Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

FDA ADVISORY
No. 2021-0759

17 APR 2021

TO : **ALL HEALTHCARE PROFESSIONAL AND THE GENERAL PUBLIC**

SUBJECT : **Clarification on the Approval and Use of Remdesivir**

The Food and Drug Administration (FDA) clarifies that Remdesivir has no Certificate of Product registration in the Philippines.

Remdesivir is used in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization.

The FDA granted Compassionate Special Permits (CSP) for Remdesivir as requested by doctors and hospitals for the treatment of COVID-19 patients.

It is clarified that a CSP is a special permit granted to physicians or hospitals to use investigational drugs or drugs which are not yet registered or in the process of registration here in the Philippines for the treatment of seriously ill patients. A CSP can only be requested by physicians in charge or by the institution where patients are being treated, who takes full responsibility for the use and dispensing of the requested drug product. The CSP holder must fully inform the patient of the benefits and risks of the product, and provide a report to the FDA of the outcomes for every patient given the product. This permit is given only to qualified doctors or health facilities who are authorized to use the product for a specific number of patients with an estimated small volume, and is valid for 1 year.

The public is assured that FDA recognizes the potential help of investigational products to manage COVID-19. FDA ensures that access to these types of drugs is in place in the Philippines. However, while a CSP grants access to investigational drugs or drugs which are not yet registered in the Philippines, the permit is not intended to replace the prescribed drug registration process which involves a systematic evaluation of evidence-based data. It must be stressed that an approved CSP is not a Certificate of Product Registration (CPR) or an Emergency Use Authorization (EUA), hence it is not an assurance of the product quality, safety, and efficacy. No product granted with CSP can be marketed commercially.

The FDA continues to work with the government and private sector to address the effects and impact of this pandemic while adhering to health regulatory standards.

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