EMA/391612/2014

European Medicines Agency decision

P/0177/2014

of 7 July 2014

on the acceptance of a modification of an agreed paediatric investigation plan for tobramycin (Tobi Podhaler), (EMEA-000184-PIP01-08-M02) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the acceptance of a modification of an agreed paediatric investigation plan for tobramycin (Tobi Podhaler), (EMEA-000184-PIP01-08-M02) 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 European Medicines Agency's decision P/58/2009 issued on 27 March 2009 and the decision P/0146/2012 issued on 24 July 2012,

Having regard to the application submitted by Novartis Europharm Ltd. on 14 March 2014 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 20 June 2014, 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 and to the deferral.

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

[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 tobramycin (Tobi Podhaler), inhalation powder, hard capsule, inhalation use, including changes to the deferral, 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 is addressed to Novartis Europharm Ltd., Wimblehurst Road, RH12 5AB - Horsham, United Kingdom.

Done at London, 7 July 2014

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

EMA/PDCO/196301/2014

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

EMEA-000184-PIP01-08-M02

Scope of the application

Active substance(s):

Tobramycin

Invented name:

Tobi Podhaler

Condition(s):

Treatment of *Pseudomonas aeruginosa* pulmonary infection/colonisation in patients with cystic fibrosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Inhalation powder, hard capsule

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd. submitted to the European Medicines Agency on 14 March 2014 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/58/2009 issued on 27 March 2009 and the decision P/0146/2012 issued on 24 July 2012.

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

The procedure started on 23 April 2014.

Scope of the modification

Some measures and timelines 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 and to the deferral in the scope set out in the Annex I of this opinion.

   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 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, 20 June 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

1.1. Condition:

Treatment of *Pseudomonas aeruginosa* pulmonary infection/colonisation in patients with cystic fibrosis

The waiver applies to:

- newborn and infants from birth to less than 6 years;
- inhalation powder, hard capsule, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of *Pseudomonas aeruginosa* pulmonary infection/colonisation in patients with cystic fibrosis

2.1.1. Indication(s) targeted by the PIP

Treatment of *Pseudomonas aeruginosa* pulmonary infection/colonisation in cystic fibrosis patients

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

From 6 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Inhalation powder, hard capsules for inhalation use

2.1.4. Studies

Area	Number of studies	Description
Clinical	1	1. A randomised, open-label, multicenter trial to assess the safety of tobramycin inhalation powder compared to tobramycin nebuliser solution in cystic fibrosis subjects aged 6 years and above.

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 May 2009
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of *Pseudomonas aeruginosa* pulmonary infection/colonisation in patients with cystic fibrosis

Authorised indications:

- TOBI Podhaler is indicated for the suppressive therapy of chronic pulmonary infection due to *Pseudomonas aeruginosa* in adults and children aged 6 years and older with cystic fibrosis.

Authorised pharmaceutical form(s):

Inhalation powder, hard capsule

Authorised route(s) of administration:

Inhalation use