FDA CIRCULAR
No. _____

SUBJECT : Implementing Guidelines on the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines

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I. BACKGROUND

Republic Act No. 3720, otherwise known as the "Food, Drugs and Devices, and Cosmetics Act", as amended by Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations, declare that it is the policy of the state to ensure the safety, efficacy, and quality of drug supply in the country so as to protect the health of the Filipino people. The FDA, as the national regulatory authority (NRA) in the country, together with the Department of Health (DOH), are tasked to ensure that there is (1) a constant supply of drugs, including vaccines, and (2) facilitated access to safe, effective, and quality drugs.

In 2013, the World Health Organization (WHO) issued the initial collaborative review procedure under Annex 4 of WHO Technical Report Series (TRS) No. 981, 2013. In 2016, a revised procedure was issued under Annex 8 of WHO TRS No. 996. This was adopted as per Administrative Order (AO) No. 2020-0044: Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines.

Given the current resource constraints affecting drug regulation, collaboration and regulatory convergence with international organizations such as the WHO are necessary.

This Circular is issued to guide the concerned stakeholders who will be affected bythe implementation of the collaborative procedure for accelerated registration, and the activities that must be undertaken by the concerned stakeholders.

II. OBJECTIVE

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.

III. SCOPE AND COVERAGE

This Circular shall apply to all FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified pharmaceutical products and vaccines, and shall cover applications for the registration and post-approval change/s of registered new drugs including vaccines as defined in Section IV below.

IV. DEFINITION OF TERMS

Collaborative procedure for accelerated registration, also referred to as **collaborative review procedure** or **collaborative registration procedure (CRP)**, refers to the procedure for collaboration between the WHO Prequalification Team (WHO/PQT) and interested NRAs in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines.

WHO prequalified pharmaceutical products and vaccines refer to those products which have undergone the WHO Prequalification wherein comprehensive ongoing requirements stipulated by the WHO are applied to ensure that the products are safe, efficacious, appropriate, and meet stringent quality standards. The mission of WHO Prequalification is to work in close cooperation with national regulatory agencies and other partner organizations to make quality priority medical products available for those who urgently need them.

A **national regulatory authority (NRA)** or **national medicines regulatory authority (NMRA)** is responsible for ensuring that products released for public distribution such as pharmaceuticals, biological products such as vaccines, and medical devices including test kits are evaluated properly and meet international standards of quality and safety and efficacy.

A **new drug application** refers to a registration application for a product that contains new chemical and/or biological entities proposed to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease, new dosage forms, new dosage strengths, new routes of administration, and new indications. All generic products with FDA-approved equivalent shall not be considered as new drug.

V. IMPLEMENTING DETAILS

A. General Guidelines
   1. The FDA, as a participating National Medicines Regulatory Authority (NMRA) for the Collaborative Registration Procedure, hereby promulgates the implementing details herein for the submission of an application for registration of a WHO-prequalified drug product and vaccine through CRP.
   2. The FDA adopts the WHO CRP as a registration pathway, consistent with Good Regulatory Practices. Notwithstanding this, the FDA retains its prerogative to use its own assessment of applications which may be combined with verification of compliance with relevant good practices by inspections and testing of product characteristics when applicable, and apply judgements that consider benefits and risks as it applies to the Philippine context.
   3. Submission of the registration application shall follow instructions as per FDA Advisory (FA) No. 2022-0001, Food and Drug Action Center (FDAC) Services Beginning 10 January 2022, subject to any future issuance providing for its amendment, repeal, or modification.

B. Eligibility Criteria
   1. Only FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified vaccines or drug products may apply for registration through CRP.

2. Prior to the submission of the registration application with the FDA, the applicant shall ensure that the form provided under Appendix 2 of WHO TRS 996 Annex 8, *Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure* (hereto attached as Annex B), has been duly accomplished and submitted by the Manufacturer or Prequalification Holder to the WHO/PQT.
3. The eligible product shall be the same as the product prequalified by the WHO/PQT.
    a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the WHO/PQT at the time of submission.
    b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the WHO/PQT.
4. For post-approval changes (variations), only applications submitted to FDA not later than 30 calendar days after acceptance of the post-prequalification variations by WHO/PQT may be applied for variation application through CRP.
5. The applicant may choose to avail of the CRP only if the application has not been applied through other types of facilitated review pathway (i.e. abridged review and verification review). If the any of the requirements of CRP cannot be complied with, the application shall be processed following the regular review pathway.

C. Specific Guidelines
    1. Applications for New Drug Registration
        a. Documentary requirements
            i. Accomplished application form as per FDA Circular (FC) No. 2014-003, as prescribed in FA No. 2022-0001, subject to any future issuance providing for its amendment, repeal, or modification;
            ii. Application dossier compliant with the existing requirements [e.g. Association of Southeast Asian Nations (ASEAN) – Common Technical Dossier (CTD) (ACTD), or International Council on Harmonization (ICH) – CTD (ICH-CTD)];
            iii. Appendix 3, Part A of WHO TRS 996 Annex 8, *Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO)-prequalified pharmaceutical product or vaccine* (Annex C). In cases where the applicant company is not the original WHO PQ holder, the applicant company must submit an authorization letter that indicates agreement of the original WHO PQ holder, following the prescribed format in Appendix 3, Part A of WHO TRS 996 to the FDA;
            iv. Country specific requirements such as:
                - Foreign GMP clearance issued by FDA;
                - Labeling materials consistent with country-specific requirements;
                - Stability studies conducted under Climatic Zone IVb (hot and very humid) for applicable products;

- Tabulated summary of WHO/PQT variation approvals prior to the registration application through CRP, obtained by the manufacturer/prequalification holder; and
- Additional requirement for pharmaceutical products under Monitored Release (MR) registration status: Risk Management Plan (RMP) and RMP Philippine-Specific Annex, with Periodic Safety Update Reports (PSUR)/Periodic Benefit-risk Evaluation Reports (PBRER), as applicable.

b. Processing / Timeline
   i. The FDA shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8, *Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation* (Annex D).
   ii. Upon grant of access to the shared documents by WHO/PQT, the FDA is given a maximum of ninety (90) calendar days of regulatory time to evaluate the registration application using information provided by WHO, make a decision, and inform the applicant/importer. If, upon evaluation of the submitted documents, it is found that additional documents or further clarification is required to meet the appropriate standards for safety, quality, and efficacy, the applicant/importer shall be informed in writing. Regulatory time starts after a valid registration application following the CRP has been received and access to confidential information has been granted by WHO (whichever is later) and continues until the date of decision on the registration application. The regulatory time does not include the time granted to the applicant/importer to complete missing parts of the documentation, provide additional data or respond to queries raised by FDA.
   iii. Within thirty (30) calendar days of issuing a regulatory decision to the applicant/importer, FDA shall inform WHO/PQT through Appendix 3, Part C of WHO TRS 996 Annex 8, *Notification of outcomes of national registration procedure by the NRA* (Annex E).

2. Post-Approval Changes (Variation)
   a. Documentary requirements:
      i. Accomplished application form as per FC No. 2014-003, as prescribed in FA No. 2022-0001, subject to any future issuance providing for its amendment, repeal, or modification;
      ii. Letter of Request for Post-Approval Changes (Annex F);
      iii. Proof of payment;
      iv. Certification from the WHO (for WHO certified post-approval changes); and
      v. Documentary requirements following FC No. 2014-008 (Application Process and Requirements for Post-approval Changes of Pharmaceutical Products) and its amendment, FC No. 2014-008-A, subject to any future issuance providing for its repeal, further amendment, or modification.

b. Processing / Timeline

i. The FDA shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8 (Annex D).

ii. Upon grant of access to the shared documents by WHO/PQT, the FDA is given a maximum of thirty (30) calendar days of regulatory time to evaluate the registration application using information provided by WHO, make a decision, and inform the applicant/importer. If, upon evaluation of the submitted documents, it is found that additional documents or further clarification is required to meet the appropriate standards for safety, quality, and efficacy, the applicant/importer shall be informed in writing. Regulatory time starts after a valid registration application following the CRP has been received and access to confidential information has been granted by WHO (whichever is later) and continues until the date of decision on the registration application. The regulatory time does not include the time granted to the applicant/importer to complete missing parts of the documentation, provide additional data or respond to queries raised by FDA.

iii. If the evaluation of the application for post-approval changes results in the FDA-registered product being no longer the same as the WHO-prequalified product, or if a variation of the WHO-prequalified product is not followed by a variation of the FDA-registered product and, as a consequence, the FDA-registered product is no longer the same, FDA shall inform the WHO/PQT through Appendix 4 of the WHO TRS 996 Annex 8, *Report on post-registration actions in respect of a product registered under the procedure* (Annex G) the restricted-access website within thirty (30) calendar days of obtaining access to the information and documentation from WHO/PQT, to what extent the variation of the WHO-prequalified product is not followed.

D. Fees

The appropriate fees as prescribed under existing regulations shall apply, including a Legal Research Fee (LRF) following A.O. No. 50 s. 2001, or any amendment or latest issuance thereafter.

E. Rules on Disapproval, Suspension, and Revocation

The applicable rules on the disapproval of applications, and the suspension or revocation of registrations or authorizations under AO No. 67 s. 1989 and Book II, Article I, Section 4 of the IRR of RA 9711 shall apply.

VI. PENALTY CLAUSE

The applicable penalties under Republic Act No. 9711 and its Implementing Rules and Regulations shall apply for any violations of this Circular or of AO No. 2020-0044.

VII. IMPLEMENTATION REVIEW

FDA shall conduct a review of the implementation of this order after a period of three (3) years from the effectivity of this Circular.

VIII. 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.

IX. EFFECTIVITY DATE

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).

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Secretary of Health