Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

20 June 2022

DEPARTMENT MEMORANDUM
No. 2022 - 0252

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; AND OTHERS CONCERNED**

SUBJECT: **Interim Operational Guidelines on the Administration of Additional Doses of Pfizer-BioNTech COVID-19 Vaccine to Immunocompromised Pediatric A3 ages 12 to 17 Years Old**

I. RATIONALE

On June 14, 2022, the Philippine Food and Drug Administration (FDA) issued the Emergency Use Authorization (EUA) allowing the administration of Pfizer BioNTech COVID-19 vaccine additional/booster doses to individuals **12 years of age and older**.

Likewise, on June 16, 2022, the Health Technology Assessment Council (HTAC) issued a recommendation approving the administration of a third dose of Pfizer BioNTech COVID-19 vaccine to **immunocompromised adolescent population ages 12 to 17 years** at least **28 days** after the second dose of the primary series.

In view of the foregoing, National Vaccine Operation Center (NVOC) hereby issues these guidelines to all concerned agencies, Regional Vaccination Operations Center (RVOC) or Centers for Health Developm 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 an additional dose of Pfizer BioNTech COVID-19 vaccine to **immunocompromised Pediatric A3 ages 12 to 17 years old**.

The vaccination of COVID-19 vaccine booster doses to the Rest of the Pediatric Population (ROPP) shall commence after the rollout of the administration of additional doses of COVID-19 vaccines to immunocompromised Pediatric A3 ages 12 to 17 years old.

II. OBJECTIVES

This Department Memorandum (DM) provides interim operational guidelines on the administration of an additional dose of Pfizer BioNTech COVID-19 vaccine to immunocompromised Pediatric A3 ages 12 to 17 years old.

III. SCOPE OF APPLICATION

This DM shall be applicable to all concerned agencies of the NVOC, 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.

IV. DEFINITION OF TERMS

A. **Additional dose** - a dose which would be needed as part of an extended primary series for target populations where the immune response rate following the standard primary series is deemed insufficient as indicated in the EUA issued by the FDA. The objective of an additional dose in the primary series is to optimize or enhance the immune response to establish a sufficient level of effectiveness against the disease. The particular, immunocompromised individuals often fail to mount a protective immune response after a standard primary series.

B. **Booster dose** - refers to doses administered to a vaccinated population that has completed a primary vaccination series, when, with time, vaccine effectiveness has fallen below a rate deemed sufficient in that population, as indicated in the EUA issued by the FDA.

C. **Primary vaccination dose series** - refers to the number of doses as prescribed in the product-specific EUA provided by the FDA, either a two-dose or a one-dose series.

V. GENERAL GUIDELINES

A. The immunocompromised Pediatric A3 ages 12 to 17 years old shall be recommended to be administered with an additional dose (third dose) of COVID-19 vaccine using Tozinameran COVID-19 mRNA vaccine

(nucleoside-modified)[Cominarty]Pfizer COVID-19 vaccine based on the EUA issued by the Philippine FDA. *(Copy of the EUA may be assessed at the FDA website: https:/www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization)*

B. The National COVID-19 Vaccine Deployment and Vaccination Program shall adopt future EUA or regulatory amendments from the FDA and recommendations from the HTAC on the provision of the additional/booster doses to the pediatric population.

C. Instructions for COVID-19 vaccination providers and administration 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 EUAs may be accessed at: https:/www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization/)*

D. 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 Adverse Events Following Immunization (AEFI) Pathways may be accessed at: bit.ly/RESBAKUNAFactsheets.

E. Vaccination process, including registration, screening, administration, reporting, AEFI monitoring, and referral, shall 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"*, **Department Circular No. 2021-0464** or the *"Interim Operational Guidelines on the COVID-19 Vaccination of the Pediatric Population Ages 12-17 years old with comorbidities,"* the amendment stipulated under DOH **Department Circular No. 2021-0464-A**, and other relevant policies issued by the DOH.

VI. IMPLEMENTING GUIDELINES

A. Eligible Groups

1. **Immunocompromised Pediatric A3 ages 12-17 years old** are eligible to be given an additional dose of COVID-19 vaccine. Immunocompromised individuals are defined as individuals with/are:
   a. Individuals who have been receiving active cancer treatment for tumors or cancers of the blood;
   b. Individuals who had received an organ transplant and are taking medicine to

suppress the immune system;

c. Individuals who received a stem cell transplant within the last two (2) years or are taking medicines to suppress the immune system
d. Individuals with moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome);
e. Individuals with advanced or untreated HIV infection;
f. Individuals with active treatment with high-dose corticosteroids or other drugs that may suppress immune response;
g. Individuals on chronic dialysis;
h. People living with autoimmune disease, and treatment with specific immunosuppressive medications;
i. Individuals diagnosed with conditions that are considered to have an equivalent level of immunocompromised state as advised by the attending physician (e.g. severe malnutrition).

B. Vaccine Administration of Additional COVID-19 Vaccine Doses

1. The additional COVID-19 vaccine dose administered to immunocompromised Pediatric A3 population ages 12-17 years old shall be given at least **28 days** after the administration of the second dose of the primary series.

2. For the administration of the additional COVID-19 vaccine dose, **0.3 ml/dose of Pfizer-BioNTech COVID-19 vaccine** shall be given.

C. Vaccination Rollout

1. Since the administration of additional/booster COVID-19 vaccine doses to the pediatric population ages 12-17 years old shall commence with the vaccination of the immunocompromised Pediatric A3 population, only **hospital-based vaccination sites** shall be allowed to administer the additional COVID-19 vaccine doses to this population.

2. The vaccination rollout for this population shall be conducted in a phased approach:
   a. **Pilot rollout:** selected hospital-based vaccination sites in the National Capital Region (NCR) as determined by NVOC and Metro Manila Center for Health Development..
   b. **Nationwide initial rollout:** all participating hospital-based vaccination sites in the NCR, and pilot rollout in all regions based on the readiness of selected hospital-based vaccination sites. The CHDs are responsible for determining the hospital-based vaccination sites as pilot sites, either DOH-retained, LGU-managed or privately owned medical centers or hospitals.

c. **Nationwide full-scale rollout:** all participating hospital-based vaccination sites nationwide.

3. The timelines of each rollout phase shall be determined by NVOC, in coordination with the CHDs.

D. Capacity Building and Training

1. All implementing units and vaccination sites shall ensure that all members of the vaccination teams undergo capacity building before rolling out of the administration of additional COVID-19 vaccine dose.

E. Allocation and Distribution of COVID-19 Vaccines

1. The NVOC shall allocate and distribute COVID-19 vaccines for additional doses based on the number of eligible populations which are computed based on the recommended dose interval.

2. The CHDs and LGUs may utilize available Pfizer COVID-19 vaccines for 12 years old and older for the administration of the additional COVID-19 vaccine doses, and ensure the availability of these vaccines at all times.

3. The RVOCs or the CHDs may allocate and distribute COVID-19 vaccines directly to implementing units and vaccination sites, in coordination with the LGUs.

F. Pre-registration and Scheduling

1. Medical centers and hospitals shall schedule their immunocompromised pediatric patients ages 12-17 years old for vaccination once they are eligible. Attending physicians shall actively and timely schedule patients for vaccination once they are due to be given with additional COVID-19 vaccine doses.

2. Immunocompromised pediatric A3 ages 12-17 years old patients without attending physicians and/or those who are not regularly visiting a specific health facility, shall be coordinated by the CHOs/RHUs for vaccination in specific hospital-based vaccination sites.

3. CHOs/RHUs are responsible for facilitating the vaccination of all immunocompromised pediatric A3 ages 12-17 years old in hospital-based vaccination sites within its area of jurisdiction. The CHOs/RHUs may facilitate their transportation and vaccination schedule.

4. Medical center and hospital vaccination sites shall accommodate walk-ins and any referral from CHOs/RHUs or any health facility without additional fees or payments.

G. Requirements for Vaccination of Additional/Booster Doses

1. Vaccination card with complete details of the administered two doses of the primary series.

2. A medical certification given by the attending pediatric/physician detailing the conditions qualified under the definition of the immunocompromised populations shall be secured prior to the vaccination schedule and shall be presented in the registration area in the vaccination site.

3. Valid identification cards or documents with a photo of the parent/guardian and the vaccine recipient. *(See Annex B for the list of valid identification cards or documents)*

4. Document/s to prove filiation. (*See Annex C for the list of acceptable documents)*

H. Preparation of the Vaccination Sites

1. The vaccination sites shall have sufficient assistive devices/equipment such as wheelchairs, handrails, among others, to aid the vaccine recipients.

2. The vaccination site shall be large enough to accommodate the presence of the vaccine recipients' parents/guardians.

I. Vaccination Process

1. The vaccination process and AEFI monitoring and case management shall primarily follow the steps stipulated in the DOH's **Department Circular No. 2021-0464** ,otherwise known as, *"Interim Operational Guidelines on the COVID-19 Vaccination of Pediatric Population Ages 12-17 Years old with Comorbidities"* and **Department Circular No. 2021-0464-A** as amended.

2. The vaccine recipient shall be accompanied by a parent/guardian at the vaccination site.

3. An informed consent given and signed by the parent/guardian, together with an assent given and signed by the vaccine recipient, are both required prior to the administration of an additional COVID-19 vaccine dose.

4. Without the signed informed consent of the parent/guardian or any individual authorized to act as the substitute parental authority, the vaccine recipient shall be deferred for COVID-19 vaccination unless such documentary requirements are accomplished.

5. If the vaccine recipient did not give his/her assent, he/she shall not be coerced to receive the additional COVID-19 vaccine dose.

6. In case the vaccine recipient is not capable of giving assent due to neurological comorbidities and moderate to severe intellectual impairment, the parent or the authorized parental substitute can sign on his/her behalf.

J. Vaccination Reporting

1. Vaccinated immunocompromised pediatric A3 ages 12-17 years old shall be categorized and reported under "Pediatric A3 12-17 years old".

2. All vaccination sites shall record the vaccination event and encode the dose administered as additional COVID-19 vaccine dose in the systems/tools deployed by the Department of Information and Communications Technology.

3. All participating vaccination sites shall report their accomplishments, including the quick count numbers on the doses administered and the inventory and the completed line list, to the LGU where the vaccination activities were conducted, on a daily basis. Likewise, the LGUs shall submit the following:
   a. Quick counts on vaccination accomplishment and inventory to the VORS daily.
   b. Required vaccination information of the vaccine recipients through a line list to the VAS Line List Upload Tool (https://vaslinelist.dict.gov.ph) within 24 hours after the vaccination activity.

4. The VORS and VAS line list data fields shall be updated to include the additional/booster dose.

K. Demand Generation and Communication Activities

1. All CHDs/RVOCs/LVOCs shall conduct information dissemination activities such as town hall meetings, barangay lecture series, and distribution of Information, Education, and Communication (IEC) materials.

2. LGUs and all Implementing Units shall maximize both online and offline platforms, and promote community engagement through targeted COVID-19 vaccination key messaging, and prioritization of those Most-at-Risk Population (MARP).

3. CHDs/RVOCs/LVOCs and LGUs are highly encouraged to engage with the local medical societies, faith-based organizations, and other relevant stakeholders in health promotion activities relating to COVID-19 vaccination.

4. CHDs and LGUs shall ensure feedback mechanisms and social listening by promoting the use of the Knowledge Informs Responsible Action or *Katuwang na Impormasyon para sa Responsableng Aksyon* (KIRA) chatbot (https://m.me/OfficialDOHgov).

5. All implementing units are directed to calibrate and/or recalibrate their existing crisis communication plans, in accordance with DM 2021-0224, otherwise known as, *Interim Guidelines in Adverse Events Following Immunization (AEFI) Community Management and Crisis Communications Related to COVID-19 Vaccines.*

For dissemination and strict compliance.

By Authority of the Secretary of Health:

MYRNA C. CABOTAJE, MD, MPH, CESO III
Undersecretary of Health
Field Implementation and Coordination Team
Chair, National Vaccination Operations Center

ANNEX A. List of valid identification cards or documents

Valid identification cards or documents with photo of the parent/guardian and the vaccine recipient to verify documents shall be presented. These are the list of valid identification cards of parent/guardian:

1. SSS Card
2. GSIS Card
3. Unified Multi-Purpose Identification (UMID) Card
4. Land Transportation Office (LTO) Driver's License
5. Professional Regulatory Commission (PRC) ID
6. Philippine Identification (PhilID)
7. Overseas Workers Welfare Administration (OWWA) E-Card
8. Commission on Elections (COMELEC) Voter's ID or Voter's Certificate
9. Senior Citizen ID
10. Philippine Postal ID
11. Seafarer's Record Book
12. Valid or Latest Passport
13. Others

ANNEX B. REQUIREMENTS TO PROVE FILIATION/ GUARDIANSHIP FOR PEDIATRIC COVID-19 VACCINATION

A. At least one (1) of the following documents shall be presented to prove filiation or guardianship:

1. In case the minor is accompanied by his/her parent:

a. The best evidence of filiation for the accompanying parent shall be an original copy **or** a certified true copy of the Birth Certificate issued by the Philippine Statistics Authority (PSA). In lieu of the PSA-issued Birth Certificate or certified true copy of the same, a copy of the Certification issued by the Local Civil Registrar of the City or Municipality where the vaccine recipient was registered shall be acceptable. The Certification shall set forth the following:

i. LCR Registry Number;

ii. Page and book number of the entry of registration;

iii. Date of Registration;

iv. Name of Child;

v. Sex;

vi. Date of Birth;

vii. Place of Birth;

viii. Name of the Mother;

ix. Citizenship of the Mother;

x. Name of the Father, if applicable;

xi. Citizenship of the Father, if applicable;

xii. Date of Marriage of the parents, if applicable; and

xiii. Place of Marriage, if applicable.

b. In case the vaccine recipient does not have a copy of the original or certified true copy of his/her birth certificate or a Certification from the Local Civil Registrar, secondary documents shall be acceptable as long as the same is coupled with a valid government identification card issued to the parent and the vaccine

recipient. The following are the secondary documents that may be presented (The list is not in order of preference):

i. Authenticated medical certificate of the child bearing the name of the parent, issued by the hospital or the DOH;

ii. Baptismal Certificate of the child with the name of the parent/s;

iii. School ID or records of the child (transcript of records, Form 137, etc.) bearing the name of the parent;

iv. PhilHealth, Social Security System (SSS), Government Service Insurance System (GSIS) forms indicating that the vaccine recipient is a beneficiary and a child of the parent. In lieu of physical copies, the parent may show his/her online account of the PhilHealth, SSS and GSIS online portal showing his/her filiation with the child;

v. Copies of insurance policies, health card membership, life plan, memorial plan and similar policies wherein the vaccine recipient is the child of the parent and the said policies were taken on behalf of the latter. In lieu of physical copies, the parent may show his/her online account of the online portal of the said service and health providers, showing his/her filiation with the child;

vi. Barangay Certification issued by the Barangay Captain indicating that the parent/s and the child is personally known to the latter and setting forth the filiation of the said individuals, as attested by one (1) other witness who personally knows the child and the parent;

vii. If the parent is a Solo Parent, a copy of the Solo Parent identification card from the City or Municipal Social Welfare and Development Office, a Local Social Welfare and Development Office, Tallaq or Faskh certification from the Shariah court or any Muslim Barangay or religious leader, provided that the name of the child is indicated therein;

viii. Court Decree of Adoption, in case the child is adopted;

ix. PWD ID of the child, if available, wherein the name of the parent is indicated in the ID pursuant to DOH AO No. 2017-0008 or the "*Implementing Guidelines of Republic Act 10754, otherwise known as "An Act Expanding the Benefits and Privileges of Persons with Disability", for the Provision of Medical and Health-related Discounts and Special Privileges*;

x. Other public documents enumerated under Memorandum Circular 04-12, or the "*Clarification on the Scope of Public Documents under Republic*

Act No. 9225" dated October 18, 2004 issued by the Office of the Civil Registrar General, as applicable.

c. In case the parent is residing abroad or cannot accompany their own children on the day of the scheduled vaccination, the accompanying adult may present a Special Power of Attorney executed by either parent of the minor designating the minor's companion to assist in the vaccination process. (If executed abroad, the SPA must be apostilled, if applicable, or authenticated by the Philippine Embassy/Consulate). The following documents may serve as an alternative document to the Special Power of Attorney:

   i. Notarized authorization letter;

   ii. written affidavit of parent /guardian under an oath with a public official such as the notary public or a person authorized to do so (eg. Barangay Officials) with presentation of a valid government ID; or

   iii. Barangay Certification issued by the Barangay Captain, the parent/ guardian will be accompanied by one witness personally known to the latter who can attest that the parent/ guardian is indeed the parent/ guardian of the child. Together, they will meet the Barangay Captain before issuing the Certification.

2. In case the minor is accompanied by his/her legal or judicial guardian (The list is not in order of preference):

a. Affidavit of Guardianship executed by the Guardian;

b. Court decree or order of Guardianship, or Letter of Guardianship issued by a Family Court;

c. Affidavit of Kinship;

d. PWD ID of the child, if available, wherein the name of the guardian is indicated in the ID pursuant to DOH AO No. 2017-0008;

e. Authenticated medical certificate of the child bearing the name of the guardian, issued by the hospital or the DOH;

f. Baptismal Certificate of the child with the name of the guardian;

g. School ID or record of the child which bears the name of the guardian;

h. PhilHealth, SSS, GSIS forms indicating that the vaccine recipient is a beneficiary and a child under the guardianship of the accompanying adult. In lieu of physical

copies, the parent may show his/her online account of the PhilHealth, SSS and GSIS online portal showing his/her relationship with the child;

i. Copies of insurance policies, health card membership, life plan, memorial plan and similar policies wherein the vaccine recipient is the child under the guardianship of the accompanying adult and the said policies were taken on behalf of the latter. In lieu of physical copies, the parent may show his/her online account of the online portal of the said service and health providers, showing his/her relationship with the child;

j. Barangay Certification issued by the Barangay Captain indicating that the guardian and the child are personally known to the latter and setting forth the relationship of the said individuals, as attested by one (1) other witness who personally knows the child and the parent.

k. If the accompanying person is a Solo Parent, a copy of the Solo Parent identification card from the City or Municipal Social Welfare and Development Office, a Local Social Welfare and Development Office, Tallaq or Faskh certification from the Shariah court or any Muslim Barangay or religious leader, provided that the name of the child is indicated therein.

3. **In case the minor is under the custody of a Child-Caring Agency:**

   a. A certified list of agencies as duly licensed and accredited by the Department of Social Welfare and Development (DSWD) shall be provided by the DSWD, including the corresponding heads/officers of the said agencies authorized to act as guardians of the children under their care. The said list shall be the basis to verify the names of the accompanying adult in order to determine his/her authority to give informed consent or assent, as the case may be.

   b. The Child-Caring Agency may also opt to provide the DOH a certified list of the names of the minor vaccine recipients who will be vaccinated and the name of their authorized accompanying adults, attaching photocopies of their valid IDs. If so, both the vaccine recipients and the accompanying heads/officers shall be required to present the actual valid government ID corresponding to the one submitted by the Agency. For the accompanying heads/officers, they shall be required to present the valid ID issued by the Child-Caring Agency issued under their name.

In case the above-mentioned mechanisms are not feasible, based on the assessment of the vaccination team after it has conducted due diligence in ensuring that the vaccine recipient

has difficulty in obtaining the primary documents, the accompanying adult and the vaccine recipient shall present the following documents:

a. In case of an abandoned child whose birth or parentage is unknown, a copy of the Certificate of Foundling and the valid ID issued by the Child Caring Agency to the accompanying heads/officers.

b. Affidavit of Guardianship executed by the accompanying heads/officers and the valid ID issued by the Child-Caring Agency.

c. Authenticated medical certificate of the child bearing the name of the accompanying heads/officers, issued by the hospital or the DOH;

d. Baptismal Certificate of the child with the name of the accompanying heads/officers;

e. School ID or record of the child which bears the name of the accompanying heads/officers;

f. Barangay Certification issued by the Barangay Captain indicating that the accompanying heads/officers and the child are personally known to the latter and setting forth the relationship of the said individuals, as attested by one (1) other witness who personally knows the child and the accompanying heads/officers.

g. For purposes of verifying the identity of the accompanying adult, the valid ID issued by the Child-Caring Agency and a separate government issued ID shall be presented by the latter.

ANNEX C. COVID-19 PEDIATRIC VACCINATION (12 - 17 YEARS OLD) ADDITIONAL/ BOOSTER DOSE INFORMED CONSENT FORM FOR PFIZER-BIONTECH *(may be accessed through bit.ly/PediaBoosterForms)*

COVID-19 PEDIATRIC VACCINATION (12-17 YEARS OLD) ADDITIONAL/BOOSTER DOSE INFORMED CONSENT FORM AND ASSENT FORM FOR PFIZER-BIONTECH

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program
as of June 20, 2022

Name of Minor:	**Birthdate:**	**Sex:**
Address:		
Name of Parent/Guardian:	**Relationship:**	
Contact Number:		
Vaccination Site:		

Section 1: Information on the risks and benefits of the Pfizer-BioNTech COVID-19 vaccine additional/booster dose

The Philippine Food and Drug Administration has authorized the emergency use of the Pfizer-BioNTech COVID-19 vaccine to individuals 12 years and older under an Emergency Use Authorization (EUA). An additional/booster dose of Pfizer-BioNTech may be administered 5-6 months after the second dose of the primary dose series or 28 days after the second dose for immunocompromised individuals. The vaccine may prevent the person vaccinated from getting severe COVID-19 infection and hospitalization.

Side effects that have been reported with the Pfizer-BioNTech COVID-19 vaccine include: injection site pain, redness, itching, and swelling; tiredness; headache; muscle pain, chills, joint pain; fever; nausea; vomiting; diarrhea; feeling unwell; arm pain, insomnia, decreased appetite, excessive sweating, night sweats, enlarged lymph nodes. There is a remote chance that the vaccine could cause temporary one-sided facial drooping and/or severe allergic reaction such as hives or swelling of the face. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 vaccine. For this reason, the vaccine provider may ask the recipient to stay at the vaccination site for monitoring post-vaccination.

The United States Center for Disease Control and Prevention (US CDC) and its partners are actively monitoring reports of myocarditis and pericarditis after COVID-19 vaccination.

Myocarditis is the inflammation of the heart muscle, and pericarditis is the inflammation of the outer lining of the heart. In both cases, the body's immune system causes inflammation in response to an infection or some other triggers. Both myocarditis and pericarditis have the following symptoms: chest pain, shortness of breath, feelings of having a fast-beating, fluttering, or pounding of the heart.

Cases of myocarditis reported to the US Vaccine Adverse Event Reporting System (VAERS) have occurred after mRNA COVID-19 vaccination, especially in male adolescents and young adults, more often after the second dose usually within several days after vaccination. Most patients with myocarditis or pericarditis who received care responded well to medicine and rest and felt better quickly.

Despite the side effects, recent studies show that the benefits of receiving the additional/booster dose of Pfizer-BioNTech COVID-19 vaccine far outweigh the risks.

Section 2: Parent's/Guardian's Consent for Minor's Vaccination

I confirm that I have been provided with and have read the Pfizer-BioNTech COVID-19 vaccine Emergency Use Authorization (EUA) Information Sheet and the same has been explained to me. The Philippine FDA has amended the EUA to allow its use as an additional/booster dose for the pediatric population aged 12-17 in light of new scientific evidence.

I confirm that the minor has been screened for conditions that may merit deferment or special precautions for additional/booster dose vaccination as indicated in the Health Screening Questionnaire.

I have received sufficient information on the benefits and risks of receiving an additional/booster dose of the COVID-19 vaccine and I understand the possible risks if the minor is not vaccinated with an additional/booster dose.

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 additional/booster dose of Pfizer-BioNTech COVID-19 vaccine.

ANNEX D. COVID-19 PEDIATRIC VACCINATION (12 - 17 YEARS OLD) ADDITIONAL/ BOOSTER DOSE ASSENT FORM FOR PFIZER-BIONTECH

(may be accessed through bit.ly/PediaBoosterForms)

COVID-19 PEDIATRIC VACCINATION (12-17 YEARS OLD) ADDITIONAL/BOOSTER DOSE INFORMED CONSENT FORM AND ASSENT FORM FOR PFIZER-BIONTECH

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of June 20, 2022

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 which may be experienced after vaccination.

I understand that by signing this Form, the minor has a right to health benefit packages under the Philippine Health Insurance Corporation (PhilHealth), in case he/she suffers a severe and/or serious adverse event, which is found to be associated with the Pfizer-BioNTech COVID-19 vaccine or its administration. I understand that the right to claim compensation is subject to the guidelines of 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. Nonetheless, I understand that despite such authorization and consent given by me to release all personal and sensitive information for public health purposes, I remain entitled to the rights afforded to a Data Subject under the Data Privacy Act of 2012.

In providing my consent below, I confirm that I have the legal authority to give consent for the vaccination of the minor named above with the additional/booster dose of the Pfizer-BioNTech COVID-19 vaccine.

I hereby give consent to the additional/booster dose vaccination of the minor named above with the Pfizer-BioNTech COVID-19 vaccine. I affirm that I have understood and reviewed the information included in Section 1 herein. (If this consent is not signed, dated and returned, the minor will not be vaccinated).

Signature over Printed Name of the Parent/Guardian

Date

If you choose not to have your child/ward vaccinated, please list down the reason/s:

Section 3: Minor's Assent for Vaccination

I ACKNOWLEDGE THAT:

I am being asked to decide if I, _____, _____ (Minor's Name), _____ (Age, years), want to receive the additional/booster dose of the Pfizer-BioNTech COVID-19 vaccine.

I have understood the information about the additional/booster dose of the Pfizer-BioNTech COVID-19 vaccine which will be vaccinated to me, and I confirm that I have understood the same.

I asked several questions about the additional/booster dose of the Pfizer-BioNTech COVID-19 vaccine and got answers to the same. I understand that I can ask questions and raise concern about COVID-19 vaccination anytime.

I understand the risk of the administration of the vaccine including the outcomes (that while most side effects are minor and resolve on their own, there can be a risk for adverse reactions in rare circumstances.)

I know that I can stop at any time in the process of vaccination without anyone reprimanding me. The attending physician will still take care of me.

I want to receive the COVID-19 vaccine at this time.

☐ *If the minor is **not capable of giving assent** due to neurological comorbidities and moderate to severe intellectual impairment, the **parent or the authorized parental substitute can sign on his/her behalf.***

Signature over Printed Name of the Minor / Parent / Guardian

Date

If you choose not to get vaccinated, please list down the reason/s:

ANNEX E. COVID-19 PEDIATRIC VACCINATION(12 - 17 YEARS OLD) ADDITIONAL/ BOOSTER DOSE HEALTH DECLARATION SCREENING FORM FOR PFIZER-BIONTECH *(may be accessed through bit.ly/PediaBoosterForms)*

COVID-19 PEDIATRIC VACCINATION (12-17 YEARS OLD) ADDITIONAL/BOOSTER DOSE HEALTH DECLARATION SCREENING FORM FOR PFIZER

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of June 20, 2022

Has received an received an additional/booster dose of COVID-19 vaccine?	❑	❑
If immunocompromised, has it only been less than twenty-eight (28) days since completing your 2-dose primary series? If immunocompetent, has it only been less than five (5) to six (6) months since completing your 2-dose primary series?	❑	❑
Below 12 years old?	❑	❑
Had a severe allergic reaction to any ingredient of the PFIZER vaccine? (mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6, 1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N, N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose)	❑	❑
Had a severe allergic reaction after the 1st or 2nd dose of the PFIZER vaccine?	❑	❑
Has allergy to food, egg, medicines? Has 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 securing a gauge 23 - 25 syringe for injection?	❑	❑
Has been diagnosed with Multisystem Inflammatory Syndrome (MIS-C) in the past 90 days?	❑	❑
Previously diagnosed with Multisystem Inflammatory Syndrome (MIS-C) and is STILL undergoing recovery?	❑	❑
Has SBP ≥160 mmHg and/or DBP≥ 100 mmHg WITH signs and symptoms of organ damage? Note: If BP cannot be taken, write "N/A" in YES column; measurement of BP not required prior to vaccination	❑	❑
If initially with SBP ≥160 mmHg and/or DBP≥ 100 mmHg WITHOUT signs and symptoms of organ damage, is there a problem maintaining a blood pressure of <160/100 mmHg after monitoring two times every fifteen minutes?	❑	❑
Manifests any one of the following symptoms? ❑ Fever/chills ❑ Myalgia ❑ Diarrhea ❑ Headache ❑ Rashes ❑ Shortness of breath/difficulty in breathing ❑ Cough ❑ Fatigue ❑ Nausea/ Vomiting ❑ Colds ❑ Weakness ❑ Other symptoms of existing comorbidity ❑ Sore throat ❑ Loss of smell/taste Note: Eligible vaccine recipients who have completed mandatory isolation period WITHOUT fever, but still with mild symptoms, may be vaccinated	❑	❑
Has history of exposure to a confirmed or suspected COVID-19 case in the past 14 days?	❑	❑
If previously diagnosed with COVID-19, is recipient STILL undergoing recovery or treatment?	❑	❑
Has received any vaccine in the past 14 days or plans plan to receive another vaccine 14 days following vaccination?	❑	❑
Has received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?	❑	❑
If in the 1st trimester of pregnancy, is there any objection to vaccination from the presented medical clearance from the attending physician?	❑	❑
Has any of the following diseases or health condition OR undergoing any of the following treatment? ❑ Active cancer treatment for tumors or cancers of the blood ❑ Organ transplant recipients AND taking medicine to suppress the immune system ❑ Stem cell transplant recipients within the last 2 years OR taking medicine to suppress the immune system ❑ With moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome) ❑ Advanced or untreated HIV infection ❑ Active treatment with high-dose corticosteroids OR other drugs that may suppress immune response ❑ On chronic dialysis ❑ With autoimmune disease and treatment with specific immunosuppressive medications ❑ Diagnosed with conditions considered equivalent to immunocompromised state as advised by physician ❑ Myocarditis or pericarditis OR developed myocarditis/ pericarditis after a dose of mRNA vaccine	❑	❑
If with any of the abovementioned condition, is there any objection to vaccination from presented medical clearance **prior** to vaccination day?	❑	❑

Recipient's Name:			**Sex:**
Parent's/ Legal Guardian's Name:			**Wt (kg):**
Birthdate:		**Temp:**	
Signature of Health Worker:	**HR:**	**RR:**	**O2 sat:**

VACCINATE

If any of the **white** boxes is checked, **DEFER** vaccination.

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

ANNEX F. COVID-19 PEDIATRIC VACCINATION(12 - 17 YEARS OLD) ADDITIONAL/ BOOSTER DOSE HEALTH ASSESSMENT SCREENING FORM FOR PFIZER-BIONTECH *(may be accessed through bit.ly/PediaBoosterForms)*