EMA/17336/2021

European Medicines Agency decision

P/0010/2021

of 18 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage) (EMEA-002359-PIP01-18-M02) 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 European Medicines Agency's decision P/0023/2019 issued on 4 January 2019 and the decision P/0064/2020 issued on 20 February 2020,

Having regard to the application submitted by Sanofi Pasteur on 8 September 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2020, 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 split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage), solution for injection, intramuscular 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 Sanofi Pasteur, 14 Espace Henry Vallée, 69007 - Lyon, France.

EMA/PDCO/523571/2020
Amsterdam, 11 December 2020

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

EMEA-002359-PIP01-18-M02

Scope of the application

Active substance(s):

Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage)

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi Pasteur

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted to the European Medicines Agency on 8 September 2020 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0023/2019 issued on 4 January 2019 and the decision P/0064/2020 issued on 20 February 2020.

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

The procedure started on 13 October 2020

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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:

Prevention of influenza infection

The waiver applies to:

- the paediatric population from birth to less than 6 months of age and the immunocompetent paediatric population from 9 to less than 18 years of age;
- solution for injection; intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

2. Paediatric investigation plan

2.1. Condition:

Prevention of influenza infection

2.1.1. Indication(s) targeted by the PIP

Prevention of influenza infection

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

From 6 months to less than 9 years of age and only the immunocompromised paediatric population from 9 years 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	5	**Study 1 (QHD04)** Dose-finding, randomized, modified double-blind, active-controlled trial to evaluate safety and immunogenicity of 3 different doses of Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata

Area	Number of measures	Description
		lineage) (from here defined as : Quadrivalent influenza vaccine- high dose: QIV-HD) versus an unadjuvanted QIV-standard dose (QIV-SD) in healthy children from 6 months to less than 9 years of age and an adjuvanted TIV-SD in a subset of healthy children from 6 to less than 24 months **Study 2 (QHD00014)** Randomized, modified double blind, active-controlled trial to demonstrate the superior clinical efficacy and immunogenicity of 1 or 2 doses of QIV-HD compared to standard-dose QIV (QIV-SD), and to describe the safety profile of QIV-HD in healthy children from 6 months to less than 3 years of age **Study 3 (QHD00015)** Randomized, modified double blind, active controlled trial to demonstrate superior immunogenicity of QIV-HD compared to standard-dose QIV (QIV-SD) in healthy children from 3 to less than 5 years of age **Study 4 (QHD00020)** Randomized, modified double blind, active controlled trial to demonstrate superior immunogenicity of QIV-HD compared to QIV-SD in healthy children from 5 to less than 9 years of age **Study 5 (QHD00022)** Randomized, blinding to be determined, active-controlled trial to evaluate immunogenicity and safety of QIV-HD versus QIV-SD in immunocompromised children and adolescents from 6 months to less than 18 years of age
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 June 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes