

26 July 2018  
EMA/511316/2018  
Human Medicines Evaluation Division

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

Medicinal product	
Coagadex/ human coagulation factor X	
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:	Bio Products Laboratory Limited Dagger Lane Hertfordshire Elstree WD6 3BX UNITED KINGDOM
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### Procedure

Procedure number:	EMA/H/C/003855/II/0007
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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/0389/2017. All studies in the agreed paediatric investigation plan P/0389/2017 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/0389/2017 is included in the technical dossier.