EMA/312139/2013

European Medicines Agency decision

P/0143/2013

of 3 July 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for clostridium botulinum neurotoxin type A (150 kD), free of complexing proteins (Xeomin, Bocouture), (EMEA-001039-PIP02-12) 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 application submitted by Merz Pharmaceuticals GmbH on 14 May 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 May 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a 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 paediatric investigation plan for clostridium botulinum neurotoxin type A (150 kD), free of complexing proteins (Xeomin, Bocouture), powder for solution for injection, intraparenchymal 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

A deferral for clostridium botulinum neurotoxin type A (150 kD), free of complexing proteins (Xeomin, Bocouture), powder for solution for injection, intraparenchymal 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 3

A waiver for clostridium botulinum neurotoxin type A (150 kD), free of complexing proteins (Xeomin, Bocouture) powder for solution for injection, intraparenchymal 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 4

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

Done at London, 3 July 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/138241/2013 Corr

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001039-PIP02-12

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

Route(s) of administration:

Intraparenchymal use

Name/corporate name of the PIP applicant:

Merz Pharmaceuticals GmbH

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merz Pharmaceuticals GmbH submitted for agreement to the European Medicines Agency on 14 May 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 19 June 2012.

Supplementary information was provided by the applicant on 22 February 2013.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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 Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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.

London, 17 May 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Treatment of sialorrhoea

The waiver applies to:

- The paediatric population from birth to less than 2 years;
- for powder for solution for injection, intraparenchymal 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

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Measure 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.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By November 2017.
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 the appearance of moderate to severe vertical lines between the eyebrows seen at frown (glabellar frown lines) in adults below 65 years when the severity of these lines has an important psychological impact for the patient

Authorised pharmaceutical form(s):

Powder for solution for injection

Authorised route(s) of administration:

Intramuscular use