EMA/583529/2010

European Medicines Agency decision

P/182/2010

of 24 September 2010

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-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/239/2009 issued on 1 December 2009,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 31 May 2010 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 6 August 2010, 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, 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, 1330 Rixensart, Belgium.

Done at London, 24 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/484426/2010

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

EMEA-000500-PIP01-08-M01

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):

Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / poliovirus types 1, 2 and 3

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

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 31 May 2010 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's

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decision P/239/2009 issued on 1 December 2009.
The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 10 June 2010.

Scope of the modification

Some measures and timelines of the original Opinion 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(s) agree(s) 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(es) and appendix.

London, 6 August 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed Paediatric Investigation Plan and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / Poliovirus types 1, 2 and 3

1.1. Authorised indication(s)

Booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis.

2. Waiver

2.1. Condition(s)

Active immunisation against 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, intramuscular use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / Poliovirus types 1, 2 and 3

3.1.1. 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.

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

From 3 years to less than 14 years.

3.1.3. Pharmaceutical form(s)

Suspension for injection

3.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	3	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 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) 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

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	By July 2013
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Invented Name	Strength	Pharmaceutical form	Route of administration
Boostrix Polio and associated names	A 0.5 ml dose of vaccine contains not less than 2 IU (2.5 Lf) of adsorbed diphtheria toxoid, not less than 20 IU (5 Lf) of adsorbed tetanus toxoid, 8 µg of PT, 8 µg of FHA, 2.5 µg of pertactin, 40 D antigen units of type 1 (Mahoney), 8 D antigen units of type 2 (MEF-1) and 32 D antigen units of type 3 (Saukett) of the polio virus. Excipients: Aluminum salts, Medium 199 (as stabilizer), sodium chloride, water for injections, formaldehyde, polysorbate 80, neomycin sulfate, polymyxin B sulfate are present as residuals from the manufacturing process.	Suspension for injection in pre-filled syringe. Boostrix Polio is a turbid white suspension.	Intramuscular injection