Medical Product Alert No. 03/2025

Public Health Alert Against the Purchase and Use of Counterfeit Herceptin® 600mg/5ml in Vial (Trastuzumab Solution for Injection) in Ghana

Alert Summary

The Food and Drugs Authority (FDA) Ghana has received a formal notification from Roche Products Ghana Ltd. regarding the confirmed circulation of counterfeit Herceptin® 600mg/5ml (Trastuzumab Solution for Injection) in Ghana. The counterfeit product identified with **batch number A8519**, does not correspond to any genuine batch of the product manufactured and marketed by Roche. The counterfeit product was reportedly presented by a patient in a hospital in Kumasi. Upon inquiry, the patient claimed the product was bought in Nigeria.

Herceptin is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) as monotherapy for the treatment of patients who have received at least two chemotherapy regimens for their metastatic disease or in combination with medicines for the treatment of patients who have not received chemotherapy for their metastatic disease. It is also used in combination with aromatase inhibitors for the treatment of postmenopausal patients with hormone-receptor positive MBC.

This public health alert serves to inform healthcare providers, regulatory agencies, and the general public of the potential health risks posed by the counterfeit product and to initiate immediate mitigation efforts.

How to Identify Counterfeit Herceptin® 600mg/5ml

The counterfeit Herceptin® 600mg/5ml solution for injection can be identified by the following:

- **Batch Number**: A8519 is not a valid Roche batch and not traceable in Roche's manufacturing and distribution systems.
- **Packaging Differences**:
    - Font type inconsistencies.
    - Misplacement of label text and variable data.
    - Tamper-evident seals do not match those used on authentic Roche packaging.

Risks Posed by Counterfeit Herceptin® 600mg/5ml

1. The counterfeit product may contain substandard, falsified or no active pharmaceutical ingredient (trastuzumab), rendering treatment ineffective.

2. Unknown chemical contents pose a risk of adverse drug reactions, including allergic reactions, systemic toxicity, or other severe health outcomes.

3. Use of falsified oncology products compromises the integrity of therapeutic regimens, potentially leading to disease progression or mortality.

Advice to Healthcare Providers and the General Public

Healthcare Providers

Pharmacies and healthcare facilities are warned against the sale and distribution of counterfeit medicinal products including **Herceptin® 600mg/5ml which is a contravention of** Section 123 of the Public Health Act of 2012, Act Anyone found distributing or offering for sale counterfeit products will be severely sanctioned.

Public

Purchase Herceptin® from authorized pharmacies and healthcare facilities only.

Review product packaging for irregularities, including batch number, label alignment, and seal integrity.

Promptly report any suspected counterfeit Herceptin to the National Medicines Regulatory Authority

- Submit any suspected products to the nearest healthcare facility or directly to the offices of the FDA

Action by the FDA

Post Market Surveillance (PMS) activities are ongoing to identify, seize and take regulatory action on any counterfeit Herceptin® 600mg/5ml Solution for Iinjection found in the distribution chain.

Public education on the dangers of substandard and falsified medical products is also ongoing.

IMAGES OF PRODUCT

Genuine Product

Counterfeit Product