MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100714-PIP01-22-M01

Scope of the Application

Active Substance(s)

Gepotidacin

Condition(s)

Treatment of uncomplicated urogenital gonorrhoea (GC)

Pharmaceutical Form(s)

Film-coated tablet; Age appropriate oral formulation

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 14/10/2022 13:10 BST an application for a Modification

The procedure started on 13/03/2023 16:58 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100714-PIP01-22-M01

Of 03/04/2023 16:57 BST

On the adopted decision for Gepotidacin (MHRA-100714-PIP01-22-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Gepotidacin, Film-coated tablet; Age appropriate oral formulation , ORAL USE .

This decision is addressed to GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of uncomplicated urogenital gonorrhoea The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Film-coated tablet Age appropriate oral formulation Route(s) of administration: ORAL USE Reason for granting waiver: 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(s):

Treatment of uncomplicated urogenital gonorrhoea

2.2 Indication(s) targeted by the PIP:

Treatment of uncomplicated urogenital gonorrhoea

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age appropriate oral formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 (Same as Study 1 of MHRA-100720-PIP01-22-M01 and subsequent modifications thereof) Age-appropriate oral dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 (209611) (Same as Study 2 of MHRA-100720-PIP01-22-M01 and subsequent modifications thereof) Double-blind, randomised, 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). Study 3 (BTZ116577) Randomised, open label, parallel group, comparator controlled, non-inferiority study in adolescents from 12 to less than 18 years of age (and adults) with uncomplicated urogenital gonorrhoea to evaluate the efficacy and safety of oral gepotidacin.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/11/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes