EMA/632050/2021

European Medicines Agency decision

P/0489/2021

of 3 December 2021

on the granting of a product specific waiver 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) (EMEA-003066-PIP01-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Vakzine Projekt Management GmbH on 9 July 2021 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 October 2021 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

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

Has adopted this decision:

Article 1

A waiver 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), solution for injection in pre-filled syringe, intramuscular 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 2

This decision is addressed to Vakzine Projekt Management GmbH, 9 Mellendorfer Str., 30625 – Hannover, Germany.

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

EMA/PDCO/428437/2021
Amsterdam, 15 October 2021

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-003066-PIP01-21

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)

Condition(s):

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

Pharmaceutical form(s):

Solution for injection in pre-filled syringe

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Vakzine Projekt Management GmbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Vakzine Projekt Management GmbH submitted to the European Medicines Agency on 9 July 2021 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 17 August 2021.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in 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

Grounds for the granting of the waiver

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:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for injection in pre-filled syringe, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.