



23 June 2022  
EMA/CHMP/592350/2022  
Human Medicines Evaluation Division

## Statement indicating compliance with the agreed completed paediatric investigation plan

### Medicinal product

Forxiga/dapagliflozin  
Edistride/dapagliflozin

Pharmaceutical form(s):	See Annex A
Strength(s):	See Annex A
Route(s) of administration:	See Annex A
Packaging and package size(s):	See Annex A
Number(s) in the Community Register of Medicinal Products:	See Annex A

### Marketing authorisation holder (MAH):

Name and address of the MAH: AstraZeneca AB  
151 85 Sodertralja  
Sweden

### Procedure

Procedure number: EMEA/xxxx/WS/2284

Further to the compliance check performed under Article 23 of Regulation (EC) No 1901/2006, and in accordance with Article 28(3) and Article 45(3) of the said Regulation it is concluded that:

-the development of this product has complied with all measures in the agreed paediatric investigation plan PIP/0086/2020. All studies in the agreed paediatric investigation plan PIP/0086/2020 were conducted after the entry into force of that Regulation,

-the Summary of Product Characteristics adopted by CHMP already reflected the results of studies conducted in compliance with this agreed paediatric investigation plan.

