EMA/900655/2018

European Medicines Agency decision

P/0053/2019

of 29 January 2019

on the acceptance of a modification of an agreed paediatric investigation plan for dienogest / ethinyl estradiol (lpri-424) (EMEA-002229-PIP01-17-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/0017/2018 issued on 30 January 2018,

Having regard to the application submitted by Exeltis France S. A. on 7 September 2018 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 14 December 2018, 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 dienogest / ethinyl estradiol (Ipri-424), 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 Exeltis France S.A., 7 rue Victor Hugo, 92310 - SEVRES, France.

EMA/PDCO/638416/2018
London, 14 December 2018

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

EMEA-002229-PIP01-17-M01

Scope of the application

Active substance(s):

Dienogest / ethinyl estradiol (LPRI-424)

Condition(s):

Prevention of pregnancy

Pharmaceutical form(s):

Prolonged-release tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Exeltis France S. A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Exeltis France S. A. submitted to the European Medicines Agency on 7 September 2018 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 16 October 2018.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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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 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:

- males: all subsets of the paediatric population from birth to less than 18 years of age;
- females: 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 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 January 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No