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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Marg,
New Delhi. ,

Dated

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Alert on Pholcodine containing cough and cold remedies

The WHO has alerted about a safety concern which has been identified with Pholcodine containing cough and cold remedies. WHO through its news page had alerted healthcare professionals and regulatory authorities of the risk of anaphylactic reactions in people who have taken Pholcodine containing cough and cold remedies at least 12 months prior to surgical procedures involving the administration of general anesthesia with neuromuscular blocking agents (NMBAs).

2. Further, many regulatory authorities have reviewed and withdrawn/ restricted Pholcodine containing cough and cold remedies. Some regulatory agencies have issued warnings to the healthcare professionals and consumers.

3. The matter was referred to Subject Expert Committee (Antimicrobial and Antiviral) in meeting dated 28th June 2023 to seek expert opinion on the safety alert published by WHO on Prior use of Pholcodine containing cough and cold remedies and risk of perioperative anaphylactic reactions to neuromuscular blocking agents (NMBAs) for any regulatory intervention required on the matter.

4. The committee after detailed deliberation recommended to issue advisory to Doctors, healthcare professionals and consumers.

Accordingly following advisory on Pholcodine containing cough and cold remedies is provided as follows:

I. To Doctors and healthcare professionals:

1. To advice patients to stop taking Pholcodine containing cough and cold remedies and suggest an alternative to treat their symptoms.
2. To verify whether the patient scheduled to take general anesthetics containing neuromuscular blocking agents (NMBAs) have taken Pholcodine containing cough and cold remedies in previous 12 months and also be aware of anaphylactic reactions in such patients.

II. To Consumers:

1. To be careful in taking Pholcodine containing cough and cold remedies and consult the Doctor or Pharmacist to suggest an alternative treatment.
2. In case of patients who are going to take general anesthetics and have taken Pholcodine containing cough and cold remedies in past 12 months should be reported to the Doctor or Healthcare professional prior to the procedure.


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