EMADOC-1700519818-2223385

European Medicines Agency decision

EMA/PE/0000254020

of 27 June 2025

on the acceptance of a modification of an agreed paediatric investigation plan for risankizumab (Skyrizi) 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 acceptance of a modification of an agreed paediatric investigation plan for risankizumab (Skyrizi) 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[1],

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[2],

Having regard to the European Medicines Agency's decision P/0231/2018 issued on 3 August 2018, and the decision P/0391/2023 issued on 13 September 2023,

Having regard to the application submitted by Abbvie Limited on 17 February 2025 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 May 2025, in accordance with Article 22 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 acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for risankizumab (Skyrizi), including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decisions P/0205/2016, P/0343/2017, P/0230/2018, including subsequent modifications thereof.

Article 3

This decision is addressed to Abbvie Limited, Abbvie House, 2 Vanwall Road, Maidenhead - SL6 4UB, United Kingdom.

EMADOC-1700519818-1935064 Corr[1]

Amsterdam, 23 May 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000254020

Scope of the application

Active substance(s):

Risankizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ulcerative colitis

Pharmaceutical form(s):

Concentrate for solution for infusion

Solution for injection

Age-appropriate dosage form for parenteral use

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Abbvie Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Abbvie Limited submitted to the European Medicines Agency on 17 February 2025 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines

[1] 10 June 2025.

Agency's decision P/0231/2018 issued on 3 August 2018, and the decision P/0391/2023 issued on 13 September 2023.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 24 March 2025.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 ulcerative colitis

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- concentrate for solution for infusion, solution for injection, age-appropriate dosage form for parenteral use; intravenous use, subcutaneous use;
- 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

Treatment of ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active ulcerative colitis

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion

Solution for injection

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1 - Paediatric formulation 1** Development of an age-appropriate paediatric formulation/presentation for paediatric use for induction treatment **Study 2 - Paediatric formulation 2** Development of an age-appropriate paediatric formulation/presentation for paediatric use for maintenance treatment

Non-clinical studies	Not applicable
Clinical studies	**Study 3** Study in paediatric patients from 2 years to less than 18 years of age with ulcerative colitis (UC) to evaluate the efficacy, safety, and pharmacokinetics (PK) of risankizumab (Study M19-751)
Extrapolation, modelling and simulation studies	**Study 4** Modelling and simulation population PK study
Other studies	Not applicable
Other measures	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 January 2031
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:

Condition(s) and authorised indication(s)

1. Treatment of psoriasis

Authorised indication(s):

- Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy
  - Invented name(s): Skyrizi
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure

2. Treatment of psoriatic arthritis

Authorised indication(s):

- Treatment – alone or in combination with methotrexate (MTX) - of adult patients with active psoriatic arthritis who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)
  - Invented name(s): Skyrizi
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure

3. Treatment of Crohn’s disease

Authorised indication(s):

- Treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy
  - Invented name(s): Skyrizi
  - Authorised pharmaceutical form(s): Concentrate for solution for infusion, solution for injection
  - Authorised route(s) of administration: Intravenous use, subcutaneous use
  - Authorised via centralised procedure

4. Treatment of ulcerative colitis

Authorised indication(s):

- Treatment of adult patients e treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy
  - Invented name(s): Skyrizi
  - Authorised pharmaceutical form(s): Concentrate for solution for infusion, solution for injection
  - Authorised route(s) of administration: Intravenous use, subcutaneous use
  - Authorised via centralised procedure