European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 27 March 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for tobramycin (EMEA-000184-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Novartis Europharm Limited on 4 April 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 February 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

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 granting 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 tobramycin, inhalation powder, hard capsules, nebuliser solution, inhalation 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 tobramycin, inhalation powder, hard capsules, nebuliser solution, inhalation 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 tobramycin, inhalation powder, hard capsules, nebuliser solution, inhalation 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 Novartis Europharm Limited, Wimblehurst Road, RH12 5AB Horsham, United Kingdom.

Done at London, 27 March 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

Doc. Ref. EMEA/PDCO/26495/2009
EMEA-000184-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance:
Tobramycin

Condition(s):
Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis

Pharmaceutical form(s):
Inhalation powder, hard capsules
Nebuliser solution

Route(s) of administration:
Inhalation use

Name/corporate name of the PIP applicant:
Novartis Europharm Limited

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the EMEA on 4 April 2008 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 1 July 2008.

Supplementary information was provided by the applicant on 27 November 2008.

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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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population,
  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 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 Agency, together with its annex(es) and appendix.

London, 6 February 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis

B. WAIVER

- **Condition**

Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis

The waiver applies to:

- Newborn and infants from birth to less than 3 months, for inhalation use.

on the grounds that the specific medicinal product is likely to be unsafe,
on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis

- **Proposed PIP indication**

Treatment of Pseudomonas aeruginosa infection/colonisation in cystic fibrosis patients

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 3 months to less than 18 years.

- **Formulation(s)**

Inhalation powder, hard capsules for inhalation use
Nebuliser solution for inhalation use

- **Studies**

Area	Number of studies	Description
Clinical	2	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. A randomised, double-blind, placebo-controlled, cross-over multi-center study to assess the efficacy and safety of tobramycin nebuliser solution for the treatment of early infections of *P. aeruginosa* in cystic fibrosis subjects from 3 months to less than 7 years of age.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By September 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

Invented name Name	**Strength**	**Pharmaceutical Form**	**Route of administration**
Tobramycin nebuliser solution (TOBI)	300 mg/5ml	Nebuliser Solution (5ml Ampoule)	Inhalation use