



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/696054/2011

## European Medicines Agency decision P/214/2011

of 2 September 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate, (EMA-000816-PIP02-10) 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<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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the application submitted by Ipsen Pharma on 8 December 2010 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 12 August 2011, in accordance with Article 18 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.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A paediatric investigation plan for sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate, oral solution, oral use, 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 sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate, oral solution, oral use, 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 sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate, oral solution, oral use, 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 Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France.

Done at London, 2 September 2011

For the European Medicines Agency  
Andreas Pott  
Acting Executive Director  
(Signature on file)

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

EMA-000816-PIP02-10

### Scope of the application

**Active substance(s):**

Sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate

**Condition(s):**

Diagnostic of organic and/or functional bowel diseases

**Pharmaceutical form(s):**

Oral solution

**Route(s) of administration:**

Oral use

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

Ipsen Pharma

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Ipsen Pharma submitted for agreement to the European Medicines Agency on 8 December 2010 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 19 January 2011.

Supplementary information was provided by the applicant on 26 May 2011. 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 18 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 Icelandic and the Norwegian Paediatric Committee members agree 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 annex(es) and appendix.

London, 12 August 2011

On behalf of the Paediatric Committee  
Dr Daniel Brasseur, Chairman  
(Signature on file)

## **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**

## 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.<br><br>Efficacy, safety, and tolerability, active-controlled study of BLI800 in adolescent subjects undergoing colonoscopy.<br><br>Efficacy, safety, and tolerability, active-controlled study of BLI800 in children of 3 to less than 12 years of age.<br><br>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 Feb 2019 |
| Deferral for one or more studies contained in the paediatric investigation plan:          | Yes         |