



To:

Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum
The Head of Medical Services in LNG Oman
Director of Pharmacy of Qaboos Comprehensive Cancer Care & Research Center
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
Marketing Authorization Holders & Pharmaceutical Companies
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 69 dated 12/4/2023 regarding Use of Pholcodine-containing cough and cold remedies and risk of preoperative anaphylactic reactions to neuromuscular blocking agents.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Section Head PV for Herbal Medicine & Health Products.
- Section Head PV for Human Medicine
- Section Head of Central Drug Information



Circular No. 69/ 2023

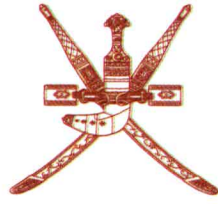
21-09-1444 H
12-04-2023

Subject: Use of Pholcodine-containing cough and cold remedies and risk of preoperative anaphylactic reactions to neuromuscular blocking agents.

The Gulf Health Council (GHC) as well as World Health Organization (WHO) and European Medicine Agency (EMA) have issued safety alerts about the risk of anaphylactic reactions in people who have taken Pholcodine-containing products and recommended the withdrawal of marketing authorizations for these products.

Following a review by the EMA, the review supports a previously suspected link between Pholcodine-containing medicines and a risk of anaphylactic reactions (a sudden, severe and life-threatening allergic reaction) to medicines called neuromuscular blocking agents (NMBAs) which are used as muscle relaxants during general anaesthesia. After investigating this safety issue, the registration of all Pholcodine-containing medicines has been canceled and recalled by some medicinal regulatory authorities.

Pholcodine is an opioid medicine that is used in adults and children for the treatment of non-productive (dry) cough and, in combination with other active substances, for the treatment of symptoms of colds and flu. It works directly in the brain, depressing the cough reflex by reducing the nerve signals that are sent to the muscles involved in coughing.



The available data showed that use of Pholcodine in the 12 months before general anaesthesia with (NMBA) is a risk factor for developing an anaphylactic reaction to NMBAs.

The above mentioned substance is available in Oman as Pholcodine injection and capsules. Healthcare professionals should:

1. Stop prescribing Pholcodine-containing medicines and consider appropriate treatment alternatives.
2. Advise patients to stop taking Pholcodine-containing medicines.
3. Healthcare professionals should also check whether patients scheduled to undergo general anaesthesia with NMBAs have used Pholcodine in the previous 12 months, and remain aware of the risk of anaphylactic reactions in these patients.

Health care professionals should follow the above recommendations until further decisions and actions and report any adverse drug reactions and drug related problems to the pharmacovigilance department DGPA&DC.

Dr. Mohammed Hamdan Al Rubaie
Director General

