Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

October 6, 2022

DEPARTMENT MEMORANDUM
No. 2022 - 0455

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: **Interim Guidelines on the Management and Administration of SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], Sinovac as Primary Series for Pediatric Population 6 to 17 Years old**

I. BACKGROUND

On 11 March 2022, the Philippine Food and Drug Administration (FDA) issued the Emergency Use Authorization (EUA) to SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], Sinovac allowing their use as primary series for clinically healthy pediatric population ages 6-17 years old. Relative to this, the Health Technology Assessment Council (HTAC) released their recommendations on 05 October 2022 on the use of **CoronaVac (Sinovac) as primary series for children 6 to 17 years old.**

This Department Memorandum 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], Sinovac COVID-19 Vaccine, referred to as Sinovac COVID-19 Vaccines in this guidelines, as part of the implementation of the COVID-19 vaccination to the pediatric population aged 6 to 17 years.

II. GENERAL GUIDELINES

A. The pediatric population ages 6 to 17 years old shall be recommended to be vaccinated with the Sinovac COVID-19 Vaccines approved for use to the aforementioned age group as an **alternative vaccine for mRNA vaccines,**

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/2022/03/Second-Amendment-to-the-EUA-Sinovac-IP-Biotech-Pedia-web.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 Department of Health (DOH). Copies of the EUA may be accessed at https:/www.fda.gov.ph/list-of-fda-issued-emergency-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

1. The vaccination rollout to 6 - 17 years old pediatric population shall be implemented simultaneously with the current eligible population groups and may be offered **as an alternative vaccine for mRNA vaccines** for those with contraindications to other available COVID-19 vaccines.

2. The LVOCs shall utilize various vaccination strategies in order to ramp up vaccination of the pediatric population. Fixed site, temporary post and/or mobile vaccination strategies may be implemented as deemed necessary while ensuring seamless integration of the Sinovac COVID-19 vaccination among 6 to 17 years with the ongoing national and local vaccination campaigns.

B. Allocation and Distribution of Vaccines

Available vaccines 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. Sinovac COVID-19 vaccine for 6 to 17 years old is an opalescent aqueous suspension in 600 SU/0.5 mL Suspension for Injection (IM) One-dose vial; or 1200 SU/mL (600 SU/0.5 mL) Two-dose vial.

b. Sinovac COVID-19 vaccine is administered as a two-dose regimen.

c. The second dose of Sinovac COVID-19 vaccine shall be administered four (4) weeks after the first dose intramuscularly.

2. **Packaging**

a. Sinovac COVID-19 vaccine comes in a single and two-dose vials. Each single-dose (0.5 mL) contains 600SU of indicated SARS-CoV-2 inactivated virus as antigen while the two-dose vial contains 1200 SU/0.5 ML.

3. **Shelf life and Storage**

The Sinovac COVID-19 vaccine has a shelf-life of 12 months for single-dose vials and 6 months for two-dose vials stored at 2° to 8° C.

D. Vaccination Teams

1. All members of the vaccination team designated in vaccination sites for the vaccination activities shall undergo training specific for Sinovac COVID-19 vaccines for 6 to 17 years old provided by the Public Health Emergency Operations (PHOC) to avoid medication errors given the difference in the product formulation along with other pediatric vaccines (e.g. Pfizer COVID-19 vaccines).

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 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*", DM No. 2021-0464 entitled "*Interim Operational Guidelines on the COVID-19 Vaccination of the Pediatric Population Ages 12-17 Years Old with Comorbidities*",

and DM No. 2022-0042 otherwise known as the *"Guidelines on the Management and Administration of Moderna (Spikevax) COVID-19 mRNA Vaccine to Pediatric Population Ages 6 to 11 Years Old".*

2. Medical certification for pediatric A3 shall be given by the attending pediatrician/ physician detailing the comorbidity/ies of the vaccine recipient, in accordance with the Administrative Order No. 2022-0005. It shall be secured prior to the vaccination schedule and shall be presented in the registration area during the vaccination schedule.

3. 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.

4. For the requirements to prove filiation/guardianship for Pediatric COVID-19 Vaccination and the List of Comorbidities among Pediatric Population requiring medical clearances, kindly refer to the DM No. 2022-0041-A dated 4 February 2022.

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

IV. EFFECTIVITY

This Department Memorandum shall take effect immediately.

By Authority of the Secretary of Health:

Date: 2022.10.17
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Undersecretary of Health
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