EMA/376110/2013

European Medicines Agency decision

P/0171/2013

of 30 July 2013

on the acceptance of a modification of an agreed paediatric investigation plan for purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B, Yamagata lineage (Influsplit Tetra and associated names), (EMEA-000817-PIP02-11-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 726/2004[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/287/2011 issued on 1 December 2011,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 22 March 2013 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 June 2013, 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 purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B, Yamagata lineage (Influsplit Tetra and associated names), suspension 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 GlaxoSmithKline Biologicals S.A., 89 rue de l'Institut, B-1330 – Rixensart, Belgium.

Done at London, 30 July 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/193120/2013 Corr.

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

EMEA-000817-PIP02-11-M01

Scope of the application

Active substance(s):

Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B, Yamagata lineage

Invented name:

Influsplit Tetra and associated names

Condition(s):

Prevention of influenza infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension 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

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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 22 March 2013 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/287/2011 issued on 1 December 2011.

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

The procedure started on 15 April 2013.

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 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.

London, 14 June 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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;
- for suspension for injection for 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 disease caused by influenza type A and B

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. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	**Study 1:** Double-blind, randomized, active-controlled trial to evaluate the immunogenicity and safety of quadrivalent influenza vaccine (FLU D-QIV) compared to Fluarix (inactivated trivalent influenza vaccine-TIV-1) in children aged 3 to less than 18 years of age and to describe the safety and immunogenicity of FLU D-QIV compared to Fluarix and TIV-2 in children aged 6 to less than 36 months of age. FLU D-QIV-003 PRI (113275). **Study 2:** Observer-blind randomized non-influenza vaccine comparator-controlled trial to evaluate the efficacy of FLU D-QIV in children aged 6 to less than 36 months of age. FLU D-QIV-004 (115345).

Area	Number of studies	Description
		Study 3: Open-label trial to evaluate the immunogenicity, safety and reactogenicity of a booster dose of FLU D-QIV in children who previously participated in study 2. FLU D-QIV-009 EXT 004 (116023).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2014
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 indication(s):

   Active immunisation of adults and children from 3 years of age for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine.

Authorised pharmaceutical form(s):

Suspension for injection

Authorised route(s) of administration:

Intramuscular use