18 August 2023
EMA/CHMP/372980/2023
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Vimizim/ elosulfase alfa	
<common name>	
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:	BioMarin International Limited Shanbally Ringaskiddy County Cork P43 R298 IRELAND

Procedure	
Procedure number:	EMEA/H/C/002779/IB/0043

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/0170/2023 with full compliance check EMEA-C-000973-PIP01-10-M04. All studies in the agreed paediatric investigation plan P/0170/2023 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.