European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 15 July 2009

on the agreement of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver for fosaprepitant dimeglumine (Ivemend) (EMEA-000406-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 Merck Sharp & Dohme Ltd**.** on 13 October 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 29 May 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 Regulation**,**

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 refusal 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 refusing 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 fosaprepitant dimeglumine (Ivemend), powder for solution for infusion, intravenous 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 fosaprepitant dimeglumine (Ivemend), powder for solution for infusion, intravenous 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 refused.

Article 3

A waiver for fosaprepitant dimeglumine (Ivemend), powder for solution for infusion, intravenous 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 Merck Sharp & Dohme Ltd., Hertford Road, Hoddesdon (Hertfordshire), EN11 9BU, United Kingdom

Done at London, 15 July 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/315222/2009
EMEA-000406-PIP01-08

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

Scope of the application

Active substance(s):
Fosaprepitant dimeglumine

(Invented) name:
Ivemend

Condition(s):
Nausea and vomiting

Pharmaceutical form(s):
Powder for solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Merck Sharp & Dohme Ltd.

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, Merck Sharp & Dohme Ltd. submitted for agreement to the EMEA on 13 October 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 13 November 2008.

Supplementary information was provided by the applicant on 18 March 2009.

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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 refuse 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, and Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Icelandic and the Norwegian Paediatric Committee member(s) 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 Agency, together with its annexes and appendix.

London, 29 May 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)

Nausea and vomiting

B. WAIVER

- **Condition**

Nausea and vomiting associated with emetogenic cancer chemotherapy

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 solution for infusion for intravenous use

on the grounds that the specific medicinal product is likely to be unsafe, and
on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

- Nausea and vomiting associated with emetogenic cancer chemotherapy

- **Proposed PIP indication**

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.

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

From 6 months to less than 18 years.

- **Formulation(s)**

Powder for solution for infusion, intravenous use

- **Studies**

Area	Number of studies	Description
Non-clinical	2	Range-finding juvenile toxicity study in rats (exploratory) Juvenile animal toxicity study
Clinical	1	A multi-center, open-label, 6-part study to evaluate the pharmacokinetics, safety, and tolerability of aprepitant and fosaprepitant dimeglumine in paediatric patients from 6 months to less than 18 years of age receiving emetogenic chemotherapy

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 December 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

- **Deferral**

Grounds for denying a deferral: Sufficient safety and efficacy data in adults are available.

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Packaging**	**Content (concentration)**	**Package size**
EU/1/07/437/001	Ivemend	115 mg	Powder for solution for infusion	Intravenous use	vial (glass)	10 ml	1 vial
EU/1/07/437/002	Ivemend	115 mg	Powder for solution for infusion	Intravenous use	vial (glass)	10 ml	10 vials