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-100168-PIP01-21-M01

Scope of the Application

Active Substance(s)

Naloxegol (as naloxegol oxalate)

Condition(s)

Treatment of opioid-induced constipation

Pharmaceutical Form(s)

Age appropriate liquid formulation; Film-coated tablet

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

Kyowa Kirin Pharmaceutical Development Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Kyowa Kirin Pharmaceutical Development Limited submitted to the licensing authority on 13/07/2021 13:54 BST an application for a Modification

The procedure started on 08/12/2021 14:50 GMT

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-100168-PIP01-21-M01

Of 13/12/2021 16:38 GMT

On the adopted decision for Naloxegol (as naloxegol oxalate) (MHRA-100168-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 Naloxegol (as naloxegol oxalate), Age appropriate liquid formulation; Film-coated tablet , Oral use .

This decision is addressed to Kyowa Kirin Pharmaceutical Development Limited, Galabank Business Park, Galashiels, United Kingdom, TD1 1QH

ANNEX I

1. Waiver

1.1 Condition:

Treatment of opioid-induced constipation The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Age appropriate liquid formulation; Film-coated tablet Route(s) of administration: Oral use Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of opioid-induced constipation

2.2 Indication(s) targeted by the PIP:

Treatment of opioid-induced constipation

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Age appropriate liquid formulation; Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral liquid formulation.
Non-Clinical Studies	2	Study 2 Pre- and postnatal development study in the rat Study 3 Rat juvenile toxicity study
Clinical Studies	1	Study 4 Open label, sequential, multiple oral dose, study to assess the PK and safety of naloxegol in paediatric patients receiving opioids (D3820C00016)
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:	31/10/2021
Deferral of one or more studies contained in the paediatric investigation plan:	Yes