EMA/348043/2017

European Medicines Agency decision

P/0180/2017

of 3 July 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for live, attenuated, chimeric dengue virus, serotype 1 / live, attenuated dengue virus, serotype 2 / live, attenuated, chimeric dengue virus, serotype 3 / live attenuated, chimeric dengue virus, serotype 4 (EMEA-001888-PIP01-15) 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/0180/2017

of 3 July 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for live, attenuated, chimeric dengue virus, serotype 1 / live, attenuated dengue virus, serotype 2 / live, attenuated, chimeric dengue virus, serotype 3 / live attenuated, chimeric dengue virus, serotype 4 (EMEA-001888-PIP01-15) 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 application submitted by Takeda Vaccines, Inc. on 4 May 2016 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 May 2017, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for live, attenuated, chimeric dengue virus, serotype 1 / live, attenuated dengue virus, serotype 2 / live, attenuated, chimeric dengue virus, serotype 3 / live attenuated, chimeric dengue virus, serotype 4, powder and solvent for solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for live, attenuated, chimeric dengue virus, serotype 1 / live, attenuated dengue virus, serotype 2 / live, attenuated, chimeric dengue virus, serotype 3 / live attenuated, chimeric dengue virus, serotype 4, powder and solvent for solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for live, attenuated, chimeric dengue virus, serotype 1 / live, attenuated dengue virus, serotype 2 / live, attenuated, chimeric dengue virus, serotype 3 / live attenuated, chimeric dengue virus, serotype 4, powder and solvent for solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Takeda Vaccines, Inc., One Takeda Parkway, 60015 – Deerfield, United States.

EMA/PDCO/194951/2017 Corr
London, 19 May 2017

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001888-PIP01-15

Scope of the application

Active substance(s):

Live, attenuated, chimeric dengue virus, serotype 1 / live, attenuated dengue virus, serotype 2 / live, attenuated, chimeric dengue virus, serotype 3 / live attenuated, chimeric dengue virus, serotype 4

Condition(s):

Prevention of dengue fever

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Takeda Vaccines, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Takeda Vaccines, Inc. submitted for agreement to the European Medicines Agency on 4 May 2016 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 21 June 2016.

Supplementary information was provided by the applicant on 24 February 2017. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the abovementioned recommendation of the Paediatric Committee.

2. 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 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 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 dengue fever.

The waiver applies to:

- the paediatric population from birth to less than 2 months;
- powder and solvent for solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Prevention of dengue fever.

2.1.1. Indication(s) targeted by the PIP

Active immunisation against dengue fever caused by dengue virus serotypes 1, 2, 3 and 4.

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

From 2 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality related studies	0	Not applicable.
Nonclinical studies	0	Not applicable.
Clinical studies	10	**Study 1** DEN-204. Randomized, double-blind, placebo-controlled trial to evaluate safety and immunogenicity of different schedules of Tetravalent Dengue Vaccine (TDV) in subjects 2 to less than 18 years of age. **Study 2** DEN-301, Parts 1 and 2. Randomized, double-blind, placebo-controlled study to evaluate efficacy, safety and immunogenicity of TDV in children and adolescents 4 to 16 years of age.

		Study 3 DEN-301, Part 3. Randomized, double-blind, placebo-controlled study to evaluate the long-term safety, immunogenicity and efficacy of TDV in children and adolescents 4 to 16 years of age. **Study 4** DEN-315. Randomised, double-blind, placebo-controlled trial to investigate safety and immunogenicity of 2 doses of TDV in male and female adolescents aged 12 to 17 years. **Study 5** DEN-306. Randomized, double blind trial to evaluate the safety and immunogenicity of 2 doses of TDV administered within the routine vaccine schedule of infants and toddlers 6 to less than 21 months of age. **Study 6** DEN-316. Randomised, double blind trial to evaluate safety and immunogenicity of TDV co-administered with Measles, Mumps, and Rubella Virus Vaccine Live (MMR) infants and toddlers 12 to less than 13 months of age. **Study 7** DEN-317. Randomized, observer blind trial to evaluate safety and immunogenicity of TDV co-administered with combined diphtheria and tetanus toxoids, acellular pertussis, inactivated poliomyelitis and adsorbed conjugated Haemophilus influenzae type b vaccine (DTaP/IPV/Hib) compared to placebo in infants/toddlers in infants 12 to less than 14 months of age. **Study 8** DEN-318. Randomized, double blind trial to evaluate safety and immunogenicity of TDV co-administered with Yellow Fever (YF) vaccine compared to placebo in infants 9 to less than 12 months of age. **Study 9** DEN-319.Randomized, open label trial to evaluate safety and immunogenicity of TDV co-administered with routine infant vaccines, according to different immunization schedules in infants 2 to less than 6 months of age. **Study 10** DEN-320. Randomized, double-blind, placebo-controlled study to evaluate efficacy, safety and immunogenicity of TDV in infants and children 2 months to less than 4 years of age.
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 June 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes