



**FDA CIRCULAR**  
**No.2020-012**

02 APR 2020

**SUBJECT: Guidelines for the Registration of Drug Products under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19)**

**I. RATIONALE**

The coronavirus disease (COVID-19) outbreak has been declared a pandemic. Enhanced Community Quarantine (ECQ) was declared and a state of Public Health Emergency throughout the Philippines is in effect. Undeniably, the country is in the midst of an emergency brought about by COVID-19 posing a clear and present risk to the health and lives of the general public. A global search for an effective treatment is on the race to save the lives of infected people against this emerging disease. In the management algorithm issued by the Philippine Society for Microbiology and Infectious Diseases (PSMID) for the Clinical Management of Adult Patients with Suspected or Confirmed COVID-19 Infection, as adopted by the Department of Health thru Department Memorandum No. 2020-0138, certain drug products are considered for use in hospitalized, probable or considered patients with COVID-19. There is an emergent need to address the public's need for quality, safe, and effective medicines for the disease.

**II. OBJECTIVE**

This Circular aims to provide streamlined requirements and application process for the registration of Drug Products under Emergency Use (DEU) for COVID-19.

**III. SCOPE AND COVERAGE**

This Circular shall be applicable to all Marketing Authorization Holders (MAH) intending to manufacture and import/distribute the drug products listed in the PSMID Interim Guidelines on the Clinical Management of Adult Patients with Suspected or Confirmed COVID-19 Infection. These are the only considered Drug Products under Emergency Use (DEU) for the pandemic:

<b>Generic Name</b>	<b>Dosage Form and Strength</b>
Tocilizumab	400 mg/ 20 mL Concentrate Solution for I.V. Infusion
Lopinavir + Ritonavir	200 mg/ 50 mg Film-Coated Tablet
Chloroquine Phosphate	250 mg Tablet 500 mg Tablet
Hydroxychloroquine Sulfate	200 mg Film-Coated Tablet



The list shall be updated following any change/s in the above-stated treatment guidelines.

#### **IV. GUIDELINES**

##### **A. Eligibility Criteria**

The DEU shall be locally manufactured or imported and distributed for the management of COVID-19 patients during the pandemic, following the PSMID Interim Guidelines.

##### **B. Documentary Requirements**

Only the following requirements shall be submitted by the MAHs:

1. Integrated Application Form (in excel and in pdf format)
2. Letter of Intent
3. Valid License to Operate of Drug Manufacturer/Repacker/Packer/Trader (for locally manufactured products) or Drug Importer (for imported products)
4. Certificate of Pharmaceutical Product or Certificate of Free Sale (for imported products)
5. List of countries where the product is marketed (for biologicals)
6. Certificate of Foreign Good Manufacturing Practice (GMP) Clearance duly issued by this Office and/or GMP Certificate issued by the national regulatory authority or other competent regulatory authority (for imported products)
7. Labeling Materials
  - Generic Labeling Exemption may be granted for products exceeding 12,000 units.
8. Product Composition/Formulation (Unit Dose and Batch Formulation)
9. Finished Product Technical Specifications
10. Finished Product Certificate of Analysis (CoA) and Batch Analysis
11. Stability Studies
  - Drug products with no stability studies shall be given an interim shelf-life of 6 months.
12. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip)

##### **C. Application Process**

1. There shall be no need for the scheduling of submission of applications under this Circular.
2. Applications for the registration shall be under Emergency Use Classification and shall be submitted at the Food Drug Action Center (FDAC). Submission of applications may be done either:
  - **Manual submission to FDAC**  
Submit the requirements in a flash drive at the FDAC – PACD. An Acknowledgement Receipt with a corresponding Document Tracking Number shall be issued to the applicant.

▪ **E-mail submission**

The applicant shall submit the application through [fdac.pacd.cdrr@fda.gov.ph](mailto:fdac.pacd.cdrr@fda.gov.ph). Guidance for e-mail submission shall be specified in a separate issuance.

**D. Fees**

The appropriate fees as prescribed under existing regulations shall apply, including the Legal Research Fund (LRF).

Application Type	Fees
Emergency Use Registration	Php 5,000.00 + LRF
Brand Name (if any)	Php 500.00 + LRF per brand name

**E. Validity of Certificate of Product Registration (CPR)**

The CPR shall be valid for one (1) year under Emergency Use Registration Status and is not subject for renewal registration. Automatic revocation of the CPR shall be imposed at the end of the pandemic.

**F. Post-Approval Compliance**

Post-Approval Compliance to the CPR shall be strictly required from the MAHs.

**1. Post-Approval Commitments** – shall be submitted within the CPR validity, or as prescribed below:

- a. Post-Approval Stability Data of Commercial Batch/es for products without stability data submitted upon its registration
- b. Commercial sample from the first batch of manufacture (local) or importation shall be submitted to this Office prior to distribution
- c. Reference standards of the Active Pharmaceutical Ingredient/s (API) – submission shall be within five (5) working days from the CPR issuance

**2. Post-Market Surveillance (PMS)**

Health institutions (Hospitals, other Health Facilities) and Healthcare Professionals that shall use the products approved under this Circular shall be coordinate and submit to the respective suppliers/MAH for Adverse Drug Reaction (ADR) reports. The MAH shall be responsible for the submission of the ADR reports consistent with the latest issuance with this Office.

The MAH shall undertake the PMS activities in a separate issuance.

**G. Supplemental Information**

As interim measures for applications and transactions during the community quarantine, electronic signatures in documents shall be temporarily allowed. The requirement for notarized documents shall also be temporarily suspended. Instead, the applicant shall be required to submit a commitment letter for the submission of the notarized documents once available.

**V. REPEALING CLAUSE**

In the event that any provision or part of this Circular is declared unauthorized or rendered invalid by any court of law, those provisions not affected by such declaration shall remain valid and effective.

**VI. EFFECTIVITY**

This Circular shall take effect immediately for the duration of the declared quarantine for the management of the COVID-19 situation, and the effectivity of this Circular shall likewise be automatically lifted once the imposed quarantine is lifted.

  
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