DCGI orders withdrawal of cancer drug Olaparib for certain treatments

"The matter has been reviewed in consultation with SEC (Oncology) experts in a meeting held on 19.03.2024 and 20.03.2024 at CDSCO," the communication stated.

New Delhi: The Drug Controller General of India has asked drug regulators in all states and Union territories to withdraw AstraZeneca's anti-cancer drug Olaparib tablets for treatment in patients who have received three or more prior lines of chemotherapy. State regulators have been asked to direct manufacturers of the drug to discontinue marketing of the drug for the treatment of patients with gBRCA mutation and advanced ovarian cancer and breast cancer due to potential adverse effects and submit the revised package insert.

The drug may continue to be marketed for other approved indications, the apex drug regulator said.

In a communication sent to the regulators on May 16, the DCGI stated that the firm AstraZeneca Pharma India Limited has submitted an application to them 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 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 a meeting held on 19.03.2024 and 20.03.2024 at CDSCO," the communication stated.

The communication stated that the firm presented the clinical evidence for the withdrawal of indication of Olaparib tablets.

"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... and submit the revised package insert. The drug may continue to be marketed for other approved indications," it added.

The communication added that the 100 mg and 150 mg tablets were initially approved by the DCGI on August 13, 2018 for treatment of patients for treatment of adult patients with ovarian cancer and certain forms of breast cancer.

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