MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100130-PIP01-21-M01

Scope of the Application

Active Substance(s)

BUPIVACAINE

Condition(s)

Postsurgical analgesia

Pharmaceutical Form(s)

Prolonged release dispersion for injection; Suspension for injection

Route(s) of Administration

Infiltration use, Perineural use

Name / Corporate name of the PIP applicant

Pacira Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pacira Ltd submitted to the licensing authority on 01/06/2021 15:16 BST an application for a Modification

The procedure started on 19/05/2022 14:44 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100130-PIP01-21-M01

Of 17/06/2022 14:24 BST

On the adopted decision for BUPIVACAINE (MHRA-100130-PIP01-21-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for BUPIVACAINE, Prolonged release dispersion for injection; Suspension for injection , Infiltration use, Perineural use .

This decision is addressed to Pacira Ltd, Wessex House, Marlow Road, Bourne End, United Kingdom, SL8 5SP

ANNEX I

1. Waiver

1.1 Condition:

Not Applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Postsurgical analgesia

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Prolonged release dispersion for injection; Suspension for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	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 from birth to less than 6 years undergoing hernia repair surgeries (TAP block) 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, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/01/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes