EMA/467544/2019

European Medicines Agency decision

P/0302/2019

of 10 September 2019

on the agreement of a paediatric investigation plan and on the granting of a waiver for levonorgestrel (EMEA-002474-PIP02-18) 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 application submitted by Chemo Research, S.L. on 26 November 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 July 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for levonorgestrel, vaginal delivery system, vaginal use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for levonorgestrel, vaginal delivery system, vaginal use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

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

EMA/PDCO/280427/2019
Amsterdam, 26 July 2019

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-002474-PIP02-18

Scope of the application

Active substance(s):

Levonorgestrel

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 16(1) of Regulation (EC) No 1901/2006 as amended, Chemo Research, S.L. submitted for agreement to the European Medicines Agency on 26 November 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 3 January 2019.

Supplementary information was provided by the applicant on 23 April 2019. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 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	**Number of measures**	**Description**
Quality-related studies	Not applicable	Not applicable
Non-clinical studies	Not applicable	Not applicable
Clinical studies	2	**Study 1** Open-label, multiple dose, multicentre, uncontrolled trial to evaluate efficacy, pharmacokinetics, safety and tolerability of Levonorgestrel vaginal delivery system (LPRI-211) during 13 sequential cycles of 28 days in females from the age of menarche (Study LPRI-211/301)

		Study 2 Double-blind, randomised, multiple dose, multicentre trial to evaluate efficacy, safety and tolerability of Levonorgestrel vaginal delivery system (LPRI-211) compared to Desogestrel during 9 sequential cycles of 28 days in females from the age of menarche (Study LPRI-211/302)
Extrapolation, modelling and simulation studies	Not applicable	Not applicable
Other studies	Not applicable	Not applicable
Other measures	Not applicable	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 December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	No