



21 APR 2017

FDA ADVISORY
No. 2017-131

TO: THE GENERAL PUBLIC

SUBJECT: PUBLIC WARNING AGAINST ACCESSING UNAUTHORIZED IMMUNIZATION PROGRAMS AND OTHER UNAUTHORIZED COMMUNITY PROGRAMS SPONSORED BY DRUGSTORES

On 9 September 2014, the Food and Drug Administration (FDA) issued Advisory No. 2014-067 to announce its plan to authorize pharmacists to administer adult vaccines and other immune products. Under Republic Act (R.A.) No. 10918, otherwise known as the "Pharmacy Law", administration of adult vaccines, as authorized by the FDA, constitutes practice of the profession of pharmacy. Said administration, however, should be supported by a proper training for its safe administration and adverse event following immunization (AEFI). Pharmacists, under the said law, should likewise hold a certificate of training issued by an institution accredited by the Professional Regulation Commission (PRC), to administer adult vaccines.

Under Department of Health Administrative Order (A.O.) No. 2016-0003, drugstores may conduct "other additional activities but may require appropriate regulation or be handled on a case to case basis", but should properly apply for variation of their License to Operate (LTO).

The FDA recently conducted surveillance activities on covered establishments and it was observed, among others, that some drugstores conduct immunization programs, without FDA authorization.

It is important to note that several safeguards must be in place prior to the conduct of drugstore initiated/sponsored immunization programs, such as —

1. Qualification of the person administering the vaccine
2. Dedicated space for the activity
3. Sanitation
4. Compliance to good distribution and storage practices, in particular, cold chain requirements
5. Patient Counseling
6. Monitoring and reporting of adverse events following immunization

The FDA likewise observed that some drugstores initiate/sponsor community based programs such as free consultations or check-up, free diagnostics or laboratory testing, "Operation Tuli" and other similar activities or services.



The FDA has not issued any authorization to allow said activities (immunization and community-based health services) to be conducted by these drugstores. As such, there is no assurance on the safety and quality of the services rendered in said drugstore initiated/sponsored activities, and therefore poses potential health hazards to the consuming public.

The public is thus advised not to avail of said drugstore initiated/sponsored activities.

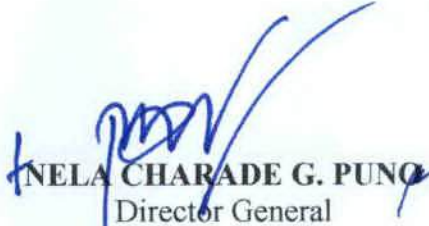
All concerned drugstores are requested to immediately cease and desist from conducting such activities until proper regulation and appropriate authorization have been issued. Regulation actions and sanctions shall be strictly pursued in case of non-compliance.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that said activities are stopped in their jurisdiction.

Continuous conduct of these activities by drugstores 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.


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Director General



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