EMA/99495/2022

European Medicines Agency decision

P/0092/2022

of 11 March 2022

on the acceptance of a modification of an agreed paediatric investigation plan for dienogest / ethinyl estradiol (EMEA-002229-PIP01-17-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/0017/2018 issued on 30 January 2018, the decision P/0053/2019 issued on 29 January 2019 date and the decision P/0169/2021 issued on 14 April 2021,

Having regard to the application submitted by Chemo Research on 22 September 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 January 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision granting a 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 dienogest / ethinyl estradiol, 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

A deferral for dienogest / ethinyl estradiol, prolonged-release tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Chemo Research, C/ Manuel Pombo Angulo 28, 3rd Floor, 28050 – Madrid, Spain.

EMA/PDCO/571239/2021
Amsterdam, 21 January 2022

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

EMEA-002229-PIP01-17-M03

Scope of the application

Active substance(s):

Dienogest / ethinyl estradiol

Condition(s):

Prevention of pregnancy

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 22 September 2021 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0017/2018 issued on 30 January 2018, the decision P/0053/2019 issued on 29 January 2019 date and the decision P/0169/2021 issued on 14 April 2021.

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

The procedure started on 22 November 2021.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified and a deferral has been added.

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.
   - to grant a deferral, the details of which are 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 annex 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

Prevention of pregnancy

The waiver applies to:

- All boys from birth to less than 18 years of age and girls from birth to age at menarche;
- prolonged-release tablet, 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 subset(s).

2. Paediatric investigation plan

2.1. Condition

Prevention of pregnancy

2.1.1. Indication(s) targeted by the PIP

Prevention of pregnancy

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

Female adolescents after age at menarche

2.1.3. Pharmaceutical form(s)

Prolonged-release tablet

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 1** Open-label, single arm, trial to evaluate safety, efficacy and pharmacokinetics of LPRI-424 (Dienogest 2.00 mg / Ethinyl Estradiol 0.02 mg) in healthy female adolescents after menarche (and in adults) during 13 Cycles of 28 days
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 June 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes