European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 15 August 2008

on the application for agreement of a Paediatric Investigation Plan for ribavirin, Rebetol (EMEA-000070-PIP01-07) 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 19 October 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended 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 4 July 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 ribavirin, Rebetol, oral solution and hard capsules, 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 waiver for ribavirin, Rebetol, oral solution and hard capsules, oral 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, 15 August 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/311564/2008
EMEA-000070-PIP01-07

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

Scope of the application

Active substance:
Ribavirin

Invented namename:
Rebetol

Condition(s):
Chronic viral hepatitis C

Pharmaceutical form(s):
Oral solution and Hard Capsules

Route(s) of administration:
Oral 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 19 October 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 22 November 2007.

Supplementary information was provided by the applicant on 24 April 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 Norwegian Paediatric Committee member agrees 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, 4 July 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, hard capsules and liquid solution, oral 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)**

Hard capsules, liquid solution.

- **Studies / Measures**

Area	Subarea	# of studies	Description
Clinical	Safety and efficacy	1	Multicenter, fixed-dose, single-arm, open-label study to assess the safety, efficacy, tolerability, and multidose pharmacokinetics of PegIntron plus Rebetol in paediatric subjects (ages 3 to 17 years, inclusive) with chronic hepatitis C.

Need for paediatric measures in a EU-Risk Management Plan: Yes
Date of completion of the Paediatric investigation plan: July 2008
A deferral has been granted: No

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/99/107/001	Rebetol	200 mg	Capsule, hard	Oral use	blister (PVC/PE/PVDC)		84 hard capsules
EU/1/99/107/002	Rebetol	200 mg	Capsule, hard	Oral use	blister (PVC/PE/PVDC)		140 hard capsules
EU/1/99/107/003	Rebetol	200 mg	Capsule, hard	Oral use	blister (PVC/PE/PVDC)		168 hard capsules
EU/1/99/107/004	Rebetol	40 mg/ml	Oral solution	Oral use	bottle (glass)	100 ml	1 bottle
EU/1/99/107/005	Rebetol	200 mg	Capsule, hard	Oral use	blister (PVC/PE/PVDC)		112 hard capsules