EMA/584751/2018

European Medicines Agency decision

P/0315/2018

of 12 September 2018

on the acceptance of a modification of an agreed paediatric investigation plan for macrogol 3350 / sodium ascorbate / sodium sulfate / ascorbic acid / sodium chloride / potassium chloride (NER1006) (EMEA-001705-PIP02-15-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 726/2004[1],

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[2],

Having regard to the European Medicines Agency's decision P/0278/2016 issued on 7 October 2016,

Having regard to the application submitted by Norgine Ltd. on 4 May 2018 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 27 July 2018, 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 macrogol 3350 / sodium ascorbate / sodium sulfate / ascorbic acid / sodium chloride / potassium chloride (NER1006), powder for 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 decision is addressed to Norgine Ltd., Norgine House, Widewater Place, Moorhall Road, Harefield, UB9 6NS – Uxbridge, United Kingdom.

EMA/PDCO/298077/2018 Corr
London, 27 July 2018

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

EMEA-001705-PIP02-15-M01

Scope of the application

Active substance(s):

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

Invented name:

Plenvu

Condition(s):

Bowel cleansing prior to clinical procedures

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Norgine Ltd.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Norgine Ltd. submitted to the European Medicines Agency on 4 May 2018 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/0278/2016 issued on 7 October 2016.

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

The procedure started on 29 May 2018.

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 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 January 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Bowel cleansing prior to clinical procedures

Authorised indication(s):

- Bowel cleansing in adults prior to any procedure requiring a clean bowel

Authorised pharmaceutical form(s):

Powder for oral solution

Authorised route(s) of administration:

Oral use