EMA/194390/2022

European Medicines Agency decision

P/0144/2022

of 13 April 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral for influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 (EMEA-002869-PIP01-21) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Seqirus Netherlands B.V. on 7 July 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 February 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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.

(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.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1, suspension for injection, 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/H5N1, suspension for injection, 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

This decision is addressed to Seqirus Netherlands B.V., Paasheuvelweg 28, 1105 BJ – Amsterdam, The Netherlands.

EMA/PDCO/432286/2021 Corr
Amsterdam, 25 February 2022

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

EMEA-002869-PIP01-21

Scope of the application

Active substance(s):

Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1

Condition(s):

Prevention of pandemic influenza

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Seqirus Netherlands B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Seqirus Netherlands B.V. submitted for agreement to the European Medicines Agency on 7 July 2021 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 17 August 2021.

Supplementary information was provided by the applicant on 19 November 2021. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Prevention of pandemic influenza

2.1.1. Indication(s) targeted by the PIP

Prevention of pandemic influenza

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1 (V89_11)** Randomised, observer-blind study to evaluate safety, tolerability and immunogenicity of 2 different dosages of influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 (aH5N1c) in paediatric subjects from 6 months to less than 18 years of age. **Study 2** Randomised, observer-blind, multi-centre study to evaluate safety and immunogenicity of 2 dosage levels of MF59-adjuvanted A/H5 pandemic vaccine in paediatric subjects from 6 months to less than 9 years of age. **Study 3** Two stage, randomised, observer-blind study to evaluate safety and immunogenicity of four different dosages of MF59-adjuvanted A/Hx pandemic vaccine in children from 6 months to less than 9 years of age.

	Study 4 Open-label, multicentre study to evaluate the immunogenicity and safety of a 2-dose series of MF59 adjuvanted, A/H5 or A/Hx vaccine in healthy infants below 6 months of age.
Extrapolation, modelling and simulation studies	Not applicable.
Other studies	Not applicable.
Other measures	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	Not later than 24 months after the declaration by the WHO of an influenza A/H5 or A/Hx virus pandemic.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.