Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 22 2020

ADMINISTRATIVE ORDER
No. 2020-0045

SUBJECT: **Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals**

I. RATIONALE

By virtue of Republic Act No. 3720, otherwise known as the "Foods, Drugs and Devices, and Cosmetics Act", as amended, and Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations, it was made the policy of the state that health products made available in the country, including drugs or medicines, are safe, effective, and of good quality. While Republic Act No. 11032 otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act of 2018, through facilitated registration pathways are envisioned to reduce workload allocated for administrative and technical evaluation by recognizing to certain defined degrees the assessments conducted by reference drug regulatory agencies.

With the advent of globalization and improvements in technology, the development, production, and distribution of health products, including drugs and medicines, have become more interconnected across countries. In turn, regulatory oversight for the safety, efficacy, and quality of health products have become shared among different national regulatory authorities (NRAs). International regulatory cooperation has thus been strategically promoted and adopted by NRAs to improve regulatory processes while ensuring timely access to medicines. Activities range from simple approaches such as adoption of internationally-recognized forms, into more complex initiatives such as regulatory harmonization where standards are synchronized across member states, reliance practices where assessments of overseas NRAs are recognized, among others.

Guided by the principles of international regulatory cooperation, while cognizant of the need for timely access to medicines and the need to streamline government transactions, the FDA hereby establishes facilitated registration pathways in the registration and evaluation of drug products, including vaccines and biologicals.

II. OBJECTIVES

This Order aims to establish facilitated registration and evaluation pathways for drugs, including vaccines and biologicals, through three routes: abridged review, verification review, and collaborative procedure. Specifically, this Order aims to:

1. Define the facilitated registration routes;

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2. Identify the eligibility criteria for the applicant and drug products; and,
3. Describe the arrangements to implement these mechanisms.

III. SCOPE AND COVERAGE

This Order shall apply to all local drug manufacturers, traders, and distributors, who intend to place in the local market, drug products with existing and valid approval/s from reference drug regulatory agency/ies, and/or existing and valid registration under recognized collaborative registration procedures.

IV. GUIDELINES

The following guidelines hereby provide the established facilitated registration routes, eligibility criteria for availing the routes, and the roles and responsibilities of FDA and the applicant.

A. Types of facilitated registration pathways. The following facilitated registration routes are hereby established:

1. **Abridged review.** A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements while relying on prior assessment from a reference drug regulatory agency or agencies to inform the local decision. The review is based on complete assessment report, including question and answer documents, and the dossier including the stability data.

2. **Verification review.** An assessment process by which the submission has been evaluated and approved by at least two (2) reference drug regulatory agencies, and the FDA only validates the submission and ensures that the product conforms to the registration conditions, standards and requirements as approved by the reference drug regulatory agencies.

3. **Collaborative procedure.** An assessment process recognized by FDA through reliance, work-sharing, or joint reviews with other international organizations, like the World Health Organization Prequalification of Medicines Programme (WHO-PQP), or other drug regulatory agencies as may be identified by the FDA.

B. Eligibility Criteria. Local drug manufacturers, traders, and distributors may avail of the above-mentioned facilitated registration pathways, subject to the following eligibility criteria:

1. Applicant shall be a holder of a valid License-to-Operate issued by the FDA;
2. Applicant may avail of the following submission pathways, subject to certain conditions.
    a. Abridged review may be availed when the drug product, vaccine, or biological has been approved by a reference drug regulatory agency.

b. Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) reference drug regulatory agencies.
c. Review through a collaborative procedure may be availed when the drug product, vaccine, or biological has been reviewed through a collaborative registration procedure recognized by FDA.

3. The eligible product shall be the same as the product duly approved in the reference drug regulatory agencies or registered or prequalified under the collaborative registration procedure.
4. The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any reference drug regulatory agency due to quality, safety, or efficacy reasons.
5. The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the reference drug regulatory agency with the addition of country-specific information stipulated in the current labelling requirements.
6. All documents must be in English.

C. **Implementation Arrangements.** For the purposes of the implementation of this Order, the FDA shall undertake the following:

1. Issue the procedural guidelines, including the application procedure, documentary requirements, and forms through separate FDA Circular/s;
2. Publish a list of reference drug regulatory agencies;
3. Endeavour to incorporate digitization initiatives and other reengineering and streamlining activities, including assignment of dedicated technical staff, to ensure efficiency of the facilitated registration process;
4. Establish mechanisms, through bilateral and/or multilateral agreements, as applicable, that are in accordance to the principles of Good Regulatory Practices, that will allow information- and work-sharing to enable seamless evaluation using the facilitated registration routes;
5. Undertake strengthening of post-marketing surveillance and pharmacovigilance activities to ensure continuous mitigation of risks; and,
6. Undertake a review of the implementation of this Order after a period of two (2) years.

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

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OCT 01 2020
MARIA CRISTINA P. RIVERA
KMITS - RECORDS SECTION
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APPENDIX
Registration routes for drug products, including vaccines and biologicals