DRAFT

FDA Circular
No. _____

SUBJECT: Guidelines on the Issuance of License to Operate for Drug Establishments Engaged in E-Pharmacy

I. BACKGROUND/RATIONALE

The World Trade Organization defines Electronic commerce (E-commerce) as the production, distribution, marketing, sale, or delivery of goods and services by electronic means (WTO). As a member state of the UN and other regional economic blocs like APEC and ASEAN that recognizes e-commerce as a tool for further development and intensification of commercial transactions to drive inclusive growth and narrow development gaps.

Republic Act (RA) No. 9792, otherwise known as the "E-Commerce Act", provides a regulatory framework for the legal recognition of electronic contracts under the Philippine law, thereby establishing the groundwork for electronic transactions in the country. It also provides penalties for violations of RA 7394, otherwise known as the "Consumer Act of the Philippines". Under the Consumer Act of the Philippines, the DOH-FDA is tasked to protect the consumers against deceptive, unfair, and unconscionable sales acts and to establish standards for the business and industry's conduct.

In compliance with the RA 9711, otherwise known as the FDA Act of 2009, and RA 10918, otherwise known as the "Philippine Pharmacy Act", there is a need for guidelines not only to protect the consumer's safety and welfare, but also to ensure that the Good Distribution Practice and Good Storage Practice, among others, are implemented in order to ensure the safety, efficacy and quality of the medicines are maintained and handled well along the medicine supply chain until it reaches the consumers. The Pharmacy Act defines "online selling" as pharmaceutical services of a duly FDA-licensed pharmaceutical outlet done over the internet. Online selling is not only confined to the pharmaceutical outlets operating in the Philippines, but also outside of the country and sends orders to consumers through mail and shipping companies, often using online pharmacy web portals.

Currently, the FDA only allows online ordering services provided that the seller has an existing FDA-licensed drug outlet with physical address. Should the drug outlet want to provide online ordering services, the drug outlet needs to apply for online ordering service subject to FDA approval as an additional activity.

In light of the current situation brought by the COVID-19 pandemic and forward-looking to the "new normal", e-pharmacy offers a platform where consumers can purchase medicines without having to visit conventional/physical pharmacies. However, as the proliferation of digital tools increases internet availability worldwide, any company can sell medicines online, making international e-commerce easier than ever before. FDA Philippines, as the drug regulatory authority in the country, deserves its own guidelines. These guidelines shall be in place to ensure that medicines in online platforms shall still be offered for sale or use, dispensed under the

supervision of a pharmacist, prescribed by physicians, transported, distributed, advertised and promoted following the provisions of the law of RA 3720, as amended by RA 9711, and RA 10918.

The FDA is compelled to draft a guideline in support of local and global trade and commerce in the country. The e-pharmacy guidelines that will be developed by FDA in collaboration with partner agencies/offices aims to ensure the safety, quality, efficacy, purity of health products sold online by facilitating responsible e-commerce activities, provide licensing requirements for online sellers, and introduce regulatory enforcement measures to punish and remove illegal online selling.

In view of the current pandemic state of the country due to COVID-19, there is a surge in the use of online pharmacy and E-services. This circular aims to regulate and license e-Pharmacies in accordance with DOH AO no. 2020- 0017 or the "Revised Guidelines on the Unified Licensing and Procedures of the Food and Drug Administration Repealing AO 2016-0003 and FDA Circular No. 2020-0030 or the "Guideline for the Use of FDA eServices Portal System for License to Operation (Application) of Drug Distributors, Drug Traders, Drugstores, Retail Outlets For Non-Prescription Drugs (RONPDs, Clinical Research Organizations (CRO), and Sponsors" in order to ensure the safety of the public and to develop a more responsive health system for a safe, equitable, quality, and affordable healthcare goods and services in the different online market platforms.

II. OBJECTIVES

This Circular aims to set guidelines on the License to Operate (LTO) application of drug establishments engaged in online pharmacy (E-Pharmacy) thereby ensuring the safety, health and welfare protection of the public.

III. SCOPE AND COVERAGE

These guidelines shall cover the licensing of establishments, including drug outlets, RONPD, and other entities that will engage in online retailing of over-the-counter or non-prescription drug products as additional activity or as pure E-Pharmacy. It shall not cover prescription drug products.

IV. DEFINITION OF TERMS

A. **Adverse Drug Event (ADE) or Adverse Drug Experience** - refers to any untoward medical occurrence during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with such treatment.

B. **Adverse Drug Reaction (ADR)** - refers to a response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis diagnosis, or therapy of disease, or for the modification of physiological function.

C. **Drugs/Medicines** – refer to (1) articles recognized in the official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by FDA; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure of any function of the body of human or animals; (4) articles intended for use as a component of any articles specified in clauses (1) (2), or (3) but do not include devices or their components, parts or accessories.

D. **Drug Distributor** – refers to the following:
   a. Drug Distributor - Exporter - refers to any establishment that exports raw materials, active ingredients and finished products for distribution to other drug establishments outside the country.
   b. Drug Distributor - Importer - refers to any establishment that imports raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed drug establishments.
   c. Drug Distributor- Wholesale - refers to any establishment that procures raw materials, active ingredients and/or finished products from a local FDA-licensed drug establishment for local distribution on wholesale basis.

E. **Drug Manufacturer** - refers to any establishment engaged in any or all operations involved in the production of drug products including preparatory processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution; provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A Drug Manufacturer can distribute and/or export in wholesale its own drug products and import raw materials for its own production.

F. **Drug Traders** - refers to any establishment which is registered owner of a drug product and the formulation and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer.

G. **Drugstore/Pharmacy/Botica and similar outlets** - shall refer to drug establishments where registered drugs, chemical products, dental, medicinal and household remedies are dispensed directly to the general public on a retail basis. Botika ng Barangay and its variants that sell the same shall be reclassified and required to secure LTO as a drugstore.

H. **E-commerce** - The sale of purchase of goods and services, whether between businesses, households, individuals, governments, and other public or private organizations, conducted over computer-mediated networks. The goods and services are ordered over those networks, but the payment and the ultimate delivery of the goods or services may be conducted on or offline.

I. **E-commerce Warehouse** - where e-commerce merchandise is stored. Can be own warehouse, third party provider, living room/garage/basement provided that the place is suitably designed and well-maintained to carry e-commerce/e-pharmacy activities.

J. **E-Pharmacy** – refers to a mode of pharmacy services that utilizes information technology or online mode of communication to better serve patients by providing more convenient

access to pharmacy services. This mode of service should be provided by a pharmacy that is duly-licensed by the FDA through a secured online platform (via own website or via online marketplace website).

K. **Good Distribution Practices or GDP** - means that part of quality assurance which ensures that the quality of a pharmaceutical product is maintained through adequate control throughout the numerous activities which occur during the distribution process.

L. **Good Storage Practices or GSP** - means that part of quality assurance which ensures that the quality of a pharmaceutical product is maintained through adequate control throughout the storage.

M. **Home/Household Remedies** - refers to any preparation containing pharmaceutical substances of common or ordinary use to relieve common physical ailments and which may be dispensed without a medical prescription in original packages, bottles or containers, of which the nomenclature has been duly approved by the FDA.

N. **Marketing Authorization Holder** - the company, corporate or legal entities in the field of pharmaceuticals in whose name the Certificate of Product Registration (CPR) or MA for a pharmaceutical product has been granted.

O. **Online eCommerce Platform** - refers to a natural, or judicial person that solicits the purchase of digital products through digital platforms and marketplaces whose business is to connect online buyers and online sellers, facilitating sales of products, goods, and services through the internet with the presence and use of monetary transactions.

P. **Online Pharmacy Service** – refers to pharmaceutical services of a duly licensed pharmaceutical outlet done over the internet;

Q. **Over the Counter (OTC) medicines** - refers to medicines used for symptomatic relief of minor ailments and which may be dispensed without a prescription;

R. **Pharmaceutical Outlets** - refers to entities licensed by appropriate agencies, and which are involved in compounding and/or dispensing and selling of pharmaceutical products directly to patients or end-users;

S. **Physical Store** - refers to physical commercial establishments, such as retail stores, by which sales are carried out within actual premises of a real estate property owned or leased by the relevant business, it being specified that e-Commerce-related sales should not be considered as Physical Stores solely by virtue of a physical pick-up or delivery involving a physical establishment.

T. **Qualified Personnel** - refers to an organic or 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.

U. **Receiving/Dispensing Orders** – refers to activities performed by a drug retail outlet or a third party with an existing agreement with a drug retail outlet to receive orders that are prescription drugs. Receiving and dispensing of orders shall require a medication order or a prescription by a prescribing physician. For clarity, posting of orders using online platforms shall be limited only to non-prescription drugs.

V. **Retail Outlets for Non-Prescription Drug Products (RONPDs)**- refer to drug establishments such as a supermarket, convenient store and other similar retail establishment authorized to sell only identified Over-the-Counter (OTC) and household remedy products directly to the general public on a retail basis. Botika ng Barangay and its variants that opt to sell the same shall be reclassified and required to secure LTO as a RONPD.

W. **Seller / Retailer** - means any establishment which sells or offers to sell any health product directly to the general public.

V. GENERAL GUIDELINES

1. Posting of advertisements, offers for sale or use, and orders using online platforms shall be limited only to non-prescription drugs.

2. Only FDA-registered products are allowed to be offered for sale/use in online platforms.

3. All drug establishments that intends to sell and process online ordering and delivery of drug product/s must comply with Good Distribution Practices and Good Storage Practices to ensure the integrity and stability of the health products supplied.

4. Administrative Order No. 2020-0017 on the "Revised Guidelines on the Unified Licensing and Procedures of the Food and Drug Administration Repealing AO 2016-0003" and FDA Circular No. 2020-030 on the "Guideline for the Use of FDA eServices Portal System for License to Operation (Application) of Drug Distributors, Drug Traders, Drugstores, Retail Outlets For Non-Prescription Drugs (RONPDs, Clinical Research Organizations (CRO), and Sponsors" and FDA Circular No. 2020-0030 shall apply and shall be expounded in this circular.

5. All drug establishments directly selling to consumers and patients using online platform shall be required to secure an e-LTO as Drugstore and RONPD with an additional activity as e-pharmacy or as a pure E-Pharmacy. Approval and issuance of the License to Operate applications to CDRR shall require inspection by the RFOs under the FROO.

6. The validity of the e-pharmacy LTO shall coincide with the validity of the previously-issued LTO as Drugstore or RONPD.

7. Drug establishments directly selling to a non-retail business establishment, e.g. manufacturer, distributor, or trader, shall not be required to secure a License to Operate with additional activity as e-pharmacy. Should these types of establishments venture into direct selling to consumers and patients, i.e. retailing, they shall be required a License to Operate as Drugstore or RONPD with additional activity. For emphasis, sub-distributors that directly sells to

patients and consumers without License to Operate as Drugstore or RONPD are prohibited by RA 9711.

8. All online ordering/e-pharmacy services rendered by FDA-licensed establishments shall be hosted only in the Philippine domain.

9. All drug establishments securing License to Operate as Drugstore or RONPD with additional activity as e-pharmacy shall appoint a PRC-licensed Pharmacist Qualified Person (QP). The current QP of the drug establishment shall be declared and updated with the FDA and he/she shall be responsible and accountable for compliance with FDA laws, rules and regulations pertaining to product safety, efficacy and quality. The QP shall act as the Chief Pharmacist in case of multiple shifts in a 24/7 operation.

10. All licensed Drugstores and RONPD with additional activity as e-pharmacy shall be subject to spot-check inspections by the RFOs under the FROO anytime.

11. All e-pharmacies may use market online platforms or may create their own website. E-pharmacies with their own website shall have a consumer complaint button on the navigation bar with the statement that "The FDA may be copied with all complaints and reports at oddgfroo@fda.gov.ph" upon clicking of the said button.

12. Drug Outlets that do not have any physical establishment for face-to-face dispensing shall be issued a LTO as pure E-Pharmacy by the FDA provided it has a warehouse and an office that can hold product inventories or stocks. All additional warehouses operating under the same licensed office address shall be declared and subject to inspection by the FDA. When applicable, existing drug outlets with additional online activity as E-Pharmacy, they shall declare all warehouses which shall be subjected to inspection by the FDA.

13. The use of online marketplace, such as but not limited to Lazada, Shopee and Facebook may be utilized for receiving orders by e-licensed drug retailers as online platforms in selling their products. Online marketplaces are not drug outlets, hence, they are not required to secure e-pharmacy LTO unless they venture or operate their own drug retailing business or operation. The use of such platforms for promotional purposes shall be allowed only with the approval of the FDA under the e-promo permit guidelines and subject to compliance to AO on advertisement guidelines, provisions of FDA on non-advertisement of prescription drugs and monitoring by the FROO.

VI. SPECIFIC GUIDELINES

1. Filing Of Applications

A. Drug Outlet with Additional Activity as E-Pharmacy

i. Establishments must have a valid LTO of not less than ninety (90) days from the application of additional activity.
ii. Current licensing regulations of the FDA for additional activity as e-pharmacy shall be adopted.

iii. When applicable, additional documentary requirements for the application are as follows:

1. Standard Operating Procedure
2. A screenshot of the website owned and maintained by the drug outlet shall be required when receiving orders are made online in addition to orders made through telephone/mobile phones or other means. The website shall have provision for consumer complaint as stated under Section 5, no. 11 in the General Guidelines of this Circular.

B. **Pure E-Pharmacy**

i. Establishments applying for Pure E-Pharmacy, that is i.e., no physical store for dispensing medicines and medical devices, shall have an e- commerce warehouse and office which maybe owned or leased by a third party. The warehouse or office shall be used solely as storage and distribution/dispensing point of duly-registered drug products or medical devices.

ii. Submission of application for LTO as drugstore, pharmacy or botica, establishments shall follow current licensing regulations of the FDA with a–note "e-pharmacy" service as a mode of retail pharmacy service.

iii. Documentary requirements for the application shall be based on the provisions stipulated in A.O 2020-0017.

2. **Inspection of Establishments**

a. A pre-approval inspection shall be conducted for all establishments applying for additional activity for online ordering and delivery and for Pure E-Pharmacy. The pre-approval inspection shall focus on the warehouse, SOP for compliance to Good Distribution and Storage Practices, mode of delivery, dispensing of medicines, training of personnel, and IT system used. Post-approval inspections may also be conducted to ensure continuous compliance to regulations.

b. Establishments found to be non-compliant may be subjected to appropriate regulatory actions such as but not limited to disapproval of application of the additional activity, issuance of warning letter, or suspension, revocation of licenses.

VII. PENALTY CLAUSE

Establishments/entities who will participate in the conduct of E-pharmacy/Online Pharmacy Services without prior authorization or violate provisions of this Circular shall be subject to imposable penalties stipulated in RA No. 10918, RA No. 9711, and their respective implementing rules and regulations.

VIII. REPEALING AND SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

These guidelines shall be reviewed after three (3) years in collaboration with the concerned stakeholders.

IX. EFFECTIVITY

This Circular shall take effect after fifteen (15 days) following its publication in a newspaper of a national circulation or upon filing to the University of the Philippines Law Center Office of the National Administrative Register.