Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 MAR 2024

FDA ADVISORY
No. 20240539

TO: **ALL MEDICAL DEVICE RETAILERS AND OTHER CONCERNED STAKEHOLDERS**

SUBJECT: **Full Implementation of FDA Circular No. 2021-021 Entitled "Guidelines on the Licensing of Retailers of Medical Devices in the Philippines"**

On 7 October 2021, FDA Circular (FC) No. 2021-021 was issued to provide specific guidelines on the licensing of retailers of medical devices supplementing the provisions of Department of Health Administrative Order (AO) No. 2020-0017[1]. The said Circular took effect on 18 December 2021 following its publication in a newspaper of general circulation on 3 December 2021.

Section IX of the said Circular stipulates that "*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.*" Based on this provision, the transitory period for the said establishments will end on 18 December 2023.

In view of the above, all concerned retailers of medical devices are hereby advised to secure a License to Operate (LTO) from the Food and Drug Administration (FDA) through the eServices Portal System (https://eservices.fda.gov.ph/) following the provisions of AO No. 2020-0017, FC No. 2021-021, and FC No. 2022-007[2].

FDA-licensed traders or distributors (importers, exporters, and/or wholesalers) of medical devices that sell or intend to sell directly to the general public may apply for variation (additional activity) of their existing LTO through the eServices Portal System following the provisions of AO No. 2020-0017, FC No. 2021-021, and FC No. 2021-014[3].

The transitory provision for FDA-licensed medical device manufacturers that sell or intend to sell directly to the general public is hereby extended until the migration of the online licensing

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[1] Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003
[2] Guidelines on the Use of the Food and Drug Administration eServices Portal System for License to Operate (LTO) Application of Retailers of Medical Devices
[3] Guidelines for the Use of the Food and Drug Administration (FDA) eServices Portal Sytem for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Medical Devices, Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste and Water Treatment Devices/Systems

application process from the ePortal System to the eServices Portal System has been completed for the said establishments. A separate FDA Circular shall be issued to this effect.

All concerned entities are strongly reminded that the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, or **retail** of any health product including medical devices without LTO from the FDA is prohibited pursuant to the provisions of Republic Act No. 9711 or the "Food and Drug Administration (FDA) Act of 2009".

For more information and inquiries, kindly contact the FDA – Center for Device Regulation, Radiation Health, and Research through email at cdrrhr@fda.gov.ph or call (02) 8807-2843.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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