EMA/430122/2020

European Medicines Agency decision

P/0358/2020

of 9 September 2020

on the acceptance of a modification of an agreed paediatric investigation plan for hydrocortisone (hemisuccinate) (EMEA-002305-PIP01-17-M01) 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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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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0407/2019 issued on 4 December 2019,

Having regard to the application submitted by Laboratoire Aguettant on 16 April 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 July 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for hydrocortisone (hemisuccinate), powder and solvent for solution for injection, intravenous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Laboratoire Aguettant, 1 rue Alexander Fleming, 69007 – Lyon, France.

EMA/PDCO/249825/2020
Amsterdam, 24 July 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002305-PIP01-17-M01

Scope of the application

Active substance(s):

Hydrocortisone (hemisuccinate)

Condition(s):

Prevention of bronchopulmonary dysplasia

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Laboratoire Aguettant

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Laboratoire Aguettant submitted to the European Medicines Agency on 16 April 2020 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0407/2019 issued on 4 December 2019.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 26 May 2020.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 (BPD)

The waiver applies to:

- preterm newborn infants from 28+0 to less than 37+0 weeks gestational age (GA)
- powder and solvent for solution for injection; intravenous use;
- on the grounds that the specific medicinal product is likely to be ineffective;

and

- term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months), children (from 2 to less than 12 years of age) and adolescents (from 12 to less than 18 years of age);
- powder and solvent for solution for injection, 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

2.1.1. Indication(s) targeted by the PIP

Prophylactic use in preterm infants born at or less than 28 weeks of gestation to prevent bronchopulmonary dysplasia (BPD)

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

Preterm infants less than 28+0 weeks gestational age

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a powder and solvent for solution for injection of hydrocortisone hemisuccinate with a strength of 1 mg/ml with a reconstitution set
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 2** Double blinded, randomised, placebo controlled parallel group clinical trial to evaluate safety and efficacy of hydrocortisone hemisuccinate to prevent bronchopulmonary dysplasia (BPD) in preterm neonates from 24+0 to less than 28+0 weeks gestational age (GA). (PREMILOC study; EudraCT: 2007-002041-20)
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:	Yes
Date of completion of the paediatric investigation plan:	By November 2020
Deferral for one or more measures contained in the paediatric investigation plan:	No