



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 3 June 2026
EMADOC-1700519818-3211686
PIP compliance
EMA/VR/0000348619

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

Lynparza / Olaparib

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: AstraZeneca AB
- 151 85 Sodertalje Sweden

Procedure

Procedure number: EMA/VR/0000348619

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/0148/2024. All studies in the agreed paediatric investigation plan P/0148/2024 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/0148/2024 is included in the technical dossier.

