MHRA
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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-100564-PIP01-22-M01

Scope of the Application

Active Substance(s)

TEDIZOLID PHOSPHATE

Condition(s)

Treatment of acute bacterial skin and skin structure infections

Pharmaceutical Form(s)

Film-coated tablet; Powder for oral suspension; Powder for concentrate for solution for infusion .

Route(s) of Administration

Oral use; Intravenous use

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme UK Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme UK Ltd. submitted to the licensing authority on 09/06/2022 11:12 BST an application for a Modification

The procedure started on 22/07/2022 07:28 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-100564-PIP01-22-M01

Of 28/07/2022 15:50 BST

On the adopted decision for TEDIZOLID PHOSPHATE (MHRA-100564-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 TEDIZOLID PHOSPHATE, Film-coated tablet; Powder for oral suspension; Powder for concentrate for solution for infusion. , Oral use; Intravenous use .

This decision is addressed to Merck Sharp & Dohme UK Ltd., 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of acute bacterial skin and skin structure infections

2.2 Indication(s) targeted by the PIP:

Treatment of acute bacterial skin and skin structure infections

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):

Film-coated tablet; Powder for oral suspension; Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Development of an age appropriate oral formulation (Powder for oral suspension) for children under 12 years of age. Study 2 Development of an age appropriate method of administration of the powder for concentrate for solution for infusion for use in the paediatric population under 12 months of age.
Non-Clinical Studies	3	Study 3 (TE.701.TX.001) Dose-range finding study in juvenile rats. Study 4 (TE.701.TX.002) Subacute toxicity study in juvenile rats. Study 5 (TE.701.TX.003) Subacute toxicity study in juvenile Long Evans rats to assess neurotoxicity of tedizolid phosphate.
Clinical Studies	4	Study 6 (MK-1986-014) Open-label multicentre, 2 part single and multiple dose study to assess the pharmacokinetics (PK) of tedizolid phosphate and its active metabolite, tedizolid and the safety of tedizolid phosphate following administration of a single and multiple doses IV and single oral dose. Study 7 (MK-1986-013) Single-Dose trial to evaluate pharmacokinetics and safety of oral and intravenous (iv) administration of tedizolid phosphate in patients 2 years to less than 12 years of age. Study 8 (MK-1986-012) Randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in patients 12 years to less than 18 years of age. Study 9 (MK-1986-018) Randomised, active controlled, investigator-blind, multicentre trial to evaluate safety and efficacy in

		patients from birth to less than 12 years of age.
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:	No
Date of completion of the paediatric investigation plan:	31/03/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes