



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/447544/2014

European Medicines Agency decision

P/0191/2014

of 6 August 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863) (EMEA-001452-PIP01-13) 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 726/2004¹,

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 application submitted by GlaxoSmithKline Trading Services Limited on 5 August 2013 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 20 June 2014, in accordance with Article 18 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 N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863), oral solution, oral suspension, 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 N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863), oral solution, oral suspension, 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 for N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863), oral solution, oral suspension, 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 GlaxoSmithKline Trading Services Limited, 6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland.

Done at London, 6 August 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/539965/2013

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

EMA-001452-PIP01-13

Scope of the application

Active substance(s):

N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine
(GSK1278863)

Condition(s):

Treatment of anaemia due to chronic disorders

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral solution

Oral suspension

Tablet

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted for agreement to the European Medicines Agency on 5 August 2013 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 10 October 2013.

Supplementary information was provided by the applicant on 20 March 2014. The applicant proposed modifications to the paediatric investigation plan.

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 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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(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.

London, 20 June 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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 anaemia due to chronic disorders

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- oral solution, oral suspension, tablet , oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of anaemia due to chronic disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of anaemia associated with chronic renal disease

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral solution

Oral suspension

Tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of an oral solution or oral suspension.
Non-clinical studies	2	Study 2: Dose range finding study in juvenile rats. Study 3: Definitive toxicity study in juvenile rats.
Clinical studies	5	Study 4: Relative bioavailability study of oral solution or oral suspension in adults.

		Study 5: Open-label, single-arm sequential cohort trial to evaluate pharmacokinetics and safety of GSK1278863 in children from 1 to less than 18 years of age who are undergoing dialysis. Study 6: Open-label, single-arm sequential cohort trial to evaluate pharmacokinetics and safety of GSK1278863 in children from 1 to less than 18 years of age who are NOT undergoing dialysis. Study 7: Open-label, randomised, dose-titration, active controlled trial to evaluate efficacy and safety of GSK1278863 in children from 1 to less than 18 years of age with anaemia who are undergoing dialysis. Study 8: Open-label, randomised, dose-titration, active controlled trial to evaluate efficacy and safety of GSK1278863 in children from 1 to less than 18 years of age with anaemia who are NOT undergoing dialysis.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety or efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By January 2027.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes