WORLD TRADE ORGANIZATION

G/TBT/N/PHL/290

15 June 2022

(22-4651)

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: cdrr.od@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):** WHO-prequalified pharmaceutical products and vaccines
5.	**Title, number of pages and language(s) of the notified document:** Implementing Guidelines on the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines; (6 page(s), in English)
6.	**Description of content:** The proposed issuance aims to provide the implementing guidelines of the collaborative procedure for accelerated registration of WHO-prequalified pharmaceutical products and vaccines to guide the concerned stakeholders.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The FDA, together with the DOH, are tasked to ensure that there is a constant supply of drugs, including vaccines, and that there is facilitated access to safe, effective, and quality drugs. Given the current resource constraints affecting drug regulation, collaboration and regulatory convergence with international organizations such as the WHO are necessary. This Circular aims to provide the implementing guidelines of AO No. 2020-0044 which adopted the collaborative procedure for accelerated registration of WHO-prequalified pharmaceutical products and vaccines.; Protection of human health or safety

8. **Relevant documents:**

- Republic Act No. 9711 "Food and Drug Administration (FDA) Act of 2009"
- Administrative Order No. 2020-0044 "Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines"
- World Health Organization (WHO) Technical Report Series, No. 996, 2016 (Annex 8, Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines)

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:** 17 June 2022

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) 7791.3127 ; (632) 7791.3128
Email: bps@dti.gov.ph
Website: http://www.bps.dti.gov.ph

https://www.fda.gov.ph/draft-for-comments-implementing-guidelines-on-the-collaborative-procedure-for-the-accelerated-registration-of-world-health-organization-who-prequalified-pharmaceutical-products-and-vacc/

https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_00_e.pdf
https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_01_e.pdf
https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_02_e.pdf
https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_03_e.pdf
https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_04_e.pdf
https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_05_e.pdf
https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_06_e.pdf
https://members.wto.org/crnattachments/2022/TBT/PHL/22_4120_07_e.pdf