Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 March 2014

FDA ADVISORY No. 2014-019

SUBJECT: FDA Cautions Medical Practitioners to Attend to Vaccine Cold Chain Management.

Vaccines are sensitive biological substances that can lose their potency when they are exposed to temperatures that are outside the required temperature range of +2 °C to +8 °C or when they are exposed to light. Compliance with cold chain requirements ensures the use of vaccines according to the potency and quality specifications approved by the FDA. It also minimizes wastage of vaccines in clinics, centers and hospitals. The "cold chain" includes all of the equipment and procedures used to maintain the required temperature range of +2 °C to +8 °C from the moment a vaccine leaves the manufacturing plant until the moment it is administered by health workers to a patient.

The FDA is providing this initial advisory to caution hospitals and clinics that were inspected to do corrective and preventive actions immediately.

From December 2-5, 2013, the FDA monitored the storage conditions of vaccines in 18 clinics, managed by around 21 pediatricians and other medical practitioners, in 4 big private hospitals located in Quezon City, Muntinlupa City, and Makati City. The FDA inspectors noted that some of the refrigerators had no temperature monitoring devices and charts that are both important in case temperature adjustment is needed. Other refrigerators contained items other than vaccines, like food and beverages, kitchen utensils, and toothbrush, which indicated unnecessary opening of refrigerators that may result to fluctuation of temperature. Improper stacking of vaccines and other biological products in refrigerators were common in some clinics. In some hospitals, there were no written provisions for contingency or emergency measures in case of breakage or other incident that may arise during handling and storage. Some hospitals allowed medical practitioners to accept delivery of vaccines without passing through the central pharmacy, and to keep delivery receipts. All 4 hospitals, however, have backup generators in case of brownouts.

The FDA is now working with the said hospitals and clinics to correct non-compliance to cold chain requirements. The FDA inspectors will continue to audit other clinics and hospitals.

All medical professionals and their appointed staff are advised to take their pharmaceutical management obligations seriously when handling and storing vaccines in their clinics to afford full protection to their patients from vaccine-preventable diseases. As health professionals, they are reminded to adhere to good pharmacovigilance (PV) practices and to report to FDA all Adverse Event Following Immunization (AEFI).

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To report any AEFI or adverse drug reaction (ADR), kindly email us via report@fda.gov.ph. To facilitate investigation, all health workers are requested to accomplish the ADR or *Bantay Gamot* Report Form online by logging in at the FDA website and clicking on the ADR Report platform (www.fda.gov.ph/sysFDA_WorkFlow/en/classic/63866899151ef25b75f7f59042808866/ADR_Form.php).

All pharmaceutical companies are hereby advised to supply or distribute biological products only to drug outlets, clinics and hospitals that have refrigerators that are able to provide proper and stable temperature.

For more information or clarification, kindly email us at info@fda.gov.ph.

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