Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20220604

16 MAR 2022

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

SUBJECT: **Public Health Warning on Falsified Drug Product "DESREM" Confirmed by the World Health Organization (WHO)**

The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on falsified Remdesivir 100 mg/vial Lyophilized Powder for Injection for IV Infusion with brand name "DESREM" which were detected in the Americas and South-East Asia regions in February 2022:

DRUG PRODUCT	**Remdesivir 100 mg/vial Lyophilized Powder for Injection for IV Infusion [DESREM]**		
BATCH/LOT NO./EXP. DATE/PACKAGING LANGUAGE	**7605854B**	**09/2022**	**English**
	CRM21001MA	**07/10/2022**	**Spanish**
STATED MANUFACTURER	**Mylan Laboratories Ltd.**		

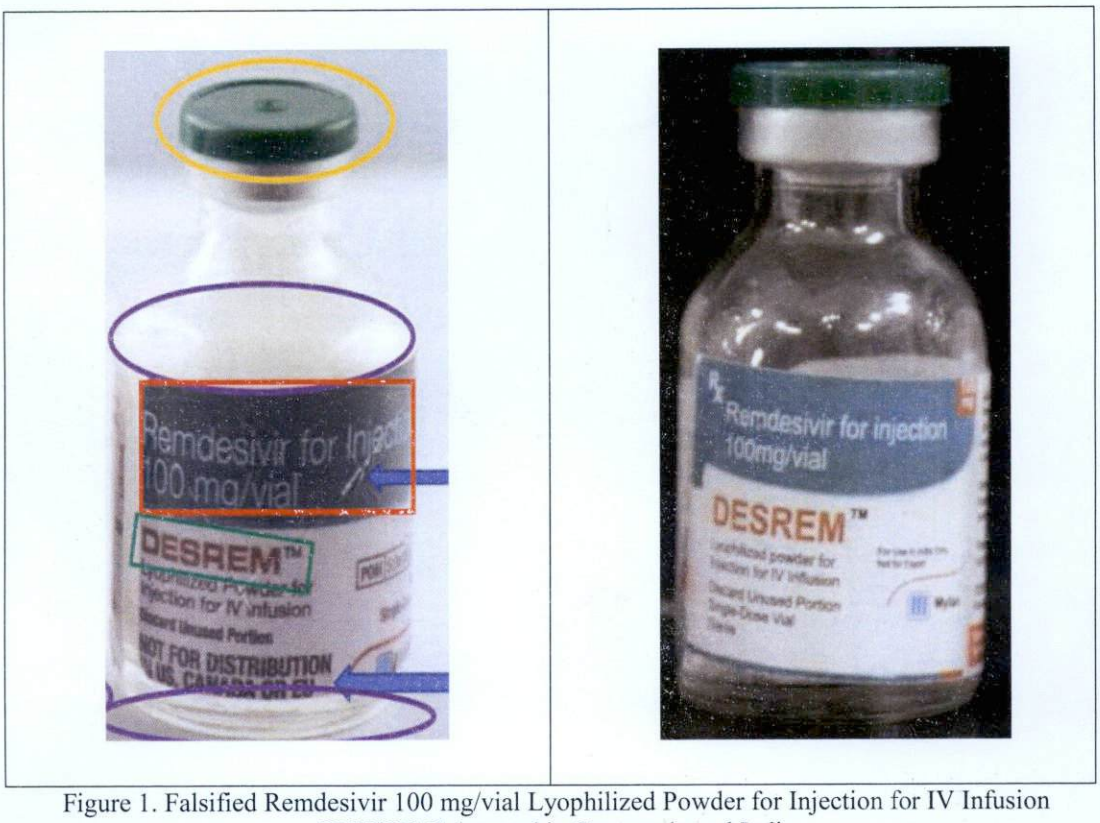

Figure 1. Falsified Remdesivir 100 mg/vial Lyophilized Powder for Injection for IV Infusion [DESREM] detected in Guatemala and India

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The FDA strongly advises the public to be vigilant on the circulation of this falsified drug product since this poses a risk to global public health and hamper efforts to treat patients with COVID-19. A falsified drug product deliberately or fraudulently misrepresents its identity, composition, or source. Laboratory analysis conducted by the genuine manufacturer established that the falsified products do not contain any active pharmaceutical ingredient (API) and confirmed as non-compliant to the specifications. It was also confirmed that the expiration dates of Batch/Lot Nos. 7605854B and CRM21001MA do not correspond to genuine manufactured "DESREM".

This is to emphasize that Remdesivir 100 mg/vial Lyophilized Powder for Injection for IV Infusion [DESREM] is not registered with FDA. Authentic Remdesivir is a broad-spectrum antiviral medication that has been approved or authorized to treat COVID-19 in several countries.

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that this falsified drug product is not sold or not administered to patients in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report unauthorized sale, or distribution of the abovementioned, kindly e-mail us via **cdrr.od@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**.

Dissemination of the information to all concerned is highly requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

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