13 April 2021
EMA/207785/2021
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Xarelto/Rivaroxaban	
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:	Bayer AG 51368 Leverkusen Germany

Procedure	
Procedure number:	EMEA/H/C/000944/IB/0088

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 applicant has full compliance confirmed by PDCO.

All the results of the PIP are already represented in the SmPC.

In the paediatric line extension X-74-G the following PIP measures were presented and the assessment report concluded:

- extension of indication to include treatment and prevention of venous thromboembolism in term neonates, infants and toddlers, children, and adolescents aged less than 18 years.

The development of this product has complied with all measures in the agreed paediatric investigation plan P/0126/2019. All studies in the agreed paediatric investigation plan P/0126/2019 were conducted after the entry into force of that Regulation.

All conditions for the compliance statement are fulfilled.

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