

EMA/182144/2024

## European Medicines Agency decision P/0175/2024

of 3 May 2024

on the agreement of a paediatric investigation plan for Human rabies immune globulin (EMA-003552-PIP01-23) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

### **Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

# European Medicines Agency decision

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on the agreement of a paediatric investigation plan for Human rabies immune globulin (EMA-003552-PIP01-23) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>1</sup>,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the application submitted by Kamada Ireland Limited on 14 December 2023 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 March 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

**Article 1**

A paediatric investigation plan for human rabies immune globulin, solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

**Article 2**

This decision is addressed to Kamada Ireland Limited, Greenmount Avenue, Dublin 12, Ireland, D12 – Dublin, Ireland.

EMA/PDCO/98868/2024  
Amsterdam, 22 March 2024

## Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMA-003552-PIP01-23

### Scope of the application

**Active substance(s):**

Human rabies immune globulin

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Prevention of rabies infection

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Intramuscular use

**Name/corporate name of the PIP applicant:**

Kamada Ireland Limited

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Kamada Ireland Limited submitted for agreement to the European Medicines Agency on 14 December 2023 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 22 January 2024.

## Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

## **Annex I**

**The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)**

## 1. Waiver

Not applicable

## 2. Paediatric investigation plan

### 2.1. Condition:

Prevention of rabies infection

#### 2.1.1. Indication(s) targeted by the PIP

Post-exposure prophylaxis of rabies infection in persons after exposure to scratches, bites or other injuries including mucous membrane contamination with infectious tissue, such as saliva, caused by a suspected rabid animal. Human rabies immunoglobulin must always be used in combination with a rabies vaccine.

#### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

#### 2.1.3. Pharmaceutical form(s)

Solution for intramuscular use

#### 2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	<b>Study 1 - KamRAB-004</b>  Prospective, open-label, study to confirm safety and effectiveness of human rabies immune globulin (HRIG) as part of post-exposure prophylaxis (PEP) in children from birth to less than 18 years of age.
Modelling and simulation analyses	Not applicable
Other studies	Not applicable
Extrapolation plan	Not applicable

### 3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By November 2019
Deferral for one or more measures contained in the paediatric investigation plan:	No



## **Annex II**

### **Information about the authorised medicinal product**

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**