



**TO: DDG: CHIEF OF OPERATIONS/ CHIEF DIRECTORS/ DIRECTORS
HEADS OF INSTITUTIONS
HEAD OF HEALTH: CITY OF CAPE TOWN
N.B. FOR CIRCULATION TO ALL MEDICAL, PARAMEDICAL, PHARMACEUTICAL AND
NURSING PERSONNEL**

CIRCULAR NO. H.....48...../2023

MEDICINE RECALL AND WITHDRAWAL FROM MARKET: PHOLCODINE SYRUP

Background

An urgent medicine recall and withdrawal from market has been initiated for all pholcodine containing syrups by the manufacturers, in consultation with the South African Health Products Regulatory Authority (SAHPRA). A recall and withdrawal notice received from one of the manufacturers, iNova Pharmaceuticals, has been attached as Appendix 1.

Facility requirements

Facility pharmacies are to collect and quarantine all unused pholcodine 15mg/ 5ml syrup batches.

A call must be logged with the CMD Helpdesk by no later than 21 April 2023, informing of the total quantity of pholcodine 15mg/ 5ml syrup to be uplifted. A single pick-up per facility will be arranged.

Stock will not be replaced. Facilities will be credited for the returned stock.

Central Hospitals are to arrange directly with the relevant supplier(s) for upliftment via their respective pharmacy departments.

All orders placed by demanders with the CMD for pholcodine 15mg/5ml syrup will be cancelled.

CMD contact details:

Email: CMDHELPDESK.CMDHELPDESK@westerncape.gov.za

Tel: 021 483 2376 or 2437

Your co-operation is appreciated.

Sincerely



MS K LOWENHERZ

DIRECTOR: MEDICINE MANAGEMENT, LABORATORY & BLOOD SERVICES SUPPORT

DATE: 13 / 4 / 23





Date: 29 March 2023

URGENT MEDICINE RECALL – CLASS II TYPE B

Dear Customer/Healthcare Professional

Inova Pharmaceuticals (Pty) Ltd, in consultation with the South African Health Products Regulatory Authority (SAHPRA) is taking a decision to recall and withdraw the following products from the market based on the safety findings outlined below:

Product name	Registration number	Active Ingredient(s) per 5 ml	Batch numbers	Pack size
Pholrex Junior	29/10.1/0013	Pholcodine 5 mg	All batches	100 ml 200 ml
Pholrex Forte	32/10.1/0116	Pholcodine 15 mg	All batches	100 ml 200 ml
Pholrex Plus	46/16.5/0711	Pholcodine 5 mg; Phenylephrine HCl 3.3 mg	All batches	100 ml 200 ml

The decision to recall pholcodine containing medicines is linked to a recently concluded French clinical study (the ALPHO Study) which reviewed a possible association between pholcodine and very rare but serious anaphylactic reactions to medicines called neuromuscular blocking agents (NMBAs) used in anaesthesia.

Data from the ALPHO study indicates that the use of pholcodine in the 12 months leading up to anaesthesia using NMBAs increases the risk of developing an anaphylactic reaction. The relationship between pholcodine and anaphylactic reactions to NMBAs has been hypothesised over the last decade, however, until the ALPHO study no association had previously been established in any clinical study globally. There is still no evidence showing causal risk.

Based on the available data, there are currently no possible effective risk minimization measures which have been identified to mitigate against this risk, nor to identify a patient population for whom the benefits of pholcodine outweigh the risks.

Due to these considerations and the nature of the adverse reactions (including its unpredictability and clear timelines to onset), SAHPRA has recommended the withdrawal of all pholcodine-containing medicines from the South African market.

Inova Pharmaceuticals (Pty) Ltd, Reg No. 1952/2016/06/07
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 Directors: K. J. Hampton and M. Dekker

**Actions to be taken by customers/Healthcare professionals**

- Distribution and sale of the above-mentioned products should be ceased immediately.
- Please return all batches of Pholrex Junior, Pholrex Forte and Pholrex Plus to your wholesaler/distributor.
- We request that you retain this letter and place it in a prominent position for one month in case stock is in transit.

Yours Sincerely,

Kristin Holmes

Responsible Pharmacist

Name	Title	Qualification	Designation	Contact Number
Kristin Holmes	Mrs	MSc; B. Pharm	Responsible Pharmacist	Tel: (011) 087 0500/082 941 7152 E-mail: k.holmes@inovapharma.com