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ETHIOPIAN FOOD & DRUG AUTHORITY

PUBLIC ALERT NOTICE ON COUNTERFEITED HERCEPTIN 440MG

Date: 11th July, 2024

To: All medicine Importers, Wholesalers, Retailers and General Public

Medical Product Alert (01/2024)

Ethiopian Food and Drug Authority is mandated by article 38 of the Food and Medicine Administration Proclamation 1112/2019 to perform or conduct periodic monitoring of the quality, safety, and efficacy of medicines through Surveillance.

Reference made to the notifications received from Hoffman Roche ltd commercial representative office in Ethiopia and alert notice circulated by Kenya, PPB. On the bases of this, the Authority has conducted preliminary assessment regarding to the market authorization status of the products under question. On this background, although Herceptin 440mg is registered and authorized to be marketed in Ethiopia, the Authority confirmed that the drug product for which it details described in table 1 below was not imported to Ethiopian market through authorized importers and distributers. Moreover, the legal representative office declared that the drug is not exported to Ethiopia, but Roche Kenya was notified by internal commercial colleague in Ethiopia regarding a unit of Herceptin 440mg which was purchased by a patient in Ethiopia from unverified source. The picture displaying part of the drug folding box & picture of drug vial showing the batch number H5170 confirmed counterfeited and the same confirmed counterfeited drug product is circulating in Kenya.

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Table 1: Product details:

Brand Name	Generic Name	Manufacturer	License Holder	Formulation	Batch Number	Reported from
Herceptin 440mg	Trastuzumab	Genentch Inc (United States of America)	F.HOFFMANN-LA ROCHE LTD	Powder for concentrate for solution for infusion	05830083	Kenya and confirmed to be counterfeit
					H5170	Ethiopia

From the above details of the drug product we can conclude that, although this falsified batch product was identified in Kenya, it may likely have been distributed to Ethiopia through informal markets. Consequently, it is important to detect and remove it from circulation to prevent harm to patients.

Therefore, the Authority would like to alert medicine importers, distributors, retailers, and healthcare providers to be alert and vigilant within the supply chain to avoid the importation, distribution, sale, and administration or use of falsified or substandard medicinal products. All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked.

Healthcare professionals and consumers are advised to report any suspicious substandard and falsified medicines to the nearest EFDA office or make free call using free call service number 8482 or contact via email: contactefda@efda.gov.et

Advice to the public:

If you have this counterfeit product, please DO NOT use it. If you, or anyone you know, have used this product, or suffered any adverse reaction/event after use, you are advised to seek immediate medical advice from a qualified healthcare professional.
Should you need any further clarification, please do not hesitate to contact the Authority

Seyoum Wolde

Deputy Director General-Medicine Sector

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