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-100855-PIP01-23-M01

Scope of the Application

Active Substance(s)

DOPAMINE HYDROCHLORIDE

Condition(s)

Treatment of vascular hypotensive disorders

Pharmaceutical Form(s)

Solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

BrePco Biopharma Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, BrePco Biopharma Ltd submitted to the licensing authority on 25/01/2023 17:04 GMT an application for a Modification

The procedure started on 08/02/2023 18:11 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-100855-PIP01-23-M01

Of 28/02/2023 18:17 GMT

On the adopted decision for DOPAMINE HYDROCHLORIDE (MHRA-100855-PIP01-23-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

This decision applies to a Modification for DOPAMINE HYDROCHLORIDE, Solution for infusion , INTRAVENOUS USE .

This decision is addressed to BrePco Biopharma Ltd, Suite One, The Avenue Beacon Court, Sandyford, Dublin 18 , Dublin, IRELAND, D18HX31

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of vascular hypotensive disorders.

2.2 Indication(s) targeted by the PIP:

Treatment of hypotension in neonates including the extremely low gestational age newborn. Treatment of hypotension in infants and children.

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

All subsets of the paediatric population from birth to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Solution for infusion.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development solution for intravenous use, 1500 micrograms/ml and 4500 micrograms/ml.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 3 Double-blinded, randomised, multi-centre, placebo controlled trial to evaluate safety and efficacy of dopamine in neonates with a gestational age at birth less than 28 completed weeks.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	1	Study 2 A systematic literature review of dopamine for the treatment of vascular hypotensive disorders in Childhood
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:	30/04/2021
Deferral of one or more studies contained in the paediatric investigation plan:	Yes