EMA/501874/2008

European Medicines Agency decision

P/0303/2016

of 4 November 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) (EMEA-001894-PIP01-15) 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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An agency of the European Union

European Medicines Agency decision

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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 Seqirus GmbH on 21 December 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 September 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation 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 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 influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage), prevention of influenza infection, intramuscular 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 influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage), prevention of influenza infection, intramuscular 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 influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage)/ influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage), prevention of influenza infection, intramuscular 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 NDA Regulatory Service GmbH, Neumarkter Straße 18, 81673 - Munich Germany.

EMA/PDCO/481414/2016 corr
London, 16 September 2016

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

EMEA-001894-PIP01-15

Scope of the application

Active substance(s):

Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)/ Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)/ Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage)/ Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage)

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Seqirus GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, NDA Regulatory Service GmbH submitted for agreement to the European Medicines Agency on 21 December 2015 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 2 February 2016.

Supplementary information was provided by the applicant on 23 June 2016. The applicant proposed modifications to the paediatric investigation plan.

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 Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 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:

Prevention of influenza infection

The waiver applies to:

- the paediatric population from birth to less than 6 months;
- suspension for injection, intramuscular use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of influenza infection

2.1.1. Indication(s) targeted by the PIP

Prophylaxis of influenza in children from 6 months to less than 18 years of age.

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 1** Randomised, observer- blind, multicentre, active controlled study to evaluate immunogenicity, safety and tolerability of Seqirus quadrivalent influenza vaccine compared to an active quadrivalent influenza vaccine in children from 5 to less than 18 years of age (CSLCT-QIV-13-02)

		Study 2 Randomised, observer- blind, multicentre, active controlled study to evaluate immunogenicity, safety and tolerability of Seqirus quadrivalent influenza vaccine compared to an active quadrivalent influenza vaccine in children from 6 months to less than 5 years of age.(CSLCT-QIV-15-03) **Study 3** Randomised, observer- blind, multicentre, active controlled study to evaluate the efficacy, immunogenicity, safety and tolerability of Seqirus quadrivalent influenza vaccine compared to a non-influenza vaccine in children from 6 months to less than 3 years of age (CSLCT-QIV-15-04).
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By July 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes