F. No. 12-07/18-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi 110002,
Dated: 16 MAY 2024

To

All State/UTs Drugs Controller

Subject: Withdrawal of indication for Olaparib Tablets 100mg and 150mg in the treatment of patient with gBRCA mutation and advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy- reg.

The Olaparib Tablets 100mg/150mg was initially approved by this office in 13.08.2018 for following indications:

Ovarian cancer:

- For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.

- For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

Breast cancer:

- In patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment.

The firm M/s. Astrazeneca Pharma India limited has submitted application to this directorate for the withdrawal of indications for Olaparib Tablets 100mg and 150mg in the treatment of patient with gBRCA mutation and advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Based on post hoc subgroup analysis indicating a potential detrimental effect on overall survival (OS) for Olaparib compared to the chemotherapy control arm in the subgroup of patients who had received three or more prior lines of chemotherapy.

The matter has been reviewed in consultation with SEC (Oncology) experts in the 06th/24 meeting held on 19.03.2024 & 20.03.2024 at CDSCO (HQ), New Delhi.

The firm presented the clinical evidence for the withdrawal of indication of Olaparib 100mg and 150mg tablets in the treatment of patient with gBRCA mutation and advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy and accordingly, the firm has been directed to withdraw the said indication and revise the package insert.

In view of the above circumstances, you are requested to direct all the manufacturers of said drug under your jurisdiction to withdraw marketing of the product Olaparib Tablets 100mg and 150mg approved by your office for the treatment of patients with gBRCA mutation and advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy indication and submit the revised package insert. The drug may continue to be marketed for other approved indications.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to: -

1. All Zonal/Sub Zonal offices of CDSCO
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO