EMA/885/2024

European Medicines Agency decision

P/0003/2024

of 3 January 2024

on the acceptance of a modification of an agreed paediatric investigation plan for dengue tetravalent vaccine (live, attenuated) (Qdenga), (EMEA-001888-PIP01-15-M02) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0180/2017 issued on 3 July 2017, and the decision P/0429/2020 issued on 30 October 2020,

Having regard to the application submitted by Takeda Vaccines, Inc. on 29 August 2023 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 15 December 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for dengue tetravalent vaccine (live, attenuated) (Qdenga), powder and solvent for solution for injection, subcutaneous 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 Takeda Vaccines, Inc., 40 Landsdowne Street, 02139 - Cambridge, MA, USA.

EMA/PDCO/417810/2023
Amsterdam, 15 December 2023

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

EMEA-001888-PIP01-15-M02

Scope of the application

Active substance(s):

Dengue tetravalent vaccine (live, attenuated)

Invented name and authorisation status:

See Annex II

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 22 of Regulation (EC) No 1901/2006 as amended, Takeda Vaccines, Inc. submitted to the European Medicines Agency on 29 August 2023 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/0180/2017 issued on 3 July 2017, and the decision P/0429/2020 issued on 30 October 2020.

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

The procedure started on 16 October 2023.

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 Paediatric Committee member of Norway 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 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	Description
Quality related studies	Not applicable.
Nonclinical studies	Not applicable.
Clinical studies	**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** Study deleted in EMEA-001888-PIP01-15-M02. **Study 8** Study deleted in EMEA-001888-PIP01-15-M02. **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** Study deleted in EMEA-001888-PIP01-15-M02.
Extrapolation, modelling and simulation studies	Not applicable.
Other studies	Not applicable.
Other measures	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 July 2032
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of dengue fever

Authorised indication(s):

- Qdenga is indicated for the prevention of dengue disease in individuals from 4 years of age. The use of Qdenga should be in accordance with official recommendations
  - Invented name(s): Qdenga
  - Authorised pharmaceutical form(s): powder and solvent for solution for injection
  - Authorised route(s) of administration: subcutaneous injection
  - Authorised via centralised procedure