Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-1493

23 JUN 2021

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Counterfeit (RoActemra) 20 mg/mL Concentrate for solution for infusion Tocilizumab 400mg/20mL**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit (RoActemra) 20 mg/mL Concentrate for solution for infusion Tocilizumab 400mg/20mL:

Authentic	Counterfeit
 Lot No.: B3044B04	 Lot No.: 83044804 Note: • The labeled vial does not correspond to genuine Roche packaging material: -Poor printing quantity of the label -Different flip-off cap and crimping cap

Figure 1. Comparison between the Authentic and Verified Counterfeit (RoActemra) 20 mg/mL Concentrate for solution for infusion Tocilizumab 400mg/20mL

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

The FDA together with the Marketing Authorization Holder (MAH), Roche (Philippines) Inc., have verified that the above-mentioned sample drug product is counterfeit.

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of this drug product with the abovementioned features of a counterfeit drug product. The importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009, and Republic Act No. 8203 or the Special Law on Counterfeit Drugs. Anyone found selling the said counterfeit drug product will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of counterfeit health products, kindly e-mail us via **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20210618084739