Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-026

04 MAR 2016

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Reporting of Suspected Adverse Drug Reaction

Under Republic Act No. 9711, the Food and Drug Administration (FDA) is mandated to strengthen the post-marketing surveillance (PMS) system in monitoring health products. PMS refers to activities involved in safety, efficacy, and quality monitoring of health products, including drug products. This shall also include among others adverse events reporting, product safety update reporting, collection and testing of health products in the market.

To operationalize this mandate, under the same law, all drug establishments, including consumers and non-consumer users (e.g. healthcare professionals) are enjoined to take part in PMS, by reporting to FDA any incident that reasonably indicates that a health product has caused or contributed to the death, serious illness, or serious injury to a consumer, a patient, or any person.

Thus, in the interest of protecting public health and safety, the FDA reiterates to all consumers and healthcare professionals to report any suspected adverse reactions on the use of medicines, and any suspected adverse events on the use of vaccines, using the prescribed adverse drug reactions (ADR) form (http://www.fda.gov.ph/industry-corner/downloadables/265-suspected-adverse-reaction). Reports may be submitted via:

- mail at adr@fda.gov.ph
- fax: +63 2 809-5596
- phone: +63 2 809-5596
- online reporting using the ADR tab at http://www.fda.gov.ph/adr-report-new
- courier at FDA Central office at Civic Drive, Filinvest City, Alabang 1781 Muntinlupa City, Philippines
- or though the nearest DOH-FDA Regional Office

The public is hereby reminded that drug safety is everybody's concern.

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