Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 2 2 2020

ADMINISTRATIVE ORDER
No. 2020 - 0044

SUBJECT: **Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) - Prequalified Pharmaceutical Products and Vaccines**

I. RATIONALE

Republic Act No. 3720, otherwise known as the "Foods, Drugs and Devices, and Cosmetics Act", as amended, and Republic Act (RA) 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. As the national regulatory authority (NRA) under the Department of Health (DOH), the Food and Drug Administration ensures the constant supply of and facilitate access to safe, effective, and quality pharmaceutical products and vaccines.

Given the current resource constraints, increased workload with limited number of evaluators and complexity of regulatory oversight for emerging national regulatory authorities (NRAs), regulatory convergence and reliance became increasingly-adopted approaches that offer solutions to ensure that innovative drugs, particularly vaccines and life-saving drugs, are made available and accessible to patients and the public in a country.

Globally, the World Health Organization (WHO) has developed a prequalification scheme, which enables an accelerated registration pathway work-sharing and information-sharing mechanisms between the WHO Prequalification of Medicines Programme (PQP) and NRAs. FDA Philippines joined this scheme through the WHO Collaborative Registration Procedure (CRP). It is envisioned that by adopting the CRP, the national registration procedures of WHO-prequalified pharmaceutical products and vaccines can be facilitated while maintaining the highest quality of regulatory assessments.

II. OBJECTIVES

This Administrative Order is issued to establish an accelerated review process for prequalified pharmaceutical products and vaccines, through the adoption of the WHO CRP into the national registration procedures and requirements.

III. SCOPE AND COVERAGE

This Administrative Order shall apply to all FDA-licensed drug distributors, traders, and manufacturers with WHO Prequalified vaccines or drug products for registration in the country.

IV. ADOPTION OF THE WHO CRP

1. The FDA hereby adopts the current version of the Annex 8 of WHO TRS No. 996, *"Collaborative procedure between the World Health Organization Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines", including a*ll further supplements and revisions related thereto, as an alternative registration pathway for drug products, including vaccines.

2. Only FDA-licensed drug distributors, traders, and manufacturers with WHO Prequalified vaccines or drug products may apply for a Certificate of Product Registration through the Collaborative Procedure pathway.

3. Procedural guidelines, including the application process, documentary requirements, forms, and evaluation processes shall be issued via separate FDA Circular, for effective and efficient implementation of this Order.

V. REPEALING AND SEPARABILITY CLAUSE

Provisions in existing administrative orders, bureau circulars and memoranda inconsistent with this Administrative Order are hereby withdrawn, repealed, and revoked accordingly.

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

VI. EFFECTIVITY DATE

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

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health