



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/470765/2021

European Medicines Agency decision P/0394/2021

of 8 September 2021

on the acceptance of a modification of an agreed paediatric investigation plan for solriamfetol (EMA-002184-PIP01-17-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for solriamfetol (EMEA-002184-PIP01-17-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0207/2018 issued on 17 July 2018,

Having regard to the application submitted by Jazz Pharmaceuticals Ireland Limited on 15 April 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 July 2021, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for solriamfetol, tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Jazz Pharmaceuticals Ireland Limited, 5th Floor, Waterloo Road, Waterloo Exchange, D04 E5W7 - Dublin, Ireland.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/260562/2021
Amsterdam, 23 July 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002184-PIP01-17-M01

Scope of the application

Active substance(s):

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 Ireland Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Jazz Pharmaceuticals Ireland Limited submitted to the European Medicines Agency on 15 April 2021 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0207/2018 issued on 17 July 2018.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 25 May 2021.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.



Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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