



Statement indicating compliance with the agreed completed paediatric investigation plan

30 March 2023

Medicinal product	
Pedmarqsi	
sodium thiosulfate	
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:	Fennec Pharmaceuticals (EU) Limited Block A, 5th Floor, The Atrium Blackthorn Road Sandyford Dublin 18 IRELAND
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Procedure

Procedure number:	EMA/H/C/005130/0000
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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/0368/2019. All studies in the agreed paediatric investigation plan P/0368/2019 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.

