EMA/797364/2017

European Medicines Agency decision

P/0389/2017

of 19 December 2017

on the acceptance of a modification of an agreed paediatric investigation plan for human coagulation factor X (Coagadex), (EMEA-000971-PIP01-10-M03) 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/57/2011 issued on 4 March 2011, decision P/0017/2014 issued on 22 January 2014 and decision P/0188/2014 issued on 6 August 2014,

Having regard to the application submitted by Bio Products Laboratory Limited on 17 August 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 November 2017, 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 human coagulation factor X (Coagadex), powder 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 Bio Products Laboratory Limited, Dagger Lane, WD6 3BX - Elstree, Hertfordshire, United Kingdom.

EMA/PDCO/571259/2017
London, 10 November 2017

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

EMEA-000971-PIP01-10-M03

Scope of the application

Active substance(s):

Human coagulation factor X

Invented name:

Coagadex

Condition(s):

Treatment of hereditary factor X deficiency

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Bio Products Laboratory Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bio Products Laboratory Limited submitted to the European Medicines Agency on 17 August 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/57/2011 issued on 4 March 2011, decision P/0017/2014 issued on 22 January 2014 and decision P/0188/2014 issued on 6 August 2014.

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

The procedure started on 12 September 2017.

Scope of the modification

Some measures 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 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 annexes 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)

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

Not applicable

2. Paediatric Investigation Plan

2.1. Condition: Treatment of hereditary factor X deficiency

2.1.1. Indication(s) targeted by the PIP

Treatment of hereditary factor X deficiency

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	3	**Study 1** Open-label, multicentre, non-controlled trial to evaluate the pharmacokinetics, efficacy and safety of Human coagulation factor X in the treatment of bleeding episodes over at least 6 months, in children from 12 to less than 18 years of age (and in adults) with moderate to severe hereditary factor X deficiency **Study 2** Open-label, multicentre, non-controlled trial to evaluate the efficacy, safety and pharmacokinetics of Human coagulation factor X in the prevention of bleeding when given as routine prophylaxis over 6 months, in children from birth to less than 12 years of age with severe or moderate hereditary factor X deficiency **Study 3** Open-label, multicentre, non-controlled trial to evaluate safety and efficacy of Human coagulation factor X administered by bolus infusion to prevent bleeding and achieve haemostasis in factor X deficient subjects undergoing surgery, in children from 12 to less than 18 years of age (and in adults) with mild to severe hereditary factor X deficiency

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of hereditary factor X deficiency

Authorised indication(s):

- Treatment and prophylaxis of bleeding episodes and for peri-operative management in patients with hereditary factor X deficiency

Authorised pharmaceutical form(s):

Powder and solvent for solution for injection

Authorised route(s) of administration:

Intravenous use