EMA/399717/2016

European Medicines Agency decision

P/0188/2016

of 15 July 2016

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein (EMEA-001156-PIP01-11-M07) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

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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/0012/2012 issued on 24 January 2012, the decision P/0094/2013 issued on 29 April 2013, the decision P/0171/2014 issued on 10 July 2014, and the decision P/0068/2016 issued on 18 March 2016,

Having regard to the application submitted by Statens Serum Institut on 25 February 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 May 2016, 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 recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein, solution for injection, intradermal 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 Statens Serum Institut, Artillerivej 5, 2300 - Copenhagen S, Denmark.

Done at London, 15 July 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/173052/2016
London, 27 May 2016

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

EMEA-001156-PIP01-11-M07

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 22 of Regulation (EC) No 1901/2006 as amended, Statens Serum Institut submitted to the European Medicines Agency on 25 February 2016 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0012/2012 issued on 24 January 2012, the decision P/0094/2013 issued on 29 April 2013, the decision P/0171/2014 issued on 10 July 2014, and the decision P/0068/2016 issued on 18 March 2016.

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

The procedure started on 29 March 2016.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

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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 Norwegian Paediatric Committee member agrees 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 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)

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. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	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 in relation to age 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 children from 6 weeks to less than 18 years of age, suspected to have tuberculosis.
Extrapolation, modelling & simulation studies	1	**Study 3** Analysis of existing data on the diagnostic performance of C-Tb in the paediatric population with or without *M. tuberculosis* infection.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

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 May 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No