

EMA/78582/2011

European Medicines Agency decision

P/57/2011

of 4 March 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral for human coagulation factor X (EMA-000971-PIP01-10) 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 deferral for human coagulation factor X (EMA-000971-PIP01-10) 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 Bio Products Laboratory on 30 April 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 January 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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 deferral.
- (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 deferral.

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 human coagulation factor X, powder 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 deferral for human coagulation factor X, powder 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 Bio Products Laboratory, Dagger Lane, Elstree, Hertfordshire WD6 3BX, United-Kingdom.

Done at London, 4 March 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/755012/2010

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

EMA-000971-PIP01-10

Scope of the application

Active substance(s):

Human coagulation factor X

Condition(s):

Treatment of hereditary factor X deficiency

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Bio Products Laboratory

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bio Products Laboratory submitted for agreement to the European Medicines Agency on 30 April 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 10 June 2010.

Supplementary information was provided by the applicant on 8 November 2010.

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 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation.

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 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(es) and appendix.

London, 14 January 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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 12 months, in children from birth to less than 12 years of age with severe 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

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes