Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 AUG 2021

FDA ADVISORY
No. 2021-2209

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Co-Amoxiclav (Clavistan-625) 500 mg / 125 mg Film Coated Tablet**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit Co-Amoxiclav (Clavistan-625) 500 mg / 125 mg Film Coated Tablet:

Authentic

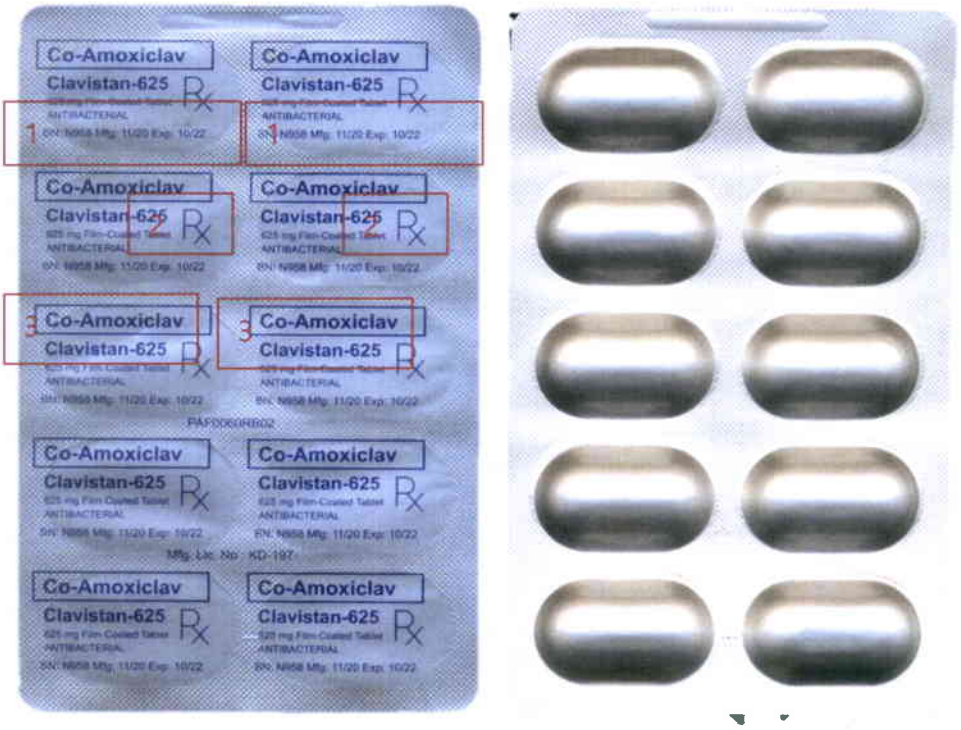

Figure 1. Comparison between the Authentic and Verified Counterfeit Co-Amoxiclav (Clavistan-625) 500 mg / 125 mg Film Coated Tablet (Expiry Date: 12 2023)

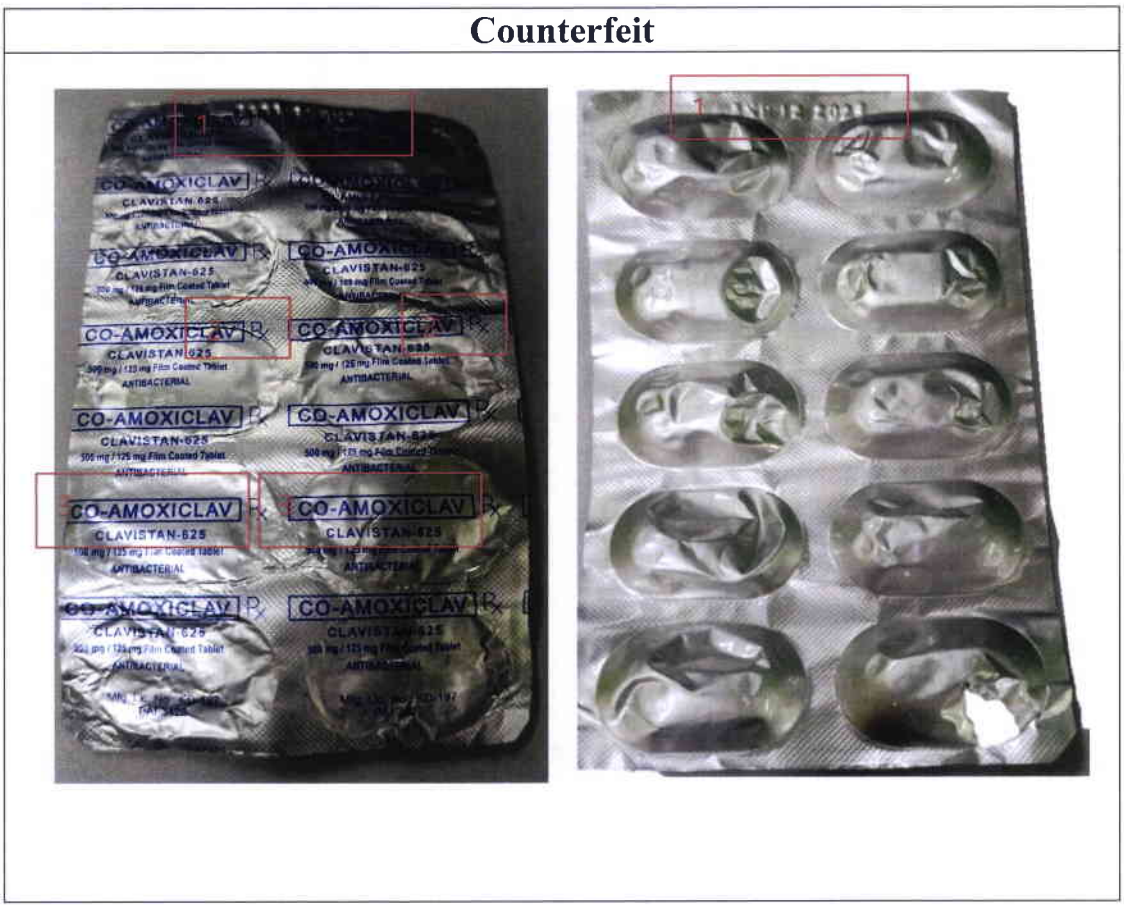

Figure 2. Comparison between the Authentic and Verified Counterfeit Co-Amoxiclav (Clavistan-625) 500 mg / 125 mg Film Coated Tablet (Expiry Date: 12 2023)

The FDA together with the Marketing Authorization Holder (MAH), Hexagon Healthcare Corporation, have verified that the above-mentioned sample drug product is counterfeit. The comparison of the collected counterfeit drug product and the distinguishing feature of the authentic are as follows:

Authentic	Counterfeit
1. The blister pack has batch number, manufacturing date, and expiry date on the lower part of the word ANTIBACTERIAL.	1. The blister pack has an engraved expiry date on the upper middle part and has no batch number.
2. The Rx symbol is larger in font and is printed vertically on the right side covering the space on the right of the "brand name, the 625 mg and antibacterial" print	2. The Rx symbol is smaller in font and printed on the right side of the generic name only
3. The generic and brand names are printed in lower cases with the first letter of the name in capital letter.	3. The generic and brand names are printed in all capital letters

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 product only from FDA-licensed establishments. Always check if a product is registered with the FDA by using the FDA Verification Portal feature accessible at **http://verification.fda.gov.ph.**

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.

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