EMADOC-1700519818-1792265

European Medicines Agency decision

EMA/PE/0000221751

of 5 December 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ascorbic acid, macrogol 3350, potassium chloride, sodium ascorbate, sodium chloride, sodium sulphate (Plenvu) 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 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/0278/2016 issued on 7 October 2016, the decision P/0315/2018 issued on 12 September 2018 and the decision P/0196/2019 issued on 20 May 2019 and the decision P/0458/2020 issued on 1 December 2020,

Having regard to the application submitted by Norgine Limited on 8 July 2024 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 18 October 2024, 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, 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 ascorbic acid, macrogol 3350, potassium chloride, sodium ascorbate, sodium chloride, sodium sulphate (Plenvu), 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 Limited, Widewater Place, UB9 6NS - Uxbridge, United Kingdom.

EMADOC-1700519818-1623295 Corr[1]
Amsterdam, 18 October 2024

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

EMA/PE/0000221751

Scope of the application

Active substance(s):

Ascorbic acid, Macrogol 3350, Potassium chloride, Sodium ascorbate, Sodium chloride, Sodium sulphate (Plenvu)

Invented name and authorisation status:

See Annex II

Condition(s):

Bowel cleansing prior to clinical procedures

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

Norgine Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Norgine Limited submitted to the European Medicines Agency on 8 July 2024 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 decision P/0315/2018 issued on 12 September 2018 and the decision P/0196/2019 issued on 20 May 2019 and the decision P/0458/2020 issued on 1 December 2020.

[1] 13 November 2024

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

The procedure started on 19 August 2024.

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 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

Bowel cleansing prior to clinical procedures

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- powder for oral solution, oral use, gastric 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 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	Description
Quality-related studies	**Study 1** *This study was deleted as a result of procedure EMA/PE/0000221751.* **Study 2** Evaluation of physical compatibility of Plenvu with feeding tubes.
Non-clinical studies	Not applicable.
Clinical studies	**Study 3** Randomised, colonoscopist/central reader-blind, controlled, parallel group study to evaluate bowel cleansing efficacy, safety, tolerability, acceptability and palatability of Plenvu in children from 1 year to less than 18 years of age undergoing colonoscopy, using a standardised active comparator, a sodium picosulfate/magnesium salt (SP+MS)-based bowel preparation.

	Study 4 *This study was deleted as a result of procedure EMA/PE/0000221751.* **Study 5** *This study was deleted as a result of procedure EMA/PE/0000221751.*
Extrapolation, modelling and simulation studies	Not applicable.
Other studies	Not applicable.
Other measures	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 April 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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
  - Invented name(s): PLENVU
  - Authorised pharmaceutical form(s): Powder for oral solution
  - Authorised route(s) of administration: Oral use
  - Authorised via decentralised procedure