**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 grant a product specific waiver

MHRA-100758-PIP01-22-M01

# Scope of the Application

## Active Substance(s)

BEZLOTOXUMAB

## Condition(s)

Prevention of recurrence of Clostridioides difficile infection

## Pharmaceutical Form(s)

Concentrate for solution for infusion

## Route(s) of Administration

INTRAVENOUS USE

## Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Limited

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Limited submitted to the licensing authority on 21/11/2022 18:55 GMT an application for a Modification

The procedure started on 03/04/2023 08:15 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 accept change(s) to the agreed paediatric investigation plan and 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-100758-PIP01-22-M01

Of 17/07/2023 06:59 BST

On the adopted decision for BEZLOTOXUMAB (MHRA-100758-PIP01-22-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 BEZLOTOXUMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Prevention of recurrence of Clostridioides difficile infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: For the paediatric population from birth to less than 1 year of age: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s). For the paediatric population from 1 year to less than 18 years of age: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. |

### 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** | 0 | All studies were deleted during procedure MHRA-100758-PIP01-22-M01 |
| **Non-Clinical Studies** | 0 | Not applicable |
| **Clinical Studies** | 0 | Not applicable |
| **Extrapolation, Modeling & Simulation Studies** | 0 | Not applicable |
| **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:** | |
| **Date of completion of the paediatric investigation plan:** | |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | |