EMA/27422/2020

European Medicines Agency decision

P/0036/2020

of 29 January 2020

on the acceptance of a modification of an agreed paediatric investigation plan for bupivacaine (EMEA-000877-PIP03-17-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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on the acceptance of a modification of an agreed paediatric investigation plan for bupivacaine (EMEA-000877-PIP03-17-M01) 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 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/0402/2018 issued on 7 December 2018,

Having regard to the application submitted by Pacira Ltd on 5 September 2019 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 11 December 2019, 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 bupivacaine, suspension for injection, perineural use, infiltration 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 Pacira Ltd, Wessex House, Marlow Road, SL8 5SP - Bourne End, United Kingdom.

EMA/PDCO/535469/2019
Amsterdam, 11 December 2019

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

EMEA-000877-PIP03-17-M01

Scope of the application

Active substance(s):

Bupivacaine

Condition(s):

Postsurgical analgesia

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Perineural use

Infiltration use

Name/corporate name of the PIP applicant:

Pacira Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pacira Ltd submitted to the European Medicines Agency on 5 September 2019 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/0402/2018 issued on 7 December 2018.

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

The procedure started on 15 October 2019.

Scope of the modification

Some measures and 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 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:

Postsurgical analgesia

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- suspension for injection, perineural and infiltration use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Postsurgical analgesia

2.1.1. Indication(s) targeted by the PIP

Local or regional analgesia when administered into the surgical site or as a nerve block in children from 1 to less than 18 years of age.

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	4	**Study 1 (402-C-319)** A multicentre study to evaluate the pharmacokinetics and safety of liposomal bupivacaine (hereinafter: Exparel) for postsurgical analgesia in paediatric subjects aged 6 to less than 17 years of age **Study 2 (402-C-WI2)** Multicentre, open-label, randomised, ropivacaine-controlled study to evaluate the pharmacokinetics, safety and efficacy of Exparel for postsurgical analgesia in

		paediatric subjects aged 1 to less than 6 years undergoing hernia repair surgeries (TAP block) (402-C-WI2) **Study 3 (402-C-NB1)** Multicentre, open-label, randomised, ropivacaine-controlled study to evaluate the safety and pharmacokinetics of Exparel when administered as a nerve block for surgical procedures like anterior cruciate ligament (ACL) repair, upper or lower extremity fractures in paediatric subjects aged 6 to less than 18 years **Study 4 (402-C-NB2)** Multicentre, open-label, randomised, ropivacaine-controlled study to evaluate the safety and pharmacokinetics of Exparel in paediatric subjects aged 1 to less than 6 years when administered as a nerve block for surgical procedures like repair of fractured femoral shaft (femoral block), hand or forearm surgery (axillary block), or inguinal hernia repair (ilio-inguinal block)
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 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes