Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

02 APR 2020

FDA CIRCULAR
No. 2020-013

SUBJECT: **Guidelines for Monitoring Drug Products Used for the Treatment of COVID-19**

I. INTRODUCTION

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. Drug products opted to be used in this emergency crisis must be of good quality and its safety is monitored.

II. OBJECTIVE

This Circular aim to provide interim guidelines on the (1) reporting of adverse drug reactions (ADR) on the medicines used for the treatment of COVID-19 and (2) quality monitoring of these drug products.

III. SCOPE

This Circular applies to all Marketing Authorization Holders (MAHs), in coordination with hospitals and other health facilities, of the following drug products that will be used for the treatment of patients with COVID-19:

- Chloroquine (CQ)
- Hydroxychloroquine (HCQ)
- Lopinavir + Ritonavir
- Tocilizumab
- Other drug product/s that will either be used as a monotherapy or in combination with any of the mentioned drug product for an effective treatment of COVID-19

IV. GUIDELINES

A. For Hospitals, other Health Facilities, and Healthcare Professionals

1. All government and private hospitals, and other health facilities including healthcare professionals shall monitor the safety of the drug products used for the treatment of COVID-19 patients.

2. ADR reports shall be coordinated and submitted to the respective suppliers/MAH who will be responsible in submitting these reports to the FDA.
3. If the products were donated with no local MAH and supplied by the Department of Health (DOH), ADR reports shall be directly submitted to the FDA through any of the following:
    - The online reporting tool may be used via https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH. Indicate "COVID-19" in the field *reason for taking the medicine*.
    - Hospitals with VigiFlow accounts shall utilize this electronic ADR reporting system. Indicate that the product/s were used to treat COVID-19 in the field *Indication as reported by initial reporter*.
    - E-mail us at pharmacovigilance@fda.gov.ph.

B. For Marketing Authorization Holders

1. **Adverse Drug Reaction Reporting**
    a. All provisions of the FDA Circular No. 2020-003: Guidelines for Pharmaceutical Industry on Pharmacovigilance shall be followed including those specified in this Interim Guidelines.
    b. All ADRs whether serious, non-serious, expected, or unexpected which are experienced by the patients receiving any of the above-mentioned drug products as off-label use for the treatment of COVID-19 must be reported to the FDA.
    c. All ADR reports must be treated as solicited reports and there must be an organized data collection system in coordination with hospitals and other health facilities using their products in treating patients with COVID-19.
    d. Discharged patients treated and prescribed with take home medicines of the aforementioned drug products shall be followed up for any side effects or ADR.
    e. Any outcome on the use of these drug products during pregnancy shall be monitored in reference to the FDA Circular No. 2020-003.
    f. All ADRs must be notified to the FDA on a daily basis, updated in the line-listing, and must be sent through email to pharmacovigilance@fda.gov.ph. Each drug product should have a separate line-listing and must have at least the following information:
        - Date of receipt of information
        - Age
        - Sex
        - Suspected adverse reaction (MedDRA)
        - Date of onset of reaction
        - Seriousness (non-serious or serious [criteria])
        - Indicate if no ADR report was received on a particular date.

g. All notified ADRs must be completed and reported to the FDA as soon as possible, regardless of its seriousness and expectedness, but not later than fifteen (15) calendar days. The reporting time clock starts after the first knowledge of any personnel of the MAH on the said adverse reaction. Indicate in the Individual Case Safety Report that the drug was used for the treatment of COVID-19 [for E2B, use "coronavirus infection" as MedDRA term in element *17. Indication(s) for use* then indicate "COVID-19" in the element *Case narrative*; for CIOMS Form I indicate "COVID-19" directly in *17. Indication(s) for use*].

2. Product Quality Monitoring for MAH

a. Distribution records of each drug product must be submitted by the MAH to the FDA with the following conditions for monitoring and traceability, especially when untoward events or situations arise:

i. Submission of these records must be made from the start of distribution to the market and must be updated weekly, every Thursday.

ii. These must be sent to cdrr_postmarketsurveillance@fda.gov.ph with the subject: Distribution Records [COVID19]-*[Registration No.]*, e.g., Distribution Records [COVID19]-DR-XY*xxxxx*.

iii. The records must start with the total quantity of stocks manufactured or imported. Thereafter, distributed stocks must be deducted from this total quantity.

iv. The said records must be provided in an .xlsx or .xlsm file format (Microsoft Excel) with the following format for consistency:

REG. NO.	TOTAL QTY. (manufactured or imported)	BATCH/ LOT NO.	MFG. DATE	EXP. DATE	NAME OF RECIPIENT ESTABLISHMENT	CLASSIFICATION (Distributor, Community Drugstore, Hospital, Other Health Facility)	QTY. DISTRIBUTED	REMAINING STOCKS

v. In another worksheet in your Excel workbook, list down all of the names of recipient establishments with the following format for consistency:

NAME OF RECIPIENT ESTABLISHMENT	COMPLETE ADDRESS	CONTACT PERSON	DESIGNATION OF CONTACT PERSON	TEL. NO.	MOBILE NO.	E-MAIL ADDRESS

b. The MAH shall implement their extensive post-marketing surveillance for the abovementioned drug products. Verified counterfeits of these shall be immediately reported to the FDA by sending an e-mail to covidresponse@fda.gov.ph as an advance notification and shall submit the actual sample thereafter at the FDA Action Center. This shall form as part of the Risk Management Plan for establishment of the MAH.

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 Order shall take effect immediately and deemed valid until further notice.

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Director General