Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

August 4, 2020

DEPARTMENT CIRCULAR
No. 2020 - 0314

TO: **ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES OF HEALTH; MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO; DIRECTORS OF BUREAUS, SERVICES, AND CENTERS FOR HEALTH DEVELOPMENT (CHD); CHIEFS OF DEPARTMENT OF HEALTH MEDICAL CENTERS, HOSPITALS; AND OTHERS CONCERNED**

SUBJECT: **Circulation of the Reiteration of the Guidelines on the Management and Use of Investigational Drugs for COVID-19**

The DOH hereby reiterates the guidelines related to the management and use of investigational drugs for COVID-19 for the adherence of healthcare professionals in all recognized health facilities as follows:

1. Adoption of the Interim Guidance on the Clinical Management of Adult Patients with Suspected or Confirmed COVID-19 Infection, Version 3.1, dated July 20, 2020 (see attached) which include:

Management of patients confirmed or suspected to have COVID-19

Classification	Signs and Symptoms	Recommended Diagnostics	Management
Mild	Fever, cough, fatigue, anorexia, myalgias Other non-specific symptoms such as sore throat, nasal congestion, headache, diarrhea, nausea and vomiting, Loss of smell (anosmia) or loss of taste (ageusia) preceding the onset of respiratory	SARS CoV-2 RT-PCR	Home isolation for 14 days with instructions or send to community quarantine facility. Admit if elderly or with unstable/uncontrolled co-morbid conditions. Give symptomatic treatment and supportive care as

	symptoms NO signs of pneumonia or hypoxia		needed. Empiric antibiotics NOT needed
Moderate	With signs of Non-severe pneumonia (e.g. fever, cough, dyspnea, RR <30/minute, SpO_2 >92% on room air)	SARS CoV-2 RT-PCR CXR or CT scan CBC, ALT, AST, Creatinine ECG	Admit to a COVID-19 designated room/unit
Severe	Severe Pneumonia or severe acute respiratory infection, as follows: Fever, cough, dyspnea RR >30 breaths/minute, severe respiratory distress or SpO_2 ≤92% on room air	SARS CoV-2 RT-PCR CBC Comprehensive metabolic panel Ferritin, LDH, Procalcitonin or CRP, INR/PT, D-dimer, Lactate CXR or CT scan Sputum GS/CS, Blood cultures, as appropriate ABG	Supportive Therapy and Monitoring for COVID-19 Patients with Pneumonia
Critical	Onset within 1 week of known clinical insult (pneumonia) or new or worsening respiratory symptoms, progressing infiltrates on CXR or chest CT, with respiratory failure not fully explained by cardiac failure or fluid overload (COVID-ARDS)	SARS CoV-2 RT-PCR CBC Comprehensive metabolic panel ABG Ferritin, LDH, Procalcitonin, CRP, INR/PT, D- dimer, Lactate Repeat CXR or CT scan ETA GS/CS, Blood cultures, as appropriate	Management of COVID-19 Acute Respiratory Distress Syndrome (CARDS)
	Sepsis: life-threatening organ dysfunction caused by a dysregulated host response to suspected or proven infection, Signs of organ dysfunction: altered mental status		Management of Severe Sepsis or Septic Shock

	difficult or fast breathing low oxygen saturation reduced urine output fast heart rate, weak pulse, cold extremities or low blood pressure, skin mottling, or laboratory evidence of coagulopathy, thrombocytopenia, acidosis, high lactate or hyperbilirubinemia		
	Septic Shock: persisting hypotension despite volume resuscitation, requiring vasopressors to maintain MAP $\geq$ 65 mmHg and serum lactate level >2 mmol/L		

These shall be used in the clinical management of COVID-19 cases in all hospitals and health facilities, both public and private, subject to the continuous update based on emerging best available evidence.

2. All health facilities where the investigational products (IPs) are deployed and all healthcare professionals must comply with the existing FDA protocols on clinical trials, off label and compassionate use of drugs, and pharmacovigilance, i.e., FDA Circular No. 2020-013 dated April 2, 2020 with subject, "Guidelines for Monitoring Drug Products Used for the Treatment of COVID-19," FDA Advisory 2020-1038 dated June 5, 2020 with subject, "Risks Associated with the Use of Favipiravir," Administrative Order (AO) No. 4 series of 1992 dated November 3, 1992 with subject, "Policy and Requirements for Availing of Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/Preparation," (attached) and other related issuances. Moreover, the facilities can refer to the rapid evidence reviews on COVID-19 management as provided in the updated Philippine Society for Microbiology and Infectious Diseases, Inc. (PSMID) guidelines and can be viewed at https://www.psmid.org/rapid-evidence-review-on-covid-19-management/.

3. All hospitals and health facilities, both public and private, especially where the IPs are deployed, must submit all adverse drug reaction (ADR) reports directly to the FDA through e-mail at pharmacovigilance@gov.ph or via an online reporting tool https://primaryreporting.whoumc.org/Reporting/Reporter?OrganizationID=PH.

The guidelines are provided in the FDA Circular No. 2020-013 and FDA Circular No. 2020-003 dated February 26, 2020 with subject, "Guidelines for Pharmaceutical Industry on Pharmacovigilance" (attached).

4. The adherence to guidelines set by the DOH, National Ethics Committee, and the PSMID in ensuring patient rights and safety in accessing investigational treatments for COVID-19, as reiterated by the Health Technology Assessment Council (HTAC), on the use of investigational treatments particularly for patients who will not be eligible to participate in clinical trials but are allowed for compassionate use, are as follows:

    - There must be a credible (reasonable) justification for its use.
    - Informed consent must be obtained from the patient or the legally accepted representative of the patient. The informed consent process must avoid coercive presence and possible sources of undue influence and shall include the description of probable risks and out-of-pocket costs.
    - The clinical outcomes should be well-documented and shall be submitted by each participating hospital to the DOH and FDA; and,
    - The use of the drug should follow a strict protocol, with exercise of due diligence to evolve into a clinical trial.

Dissemination of the attached guidelines to all concerned is hereby requested.

Thank you.

By Authority of the Secretary of Health

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for Investigational Treatment for COVID-19
OIC-Undersecretary, Health Regulation Team