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Sixth Amendment to the Emergency Use Authorization (EUA) for COVID-19 Vaccine (Ad26.COV2-S [recombinantl)[1]

This refers to the request to amend the Emergency Use Authorization (EUA) for COVID-19 vaccine (Ad26.COV2-S [recombinant]) ("Janssen COVID-19 Vaccine") to delete Aspen SVP, South Africa as Final Release Site to reflect the correct drug product supply flow.

After due consideration, the Food and Drug Administration (FDA) hereby revises the EUA granted to Janssen COVID-19 Vaccine to reflect the requested change.

The foregoing revisions are made pursuant to the discretionary power of the FDA under Section 6 of Executive Order (EO) No. 121, entitled *"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,* " to revisit any issued EUA as may be appropriate to protect the general public health and safety.

The details of the Janssen COVID-19 vaccine are as follows:

Product Name:	COVID-19 vaccine (Ad26.COV2-S [recombinant])
Dosage Strength:	5 x 10^{10} virus particles (VP)
Dosage Form:	Suspension for injection
Pharmacologic category:	Vaccine, other viral vaccines
Shelf Life and Storage:	11 months at 2-8^{0}C The shelf-life of the Ad26.COV2-S drug product is 24 months when stored frozen at the recommended storage condition of -25 ^{0}C to -15 ^{0}C, and within these 24 months. The drug product should not be frozen after it has been placed in storage at 2-8 ^{0}C. The drug product must be stored in the original packaging in order to protect it from light.
Presentation:	2.5 mL multi-dose vial/Box of 10's
Manufacturer:	Janssen, Pharmaceutical Companies of Johnson and Johnson

[1]We refer you to the EUAs dated 19 April 2021 and 26 April 2021, Amended EUA dated 07 September 2021, Second Amendment to the EUA dated 19 November 2021, Third Amendment to the EUA dated 31 December 2021, Fourth Amendment to the EUA dated 12 January 2022, and the Fifth Amendment to the EUA dated 28 March 2022.

Indication: For active immunization to prevent COVID-19 caused by SARS COV-2 in individuals 18 years of age and older

After careful consideration of the application, with all its supporting documents and a review of local experts, the FDA has been satisfied that all the conditions for the issuance of an EUA exist as provided under Executive Order (EO) No. 121, s. 2020 entitled "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 Therefore, and for Other Purposes, " particularly:

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

In issuing this EUA, recognition and reliance have been accorded to, the Emergency Use Listing (EUL) of the World Health Organization (WHO), and emergency use authorizations given by mature and established National Regulatory Authorities (NRAs) such as the United States of America, Canada and the European Medicines Agency, respectively. Under Section 5 of EO No. 121, the Director General of the FDA has been granted power to implement reliance and recognition processes, and accept regulatory decisions of recognized and established regulatory authorities.

This EUA is not a marketing authorization or a Certificate of Product Registration (CPR). Hence, this EUA cannot be used as an authorization to market the vaccine commercially.

While the evaluation process was facilitated, strict conditions on the authorization granted in this Letter shall be imposed as follows:

I. Scope

The scope of the EUA shall be limited as follows:

A. Johnson and Johnson (Philippines), Inc. shall supply the Janssen COVID-19 Vaccine only to emergency response stakeholders consistent with the terms and conditions of this EUA.

   "Emergency response stakeholders" shall refer to the Department of Health (DOH) or the National Task Force Against COVID-19 (NTF) or their designees authorized to procure or purchase Janssen COVID-19 Vaccine in line with the COVID-19 vaccination program. Designees may include hospitals (public and private), health facilities of other National Government Agencies, Local Government Units (LGUs) and other members of the Private Sector.

B. The Janssen COVID-19 Vaccine shall be administered only by vaccination providers, and used only to prevent COVID-19 in individuals ages 18 and older.

"Vaccination providers" shall refer to the facility, organization, or a healthcare provider, including non-physician healthcare providers such as nurses or pharmacists, authorized by the DOH or the NTF to administer the Janssen COVID-19 Vaccine in accordance with the COVID-19 vaccination program.

II. Dosage Strength, Form and Administration

Janssen COVID-19 Vaccine is supplied as a suspension in multi-dose (5 doses) vials. The dosing regimen is a single dose of 0.5mL administered as intramuscular injection. Each 0.5 mL dose of the Janssen COVID-19 Vaccine is formulated to contain $5x10^{10}$ virus particles of the Ad26 vector encoding the S glycoprotein of SARS-CoV-2.

A booster dose (second dose) of 0.5 mL of COVID-19 Vaccine Janssen may be administered intramuscularly at least 2 months after the primary vaccination in individuals 18 years of age and older.

A single booster dose of the Janssen COVID-19 Vaccine (0.5ml) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, Johnson and Johnson (Philippines), Inc. shall provide appropriate cold chain requirements for storage, transport and handling until it is delivered to the inoculation sites, and ensure that a contingency plan is in place.
Johnson and Johnson (Philippines), Inc. shall have a system of monitoring to ensure traceability and that the vaccine is consistent with the storage requirements from the manufacture and transport to the inoculation sites.

Johnson and Johnson (Philippines), Inc. shall observe strict compliance with the standards for Good Distribution Practices (GDP) and Good Storage Practices (GSP) adopted pursuant to Administrative Order No. 2013-0027 including supplements thereto (i.e. WHO Technical Report Series No. 961, 2011, Annex 9 and Technical Report Series No. 992, 2015, Annex 5). Johnson and Johnson (Philippines), Inc. shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

Johnson and Johnson (Philippines), Inc. shall have a comprehensive pharmacovigilance system for Janssen COVID-19 Vaccine following system or protocol for a registered drug and biologic product as stated in the FDA Circular No. 2020-003. Submission of serious and non-serious adverse reaction reports is mandatory.

Johnson and Johnson (Philippines), Inc. shall ensure compliance with the Risk Management Plan (RMP) along with the Philippine-specific Annex. Additional pharmacovigilance activities such as interventional and non-interventional studies (ongoing or new studies, or additional activities) shall be implemented as stated in the RMP. The RMP must be updated

whenever there is a significant change which may affect the benefit-risk profile of the vaccine or when an important milestone is reached.
Johnson and Johnson (Philippines), Inc. shall submit monthly summary safety reports as planned and discussed in the RMP.

V. Responsibility of Emergency Response Stakeholders and Vaccination Providers

Under FDA Circular No. 2020-036 or the Guidelines for the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19, the pharmacovigilance obligations and pose authorization commitments imposed in the Letter shall be shared to the fullest extent possible and applicable by the national procurer and health program implementors, and their designees. Emergency response stakeholders and vaccination providers shall have the following responsibilities.

A. Emergency response stakeholders shall:
    1. Identify inoculation sites to receive the Janssen COVID-19 Vaccine, and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with Johnson and Johnson (Philippines), Inc;
    2. Ensure administration of the Janssen COVID-19 is consistent with the terms of this Letter, latest product information and the COVID-19 Vaccination Program; and
    3. Ensure that vaccination providers of the procured Janssen COVID-19 Vaccine are aware of this Letter of Authorization and the terms herein and any subsequent amendments thereof, instructed about the means which they are to obtain and administer the Janssen COVID-19 Vaccine, and provided with approved fact sheets.

B. On the Other hand, vaccination providers shall:
    1. Administer the Janssen COVID-19 Vaccine, in accordance with this EUA, and participate and comply with the terms and training required by the DOH for the COVID-19 Vaccination Program;
    2. Provide fact sheets to the recipients and caregivers, and provide necessary information for receiving their second dose;
    3. Obtain written informed consent from the recipient of the Janssen COVID-19 Vaccine prior to vaccination;
        a. Report any Adverse Events Following Immunization on the use of Janssen COVID-19 Vaccine;
        b. Monitor and comply with vaccine management requirements (e.g. obtaining, tracking and handling vaccine) of the DOH; and
        c. Ensure that records associated with this EUA are maintained until notified by FDA. Such records shall be made available to DOH and FDA for inspection upon request.

Notwithstanding the foregoing, Johnson and Johnson (Philippines), Inc. has the ultimate responsibility for monitoring the safety and quality of the Janssen COVID-19 Vaccine.

VI. Validity

Unless otherwise revoked, this EUA shall be valid only within the duration of the declared public health emergency due to COVID-19, or upon issuance of a marketing authorization/Certificate of Product Registration.
In the event that the declared public health emergency is lifted, or when a COVID-19 drug or vaccine is registered with the FDA, this EUA shall have a provisional validity for a period of one (1) year from date of lifting of the declaration or registration of the drug or vaccine for the sole purpose of exhausting remaining products.

This EUA is subject to revocation, suspension or cancellation due to violations of pharmacovigilance obligations and post authorization commitments, as well as any violation of the EO No. 121, and RA 3720 as amended by RA No. 9711, FDA Circular No. 2020-036, and other rules and regulations issued thereunder.

For strict compliance.