



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



20 MAR 2020

FDA CIRCULAR
No. 2020-010

TO: ALL CONCERNED STAKEHOLDERS AND PARTIES

SUBJECT: Prohibition of Online Selling of Unregistered/Unnotified Medical Devices

Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, specifically *prohibits* the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products (including medical devices and supplies) *without the proper authorization*.

Likewise, the DTI-DOH-DA Joint Administrative Order No. 01 series of 2008 entitled “Rules and Regulations for Consumer Protection in a Transaction Covered by the Consumer Act of the Philippines (R.A. 7394) Through Electronic Means Under the E-Commerce Act (R.A. 8792)” mandatorily requires that all retailers, sellers, distributors, suppliers or manufacturers engaged in electronic commerce with consumers must ensure compliance with the requirements for safe and good quality of devices under Title II of the R.A. 7394.

Therefore, all concerned establishments are strongly reminded that **online selling of medical devices and supplies without the corresponding authorizations issued by the FDA (i.e. License to Operate, Certificate of Medical Device Notification or Certificate of Medical Device Registration/Certificate of Product Registration) is strictly prohibited.**

Also, the public is advised not to purchase any unregistered or violative medical devices and supplies sold or offered for sale through online platforms.

All FDA Regional Field Offices and Regulatory Enforcement Units are directed to conduct exhaustive monitoring of all online platforms to ensure full compliance of this circular and to pursue and implement immediate regulatory and enforcement actions as warranted.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at cdrrhr@fda.gov.ph.

To report any sale or distribution of unregistered medical device, the online reporting facility, eReport can be accessed at www.fda.gov.ph/ereport.

For your guidance and strict compliance.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20200312125922

