EMA/153118/2024

European Medicines Agency decision

P/0136/2024

of 6 May 2024

on the granting of a product specific waiver for clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins (Xeomin, Bocouture), (EMEA-001039-PIP04-23) 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 Merz Pharmaceuticals GmbH on 18 December 2023 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 22 March 2024 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.

[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

A waiver for clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins (Xeomin, Bocouture), powder for solution for injection, intramuscular use, intraglandular 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 Merz Pharmaceuticals GmbH, Eckenheimer Landstr. 100, 60318 - Frankfurt (Main), Germany.

EMA/PDCO/5927/2024
Amsterdam, 22 March 2024

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

EMEA-001039-PIP04-23

Scope of the application

Active substance(s):

Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of essential tremor

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intramuscular use

Intraglandular use

Name/corporate name of the PIP applicant:

Merz Pharmaceuticals GmbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Merz Pharmaceuticals GmbH submitted to the European Medicines Agency on 18 December 2023 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 22 January 2024.

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 Paediatric Committee member of Norway 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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of essential tremor

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for solution for injection, intramuscular use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subsets.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s):

Authorised indications:

- Treatment of muscle spasticity and dystonia:
  - XEOMIN is indicated for the symptomatic treatment of blepharospasm and hemifacial spasm, cervical dystonia of a predominantly rotational form (spasmodic torticollis), spasticity of the upper limb in adults and chronic sialorrhea due to neurological disorders in adults, and chronic sialorrhea due to neurological/neurodevelopmental disorders in children and adolescents from 2 to 17 years of age and weighing more than 12 kg
  - Authorised pharmaceutical form: powder for solution for injection
  - Authorised routes of administration: intramuscular use, intraglandular use
  - Authorised via national procedures
- Treatment of wrinkles:
  - BOCOUTURE is indicated for the temporary improvement in the appearance of upper facial lines in adults below 65 years when the severity of these lines has an important psychological impact for the patient:
    - moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar frown lines) and/or
    - moderate to severe lateral periorbital lines seen at maximum smile (crow's feet lines) and/or
    - moderate to severe horizontal forehead lines seen at maximum contraction
  - Authorised pharmaceutical form: powder for solution for injection
  - Authorised route of administration: intramuscular use
  - Authorised via national procedures