MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-102155-PIP01-25

Scope of the Application

Active Substance(s)

Zosurabalpin

Condition(s)

Treatment of infections due to Acinetobacter baumannii-calcoaceticus complex

Pharmaceutical Form(s)

Solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Roche Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 19/11/2025 13:09 GMT an application for a Paediatric Investigation Plan

The procedure started on 08/12/2025 13:07 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 agree a paediatric investigation plan and grant a 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.

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Final Decision Letter

MHRA-102155-PIP01-25

Of 18/05/2026 08:50 BST

On the adopted decision for Zosurabalpin (MHRA-102155-PIP01-25) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Zosurabalpin, Solution for infusion , INTRAVENOUS USE .

This decision is addressed to Roche Products Limited, 6 Falcon Way, Welwyn Garden City, UNITED KINGDOM, AL71TW

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of infections due to Acinetobacter baumannii-calcoaceticus complex

2.2 Indication(s) targeted by the PIP:

Treatment of infections due to Acinetobacter baumannii-calcoaceticus (ABC organisms) in paediatric patients with limited treatment options.

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation and method of administration of the solution for infusion of zosurabalpin for use in paediatric patients.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Open-label, multiple dose trial to evaluate pharmacokinetics, safety, and tolerability of zosurabalpin (as add-on to standard of care) in male and female paediatric participants from birth (including preterm neonates) to less than 18 years of age receiving intravenous (IV) antibiotic therapy for pneumonia or bacteraemia suspected or confirmed to be caused by Acinetobacter baumannii-calcoaceticus complex (ABC) organisms.
Extrapolation, Modeling & Simulation Studies	3	Study 3 Use of physiologically based pharmacokinetic modelling for prediction of paediatric doses for zosurabalpin. Study 4 Use of population pharmacokinetic modelling for dose selection of zosurabalpin, definition of sample size and pharmacokinetic sampling timelines required in study 2 and to support extrapolation of efficacy. Study 5 Extrapolation study to evaluate the use of zosurabalpin in children from birth (including pre-term) to less than 18 years of age for the treatment of infections

		due to Acinetobacter baumannii-calcoaceticus complex.
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:	31/01/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes