EMA/627032/2021

European Medicines Agency decision

P/0490/2021

of 3 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for cyclophosphamide (Zenew and associated names), (EMEA-002644-PIP01-19-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/0191/2020 issued on 15 May 2020,

Having regard to the application submitted by Accord Healthcare S.L.U. on 12 July 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 October 2021, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for cyclophosphamide (Zenew and associated names), powder for oral solution, oral use, gastric 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 Accord Healthcare S.L.U., World Trade Center, Moll De Barcelona s/n, Edifici Est, 6a Planta, 08039 – Barcelona, Spain.

EMA/PDCO/405080/2021 corr
Amsterdam, 15 October 2021

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

EMEA-002644-PIP01-19-M01

Scope of the application

Active substance(s):

Cyclophosphamide

Invented name:

Zenew and associated names

Condition(s):

Treatment of all malignant neoplasms

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

Accord Healthcare S.L.U.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Accord Healthcare S.L.U. submitted to the European Medicines Agency on 12 July 2021 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0191/2020 issued on 15 May 2020.

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

The procedure started on 17 August 2021.

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 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 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 all malignant neoplasms

2.1.1. Indication(s) targeted by the PIP

Cyclophosphamide is a cytotoxic drug for the treatment of malignant disease in children. As a single agent, it has successfully produced an objective remission in a wide range of malignant conditions. Cyclophosphamide is also frequently used in combination with other cytotoxic drugs, radiotherapy or surgery.

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)

Powder for oral solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a powder for oral solution.
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 2** (0068-20) Standard adult comparative bioavailability study **Study 3** (0069-20) Open label, single arm, multiple dose palatability study of cyclophosphamide oral solution of 30 mg/ml strength in patients from birth to less than 18 years of age with a malignant disease requiring cyclophosphamide treatment
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 2023
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of all malignant neoplasms

Authorised indication(s):

- Cyclophosphamide is a cytotoxic drug for the treatment of malignant disease in adults and children. As a single agent, it has successfully produced an objective remission in a wide range of malignant conditions. Cyclophosphamide is also frequently used in combination with other cytotoxic drugs, radiotherapy or surgery.

Authorised pharmaceutical form(s):

Coated tablet

Authorised route(s) of administration:

Oral use