



Medicines Control Authority of Zimbabwe

106 Baines Avenue
Tel: +263 242 736 981-7
708 255 / 792 165 / 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/18b/145/2023

14th April 2023

Inova Pharmaceuticals (Pty) Ltd,
15E Riley Road, Bedfordview 2007,
Johannesburg,
SOUTH AFRICA

ATT: Mrs. Praenisha Ramnath

Dear Sir/Madam,

RE: Instruction to recall the following pholcodine-containing products:

- i. **Phenylephrine hydrochloride/Pholcodine 3.3mg/5mg per 5ml syrup (Pholtex Plus), File 5734; and**
- ii. **Pholcodine 15mg/5ml syrup (Pholtex Forte), File 3624**

Reference is made to the following:

- i. Your correspondence regarding the significant safety issue (SSI) associated with pholcodine-containing medicines and the attached highlights of the Pharmacovigilance Risk Assessment Committee (PRAC) meeting held on the 28th of November, 2022 to the 1st of December 2022; and to
- ii. The notification of withdrawal of pholcodine-containing products from the South African market that you provided.

The submissions were reviewed and tabled at the 221st Pharmacovigilance and Clinical Trial Committee meeting held on the 5th of April 2023 and at the 574th Registration Committee meeting held on the 12th of April 2023.

The Authority is of the view that there are no effective measures to minimize this risk, nor is there an identified patient population for whom the benefits of pholcodine outweigh its risks. As such, due to the seriousness of the safety risk, all pholcodine-containing products should be immediately recalled in line with the procedures in the Guidelines for the Notification of Medicinal Product Problem or Defect and Recall Procedure in Zimbabwe, Rev 0 February 2022 (MCAZ/LED/GL-15). You are therefore required to complete the attached Recall Notification Form (LEF 62) and submit it to MCAZ within 48 hours of your receipt of this letter.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

R.T. Rukwata (Mr.)

DIRECTOR-GENERAL

cc: Pulse Medical Care (Pvt) Ltd, 15 Borgward Road, Msasa, **HARARE**

