EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2021
EMA/654654/2021
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Revestive/ teduglutide	
teduglutide	
Pharmaceutical form(s):	See Annex A of the CHMP Opinion
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:	Shire Pharmaceuticals Ireland Limited Miesian Plaza Blocks 2 and 3 50-58 Baggot Street Lower Dublin 2 D02 Y754 IRELAND

Procedure	
Procedure number:	EMEA/H/C/002345/II/0053

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 P/0479/2020. All studies in the agreed paediatric investigation plan P/0479/2020 were conducted after the entry into force of that Regulation,

-the Summary of Product Characteristics reflects the results of studies conducted in compliance with this agreed paediatric investigation plan.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0479/2020 is included in the technical dossier.