



FDA ADVISORY
No. **2022-1966**

09 DEC 2022

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Unauthorized Selling of Herpes Zoster "SHINGRIX" Vaccine

The Food and Drug Administration (FDA) warns all healthcare professionals and the public on significant risks associated with the use of the drug product Herpes Zoster vaccine [SHINGRIX] from unauthorized sources.

A report has been received by this Office on the alleged selling of the product below:



Figure 1: Zoster Vaccine Recombinant, Adjuvanted [SHINGRIX]

SHINGRIX is a product of GlaxoSmithKline Philippines (GSK) Inc. that is currently undergoing evaluation for its monitored release registration application. To date, there is no authorized importation nor distribution yet of the said vaccine.

Buying medicines without approval from FDA can pose serious health risks. Furthermore, a medicine bought from an unlicensed establishment may contain no active ingredient, too much or too little active ingredient which may result in the condition/ailments not being treated correctly or worst, may lead to fatal outcome. Also, the manufacturing processes of such medicine are not guaranteed and may not be stored correctly in accordance with its appropriate storage and handling condition.



Healthcare professionals, patients and consumers are strongly advised to only access authorized medicines/drug products through FDA licensed establishments. You may verify its authorization and license through the FDA Verification Portal (<https://verification.fda.gov.ph>).

To report on the illicit and illegal distribution and selling of this product, kindly email us at report@fda.gov.ph or 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 the suspected adverse drug reactions (ADR), kindly report immediately through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> by filling out the required fields.

For more information and inquiries, please email us at info@fda.gov.ph.


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