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

MHRA-100108-PIP01-21-M01

Scope of the Application

Active Substance(s)

BRIVARACETAM

Condition(s)

Treatment of epilepsy with partial onset seizures.

Pharmaceutical Form(s)

Film-coated tablet, Oral solution, Solution for injection

Route(s) of Administration

Oral use; Intravenous use

Name / Corporate name of the PIP applicant

UCB Pharma Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, UCB Pharma Limited submitted to the licensing authority on 07/06/2021 22:38 BST an application for a Modification

The procedure started on 22/02/2022 19:40 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-100108-PIP01-21-M01

Of 30/03/2022 12:48 BST

On the adopted decision for BRIVARACETAM (MHRA-100108-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 BRIVARACETAM, Oral solution, Solution for injection, Film-coated tablet , Oral use, Parenteral use .

This decision is addressed to UCB Pharma Limited, 208 Bath Road, Slough, Slough, Berkshire, United Kingdom, SL1 3WE

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of epilepsy with partial onset seizures

2.2 Indication(s) targeted by the PIP:

Treatment of epilepsy with partial onset seizures

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):

Film-coated tablet; Oral solution; Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	3	(Same studies as in MHRA-100099-PIP01-21-M02 for condition: Treatment of paediatric epilepsy syndromes) Study 1 (NCD1671) Nine week oral toxicity study followed by a 30 day recovery period in juvenile rats. Study 2 (NCD1883) Study to evaluate brain weight in juvenile and adult Wistar rats. Study 3 (NCD1863) Nine month oral toxicity study in juvenile dogs with a 2 month recovery period.
Clinical Studies	3	Study 5 (N01263) (Same study as in MHRA-100099-PIP01-21-M02 for condition: Treatment of paediatric epilepsy syndromes) Open label single arm multicentre, pharmacokinetic, safety and efficacy study of adjunctive administration of brivaracetam in children aged 1 month to less than 16 years with refractory paediatric epilepsy syndromes or epilepsy. Study 7 (N01266) Open label, single arm, long term follow study of brivaracetam in children with epilepsy. Study 9 (N01349) deleted during procedure MHRA-100108-PIP01-21-M01 Study 10 Systematic review of the literature of all published trials focusing on the possibility of extrapolating efficacy from adult to paediatric patients with partial onset seizures.

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:	Yes
Date of completion of the paediatric investigation plan:	31/07/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes