EMA/466443/2018

European Medicines Agency decision

P/0207/2018

of 17 July 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for (R)-2-amino-3-phenylpropylcarbamate hydrochloride (solriamfetol) (EMEA-002184-PIP01-17) 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.

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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 application submitted by Jazz Pharmaceuticals UK Ltd on 15 May 2017 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 June 2018, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting 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 (R)-2-amino-3-phenylpropylcarbamate hydrochloride (solriamfetol), tablet, 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 deferral for (R)-2-amino-3-phenylpropylcarbamate hydrochloride (solriamfetol), tablet, 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 granted.

Article 3

A waiver (R)-2-amino-3-phenylpropylcarbamate hydrochloride (solriamfetol), tablet, 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 granted.

Article 4

This decision is addressed to Jazz Pharmaceuticals UK Ltd, Wing B, Building 5700, Spires House, John Smith Drive, Oxford Business Part South, OX4 2RW – Oxford, United Kingdom.

EMA/PDCO/195558/2018
London, 1 June 2018

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-002184-PIP01-17

Scope of the application

Active substance(s):

(R)-2-amino-3-phenylpropylcarbamate hydrochloride (solriamfetol)

Condition(s):

Treatment of narcolepsy

Treatment of obstructive sleep apnoea

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Jazz Pharmaceuticals UK Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Jazz Pharmaceuticals UK Ltd submitted for agreement to the European Medicines Agency on 15 May 2017 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 20 June 2017.

Supplementary information was provided by the applicant on 12 March 2018. The applicant proposed modifications to the paediatric investigation plan and requested an additional waiver.

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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 17(1) of said Regulation;
   - to grant 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)(c) of said Regulation, 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 European Medicines Agency, together with its annex and appendix.

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 (PIP)

1. Waiver

1.1. Condition

Treatment of narcolepsy

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition

Treatment of obstructive sleep apnoea

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- tablet for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of narcolepsy

2.1.1. Indication(s) targeted by the PIP

Symptomatic treatment of excessive daytime sleepiness in narcolepsy

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate tablet strength to support dosing for the youngest age subsets.

Non-clinical studies	1	**Study 2** Definitive juvenile toxicity study (20091367)
Clinical studies	3	**Study 3** Open-label study to evaluate the PK and safety of solriamfetol after single ascending dose escalation (JZP-865_101) **Study 4** 12-week, randomized, double-blind, placebo-controlled, parallel group study of the safety and efficacy of solriamfetol (JZP-865_301) **Study 5** Multi-centre, open-label study to evaluate the tolerability, safety and maintenance of efficacy of solriamfetol under open-label conditions (JZP-865_302)
Extrapolation, modelling and simulation studies	2	**Study 6** Population PK (/PD) model data analysis – inferential (JAZP-PCS-100) **Study 7** Extrapolation study to support efficacy assumptions in the paediatric population
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes