European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 14 October 2008

on the application for agreement of a Paediatric Investigation Plan for peginterferon alfa-2b (ViraferonPeg) (EMEA-000384-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)

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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 Schering-Plough Europe on 21 July 2008 under Article 16(1) also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 August 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 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 a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) 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 peginterferon alfa-2b, ViraferonPeg, Powder and solvent for solution for injection in vial and in pre-filled pen, Subcutaneous 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 waiver for peginterferon alfa-2b, ViraferonPeg, Powder and solvent for solution for injection in vial and in pre-filled pen, Subcutaneous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Schering-Plough Europe, 73, rue de Stalle, 1180 – Brussels, Belgium.

Done at London, 14 October 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

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

EMEA/PDCO/386122/2008
EMEA-000384-PIP01-08

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Peginterferon alfa-2b

Invented names:
ViraferonPeg

Condition:
Chronic viral hepatitis C

Pharmaceutical forms:
Powder and solvent for solution for injection in vial and in pre-filled pen

Route(s) of administration:
Subcutaneous use

Name/corporate name of the PIP applicant:
Schering-Plough Europe

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, Schering-Plough Europe submitted for agreement to the EMEA on 21 July 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 31 July 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 Regulation (EC) No 1901/2006 as amended;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with: 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 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 of the paediatric population 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(ces).

London, 29 August 2008

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) / DISEASE(S)

Chronic Hepatitis C

B. WAIVER

- **Condition**

Chronic Hepatitis C

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to: children from 0 to less than 3 years of age, powder and solvent for solution for injection in vial and in pre-filled pen, subcutaneous use.

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Chronic Hepatitis C

- **Subset(s) covered**

Children from 3 to less than 18 years of age.

- **Formulation(s)**

Powder and solvent for solution for injection in vial and in pre-filled pen.

- **Studies / Measures**

- PHARMACEUTICAL FORM: Powder and solvent for solution for injection in vial. Powder and solvent for solution for injection in pre-filled pen. 50,80,100, 120, and 150 mcg/0.5 ml

- CLINICAL: The clinical study must be completed by July 2008.

#	Area	Subarea	Description
1	Clinical	Safety and efficacy	Multicenter, fixed-dose, single-arm, open-label study to assess the safety, efficacy, tolerability, and multidose pharmacokinetics of peginterferon alfa-2b plus Rebetol in paediatric subjects (ages 3 to less than 18 years) with chronic hepatitis C.

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/00/132/001	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (50 µg/0.5 ml)	1 vial + 1 ampoule
EU/1/00/132/002	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (50 µg/0.5 ml)	1 vial + 1 ampoule + 1 injection set
EU/1/00/132/003	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (50 µg/0.5 ml)	4 vials + 4 ampoules
EU/1/00/132/004	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (50 µg/0.5 ml)	4 vials + 4 ampoules + 4 injection sets
EU/1/00/132/005	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (50 µg/0.5 ml)	6 vials + 6 ampoules
EU/1/00/132/006	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (80 µg/0.5 ml)	1 vial + 1 ampoule
EU/1/00/132/007	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (80 µg/0.5 ml)	1 vial + 1 ampoule + 1 injection set
EU/1/00/132/008	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (80 µg/0.5 ml)	4 vials + 4 ampoules
EU/1/00/132/009	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (80 µg/0.5 ml)	4 vials + 4 ampoules + 4 injection sets
EU/1/00/132/010	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (80 µg/0.5 ml)	6 vials + 6 ampoules
EU/1/00/132/011	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (100 µg/0.5 ml)	1 vial + 1 ampoule

EU/1/00/132/012	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (100 µg/0.5 ml)	1 vial + 1 ampoule + 1 injection set
EU/1/00/132/013	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (100 µg/0.5 ml)	4 vials + 4 ampoules
EU/1/00/132/014	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (100 µg/0.5 ml)	4 vials + 4 ampoules + 4 injection sets
EU/1/00/132/015	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (100 µg/0.5 ml)	6 vials + 6 ampoules
EU/1/00/132/016	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (120 µg/0.5 ml)	1 vial + 1 ampoule
EU/1/00/132/017	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (120 µg/0.5 ml)	1 vial + 1 ampoule + 1 injection set
EU/1/00/132/018	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (120 µg/0.5 ml)	4 vials + 4 ampoules
EU/1/00/132/019	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (120 µg/0.5 ml)	4 vials + 4 ampoules + 4 injection sets
EU/1/00/132/020	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (120 µg/0.5 ml)	6 vials + 6 ampoules
EU/1/00/132/021	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (150 µg/0.5 ml)	1 vial + 1 ampoule
EU/1/00/132/022	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (150 µg/0.5 ml)	1 vial + 1 ampoule + 1 injection set
EU/1/00/132/023	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent:	0.7 ml (150 µg/0.5 ml)	4 vials + 4 ampoules

					ampoule (glass)		
EU/1/00/132/024	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (150 µg/0.5 ml)	4 vials + 4 ampoules + 4 injection sets
EU/1/00/132/025	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (150 µg/0.5 ml)	6 vials + 6 ampoules
EU/1/00/132/026	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (50 µg/0.5 ml)	12 vials + 12 ampoules + 12 injection sets
EU/1/00/132/027	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (80 µg/0.5 ml)	12 vials + 12 ampoules + 12 injection sets
EU/1/00/132/028	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (100 µg/0.5 ml)	12 vials + 12 ampoules + 12 injection sets
EU/1/00/132/029	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (120 µg/0.5 ml)	12 vials + 12 ampoules + 12 injection sets
EU/1/00/132/030	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	0.7 ml (150 µg/0.5 ml)	12 vials + 12 ampoules + 12 injection sets
EU/1/00/132/031	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (50 µg/0.5 ml)	1 pen + 1 injection needle + 2 cleansing swabs
EU/1/00/132/032	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (50 µg/0.5 ml)	4 pens + 4 injection needles + 8 cleansing swabs
EU/1/00/132/033	ViraferonPeg	50 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (50 µg/0.5 ml)	6 pens + 6 injection needles + 12 cleansing swabs
EU/1/00/132/034	ViraferonPeg	50 micrograms	Powder and solvent for	Subcutaneous	pre-filled pen	0.5 ml (50 µg/0.5	12 pens + 12

			solution for injection in pre-filled pen	use	(cartridge, glass) Solvent: ampoule (glass)	ml)	injection needles + 24 cleansing swabs
EU/1/00/132/035	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (80 µg/0.5 ml)	1 pen + 1 injection needle + 2 cleansing swabs
EU/1/00/132/036	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (80 µg/0.5 ml)	4 pens + 4 injection needles + 8 cleansing swabs
EU/1/00/132/037	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (80 µg/0.5 ml)	6 pens + 6 injection needles + 12 cleansing swabs
EU/1/00/132/038	ViraferonPeg	80 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (80 µg/0.5 ml)	12 pens + 12 injection needles + 24 cleansing swabs
EU/1/00/132/039	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (100 µg/0.5 ml)	1 pen + 1 injection needle + 2 cleansing swabs
EU/1/00/132/040	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (100 µg/0.5 ml)	4 pens + 4 injection needles + 8 cleansing swabs

EU/1/00/132/041	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (100 µg/0.5 ml)	6 pens + 6 injection needles + 12 cleansing swabs
EU/1/00/132/042	ViraferonPeg	100 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (100 µg/0.5 ml)	12 pens + 12 injection needles + 24 cleansing swabs
EU/1/00/132/043	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (120 µg/0.5 ml)	1 pen + 1 injection needle + 2 cleansing swabs
EU/1/00/132/044	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (120 µg/0.5 ml)	4 pens + 4 injection needles + 8 cleansing swabs
EU/1/00/132/045	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (120 µg/0.5 ml)	6 pens + 6 injection needles + 12 cleansing swabs
EU/1/00/132/046	ViraferonPeg	120 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (120 µg/0.5 ml)	12 pens + 12 injection needles + 24 cleansing swabs
EU/1/00/132/047	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (150 µg/0.5 ml)	1 pen + 1 injection needle + 2 cleansing swabs
EU/1/00/132/048	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (150 µg/0.5 ml)	4 pens + 4 injection needles + 8 cleansing swabs

EU/1/00/132/049	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (150 µg/0.5 ml)	6 pens + 6 injection needles + 12 cleansing swabs
EU/1/00/132/050	ViraferonPeg	150 micrograms	Powder and solvent for solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (cartridge, glass) Solvent: ampoule (glass)	0.5 ml (150 µg/0.5 ml)	12 pens + 12 injection needles + 24 cleansing swabs