

EMA/501874/2008

European Medicines Agency decision

P/0278/2016

of 7 October 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for macrogol 3350 / sodium sulfate / sodium chloride / potassium chloride / sodium ascorbate / ascorbic, (EMA-001705-PIP02-15) 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 application submitted by Norgine Ltd. on 22 February 2016 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 16 September 2016, 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.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for macrogol 3350 / sodium sulfate / sodium chloride / potassium chloride / sodium ascorbate / ascorbic, powder for 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 macrogol 3350 / sodium sulfate / sodium chloride / potassium chloride / sodium ascorbate / ascorbic, powder for 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 macrogol 3350 / sodium sulfate / sodium chloride / potassium chloride / sodium ascorbate / ascorbic, powder for 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 Norgine Ltd. Norgine House, Widewater Place Moorhall Road, Harefield UB9 6NS Uxbridge, United Kingdom.

EMA/PDCO/213638/2016
London, 16 September 2016

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

EMA-001705-PIP02-15

Scope of the application

Active substance(s):

Macrogol 3350 / sodium sulfate / sodium chloride / potassium chloride / sodium ascorbate / ascorbic acid (NER1006)

Condition(s):

Bowel cleansing prior to clinical procedures

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Norgine Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Norgine Ltd. submitted for agreement to the European Medicines Agency on 22 February 2016 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 29 March 2016.

Supplementary information was provided by the applicant on 27 June 2016.

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 Norwegian Paediatric Committee member agrees 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 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 large intestine disorders

The waiver applies to:

- the paediatric population from birth to less than 1 year;
- powder for oral solution, 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:

Bowel cleansing prior to clinical procedures

2.1.1. Indication(s) targeted by the PIP

Bowel cleansing prior to any clinical procedures requiring a clean bowel

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for oral solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	Study 1 Development of a measuring/dispenser device with suitable graduation for all paediatric age groups. Study 2 Evaluation of physical compatibility with nasogastric tubes.
Non-clinical studies	0	Not applicable.

Clinical studies	3	Study 3 Randomised, colonoscopist-blind, controlled, parallel group study, with a dose determination run-in phase, to evaluate efficacy, safety, pharmacokinetics, tolerability, acceptability and palatability of NER1006 in children from 12 to less than 18 years of age undergoing colonoscopy, using a standardised active comparator. Study 4 Randomised, colonoscopist-blind, controlled, parallel group study, with a dose determination run-in phase, to evaluate efficacy, safety, pharmacokinetics, tolerability, acceptability and palatability of NER1006 in children from 2 to less than 12 years of age undergoing colonoscopy, using a standardised active comparator. Study 5 Randomised, colonoscopist-blind, controlled, parallel group study, with a dose determination run-in phase, to evaluate efficacy, safety, pharmacokinetics and tolerability of NER1006 in children from 1 to less than 2 years of age undergoing colonoscopy, using a standardised active comparator.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 December 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes