

Pharma firms asked for side-effects of common medicines

The instructions have been given following recommendations by the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) of the Indian Pharmacopoeia Commission (IPC).



New Delhi: India's drug regulator has issued safety warnings to commonly used drugs, linking the medication to serious side effects. In a letter issued this week it asked the manufacturers to mention that commonly used

antibiotic doxycycline can cause side effects like restlessness, anxiety, irritability, nervousness and dizziness. It has instructed the state regulators to make sure that the adverse drug reaction is mentioned in the caution section of the package insert and promotional literature of the drug.

Similarly, it has been found that anti-thyroid medicine carbimazole can cause agranulocytosis, a life-threatening problem. The drug regulator has also asked the companies to include it as an adverse drug reaction into the prescribing information leaflet (PIL) of the carbimazole-based medical products marketed in the country.

The instructions have been given following recommendations by the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) of the Indian Pharmacopoeia Commission (IPC).

The IPC has forwarded recommendations arising from the assessment of adverse drug reaction (ADR) reports pertaining to doxycycline formulations. The PvPI has evaluated the patient population incidence-adverse drug reactions (PPIs-ADR) based on individual case study reports (ICSR) and made recommendation to Central Drugs Standard Control Organisation (CDSCO) to take necessary measures to incorporate "CNS side effects (restlessness, anxiety, irritability, nervousness, and dizziness)" as an adverse drug reaction into the PIL of the doxycycline-based medical products marketed in the country," said the letter.

ET has seen a copy of the letter.

Panel Recommendations

The recommendations were also reviewed by the subject expert committee (SEC) on antimicrobial and anti-parasitic in its meeting this January. "After detailed deliberations, the committee recommended that CDSCO should request the state drugs controllers to direct the manufacturers to incorporate CNS side effects with doxycycline. The committee also recommended to include above side effects in the caution section of the PIL," the letter further said.

Likewise, the SEC committee recommended to direct the manufacturers to incorporate agranulocytosis associated with carbimazole as ADR in the corresponding PIL of the drug.

The drug regulator has asked the state drug regulators to intimate its office regarding the action taken in this regard.

News Source:

<https://pharma.economictimes.indiatimes.com/news/policy-and-regulations/pharma-firms-asked-for-side-effects-of-common-medicines/128545693>