WORLD TRADE ORGANIZATION

G/TBT/N/PHL/287

29 April 2022

(22-3389)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** PHILIPPINES **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** DR. OSCAR G. GUTIERREZ, JR., MPA Officer-in-Charge Director General Food and Drug Administration DEPARTMENT OF HEALTH **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:** JESUSA JOYCE N. CIRUNAY, RPh Director IV Center for Drug Regulation and Research Food and Drug Administration DEPARTMENT OF HEALTH Email: jjncirunay@fda.gov.ph / cdrr.sds@fda.gov.ph www.fda.gov.ph
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Pharmaceutics (ICS code(s): 11.120); Drug products under Maximum Retail Price (MRP)
5.	**Title, number of pages and language(s) of the notified document:** Guidelines on Labeling Requirements of Drug Products under Maximum Retail Price (MRP); (4 page(s), in English)
6.	**Description of content:** The proposed issuance aims to provide streamlined and rational application process for the change of labeling materials under MRP including drug molecules or drug formula that will be included in succeeding Executive Orders of MRP.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Streamlining process for the change of labeling materials of drug products under MRP and exhaustion period of old labeling materials at the manufacturing level.; Reducing trade barriers and facilitating trade

8.	**Relevant documents:** • Republic Act No. 9502 "Universally Accessible Cheaper and Quality Medicines Act of 2008" • Executive Order No. 821 s. 2009 "Prescribing the Maximum Drug Retail Prices for Selected Drugs and Medicines that Address Diseases that Account for the Leading causes of Morbidity and Mortality" • Executive Order No. 104 s. 2020 "Improving Access to Healthcare through the Regulation of Prices in the Retail of Drugs and Medicines" • Executive Order No. 155 s. 2021 "Further Improving Access to Healthcare through the Regulation of Prices in the Retail of Drugs and Medicines" • Administrative Order No. 2016-0008 "Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use" • Administrative Order No. 2020-0039 "Guidelines in the Implementation of Maximum Retail Price (MRP) on Drugs and Medicines" • FDA Circular No. 2016-017 "Additional Post-Approval Changes for Pharmaceutical Products
9.	**Proposed date of adoption:** This Circular shall take effect fifteen (15) calendar days after publication in one (1) newspaper of general circulation and upon filing with the University of the Philippines, Office of the National Administrative Register (ONAR) **Proposed date of entry into force:** Upon effectivity
10.	**Final date for comments:** 6 May 2022; This is considered as an urgent policy as this will help to reduce regulatory burden in the application and approval of the inclusion or update of the MRP statement to the labeling materials of drug products especially that these drug products are lifesaving drugs.
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Mr. Neil P. Catajay Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City Philippines Tel: (632) 751 4700; (632) 7913128 Email: bps@dti.gov.ph Website: http://www.bps.dti.gov.ph https://www.fda.gov.ph/wp-content/uploads/2022/04/FDA-Circular-MRP-Variation-on-Labelings-DRAFT_For-posting.pdf https://members.wto.org/crnattachments/2022/TBT/PHL/22_3098_00_e.pdf