13 October 2022
EMA/828539/2022
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Nuwiq/Vihuma (simoctocog alfa)	
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:	Octapharma AB Lars Forssells gata 23 112 75 Stockholm SWEDEN

Procedure	
Procedure number:	EMEA/H/C/2244/WS/2244

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/0014/2020 of 6 January 2020. All studies in the agreed paediatric investigation plan P/0014/2020 were conducted after the entry into force of that Regulation.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0014/2020 is included in the technical dossier.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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