EMA/693805/2018

European Medicines Agency decision

P/0338/2018

of 12 October 2018

on the review of a granted 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0338/2018

of 12 October 2018

on the review of a granted 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

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 opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 March 2018,

Having regard to the decision of the European Medicines Agency P/0131/2018, adopted on 13 April 2018,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued of its own motion on 21 September 2018 in accordance with Article 14(2) 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 of its own motion on the review of the granted waiver.

(2) It is therefore appropriate to adopt a decision reviewing the granted waiver.

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

Has adopted this decision:

Article 1

A review of the granted waiver for clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins (Xeomin, Bocouture), powder for solution for injection, 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 agreed.

Article 2

This decision is addressed to Merz Pharmaceuticals GmbH, Eckenheimer Landstr. 100, 60318 - Frankfurt (Main), Germany.

EMA/PDCO/517221/2018
London, 21 September 2018

Opinion of the Paediatric Committee on the review of a granted product specific waiver

EMEA-001039-PIP03-17

Scope of the reviewed (part of the) waiver

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

Solution for injection in pre-filled syringe

Route(s) of administration:

Intramuscular use

Name/corporate name of the waiver addressee:

Merz Pharmaceuticals GmbH

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scope of the review

Condition: Treatment of hemifacial spasm

Scope of the changes: a pharmaceutical form (solution of injection in pre-filled syringe) has been added.

Basis for opinion

On 23 March 2018, an opinion on the granting of a product specific waiver was adopted by the Paediatric Committee, followed by the European Medicines Agency's decision P/0131/2018 issued on 13 April 2018.

According to Article 14(2) of Regulation (EC) No 1901/2006, the Paediatric Committee may, at any time, adopt an opinion advocating the review of a granted waiver.

The procedure started on 21 August 2018.

Opinion

1. The Paediatric Committee, having assessed the granted product specific waiver, recommends as set out in the appended summary report:

    - to review the granted product-specific waiver for all subsets of the paediatric population in the above specified condition(s) on its own motion in accordance with Article 14(2) of said Regulation;

    - the reviewed waiver is based on:

      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 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 addressee of the waiver 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

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, solution for injection in pre-filled syringe, 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