

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. <u>2017-</u>265 06 SEP 2017

TO:

THE GENERAL PUBLIC

SUBJECT:

Public Warning Against Accessing Japanese Encephalitis Vaccine and other Vaccines from Online Sellers and other Unauthorized

Distributors/Retailers

The Food and Drug Administration (FDA) has received several reports of Japanese Encephalitis vaccines and other vaccines being sold or offered for sale online (e.g. social media and websites) and from other unauthorized distributors or retailers.

Following R.A. No. 3720, as amended by R.A. No. 9711, all establishments that sell or offer for sale vaccines and other drug products must first secure appropriate License to Operate (LTO) or authorization from FDA prior to engaging such activities. The issuance of LTO is proof that the establishment is legitimate and complies with good distribution and storage practices, especially cold-chain management which is required for temperature-sensitive products such as vaccines.

In view of these reports, the FDA warns the public against availing vaccines from online sellers and other unauthorized distributors or retailers. Consumers availing from these unauthorized distributors or retailers are at risk of buying vaccines of poor quality, compromised by non-compliance to the required standards of FDA, or worse, at risk of buying counterfeit products.

To determine whether an establishment is licensed with the FDA, kindly validate with the FDA website. Just type in the name of the establishment in the search box (upper right corner).

The FDA has already initiated the conduct of regulatory actions together with concerned marketing authorization holders (MAHs) on the proliferation of vaccines being sold or offered for sale online and from other unauthorized distributors or retailers.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure the sale or offer for sale of vaccines by unauthorized distributors or retailers are stopped in their jurisdiction.

Continuous conduct of these activities may be reported to the FDA 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 (CDRR) at telephone number (02) 809-5596.

For more information, please email us at info@fda.gov.ph or visit us at fda.gov.ph.

Dissemination of the information to all concerned is requested.

Director General

