REPUBLIC OF THE PHILIPPINES
INTER-AGENCY TASK FORCE
FOR THE MANAGEMENT OF EMERGING INFECTIOUS DISEASES
NATIONAL TASK FORCE AGAINST COVID-19

MEMORANDUM CIRCULAR
No. 2, s. 2021

TO : **ALL MEMBER AGENCIES OF THE VACCINE CLUSTER**

FROM : **SECRETARY CARLITO G. GALVEZ, JR.**
Vaccine Czar and Chief Implementer
National Task Force Against COVID19

SUBJECT : **CLARIFICATION ON THE ISSUANCE OF AN EMERGENCY USE AUTHORIZATION (EUA)**

DATE : **02 FEBRUARY 2021**

A. On 1 December 2020, Executive Order No. 121, s. 2020 was issued "Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefor, and For Other Purposes.

B. E.O. 121 provides that COVID-19 drugs and vaccines under development and have not yet completed the clinical trial phase can be granted an Emergency Use Authority (EUA) by the Food and Drug Administration (FDA) only when the following conditions are present:

1. Based on the totality of evidence available, including data from adequate and well-known controlled trials, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose or treat COVID-19;
2. The known and potential benefits of the drug or vaccine when used to diagnose, prevent or treat COVID-19 outweigh the known and potential risks of the drug or vaccine, if any; and
3. There is no adequate, approved and available alternative to the drug or vaccine for diagnosing, preventing or treating COVID-19.

C. The approval of the EUA will be based on the results of thorough and robust evaluation conducted by regulatory officers and medical / vaccine experts. It shall also be based on the submitted requirements of pharmaceutical companies in accordance to the FDA Circular 2020-036 "Guidelines on the Issuance of EUA for Drugs and Vaccine for COVID-19". The EUA shall be valid only within the duration of the declared public health emergency due to COVID-19, without prejudice to the discretion of the FDA Director General to revisit or revoke the same, as may be appropriate, to protect the general public health and safety.

D. In view of the foregoing, this is to reiterate that **the issuance of the EUA is not equivalent to a marketing authorization / Certificate of Product Registration. Hence, the COVID-19 vaccines are not to be treated as commercial products even if issued with EUA.**

E. Furthermore, all are enjoined to cause the widest dissemination of this information where appropriate and to clarify or correct any misinformation, when necessary.

FOR GUIDANCE AND APPROPRIATE ACTION.