MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

PRESS STATEMENT

FLUOROQUINOLE ANTIBIOTICS, HYDROCHLORTHIAZIDE PRODUCTS AND VALSARTAN CONTAINING PRODUCTS

The attention of the Pharmacy and Poisons Board (PPB) has been drawn to an article published in the "***Daily Nation dated 14th March 2019; Page 8 titled: Cancer -Tied drugs still being sold".***

PPB would like to clarify as follows;

1. ***FLUOROQUINOLE ANTIBIOTICS, HYDROCHLORTHIAZIDE PRODUCTS***

In January 2019, Pharmacy and Poisons Board issued two safety updates to health care providers on Fluoroquinolone & Quinolones antibiotics and Hydrochlorothiazide containing antihypertensives. See Link: https://pharmacyboardkenya.org/e-shots.

Fluoroquinolones and Quinolone antibiotics

These antibiotics used to treat various bacterial infections have been associated with increased risk of disabling adverse drug reactions affecting muscles, tendons and the nervous system.

HealthCare Providers (HCPs) have been advised to prescribe Fluoroquinolones & Quinolones only when there are no other antibiotics that can be used to treat the infection because of the nature of these adverse events. Importantly, Fluoroquinolones & Quinolones should generally be avoided in patients who have previously had serious side effects with a Fluoroquinolone or Quinolone antibiotic. They should be used with special caution in the elderly, patients with kidney disease and those who have had an organ transplant because these patients are at a higher risk of tendon injury. Since the use of a corticosteroid with a Fluoroquinolone also increases this risk, combined use of these medicines should be avoided

Hydrochlorothiazide (HCTZ)

Safety updates on Hydrochlorothiazide an antihypertensive medicine was issued following a study that claimed a link to skin cancer on exposure to sunlight. However, it is important to note that the study was carried out retrospectively, in a white population who are already at a high risk of skin cancer because of their skin color. Therefore, there is no strong evidence to warrant the stoppage of use of HCTZ in our local setting.

Nevertheless, HCPs are advised to encourage the patients not to stop their medication but to look out for any suspicious lesions on their skin and report to the nearest health facility or HCP. In addition, HCPs need to take proper history of patients so that those who may be genetically predisposed to skin cancer because of family history are given alternative medicines.

This is therefore a routine post authorization safety update based on epidemiological studies that reported increase in the risk of the Adverse Drug Reactions (ADRs) in certain

populations, however the data does ***not warrant the recall or withdrawal of the products*** rather calls for restrictions in prescribing and closer monitoring of patients using this group of medicines. As medicines continue to be used by large populations, adverse effects that were not picked out during clinical trials emerge. Any significant safety updates on medicines such as those of the above mentioned have to be updated on the patient information leaflet/medicines insert.

The healthcare providers are therefore called upon to be vigilant and report any of the suspects adverse events to PPB.

Information to patients:

Fluoroquinolone Antibiotic: Patients should contact your healthcare provider immediately if you experience any serious side effects while taking your fluoroquinolone medicine. Some signs and symptoms of serious side effects include tendon, joint and muscle pain, a "pins and needles" tingling or pricking sensation, confusion, and hallucinations. Patients should talk with your health care professional if you have any questions or concerns.

Hydrochlorothiazide: Patients should regularly check for and report any suspicious skin lesions or mole. Inform providers if you have had treatment for skin cancer before or have a family history of cancer.

2. ***VALSARTAN CONTAINING PRODUCTS:***

Valsartan, is an active pharmaceutical ingredient (API) used either alone or in combination with other active pharmaceutical ingredients for the treatment of hypertension. In July 2018, PPB issued an alert on a recall instituted on some products containing valsartan. The recall was instituted after reports of contamination of specific valsartan active pharmaceutical ingredient manufactured in different countries and used to manufacture valsartan containing products. ***The recall affected only those products and batches that contained the affected valsartan API that had been contaminated.***

PPB issued a recall alert of the following batches (see link https://pharmacyboardkenya.org/e-shots)of Valsartan containing products that were manufactured using the Active Pharmaceutical Ingredients sourced at Zhejiang Huahai Pharmaceuticals, based in Linhai, China**.**

Information to patients:

There are other valsartan products in the market not affected by the recall hence your healthcare provider will guide you appropriately.

PPB reminds the public that these medicines should only be obtained on prescription from a qualified medical practitioner.

We are also encouraging consumers and healthcare providers to report any suspected adverse drug reactions or suspected poor-quality medicines/vaccines to www.pv.pharmacyboardkenya.org.

CONCLUSION

As indicated above, guidance was provided to HCPs through an alert on use of Fluoroquinolone & Quinolone antibiotics and Hydrochlorothiazide as well as on the recall of valsartan containing products.

Chief Executive Officer
14th March 2019