EMA/444271/2019

European Medicines Agency decision

P/0299/2019

of 14 August 2019

on the acceptance of a modification of an agreed paediatric investigation plan for purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) like strain used (NIBRG-14) purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) like strain used (PR8-IBCDC-RG2) (Adjupanrix/ Prepandrix), (EMEA-000160-PIP01-07-M05) 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/80/2009 issued on 24 April 2009, the decision P/47/2011 issued on 4 March 2011, the decision P/0152/2012 issued on 25 July 2012, the decision P/0262/2013 issued on 30 October 2013 and the decision P/0087/2015 issued on 8 May 2015,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 11 April 2019 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 28 June 2019, 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 purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) like strain used (NIBRG-14) purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) like strain used (PR8-IBCDC-RG2) (Adjupanrix/ Prepandrix), emulsion and suspension for 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 GlaxoSmithKline Biologicals SA, Rue de l'Institut, 89, 1330 – Rixensart, Belgium.

EMA/PDCO/258666/2019
Amsterdam, 26 July 2019

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

EMEA-000160-PIP01-07-M05

Scope of the application

Active substance(s):

Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) like strain used (NIBRG-14)

Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) like strain used (PR8-IBCDC-RG2)

Invented name:

Adjupanrix

Prepandrix

Condition(s):

Prevention of influenza infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Emulsion and suspension for emulsion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals S.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals S.A. submitted to the European Medicines Agency on 11 April 2019 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/80/2009 issued on 24 April 2009, the decision P/47/2011 issued on 4 March 2011, the decision P/0152/2012 issued on 25 July 2012, the decision P/0262/2013 issued on 30 October 2013 and the decision P/0087/2015 issued on 8 May 2015.

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

The procedure started on 28 May 2019.

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 infection

The waiver applies to:

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

and to

- infants from 2 to less than 6 months;
- for emulsion and suspension for emulsion for injection, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition

Prevention of influenza infection

2.1.1. Indication(s) targeted by the PIP

Active immunisation against H5N1 subtype of influenza A virus in a pandemic situation

Active immunisation against H5N1 subtype of influenza A virus in a prepandemic situation

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)

Emulsion and suspension for emulsion 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 study to evaluate the safety and immunogenicity of the paediatric formulation of the (pre-) pandemic H5N1 influenza candidate vaccine following a heterologous prime-boost schedule (six months apart) in children aged from 6 months to less than 36 months (H5N1-013). **Study 2** Randomised, open-label study to evaluate the safety and immunogenicity of a prime-boost schedule of the paediatric formulation of H5N1 candidate vaccine administered to subjects aged from 3 years to less than 18 years (H5N1-032). **Study 3** Randomised, observer-blind, dose-range study to assess immunogenicity and safety of varying quantities of the Quebec manufactured H5N1 HA antigen (Q-Pan) adjuvanted with varying quantities of AS03 as compared to the reference vaccine dose of 1.9 µg HA with AS03B (Q-Pan-H5N1-023). **Study 4** Deleted in EMEA-000160-PIP01-07-M05
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:	Yes
Date of completion of the paediatric investigation plan:	By May 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of influenza infection

Authorised indications (Adjupanrix):

- Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance (see sections 4.2 and 5.1).

Authorised indication (Prepandrix)

- Active immunisation against H5N1 subtype of influenza-A virus.

  This indication is based on immunogenicity data from healthy subjects from the age of 18 years onwards following administration of two doses of vaccine prepared with H5N1 subtype strains.

  Prepandrix should be used in accordance with official guidance.

Authorised pharmaceutical form(s):

Suspension and emulsion for emulsion for injection

Authorised route(s) of administration:

Intramuscular use