EMA/58038/2011

European Medicines Agency decision

P/32/2011

of 28 January 2011

on the acceptance of a modification of an agreed paediatric investigation plan for C1 inhibitor (EMEA-000568-PIP01-09-M02) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the acceptance of a modification of an agreed paediatric investigation plan for C1 inhibitor (EMEA-000568-PIP01-09-M02) 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 European Medicines Agency's decision P/193/2009 issued on 2 October 2009 and the decision P/114/2010 issued on 7 July 2010,

Having regard to the application submitted by ViroPharma SPRL on 8 November 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 December 2010, 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 C1 inhibitor, 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 ViroPharma SPRL (UK Branch), Chatsworth House, 29 Broadway, Maidenhead SL6 1LY, United-Kingdom.

Done at London, 28 January 2011

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

EMEA/PDCO/778444/2010

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

EMEA-000568-PIP01-09-M02

Scope of the application

Active substance(s):

C1 inhibitor

Condition(s):

C1 inhibitor deficiency

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

ViroPharma SPRL

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ViroPharma SPRL submitted to the European Medicines Agency on 08 November 2010 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/193/2009 issued on 02 October 2009 and the decision P/114/2010 issued on 07 July 2010.

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

The procedure started on 18 November 2010.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 Icelandic and the Norwegian Paediatric Committee member(s) agree 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(es) and appendix.

London, 10 December 2010

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

1.1. Condition: C1 inhibitor deficiency

The waiver applies to:

- Children from birth to less than 24 months (for treatment of acute attacks), children from birth to less than 6 years (for chronic prophylaxis of acute attacks);
- for powder for solution for injection for intravenous use of C1 inhibitor identified as “Cinryze”;
- 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: C1 inhibitor deficiency

2.1.1. Indication(s) targeted by the PIP

Treatment of acute attacks in children from 2 to less than 18 years with C1 inhibitor deficiency.

Prevention of angioedema attacks in children from 6 to less than 18 years with C1 inhibitor deficiency with severe or frequent attacks and in whom antifibrinolytics and/or attenuated androgens are ineffective or not indicated.

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

From 2 to less than 18 years.

2.1.3. Pharmaceutical form(s)

Powder for solution for infusion for intravenous use 500 U.

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	4	Study 1 Open-label multicentre acute treatment trial to evaluate safety and efficacy of C1 inhibitor in children and adults as a therapeutic agent for repeated use to treat acute hereditary angioedema attacks. Study 2 Open-label multicentre acute treatment and chronic prophylaxis trial to evaluate safety and efficacy of C1 inhibitor in children and adults as a therapeutic agent for prevention of hereditary angioedema attacks and to treat acute hereditary angioedema attacks. Study 3

		Open label dose-response trial to evaluate the response and pharmacokinetics/pharmacodynamics of C1 inhibitor for treatment of acute attacks in children less than 12 years old with hereditary angioedema. Study 4 Open label dose escalation prophylaxis trial to assess safety, tolerability and immunogenicity of C1 inhibitor in adults and children age 6 years and older with hereditary angioedema.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues , efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2013
Deferral for some or all studies contained in the paediatric investigation plan:	Yes