**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-100243-PIP01-21

# Scope of the Application

## Active Substance(s)

DAPAGLIFLOZIN; 2-{(3S)-7-fluoro-4-[(3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)carbonyl]-3,4-dihydro-2H-1,4-benzoxazin-3-yl}-N-methylacetamide (AZD9977)

## Condition(s)

Prevention of cardiovascular events in patients with chronic heart failure

## Pharmaceutical Form(s)

All pharmaceutical forms

## Route(s) of Administration

All routes of administration

## 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 17/02/2022 15:02 GMT an application for a Waiver

The procedure started on 20/06/2022 10:30 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-100243-PIP01-21

Of 07/07/2022 08:22 BST

On the adopted decision for DAPAGLIFLOZIN; 2-{(3S)-7-fluoro-4-[(3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)carbonyl]-3,4-dihydro-2H-1,4-benzoxazin-3-yl}-N-methylacetamide (AZD9977) (MHRA-100243-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 Waiver for DAPAGLIFLOZIN; 2-{(3S)-7-fluoro-4-[(3-oxo-3,4-dihydro-2H-1,4-benzoxazin-6-yl)carbonyl]-3,4-dihydro-2H-1,4-benzoxazin-3-yl}-N-methylacetamide (AZD9977), All pharmaceutical forms , 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:

| |
|---|
| Prevention of cardiovascular events in patients with chronic heart failure 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): All Pharmaceutical forms Route(s) of administration: All routes of administration Reason for granting waiver: on the grounds that the specific medicinal product is likely to be 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** | | |
| **Non-Clinical Studies** | | |
| **Clinical Studies** | | |
| **Extrapolation, Modeling & Simulation Studies** | | |
| **Other Studies** | | |
| **Other Measures** | | |

## 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:** | |