



22 February 2018
EMA/CHMP/86143/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Lynparza olaparib

On 22 February 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Lynparza. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP recommended the approval of a new presentation and new strengths: Lynparza 100 mg and 150 mg tablets, which will allow for fewer dose units. The dose of the currently authorised form (50 mg capsules) is 8 capsules taken twice a day, whereas the dose for the new form will be 2 tablets twice a day.

The indication of Lynparza 100 mg and 150 mg tablet will be as follows:

“Lynparza is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.”

For information, the indication for Lynparza capsules will remain as follows:

“Lynparza is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed *BRCA*-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

