	Reference Number **CASE_35**

Rapid Alert Notification of a Quality Defect

1. To: The Regulatory Authority	
2. Product Recall Class & Type of Defect: Class: II Type: B	3. Falsification / Fraud (specify): Not Applicable
4. Product: **PHOLTEX Syrup Range** **(Pholtex Junior; Pholtex Forte; Pholtex Plus)**	5. Marketing Authorisation Number: Not Applicable For use in humans
6. Brand/Trade Name: PHOLTEX Syrup Range: (Pholtex Junior; Pholtex Forte & Pholtex Plus)	7. INN or Generic Name (APIs): **Pholtex Junior** (polcodine 5 mg), **Pholtex Forte** (pholcodine 15 mg), **Pholtex Plus** (Pholcodine 5 mg with Phenylephrine HCl 3,3 mg)
8. Dosage Form: Syrup	9. Strength: (see section 7.)
10. Batch number(s) (and bulk, if different): All batches (see section 18)	11. Expiry Date: Expiry dates for all batches (see section 18)
12. Pack size and Presentation: 100 ml and 200 ml	13. Date of Manufactured (for batches above): All batches (see section 18)
14. Marketing Authorisation Holder iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007, South Africa. Contact person: Kristin Holmes: k.holmes@inovapharma.com Telephone: + 27 11 087000 / +27 829417152	
15. Manufacturer (Compounder): 15.1 iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007, South Africa.	16. Recalling Firm (if different): Not Applicable Contact Person: Not Applicable Telephone: Not Applicable
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1): Not Applicable	
17. Recall Number Assigned (if available): Not Applicable	

18. Details of Defect/Reason for Recall and for withdrawal from the market:

iNova Pharmaceuticals (Pty) Ltd, in consultation with SAHPRA has taken a decision to recall AND to withdraw **all pholcodine containing medicines completely from the market**.
The decision to recall AND to withdraw 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. It is further confirmed that there is still no evidence showing causal risk. However, based on the available data, there are currently no possible risk minimization measures which have been identified to mitigate against effective 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.

19. Information on distribution including exports (type of customer, e.g. hospitals): The company confirms that the batches were distributed only in South Africa.

For more information about exporting or batch destination, please contact the Marketing Authorisation Holder and/ or local Regulatory Authority (SAHPRA) **portia.nkambule@sahpra.org.za/ maphutheho.selikane@sahpra.org.za**

20. Action taken by Issuing Authority: Conduct a recall (Class II, Type B):
https://www.sahpra.org.za/product-recalls/

21. Proposed Action: SAHPRA is monitoring the recall.

22. From (Issuing Authority):

South Africa Health Products Regulatory Authority (SAHPRA) Loftus Park, Building A, 402 Kirkness St, Arcadia, Pretoria, 0083, South Africa.

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Signed:  Date: 31/03/2023 02:16:10 PM

Deon Poovan – Senior Manager: Inspectorate & Regulatory Compliance