Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

04 DEC 2017

FDA ADVISORY
No. 2017-318

TO : **THE GENERAL PUBLIC**

SUBJECT : **Suspension of Sale/Marketing/Distribution of Sanofi Pasteur, Inc.'s Tetravalent Vaccine (Live, Attenuated) (Dengvaxia)**

On 29 November 2017, Sanofi Pasteur, Inc. (Sanofi) released an advisory providing updated information on the Dengue Tetravalent Vaccine (Live, Attenuated), the drug locally registered as Dengvaxia. The advisory contained information on the completion of a post-clinical trial study of the said product indicating potential risk to patients who have *not* had dengue prior to immunization.

In order to protect the general public, the Food and Drug Administration (FDA) immediately directed Sanofi to SUSPEND the sale/distribution/marketing of Dengvaxia and cause the WITHDRAWAL of Dengvaxia in the market pending compliance with the directives of the FDA. Sanofi was further directed to conduct an information dissemination campaign through Advisories, Dear Doctor Letters and Patient fora.

The FDA is closely coordinating with the Department of Health (DOH) for any adverse events/ reactions that may be reported by the recipients following their immunization of the Dengvaxia, and will immediately take appropriate measures to protect the public.

All drug establishments, including consumers and non-consumer user (e.g. healthcare professionals) are enjoined to take part in the post marketing surveillance of Dengvaxia, by reporting to FDA any incident that reasonably indicates that Dengvaxia has caused or contributed to the death, serious illness, or serious injury to a consumer, a patient, or any person.

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