EMADOC-1700519818-2113975

European Medicines Agency decision

EMA/PE/0000240469

of 16 May 2025

on the acceptance of a modification of an agreed paediatric investigation plan for levonorgestrel 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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on the acceptance of a modification of an agreed paediatric investigation plan for levonorgestrel in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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, the decision P/0447/2022 issued on 28 October 2022 and the decision P/0163/2024 issued on 6 May 2024,

Having regard to the application submitted by Chemo Research S.L. on 20 December 2024 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 28 March 2025, in accordance with Article 22 of Regulation (EC) No 1901/2006 and of its own motion in accordance with 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 levonorgestrel, 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 levonorgestrel, 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 S.L., 3rd Floor, Calle Manuel Pombo Angulo 28, 28050 Madrid, Spain.

EMADOC-1700519818-1850788
Amsterdam, 28 March 2025

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

EMA/PE/0000240469

Scope of the application

Active substance(s):

Levonorgestrel

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 20 December 2024 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, the decision P/0447/2022 issued on 28 October 2022 and the decision P/0163/2024 issued on 6 May 2024.

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

The procedure started on 27 January 2025.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A deferral was added to the plan.

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 of its own motion in accordance with Article 21 of said Regulation.

   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 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.