

Republic of the Philippines FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2017-286

0 6 OCT 2017

TO:

THE GENERAL PUBLIC

SUBJECT:

Public Warning Against Accessing Drug Products from Medical Doctors from Unauthorized Clinics and other Health Facilities

Under Republic Act (R.A.) No. 10918, dispensing was defined as the sum of processes performed by a pharmacist from reading, validating, and interpreting prescriptions; preparing; packaging; labeling; record keeping; dose calculations; and counseling or giving information, in relation to the sale or transfer of pharmaceutical products, with or without a prescription or medication order. Dispensing is an exclusive activity of a pharmacist, to be conducted only within a licensed establishment.

Following R.A. No. 3720, as amended by R.A. No. 9711, the Department of Health (DOH) issued Administrative Order No. 2016-0003 requiring all establishments that sell or offer for sale drug products to first secure appropriate License to Operate (LTO) or authorization from FDA prior to engaging such activities.

Medical doctors, as part of their practice, utilize drug products. However, several doctors procure, store, sell and offer for sale drug products to their patients:

1) without proper authorization issued by FDA, which is a violation of R.A. No. 3720 as amended by R.A. No. 9711;

2) without the supervision of a pharmacist, which is a violation of R.A. No. 10918;

3) without issuing receipts, which is a violation of existing trade and revenue regulations; and

4) without observing good distribution and storage practices, which is a violation of standards implemented by FDA.

In consideration of the above, FDA hereby reiterates that doctors are not allowed to procure, store, and sell medicines, unless:

1) they have secured an LTO from FDA as retailer; or

2) such medicines are used as part of clinic procedures (i.e. surgery, diagnostic procedures, dialysis, cauterization, and vaccination). The volume of these medicines should not be in excess to the demand of his/her practice. The total volume stored for vaccines (any combination) per doctor should fit in a refrigerator (maximum dimensions of 443 x 501 x 450 mm), compliant to the required temperature.

Likewise, the FDA hereby reiterates that all licensed drug manufacturers and distributors are not authorized to sell to unlicensed retail outlets, including clinics of medical doctors.



The public is advised not to avail of medicines from clinics of doctors unless the abovementioned requirements are met.

All concerned are requested to immediately cease from conducting such activities until proper authorization has been secured. Regulatory 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 the said activities are stopped in their jurisdiction.

Continuous conduct of these activities by doctors 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.

NELA CHARADE G. PUNO

Director General

