Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

February 26, 2021

DEPARTMENT MEMORANDUM
No. 2021 - 0114

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 on the Management and Administration of the Initial 600,000 Donated SARS COV-2 Vaccine (Vero Cell) Inactivated CoronoVac (Sinovac) Doses**

I. RATIONALE

The Department of Health (DOH), through the Task Group COVID-19 Immunization Program, and in consultation with all agencies comprising the COVID-19 Vaccine Cluster, diligently developed a comprehensive plan for vaccine deployment and vaccination. The Philippine National Deployment and Vaccination Plan (NDVP) for COVID-19 Vaccines seeks to provide the overall operational guidance in the implementation of the COVID-19 vaccine deployment and vaccination program in the Philippines.

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 (FDA) and positive recommendation from the Health Technology Assessment Council (HTAC) will be purchased by the government.

Likewise, policy decisions and recommendations are informed based on the recommendations of technical experts, convened to provide independent recommendations to the DOH, Vaccine Cluster, and Inter-Agency Task Force (IATF) on vaccine implementation and health service delivery. These expert groups include the interim National Immunization Technical Advisory Group (iNITAG), Technical Advisory Group (TAG), Vaccine Expert Panel (VEP) and National Adverse Events Following Immunization Committee (NAEFIC).

On February 22, 2021, the Philippine Food and Drug Administration (FDA) granted an EUA for the SARS - COV - 2 Vaccine (Vero Cell) Inactivated Coronovac (Sinovac), referred to as Sinovac vaccines, in this guideline. Its commercial name is CoronaVac 0.5mL/ dose containing 600SU of inactivated SARS-CoV-2 virus as antigen. The vaccine is injected intramuscularly, with a total of two-doses at an interval of four (4) weeks.

The recommendations endorsed by the interim National Immunization Technical Advisory Group (iNITAG) takes into consideration the immediate need to roll out the COVID-19 vaccination program, and its associated concerns of operational feasibility. The said recommendations have also 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. These guidelines may be updated upon availability of recommendations from the HTAC especially for vaccines, which will be procured; and from new scientific evidence or Emergency Use Listing (EUL) of the World Health Organization (WHO).

This interim guideline is issued specifically for the distribution, handling, storage and administration of the 600,000 donated Sinovac vaccines.

II. GENERAL GUIDELINES

A. Implementation of this guideline shall be consistent with Department Memorandum 2021-0099 or the "Interim Omnibus Guidelines for the Implementation of the National Deployment and Vaccination Plan for COVID-19".

B. All LGU and other identified COVID 19 vaccination sites shall formulate their microplans to determine local needs and gaps to ensure smooth and satisfactory vaccine implementation in accordance with the NDVP

C. The head of implementing unit/ institution shall ensure compliance to the DOH/ FDA guidelines including but not limited to delivery, handling, administration, storage, administration and reporting requirements of the Sinovac vaccines

D. 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.

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

F. Sinovac vaccines shall be administered by trained healthcare providers in individuals 18 to 59 years of age, as indicated in the EUA issued by the Philippine FDA.

G. Protocols for the management of Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) shall follow the provisions of Sinovac vaccine Emergency Use Authorization of the Philippine FDA and other succeeding guidelines from the FDA, Sinovac, and other recognized professional organizations and regulatory bodies, as new evidence arise.

H. The second dose of the Sinovac vaccine shall be given after four (4) weeks from the first dose. Follow-up notification shall be sent in accordance with the DM 2021-0099.

I. Registration, screening, counselling, vaccine recipient reporting, AEFI monitoring and referral shall follow DM 2021-0099 and other relevant policies.

J. All related information and education communication materials and other vaccination related materials such as vaccination card ***(See Annex B)*** can be accessed through this link: bit.ly/RESBAKUNAMaterials. A printing guide for the

communication materials is made available through this link: bit.ly/RESBAKUNAPrintingInstructions.

III. IMPLEMENTING GUIDELINES

A. Vaccine Allocation for Priority Groups

1. Considering the institutionalized prioritization criteria and order of priority populations recommended by the iNITAG, the EUA issued by Philippine FDA where the use of Sinovac vaccine among healthcare workers providing direct care to COVID-19 cases, though not contraindicated, is not recommended based on existing evidence, and the current absence of any other available COVID-19 vaccine, Sinovac shall be administered to the **consenting members of Priority Group A1**, without prejudice to their immediate eligibility to receive the other vaccine brands which may be available at a later date.

2. The Sinovac donation shall be offered 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.), consistent with the prioritization framework. The Sinovac vaccine can be used for health workers <60 years old with clinically-controlled disease comorbidities.

    a. The informed consent form ***(See Annex C)*** for the COVID-19 vaccination program shall be adopted specifically for the Sinovac vaccine donation to clearly indicate willingness to be vaccinated given full information about Sinovac vaccine explained to them including the prioritization framework and the Philippine EUA for Sinovac.

    b. The national government shall ensure adequacy of risk communications to potential vaccine recipients and to the general public on the specific circumstances of the Sinovac vaccine 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.

3. 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 - Following the EUA issued by the Philippine FDA, eligible population for the donated Sinovac vaccines include people from ages 18-59 years old. Hence, senior citizens are not recommended to be included in this first batch of Sinovac vaccines despite being considered the next group in the original allocation framework.

    b. Priority Group A3 - In addition, following the EUA issued by the Philippine FDA, the donated Sinovac vaccines are only suitable for clinically healthy individuals. Hence, adults with comorbidities (classified as A3 population group) are not recommended to be given the first batch of Sinovac vaccines.

B. Vaccine Distribution and Quick Substitution List

1. Health facilities shall ensure social preparations within their facilities such as but not limited to town halls meetings, social media boosting, online training and orientations and update their master listing data on workers belonging to Priority Group A1 based on an updated survey of willingness to be vaccinated.

2. The quantity of the COVID-19 vaccines to be distributed to the hospitals and vaccination facilities shall be based on the anticipated number of the recipients (hospital-based health care workers) of the vaccines and the ability of the vaccination facility to store, handle and transport the vaccine appropriately in order to minimize vaccine wastage and spoilage.

3. Allocation and quick substitution shall ensure following the sub prioritization framework wherein the order of priority for scheduling and vaccination shall start with hospitals, then community based health facilities, Priority A1 workers in different regions based on geographic risk. ***(See Annex D)***

4. The Program Implementation Task Group of the Field Implementation Coordination Team (FICT) shall provide the allocation list to the Supply Chain and Management Service (SCMO). This shall serve as the reference for the (re)-distribution of the vaccines to the different hospitals, Centers for Health Development (CHD) and/or to the identified COVID 19 vaccination sites as needed.

5. All the hospitals shall receive the 100% total quantity vaccine requirement indicated in the approved allocation list. Since the vaccine is given at a 2-dose schedule, a staggered release of the vaccines is recommended in consideration of the storage capacity of the vaccination facility.

    a. Fifty percent (50%) of the total vaccine requirement shall be reserved for 2nd dose vaccination and shall be stored in the cold chain storage appropriate for the vaccine temperature requirement located in the Metropac or in the cold storage facility of the Third Party Logistics Providers.

    b. The remaining 50% of the total requirement shall represent the quantity to be administered for the 1st Dose of the eligible vaccine.

6. Any variation to the allocation list submitted to the Supply Chain and Management Service (SCMS) and request for additional vaccines beyond the allocated shall be approved by the Undersecretary of Health - FICT.

7. In cases of low vaccine uptake, health facilities shall make the vaccines available to all eligible populations based on their submitted, FICT - approved Quick Substitution List. Those health workers who declined the Sinovac vaccination shall still be eligible for the next round of vaccination of other available vaccines of their preference.

8. If there are remaining stocks of vaccines that have not yet been allocated to a designated health facility, the FICT shall identify the next eligible facility using the prioritization framework.

C. Precautions and Contraindications

1. As a general rule, co- administration of the Sinovac vaccines with other COVID-19 vaccines is not recommended.

2. The Health Screening Form for Sinovac ***(See Annex E)*** (bit.ly/RESBAKUNAMaterials) shall be used to assess eligibility of vaccine recipients.

3. Individuals with hypersensitivity to any of the vaccine components shall not be administered with the Sinovac vaccine.

4. The AEFI team of the COVID 19 vaccination site shall monitor the following adverse events including injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills, arthralgia, and nausea, following Sinovac vaccination.

D. Vaccine Storage, Handling and Transfer

1. Implementation of vaccine storage, handling, and transfer shall be in line with the EUA issued by the FDA. ***(See Annex F)***

2. Inactivated Coronavac vaccine is supplied as an opalescent, aqueous suspension in single dose vials. Each vial of the Sinovac Vaccine contains 600 SU of inactivated SARS-COV-2 virus as antigen per 0.5 mL suspension for injection.

3. Unopened vial of Sinovac vaccine shall be stored in a refrigerator at 2 to 8°C. Vials shall not be allowed to freeze and shall be protected from light.

4. Shelf life of unopened single dose vial is 3 years.

5. Vaccines exposed to temperatures outside the recommended ranges can have reduced potency and protection. Vaccines shall be stored properly from the time they are manufactured until they are administered.

6. Health workers managing the vaccines shall check and take temperature readings at least four (4) times a day (8:00 AM, 11:00 AM, 1:00 PM, and 4:00 PM), 7 days a week, including during weekends and holidays.

7. Contingency plan shall be in place which include alternate person-in-charge of cold chain storage facilities, back-up storage units in case of the primary storage unit failure, power outages, etc.(e.g. generator). Ideally, other staff should know the ideal temperature for the vaccines, aside from the cold chain manager.

8. If the storage temperatures fluctuate out of the recommended range in a cold room, vaccine refrigerators, perform the recommended actions in the DOH Manual of Operations on Vaccines, Cold Chain and Logistics Management version 2018.

E. Vaccine Administration, Dosage, and Disposal

1. Each vaccine in single dose vials amounts to 0.5 ml of the solution. Sinovac vaccine shall be given through intramuscular (IM) injection only, preferably in the non-dominant deltoid muscle.

2. The vaccine is an opalescent suspension, stratified precipitate may form which can be dispersed by shaking. Shake well before injection.

3. The Sinovac vaccine requires the completion of a two-dose regimen. The first dose shall be given upon health worker contact with the potential vaccine recipient. The second dose shall be administered 4 weeks after the first dose.

4. Sinovac vaccine shall be administered only by a trained health worker and be used in accordance with the official product information.

5. Infection prevention and control procedures shall be observed during vaccine administration.

6. Any unused vaccine or waste material shall be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant.

7. After being injected with Sinovac 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.

8. 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.

For strict compliance.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX A. Philippine FDA Fact Sheet for vaccination providers

克尔来福
CoronaVac

SARS-CoV-2 Vaccine (Vero Cell), Inactivated

On medical prescription only

Please read the leaflet carefully and use the vaccine under the guidance of a physician.

【Name of the Medical Product】
Generic Name: SARS-CoV-2 Vaccine (Vero Cell), Inactivated
Trade Name: CoronaVac
English Name: SARS-CoV-2 Vaccine (Vero Cell), Inactivated

【Composition and Character】
The product is manufactured by inoculation of SARS-CoV-2 virus (CZ02 Strain) into African Green Monkey Kidney Cell (Vero Cell), then the virus is incubated, harvested, inactivated, concentrated, purified and adsorbed by aluminum hydroxide. The vaccine is an opalescent suspension, stratified precipitate may form which can be dispersed by shaking.
Active ingredient: Inactivated SARS-CoV-2 Virus.
Excipients: Aluminum hydroxide, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium chloride.
This product contains no preservatives.

【Object of Vaccination】
This product is suitable for people (aged 18 years and over) susceptible to virus.

【Usage】
Vaccination of this product stimulates body to induce immunity against SARS-CoV-2 virus for the prevention of disease caused by SARS-CoV-2 virus.

【Dosage】
Each dose containing 600 SU of inactivated SARS-CoV-2 virus as antigen.

【Route of Administration】
The recommended route of administration is via intramuscular injection at deltoid of upper arm. Shake well before use.

【Immunization Schedule】
For emergency vaccination, the basic immunization schedule is 2 doses at 2-week interval. The routine immunization schedule is 2 doses at 1-month interval, each inoculation dose is 0.5 mL.
Whether the immunity of product needs to be strengthened is not yet determined.

【Adverse Reactions】
According to the adverse reaction occurrence rate from Council for International Organization of Medical Sciences (CIOMS), the grading can be classified as: Very common (≥10%), common (1%-10%, 1% is inclusive), uncommon (0.1%-1%, 0.1% is inclusive), rare (0.01%-0.1%, 0.01% is inclusive), very rare (<0.01%). The specific results are based on clinical trial data.
The following adverse reactions have been observed upon the marketing of other inactivated virus vaccines: 1) local lymphadenopathy at the injection site, 2) allergic reactions caused by any component of the vaccine: hives, allergic rashes and purpura, anaphylactic shock, 3) convulsion (with or without fever) etc. Although the mentioned adverse reactions were not observed in the pre-marketing studies, they still need to be paid attention to during the use of this vaccine.
In case of any discomfort not mentioned above, please contact your doctor immediately.

【Contraindications】
This product is contraindicated in person:
1. who is known to be allergic to any of the components of this vaccine.
2. who is febrile, patient in the acute illness period and acute attack of chronic disease.

【Precautions】
1. Intravascular injection of this vaccine is strictly prohibited.
2. Epinephrine injection and other appropriate agents and devices should be available to control immediate serious allergic reactions. Recipients should be observed on site for at least 30 minutes after vaccination.
3. Under the following circumstances, the use of this vaccine should be carefully used:
1) In patients with thrombocytopenia or bleeding disorders, intramuscular injection of this vaccine may cause bleeding.
2) Patients who are receiving immunosuppressive therapy or with immunodeficiency, the immune response to the vaccine may be weakened. Vaccination should be deferred until the end of treatment or ensured patients to be well protected. The vaccine should be recommended for patients with chronic immune deficiency, even if the underlying disease may lead to a limited response.
3) Patients with uncontrolled epilepsy and other progressive neurological disorders, such as Guillain-Barre Syndrome.
4. As with any vaccine, vaccination with this product may not protect 100% of individuals.
5. The vaccine must be kept out of reach of children.
6. Do not expose the disinfectant to the vaccine when opening the vaccine vial and injection.
7. Shake well when using. Do not use if the vaccine bottle is cracked, poorly marked or ineffective, or if there is a foreign matter in the vaccine bottle.
8. Do not combine this product with other vaccines in the same syringe.
9. Do not freeze this product. The vaccine should be used immediately after it is open.

【Drug Interactions】
Concomitant administration of other vaccines: there has been no clinical studies on the effect of concomitant (pre, post or simultaneous) administration of other vaccines on the immunogenicity of this vaccine. There is no data available to assess the effect of simultaneous administration of this product with other vaccines.
Immunosuppressive drugs: immunity inhibitor, chemotherapy drug, antimetabolites, alkylating agents, cytotoxic drugs, corticosteroids etc. may reduce the body's immune response to this vaccine.
Patients who are receiving treatment: for those who are using the drug, it is recommended to consult a professional physician before receiving the vaccine to avoid possible drug interactions.

【Clinical Trial】
Referring to the data of clinical trials.

【Storage】
Store between +2°C and +8°C and protect from light. Do not freeze.

【Packaging】
This product is packaged into vial, 40 vials per box.

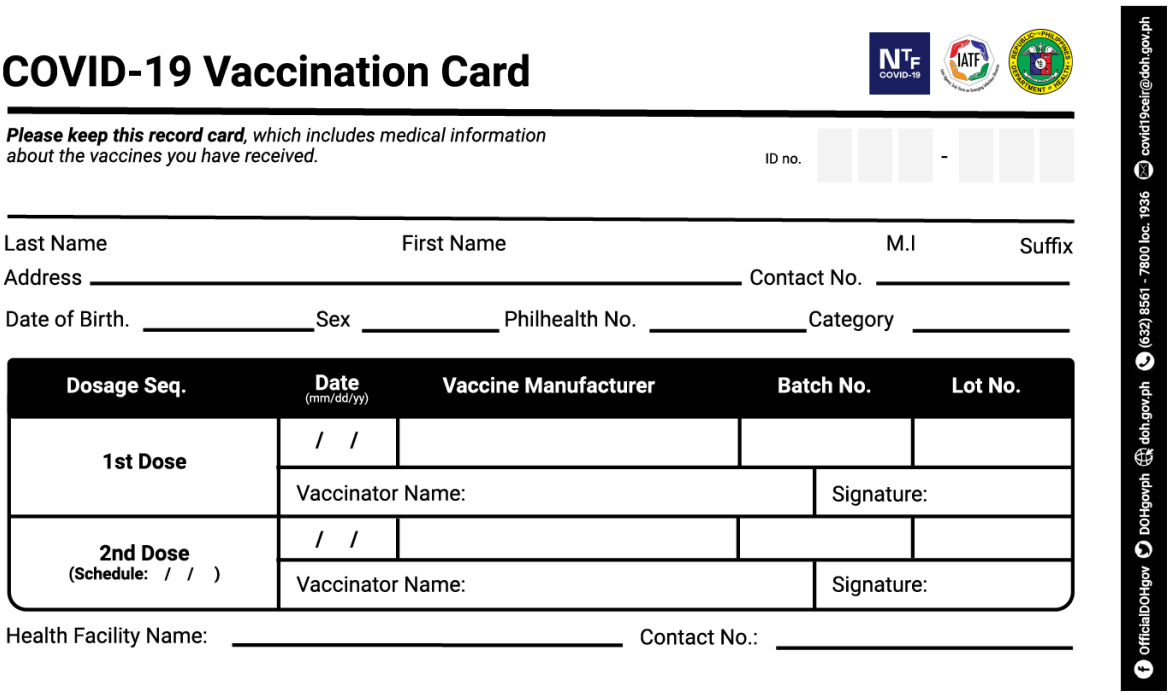
【Expiry Date】
The expiry date of the vaccine is tentatively scheduled as 36 months.

【Manufacturer】
Manufacturer: SINOVAC LIFE SCIENCES CO., LTD.
Address: No.21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R.China
Zip Code: 102601
Tel.: 86-10-56897188
Fax: 86-10-56897123
Website:www.sinovac.com
E-mail: sinovac@sinovac.com

SINOVAC

ANNEX B. Vaccination Card

Access the document here: bit.ly/RESBAKUNAMaterials



COVID-19 Vaccination Card

Please keep this record card, *which includes medical information about the vaccines you have received.*

ID no. -

Last Name First Name M.I Suffix

Address _____ Contact No. _____

Date of Birth. _____ Sex _____ Philhealth No. _____ Category _____

Dosage Seq.	Date (mm/dd/yy)	Vaccine Manufacturer	Batch No.	Lot No.
1st Dose	/ /			
	Vaccinator Name:		Signature:	
2nd Dose (Schedule: / /)	/ /			
	Vaccinator Name:		Signature:	

Health Facility Name: _____ Contact No.: _____

OfficialDOHgov DOHgovph doh.gov.ph (632) 8561 - 7800 loc. 1936 covid19ceir@doh.gov.ph

ANNEX C. INFORMED CONSENT FORM

Access the document here: bit.ly/RESBAKUNAMaterials

INFORMED CONSENT FORM FOR THE SINOVAC COVID-19 VACCINE

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of March 5, 2021

Name:	**Birthdate:**	**Sex:**
Address:		
Occupation:	**Contact Number:**	
Health facility:		

INFORMED CONSENT

I confirm that I have been provided with adequate information about the donated SINOVAC COVID-19 vaccine, its Emergency Use Authorization from the Philippine Food and Drug Administration with advice for healthcare workers directly exposed to COVID-19 patients and those with comorbidities, and the recommendations of the interim National Immunization Technical Advisory Group in the absence of any other vaccine to provide workers in frontline health services the autonomy to decide to be vaccinated with this specific batch of donated SINOVAC vaccines without prejudice to immediate eligibility for other vaccines. 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 confirm that I have been screened for health conditions that may merit deferment or special precautions during vaccination as indicated in the Health Screening Questionnaire.

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 SINOVAC COVID-19 vaccine.

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 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 I may experience after vaccination.

I understand that in case I suffer a serious adverse event, which is found to be associated with the SINOVAC COVID-19 vaccine or its administration, I have a right to health benefit packages under the Philippine Health Insurance Corporation (PhilHealth) program in case I experience hospitalization due to severe and/or serious adverse reactions.

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 SINOVAC COVID-19 Vaccine.

_____ _____

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 SINOVAC COVID-19 Vaccine.

_____ _____

Signature over Printed Name | Date

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

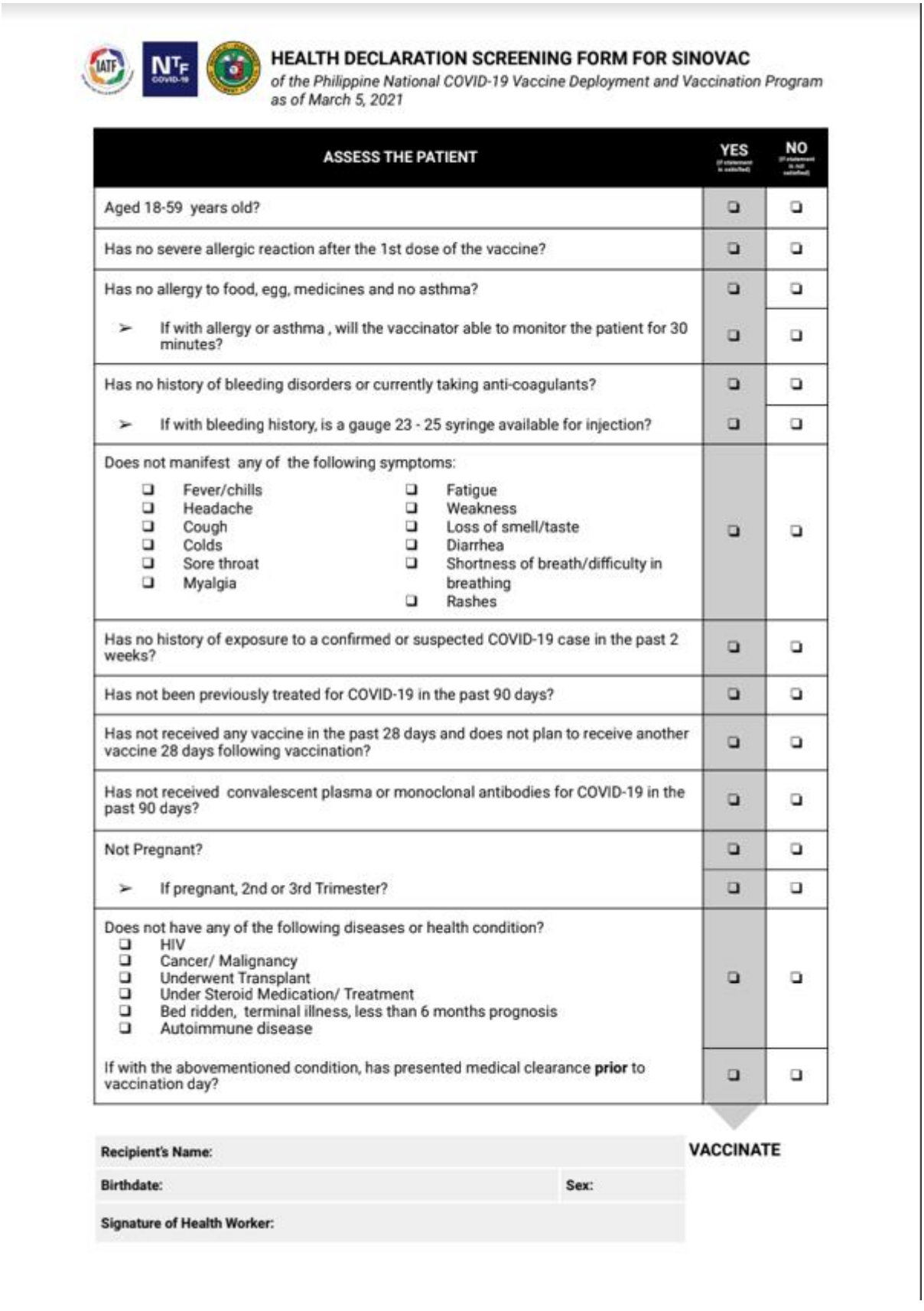
ANNEX D. ORDER OF PRIORITY FOR PRIORITY GROUP A1

For priority group A1, all workers in a health facility shall be taken as a group and provided vaccines in the following order of precedence:

1. COVID-19 referral hospitals designated by the DOH;
2. Public and private hospitals and infirmaries providing COVID-19 care, as prioritized based on service capability, starting from level 3 hospitals, to level 2 hospitals to level 1 hospitals, and then infirmaries;
3. Among hospitals with a common service capability, the order of priority shall be from facilities owned by the DOH, then facilities owned by LGUs, and then facilities owned by private entities;
4. Isolation and quarantine facilities such as temporary treatment and monitoring facilities and converted facilities (e.g. hotels, schools, etc) that cater to COVID-19 suspect, probable, and confirmed cases, close contacts, and travellers in quarantine;
5. Remaining hospitals including facilities of uniformed services not catering to COVID-19 cases;
6. Government owned primary care based facilities such as Urban Health Centers, Rural Health Units and Barangay Health Stations, birthing homes, and Local Health Offices to include members of BHERTS, contact tracers, social workers;
7. Stand-alone facilities, clinics and diagnostic centers, and other facilities otherwise not specified (e.g. clinics, dialysis centers, dental clinics, and COVID-19 laboratories), dealing with COVID-19 cases, contacts, and specimens for research purposes, screening and case management coordinated through their respective local government units; and
8. Closed institutions and settings such as, but not limited to, nursing homes, orphanages, jails, detention centers, correctional facilities, drug treatment and rehabilitation centers, and Bureau of Corrections.

ANNEX E. HEALTH ASSESSMENT FORM

Access the document here: bit.ly/RESBAKUNAMaterials



HEALTH DECLARATION SCREENING FORM FOR SINOVAC

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of March 5, 2021

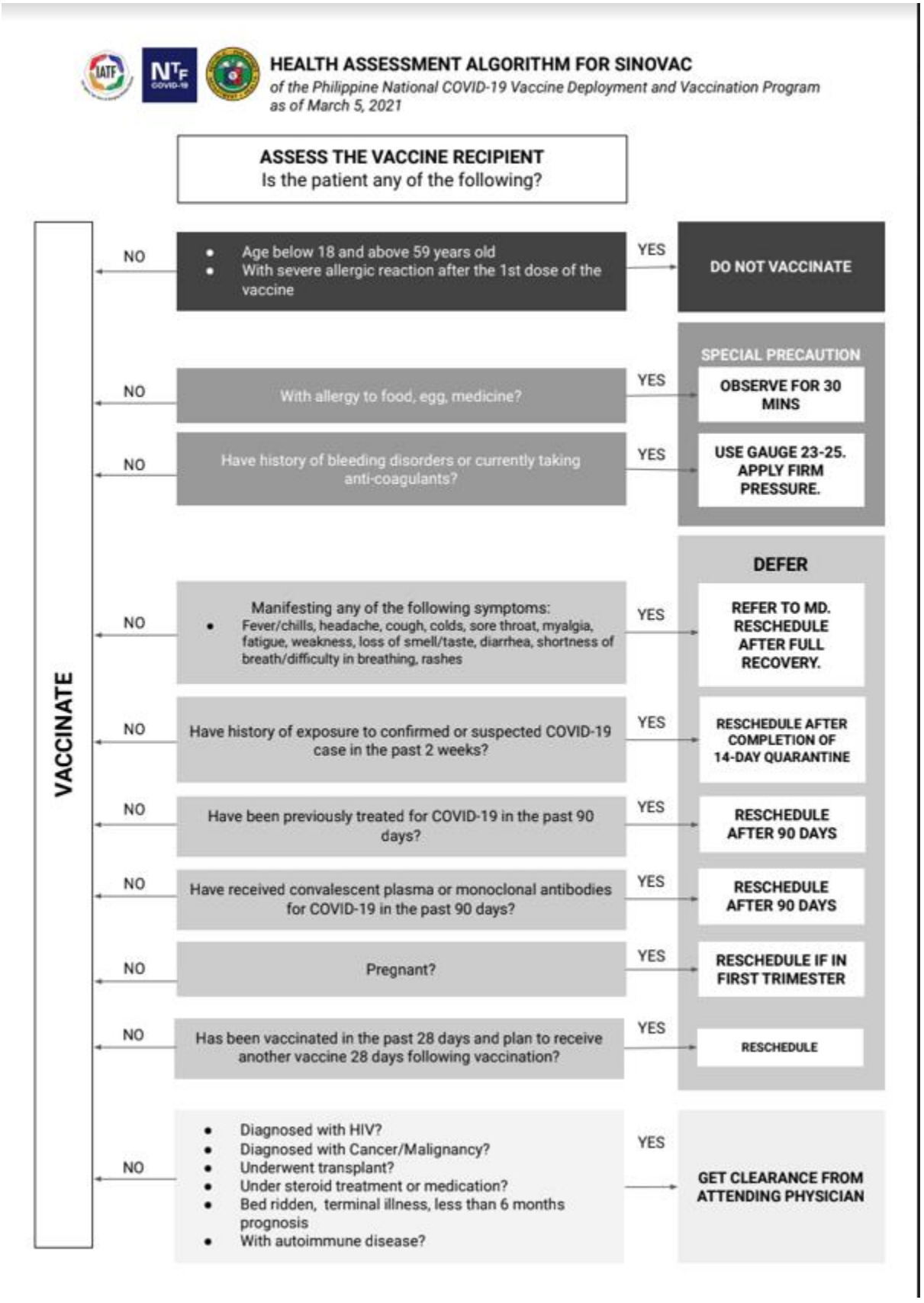
ASSESS THE PATIENT	YES	NO
Aged 18-59 years old?	❑	❑
Has no severe allergic reaction after the 1st dose of the vaccine?	❑	❑
Has no allergy to food, egg, medicines and no asthma?	❑	❑
➢ If with allergy or asthma , will the vaccinator able to monitor the patient for 30 minutes?	❑	❑
Has no history of bleeding disorders or currently taking anti-coagulants?	❑	❑
➢ If with bleeding history, is a gauge 23 - 25 syringe available for injection?	❑	❑
Does not manifest any 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 ❑ Rashes	❑	❑
Has no history of exposure to a confirmed or suspected COVID-19 case in the past 2 weeks?	❑	❑
Has not been previously treated for COVID-19 in the past 90 days?	❑	❑
Has not received any vaccine in the past 28 days and does not plan to receive another vaccine 28 days following vaccination?	❑	❑
Has not received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?	❑	❑
Not Pregnant?	❑	❑
➢ If pregnant, 2nd or 3rd Trimester?	❑	❑
Does not have any of the following diseases or health condition? ❑ HIV ❑ Cancer/ Malignancy ❑ Underwent Transplant ❑ Under Steroid Medication/ Treatment ❑ Bed ridden, terminal illness, less than 6 months prognosis ❑ Autoimmune disease	❑	❑
If with the abovementioned condition, has presented medical clearance **prior** to vaccination day?	❑	❑

VACCINATE

Recipient's Name:

Birthdate: **Sex:**

Signature of Health Worker:


HEALTH ASSESSMENT ALGORITHM FOR SINOVAC
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program
as of March 5, 2021
ASSESS THE VACCINE RECIPIENT
Is the patient any of the following?
VACCINATE
NO
Age below 18 and above 59 years old
With severe allergic reaction after the 1st dose of the vaccine
YES
DO NOT VACCINATE
SPECIAL PRECAUTION
With allergy to food, egg, medicine?
YES
OBSERVE FOR 30 MINS
Have history of bleeding disorders or currently taking anti-coagulants?
YES
USE GAUGE 23-25. APPLY FIRM PRESSURE.
DEFER
Manifesting any of the following symptoms:
Fever/chills, headache, cough, colds, sore throat, myalgia, fatigue, weakness, loss of smell/taste, diarrhea, shortness of breath/difficulty in breathing, rashes
YES
REFER TO MD. RESCHEDULE AFTER FULL RECOVERY.
Have history of exposure to confirmed or suspected COVID-19 case in the past 2 weeks?
YES
RESCHEDULE AFTER COMPLETION OF 14-DAY QUARANTINE
Have been previously treated for COVID-19 in the past 90 days?
YES
RESCHEDULE AFTER 90 DAYS
Have received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?
YES
RESCHEDULE AFTER 90 DAYS
Pregnant?
YES
RESCHEDULE IF IN FIRST TRIMESTER
Has been vaccinated in the past 28 days and plan to receive another vaccine 28 days following vaccination?
YES
RESCHEDULE
Diagnosed with HIV?
Diagnosed with Cancer/Malignancy?
Underwent transplant?
Under steroid treatment or medication?
Bed ridden, terminal illness, less than 6 months prognosis
With autoimmune disease?
YES
GET CLEARANCE FROM ATTENDING PHYSICIAN

ANNEX F. EMERGENCY USE AUTHORIZATION FOR SINOVAC
(https://www.fda.gov.ph/wp-content/uploads/2021/03/EUA-SINOVAC-WEBSITE-3.pdf)

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 February 2021

IP BIOTECH, INC.

Emergency Use Authorization (EUA) for SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], Sinovac Life Sciences Co., Ltd

This applies to your application for the issuance of Emergency Use Authorization (EUA) for the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac].

The details of the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] are as follows:

Product Name:	SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]
Dosage Strength and Form:	600 SU/0.5 mL Suspension for Injection (IM)
Pharmacologic category:	Vaccine
Storage:	Store at 2 to 8°C. Protect from light. Do not freeze.
Shelf-life:	6 months
Packaging:	Vial (Box of 40's)
Manufacturer:	Sinovac Life Sciences Co., Ltd.
Indication:	This product is suitable for clinically healthy people (aged 18 to 59 years) susceptible to the virus. Vaccination of this product stimulates the body to induce immunity against SARS-CoV-2 virus for the prevention of disease caused by SARS-CoV-2 virus. This product is not recommended for use on healthcare workers with exposure to COVID-19 patients.

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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], 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, consideration has been given to the emergency use authorizations given by counterpart National Regulatory Authorities (NRAs) such as China, Brazil and Indonesia. This was followed by a rigorous and thorough review of all submitted published and unpublished clinical trial data and product information.

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. IP Biotech, Inc. shall supply SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] shall be administered only by vaccination providers, and used only to prevent COVID-19 in clinically healthy individuals ages 18 to 59 years.

The current data does not support the use of SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] on healthcare workers exposed to COVID-19 patients as it has a low efficacy of 50.4% in this group.

"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 SARS-CoV-2

Vaccine (Vero Cell), Inactivated [CoronaVac] in accordance with the COVID-19 vaccination program.

II. Dosage Strength and Form

SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] should be supplied as an opalescent aqueous suspension in single dose vials. Each vial must contain 0.5ml per dose containing 600SU of indicated SARS-CoV-2 inactivated virus as antigen. The second dose should be given after four weeks (4) from the first dose.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, IP Biotech, 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.

IP Biotech, 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.

IP Biotech, 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). IP Biotech, Inc. shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

IP Biotech, Inc. shall have a comprehensive pharmacovigilance system for SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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.

IP Biotech, Inc. shall ensure compliance with the SARS-CoV-2 Vaccine (Vero Cell), Inactivated 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.

IP Biotech, Inc. shall submit summary safety reports every 6 months or as required by the FDA.

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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with IP Biotech, Inc.;
2. Ensure administration of the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac];
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, IP Biotech, Inc. has the ultimate responsibility for monitoring the safety and quality of the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac].

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.