EMA/64952/2015

European Medicines Agency decision

P/0035/2015

of 6 March 2015

on the acceptance of a modification of an agreed paediatric investigation plan for diphtheria toxoid / Tetanus toxoid / Bordetella pertussis antigen: Pertussis toxoid / Bordetella pertussis antigen: Filamentous Haemagglutinin / Bordetella pertussis antigen: Pertactin / Inactivated poliovirus: type 1 (Mahoney strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 3 (Saukett strain) (Boostrix Polio and associated names) (EMEA-000500-PIP01-08-M03) 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 decision P/239/2009 issued on 1 December 2009, the decision P/182/2010 issued on 24 September 2010, and the decision P/0264/2013 issued on 30 October 2013,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 21 October 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 January 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.

(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 diphtheria toxoid / Tetanus toxoid / Bordetella pertussis antigen: Pertussis toxoid / Bordetella pertussis antigen: Filamentous Haemagglutinin / Bordetella pertussis antigen: Pertactin / Inactivated poliovirus: type 1 (Mahoney strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 3 (Saukett strain) (Boostrix Polio and associated names), suspension for injection, suspension for injection in pre-filled syringe, 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 Biologocals S.A., 89, Rue de l'Institut, 1330 - Rixensart, Belgium.

Done at London, 6 March 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/653279/2014

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

EMEA-000500-PIP01-08-M03

Scope of the application

Active substance(s):

Diphtheria toxoid / Tetanus toxoid / Bordetella pertussis antigen: Pertussis toxoid / Bordetella pertussis antigen: Filamentous Haemagglutinin / Bordetella pertussis antigen: Pertactin / Inactivated poliovirus: type 1 (Mahoney strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 3 (Saukett strain)

Invented name:

Boostrix Polio and associated names

Condition(s):

Prevention of infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / Poliovirus types 1, 2 and 3

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Suspension for injection in pre-filled syringe

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 21 October 2014 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/239/2009 issued on 1 December 2009, the decision P/182/2010 issued on 24 September 2010, and the decision P/0264/2013 issued on 30 October 2013.

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

The procedure started on 19 November 2014.

Scope of the modification

Some 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 Icelandic and the Norwegian Paediatric Committee members agree 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, 16 January 2015

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

1.1. Condition

Prevention of infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / Poliovirus types 1, 2 and 3

The waiver applies to:

- preterm newborn infants, term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months), children (from 2 to less than 3 years), adolescents (from 14 to less than 18 years);
- for suspension for injection and suspension for injection in pre-filled syringe, 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 infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / Poliovirus types 1, 2 and 3

2.1.1. Indication(s) targeted by the PIP

Booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis of individuals from the age of three years to less than fourteen years

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

From 3 years to less than 14 years

2.1.3. Pharmaceutical form(s)

Suspension for injection

Suspension for injection in pre-filled syringe

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.

Clinical studies	3	**Study 1** Open-label, multicentre, study of the reactogenicity and immunogenicity of a single booster dose of dTpa-IPV vaccine in children and adolescents aged 9 to less than 14 years, 5 years after being randomised to a previous booster vaccination with three different lots of dTpa-IPV or dTpa + IPV. **Study 2** Open-label, randomized, multicentre study of the immunogenicity and safety of a single booster dose of two different dTpa-IPV vaccines, when co-administered with MMR vaccine in preschool children aged 3 to less than 5 years (including a historical comparison of immunogenicity with a DTPa vaccine primary immunisation). **Study 3** Open-label, randomized, multicentre study of the immunogenicity of single booster doses of dTpa-IPV vaccine versus a DTPa-IPV vaccine (each administered together with a booster dose of MMRV vaccine) to preschool children aged 5 to less than 7 years, previously primed with 3 doses of DTPa-based combination vaccines.
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 and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Prevention of infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / Poliovirus types 1, 2 and 3

Authorised indication(s)

- Booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis of individuals from the age of four years onwards

Authorised pharmaceutical form(s)

Suspension for injection

Suspension for injection in pre-filled syringe

Authorised route(s) of administration

Intramuscular injection