Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20202213

29 DEC 2020

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Fluarix™ 0.5ml I.M./S.C.**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit Fluarix™ 0.5ml I.M./S.C.:

Counterfeit

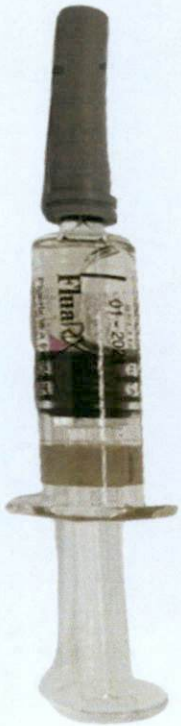

Figure 1. Verified Counterfeit Fluarix™ 0.5ml I.M./S.C. with Lot No. AFLUA829AA
Type of Influenza Vaccine: Trivalent
(Manufacturing date: 02-2020; Expiry date: 01-2021)

GlaxoSmithKline (GSK) has discontinued production of the trivalent vaccine (Fluarix) since 2016 and has shifted to quadrivalent vaccine (Fluarix-Tetra) starting 2017. GSK has stopped using the brand Fluarix because that was for trivalent format which is no longer registered.

Authentic

Counterfeit

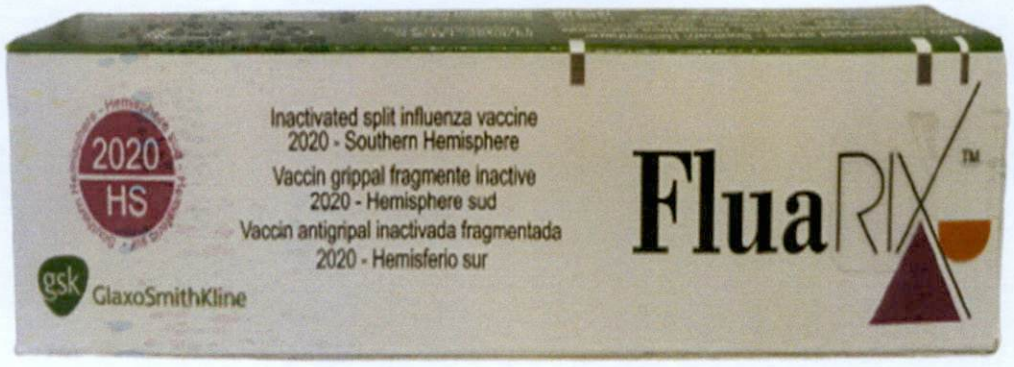

Figure 2. Comparison between the Authentic and Verified Counterfeit Fluarix™ 0.5ml I.M./S.C. with Lot No. AFLUA829AA (Manufacturing date: 02-2020; Expiry date: 01-2021)

Currently, the **only** registered and marketed flu vaccine of GSK is the quadrivalent Fluarix-Tetra SH 2020 as seen below:

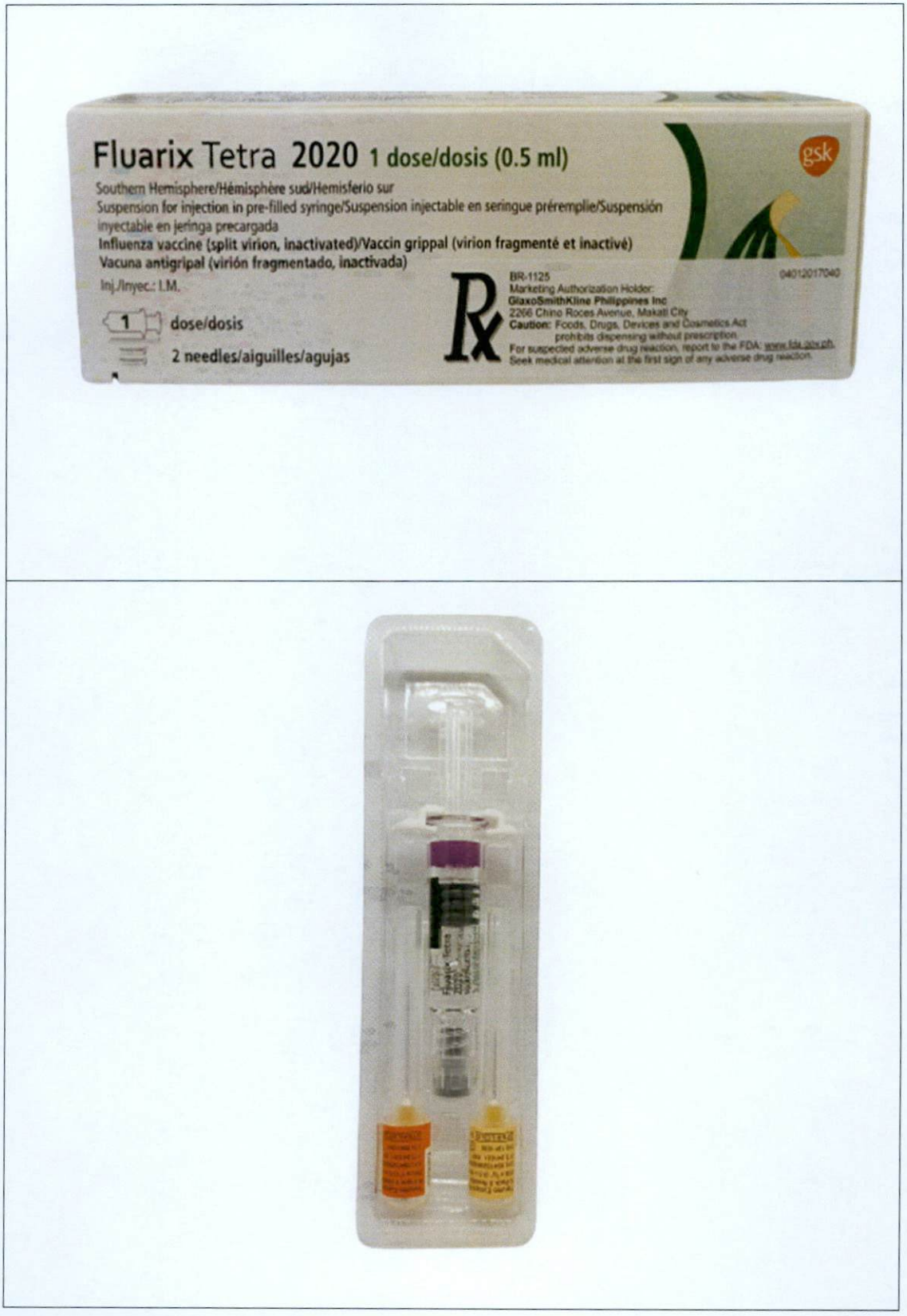

Figure 3. Registered Fluarix Tetra 2020 SH 1 dose/dosis (0.5 ml)

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.

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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Director General

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