

**INTERIM NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUP FOR
COVID-19 VACCINES
RESOLUTION NO. 4
*Series of 2021***

“**WHEREAS**, on 30 January 2020, the World Health Organization (WHO) declared Coronavirus Disease 2019 (COVID-19), a disease caused by a novel Severe Acute Respiratory Syndrome - Coronavirus2 (SARS-CoV2), as a Public Health Emergency of International Concern (PHEIC)”.

“**WHEREAS**, the Philippines since January 2020, has been responding to the COVID-19 pandemic and has implemented numerous interventions in response to the pandemic”.

“**WHEREAS**, the National Government intends to introduce safe and effective COVID-19 vaccine to:

- a) reduce morbidity and mortality while maintaining the most critical essential services;
- b) protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others;
- c) substantially slow down rate of transmission and minimize disruption of social, economic, and security functions; and
- d) responsibly resume social and economic day-to-day operations and activities.

“**WHEREAS**, the Interim National Immunization Technical Advisory Group for COVID-19 vaccines adheres to the guiding principles of Transparency, Timing, Equity, Solidarity, Trust and Prioritization”;

“**WHEREAS**, based on the Emergency Use Authorization (EUA), the Philippine Food and Drug Administration (FDA) recommended that the SINOVAC donation shall only be provided to 18 to 59 years old healthy population, and not recommended for healthcare workers with direct exposure to COVID-19 patients;

“**WHEREAS**, iNITAG has reviewed the currently available unpublished data from the product brief and preliminary clinical trial results submitted by SINOVAC, and concluded that the vaccine is generally safe for health care workers;

“**NOW, THEREFORE, BE IT RESOLVED** that the Interim National Immunization Technical Advisory Group for COVID-19 vaccines issues the following recommendations:

1. The National COVID-19 Immunization Program shall ensure that donations as well as government procurement of vaccines shall have an EUA from the Philippine FDA to ensure safety and effectiveness. Health technology assessment for potential vaccines to be procured should be conducted to ensure cost-effectiveness in using government resources.

2. Expert bodies convened by the National COVID-19 Immunization Program should be provided access to documents and other evidence on efficacy and safety of vaccines (in both completed and ongoing trials) to be used in the program, to be able to provide evidence-based recommendations. Expert bodies shall have certificates of undertaking, and use said references in strict confidence and only for the purpose of analysis.
3. The product brief and preliminary clinical trial results submitted by SINOVAC for their Philippine FDA application as well as the Note Verbale from the Embassy of the People's Republic of China, do not explicitly indicate that the vaccine is not contraindicated for health care workers exposed to COVID-19 patients.
 - a. In the COVID-19 vaccination roll-out of Brazil, Indonesia and Turkey, the SINOVAC vaccine is being given to health care workers. The clinical trial data of SINOVAC vaccination in Brazil showed reduction of hospitalization and deaths in COVID-19 patients. The SINOVAC vaccine efficacy rate is 50% for mild cases and 100% for moderate to severe cases, similar to the other novel COVID-19 vaccines.
 - b. The iNITAG recommends implementation of the prioritization framework wherein allocation shall be consistent with the principles of providing access to those who will benefit the most from the vaccine due to their high risk for severe COVID-19 disease and death. Therefore, the SINOVAC donation shall be provided first and reserved for Priority Group A1 (Front line workers in health facilities, both national and local, private and public; health and allied health professionals; individuals engaged in health-related institutions and given clinical responsibilities like medical students, interns, clinical researchers, research assistants/ coordinators; nursing aides, janitors, barangay health workers, etc.).
4. In this instance wherein the Philippine FDA states that the current data does not support the use of SINOVAC vaccine among healthcare workers providing direct care to COVID-19 cases; and in the absence of any other available COVID-19 vaccine the iNITAG recommends allowing Priority Group A1 the autonomy to decide to be vaccinated with the SINOVAC vaccine and to exercise informed choice. Such offering of the opportunity for vaccination with SINOVAC is without prejudice to their immediate eligibility to receive the other vaccine brands which may be available at a later date. In light of this, the following corollary actions are recommended:
 - a. The informed consent form for the COVID-19 vaccination program shall be adapted specifically for the SINOVAC vaccine donation to clearly indicate willingness to be vaccinated given the prioritization framework and the Philippine EUA for Sinovac.

- b. The eligible list of potential recipients for succeeding vaccine allocations shall start with Priority Group A1 and for the same health facilities as indicated in the prioritization framework in Department Circular 2021-0055.
 - c. Health facilities and vaccination sites shall ensure appropriate monitoring and disaggregated reporting of recipients.
 - d. National government shall provide the appropriate healthcare and financial support to vaccine recipients who experience Adverse Events Following Immunization.
 - e. National government shall ensure adequacy of risk communications to potential vaccine recipients and to the general public on the specific circumstances of the SINOVAC donation to enable people to make informed decisions regarding potential vaccination with SINOVAC; and to preserve confidence and trust in the COVID-19 Immunization program.
5. Any excess vaccine donation of SINOVAC from Priority Group A1 shall be provided to Priority Group A4 Frontline Essential Workers, starting with military and uniformed personnel (MUP).
 - a. Priority Group A2 - Senior Citizens are not recommended to be given the SINOVAC vaccine as indicated in the Philippine FDA EUA that the eligible population is only from ages 18-59 years. It was indicated in the interim analysis of the clinical trial done in Brazil that the study design did not allow conclusions to be drawn regarding efficacy in participants aged 60 years and older due to a small number of participants in this age group .
 - b. Priority Group A3 - Adults with comorbidities are not recommended to be given the SINOVAC vaccine as the Philippine FDA EUA indicates use for clinically healthy adults only. There is also a current operational difficulty of identifying and consolidating patients with comorbidities, especially excluding those with active disease in a short span of time.
6. These policy recommendations are specifically being issued for the incoming donation of SINOVAC, and with consideration for the immediate need to roll out the COVID-19 vaccination program, and its associated concerns of operational feasibility. The said recommendations have taken into consideration the due diligence of the Philippine FDA in issuing its EUA even in the absence of published efficacy evidence of the SINOVAC vaccine.
7. Recognizing the fragility of vaccine confidence in the country, including among health care workers, the manner (i.e., timing and avenue) for public announcements must be carefully crafted and calibrated to foster trust and improve credibility. From hereon, it is highly recommended that:

- a. Only the National Chief Implementer and Vaccine Czar, the Secretary of Health, the FDA Director General and the appointed representatives of the expert groups shall be authorized to speak about the vaccine program for COVID-19;
 - b. Talking points and media engagements shall be coordinated with TG Demand Generation;
 - c. IATF resolutions pertaining to vaccines shall be withheld until after the appropriate communication messages and information dissemination plans have been worked out; and partner agencies (including potential recipient health facilities, etc.) have had adequate time and resources for preparation.
8. Social preparation among health care workers who are potential vaccine recipients of the SINOVAC vaccines must be ensured through town halls with experts and the Director General of the Food and Drug Administration. The National Chief Implementer and Vaccine Czar and the Secretary of Health will be solely responsible for communication with the public about the allocation of SINOVAC vaccine donations (and succeeding arrivals of COVID-19 vaccines) for HCWs as well as for other groups.
 9. These policy recommendations are specifically being issued for the incoming donation of SINOVAC scheduled to be delivered in the last week of February 2021, and shall be updated upon availability of recommendations from the Health Technology Assessment Council (HTAC) specially for vaccines which will be procured; new scientific evidences or Emergency Use Listing (EUL) of the World Health Organization (WHO).

RESOLVED during the 12th Meeting of the Interim NITAG for COVID-19 Vaccine, as reflected in the minutes of the meeting, held on 23rd of February, 2021 via Zoom video conference.

APPROVED BY:

[SGD]

[SGD]

MAY MONTELLANO, MD
Interim National Immunization Technical
Advisory Group

EDDIE DOROTAN, MD, MPA
Interim National Immunization Technical
Advisory Group

[SGD]

NINA CASTILLO-CARANDANG, PhD
Interim National Immunization Technical
Advisory Group

[SGD]

SHELLEY DELA VEGA, MD, MSc
Interim National Immunization Technical
Advisory Group

[SGD]

MARIA CONSORCIA QUIZON, MD
Interim National Immunization Technical
Advisory Group

[SGD]

MARY ANN BUNYI, MD
Interim National Immunization Technical
Advisory Group

[SGD]

MINETTE ROSARIO, MD
Interim National Immunization Technical
Advisory Group