Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

07 OCT 2021

FDA CIRCULAR
No. 2021-021

SUBJECT: **Guidelines on the Licensing of Retailers of Medical Devices in the Philippines**

I. RATIONALE

Republic Act (RA) No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", mandated the FDA to develop policies, guidelines and standards on the regulation of health products including medical devices to ensure the safety, quality and efficacy of these products in the market. Furthermore, pursuant to the provisions of the same law, a License to Operate (LTO) is required for establishments engaged in the sale, offering for sale or retail of any medical device including in-vitro diagnostic device.

In the absence of the LTO requirement and specific guidelines for the licensing of retailers of medical devices, these establishments or entities are not compelled to comply with the government regulations covering the said health products which cause the proliferation of unregistered medical devices in the market as evidenced by the numerous issued FDA Advisories on unregistered or unnotified medical devices.

On 8 May 2020, Department of Health (DOH) Administrative Order (AO) No. 2020-0017 entitled "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003" was issued wherein retailers of medical devices are included in the list of establishments that are required to secure a License to Operate from the FDA before engaging in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship activities of health products.

Licensing of retailers of medical devices will ensure access of patient and the general public to safe, quality and effective medical devices.

To provide specific guidelines supplementing the provisions of AO No. 2020-0017 on the licensing of retailers of medical devices, this Circular is hereby issued.

II. OBJECTIVE

This Circular aims to:

A. Specify the establishments classified as retailers of medical devices;
B. Clarify the licensing of drug outlets which are also retailers of medical devices;

C. Provide specific requirements for and responsibilities of qualified persons of retailers of medical devices; and
D. Provide specific requirements for post-licensing inspection of retailers of medical devices.

III. SCOPE

This Circular shall apply to the following retailers of medical devices:

A. Retail stores for medical devices;
B. Clinics that sell products classified as medical devices except those that are covered by the DOH One Stop Shop Licensing System;
C. Sellers using online shopping website, social media platforms and/or TV shopping companies in selling or offering to sell medical device directly to the general public;
D. Operator of medical device vending machine;
E. Optical shops; and
F. Drug outlets, such as drugstores, or boticas, and retail outlets for non-prescription drugs (RONPD) that also sell or offer to sell medical devices

In consonance with AO No. 2020-0017, this FDA Circular shall not cover grocery stores, supermarkets, convenience stores, chandler, kiosks and other similar stores. However, although these establishments are exempted from securing the LTO, they shall be held liable and shall be considered violating the FDA regulations if they sell or offer to sell unregistered/unnotified medical devices.

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the meaning as defined in RA 9711 and its implementing rules and regulations, AO No. 2020-0017 and related laws and regulations. However, for clarity and for purposes of these guidelines, the following terms are defined as follows:

A. **Certificate of Medical Device Notification (CMDN)** – refers to the authorization issued for a medical device that complies with all the requirements for Notification of a medical device. The CMDN is issued for medical devices that will fall under Class A or low risk medical devices.

B. **Certificate of Medical Device Registration (CMDR)** – refers to the authorization issued for a medical device that complies with all the requirements for Registration of a medical device.

C. **Distributor/Importer/Exporter** – refers to any establishment that imports or exports raw materials, active ingredients and/or finished product for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

D. **Distributor/Wholesaler** – refers to any establishment that procures raw material, active ingredients and/or finished products from a local establishment for local distribution on wholesale basis.

E. **Medical Device** – refers to any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in intended function by such means.

F. **Qualified Person** – refers to an organic of full-time employee of the establishment who possesses technical competence related to the establishment's activities and health products by virtue of his profession, training or experience. A qualified person has the responsibility to comply with the technical requirements of the FDA or discuss or clarify matters with the FDA when submitting technical requirements or engage the FDA officials when conducting inspection or post-market surveillance activities. The qualified person may also be the duly Authorized Person of the establishment.

G. **Prescription Medical Device** – refers to a medical device that requires prescription by a licensed professional in accordance with the law and pertinent rules and regulations.

H. **Retailer** – means any establishment which sells or offers to sell medical device directly to the general public.

V. GUIDELINES

A. License to Operate

1. As provided for in AO No. 2020-0017, all retailers identified in Section III shall apply for a License to Operate (LTO) at the FDA.
2. An FDA licensed drug retailer (drugstore, pharmacy, botica) or RONPD that also sells or offers to sell any medical device product shall secure a separate LTO from the FDA as a retailer of medical device.
3. The LTO issued by the FDA shall be conspicuously displayed inside the establishment.

B. Qualified Person

1. The qualification and credential requirements for qualified person for retailers of medical device shall be the same as the requirements for manufacturers, traders and distributors of medical devices as specified in AO No. 2020-0017.
2. For retailers of ophthalmic lenses, prisms, contact lenses and their accessories and solutions, low vision aids, and similar appliances and devices wherein dispensing is governed by RA 8050 or the "Revised Optometry Law of 1995", the Qualified Person shall be an optometrist.

C. Post-licensing Inspection

All licensed retailers shall be subjected to routine or spot check inspection during operating hours by authorized FDA personnel. The following documents shall be verified during inspection:

1. Proof of business name registration
2. Business Permit if the establishment's address is different from the business name registration address
3. Credentials of qualified person such as:
   a. Valid PRC ID for professions with Board/Licensure exam or Diploma for profession without Board/Licensure exam
   b. Certificate of attendance to seminars, training, learning and development activities on medical device safety, quality and use given by the academe or industry
4. Standard operating procedures that includes monitoring of quality of medical device products and reflects observance of good storage and distribution practices
5. Relevant reference materials (RA 9711, AO No. 2018-0002, FDA Circular No. 2020-001 and other related issuances on medical devices)
6. Valid LTO issued by the FDA
7. Copies of CMDN/CMDR (as applicable) of medical devices being sold
8. Risk management plan

D. Fees for licensing of retailers of medical devices shall be similar to fees for licensing of drug outlets as per AO No. 50 s. 2001 entitled "Revised 2001 Schedule of Fees and Charges for the Corresponding Services by the Bureau of Food and Drugs" which shall be as follows:

1. Initial: ₱2,000.00 valid for 2 years
2. Renewal: ₱3,000.00 valid for 3 years
3. Fee for variation of LTO: ₱500.00

An additional 1% thereof for the Legal Research Fee (LRF) shall be collected by the FDA. The LRF imposition is pursuant to FDA Circular No. 2011-003 or the "Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856".

E. All retailers of medical devices shall only sell or offer to sell medical devices with appropriate authorization (Certificate of Medical Device Registration or Certificate of Medical Device Notification) issued by the FDA, as applicable.

F. Retailers shall only sell prescription medical devices to customers with a valid prescription issued by an authorized professional in accordance with existing laws, rules and regulations. For ophthalmic lenses, prisms, contact lenses and their accessories and solutions, low vision aids, and similar appliances and devices, ophthalmic prescription shall be required wherein such products shall only be dispensed by a registered optometrist.

G. Online selling of prescription medical devices is prohibited. Retailers of prescription medical devices may advertise these products online; however, advertisement with link for online purchase of prescription medical devices shall not be allowed.

H. All retailers of medical devices shall immediately stop the sale of medical devices which have been banned or withdrawn for health and safety issues in the country of origin and those that are declared by FDA to be unregistered, counterfeit, injurious, unsafe or dangerous.

I. FDA licensed manufacturers, traders or distributors (importers, exporters and/or wholesalers) of medical devices that intend to sell medical devices directly to general public shall apply for a minor variation (additional activity) of their existing LTO. Requirements include submission of application form and payment of corresponding fee.

VI. RESPONSIBILITIES OF THE QUALIFIED PERSON

The qualified person of the establishment shall be responsible in assuring the safety, quality and efficacy/performance of medical devices, which shall include the following:

A. Observance of good storage and distribution practices and other relevant and applicable practices

B. Monitoring of inventory of products including expiry dates (if applicable)

C. Ensuring that any adverse event experienced by a patient/consumer is properly handled, documented and reported to the establishment's supplier/distributor. Incident that caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person shall be reported to the Food and Drug Administration through the Center for Device Regulation, Radiation Health and Research.

D. Ensuring that all medical device products offered for sale are with issued corresponding authorization from FDA

E. Ensuring compliance of the establishment with the existing FDA regulations and advisories on medical devices

F. Requiring appropriate authorization from the establishment's supplier/distributor prior to purchase and selling of the medical device

G. Keeping himself updated regarding the full implementation of AO No. 2018-0002 re: Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements and/or its subsequent amendment(s) and other FDA policies/issuances on the regulation of medical devices in coordination with the establishment's supplier/distributor

VII. PENALTY CLAUSE

Sanctions over violations of any of the provisions of this Circular shall follow the Rules of Administrative Procedure provided in the Implementing Rules and Regulations of RA 9711.

VIII. SEPARABILITY CLAUSE

In the event that any provision or part of this Circular is declared invalid, the other provisions hereof shall not be affected.

IX. TRANSITORY PROVISION

All existing retailers of medical devices prior to the issuance of this Circular shall be given a period of two (2) years from the effectivity of this Circular to comply with the provisions thereof.

X. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies with the University of the Philippines Law Center.

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Director General

DTN: 20200521130631

Annex 1

References

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