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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-100150-PIP01-21

Scope of the Application

Active Substance(s)

AZITHROMYCIN

Condition(s)

Prevention of bronchopulmonary dysplasia (BPD)

Pharmaceutical Form(s)

Age appropriate dosage form for parenteral use.

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Aspire Pharma Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Aspire Pharma Limited submitted to the licensing authority on 09/07/2021 17:04 BST an application for a Paediatric Investigation Plan

The procedure started on 02/02/2022 16:24 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 agree a paediatric investigation plan and grant a waiver

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-100150-PIP01-21

Of 15/02/2022 16:10 GMT

On the adopted decision for AZITHROMYCIN (MHRA-100150-PIP01-21) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for AZITHROMYCIN, Age appropriate dosage form for parenteral use. , Intravenous use .

This decision is addressed to Aspire Pharma Limited, 4 Rotherbrook Court, Bedford Road, Petersfield, United Kingdom, GU32 3QG

ANNEX I

1. Waiver

1.1 Condition:

Prevention of bronchopulmonary dysplasia (BPD) The waiver applies / applied to: Paediatric Subset(s): Preterm infants born at 30 weeks' gestation or older; The paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Age appropriate dosage form for parenteral use. Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of bronchopulmonary dysplasia (BPD)

2.2 Indication(s) targeted by the PIP:

Prevention of BPD in preterm neonates less than 30 weeks gestational age

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

Preterm neonates born prior to 30 weeks gestation

2.4 Pharmaceutical Form(s):

Age appropriate dosage form for parenteral use.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate dosage form for parenteral use
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 (AZTEC) Double-blind placebo-controlled study to assess the efficacy of azithromycin in terms of superiority over placebo in the prevention of bronchopulmonary dysplasia in preterm neonates born prior to gestational week 30. Study 3 (AZTEC at1) Follow-up study to assess long-term efficacy of azithromycin in the prevention of bronchopulmonary dysplasia in former preterm neonates after 1 year.
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:	29/02/2024
Deferral of one or more studies contained in the paediatric investigation plan:	No