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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-100081-PIP01-21

Scope of the Application

Active Substance(s)

Zibotentan/Dapagliflozin propanediol monohydrate; Zibotentan; DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE

Condition(s)

Treatment of Chronic Kidney Disease

Pharmaceutical Form(s)

Tablet, Hard capsule

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 11/06/2021 11:07 BST an application for a Paediatric Investigation Plan

The procedure started on 29/10/2021 13:18 BST

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 grant a product specific waiver

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-100081-PIP01-21

Of 10/11/2021 13:30 GMT

On the adopted decision for Zibotentan; DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE (MHRA-100081-PIP01-21) in accordance with the Human Medicines Regulations 2012.

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

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Paediatric Investigation Plan for Zibotentan; DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, Tablet, Hard capsule , Oral use .

This decision is addressed to AstraZeneca UK Limited, 600 Capability Green, Luton, United Kingdom, LU1 3LU

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Chronic Kidney Disease The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Tablet; Hard capsule Route(s) of administration: Oral use; Reason for granting waiver: on the grounds that the specific medicinal product is likely to be ineffective or unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not applicable

2.2 Indication(s) targeted by the PIP:

Not applicable

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

Not applicable

2.4 Pharmaceutical Form(s):

Not applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	0	Not applicable
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	