EMA/697254/2011

European Medicines Agency decision

P/207/2011

of 1 September 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for colestilan (EMEA-000878-PIP02-11) 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 Mitsubishi Pharma Europe Ltd on 10 May 2011 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 12 August 2011, 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 colestilan, granules, film-coated tablet, oral 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 colestilan, granules, film-coated tablet, oral 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 colestilan, granules, film-coated tablet, oral 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 Mitsubishi Pharma Europe Ltd, Dashwood House, 69 Old Broad Street, EC2M 1QS, London, United Kingdom.

Done at London, 1 September 2011

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

EMA/PDCO/601166/2011

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

EMEA-000878-PIP02-11

Scope of the application

Active substance(s):

Colestilan

Condition(s):

Treatment of hyperphosphataemia

Pharmaceutical form(s):

Granules

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Mitsubishi Pharma Europe Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Mitsubishi Pharma Europe Ltd. submitted for agreement to the European Medicines Agency on 10 May 2011 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 15 June 2011.

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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.

   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 annex and appendix.

London, 12 August 2011

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 hyperphosphataemia

The waiver applies to:

- all subsets of the paediatric population from birth to less than 2 years of age;
- for granules, film-coated tablet; oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of hyperphosphataemia

2.1.1. Indication(s) targeted by the PIP

Treatment of hyperphosphataemia in children with CKD stage V on dialysis.

Treatment of hyperphosphataemia in children with CKD stage IIIb-V not on dialysis.

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)

Granules, film-coated tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	3	Study 1 *In-vitro* study/studies to determine the feasibility of administration through a nasogastric tube. Study 2 Provision of a device which will be suitable for counting colestilan granules to facilitate dosing of less then 1000 mg. Study 3 *In-vitro* study/studies investigating mixing of colestilan with food to obtain information on how to administer colestilan with food.
Non-clinical	0	Not applicable.
Clinical	3	Study 4 Multi-Centre, randomised, controlled, parallel group, open label study to

Area	Number of studies	Description
		evaluate efficacy, safety and tolerability of 3 doses of colestilan compared to standard therapy with a calcium-based phosphate binder, in paediatric chronic kidney disease (CKD) stage V patients on dialysis with hyperphosphataemia. Study 5 Multi-Centre, flexible dose, parallel group, open-label, active control (calcium-based phosphate binder), long-term extension study evaluating efficacy, safety and tolerability of colestilan in chronic kidney disease (CKD) Stage V patients on dialysis with hyperphosphataemia aged from 2 years to less than 18 years. Study 6 Multi-centre, open-label, study to evaluate safety and tolerability of colestilan in children aged from 2 years to less than 18 years with chronic kidney disease (CKD) Stages IIIb to V and hyperphosphataemia (HP) not on dialysis.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes