

EMA/385684/2016 Corr

European Medicines Agency decision

P/0169/2016

of 17 June 2016

on the acceptance of a modification of an agreed paediatric investigation plan for sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (Izinova and associated names), (EMA-000816-PIP02-10-M01) 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 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/214/2011 issued on 2 September 2011,

Having regard to the application submitted by Ipsen Pharma on 5 February 2016 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 29 April 2016, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (Izinova), oral solution, 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 agreed paediatric investigation plan covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/214/2011 issued on 2 September 2011, including subsequent modifications thereof.

Article 3

This decision is addressed to IPSEN Pharma, 65 quai George Gorse, 92100 - Boulogne-Billancourt, France.

Done at London, 17 June 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/130933/2016 Corr
London, 29 April 2016

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000816-PIP02-10-M01

Scope of the application

Active substance(s):

Sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (BLI800)

Invented name:

Izinova (and associated names)

Condition(s):

Diagnostic of organic and/or functional bowel diseases

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral solution

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Ipsen Pharma

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 Pharma submitted to the European Medicines Agency on 5 February 2016 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/214/2011 issued on 2 September 2011.

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

The procedure started on 1 March 2016.

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 Norwegian Paediatric Committee member 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:

- newborns and infants from birth to less than 6 months of age;
- 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.

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 6 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral solution

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	4	Dose-ranging, open-label, study to assess efficacy of BLI800 as bowel cleansing preparation in adolescents of 12 to less than 18 years of age. Efficacy, safety, and tolerability, active-controlled study of BLI800 in adolescent subjects undergoing colonoscopy. Efficacy, safety, and tolerability, active-controlled study of BLI800 in children of 3 to less than 12 years of age. Open-label study to assess the safety of BLI800 in children 6 months to less than 3 years of age.

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 September 2020
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