EMA/706126/2021

European Medicines Agency decision

P/0561/2021

of 31 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for estetrol / drospirenone (Lydisilka), (EMEA-001332-PIP01-12-M05) 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/0146/2013 issued on 3 July 2013, the decision P/0359/2016 issued on 21 December 2016, the decision P/0256/2020 issued on 15 July 2020 and the decision P/0478/2020 issued on 1 December 2020,

Having regard to the application submitted by Estetra SRL on 2 August 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 November 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 and to the deferral.

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

[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 estetrol / drospirenone (Lydisilka), film-coated tablet, oral use, including changes to the deferral, 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 Estetra SRL, Rue Saint-Georges, 5, 4000 – Liège, Belgium.

EMA/PDCO/461186/2021
Amsterdam, 12 November 2021

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

EMEA-001332-PIP01-12-M05

Scope of the application

Active substance(s):

Estetrol / drospirenone

Invented name:

Lydisilka

Condition(s):

Prevention of pregnancy

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Estetra SRL

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Estetra SRL submitted to the European Medicines Agency on 2 August 2021 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0146/2013 issued on 3 July 2013, the decision P/0359/2016 issued on 21 December 2016, the

decision P/0256/2020 issued on 15 July 2020 and the decision P/0478/2020 issued on 1 December 2020.

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

The procedure started on 14 September 2021.

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 and to the deferral 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 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

Prevention of pregnancy

The waiver applies to:

- all male paediatric population from birth to less than 18 years of age and pre-menarche female population;
- for film-coated 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

Girls from menarche to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated 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 (MIT-Es001-C303)** Open-label, single-arm study to evaluate the safety and pharmacokinetics of the combined oral contraceptive (COC) containing estetrol and drospirenone for 6 cycles of 28 days in post-menarcheal female adolescents from 12 to less than 18 years of age

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 and 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

Condition(s) and authorised indication(s):

1. Oral contraception

Authorised indication(s):

- Oral contraception. The decision to prescribe Lydisilka should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with Lydisilka compares with other combined hormonal contraceptives (CHCs).

Authorised pharmaceutical form(s):

Film-coated tablets

Authorised route(s) of administration:

Oral use