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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-102238-PIP01-25-M01

Scope of the Application

Active Substance(s)

ozanimod hydrochloride

Condition(s)

Treatment of ulcerative colitis

Pharmaceutical Form(s)

Capsule, hard; Age-appropriate oral solid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb Pharmaceuticals Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb Pharmaceuticals Limited submitted to the licensing authority on 21/11/2025 15:57 GMT an application for a Modification

The procedure started on 18/12/2025 09:43 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 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-102238-PIP01-25-M01

Of 27/01/2026 10:13 GMT

On the adopted decision for ozanimod hydrochloride (MHRA-102238-PIP01-25-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 ozanimod hydrochloride, Capsule, hard; Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Bristol-Myers Squibb Pharmaceuticals Limited, Arc Uxbridge Sanderson Road, Denham, UNITED KINGDOM, UB8 1DH

ANNEX I

1. Waiver

1.1 Condition:

Treatment of ulcerative colitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Capsule, hard; Age-appropriate oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of ulcerative colitis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severely active ulcerative colitis

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard; Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid dosage form
Non-Clinical Studies	1	Study 2 33-Day oral immunotoxicity study in juvenile Sprague-Dawley rats
Clinical Studies	1	Study 3 (RPC01-3101) This study was deleted during procedure MHRA-102238-PIP01-25-M01. Study 4 (RPC01-3102) This study was deleted during procedure MHRA-102238-PIP01-25-M01. Study 5 (UC-PED-PK) This study was deleted during procedure MHRA-102238-PIP01-25-M01. Study 6 (UC-PED-PH3) This study was deleted during procedure MHRA-102238-PIP01-25-M01. Study 8 (RPC1063-UC-002) This study was added during procedure MHRA-102238-PIP01-25-M01. Randomised, double-blind study to estimate the efficacy, safety and tolerability, and pharmacokinetics (PK)/ pharmacodynamics (PD) of two doses of oral ozanimod in paediatric patients from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis (UC).
Extrapolation, Modeling & Simulation Studies	3	Study 7 Extrapolation/ Interpolation population pharmacokinetic

		modelling and simulation study, to evaluate use of ozanimod in children from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis. Study 9 This study was added during procedure MHRA-102238-PIP01-25-M01. Modelling and simulation study, to characterise the PK/PD and exposure response (E-R) efficacy relationships of ozanimod in paediatric patients from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis (UC). Study 10 This study was added during procedure MHRA-102238-PIP01-25-M01. Integrated analysis of population PK, population PK/ PD and exposure-response modelling results of ozanimod for treatment of paediatric patients from 2 years to less than 18 years of age with ulcerative colitis (UC).
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:	30/04/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes