EMA/152188/2018

European Medicines Agency decision

P/0118/2018

of 11 April 2018

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 H1 haemagglutinin / influenza virus H3 haemagglutinin /influenza virus haemagglutinin from strain B Victoria lineage / influenza virus haemagglutinin from strain B Yamagata lineage (expressed as virus-like particle [VLP]) (EMEA-002220-PIP01-17) 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 Medicago Inc. on 10 July 2017 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 23 February 2018, in accordance with Article 17 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 H1 haemagglutinin / influenza virus H3 haemagglutinin /influenza virus haemagglutinin from strain B Victoria lineage / influenza virus haemagglutinin from strain B Yamagata lineage (expressed as virus-like particle [VLP]), solution 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 H1 haemagglutinin / influenza virus H3 haemagglutinin /influenza virus haemagglutinin from strain B Victoria lineage / influenza virus haemagglutinin from strain B Yamagata lineage (expressed as virus-like particle [VLP]), solution 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

A waiver for influenza virus H1 haemagglutinin / influenza virus H3 haemagglutinin /influenza virus haemagglutinin from strain B Victoria lineage / influenza virus haemagglutinin from strain B Yamagata lineage (expressed as virus-like particle [VLP]), solution 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 4

This decision is addressed to Medicago Inc., 1020 Route de L'Église, bureau 600, G1V3V9 – Québec, Canada.

EMA/PDCO/846007/2017
London, 23 February 2018

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

EMEA-002220-PIP01-17

Scope of the application

Active substance(s):

Influenza virus H1 haemagglutinin / influenza virus H3 haemagglutinin /influenza virus haemagglutinin from strain B Victoria lineage / influenza virus haemagglutinin from strain B Yamagata lineage (expressed as virus-like particle [VLP])

Condition(s):

Prevention of influenza

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Medicago Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Medicago Inc. submitted for agreement to the European Medicines Agency on 10 July 2017 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 3 January 2017.

Supplementary information was provided by the applicant on 11 December 2017. 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 17(1) 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

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- solution 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

2.1.1. Indication(s) targeted by the PIP

Prevention of influenza

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)

Solution 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** Open-label, uncontrolled trial to evaluate safety and immunogenicity of influenza virus H1 haemagglutinin / influenza virus H3 haemagglutinin /influenza virus haemagglutinin from strain B Victoria lineage / influenza virus haemagglutinin from strain B Yamagata lineage (expressed as virus-like particle [VLP]) *(hereafter referred to as quadrivalent VLP influenza vaccine)* in healthy children and adolescents from 7 to less than 18 years of age (PedQVLP-001).

		Study 2 Open-label, randomised trial to evaluate safety and immunogenicity of 2 different doses of quadrivalent VLP influenza vaccine in healthy children and adolescents from 6 months to less than 7 years of age (PedQVLP-002). **Study 3** Observer-blind, randomised, active-controlled trial to evaluate efficacy, safety and immunogenicity of quadrivalent VLP influenza vaccine compared to an authorised influenza vaccine in healthy children from 6 to less than 36 months of age (Ped-QVLP-003).
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:	No
Date of completion of the paediatric investigation plan:	By December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes