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

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-101857-PIP01-25

Scope of the Application

Active Substance(s)

Humanised afucosylated IgG1 monoclonal antibody against CCR8

Condition(s)

Treatment of all conditions included in the category of malignant neoplasms except melanoma, nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intravenous Use; Subcutaneous use

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb Pharma EEIG

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb Pharma EEIG submitted to the licensing authority on 09/05/2025 16:07 BST an application for a Waiver

The procedure started on 28/05/2025 14:55 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 grant a product specific waiver

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-101857-PIP01-25

Of 28/07/2025 08:02 BST

On the adopted decision for Humanised afucosylated IgG1 monoclonal antibody against CCR8 (MHRA-101857-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:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for Humanised afucosylated IgG1 monoclonal antibody against CCR8, Solution for injection , Intravenous use; Subcutaneous use .

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2, DUBLIN, UNITED KINGDOM, D15 T867

ANNEX I

1. Waiver

1.1 Condition:

Treatment of all conditions included in the category of malignant neoplasms (except melanoma, nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms)

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not Applicable

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	