



Amsterdam,
EMADOC-1700519818-3014602
PIP compliance
EMA/VR/0000337283

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Doptelet / Avatrombopag	
Pharmaceutical form(s):	See Annex A of the Notification
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:	Swedish Orphan Biovitrum AB (publ) - 112 76 Stockholm Sweden

Procedure	
Procedure number:	EMA/VR/0000337283

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/0137/2024. For the purpose of the application of Article 45(3) of Regulation (EC) No 1901/2006, significant studies in the agreed paediatric investigation plan EMEA-C-001136-PIP01-11-M03 were completed after the entry into force of that Regulation.

-the Summary of Product Characteristics already 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 EMEA-C-001136-PIP01-11-M03 is included in the technical dossier.