EMA/571559/2023

European Medicines Agency decision

P/0541/2023

of 14 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for birch bark extract (Filsuvez), (EMEA-001299-PIP03-17-M03) 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/0338/2019 issued on 11 September 2019, the decision P/0425/2020 issued on 22 October 2020, and the decision P/0243/2023 issued on 16 June 2023,

Having regard to the application submitted by Amryt Pharmaceuticals DAC on 13 December 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 December 2023, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 birch bark extract (Filsuvez), gel, cutaneous use, 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 Amryt Pharmaceuticals DAC, 45 Mespil Road, D04W2F1 - Dublin 4, Ireland.

EMA/PDCO/571521/2023
Amsterdam, 14 December 2023

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

EMEA-001299-PIP03-17-M03

Scope of the application

Active substance(s):

Birch bark extract

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of epidermolysis bullosa

Pharmaceutical form(s):

Gel

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Amryt Pharmaceuticals DAC

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Amryt Pharmaceuticals DAC submitted to the European Medicines Agency on 13 December 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0338/2019 issued on 11 September 2019, the decision P/0425/2020 issued on 22 October 2020, and the decision P/0243/2023 issued on 16 June 2023.

The application for modification proposed deleting of a cross reference to another agreed paediatric investigation plan.

The procedure started on 13 December 2023

Scope of the modification

Deleting of a cross reference to all indications, pharmaceutical forms, routes of administration, measures timelines, waivers and deferrals in the condition of treatment of skin injuries, covered by a separate agreed paediatric investigation plan as set out in the EMA decision P/0156/2013.

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 deleting of a cross reference to all indications, pharmaceutical forms, routes of administration, measures timelines, waivers and deferrals in the condition of treatment of skin injuries, covered by a separate agreed paediatric investigation plan as set out in the EMA decision P/0156/2013.

   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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of epidermolysis bullosa

2.1.1. Indication(s) targeted by the PIP

Treatment of epidermolysis bullosa

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Gel

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (EASE study; BEB-13) Double-blind, randomised, placebo (vehicle) controlled trial to evaluate efficacy and safety of birch bark extract on top of standard of care in children from birth to less than 18 years of age (and adults) with epidermolysis bullosa
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 December 2022
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. Treatment of epidermolysis bullosa

Authorised indication(s):

- Treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older.
  - Invented name(s): Filsuvez
  - Authorised pharmaceutical form(s): gel
  - Authorised route(s) of administration: cutaneous use
  - Authorised via centralised procedure