EMA/176728/2024

European Medicines Agency decision

P/0163/2024

of 6 May 2024

on the acceptance of a modification of an agreed paediatric investigation plan for levonogestrel (EMEA-002474-PIP02-18-M02), 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/0302/2019 issued on 10 September 2019 and the decision P/0447/2022 issued on 28 October 2022,

Having regard to the application submitted by Chemo Research, S.L. on 17 December 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 22 March 2024, 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 levonogestrel, vaginal delivery system, vaginal 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, S.L., C/ Manuel Pombo Angulo 28, 3rd Floor, 28050 – Madrid, Spain.

EMA/PDCO/120399/2024
Amsterdam, 22 March 2024

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

EMEA-002474-PIP02-18-M02

Scope of the application

Active substance(s):

Levonogestrel

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of pregnancy

Pharmaceutical form(s):

Vaginal delivery system

Route(s) of administration:

Vaginal use

Name/corporate name of the PIP applicant:

Chemo Research, S.L.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chemo Research, S.L. submitted to the European Medicines Agency on 17 December 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/0302/2019 issued on 10 September 2019 and the decision P/0447/2022 issued on 28 October 2022.

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

The procedure started on 22 January 2024.

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:

Prevention of pregnancy

The waiver applies to:

- all subsets of the male paediatric population from birth to less than 18 years of age and the female paediatric population from birth to the age of menarche;
- vaginal delivery system, vaginal 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

Contraception

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

Females from the age of menarche to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Vaginal delivery system

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (LR-301)** Open-label, multiple dose, multicentre, uncontrolled trial to evaluate efficacy, safety and tolerability of Levonorgestrel vaginal delivery system (LVDS) during 13 sequential cycles of 28 days in females from the age of menarche. **Study 2** *Study removed during the procedure EMEA-002474-PIP02-18-M01* **Study 3 (LR-303)** *Study added during the procedure EMEA-002474-PIP02-18-M01*

	Open label, multi-centre, non-comparative trial on the contraceptive activity, safety, tolerability and pharmacokinetics of Levonorgestrel Vaginal Delivery System (LVDS -75 µg/day) during 13 cycles in females from the age of menarche to less than 18 years of age (and in adults).
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:	Yes
Date of completion of the paediatric investigation plan:	By November 2025
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.