

EMA/619853/2015

European Medicines Agency decision

P/0249/2015

of 30 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain (EMEA-001254-PIP01-11-M01) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0203/2012 issued on 31 August 2012,

Having regard to the application submitted by Sanofi Pasteur, Sanofi Pasteur MSD on 19 June 2015 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 September 2015, 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 and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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 B-like strain (B/Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain, suspension for injection, subcutaneous use, intramuscular use, including changes to the deferral 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 (SP), 2 avenue Pont Pasteur, 69007 – Lyon, France and Sanofi Pasteur MSD, 162 avenue Jean Jaurès, 69007 – Lyon, France.

Done at London, 30 October 2015

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

EMA/PDCO/443297/2015

London, 11 September 2015

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001254-PIP01-11-M01

Scope of the application

Active substance(s):

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

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Subcutaneous use

Intramuscular use

Name / corporate name of the PIP applicant:

Sanofi Pasteur, Sanofi Pasteur MSD

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur, Sanofi Pasteur MSD submitted to the European Medicines Agency on 19 June 2015 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/0203/2012 issued on 31 August 2012.

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

The procedure started on 14 July 2015.

Scope of the modification

Some measures and timelines 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 and to the deferral 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:

- Infants from birth to less than 6 months;
 - for suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition:

Prevention of influenza infection

2.1.1. Indication(s) targeted by the PIP

Active immunisation against influenza infection

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: Randomized, double-blind (for Quadrivalent Influenza Vaccine [QIV] lots), open (for QIV or Trivalent Influenza Vaccine [TIV]), controlled, 4-arm trial to assess safety, immunogenicity, and lot consistency Study 2: Randomized, observer-blind (except for TIV groups), controlled, 4-arm trial to assess efficacy of QIV

Area	Number of measures	Description
		Study 3: Randomized, double-blind, active-controlled, 3-arm trial to assess immunogenicity of QIV as compared to TIV
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 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes