

EMA/825134/2022

European Medicines Agency decision

P/0444/2022

of 28 October 2022

on the acceptance of a modification of an agreed paediatric investigation plan for gepotidacin (EMA-002443-PIP01-18-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 gepotidacin (EMA-002443-PIP01-18-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0213/2020 issued on 16 June 2020,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 18 May 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 9 September 2022, 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 and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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, including changes to the deferral, 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/566908/2022
Amsterdam, 9 September 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002443-PIP01-18-M01

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 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 18 May 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.

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

The procedure started on 11 July 2022.

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 and to the deferral 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 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, 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	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 of repeat 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 C_{max}) 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