

MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the adopted paediatric investigation plan and to the deferral

MHRA-102316-PIP01-26-M01

Scope of the Application

Active Substance(s)

ERAVACYCLINE

Condition(s)

Treatment of complicated intra-abdominal infection

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

PAION Pharma GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, PAION Pharma GmbH submitted to the licensing authority on 15/01/2026 14:42 GMT an application for a Modification

The procedure started on 19/01/2026 16:56 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 adopted 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-102316-PIP01-26-M01

Of 27/01/2026 09:08 GMT

On the adopted decision for ERAVACYCLINE (MHRA-102316-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 ERAVACYCLINE, Powder for concentrate for solution for infusion , INTRAVENOUS .

This decision is addressed to PAION Pharma GmbH, Heussstrasse 25, Aachen, GERMANY, 52078

ANNEX I

1. Waiver

1.1 Condition:

Treatment of complicated intra-abdominal infection. The waiver applies / applied to: Paediatric
Subset(s): The paediatric population from birth to less than 8 years of age. Pharmaceutical form(s):
Powder for concentrate for solution for infusion. Route(s) of administration: INTRAVENOUS
USE Reason for granting waiver: On the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of complicated intra-abdominal infection.

2.2 Indication(s) targeted by the PIP:

Treatment of complicated intra-abdominal infection.

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

The paediatric population from 8 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Powder for concentrate for solution for infusion.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 deleted during procedure EMEA-001555-PIP01-13-M02.
Non-Clinical Studies	2	Study 2 Definitive juvenile toxicity study to determine the toxicity of eravacycline following multiple dose administrations by intravenous injection to juvenile rats. Study 3 Reprotox: (enhanced) pre- and post-natal development study to evaluate toxicity of eravacycline in F1 generation rats following intravenous administration of eravacycline to FO dams during pregnancy and lactation.
Clinical Studies	1	Study 4 (TP-434-028) Open-label single dose trial to evaluate pharmacokinetics and safety of intravenous (IV) eravacycline in children from 8 to less than 18 years of age with suspected or confirmed bacterial infection and receiving other systemic antibiotic therapy. Study 5 deleted during procedure MHRA-102316-PIP01-26-M01.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Modelling and simulation study to evaluate the use of eravacycline for the treatment of complicated intra-abdominal infections in children from 8 years to less than 18 years of age. Study 7 deleted during procedure MHRA-102316-PIP01-26-M01.
Other Studies	0	Not applicable

Other Measures	1	Extrapolation plan - Studies 4 and 6 are part of an extrapolation plan covering the paediatric population from 8 years to less than 18 years of age, as agreed by the Regulatory Agency.
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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:	30/11/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes