



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/501922/2008

European Medicines Agency decision P/0131/2018

of 13 April 2018

on the granting of a product specific waiver for clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins (Xeomin, Bocouture), (EMEA-001039-PIP03-17) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Merz Pharmaceuticals GmbH on 1 December 2017 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 23 March 2018 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 clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins (Xeomin, Bocouture), powder for solution for injection, 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 Merz Pharmaceuticals GmbH, Eckenheimer Landstr. 100, 60318 - Frankfurt (Main), Germany.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/4534/2018
London, 23 March 2018

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

EMA-001039-PIP03-17

Scope of the application

Active substance(s):

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

Invented name:

Xeomin

Bocouture

Condition(s):

Treatment of hemifacial spasm

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intramuscular use

Name / corporate name of the PIP applicant:

Merz Pharmaceuticals GmbH

Information about the authorised medicinal product:

See Annex II

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 1 December 2017 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 23 January 2018.

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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition

Treatment of hemifacial spasm

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 the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of muscle spasticity, dystonia and wrinkles

Authorised indication(s):

- XEOMIN is indicated for the symptomatic treatment of blepharospasm, cervical dystonia of a predominantly rotational form (spasmodic torticollis) and spasticity of the upper limb in adults.
- 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(s):

Powder for solution for injection

Authorised route(s) of administration:

Intramuscular use