Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

June 18, 2021

DEPARTMENT MEMORANDUM
No. 2021 - 0287

TO : **ALL DEPARTMENT UNDERSECRETARIES AND ASSISTANT SECRETARIES; CENTERS FOR HEALTH DEVELOPMENT AND MINISTRY OF BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (BARMM); AND BUREAU DIRECTORS; SPECIAL AND SPECIALTY HOSPITAL DIRECTORS; CHIEFS OF MEDICAL CENTERS, HOSPITALS AND SANITARIA; AND OTHER CONCERNED OFFICES**

SUBJECT : **Guidelines for the Management and Administration of COVID-19 mRNA Vaccine (Nucleoside Modified) Moderna COVID – 19 Vaccine**

I. RATIONALE

In light of the absence of definitive treatment for COVID-19, it is expected that COVID-19 morbidity and mortality will continue to increase. The development of vaccines against COVID-19 is among the solutions that will greatly mitigate the increasing cases in the country, complemented by already existing prevention measures and practices in place.

To ensure safety and efficacy of vaccines to be administered to the public, ONLY vaccines which are granted with Emergency Use Authorization (EUA) by the Philippine Food and Drug Administration and a positive recommendation from the Health Technology Assessment Council (HTAC) will be purchased by the government. Moderna COVID-19 vaccine was granted an EUA by the Philippine FDA last May 5, 2021.

Likewise, guidance on vaccine implementation shall be ***vaccine-specific***, strictly following the approved use stated in the EUA issued by the Philippine FDA. The DOH hereby issues these specific guidelines to supplement the National Deployment and Vaccination Plan (NDVP) technical guidance document for public and private healthcare facilities in the implementation of the COVID-19 Immunization Program specifically for COVID- 19 mRNA Vaccine (Nucleoside Modified) Moderna COVID- 19 Vaccine, referred to as Moderna COVID-19 vaccine in this guidelines.

II. GENERAL GUIDELINES

1. Prioritization of population groups, allocation, and quick substitution listing for Moderna COVID-19 vaccines shall be based on the Department Memorandum No. 2021-0099, otherwise known as "*Interim Omnibus Guidelines for the*

Implementation of the National Vaccine Deployment Plan for COVID-19" and other updated guidelines (Department Memorandum 2021-0157: "Implementing Guidelines for Priority Group A3 and Further Clarification of the National Deployment and Vaccination Plan for COVID-19 Vaccines"; DM No. 2021-0175: "Further Clarification of the National Deployment and Vaccination Plan for COVID-19 Vaccines and Additional Guidelines for Sinovac Vaccine Implementation", DM No. 2021-0259: "Implementing Guidelines for Priority Groups A4, A5 and Further Clarification of the National Deployment and Vaccination Plan for COVID-19 Vaccines").

2. All LGUs shall ensure that Rural Health Units and identified COVID-19 Vaccination Sites shall formulate/revisit their microplans to determine local needs and gaps to ensure smooth and satisfactory vaccine implementation in accordance with the National Deployment and Vaccination Plan.

3. Inventory management of vaccines, from delivery and acceptance to disposal shall be based on Department Memorandum 2021-0053 and 2021-0031 entitled, "*Interim Guidelines on the Shipment and Acceptance of COVID-19 vaccines and ancillary immunization commodities*" and "*Interim Guidelines on the Management of Health Care Wastes generated from COVID-19 vaccination*", respectively.

4. Instructions for COVID-19 vaccination providers and administrators on storage and handling, dosing and schedule, administration, contraindications, warnings, adverse reactions, and use with other vaccines shall follow the Philippine FDA Fact Sheet for vaccination providers and EUA ***(See Annex A).***

5. Moderna COVID-19 vaccines shall be administered for active immunization to prevent COVID-19 in individuals 18 years of age and older, by healthcare providers, as indicated in the EUA issued by the Philippine FDA.

6. Protocols for the management of Adverse Effects Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) shall follow the provisions of the Moderna COVID-19 Vaccine Emergency Use Authorization of the FDA, succeeding guidelines from the FDA, and other recognized professional organizations and regulatory bodies, as new evidence arise.

7. The second dose of the Moderna COVID-19 Vaccine shall be given twenty-eight (28) days after the first dose. Follow-up notification shall be sent in accordance with the Department Memorandums 2021- 0099 and 2021-0175.

8. Registration, screening, counseling, vaccine recipient reporting, AEFI monitoring, and referral shall follow Department Memorandum 2021- 0099 and other relevant policies.

9. All Moderna-related information and education communication materials and other vaccination-related materials can be accessed through this link: bit.ly/RESBAKUNAVaxSpecific. A printing guide for the communication materials is made available through this link: bit.ly/RESBAKUNAPrintingInstructions.

III. IMPLEMENTING GUIDELINES

A. Moderna COVID-19 Vaccine Product Specifications

1. The Moderna COVID-19 Vaccine is a messenger RNA vaccine. It is a frozen, sterile, preservative-free, multi-dose suspension. One vial contains 10 doses of vaccine after thawing. The recommended age for inoculation of this vaccine is 18 years old and above.

2. Shelf life of an unopened vial is 7 months at -25°C to -15 °C.

3. Administration of the vaccine is done in two doses, with an interval of twenty-eight (28) days. Due to the novelty of the said vaccine, health assessment by a health care provider must be conducted prior to administration.

B. Vaccine Allocation

1. Allocation of Moderna COVID- 19 Vaccine shall be in accordance with Department Memorandum No. 2021-0099, otherwise known as, "*Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19.*"

2. Because of the sensitivity required in the handling of Moderna COVID- 19 vaccines, all COVID- 19 Vaccination Sites shall strictly provide a Quick Substitution List.

C. Indications, Precautions and Contraindications

1. Consistent with the EUA, the Moderna vaccine shall be used for individuals 18 years of age and older.

2. Co-administration of the Moderna COVID-19 Vaccine with other COVID-19 vaccines shall not be allowed.

3. The informed consent form (Annex B: bit.ly/RESBAKUNAVaxSpecific) for the COVID-19 vaccination program shall be adopted specifically for the Moderna vaccine to clearly indicate willingness to be vaccinated given full information.

4. The Health Screening Form (Annex C: bit.ly/RESBAKUNAVaxSpecific) for Moderna vaccine shall be used by the health care provider to assess the eligibility of vaccine recipients. Decision algorithms regarding deferral, need for clearance, special precautions, and non-vaccination shall follow set DOH guidelines.

5. Individuals with the following contraindications shall not be administered with the Moderna COVID-19 vaccine:

    a. Known history of a severe allergic reaction (e.g. anaphylaxis) to any component of the Moderna COVID-19 Vaccine;
    b. Age under 18 years old;

6. Moderna COVID-19 vaccine may be offered to pregnant women not in the first trimester of pregnancy if the benefits will outweigh the risks per assessment of a physician.

7. Special warnings and precautions for use:

    a. Appropriate medical treatment and supervision shall always be readily available in case of an anaphylactic reaction following administration of the vaccine. Close observation for at least 15 minutes is recommended following vaccination. The second dose of the vaccine shall not be given to those who have experienced anaphylaxis to the first dose of the Moderna COVID-19 vaccine.

    b. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation, or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. Precautions shall be in place to avoid injury from fainting.

    c. Vaccination shall be postponed in individuals suffering from acute severe febrile illness or acute infection. Vaccination shall not be delayed despite the presence of a minor infection and/or low-grade fever.

    d. As with other intramuscular injections, the vaccine shall be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

8. Possible Adverse Reactions:

    a. The majority of adverse reactions are mild to moderate in severity. Adverse reactions to the vaccine can develop 1 – 2 days after vaccination and usually resolve within 3 subsequent days.

    b. Most common adverse reactions include headache, nausea, vomiting, myalgia, arthralgia and stiffness, pain at the injection sites, fatigue, chills, fever, lymphadenopathy.

    c. Less common adverse reactions include rash, injection site redness or swelling, diarrhea.

D. Vaccine Storage, Handling, and Transfer

1. Moderna COVID-19 Vaccine Multiple Dose Vials shall be stored in the original carton in a freezer at -25° to -15° Celsius. Upon arrival, vaccines shall be stored in the following storage temperature conditions:

    a. During storage, minimize exposure to room light.

    b. The Moderna COVID-19 vaccine multiple-dose vials are stored frozen between -25°C to -15°C. Store in the original carton to protect from light.

    c. Do not store on dry ice or below -40°C. Use of dry ice may subject vials to temperatures colder than -40°C.

    d. Unopened vials may be stored refrigerated between 2°C to 8°C for a maximum to 30 days prior to first use.

    e. Unopened vials may be stored between 8°C to 25°C for a total of 12 hours after removal from refrigerated conditions

    f. After the first dose has been withdrawn, the vial should be held between 2°C to 25°C. Vials should be discarded 6 hours after the first puncture.

    g. Thawed vials can be handled in room light conditions.

    h. Do not refreeze once thawed.

2. If transport of Moderna COVID-19 vaccines at -25° to -15° Celsius is not feasible, thawed vials may be stored up to 12 hours at 2° to 8° C when shipped using shipping containers that have been qualified to maintain 2°C to 8°C and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2°C to 8°C, vials shall not be refrozen and shall be stored at 2°C to 8°C until use.

3. Only trained personnel shall handle Moderna COVID-19 Vaccines using protective gear (e.g. cryogenic gloves and goggles) at all times to avoid serious and/or debilitating injuries.

E. Vaccine Administration and Disposal

1. Prior to administration, vaccines shall be thawed using either the following techniques:

    a. Thawing in refrigerated conditions at +2°C to +8 °C: When vaccines are thawed at 2°C to 8°C, keep at room temperature for 15 minutes before use.

b. Thawing at room temperature between 15°C to 25°C – When vaccines are thawed at room temperature for one hour, vaccines can be used immediately.

2. Swirl vial gently after thawing and between each withdrawal. Do not shake and do not dilute the vaccine.

3. Withdraw 0.5 mL (single dose) to be administered intramuscularly, preferably deltoid muscle. Each vial contains 10 doses of vaccine. After the first dose has been withdrawn, keep in +2 °C to +25 °C and record the date and time of first use. Discard the vial after 6 hours and do not refreeze.

4. Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration.
   a. Verify final dosing volume of 0.5 ml
   b. Confirm that it does not contain other particulates and there is no discoloration. Do not administer if it is discolored and contains other particulate matter.

5. Upon confirmation that vials do not contain any discoloration or particulates and the final dose volume is at 0.5 mL, doses shall be immediately administered intramuscularly. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, any excess volume shall be discarded. Pooling of excess vaccine fluids from multiple vials shall be **STRICTLY PROHIBITED**.

6. After being injected with the Moderna COVID-19 Vaccine, the vaccine recipient shall be monitored for possible adverse events following immunization in a predetermined observation area prior to being sent home. Persons with a previous history of anaphylaxis, with allergies to food, egg, medicines, and persons experiencing asthma shall be observed for 30 minutes after vaccination, while persons who do not meet any of the criteria otherwise stated shall be observed for 15 minutes after vaccination.

7. Health care workers in vaccination sites shall ensure that the minimum public health standards are still implemented in the monitoring areas to prevent possible transmission of COVID-19.

This Memorandum shall take effect immediately.

By Authority of the Secretary of Health:

MARIA ROSARIO S. VERGEIRE, MD, MPH, CESO IV
OIC - Undersecretary of Health
Public Health Services Team

ANNEX A. EMERGENCY USE AUTHORIZATION FOR MODERNA
(https://www.fda.gov.ph/wp-content/uploads/2021/05/EUA-Moderna-Website.pdf)

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

5 May 2021

ZUELLIG PHARMA CORPORATION
Km. 14 West Service Rd.
South Superhighway cor., Edison Avenue Ave., Sun Valley
Parañaque, Metro Manila

Emergency Use Authorization (EUA) for COVID-19 mRNA Vaccine (Nucleoside Modified) (COVID-19 Vaccine Moderna)

This applies to the application for the issuance of Emergency Use Authorization (EUA) for COVID-19 mRNA Vaccine (Nucleoside Modified) (COVID-19 Vaccine Moderna).

The details of the COVID-19 Vaccine Moderna are as follows:

Product Name:	COVID-19 mRNA Vaccine (Nucleoside Modified) (COVID-19 Vaccine Moderna
Dosage Strength and Form:	100 mcg frozen suspension for injection
Pharmacologic category:	Vaccine
Storage and Shelf Life:	Store frozen between -25°C to -15°C. Shelf life is 7 months. Once thawed, the unopened vaccine may be stored at 2^0 to 8^0C, protected from light for a maximum of 30 days.
Packaging:	Multidose vial which contains 10 doses of 0.5 mL per dose
Manufacturer:	Moderna Biotech Spain S.L., Calle Monte Equinza 30, 28010 Madrid, Spain
Indication:	For active immunization for the prevention of 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 Therefor, and for Other Purposes,"* particularly:

1. Based on the totality of evidence available to date, including data from adequate and well- known controlled trials, it is reasonable to believe that the COVID-19 Vaccine Moderna may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the COVID-19 Vaccine Moderna, when used to diagnose, prevent, 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. 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. Zuellig Pharma Corporation shall supply COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna in accordance with the COVID-19 vaccination program.

II. Dosage Strength and Form

COVID-19 Vaccine Moderna should be supplied as a white to off white frozen suspension for injection in multidose vials. Each vial contains 100mcg of nucleoside-modified messenger RNA. The multidose vial contains 10 doses of 0.5 mL per dose. COVID-19 Vaccine Moderna vaccine is a course of 2 doses (0.5 mL each). The second dose should be administered 28 days after the first dose intramuscularly.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, Zuellig Pharma Corporation 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.

Zuellig Pharma Corporation 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.

Zuellig Pharma Corporation 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). Zuellig Pharma Corporation shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

Zuellig Pharma Corporation shall have a comprehensive pharmacovigilance system for COVID-19 Vaccine Moderna 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.

Zuellig Pharma Corporation 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.

Zuellig Pharma Corporation shall submit six (6) 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 post-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 COVID-19 Vaccine Moderna, and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with Zuellig Pharma Corporation;
2. Ensure administration of the COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna, and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the COVID-19 Vaccine Moderna, 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 COVID-19 Vaccine Moderna prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of COVID-19 Vaccine Moderna;
5. Monitor and comply with vaccine management requirements (e.g. obtaining, tracking and handling vaccine) of the DOH; and
6. 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, Zuellig Pharma Corporation has the ultimate responsibility for monitoring the safety and quality of the COVID-19 Vaccine Moderna.

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.

ANNEX B. INFORMED CONSENT FOR FOR MODERNA COVID-19 VACCINE (bit.ly/RESBAKUNAVaxSpecific)

INFORMED CONSENT FORM FOR THE COVID-19 VACCINE MODERNA
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program
as of June 18, 2021

Name: **Birthdate:** **Sex:**

Address:

Occupation: **Contact Number:**

Health facility:

INFORMED CONSENT

I confirm that I have been provided with and have read the COVID-19 Vaccine Moderna Emergency Use Authorization (EUA) Information Sheet and the same has been explained to me. The FDA has authorized the use of the COVID-19 Vaccine Moderna under an EUA since the gathering of scientific evidence for the approval of the said Vaccine and any other COVID-19 vaccine is still ongoing.

I confirm that I have been screened for conditions that may merit deferment or special precautions during vaccination as indicated in the Health Screening Questionnaire.

I have received sufficient information on the benefits and risks of COVID-19 vaccines and I understand the possible risks if I am not vaccinated.

I was provided an opportunity to ask questions, all of which were adequately and clearly answered. I, therefore, voluntarily release the Government of the Philippines, the vaccine manufacturer, their agents and employees, as well as the hospital, the medical doctors and vaccinators, from all claims relating to the results of the use and administration of, or the ineffectiveness of the COVID-19 Vaccine Moderna.

I understand that while most side effects are minor and resolve on their own, there is a small risk of severe adverse reactions, such as, but not limited to allergies and blood clots associated with low platelet counts (vaccine-induced thrombotic thrombocytopenia), and that should prompt medical attention be needed, referral to the nearest hospital shall be provided immediately by the Government of the Philippines. I have been given contact information for follow up for any symptoms which I may experience after vaccination.

I understand that by signing this Form, I have a right to health benefit packages under the Philippine Health Insurance Corporation (PhilHealth), in case I suffer a severe and/or serious adverse event, which is found to be associated with the COVID-19 Vaccine Moderna or its administration. I understand that the right to claim compensation is subject to the guidelines of the PhilHealth.

I authorize releasing all information needed for public health purposes including reporting to applicable national vaccine registries, consistent with personal and health information storage protocols of the Data Privacy Act of 2012.

I hereby give my consent to be vaccinated with the COVID-19 Vaccine Moderna.

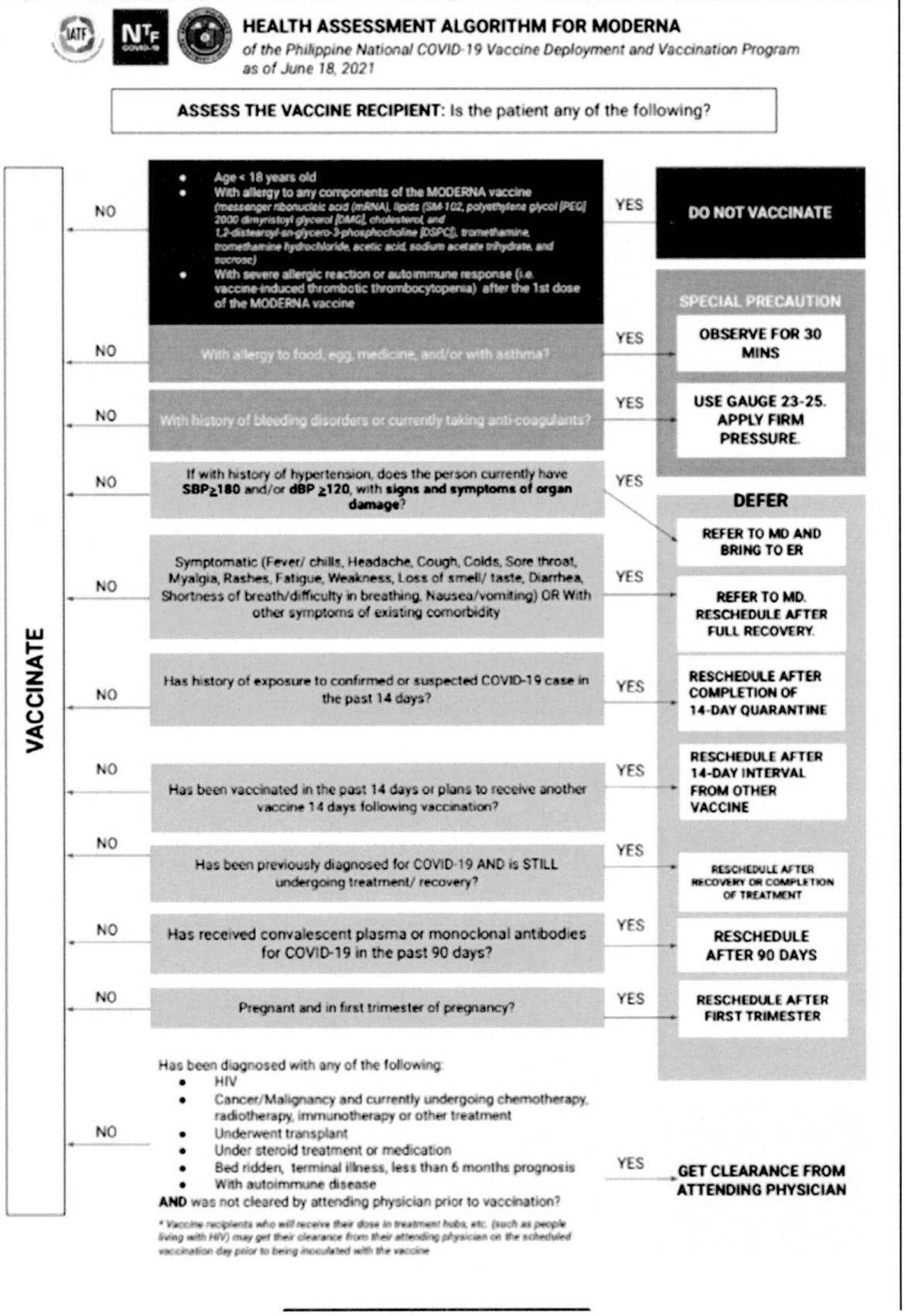
_____ _____
Signature over Printed Name Date

In case eligible individual is unable to sign:
I have witnessed the accurate reading of the consent form and liability waiver to the eligible individual; sufficient information was given and queries raised were adequately answered. I hereby confirm that he/she has given his/her consent to be vaccinated with the COVID-19 Vaccine Moderna.

_____ _____
Signature over Printed Name Date

If you chose not to get vaccinated, please list down your reason/s:

ANNEX C. HEALTH ASSESSMENT AND SCREENING FORM FOR MODERNA COVID-19 VACCINE (bit.ly/RESBAKUNAVaxSpecific)



HEALTH DECLARATION SCREENING FORM FOR MODERNA

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of June 18, 2021

ASSESS THE PATIENT	NO	YES
Below 18 years old?		
With allergy to any components of the MODERNA vaccine *(messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose)*?		
Had a severe allergic reaction or an autoimmune reaction (i.e Vaccine-Induced Thrombotic Thrombocytopenia) after the 1st dose of the MODERNA vaccine?		
Has allergy to food, egg, medicines and/or with asthma?		
➢ If with allergy or asthma, will monitoring the patient for 30 minutes be a problem?		
Has history of bleeding disorders or currently taking anti-coagulants?		
➢ If with bleeding history or currently taking anti-coagulants, is there a problem in securing a gauge 23 - 25 syringe for injection?		
Manifests any one of the following symptoms? ❑ Fever/chills ❑ Fatigue ❑ Headache ❑ Weakness ❑ Cough ❑ Loss of smell/taste ❑ Colds ❑ Diarrhea ❑ Sore throat ❑ Shortness of breath/difficulty in breathing ❑ Myalgia ❑ Nausea/Vomiting ❑ Rashes ❑ Other symptoms of existing comorbidity		
Has history of hypertension (*high blood pressure*)?		
➢ If with history of hypertension, does the person currently have SBP≥180 and/or dBP ≥120, with signs and symptoms of organ damage?		
Has history of exposure to a confirmed or suspected COVID-19 case in the past 14 days?		
If previously diagnosed with COVID-19, is STILL undergoing recovery or treatment?		
Has received any vaccine in the past 14 days, or plans to receive another vaccine 14 days following vaccination?		
Has received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?		
Are you pregnant?		
➢ If pregnant, are you in the 1st trimester?		
Has any of the following diseases or health condition? ❑ HIV ❑ Cancer/ Malignancy and is currently undergoing chemotherapy, radiotherapy, immunotherapy or other treatment ❑ Underwent Transplant ❑ Under Steroid Medication/ Treatment ❑ Bed ridden, terminal illness, less than 6 months prognosis ❑ Autoimmune disease		
If with any of the abovementioned condition, is there any objection to vaccination from presented medical clearance **prior** to vaccination day?		

Recipient's Name:

Birthdate: **Sex:**

Signature of Health Worker:

VACCINATE

If any of the non-gray responses is checked, defer vaccination

If vital signs are taken, pls. record them here: Time: _____ BP: _____ HR: _____ RR: _____ Temp: _____ O2 sat: _____

** Please keep this health screening form as part of the patient's official vaccination and medical record*

ANNEX C. FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING MODERNA VACCINE

(https://www.fda.gov.ph/covid-19-mrna-vaccine-nucleoside-modified-covid-19-vaccine-moderna/)

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE COVID-19 VACCINE MODERNA TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The Philippines Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **COVID-19 VACCINE MODERNA**, for active immunisation to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit https://www.modernacovid19global.com.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include fever or chills, cough, shortness of breath, fatigue, muscle and body aches, headache, loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

The COVID-19 Vaccine Moderna multiple-dose vials are stored frozen between -25°C to -15°C. Store in the original carton to protect from light.

Do not store on dry ice or below -40°C. Use of dry ice may subject vials to temperatures colder than -40°C.

Shelf-life of unopened vial: 7 months between -25°C to -15°C.

The unopened vials may be stored refrigerated between 2°C to 8°C, protected from light, for up to 30 days prior to first use.

The unopened vials may be stored between 8°C to 25°C for a total of 12 hours after removal from refrigerated conditions.

After the first dose has been withdrawn, the vial should be held between 2°C to 25°C. Vials should be discarded 6 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Dosing and Schedule
The COVID-19 Vaccine Moderna is administered intramuscularly as a series of two doses (0.5 mL each) 28 days apart.

There are no data available on the interchangeability of the COVID-19 Vaccine Moderna with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the COVID-19 Vaccine Moderna should receive a second dose of the COVID-19 Vaccine Moderna to complete the vaccination series.

Dose Preparation

- The COVID-19 Vaccine Moderna multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Thaw in Refrigerator	Thaw at Room Temperature
Thaw in refrigerated conditions between 2°C to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15°C to 25°C for 1 hour.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The COVID-19 Vaccine Moderna is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the COVID-19 Vaccine Moderna vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The COVID-19 Vaccine Moderna is supplied in a multidose vial containing 10 doses.
- After the first dose has been withdrawn, the vial should be held between 2°C to 25°C. Record the date and time of discard on the COVID-19 Vaccine Moderna vial label. Discard vial after 6 hours. Do not refreeze.

Administration
Visually inspect each dose of the COVID-19 Vaccine Moderna in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the COVID-19 Vaccine Moderna intramuscularly.

CONTRAINDICATION
Do not administer the COVID-19 Vaccine Moderna to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the COVID-19 Vaccine Moderna *(see Full EUA Prescribing Information)*.

WARNINGS
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the COVID-19 Vaccine Moderna.

Monitor COVID-19 Vaccine Moderna recipients for the occurrence of immediate adverse reactions.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the COVID-19 Vaccine Moderna.

The COVID-19 Vaccine Moderna may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse reactions reported in a clinical trial following administration of the COVID-19 Vaccine Moderna include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea or vomiting, axillary swelling or tenderness, fever, swelling at the injection site, and erythema at the injection site *(See Full EUA Prescribing Information)*.

Severe allergic reactions, including anaphylaxis, have been reported following administration of the COVID-19 Vaccine Moderna during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the COVID-19 Vaccine Moderna.

USE WITH OTHER VACCINES

There is no information on the co-administration of the COVID-19 Vaccine Moderna with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS OR CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" or direct the individual to the website https://www.modernacovid19global.com/ to obtain the Fact Sheet prior to the individual receiving each dose of the COVID-19 Vaccine Moderna, including:

- FDA has authorized the emergency use of the COVID-19 Vaccine Moderna, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the COVID-19 Vaccine Moderna.
- The significant known and potential risks and benefits of the COVID-19 Vaccine Moderna, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of COVID-19 Vaccine Moderna.

MANDATORY REQUIREMENTS FOR COVID-19 VACCINE MODERNA ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using the unapproved COVID-19 Vaccine Moderna for active immunisation to prevent COVID-19 and to optimize the potential benefit of the COVID-19 Vaccine Moderna, use under the EUA is limited to the following (all requirements **must** be met):

1. The COVID-19 Vaccine Moderna is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the

COVID-19 Vaccine Moderna or their caregiver information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the COVID-19 Vaccine Moderna.

3. The vaccination provider is responsible for mandatory reporting of the following to the FDA at (02) 8809 5596 or report online to https://www.fda.gov.ph/covid-19-vaccine-report-a-side-effect/:
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
    - cases of COVID-19 that result in hospitalisation or death.

*Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalisation or prolongation of existing hospitalisation;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalisation or death following administration of the COVID-19 Vaccine Moderna to recipients.

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent COVID-19 Vaccine Moderna Fact Sheets, visit the website https://www.modernacovid19global.com/.

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

Pursuant to Proclamation Nos. 922 (s. 2020) and 1021 (s. 2020), the Philippines was declared under a State of Public Health Emergency, and a State of Calamity due to the COVID-19 pandemic.

Subsequently, Republic Act No. 11494 or the "Bayanihan to Recover as One Act" was enacted authorizing the President of the Republic of the Philippines to suppress the COVID-19 pandemic through the procurement of drugs and vaccines.

Considering that no registered drug and vaccine exist for COVID-19 in the Philippines, the President issued Executive Order No. 121 entitled "Granting Authority to the Director General of the Food and Drug Administration to issue Emergency Use Authorization (EUA) for COVID-19 Drugs and Vaccines Prescribing Conditions Therefor and for Other Purposes". Said issuance gave authority to the Director General to issue an EUA, and established the conditions under which said authorization may be issued.

Moderna collaborated with Zuellig Pharma Corporation to submit the relevant data to support the EUA submission.

In response, the FDA has issued an EUA for the unapproved product, COVID-19 Vaccine Moderna, for active immunisation to prevent COVID-19 in individuals 18 years of age and older.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the COVID-19 Vaccine Moderna may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

Unless otherwise revoked, the 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 or 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, the 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 stocks.

For additional information about the Emergency Use Authorization, visit the FDA https://www.fda.gov.ph/.

MODERNA BIOTECH SPAIN, S.L.
Calle Monte Esquinza 30
28010 Madrid
Spain

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END OF SHORT VERSION FACT SHEET

LONG VERSION (FULL EUA PRESCRIBING INFORMATION) BEGINS ON NEXT PAGE