

Circular No. 08/DG-Peshi/2024.

Date: 24-05-2024

CIRCULAR

Sub: Withdrawal of indication for Olaparib Tablets 100 mg and 150 mg, by DCG(I), for the treatment of patients with gBRCA mutation and advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy – Reg.

Ref: Letter dated: 16-05-2024 in File No. 12-07/18-DC of the Drugs Controller General (India).

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With reference to the letter of the Drugs Controller General (India) cited, all the manufacturers of Olaparib Tablets 100 mg and 150 mg are hereby directed to withdraw marketing of the product Olaparib Tablets 100 mg and 150 mg 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.

Manufacturers of Olaparib Tablets 100 mg and 150 mg are further directed to submit the revised package insert in this regard.

The drug may continue to be marketed for other approved indications.

This is for strict adherence and submission of compliance to this office.

Kamalaranjan
24/5/24
DIRECTOR GENERAL

To

All the manufacturers of Olaparib Tablets 100 mg and 150 mg in the State.

Copy to :

All the Drugs Inspectors in the State are instructed to communicate to the manufacturers of Olaparib Tablets 100 mg and 150 mg in their jurisdiction.

All the Assistant Directors in the State for monitoring compliance.

The Joint Director and all the Deputy Directors in the State for monitoring compliance.

Copy submitted to :

The Drugs Controller General (India), CDSCO, New Delhi for information. (by e-mail)