



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/464763/2021

European Medicines Agency decision P/0381/2021

of 8 September 2021

on the agreement of a paediatric investigation plan and on the granting of a waiver for azithromycin (EMA-003021-PIP01-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.



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on the agreement of a paediatric investigation plan and on the granting of a waiver for azithromycin (EMA-003021-PIP01-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by Aspire Pharma Limited on 19 April 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 July 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for azithromycin, age-appropriate dosage form for parenteral use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for azithromycin, age-appropriate dosage form for parenteral use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/357778/2021
Amsterdam, 23 July 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMA-003021-PIP01-21

Scope of the application

Active substance(s):

Azithromycin

Condition(s):

Prevention of bronchopulmonary dysplasia

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 opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Aspire Pharma Limited submitted for agreement to the European Medicines Agency on 19 April 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 25 May 2021.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:



- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Prevention of bronchopulmonary dysplasia

The waiver applies to:

- Preterm neonates born at gestational week 30 or later, and the paediatric population from birth at term to less than 18 years of age;
- age-appropriate dosage form for parenteral use, intravenous use;
- 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:

Prevention of bronchopulmonary dysplasia (BPD)

2.1.1. Indication(s) targeted by the PIP

Prevention of BPD in preterm neonates <30 weeks gestational age.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

Neonates born prior to 30 weeks of gestational age.

2.1.3. Pharmaceutical form(s)

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	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.

Area	Number of measures	Description
		Study 3 (AZTEC@1) Follow-up study to assess long-term efficacy of azithromycin in the prevention of bronchopulmonary dysplasia in former preterm neonates after 1 year.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No