted decision for PRETOMANID (MHRA-102445-PIP01-26-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 PRETOMANID, Tablet, Dispersible tablet , ORAL USE .

This decision is addressed to Viatris Products Limited, 20 Station Close, Potters Bar, UNITED KINGDOM, EN6 1TL

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of multi-drug-resistant tuberculosis.

2.2 Indication(s) targeted by the PIP:

Pretomanid is indicated for use as part of an appropriate combination regimen for pulmonary multidrug resistant tuberculosis (MDR-TB) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

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

The paediatric population from birth to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Tablet Dispersible tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of dispersible tablet formulation.
Non-Clinical Studies	1	Study 2 Juvenile toxicity study in rats.
Clinical Studies	3	Study 3 (BA-Study) An open-label, randomized, 4-period crossover study in 2 panels of healthy, adult subjects to assess the relative bioavailability, food effect, and dose dependence of the formulations of pretomanid. Study 4 (PAEDIATRIC-1) An open-label, single-dose study to assess the pharmacokinetics, safety and tolerability of pretomanid in paediatric patients with rifampin-resistant (RR) tuberculosis (TB). Study 5 (PAEDIATRIC-2) An open-label, multicentre study to evaluate the pharmacokinetics, safety, tolerability and anti-mycobacterial activity of pretomanid in combination with bedaquiline and linezolid (B-Pa-L) for the treatment of paediatric patients with confirmed or probable pulmonary pre-extensively-resistant or extensively drug-resistant tuberculosis (pre-XDR/XDR-TB), or those who have failed or are intolerant to treatment for multidrug-resistant tuberculosis (MDR-TB).
Extrapolation, Modeling & Simulation Studies	2	Study 6 Population pharmacokinetic (PK) modelling and simulation study

		in paediatric patients with pulmonary (with or without extrapulmonary) infection of either extensively drug-resistant tuberculosis (XDR-TB), pre-XDR-TB or treatment intolerant or non-responsive multi-drug resistant tuberculosis (MDR-TB). Study 7 Extrapolation study of the clinical efficacy and safety data for pretomanid in combination with bedaquiline and linezolid (B-Pa-L regimen) from adult patients to paediatrics patients with pulmonary (with or without extrapulmonary) infection of either extensively drug-resistant tuberculosis (XDR-TB), pre-XDR-TB or treatment intolerant or non-responsive multi-drug resistant tuberculosis (MDR-TB).
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:	28/02/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes