

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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100349-PIP01-26

Scope of the Application

Active Substance(s)

REZAFUNGIN ACETATE

Condition(s)

Prevention of invasive fungal infections

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Napp Pharmaceuticals

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Napp Pharmaceuticals submitted to the licensing authority on 22/05/2026 15:21 BST an application for a Paediatric Investigation Plan

The procedure started on 16/06/2026 14:21 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 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.

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Final Decision Letter

MHRA-100349-PIP01-26

Of 04/09/2026 15:11 BST

On the adopted decision for REZAFUNGIN ACETATE (MHRA-100349-PIP01-26) 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 REZAFUNGIN ACETATE, Powder for concentrate for solution for infusion , Intravenous use .

This decision is addressed to Napp Pharmaceuticals, Cambridge Science Park, Milton Road, Cambridge, UNITED KINGDOM, CB4 0GW

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of invasive fungal infections
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2.2 Indication(s) targeted by the PIP:

Prophylaxis of invasive fungal infections in paediatric patients less than 18 years of age at high risk of developing invasive fungal infections
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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):

Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate dosage form for parenteral use suitable for the paediatric population from birth with polysorbate 80 level safe for young infants.
Non-Clinical Studies	1	Study 2 (MR907-R24605) Definitive juvenile toxicity study in rats to investigate repeat dose effects of rezafungin on neonatal and juvenile rats.
Clinical Studies	1	Study 3 (MR907-2503) Open-label study to evaluate the safety, tolerability and pharmacokinetics (PK) of rezafungin acetate in immunocompromised children from birth to less than 18 years of age with a clinical indication to receive antifungal prophylaxis.
Extrapolation, Modeling & Simulation Studies	2	Study 4 Population PK modelling of rezafungin acetate to confirm the paediatric posology in immunocompromised children from birth to less than 18 years of age with a clinical indication to receive antifungal prophylaxis. Extrapolation Plan Study MR907-2503 and the population PK modelling (PIP studies 3 and 4) are part of the extrapolation plan of efficacy data from adult patients to the paediatric population from birth to less than 18 years of age of immunocompromised individuals indicated to receive antifungal prophylaxis.

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:	30/04/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes