EMA/157768/2020

European Medicines Agency decision

P/0125/2020

of 30 March 2020

on the acceptance of a modification of an agreed paediatric investigation plan for Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins, (Xeomin, Bocouture), (EMEA-001039-PIP02-12-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 European Medicines Agency's decision P/0143/2013 issued on 3 July 2013, the decision P/0005/2016 issued on 25 January 2016, the decision P/0156/2016 issued on 15 June 2016 and the decision P/0195/2019 issued on 15 May 2019,

Having regard to the application submitted by Merz Pharmaceuticals GmbH on 29 November 2019 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2020, in accordance with Article 22 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 on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins, (Xeomin, Bocouture), powder for solution for injection, solution for injection, intraglandular use, intramuscular use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0042/2012 issued on 28/02/2012, including subsequent modifications thereof.

Article 3

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

EMA/PDCO/690757/2019
Amsterdam, 28 February 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001039-PIP02-12-M04

Scope of the application

Active substance(s):

Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins

Invented name:

Xeomin

Bocouture

Condition(s):

Treatment of sialorrhoea

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Solution for injection

Route(s) of administration:

Intraglandular use

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 22 of Regulation (EC) No 1901/2006 as amended, Merz Pharmaceuticals GmbH submitted to the European Medicines Agency on 29 November 2019 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0143/2013 issued on 3 July 2013, the decision P/0005/2016 issued on 25 January 2016, the decision P/0156/2016 issued on 15 June 2016 and the decision P/0195/2019 issued on 15 May 2019.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 6 January 2020.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the paediatric investigation plan and 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 applicant 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 and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition

Treatment of sialorrhoea

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- powder for solution for injection, solution for injection, intraglandular use, 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 subset(s).

2. Paediatric Investigation Plan

2.1. Condition

Treatment of sialorrhoea

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic sialorrhoea associated with neurologic conditions and/or intellectual disability

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection, solution for injection

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 1** Double-blind, randomised, multi-centre, placebo controlled trial to evaluate safety and efficacy of Clostridium Botulinum neurotoxin type A (150 kD) in children from 2years to less than 18 years of age with chronic sialorrhoea associated with neurologic conditions and/or intellectual disability, with an open-label extension study to evaluate safety

Area	Number of studies	Description
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of muscle spasticity

Authorised indications (Xeomin):

- treatment of post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adult patient.

2. Treatment of dystonia

Authorised indications (Xeomin):

- treatment of cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adult patients;
- treatment of blepharospasmus in adult patients.

3. Treatment of muscle-induced wrinkles

Authorised indications (Bocouture):

- treatment 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

Intraglandular use