EMA/169200/2022

European Medicines Agency decision

P/0159/2022

of 13 May 2022

on the acceptance of a modification of an agreed paediatric investigation plan for magnesium sulphate heptahydrate / potassium sulphate / sodium sulphate anhydrous (Izinova and associated names), (EMEA-000816-PIP02-10-M03) 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

P/0159/2022

of 13 May 2022

on the acceptance of a modification of an agreed paediatric investigation plan for magnesium sulphate heptahydrate / potassium sulphate / sodium sulphate anhydrous (Izinova and associated names), (EMEA-000816-PIP02-10-M03) 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/0214/2011 issued on 2 September 2011, the decision P/0169/2016 issued on 17 June 2016 and the decision P/0035/2019 issued on 29 January 2019,

Having regard to the application submitted by IPSEN Consumer Healthcare on 24 November 2021 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 25 March 2022, 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 and to the waiver.

(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 and to the waiver.

[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 magnesium sulphate heptahydrate / potassium sulphate / sodium sulphate anhydrous (Izinova and associated names), concentrate for oral solution, oral use, including changes to the deferral and to the waiver, 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 IPSEN Consumer Healthcare, 65 quai George Gorse, 92100 - Boulogne-Billancourt, France.

EMA/PDCO/736166/2021 Corr
Amsterdam, 25 March 2022

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

EMEA-000816-PIP02-10-M03

Scope of the application

Active substance(s):

Magnesium sulphate heptahydrate / potassium sulphate / sodium sulphate anhydrous

Invented name:

Izinova and associated names

Condition(s):

Diagnosis of organic and/or functional bowel diseases

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Concentrate for oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

IPSEN Consumer Healthcare

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, IPSEN Consumer Healthcare submitted to the European Medicines Agency on 24 November 2021 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/0214/2011 issued on 2 September 2011, decision P/0169/2016 issued on 17 June 2016 and the decision P/0035/2019 issued on 29 January 2019.

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

The procedure started on 31 January 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to waiver 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

Diagnosis of organic and/or functional bowel diseases

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- concentrate for oral solution, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

and to:

- the paediatric population from 6 months to less than 12 years of age;
- concentrate for oral solution, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition

Diagnosis of organic and/or functional bowel diseases

2.1.1. Indication(s) targeted by the PIP

Bowel cleansing prior to any procedure requiring a clean bowel in patients above 6 months of age

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

From 12 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Concentrate for oral solution

2.1.4. Studies

Area	**Description**
Quality	Not applicable
Non-clinical	Not applicable
Clinical	**Study 1** Dose-ranging, open-label, study to assess efficacy of magnesium sulphate heptahydrate / potassium sulphate / sodium sulphate anhydrous (BLI800) in adolescents of 12 to less than 18 years of age. (BLI800-501)

	Study 2 Efficacy, safety, and tolerability, active-controlled study of BLI800 in adolescent subjects undergoing colonoscopy. (EASYKID) **Study 3** Study deleted in EMEA-000816-PIP02-10-M03. **Study 4** Study deleted in EMEA-000816-PIP02-10-M03.

3. Follow-up, completion and deferral of PIP

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Diagnostic of organic and/or functional bowel diseases

Authorised indication(s):

- Izinova is indicated in adults for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualisation including endoscopy and radiology or surgical procedure).
  Izinova is not a treatment for constipation.

Authorised pharmaceutical form(s)

Concentrate for oral solution

Authorised route(s) of administration

Oral use