EMA/89807/2024

European Medicines Agency decision

P/0077/2024

of 8 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for sodium zirconium cyclosilicate (Lokelma), (EMEA-001539-PIP01-13-M06) 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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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/0210/2014 issued on 12 August 2014, the decision P/0296/2016 issued on 4 November 2016, the decision P/0226/2017 issued on 11 August 2017, the decision P/0053/2018 issued on 1 March 2018, the decision P/0069/2020 issued on 18 March 2020, and the decision P/0477/2021 issued on 3 December 2021,

Having regard to the application submitted by AstraZeneca AB on 12 October 2023 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 19 January 2024, 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 sodium zirconium cyclosilicate (Lokelma), powder for oral suspension, oral use, 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 is addressed to AstraZeneca AB, SE-15185 – Södertälje, Sweden.

EMA/PDCO/500727/2023
Amsterdam, 19 January 2024

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

EMEA-001539-PIP01-13-M06

Scope of the application

Active substance(s):

Sodium zirconium cyclosilicate

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hyperkalaemia

Pharmaceutical form(s):

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 12 October 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0210/2014 issued on 12 August 2014, the decision P/0296/2016 issued on 4 November 2016, the decision P/0226/2017 issued on 11 August 2017, the decision P/0053/2018 issued on 1 March 2018, the decision P/0069/2020 issued on 18 March 2020, and the decision P/0477/2021 issued on 3 December 2021.

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

The procedure started on 20 November 2023.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 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 hyperkalaemia

The waiver applies to:

- newborn infants less than 37 weeks gestation or under 2500 g birth weight;
- powder for oral suspension, oral 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 hyperkalaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of hyperkalaemia

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

From birth (excluding newborn infants less than 37 weeks gestation or under 2500 g birth weight) to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for oral suspension

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate oral formulation *Study 2 deleted during procedure EMEA-001539-PIP01-13-M02*
Non-clinical studies	Not applicable
Clinical studies	*Study 3 deleted during procedure EMEA-001539-PIP01-13-M01* **Study 4** Open-label correction phase followed by open-label, dose titration phase study in children less than 18 years of age with hyperkalaemia

Extrapolation, modelling and simulation studies	Not applicable
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 June 2026
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 hyperkalaemia

Authorised indication(s):

- Lokelma is indicated for the treatment of hyperkalaemia in adult patients
  - Invented name(s): Lokelma
  - Authorised pharmaceutical form(s): powder for oral suspension
  - Authorised route(s) of administration: oral use
  - Authorised via centralised procedure