FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority

Head Office
Mail: P.O. Box CT 2783, Cantonments-Accra, Ghana
(+233)-302-233200/235100
(+233)-551-112223/4/5 (Hotline)
Email: fda@fda.gov.gh
Digital Address: GA-237-7316

FDA/HPT/VVC/SMD/VGU/23/0022

27th January 2023

Dear Healthcare Professional,

SAFETY ALERT: - RECALL OF LUPIN's QUINAPRIL HYDROCHLORIDE TABLETS

The Food and Drugs Authority (FDA) wishes to bring to your notice a voluntary recall by Lupin Pharmaceuticals Inc. of four batches of its antihypertensive drug, Quinapril hydrochloride Tablets, due to the presence of N-Nitroso-Quinapril, a cancer-causing impurity.

Quinapril hydrochloride is indicated for the treatment of hypertension and in the management of heart failure as adjunctive therapy when added to conventional therapy including diuretics and/or digitalis.

Although, the FDA has **not approved** Quinapril hydrochloride for use in Ghana or granted approval for its importation on a named patient basis, this information is being brought to your notice to enable you advise your patients who may have been prescribed Lupin's Quinapril Tablets from other jurisdictions where they are approved for use.

The recall follows recent testing of the products that indicated that N-nitroso-quinapril was present in these batches above Acceptable Daily Intake (ADI) level.

The affected products are Quinapril hydrochloride tablets of strength 20mg and 40mg with batches listed below:

Batch	Expiration Date	Strength	Package Type
G102929	APR 2023	20 mg	1 x 90 count bottle
G100533	DEC 2022	40 mg	1 x 90 count bottle
G100534	DEC 2022	40 mg	1 x 90 count bottle
G203071	MAR 2024	40 mg	1 x 90 count bottle

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables but these impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

Advice to patients:
Patients taking Lupin's Quinapril tablets are not at an immediate risk of developing cancer. The risk, however, increases with long term exposure to the impurity at levels above the ADI. Patients taking any of the affected batches should contact their healthcare provider for advice.

Advice to healthcare professionals:
Healthcare professionals with patients taking these medicines should assess if their products are affected and provide alternatives.

The FDA would also like to advice patients and healthcare professionals to report adverse reactions to all products including **lack of therapeutic effect** and **medication errors** through the following:

- Download and complete the Med Safety App (Google Play Store or App Store)
- Complete and submit the report online at http://adr.fdaghana.gov.gh/patient.php;
- Call Mobile No. 024 4310 297
- Call Hot line No. 0308250070
- Download and complete the Adverse Drug Reaction (ADR) Form, then submit it at the nearest heath facility

Yours faithfully,

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER