



6 March 2023
EMA/CHMP/106165/2023
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

Tivicay/ dolutegravir

<common name>

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: ViiV Healthcare B.V.
Van Asch van Wijckstraat 55H
3811 LP Amersfoort
NETHERLANDS

Procedure

Procedure number: EMEA/H/C/002753/IB/0086

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 P/0267/2021 with the full compliance check PIP EMEA-C-000409-PIP01-08-M06. All studies in the agreed paediatric investigation plan PIP P/0267/2021 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.

