EMA/170274/2023

European Medicines Agency decision

P/0155/2023

of 12 May 2023

on the acceptance of a modification of an agreed paediatric investigation plan for gepotidacin (EMEA-002443-PIP01-18-M02) 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.

European Medicines Agency decision

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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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0213/2020 issued on 16 June 2020 and the decision P/0444/2022 issued on 28 October 2022,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 14 December 2022 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 31 March 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for gepotidacin, film-coated tablet, age appropriate oral formulation, 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 GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest, Business Campus, 24 – Dublin, Ireland.

EMA/PDCO/4979/2023
Amsterdam, 31 March 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002443-PIP01-18-M02

Scope of the application

Active substance(s):

Gepotidacin

Invented name and authorisation status:

See Annex II

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 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 14 December 2022 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/0213/2020 issued on 16 June 2020 and the decision P/0444/2022 issued on 28 October 2022.

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

The procedure started on 30 January 2023.

Scope of the modification

Some measures 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 Paediatric Committee member of Norway 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 annexes 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, 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 years to less than 18 years of age

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

From 2 years 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	**Description**
Quality-related studies	**Study 1** Age-appropriate oral dosage form Same as Study 1 in EMEA-002443-PIP02-18
Non-clinical studies	Not applicable
Clinical studies	**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	**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** Study deleted during procedure EMEA-002443-PIP01-18-M01
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 March 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.