



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2036382

## European Medicines Agency decision

EMA/PE/0000232762

of 14 April 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for frexalimab 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.**



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on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for frexalimab 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 Sanofi Winthrop Industrie on 22/03/2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2025, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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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 frexalimab, 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**

A deferral for frexalimab, 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 granted.

**Article 3**

A waiver for frexalimab, 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 granted.

**Article 4**

This decision is addressed to Sanofi Winthrop Industrie, 82 Avenue Raspail, 94250 – Gentilly, France.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1800599  
Amsterdam, 28 February 2025

## Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA/PE/0000232762

### Scope of the application

**Active substance(s):**

Frexalimab

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of multiple sclerosis

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Intravenous use

Subcutaneous use

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

Sanofi Winthrop Industrie

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Winthrop Industrie submitted for agreement to the European Medicines Agency on 22 March 2024 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 29 April 2024.

Supplementary information was provided by the applicant on 25 November 2024. The applicant proposed modifications to the paediatric investigation plan.



## 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;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

## 1.1. Condition:

Treatment of multiple sclerosis

The waiver applies to:

- the paediatric population from birth to less than 10 years;
- solution for injection, intravenous use, subcutaneous use;
- 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:

Treatment of multiple sclerosis

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

Treatment of relapsing multiple sclerosis (RMS)

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

From 10 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Solution for injection

### 2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Study 1 (TER0758) Enhanced prenatal and postnatal developmental (ePPND) toxicity study following once weekly intravenous injection of frexalimab to cynomolgus monkeys with a 6-month post partum period.
Clinical studies	Study 2 Double-blind, randomised trial to evaluate pharmacokinetics, safety and efficacy of frexalimab compared to an active comparator in children from 10 years to less than 18 years of age with relapsing multiple sclerosis.

Modelling and simulation analyses	<p>Study 3</p> <p>Population PK to predict initial paediatric doses of frexalimab to be used in study 2 in children from 10 years to less than 18 years of age with RMS.</p> <p>Study 4</p> <p>Physiologically based model to predict initial paediatric doses of frexalimab to be used in study 2 in children from 10 years to less than 18 years of age.</p>
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 June 2035
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

## **Annex II**

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

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

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