EMA/513790/2011

European Medicines Agency decision

P/153/2011

of 4 July 2011

on the acceptance of a modification of an agreed paediatric investigation plan for colistimethate sodium (EMEA-000176-PIP01-07-M03) 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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on the acceptance of a modification of an agreed paediatric investigation plan for colistimethate sodium (EMEA-000176-PIP01-07-M03) 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/7/2009 issued on 27 January 2009, the decision P/32/2010 issued on 10 March 2010, and the decision P/178/2010 issued on 24 September 2010,

Having regard to the application submitted by Forest Laboratories UK Limited on 2 March 2011 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 May 2011, 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 colistimethate sodium, inhalation powder, hard capsule, inhalation 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 is addressed to Forest Laboratories UK Limited, Riverbridge House, Anchor Boulevard, Crossways Business Park, DA2 6SL - Dartford, Kent, United Kingdom.

Done at London, 4 July 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/370144/2011

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

EMEA-000176-PIP01-07-M03

Scope of the application

Active substance(s):

Colistimethate sodium

Condition(s):

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

Pharmaceutical form(s):

Inhalation powder, hard capsule

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Forest Laboratories UK Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Forest Laboratories UK Limited submitted to the European Medicines Agency on 2 March 2011 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/7/2009 issued on 27 January 2009, the decision P/32/2010 issued on 10 March 2010 and the decision P/178/2010 issued on 24 September 2010.

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

The procedure started on 23 March 2011.

Scope of the modification

The applicant proposed modifications to the agreed PIP to clarify some of the agreed measures and timelines.

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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 Icelandic and the Norwegian Paediatric Committee member 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 annex(es) and appendix.

London, 20 May 2011

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

1. Condition(s)

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

2. Waiver

2.1. Condition(s)

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

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

The waiver applies to:

- the paediatric population from birth to less than 6 years,
- for inhalation powder, hard capsule for inhalation use,
- on the grounds that the specific medicinal product is likely to be unsafe because of the difficulties of handling a dry powder inhaler device in this age group and the high amount of powder applied.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

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

3.1.1. Indication(s) targeted by the PIP

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

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

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

From 6 years to less than 18 years.

3.1.3. Pharmaceutical form(s)

Inhalation powder, hard capsule; 125 mg

3.1.4. Studies

Area	Number of studies	Description
Quality	**0**	Not applicable.
Non-clinical	**0**	Not applicable.
Clinical	**6**	Study 1 A pilot study assessing total and regional lung deposition of colistimethate sodium delivered using a dry powder inhaler and a nebuliser device in adult patients with cystic fibrosis. Study 2 An open label study to compare tolerance and bronchial response to nebulised colistimethate sodium and colistimethate sodium dry powder inhalation in healthy adults and adult patients with mild asthma and cystic fibrosis. Study 3 A randomised, open label study to compare tolerability and bronchial response to nebulised colistimethate sodium and colistimethate sodium dry powder inhalation in adult patients with cystic fibrosis. Study 4 A randomised, open label cross-over study to compare the safety of a dry powder formulation of inhaled colistimethate sodium and nebulised colistimethate sodium in adult and paediatric cystic fibrosis patients with *Pseudomonas aeruginosa* lung infection. Study 5 A randomised, open label study to compare the efficacy and safety of a dry powder formulation of inhaled Colistimethate Sodium and nebulised TNSFI (Tobramycin nebuliser solution for inhalation, TOBI) in children from 6 to less than 18 years (and adults) with chronic *Pseudomonas* lung infection (including colonization) with cystic fibrosis. Study 6 A randomised, prospective, controlled, longitudinal study to compare the efficacy and safety of a dry powder formulation of inhaled Colistimethate Sodium and nebulised active comparator in children from 6 to less than 18 years with early *Pseudomonas* lung infection (including colonization) with cystic fibrosis.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By October 2015**
Deferral for one or more studies contained in the paediatric investigation plan:	**Yes**