EMA/968339/2011

European Medicines Agency decision

P/0012/2012

of 24 January 2012

on the agreement of a paediatric investigation plan and on the granting of a waiver for recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein (EMEA-001156-PIP01-11) 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 application submitted by Statens Serum Institut on 8 April 2011 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 9 December 2011, in accordance with Article 18 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 recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein, solution for injection, intradermal 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 recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein, solution for injection, intradermal 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 Statens Serum Institut, Artillerivej 5, 2300 - Copenhagen S, Denmark.

Done at London, 24 January 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/849486/2011

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

EMEA-001156-PIP01-11

Scope of the application

Active substance(s):

Recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein

Condition(s):

Diagnosis of tuberculosis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intradermal use

Name/corporate name of the PIP applicant:

Statens Serum Institut

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Statens Serum Institut submitted for agreement to the European Medicines Agency on 8 April 2011 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 18 May 2011.

Supplementary information was provided by the applicant on 3 October 2011. The applicant proposed modifications to the paediatric investigation plan.

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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 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.

   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(es) and appendix.

London, 9 December 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

1.1. Condition: Diagnosis of tuberculosis

The waiver applies to:

- The paediatric population from birth to less than 28 days of age;
- for solution for injection, intradermal use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition: Diagnosis of tuberculosis

2.1.1. Indication(s) targeted by the PIP

Diagnosis of patients suspected to be infected with Mycobacterium tuberculosis from 28 days of age.

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

From 28 days to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	**Study 1** Double blind, randomised, multicentre, single dose, active-controlled trial to evaluate the diagnostic outcome of Recombinant dimer of 6 kD early secretory antigenic target / Recombinant 10 kD culture filtrate protein compared to QuantiFERON-TB Gold In-Tube and Tuberculin PPD tests in children from 28 days to less than 18 years of age, suspected to have tuberculosis. **Study 2** Double blind, randomised, multicentre, single dose, active-controlled contact tracing trial to evaluate the diagnostic outcome of Recombinant dimer of 6 kD early secretory antigenic target / Recombinant 10 kD culture filtrate protein compared to QuantiFERON-TB Gold In-Tube and Tuberculin PPD tests in

Area	Number of studies	Description
		children from 6 weeks to less than 18 years of age, suspected to have tuberculosis.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By November 2013
Deferral for one or more studies contained in the paediatric investigation plan:	No