PRESS STATEMENT
08 January 2021

Updates on Applications for Conduct of Clinical Trials and Emergency Use Authorization of COVID-19 Vaccines

The Food and Drug and Drug Administration (FDA) continues to accept applications for the conduct of COVID-19 Vaccine clinical trial (CT) in the Philippines. To date, FDA has received three (3) applications which underwent review and assessment of the Department of Science and Technology - Vaccine Expert Panel (DOST-VEP) and the Single Joint Ethics Review Board (SJREB).

On 28 December 2020, the FDA has granted approval for the conduct of CT on COVID-19 vaccine developed by Janssen Vaccines & Prevention B.V. The FDA also approved the clinical trial for the vaccine developed by Clover Biopharmaceuticals AUS Pty Ltd. today, 08 January 2021. "The FDA is currently awaiting response to clarifications for the proposed study on the Sinovac Life Sciences vaccine before issuing a decision on the application", Director General Eric Domingo said.

Acceptance and review of applications for Emergency Use Authorization (EUA) of COVID-19 vaccines is also underway. Evaluation of Pfizer-BioNTech COVID-19 Vaccine and AztraZeneca Pharmaceuticals-ChAdOx1-S (recombinant) COVID-19 Vaccine is ongoing. DG Domingo stated that the decision of approval is expected to be released within 21 calendar days upon filing of application.

The EUA application for Sputnik V developed by Gamaleya National Center of Epidemiology and Microbiology- Ministry of Health Russia was received on 07 January 2021. "The submission was pre-assessed and the applicant was instructed to comply with the lacking documents," DG Domingo ended.