EMA/300173/2020

European Medicines Agency decision

P/0213/2020

of 16 June 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for gepotidacin (EMEA-002443-PIP01-18) 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 GlaxoSmithKline Trading Services Limited on 9 September 2018 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 30 April 2020, 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 gepotidacin, film-coated tablet, age appropriate oral formulation, 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 gepotidacin, film-coated tablet, age appropriate oral formulation, 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 gepotidacin, film-coated tablet, age appropriate oral formulation, 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, 12 Riverwalk, City West, Business Campus, 24 - Dublin, Ireland.

EMA/PDCO/83508/2020
Amsterdam, 30 April 2020

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

EMEA-002443-PIP01-18

Scope of the application

Active substance(s):

Gepotidacin

Condition(s):

Treatment of uncomplicated urinary tract infections

Pharmaceutical form(s):

Film-coated tablet

Age appropriate oral formulation

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 9 September 2018 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 16 October 2018.

Supplementary information was provided by the applicant on 17 January 2020. 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 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)(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 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 uncomplicated urinary tract infections

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- film-coated tablet and age appropriate oral formulation, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Treatment of uncomplicated urinary tract infections

2.1.1. Indication(s) targeted by the PIP

Treatment of recurrent uncomplicated lower urinary tract infections (acute cystitis) in children from 2 to less than 18 years of age

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age appropriate oral formulation

2.1.4. Measures

Area	**Number of studies**	**Description**
Quality-related studies	1	**Study 1** Age-appropriate oral solid dosage form (*same as Study 1 in EMEA-002443-PIP02-18*)
Non-clinical studies	0	Not applicable
Clinical studies	4	**Study 2** Double-blind, randomized, sequential, two-part study to investigate the PK of gepotidacin tablets in healthy adult participants (Part 1) and healthy adolescent participants from 12 to less than 18 years of age (Part 2), (209611).

		(*same as Study 2 in EMEA-002443-PIP02-18*) **Study 3** Randomized, parallel-group, double blind, double-dummy, active comparator-controlled, non-inferiority study in adolescent female patients from 12 to less than 18 years of age (and adults) with uncomplicated urinary tract infection (acute cystitis), to assess the combined clinical and microbiological efficacy of gepotidacin compared with nitrofurantoin at the test of cure visit (204989). **Study 4** Randomized, parallel-group, double blind, double-dummy, active comparator-controlled, non-inferiority study in adolescent female patients from 12 to less than 18 years of age (and adults) with uncomplicated urinary tract infection (acute cystitis), to assess the combined clinical and microbiological efficacy of gepotidacin compared with nitrofurantoin at the test of cure visit (212390). **Study 5** Two-part study to investigate the pharmacokinetics (PK) parameters and safety following repeat doses of oral gepotidacin for 5 days in male and female paediatric participants from 2 to less than 12 years of age with a confirmed or suspected lower UTI (Part 1- open-label, non-comparator study) to determine the PK, safety and tolerability ofrepeat doses of oral gepotidacin for 5 days adjusted by body weight ranges in hospitalised participants (Part 2- open-label, active-controlled comparator study) in male and female paediatric participants from 2 to less than 12 years of age with confirmed or suspected lower UTI (207705).
Extrapolation, modelling and simulation studies	2	**Study 6** Population PK analysis (PopPK) to determine a paediatric dose/posology in children from 2 to less than 12 years of age that should achieve the systemic exposures (AUC and Cmax) equivalent to that observed in adults and children from 12 years and older. **Study 7** Extrapolation of safety and efficacy from adults and children (12 years and older) to support use of oral gepotidacin for treatment of uncomplicated urinary tract infections in children from 2 to less than 12 years of age.
Other studies		Not applicable

Other measures		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 July 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes