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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

grant a product specific waiver

MHRA-101676-PIP01-24

# Scope of the Application

## Active Substance(s)

HUMAN ANTI-D IMMUNOGLOBULIN

## Condition(s)

Prevention of Rhesus (Rh) isoimmunisation

## Pharmaceutical Form(s)

Solution for injection

## Route(s) of Administration

INTRAMUSCULAR USE

## Name / Corporate name of the PIP applicant

Kedrion S.p.A.

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Kedrion S.p.A. submitted to the licensing authority on 19/12/2024 17:19 GMT an application for a Waiver

The procedure started on 13/01/2025 15:07 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 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-101676-PIP01-24

Of 01/04/2025 17:06 BST

On the adopted decision for HUMAN ANTI-D IMMUNOGLOBULIN (MHRA-101676-PIP01-24) 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 HUMAN ANTI-D IMMUNOGLOBULIN, Solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Kedrion S.p.A., Localita' Ai Conti, Castelvecchio Pascoli, Barga, Lucca, ITALY, 55051

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Prevention of Rhesus (Rh) isoimmunisation The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: For males from birth to less than 18 years of age and females from birth to menarche: - on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). For females from menarche to less than 18 years of age: - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible. |

### 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:** | |