EMA/895159/2018

European Medicines Agency decision

P/0022/2019

of 4 January 2019

on the acceptance of a modification of an agreed paediatric investigation plan for split influenza virus, inactivated containing antigen equivalent to A/California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)),adjuvanted HUMENZA (INN: Pandemic Influenza vaccine (H1N1) (split virion, inactivated))(EMEA-000669-PIP01-09-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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0022/2019

of 4 January 2019

on the acceptance of a modification of an agreed paediatric investigation plan for split influenza virus, inactivated containing antigen equivalent to A/California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)),adjuvanted HUMENZA (INN: Pandemic Influenza vaccine (H1N1) (split virion, inactivated))(EMEA-000669-PIP01-09-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/196/2009 issued on 7 October 2009, and the decision P/36/2010 issued on 18 March 2010,

Having regard to the application submitted by Sanofi Pasteur SA on 7 September 2018 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 14 December 2018, 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 antigen equivalent to A/California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)),adjuvanted(HUMENZA (INN: Pandemic Influenza vaccine (H1N1) (split virion, inactivated)), suspension for injection, emulsion for injection, 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 SA, 14 Espace Henry Vallée, 69007 - Lyon, France.

EMA/PDCO/645220/2018 Corr
London, 14 December 2018

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

EMEA-000669-PIP01-09-M02

Scope of the application

Active substance(s):

Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)),adjuvanted

Invented name:

HUMENZA (INN: Pandemic Influenza vaccine (H1N1) (split virion, inactivated))

Condition(s):

Prevention of influenza

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection and emulsion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi Pasteur SA

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur SA submitted to the European Medicines Agency on 7 September 2018 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/196/2009 issued on 7 October 2009, and the decision P/36/2010 issued on 18 March 2010.

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

The procedure started on 16 October 2018.

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 annexes 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:

- children from birth to less than 2 months;
- suspension and emulsion for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective.

And:

- children from 2 months to less than 6 months;
- suspension and emulsion 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 to be investigated

Prevention of influenza

2.1.1. Indication targeted by the pip

Prevention of infection by pandemic influenza virus (H1N1 strain) in the context of a pandemic

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

From 6 months to less than 18 years.

2.1.3. Pharmaceutical form(s)

Suspension and emulsion for injection, 3.8 and 7.5 µg of haemagglutinin (HA)

2.1.4. Measures

Area	Number of studies	Description
Quality	1	Suspension and emulsion for injection
Non-clinical		Not applicable.
Clinical	2	• Immunogenicity and Safety Study of Multiple Formulations of an Intramuscular Inactivated, Split Virion Swine-Origin A/H1N1 Influenza Vaccine With and Without Adjuvant in Healthy Children and Adolescents Aged 3 to 17 Years (GPF08)

		• Immunogenicity and Safety Study of Multiple Formulations of an Intramuscular Inactivated, Split Virion Swine-Origin A/H1N1 Influenza Vaccine With and Without Adjuvant in Healthy Infants and Toddlers Aged 6 to 35 Months (GPF09)

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2011
Deferral for some or all studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s): (withdrawn in 2011)

1. Prevention of influenza

Authorised indication(s):

- Prevention of infection by pandemic influenza virus (H1N1 strain) in the context of a pandemic

Authorised pharmaceutical form(s):

Suspension for injection

Authorised route(s) of administration:

Intramuscular use

Withdrawal of Marketing Authorization

On 8 June 2010 the European Commission issued a conditional marketing authorisation valid throughout the European Union for the medicinal product Humenza (pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), which had been approved for prophylaxis of influenza in an officially declared pandemic situation. The marketing authorisation holder (MAH) responsible for Humenza was Sanofi Pasteur S.A.

The European Commission was notified by a letter dated 5 May 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation for commercial reasons. Humenza was not marketed in any EU country.

On 14 June 2011 the European Commission issued a decision to withdraw the marketing authorisation for Humenza.