



17 March 2022

(22-2354)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>PHILIPPINES</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> DR OSCAR G. GUTIERREZ, JR., MPA OIC-Director General Food and Drug Administration DEPARTMENT OF HEALTH  <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>  DR OSCAR G. GUTIERREZ, JR., MPA OIC-Director General Food and Drug Administration DEPARTMENT OF HEALTH Email: <a href="mailto:odg@fda.gov.ph">odg@fda.gov.ph</a> ; <a href="mailto:oddgfroo@fda.gov.ph">oddgfroo@fda.gov.ph</a> <a href="http://www.fda.gov.ph">www.fda.gov.ph</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Pharmaceutical Products; Pharmaceuticals (ICS 11.120)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft FDA Circular No. __: Guidelines on the Issuance of License to Operate for Drug Establishments Engaged in E-Pharmacy (8 page(s), in English)
<b>6. Description of content:</b> 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.  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.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety; Reducing trade barriers and facilitating trade

**8. Relevant documents:**

- Republic Act (RA) No. 9792, "E-Commerce Act"
- RA 7394, "Consumer Act of the Philippines"
- RA 9711, "FDA Act of 2009"
- RA 10918, "Philippine Pharmacy Act"
- 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"

**9. Proposed date of adoption:** 15 July 2022**Proposed date of entry into force:** 1 August 2022**10. Final date for comments:** 2 May 2022**11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

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