20 December 2019

EMA/483758/2020
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Hemlibra/ emicizumab	
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:	Roche Registration GmbH Emil-Barell-Strasse 1 79639 Grenzach-Wyhlen GERMANY

Procedure	
Procedure number:	EMEA/H/C/004406/IB/0015

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 {decision number PIP EMEA-C-001839-PIP01-15}. For the purpose of the application of Article 45(3) of Regulation EC (No) 1901/2006, significant studies in the agreed paediatric investigation plan have been completed after the entry into force of that Regulation,

To include a statement indicating compliance with the agreed completed PIP EMEA-C-001839-PIP01-15, for: Treatment of hereditary factor VIII deficiency.

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The outcomes of the compliance checks with PIP: EMEA- C-001839-PIP01-15, are provided within this application, as follow:
- Partial compliance check 1 granted on the 19.05.2017
- Full compliance check, granted on the 26.04.2019

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