European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 7 April 2010

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for semuloparin sodium (EMEA-000562-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@ema.europa.eu http://www.ema.europa.eu

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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 as amended 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 Sanofi-aventis Recherche & Développement on 27 March 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 February 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

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 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 deferral.

(4) 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 semuloparin sodium, solution for injection, subcutaneous 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 semuloparin sodium, solution for injection, subcutaneous 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

A waiver for semuloparin sodium, solution for injection, subcutaneous 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 4

This decision is addressed to Sanofi-aventis Recherche & Développement, 1, avenue Pierre Brossolette, 91385, Chilly-Mazarin, France.

Done at London, 7 April 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

19 February 2010
EMA/PDCO/74544/2010

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

EMEA-000562-PIP01-09

Scope of the application

Active substance(s):

Semuloparin sodium

Condition(s):

Thromboembolic events

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Sanofi-aventis Recherche & Développement

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi-aventis Recherche & Développement submitted for agreement to the European Medicines Agency on 27 March 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 30 April 2009.

Supplementary information was provided by the applicant on 7 December 2009.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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,
   - 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 Articles 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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 19 February 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Thromboembolic events

2. Waiver

1.1 Condition

Prophylaxis of venous thromboembolism (VTE) in patients undergoing knee replacement surgery, hip replacement surgery or hip fracture surgery including extended prophylaxis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- for Solution for injection for subcutaneous 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).

1.2 Condition

Prophylaxis of venous thromboembolism (VTE) in patients undergoing abdominal surgery who are at risk for thromboembolic complications

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- for Solution for injection for subcutaneous 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).

1.3 Condition

Prophylaxis of venous thromboembolism (VTE) in cancer patients undergoing chemotherapy

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- for Solution for injection for subcutaneous 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).

3. Paediatric Investigation Plan

1.4 Condition to be investigated

Thromboembolic events

1.5 Indication targeted by the pip

Prophylaxis of thromboembolism (TE) in pediatric patients with Central Venous Line and additional pro-thrombotic risk factors

1.6 Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

1.7 Pharmaceutical form(s)

Solution for injection

1.8 Studies

Area	**Number of studies**	**Description**
Quality	Total number of quality studies: 1	Study 1: Development of an age-appropriate formulation
Non-clinical	Total number of studies: 0	Not applicable.
Clinical	Total number of studies: 3	Study 2: In vitro assessment of the concentration/activity relationship of semuloparin in paediatric patients from birth to less than 18 years of age. Study 3: open-label, multicentre, multiple dose trial to evaluate pharmacokinetics and safety in hospitalised children from birth to less than 18 years of age with a Central Venous Line (CVL). Study 4: open-label, randomised multicentre trial to evaluate safety and efficacy in children from birth to less than 18 years of age with with a Central

Area	Number of studies	Description
		Venous Line (CVL) and additional prothrombotic risk factors.

4. Follow-up, completion and deferral of pip

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	By April 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes