EMA/10425/2014

European Medicines Agency decision

P/0008/2014

of 22 January 2014

on the acceptance of a modification of an agreed paediatric investigation plan for aprepitant (Emend) (EMEA-000144-PIP01-07-M05) 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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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/97/2008 issued on 3 November 2008, the decision P/168/2011 issued on 8 July 2011, the decision P/0151/2012 issued on 25 July 2012 and the decision P/0060/2013 issued on 26 March 2013,

Having regard to the application submitted by Merck Sharp & Dohme Ltd. on 13 September 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver ,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 December 2013, 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 aprepitant (Emend), powder for suspension, hard capsule, oral 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 Merck Sharp & Dohme Ltd., Hertford Road, EN11 9BU – Hoddesdon, United Kingdom.

Done at London, 22 January 2014

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

EMA/PDCO/568019/2013

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

EMEA-000144-PIP01-07-M05

Scope of the application

Active substance(s):

Aprepitant

Invented name:

Emend

Condition(s):

Prevention of nausea and vomiting

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for suspension

Hard capsule

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme 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, Merck Sharpe & Dohme Ltd submitted to the European Medicines Agency on 13 September 2013 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/97/2008 issued on 3 November 2008, the decision P/168/2011 issued on 8 July 2011, P/0151/2012 issued on 25 July 2012 and the decision P/0060/2013 issued on 26 March 2013.

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

The procedure started on 10 October 2013.

Scope of the modification

Some 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 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, 6 December 2013

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

1. Waiver

1.1. Condition: prevention of nausea and vomiting

The waiver applies to:

- newborn infants (from birth to less than 28 days), Infants (from 28 days to less than 6 months);
- for powder for suspension, oral use, and for hard capsules, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: prevention of nausea and vomiting

2.1.1. Indication(s) targeted by the PIP

Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy in paediatric patients.

Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy in paediatric patients.

Prevention of postoperative nausea and vomiting in paediatric patients.

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for suspension, oral use.

Hard capsule, oral use.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	2	Study 1: Range-finding juvenile toxicity study in rats (exploratory). Study 2: Juvenile animal toxicity study
Clinical	3	Study 3: A multicenter, open-label, 5-part study to evaluate the pharmacokinetics, safety, and tolerability of aprepitant and fosaprepitant dimeglumine in paediatric patients receiving emetogenic chemotherapy Study 4: A multicenter, randomised, double-blind, parallel group, placebo-controlled study to assess the safety and efficacy of aprepitant in the prevention of chemotherapy induced nausea and vomiting in paediatric

		patients from 12 to less than 18 years of age. Study 5: A multicenter, two-Part (Part I: open-label PK and Part II: active-comparator-controlled double-blinded efficacy) study to evaluate the pharmacokinetics, safety, and tolerability and exploratory efficacy of aprepitant on nausea and vomiting in paediatric patients from 6 months to less than 18 years of age undergoing surgery.

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 October 2014.
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. Prevention of postoperative nausea and vomiting.

   Authorised indications:

   - Emend 40 mg is indicated for the prevention of postoperative nausea and vomiting (PONV) in adults.
   - Emend 80 mg, 125 mg and 125 mg/80mg are indicated for prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults.
   - Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.
   - Emend 80 mg, 125 mg and 125 mg/80mg are given as part of combination therapy.

Authorised pharmaceutical formulation(s):

Capsule, hard

Authorised route(s) of administration:

Oral use