European Medicines Agency

Doc. Ref. EMEA/416570/2008
P/69/2008

EUROPEAN MEDICINES AGENCY DECISION

of 11 August 2008

on the application for agreement of a Paediatric Investigation Plan for eplivanserin hemifumarate (EMEA-000114-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)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 11 August 2008

on the application for agreement of a Paediatric Investigation Plan for eplivanserin hemifumarate (EMEA-000114-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

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 Sanofi Aventis Recherche & Développement on 12 December 2007 under Article 16(1) 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 4 July 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation, and Article 21 of said**,**

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.

(4) It is therefore appropriate to adopt a Decision granting a deferral.

[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 eplivanserin hemifumarate, film-coated tablet, oral route, 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 eplivanserin hemifumarate, film-coated tablet, oral route, 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

A deferral for eplivanserin hemifumarate, film-coated tablet, oral route, 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 4

This decision is addressed to Sanofi Aventis Recherche & Développement, 1, avenue Pierre Brossolette, 91385, Chilly Mazarin

Done at London, 11 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/345107/2008
EMEA-000114-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:
Eplivanserin hemifumarate

Condition(s):
Insomnia

Pharmaceutical form(s):
Film-coated tablet

Route(s) of administration:
Oral route

Name/corporate name of the PIP applicant:
Sanofi Aventis Recherche & Développement

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Sanofi Aventis Recherche & Développement submitted for agreement to the EMEA on 12 December 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 16 January 2008.

Supplementary information was provided by the applicant on 29 April 2008.

A meeting with the Paediatric Committee took place on 2 July 2008.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 deferral in accordance with Article 21 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(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 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)
Insomnia

B. WAIVER

- **Condition**
  Insomnia

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

The waiver applies to:

Preterm newborn infants, term newborn infants, infants & toddlers from 0 to less than 2 years for film-coated tablet and oral use.

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Insomnia

- **Subset(s) covered**

  Children from 2 to less than 12 years and adolescents from 12 to less than 18 years.

- **Formulation(s)**

  Film-coated tablet

- **Studies / Measures**

Area	Subarea	Number	Description
Quality	Pharmaceutical Form	1	Development of a film-coated tablet formulation for the paediatric population from 6 to less than 18 years.
Quality	Pharmaceutical Form	1	Development of an age appropriate formulation for the paediatric population from 2 to less than 6 years.
Non-clinical	juvenile animal study	1	Dose-ranging safety study in juvenile rats.
Non-clinical	juvenile animal study	1	Definitive oral safety study in juvenile rats.
Clinical	pharmacokinetics, efficacy	1	Open label with sequential single ascending dose administration of three doses in children aged from 6 to less than 18 years with insomnia.
Clinical	pharmacokinetics, efficacy	1	Open label with sequential single ascending dose administration of three doses in children aged from 2 to less than 6 years with insomnia.
Clinical	efficacy, safety,	1	8 week, randomised, double-blind, placebo-controlled 'proof-of-concept' trial of eplivanserin hemifumarate for insomnia associated with Attention Deficit Disorder in patients aged from 6 to less than 18 years.
Clinical	efficacy, safety	1	8 week, randomised, double-blind, placebo-controlled trial of eplivanserin hemifumarate for insomnia associated with Attention Deficit Disorder and/or Pervasive Developmental Disorder and/or blindness in patients from 2 to less than 18 years including 4 months of open label extension and 12 months of long-term follow-up.

Need for paediatric measures in an EU-Risk Management Plan: **Yes**

Date of completion of Paediatric Investigation Plan: **by June 2018**

A deferral has been granted: **Yes**