EMA/238158/2023

European Medicines Agency decision

P/0217/2023

of 14 June 2023

on the acceptance of a modification of an agreed paediatric investigation plan for dienogest / ethinylestradiol (EMEA-002229-PIP02-21-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 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/0031/2022 issued on 31 January 2022,

Having regard to the application submitted by Chemo Research on 23 January 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 April 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 dienogest / ethinylestradiol, prolonged-release tablet, oral 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 Chemo Research, C/ Manuel Pombo Angulo 28, 3rd Floor, 28050 - Madrid Spain.

EMA/PDCO/50626/2023
Amsterdam, 26 April 2023

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

EMEA-002229-PIP02-21-M01

Scope of the application

Active substance(s):

Dienogest / ethinylestradiol

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hirsutism associated with polycystic ovary syndrome

Pharmaceutical form(s):

Prolonged-release tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Chemo Research

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chemo Research submitted to the European Medicines Agency on 23 January 2023 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0031/2022 issued on 31 January 2022.

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

The procedure started on 27 February 2023.

Scope of the modification

Some 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 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:

Treatment of hirsutism associated with polycystic ovary syndrome

The waiver applies to:

- boys from birth to less than 18 years of age and premenarcheal girls;
- prolonged-release tablets, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

And to

- post-menarcheal girls less than 2 years post-menarche or below 14 years of age for girls with primary amenorrhea;
- prolonged-release tablets, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subsets.

2. Paediatric investigation plan

2.1. Condition:

Treatment of hirsutism associated with polycystic ovary syndrome

2.1.1. Indication(s) targeted by the PIP

Treatment of adolescent girls post menarche with hirsutism associated with polycystic ovary syndrome (PCOS) who are not seeking pregnancy

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

Post-menarche adolescent girls (from 2 years post-menarche or above 14 years of age for girls with primary amenorrhea) to less than 18 years

2.1.3. Pharmaceutical form(s)

Prolonged-release tablets

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (LPRI-424/304)** Multicentre, double-blind, randomised, placebo-controlled trial to evaluate the safety and efficacy of dienogest / ethinylestradiol in adolescent girls (and adults) with hirsutism associated with polycystic ovary syndrome (PCOS).
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 January 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.