EMA/607436/2019

European Medicines Agency decision

P/0407/2019

of 4 December 2019

on the agreement of a paediatric investigation plan and on the granting of a waiver for hydrocortisone (hemisuccinate) (EMEA-002305-PIP01-17) 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.

European Medicines Agency decision

P/0407/2019

of 4 December 2019

on the agreement of a paediatric investigation plan and on the granting of a waiver for hydrocortisone (hemisuccinate) (EMEA-002305-PIP01-17) 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 726/2004[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 application submitted by Laboratoire Aguettant on 23 October 2018 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 18 October 2019, 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 hydrocortisone (hemisuccinate), powder and solvent for solution for injection, 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 hydrocortisone (hemisuccinate), powder and solvent for solution for injection, 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 Laboratoire Aguettant, 1 rue Alexander Fleming, 69007 – Lyon, France.

EMA/PDCO/413685/2019
Amsterdam, 18 October 2019

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

EMEA-002305-PIP01-17

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 16(1) of Regulation (EC) No 1901/2006 as amended, Laboratoire Aguettant submitted for agreement to the European Medicines Agency on 23 October 2018 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 4 December 2018.

Supplementary information was provided by the applicant on 1 July 2019. The applicant proposed modifications to the paediatric investigation plan.

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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population and 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 (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 February 2020
Deferral for one or more measures contained in the paediatric investigation plan:	No