Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

August 9, 2022

DEPARTMENT MEMORANDUM
No. 2022 - 0402

TO: **ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS, SERVICES AND CENTERS FOR HEALTH DEVELOPMENT; MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO; EXECUTIVE DIRECTORS OF SPECIALTY HOSPITALS AND NATIONAL NUTRITION COUNCIL; CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA AND INSTITUTES; PRIVATE SECTOR PARTNERS; ALL LOCAL GOVERNMENT UNITS; AND OTHERS CONCERNED**

SUBJECT: **Guidelines on the Management and Administration of Moderna (Spikevax) COVID-19 mRNA Vaccine to Pediatric Population Ages 6 to 11 Years Old**

I. BACKGROUND

On 20 May 2022 the Philippine Food and Drug Administration (FDA) issued the amendment of the Emergency Use Authorization (EUA) for the COVID-19 vaccine Moderna (Spikevax) and on **26 July 2022** the Health Technology Assessment Council (HTAC) issued the latest recommendation on the use of Moderna as primary series for the pediatric populations 6 to 11 years old. Relative to these updates, this Department Memorandum (DM) is issued to provide guidance to all concerned agencies, Regional Vaccination Operations Centers (RVOCs) or Centers for Health Development (CHDs), Local Vaccination Operations Center (LVOCs) or Local Government Units (LGUs), Provincial Health Offices (PHOs), City Health Offices (CHOs), Rural Health Units (RHUs), Implementing Units, and Vaccination Sites, both public and private, on the management and administration of the Moderna COVID-19 Vaccine as part of the implementation of the COVID-19 vaccination to the pediatric population.

II. GENERAL GUIDELINES

A. The pediatric population ages 6 to 11 years old shall be recommended to be vaccinated with the Moderna COVID-19 mRNA Vaccine (Nucleoside Modified) Dispersion for Injection [Spikevax] approved for use to the aforementioned age group based on the EUA issued by the Philippine FDA (Copy of the EUA may be accessed at the FDA website: https://www.fda.gov.ph/wp-content/uploads/2022/07/Sixth-Amendment-Moderna-Booster-website_1658879751.pdf).

B. 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 product-specific EUA provided by the FDA and vaccine-specific guidelines issued by the DOH. Copies of the EUA may be accessed at https:/www.fda.gov.ph/list-of-fda-issuedemergency-use-authorization/.

C. Protocols for the management of Adverse Effects Following Immunization (AEFIs) and Adverse Events of Special Interest (AESIs) shall follow the provisions of the approved COVID-19 vaccine EUA of the FDA, succeeding guidelines from the FDA, and other recognized professional organizations and regulatory bodies, as new evidence arises. Interim AEFI Pathways may be accessed at https://bit.ly/PinasLakasFactsheets.

III. IMPLEMENTING GUIDELINES

A. Implementation Roll-out and Vaccination Strategies

The vaccination rollout to 6 to 11 years old pediatric population shall be implemented simultaneously with the current eligible population groups.

The LVOCs shall utilize various vaccination strategies consistent with the Department Circular (DC) No. 2022-0131 as warranted in order to ramp up vaccination of the pediatric population. Fixed site, temporary post (*barangays*, orphanages, schools elementary and kindergarten) and/or mobile vaccination strategies may be implemented as deemed necessary while ensuring seamless integration of the Moderna vaccination among children 6 to 11 years old with any ongoing national and local vaccination campaigns.

B. Allocation and Distribution of Vaccines

Available vaccines with issued EUA from the Philippine FDA shall be allocated to LVOCs by the NVOC and RVOCs based on the latest available data on eligible pediatric population due for primary series vaccination.

C. Vaccine Administration, Storage, Handling and Preparation

1. Dosage/Form and Vaccine Administration

a. Moderna (Spikevax) vaccine for 6 to 11 years old is a white to off white suspension containing 100 mcg dispersion per vial.

b. One dose (0.25 ml) of Moderna (Spikevax) vaccine for 6 to 11 years old is administered as a two (2) - dose regimen via intramuscular injection.

c. The second dose of Moderna (Spikevax) vaccine shall be administered 28 days after the first dose.

2. **Packaging**

   a. Moderna (Spikevax) vaccine for 6 to 11 years old comes in a multidose vial containing a maximum of 20 doses of 0.25 mL each.

3. **Shelf life and Storage**

   a. The shelf life of a Moderna (Spikevax) vaccine for 6 to 11 years old unopened vial is 9 months at -25°C to -15°C.

   b. Once thawed, the unopened vaccine may be stored at 2° to 8° C, protected from light for a maximum of 30 days. Within this period, up to 12 hours may be used for transportation.

   c. The unopened vaccine may be stored at 8° to 25° C up to 24 hours after removal from refrigerated conditions.

   d. Vials should not be refrozen.

D. Vaccination Teams

1. All members of the vaccination team designated in vaccination sites for the vaccination activities shall undergo training specific for Moderna (Spikevax) COVID-19 vaccines for 6 to 11 years old provided by the NVOC to avoid medication errors given the difference in the product formulation along with other available COVID-19 pediatric vaccines (e.g. Pfizer COVID-19 vaccines) and to the adult formulation of the same vaccine.

E. Vaccination Site Preparation and Processes

1. The vaccination process, including registration, screening, administration, reporting, AEFI monitoring, referral, and demand generation shall still follow the provisions in Department of Health (DOH) Administrative Order No. 2022-0005, titled "*Omnibus Guidelines on the Implementation of the National Deployment and Vaccination Plan (NDVP) for COVID-19 Vaccines*" and other relevant COVID-19 pediatric vaccination related issuances namely: Department Memorandum (DM) No. 2022-0041 otherwise known as the *"Interim Guidelines on the Management and Administration of Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Comirnaty] Pfizer COVID-19 Vaccine to Pediatric Population Ages 5-11 Years Old"*, DM No. 2022-0041-A otherwise known as the "*Amendment to Department Memorandum No. 2022-0041 dated January 24, 2022 entitled "Interim Guidelines on the Management and Administration of Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Comirnaty] Pfizer COVID-19 Vaccine to Pediatric Population Ages 5-11 Years Old*" and DM No. 2021-0464 entitled "*Interim Operational Guidelines on the*

COVID-19 Vaccination of the Pediatric Population Ages 12-17 Years Old with Comorbidities".

2. The selection of COVID-19 vaccination sites shall follow the **DM No. 2021-0016**, titled "*Interim Guidelines on the Identification and Utilization of COVID-19 Vaccination Sites*," and all other relevant policies, guidelines, and advisories released by the DOH.

3. For the requirements to prove filiation/guardianship for Pediatric COVID-19 Vaccination and the List of Comorbidities among Pediatric Population 6 to 11 years old requiring medical clearances, kindly refer to the Department Memorandum (DM) No. 2022-0041-A dated 4 February 2022.

4. Vaccination materials such as the informed consent form, assent form, health screening and assessment forms may be accessed through this link: https://bit.ly/PinasLakasModernaPediaForms.

IV. EFFECTIVITY

This Department Memorandum shall take effect immediately.

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