EMA/950370/2022

European Medicines Agency decision

P/0043/2023

of 31 January 2023

on the granting of a product specific waiver for tetanus toxoid (Tetana), (EMEA-003311-PIP01-22) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by IBSS BIOMED S.A. on 1 September 2022 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 16 December 2022 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 tetanus toxoid (Tetana), suspension for injection, intramuscular use, 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 2

This decision is addressed to IBSS BIOMED S.A., al. Sosnowa 8, 30-224 – Krakow, Poland.

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

EMA/PDCO/781762/2022
Amsterdam, 16 December 2022

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

EMEA-003311-PIP01-22

Scope of the application

Active substance(s):

Tetanus toxoid

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of infectious disease caused by *Clostridium tetani*

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Subcutaneous use

Name/corporate name of the PIP applicant:

IBSS BIOMED S.A.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, IBSS BIOMED S.A. submitted to the European Medicines Agency on 1 September 2022 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 October 2022.

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(s) 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 Paediatric Committee members of Liechtenstein and Norway agree 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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Prevention of infectious disease caused by Clostridium tetani

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- suspension for injection, intramuscular use, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of infectious disease caused by *Clostridium tetani*

Authorised indication(s):

- The vaccine is indicated for active immunisation of children, adolescents and adults against tetanus:
  - within the National Immunisation Programme:
    - in case of contraindications for using combined vaccines containing except of tetanus toxoid, diphtheria toxoid (DT, Td) or diphtheria toxoid and Bordetella pertussis antigens (e.g. DTP),
    - as a booster dose,
  - in unvaccinated pregnant women expecting that the labour may take place in unhygienic conditions,
  - in active-passive prevention of tetanus in the case of contaminated wounds and at high risk of Clostridium tetani infection.

  The vaccine is recommended for basic and booster vaccination
  - Invented name(s): Tetana
  - Authorised pharmaceutical form(s): Suspension for injection
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via national procedure