

Republic of the Philippines Department of Health **OFFICE OF THE SECRETARY**

14 January 2021

DEPARTMENT CIRCULAR No. 2021-_____

TO: ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS AND SERVICES AND CENTERS FOR HEALTH **DEVELOPMENT; MINISTER** OF HEALTH BANGSAMORO **AUTONOMOUS** REGION IN **MUSLIM MINDANAO: EXECUTIVE** DIRECTORS OF SPECIALTY HOSPITALS; CHIEFS OF MEDICAL CENTERS, HOSPITALS AND SANITARIUM; AND ALL OTHERS CONCERNED

SUBJECT: Department of Health's Strategic Plan for COVID-19 Vaccination (2021-2023) and National Strategic Policy Framework for COVID-19 Vaccine Deployment and Immunization

As the country continuously steps up efforts to transition to a new normal amid the COVID-19 pandemic, the national government, through a whole-of-government and whole-of-society approach, needs to ensure vaccine accessibility by each and every Filipino.

In support of this, the DOH Strategic Plan for COVID-19 Vaccine 2021-2023, as attached, outline the DOH overall thrusts and direction that shall be our guideposts for operational and financial planning towards vaccine accessibility for all. This Plan further describes the key result areas as well as the requisite strategies within the next three years as we prepare for the implementation of an immunization program, pending the urgent development of a definitive treatment and an effective vaccine against COVID-19.

Another important policy document is the Administrative Order No. 2021-0005 dated 12 January 2021 entitled "National Strategic Policy Framework for COVID-19 Vaccine Deployment and Immunization", as attached, provide strategic policy guidance and direction on the selection, access, deployment of the COVID-19 vaccine and the COVID-19 immunization program.

For information and guidance. Dissemination to all concerned is requested.

By Authority of the Secretary of Health

JÉ, MD, MPH, CESO III Undersecretary of Health Public Health Services Team

Department of Health's Strategic Plan for COVID-19 Vaccination *As of 11 January 2020*

I. Introduction

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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 Coronavirus 2 (SARS-CoV-2), as a Public Health Emergency of International Concern (PHEIC).

The Philippines, since January 2020, has been responding to the COVID-19 pandemic and has implemented numerous interventions in response to the pandemic with varying levels of success. These interventions are anchored on the National Action Plan Against COVID-19 utilizing the Prevent - Detect - Isolate / Quarantine - Treat - Reintegrate (PDITR) strategy. Several months into its implementation, the Philippines is strategically exploring other interventions that will allow the country to hasten socio-economic recovery and transition to near normal. With this, countries including the Philippines, are racing to find a safe and effective vaccine.

Vaccines have saved millions of lives in the past. Countries around the world have implemented numerous immunization programs against more than 20 life-threatening diseases, such as measles, poliomyelitis, hepatitis B, influenza, and many others. These vaccination efforts prevented almost 2-3 million deaths every year and allowed people to live longer and healthier lives. Also, through vaccination, eradication and near elimination of diseases have been made possible, such as in the case of smallpox and poliomyelitis.

In the past, vaccines have also been utilized as an integral part of epidemic (*pandemic*) response to infectious diseases. Examples are the 2009 Influenza pandemic vaccines against the novel influenza A (H1N1) virus and the Recombinant Vesicular Stomatitis virus–Zaire Ebola virus (rVSV-ZEBOV) vaccine against Ebola in 2014 to 2016. Such vaccines have prevented succeeding outbreaks, further disease spread and have aided in saving thousands of lives. An exemplar of the benefit of vaccines in halting disease outbreaks and breaking the chain of transmission was in August 2018 when the Democratic Republic of Congo (DRC) declared the Kivu Ebola epidemic as 53 individuals were infected and 29 deaths were reported, 300,000 individuals were vaccinated immediately thereafter. This endeavor resulted in halting the outbreak within the region, and due to continuous efforts via *the ring vaccination strategy*, the reported number of deaths among those who were infected and infected cases of tertiary contacts (contacts of contacts) were significantly reduced.

Thus, with the COVID-19 pandemic, the Philippines is exploring all means to access COVID-19 vaccines and prepare the country for the implementation of a COVID-19 deployment and vaccination program once a safe and effective vaccine is readily available.

The Department of Health's Strategic Plan for COVID-19 Vaccination is anchored on the National Strategic Policy Framework for COVID-19 Vaccine Deployment and Immunization, and is an integral part of the National Strategic Plan for COVID-19 Vaccination, which outlines the whole-of-government plan for COVID-19 Vaccine. It shall provide guidance on the development of operational guidelines and plans for

implementation with great emphasis on scientific information as these develop following COVID-19 vaccine-related information.

II. Current Global Epidemiology of COVID-19

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For over a year now, the COVID-19 pandemic continues with the Americas accounting for almost half of the reported cases. Currently, the global picture is varied. Some countries have brought the pandemic under control and have almost returned to normal activities where societies have opened up. On one hand, other countries are seeing second or third waves of the outbreak and are implementing more restriction measures to address the increasing number of cases and deaths. In addition, concerns are mounting up on the newly reported COVID-19 mutations such as UK and South African variants.

On 3 January 2021, the World Health Organization (WHO) announced that for the third week in a row over 4 million new cases were reported globally, although this week saw a slight decrease compared to the previous week. However, this and other short-term trends in data should be interpreted with caution owing to the end-of-year holiday season, as numbers may be influenced by presentation, testing and reporting delays. The decrease seen last week in new deaths has been reversed with deaths rising by 3% to 76 000 (Figure 1, Table 1). The Region of the Americas accounted for 47% of all new cases and 42% of all new deaths globally in the past week. New cases and deaths remained high in the European Region, which accounted for 38% and 43% respectively, showing a slight decrease in new cases and a slight increase in new deaths. New cases and deaths continue to decline in the South-East Asia and Eastern Mediterranean regions. In the African Region, while both new cases and deaths remain low in absolute numbers, for the fourth week in a row, the Region is reporting the largest percentage increase globally in weekly reported case numbers and this week there was a further 13% increase in new cases and 28% increase in new deaths. In the Western Pacific Region, new cases remained comparable to the previous week, but new deaths rose by 10%. As we welcome the New Year, and look eagerly towards COVID-19 vaccination campaigns worldwide, the current epidemiological situation with near record numbers of new cases and deaths, makes it imperative to continue to adhere to safety measures to prevent further transmission and loss of life.





In the WHO-Western Pacific Region, new cases (13%) and deaths (4%) continued to increase, a trend which has been seen over the past eight weeks. The Region reported over

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53,000 new cases and nearly 700 new deaths. The highest new cases were reported in Japan (21,432 new cases; 169 new cases per 1 million), Malaysia (11,931 new cases; 369 new cases per 1 million) and the Philippines (10,961 new cases; 100 new cases per 1 million). The countries reporting the highest number of new deaths this week were Japan (340 new deaths; 3 new deaths per 1 million), the Philippines (156 new deaths; 1 new death per 1 million), and the Republic of South Korea (134 new deaths; 3 new deaths per 1 million).

WHO Region	New cases in last 7 days (%)	Change in new cases in last 7 days *	Cumulative cases (%)	New deaths in last 7 days (%)	Change in new deaths in last 7 days *	Cumulative deaths (%)
Americas	1 935 621 (47%)	-1%	36 337 439 (43%)	32 283 (42%)	3%	872 486 (47%)
Europe	1 553 332 (38%)	-3%	26 885 471 (32%)	32 898 (43%)	3%	588 770 (32%)
South-East Asia	208 592 (5%)	-10%	12 051 014 (14%)	3 756 (4%)	-3%	184 493 (10%)
Eastern Mediterranean	154 695 (3%)	-1%	4 977 852 (5%)	3 057 (4%)	-12%	122 061 (6%)
Africa	130 007 (3%)	13%	1 961 234 (2%)	3 293 (4%)	28%	43 592 (2%)
Western Pacific	52 979 (1%)	0%	1 112 724 (1%)	730 (0%)	10%	20 288 (1%)
Global	4 035 226 (100%)	-2%	83 326 479 (100%)	76 017 (100%)	3%	1 831 703 (100%)

Table 1. Newly reported and cumulative COVID-19 confirmed cases and deaths, by WHO Region, as of 3 January 2021**

^{*}Percent change in the number of newly confirmed cases/deaths in past seven days, compared to seven days prior. Regional percentages rounded to the nearest whole number, global totals may not equal 100%.

**For all figures included in this report please see data, table and figure notes

Source: World Health Organization COVID-19 Weekly Epidemiological Update as of 3 January 2020

III. Current National Epidemiology of COVID-19

In the Philippines, a decline in the weekly reported COVID-19 cases since August 2020. Concurrent to this, the National Government has opened up the economic sector and has implemented a more lenient community quarantine measures nationwide, while being vigilant to any possible outbreaks in various regions and provinces.

Figure 2. Confirmed COVID-19 cases by date of onset of illness, Philippines, as of January 9, 2021.



As of December 29, 2020, a total of 471,526 COVID-19 cases reported in the Philippines, of which 429,016 have recovered and 9,162 deaths, with a case fatality rate (CFR) of 1.9%. As shown below, the number of cases reported daily from the months of October and November are fewer compared to those reported in the months of July and August 2020.

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The majority of cases reported in the National Capital Region (NCR) account for 44.5% of the total cases (209,663), followed by CALABARZON Region (IVA) with 18.3% of the total cases (86,473), and Central Luzon (III) with 6.7% (31,479 cases). The median age of confirmed cases is 35 years old and the majority (54%) are males.

Figure 3. Confirmed COVID-19 Cases by sex and age group, Philippines, as of December 29, 2020.



The highest reported CFR was in Central Visayas (Region VII) with 5.2% of the total number of cases (1,387), followed by Caraga (XIII) with 3.7% and Zamboanga Peninsula (IX) with 3.0%. The median age of confirmed deaths is 64 years old and the majority (60%) are males.

Figure 4. Confirmed COVID-19 deaths by sec and age group, Philippines as of December 29, 2020.



IV. Principles

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The development of the Department of Health's Strategic Plan for COVDI-19 Vaccination was guided by the following principles:

A. National Ownership

The Philippine Government recognizes the huge national endeavor that the country needs to undertake to ensure equal access to vaccines and to implement quality vaccination services; the complexity of the vaccine deployment and vaccination activities; and the necessity to protect national interests while ensuring that rigorous scientific review has been undertaken prior to deployment and considering population safety. Thus, the national government shall be the primary responsible entity to ensure good governance in the implementation of vaccination services and provision of quality and effective immunization services for all.

B. Shared Responsibility

The COVID-19 vaccine deployment and vaccination program is an endeavor necessitating the participation of all members of the society where each member has a vital responsibility to uphold and role to play. The Filipino Citizen, the communities, the national government and the private sector have intertwined responsibilities in which when rightfully upholded can positively dictate the success of the COVID-19 vaccination efforts of the country.

A whole-of-society approach shall be applied where all members of the society and government are encouraged to participate and take action to achieve collective goals and objectives. In this regard, while the government leads in the deployment of vaccines and implementation of a vaccination program, the private sector and other organizations are encouraged to collaborate and work closely with the government to ensure a unified and coordinated vaccination campaign is conducted.

C. Integration

With the COVID-19 pandemic, vaccination against COVID-19 is provided to Filipino citizens as an intervention and as an integral part of the national government's pandemic response. However, the COVID-19 vaccination services shall be fully integrated into the country's health systems and eventually to the regular immunization services.

D. Innovation

There has been a tremendous abundance of innovations and breakthroughs in the development of COVID-19 vaccines. Developers and regulatory experts have collaborated early on to help speed up vaccine development by ensuring that standards of safety and efficacy are integrated in the process of development. In this regard, the Philippine government recognizes the vitality of adapting newer knowledge and scientific evidence gathered through research and innovation on COVID-19 vaccine and immunization to ensure effective implementation of COVID-19 immunization services.

V. Vision, Mission, Goals and Objectives

The following shall be the vision, mission, goals, and objectives of the Department of Health's Strategic Plan for COVID-19 Vaccination:

A. Vision

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Safe, equitable and cost-effective immunization for all Filipinos by 2023

B. Mission

To establish a sustainable and fully integrated vaccine deployment and immunization program against COVID-19 in collaboration with other government agencies

C. Goal

Protect the public and reduce morbidity and mortality rates due to COVID-19

D. Objectives

- 1. To provide equitable access to COVID-19 immunization services to priority groups or at most, 50 to 70 million Filipinos if with enough global supply by 2021.
- 2. To increase demand for vaccination services through capacity and confidence building measures;
- 3. To ensure safety in the immunization program and provide support to patients with adverse reactions; and
- 4. To institute governance, regulatory, financing and performance accountability measures for COVID-19 immunization

VI. Strategies and Performance Indicators for COVID-19 Vaccine Deployment and Immunization

Strategies	Strategic Objectives		Activities/Outputs	Performance Indicators
Access to COVID-19 immunization services	Establish quality COVID-19 immunization services	•	Developed a National Deployment and Vaccination Plan (NDVP), and cascaded to regions and LGUs Capacitated and trained implementers Ensured readiness of all implementing units for	80% coverage of identified eligible population (per campaign round) <10% refusals <10% deferrals 70M of eligible

		 vaccination Planned immunization activities undertaken Implementation of vaccination activities monitored and evaluated Achieved the desired target coverage 	Filipinos by 2021 100% of eligible Filipinos by end of 2023
Demand generation for COVID-19 immunization	Generate clients' demand and multi-sectoral support for COVID-19 immunization services	 Developed a Risk/Crisis Communications and Community Engagement Plan and cascaded to the regions and LGUs Increased knowledge, attitude and practice of the intended beneficiaries/audience LGUs, national/regional/local government agencies, (DepEd, DSWD, DILG, DND), development partners and private sector provided support for COVID-19 NDVP implementation 	100% of eligible population have informed consent
Safety, supervision, and monitoring and evaluation	Establish COVID-19 vaccine safety surveillance and response systems, and a monitoring and evaluation framework	 Functional COVID-19 National/Regional Adverse Event Following Immunization (AEFI) Committees All Regional Epidemiology and Surveillance Units (RESUs) achieved "functional status" on AEFI surveillance and response readiness Health facilities, including vaccination centers having sufficient competent staff trained on basic AEFI surveillance and response functions Vigiflow, as the national 	100% of RESUs are reporting on time <5% of vaccinees have adverse reactions and all managed accordingly

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		 AEFI surveillance information system for COVID-19 vaccine, is institutionalized in the National AEFI surveillance system. COVID-19 Vaccine Deployment and Vaccination Program Monitoring and Evaluation Framework and Guide developed and disseminated Program monitoring undertaken at various levels of operations Established monitoring and evaluation framework 	
Instituting governance structures	Operationalize governance, regulatory, financing logistics, and data management systems	 National, regional and local command and control structures are organized Financing for COVID-19 Vaccine Deployment and Vaccination Program sustained COVID-19 Immunization Logistics Management established Storage, utilization and disposal of vaccines in facilities adhered to DOH protocols Operational registry and data management system 	100% of regions has an established Vaccination Operations Center headed by the CHDs

VII. Targets and Timelines

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Strategies	Baseline	Expected Output	Activity/ Response	Im	Timeline plement:	OPR	
Strategies	Dusenne	Expected Sulput	nput Activity/ Response		2022	2023	
Access to COVID-19 immuniza-	0 vaccinees	70 Million eligible population vaccinated	Conduct of vaccination campaigns				DPCB
tion		112 Million eligible population					DPCB

services		vaccinated			
		114 Million eligible population vaccinated			DPCB
Demand generation for COVID-19 immuniza- tion	0 individuals with informed consent	100% of all eligible population with informed consent	Conduct of information and social mobilization activities		HPB
Safety, supervision and monitoring and evaluation	0 of RESU	100% of RESU are reporting on time	Conduct of AEFI/AESI surveillance and post-marketing surveillance of vaccines for a duration of a year		EB/FDA
Instituting governance structures	0 VOCs	All Regions with functional VOCs	Provision of governance, regulatory, financing logistics, and data management systems		DPCB, EB, HEMB, HPB, PHST

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Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

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ADMINISTRATIVE ORDER No. -2020-0 0005

SUBJECT:

National Strategic Policy Framework for COVID-19 Vaccine Deployment and Immunization

I. RATIONALE

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 - Coronavirus 2 (SARS-CoV2), as a Public Health Emergency of International Concern (PHEIC).

The Philippines since January 2020, has been responding to the COVID-19 pandemic and has implemented numerous interventions in response to the pandemic with varying levels of success. These interventions are anchored on the National Action Plan Against COVID-19 utilizing the Prevent-Detect-Isolate/Quarantine-Treat-Recovery/Reintegration (PDITR) strategy. Several months in its implementation, the Philippines is strategically exploring other interventions that will allow the country to hasten socio-economic recovery and transition to near normal. With this, countries including the Philippines, are racing to find a safe and effective vaccine.

Further, the Philippine government has provided a legislative guidance on the procurement of COVID-19 vaccines as mandated under Republic Act No. 11494 otherwise known as the "Bayanihan to Recover as One Act", Section 12,

Procurement of COVID-19 Drugs and Vaccine. - Notwithstanding any law to the contrary, the requirement of Phase IV trials for COVID-19 medication and vaccine stipulated in the Universal Health Care Law is hereby waived to expedite the procurement of said medication and vaccine; *Provided*, That these are recommended and approved by the WHO and/or other internationally recognized health agencies: *Provided*, *further*, That the minimum standards for the distribution of the said medication and vaccine shall be determined by the Food and Drug Administration (FDA) and Health Technology Assessment Council (HTAC); *Provided furthermore*, That nothing in this Act shall prohibit private entities from conducted research, developing, manufacturing, importing, distributing or selling COVID-19 vaccine sourced from registered pharmaceutical companies, subject to the provisions of this Act and existing laws, rules and regulations; *Provided, finally*, That this section shall remain in effect three (3) months after December 18, 2020.

Vaccines have saved millions of lives in the past and have been used to halt previous pandemics (e.g. H1N1 in 2009). With the COVID-19 pandemic, the national government is exploring all means to access COVID-19 vaccines and prepare the country for the implementation of a COVID-19 vaccine deployment and vaccination program once a safe and effective vaccine is determined.

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In light of the absence of definitive treatment for COVID-19, it is expected that the morbidity and mortality associated with COVID-19 will continue to increase, hence the Philippine Government shall utilize COVID-19 vaccines to complement its existing measures to address the COVID-19 pandemic.

II. OBJECTIVES

General Objective:

This Administrative Order shall provide strategic policy guidance and direction on the selection, access, deployment of the COVID-19 vaccine and the COVID-19 immunization program.

Specific Objectives:

- A. To provide guidance on vaccine delivery strategies, vaccine acceptance, human resource management and training, supply chain, and management of health care waste, safety and surveillance, and immunization monitoring systems
- B. To guide the implementation and provision of a free, safe, and effective, high-quality vaccine/s against SARS-CoV2, prioritizing the most-at-risk and most-vulnerable populations
- C. To ensure implementation of risk communication, health education and community engagement activities utilizing diverse platforms, and the conduct of strategies and interventions addressing vaccine hesitancy

III. SCOPE AND COVERAGE

This Administrative Order shall provide guidance and apply to the Inter-agency Task Force in the Management of Emerging Diseases (IATF) and their regional counterparts, National Task Force Against COVID-19 (NTF) and their regional and local counterparts, National Government Agencies and their regional and local counterparts, Centers for Health Development, Local Government Units, academe, implementing sectors and agencies, immunization program managers, service providers, immunization partners and the private sector, among others.

IV. DEFINITION OF TERMS

- A. Active safety surveillance is an active system for the detection of adverse events. This is achieved by active follow-up after vaccination. Events can be detected by asking patients directly or by screening patient records. It is best done prospectively.
- B. Adverse Events Following Immunization (AEFI) any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

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- C. Adverse Events of Special Interest (AESI) a pre-identified and predetermined medicallysignificant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further specific studies.
- D. Causality Assessment a systematic review of data about the AEFI case(s) to determine the likelihood of a causal association between the vent and the vaccine(s) received.
- E. Cold Chain is the system used for keeping and distributing vaccines in good condition. The cold chain consists of a series of storage and transport links, all designed to keep vaccines within an acceptable temperature range until they reach the user.
- F. Immunity is the ability of the human body to tolerate the presence of material indigenous to the "body" (self) and to eliminate "foreign" (non-self) material.
- G. **Immunization** the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease
- H. Immunization Safety the public health practices and policies dealing with the various aspects of the correct administration of vaccines, focusing on minimizing the risk of transmission of disease with vaccination and maximizing the effectiveness of the vaccine. The term encompasses the spectrum of events from proper manufacture to correct administration.
- I. **Injection safety** is the safe handling of all injection equipment, routine monitoring of the availability and use of safe injection equipment, and correct disposal of contaminated infection equipment.
- J. **Profiling -** the act or process of extrapolating information from a person based on known past and present medical history, family history and social and employment history.
- K. Social Preparation is a series of activities designed to prepare communities and identified population groups for a particular national program and encourage them to actively participate and prepare them for their societal, community and personal responsibilities in the immunization program.
- L. Vaccination is the administration of a vaccine to help the immune system develop protection from a disease.

V. GUIDING PRINCIPLES

- A. The COVID-19 vaccines shall be a main prevention commodity, and shall be made available to all members of the society as public good, without prejudice to practice of public health measures.
- B. The COVID-19 vaccine deployment and immunization program shall be anchored to the following principles:

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- 1. **National Ownership:** the national government shall ensure primary ownership and responsibility for establishing good governance and provision of quality and effective immunization services for all.
- 2. Shared Responsibility and Partnership: COVID-19 immunization is an individual, community, societal and government responsibility that cuts across borders and sectors.
- 3. **Integration:** the COVID-19 immunization services shall be fully integrated into the country's health systems and eventually to the regular immunization services.
- 4. **Innovation:** adaption and incorporation of the scientific evidence gathered through research and innovation on COVID-19 vaccine and immunization is vital to ensure effective implementation of COVID-19 immunization services.
- C. In addition, the allocation of COVID-19 vaccines and prioritization of COVID-19 immunization shall be anchored to the following principles:
 - 1. **Human well-being:** where health, social and economic security, human rights and civil liberties of all citizens and individuals are protected and promoted.
 - 2. Equal respect: where all human beings are treated equally and their interests are considered with equal moral consideration.
 - 3. National equity: where equity in vaccine access is assured nationally and those with greater burden of COVID-19 pandemic.
 - 4. **Reciprocity:** where individuals and groups who have greater burden in the COVID-19 pandemic response and have higher significant risks brought by their responsibilities and roles in the said response shall be given greater priority.
 - 5. Legitimacy: where decisions are made through transparent processes based on shared values and scientific evidence.

VI. GENERAL GUIDELINES

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- A. Recognizing that the COVID-19 vaccine deployment and vaccination program is a huge national endeavor, an encompassing and comprehensive whole-of-society and whole-of-government approach shall be executed where all members of the government and society, in solidarity, are encouraged to participate and take action to achieve collective goals and objectives.
- B. This policy shall provide guidance on the development of the National COVID-19 Vaccine Deployment and Vaccination Plan (NDVP), and its implementation plans, including macroplans and microplans in all organizational levels. Moreover, due to the fast-evolving developments on the COVID-19 vaccines, the NDVP, and its implementation plans, shall be flexible and updated regularly based on specific vaccines procured and available, its characteristics and supply, and the COVID-19 epidemiology of each particular geographical area.
- C. This policy shall adhere to evidence-based recommendations and policy guidance on COVID-19 vaccines by the National Immunization Technical Advisory Group (NITAG) for COVID-19 Vaccines.

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- D. All immunization interventions and strategies shall be anchored in the principles adhered to by the National Immunization Program (NIP).
- E. A strategic approach in optimizing the deployment of COVID-19 vaccines shall be utilized, without compromising the implementation of regular immunization services under the NIP.
- F. The vaccination of COVID-19 vaccines shall be voluntary for all Filipino citizens. Moreover, all individuals consenting to be vaccinated with COVID-19 vaccine shall be provided with sufficient information on the COVID-19 vaccine administered, and its possible adverse reactions.

VI. SPECIFIC GUIDELINES

A. Planning and Coordination

- In order to protect national interests and to effectively launch the COVID-19 vaccine deployment after rigorous scientific review and considering population safety, a multisectoral organizational structure capable of making transparent and robust decision-making, and organizational processes shall be set in place. The COVID-19 Vaccine organization structure shall be established to institutionalize a unified command, control, coordination, and communication mechanism and ensure the implementation of COVID-19 vaccine access, deployment and immunization of eligible populations.
- 2. In reference to the WHO's Vaccine Introduction Readiness Assessment Tool (VIRAT) where organizational critical activities and work streams were recommended such as the creation of a National Coordinating Committee and its Technical Working Groups and Sub-Technical Working Groups, and establishment and institutionalization of the National Immunization Technical Advisory Group (NITAG) and National Adverse Events Following Immunization Committee (NAEFIC), a multi-sectoral national organizational structure for COVID-19 vaccine shall be established, institutionalized and integrated with the existing COVID-19 response organizational structures and coordination mechanisms. Thus,
 - a. The Inter-agency Task Force for the Management of Emerging Infectious Diseases shall serve as the National Coordinating Committee.
 - b. The COVID-19 Vaccine Cluster under the National Task Force Against COVID-19 shall serve as the National Technical Working Group.
 - c. The following workstreams shall be subsumed under the COVID-19 Vaccine Cluster:
 - i. Scientific evaluation and selection
 - ii. Diplomatic engagement and negotiation
 - iii. Procurement and finance
 - iv. Cold chain and logistics
 - v. Immunization program
 - vi. Demand generation and communications.
- 3. The NITAG for COVID-19 shall serve as an independent advisory body who shall provide recommendations to the COVID-19 Vaccine Cluster and its Task Groups and Sub-Task Groups. They shall ensure transparency, credibility, and technical soundness to the decision-

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making process and contribute to building public confidence in the COVID-19 vaccine deployment and vaccination program.

- a. To ensure that appropriate expertise is utilized in the implementation of the COVDI-19 vaccine deployment and vaccination program, a dedicated NITAG for COVID-19 vaccines shall be established.
- b. The NITAG for COVID-19 Vaccines shall serve as a technical advisory role in the development of vaccine recommendations. It shall have no implementing, coordinating, nor regulatory function.
- c. There shall be two general types of membership for NITAG for COVID-19 Vaccines: Core Members and Non-core Members, where both participate in the plenary meetings, however, only the Core Members have the decision-making/voting capability. Participation of Non-core Members, however, is crucial in providing necessary information to a decision.
 - i. Core Members (at least seven (7) members):
 - 1. Do not represent a particular group or a stakeholder. He/She does not hold any position in DOH nor has any direct indirect supervisory relationship to the country's NIP.
 - 2. Shall have the following academic/specialization qualification/s: clinical medicine (internal medicine or geriatrics), epidemiology, infectious diseases and/or microbiology, public health, immunology, vaccinology, health economics, social science, and health systems and development.
 - 3. Shall serve as members as long as COVID-19 vaccines are part of the COVID-19 pandemic response. Once the COVID-19 vaccines are integrated into the regular services of the NIP, the NITAG for COVID-19 Vaccines shall then therefore be dissolved.
 - ii. Non-Core Members (no predetermined number):
 - 1. May represent a specific stakeholder/agency that can be consulted. They are invited on a per-need basis during the NITAG's plenary meetings. They shall provide technical expertise and provide background information or needed evidence and may participate in the discussion.
 - 2. They are either an Ex-officio or Liaison Member:
 - a. The Ex-officio Members are officials from the DOH which hold key positions on the Offices related to the National Immunization Program.
 - b. The Liaison Members are members of various medical societies and international organizations.
 - iii. For membership selection, the call for nomination for NITAG for COVID-19 Vaccines Core Members shall be called by the Public Health Services Team. Experts shall be invited from academic institutions, medical specialty organizations, research institutes, including independent scholars. Each applicant shall submit a comprehensive curriculum vitae and letter expressing their interest to become a NITAG for COVID-19 Vaccines Core Member.

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- iv. The selection team composed of members determined by the Public Health Services Team shall select the NITAG for COVID-19 Vaccines members through a vetting process considering their academic merits, past working experiences, technical expertise and strong commitment to support the immunization program. After vetting, the names shall be forwarded to the DOH Executive Committee for approval and endorsement to the Secretary of Health.
- v. The Secretary of Health shall then issue a Department Personnel Order for the final appointment of the NITAG for COVID-19 Vaccines Chair, Co-Chair and Core Members.
- 4. The NAEFIC shall serve as an independent body, supported by the NAEFIC secretariat, who shall review serious and cluster of Adverse Events Following Immunization (AEFI) cases and ensure evidence-based causality assessment of all AEFIs. Expertise of the NAEFIC shall include vaccinology, infectious disease, public health. allergology, immunology, pathology, microbiology, parasitology, geriatrics, and other fields deemed necessary for causality assessment of AEFI of COVID-19 vaccines.
- 5. A coordination mechanism shall be set in place to ensure sufficient communication and information are shared between Task Group, Sub-Task Groups, independent bodies such as the NITAG, NAEFIC and Health Technology Assessment Council (HTAC), and the Vaccine Expert Panel.
- 6. The Vaccine Expert Panel shall provide regular updates to the COVID-19 Vaccine Cluster Head, HTAC, NITAG, and NAEFIC.
- 7. An Incident Command System supported by an emergency operations center shall be established and operationalized at all levels, as follows:
 - a. National Emergency Operations Center
 - b. Sub-National Emergency Operations Centers (National Capital Region and Luzon EOC, and the Visayas and Mindanao EOC)
 - c. Regional Emergency Operations Centers
 - d. Local Emergency Operations Centers.

B. Financing and Funding Mechanisms

- 1. As part of the national COVID-19 response, the budget and funding for the COVID-19 vaccine shall be integrated and reflected in the national budgets of implementing agencies, as deemed necessary. However, it is essential that the budget for other essential health services, including the routine immunization budget, be not affected by the cost and funding requirements of the COVID-19 vaccine and its ancillary logistics.
- 2. In addition, with the unparalleled need and the competing demand in the global market, other funding methods and mechanisms such as multilateral development bank arrangements, local bank-facilitated loans, advance market commitments, among others, shall be explored.
- 3. The budget proposals for the implementation of the national COVID-19 vaccine deployment and immunization shall include budgetary requirements at the national, regional, and local levels.

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- 4. All participating agencies shall develop a three year budgeted COVID-19 vaccine roadmap, consistent with the NDVP. It shall be annually revised in alignment with standardized budgeting processes and based on the latest updates on COVID-19, COVID-19 vaccines, epidemiological settings and recommended strategies.
- 5. Each strategy and activity identified in the NDVP shall be costed and provided with adequate funding.

C. Identification of Eligible Population

- 1. The WHO Strategic Advisory Group of Experts (SAGE) Values Framework for the Allocation and Prioritization of COVID 19 Vaccination principles and the policies and recommendations of the NITAG of COVID-19 Vaccines shall guide the identification and finalization of the eligible population, taking into consideration the national context, the epidemiologic settings and the COVID-19 vaccine characteristics and supply.
- 2. The identification of the eligible population shall be primarily anchored on the principles of: human well-being, global equity, reciprocity, equal respect, national equity and legitimacy, taking in mind that 60-70% of the population are needed to have immunity to break the chain of transmission.
- 3. The Philippine government shall ensure equitable access to COVID-19 vaccines and that groups with high risk of exposure of COVID-19, and groups with high vulnerability risk such as those with underlying societal, geographic or biomedical factors are provided with COVID-19 vaccination services.
- 4. The identification of the eligible population shall be based on the following goals for vaccination:
 - a. Primary: direct reduction of morbidity and mortality and maintenance of most critical essential services.
 - b. Secondary: substantially control transmission and minimize disruption of social, economic and security functions.
 - c. Tertiary: resumption to near normal.
- 5. Considering all goals, principles and values stated above, a decision matrix shall be developed to guide decision-making.
- 6. In the minimum, the Philippine Government shall vaccinate the most-at-risk and mostvulnerable populations such as: a) frontline health workers, b) senior citizens and c) indigent population, and d) uniformed personnel. Persons with comorbidities and vulnerable population groups may be prioritized as soon as developments and information on the COVID-19 vaccine determines their inclusion.
- 7. The final determination of the eligible population to be vaccinated shall take into consideration the characteristics of the COVID-19 vaccine to be administered, including exclusion and inclusion criteria shared by the vaccine manufacturers.
- 8. To ensure accurate national estimates of identified eligible population, agencies and sectors involved are enjoined to conduct profiling and provide accurate information based on standardized tools and templates provided by the DOH.

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D. Vaccination Delivery Strategies

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- 1. The vaccine delivery strategies shall be tailored based on the vaccine characteristics, riskbenefit assessment for different population groups, amount and pace of vaccine supply, and in line with the NIP systems and context.
- 2. A framework-based strategy shall be developed for each vaccine candidate to ensure readiness of the system whatever vaccine shall be procured. The details on the vaccine schedule and administration shall be defined once a COVID-19 vaccine product is authorized for use by the Food and Drug Administration (FDA), and HTAC recommendations.
- 3. Other means of delivering the vaccines shall be adopted, including non-traditional, innovation and perhaps novel immunization strategies in reaching priority eligible populations.
- 4. The system shall ensure the inclusion of Infection Prevention and Control (IPC) measures and implementation of Minimum Health Standards during the provision of vaccination services, including the use of personal protective equipment (PPE) by health workers, vaccination teams and implementers.

E. Cold Chain, Supply and HealthCare Waste Management

- 1. A cold chain and logistics plan with diverse vaccine deployment strategies shall be developed to guarantee efficient deployment of COVID-19 vaccines to eligible populations groups. The plan shall be linked to the overall National Immunization Program cold chain and management plan, and shall utilize the evidence gathered from readiness assessments to contextualize implementation of strategies and interventions.
- 2. The plan shall include potential variations in storage temperature requirements of different COVID-19 vaccine products, and information on the available cold chain capacity, including surge capacity of DOH storage facilities and warehouses, and those from other government agencies and private sectors. Specifically, it shall include consideration of COVID-19 vaccine requiring ultra-cold storage (UCC) temperature (e.g. -70 °C), and identification of practical interventions, such as commissioning logistic service providers to deploy the UCC equipment and facilitate vaccine transportation and reverse logistics.
- 3. The plan shall ensure the inclusion of security and safety measures and interventions, especially for vaccine storage facilities and transportation platforms, in order to ensure integrity of vaccines during transport, and the safety of all staff responsible for managing the supply and implementing the vaccination.
- 4. Due to high global demand, first batches of COVID-19 vaccine supply may be limited, have shorter shelf-life, and not have vaccine vial monitors. A strengthened supply chain information system on stock management and distribution shall be implemented, including monitoring and reporting of vaccine utilization and wastage rates, and use of online or digital platforms, to guide appropriate allocation of subsequent supply.
- 5. There shall be a robust mechanism to track COVID-19 vaccine distribution from the national level down to the service points to avoid risk of diversion and falsification. This mechanism shall be explored extensively in the NVDP.

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6. A healthcare waste management plan shall be developed and shall cover reverse logistics, to guarantee the health and safety of vaccinators and the community.

F. Human Resource Management and Training

- 1. A human resource management and training plan shall be developed to ensure sufficient number of human resources (including Barangay Health Workers) are available for the implementation of the COVID-19 vaccine deployment and immunization, and to determine capacity building requirements of human resources. The plan shall consider various scenarios and frameworks as several unknowns still persist, and shall include identification of human resource needs, training modalities, and details on supportive supervision.
- 2. Utilization of health human resource and training for the COVID-19 vaccine deployment and vaccination program shall not be limited to the DOH and LGU health human resource. The Philippine Government shall ensure that health human resources of government agencies and the private sector shall be effectively utilized and extensively trained. There shall be clear coordination and mobilization of human resources from other government agencies, such as Armed Forces of the Philippines (AFP) and Philippine National Police (PNP), Departments of Interior and Local Government, Social Welfare and Development, Education, health personnel and support staff among others, and the private sector.
- 3. The opportunity to develop innovative systems, such as online or digital tools, for modules, training and supportive supervision shall be set in place.
- 4. The WHO and other partner agencies shall be tapped to support the capacity building activities and initiatives.
- 5. A plan on intensified supportive supervisory or monitoring visits for the duration of vaccine introduction is recommended.

G. Vaccine Acceptance and Uptake

- 1. As this is a novel vaccine, risk communication and community engagement plan including comprehensive assessment and monitoring mechanisms such as perception surveys and qualitative and quantitative assessments are significant to ensure strategies on acceptance and confidence to the vaccination program by mustering a whole-of-society approach.
- 2. The following is needed to be adopted as an integrated demand approach:
 - a. Listening to and understanding eligible populations, to generate behavioural and social data on the drivers of uptake and to design targeted strategies to respond;
 - b. Building a supportive and transparent information environment, and addresses misinformation through social listening and assessments that inform digital engagement initiatives;
 - c. Building trust and acceptance of the vaccines through engagement of communities by social mobilizers, partners and civil society organizations, particularly for vulnerable target populations;
 - d. Providing health workers with the requisite knowledge of COVID-19 vaccines as first adopters, trusted influencers and vaccinators, giving them the skills to communicate effectively and persuasively with eligible populations and communities; and

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- e. Utilizing Barangay Health Workers and Barangay Health Emergency Response Teams (BHERTs) as social mobilizers to ensure that communities are engaged, informed, appraised and thus, possibly translating their interventions and actions to social preparation and community buy-in and action.
- f. Preparing to respond to any reports of AEFI/AESI and ensuring that plans in place to mitigate any resulting crises of confidence.
- 3. Education of policymakers, health professionals, and implementers, both public and private, on COVDI-19 vaccine and its development shall be prioritized to ensure vaccine acceptance and improve vaccine confidence. The academe and the medical societies are encouraged to support these initiatives.

H. Vaccine and Immunization Safety Monitoring, AEFI/AESI and Postmarketing Surveillance and Management, and Pharmacovigilance

- 1. There shall be a comprehensive plan on vaccine safety monitoring and management of AEFI and AESI to be led by FDA and its regional counterparts and supported by the Epidemiology Bureau (EB), Regional and Local Epidemiology and Surveillance Units.
- 2. Surveillance and monitoring of AEFIs / AESIs shall be up until one year post-vaccination.
- 3. All health facilities shall perform AEFI/AESI and post-marketing surveillance activities (active and passive) based on the Phillippine Integrated Disease Surveillance and Response (PIDSR) flow and Event-based Surveillance and Response (ESR) system.
- 4. The NAEFIC/RAEFICs should be established with explicit terms of reference to serve as an independent body for AEFI and AESI causality assessment.
- 5. Responding to AEFIs and AESIs including case management and other programmatic support activities shall utilize the healthcare service delivery network of the Universal Health Care (UHC) where appropriate, while those without shall use the existing health systems referral network.
- 6. The importance of injection and immunization safety based on NIP recommendations and current policies shall form an integral part of the vaccination program.
- The Department of Health, upon recommendation from the NITAG and NAEFIC, shall have the authority to suspend the vaccination program following iminent efficacy and safety concerns of the COVID-19 vaccines which may be subjected to a product recall as ordered by the FDA.
- 8. The FDA shall continuously monitor the quality, safety and efficacy of the vaccines through its existing rules and regulations.

I. Immunization Registration, Monitoring and Data Management Systems

- 1. A robust and comprehensive data management system, preferably a digital system, shall be established and utilized to monitor progress of vaccination activity, including monitoring of vaccine safety and effectiveness. The data management system shall be use to:
 - a. Measure real-time and equitable uptake and coverage over time by geography and eligible population groups.

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- b. Monitor implementation of national policies to identify eligible populations and various settings.
- c. Retrieve personal vaccination records or certification as deemed required.
- d. Monitor safety, disease surveillance and vaccine effectiveness.
- 2. A nationwide profiling of eligible population groups shall be conducted prior to the implementation of the vaccination activity utilizing an electronic immunization registry. This shall be utilized to determine the eligibility of the priority groups receiving the vaccine. In the same way, a nationwide registry of vaccination team members, composite team members, supervisors and planning officers and individuals shall be conducted prior to the implementation of vaccination activity. The Philippine Government may utilize existing registries of government agencies.

VII. ROLES AND RESPONSIBILITIES:

A. COVID-19 Vaccine Cluster

- 1. The roles and responsibilities for the COVID-19 Vaccine Cluster are:
 - a. To provide institutionalize end-to-end vaccines delivery system for COVID-19 vaccines, including, but not limited to:
 - i. Possibility of local production, and participation therein of public or private entities.
 - ii. Demand forecasting, target setting, and budget allocation.
 - iii. Supply chain and logistics management, and participation of private sector or other government entities with competencies.
 - iv. Information systems that will enable real-time tracking of supplies and linelist of recipients of vaccines, the latter critical if vaccines will be in multiple doses.

B. Task Group on Vaccine Evaluation and Selection

- 1. The Task Group on Vaccine Evaluation and Selection shall be led by the Department of Science and Technology (DOST) with the following members: DOH (HRT), FDA, Research Institute for Tropical Medicine (RITM), and selected vaccine experts.
- 2. The roles and responsibilities of the Task Group on Vaccine Evaluation and Selection are:
 - a. To review results of clinical trials of all vaccines for COVID-19.
 - b. To coordinate with NITAG and HTAC while following the usual FDA vaccine regulation processes which shall be facilitated for the COVID-19 vaccine without compromising safety and efficacy.

C. Task Group on Diplomatic Engagement and Negotiation

1. The Task Group on Diplomatic Engagement and Negotiation shall be led by the Department of Foreign Affairs (DFA) with the following members: Department of Finance (DOF), DOH March 12 (BIHC), National Task Force for COVID-19, and Department of Science and Technology (DOST).

- 2. The roles and responsibilities of the Task Group on Diplomatic Engagement and Negotiation are:
 - a. To engage and negotiate with international parties and entities on COVID-19 vaccines on behalf of the Philippine government.
 - b. To provide feedback and updates to the other respective Technical Groups (TG) pertaining to vaccine development in the global market.
 - c. To coordinate and collaborate with TG Procurement and Finance in identifying viable global market vaccine manufacturers and entities.

D. Task Group on COVID-19 Vaccine Procurement and Financing

- 1. The Task Group on COVID-19 Vaccine Procurement and Financing shall be led by the DOF with the following members: DOH and Department of Budget and Management (DBM).
- 2. The roles and responsibilities of the Task Group on COVID-19 Vaccine Procurement and Financing are:
 - a. to facilitate procurement through various mechanisms allowed under existing laws, rules, and regulations through bilateral, multilateral and other financial modalities.
 - b. To facilitate advanced market commitment and/or framework contracting and/or procurement through international facilities such as the COVAX facility.
 - c. To activate price negotiation board subject to Health Technology Assessment's costeffective price.
 - d. To coordinate with legislators, as may be necessary on budget and co-payment ceilings.
 - e. To explore the possibility of local vaccine production.

E. Task Group on Cold Chain and Logistics Management

- The Task Group on Cold Chain and Logistics Management shall be led by the DOH (PSCMT) and the National Task Force for COVID-19's Technical Group on Resource Mobilization and Logistics with the following members: DBM, Department of Interior and Local Government (DILG)/Philippine National Police (PNP), Department of National Defense (DND)/Armed Forces of the Philippines (AFP) and Office for Civil Defense (OCD).
- 2. The roles and responsibilities of the Task Group on Cold Chain and Logistics Management are:
 - a. To develop a cold chain and logistics plan and provide a budgetary plan to the COVID-19 vaccine clusters for cold chain and logistics management.
 - b. To map the potential port(s) of entry, points of storage (stores), and fallback facilities in the country with their respective cold chain and transportation/distribution capacity for vaccines, and ancillary products and assess dry storage and cold chain capacity at all levels.
 - c. To facilitate acceptance and inventory of vaccines and logistics.

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- d. To facilitate and ensure storage, distribution and delivery of vaccines and logistics to target areas.
- e. To monitor cold chain practices and ensure that vaccines are handled and disposed correctly and properly, including reverse logistics.

F. Task Group on COVID-19 Immunization Program

- 1. The Task Group on COVID-19 Immunization Program shall be led by DOH (PHST) with the following members: Department of Justice (DOJ), FDA, DILG, Department of Social Welfare and Development (DSWD), Department of Education (DepEd), AFP, Department of Transportation (DOTr), Department of Information and Communication Technology (DICT).
- 2. The roles and responsibilities of the Task Group on COVID-19 Immunization Program are:
 - a. To develop a strategic roadmap for the COVID-19 deployment and vaccination program.
 - b. To initiate the drafting of the National COVID-19 Vaccine Deployment and Vaccination Plan.
 - c. To plan and craft policies, guidelines and standard operating procedures, and Monitoring and Evaluation (M&E) plans related to the COVID-19 vaccine deployment and program implementation (e.g. vaccine deployment and vaccination operational plan, human resource management and training plan, data management system, vaccine safety, surveillance and response plan, among others).
 - d. To estimate potential numbers of eligible populations that shall be prioritized for access to vaccines stratified by sectoral group and geographic location.
 - e. To identify potential COVID-19 vaccine delivery strategies.
 - f. To create a data information system for all vaccine recipients and implementation.
 - g. To provide capacity building and training to policymakers, health professionals and implementers.
 - h. To ensure the implementation of a quality vaccination campaign against COVID-19.
 - i. To develop or adapt existing and implement AEFI/AESI and post-marketing surveillance, and a monitoring and evaluation framework.
 - j. To craft guidelines, procedures and tools for planning and conducting vaccine pharmacovigilance activities.

G. Task Group on Demand Generation and Communications

- 1. The Task Group on Demand Generation and Communications shall be led by Presidential Communications Operations Office (PCOO) with the following members: DOH (HPCS), National Telecommunications Center (NTC) and Philippines Information Agency (PIA).
- 2. The roles and responsibilities of the Task Group on Demand Generation and Communications are:
 - a. To design a demand and risk communication plan.
 - b. To implement advocacy, social mobilization and community engagement activities.

c. To ensure social preparation of target population groups and geographical areas prior to vaccination.

H. National Immunization Technical Advisory Group (NITAG) on COVID-19 Vaccines

- 1. The roles and responsibilities of the NITAG on COVID-19 Vaccines are:
 - a. To review the latest position papers, studies, international guidelines and recommendations from internationally acknowledged resources (i.e., WHO SAGE) for possible adoption in the country policies and plans.
 - b. To conduct existing policy analysis, review of the program data and evidence in order to provide evidence-based technical advice and recommendations for the development of appropriate and sustainable immunization policies, guidelines, strategies and approaches related to immunization program
 - c. To advise the COVID-19 Vaccine Cluster and its TGs and STGs, in the formulation of policies, plans and strategies for research and development of existing and new vaccines and the vaccine delivery technology.

A. National Adverse Events Following Immunization Committee (NAEFIC)

- 1. The roles and responsibilities of the NAEFIC are:
 - a. To review all reported serious and cluster of AEFI cases presented for expert opinion and provide a final causality assessment of the AEFI cases as well as the cases that were not classified by the Regional AEFI Committee.
 - b. To ensure evidence-based causality assessment by recommending further investigation and data collection as needed.
 - c. To make final decisions on causality assessment of inconclusive investigations.
 - d. To ensure standard protocols for AEFI surveillance and investigation are correctly followed.
 - e. To engage with other national and international experts when requirements arise in establishing causality and vaccine quality issues.
 - f. To provide recommendations to the COVID-19 Vaccine Cluster, FDA, EB and National Cold Chain Manager on improving immunization service delivery, compliance with injection safety and effective vaccine management based on lessons from the AEFI cases.
 - g. To serve as a technical advisory group on vaccine and immunization safety-related issues of highest consideration such as immediate recall of vaccines from the market or temporary/permanent withdrawal of a vaccine from the immunization program.
 - h. To serve as resource person in other AEFI related meetings, conferences or capacity building activities as requested.

J. Health Technology Assessment Council (HTAC)

- 1. The roles and responsibilities of the HTAC are:
 - a. To oversee and coordinate the health technology assessment process of candidate (COVID-19 vaccine.

- b. To review and assess existing evidence of COVID-19 vaccines undergoing/undergone clinical trials.
- c. To coordinate and provide recommendations to the TG Vaccine Evaluation and Selection.

VIII. REPEALING CLAUSE

Provisions from previous and related issuances inconsistent or contrary with the provisions of this Administrative Order are hereby revised, modified, and rescinded accordingly. All other provisions of existing issuances which are not affected by this Administrative Order, still remain valid and in effect.

IX. EFFECTIVITY

This Administrative Order shall take effect immediately after publication in the Official Gazette or a newspaper of general circulation.

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







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Annex B. WHO - World Bank Vaccine Introduction Readiness Assessment Tool / Vaccine Readiness Assessment Framework

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		Sep- Oct 20	Nov - Dec 20	Jan 21	Feb 21	Mar 21
	A.1 Establish (or engage an existing committee) a National Coordinating Committee (NCC) for COVID-19 vaccine introduction with terms of reference, roles and responsibilities and regular meetings. The body and its leadership should be accountable and functional.					
	A.2 Establish (or engage an existing working group) a National Technical Working Group (NTWG) for COVID-19 vaccine introduction with terms of reference, roles and responsibilities and regular meetings.					
A. PLANNING & COORDINATION	A.3 Establish or engage existing NTWG subcommittees, if required, to cover the following workstreams: 1) service delivery 2) vaccine, cold chain & logistics, 3) demand generation & communication (4) prioritization, targeting and COVID-19 surveillance, (5) Monitoring and Evaluation: determination and proof of eligibility, proof of vaccination, monitoring of coverage among at-risk groups, and monitoring of vaccine impact (6) Safety, including injury prevention and AEFI detection and response.					
	A.4 Brief key ministries, NITAG, stakeholders and partners about COVID-19 vaccine introduction and their expected roles. Inform regularly & disseminate global and regional guidance (i.e. SAGE) with NITAGs & RITAGs and support NITAG working groups on COVID-19 vaccines.					
	A.5 Identify and plan for the national vaccine access/procurement approach (e.g. COVAX Facility, bilateral purchase agreement, procurement through UN agency, self-procurement), including costs of items, due diligence mechanisms; identify key needs, ensure regulatory compliance, and complete required paperwork. Ensure that the procurement plan and purchasing strategy includes vaccines, ancillary supplies, and Personal Protective Equipment. Budget has been approved; and monitoring arrangements are agreed and updated as needed.					

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	A.6 Plan and procure waste management supplies and equipment for appropriate implementation of waste management protocols.			
	A.7 Ensure that program objectives are defined and agreed to by key stakeholders at the central and sub- national levels, including representatives of target populations, community leaders, religious leaders, etc., and reflect the epidemiological situation and are adaptable to vaccine supply scenarios (protection of vulnerable populations, continuity of essential services, equity).			
	A.8 Develop the National Deployment and Vaccination Plan (NDVP) with input from relevant bodies (National COVID-19 Response Coordinating Committee, CNCC, CTWG, NITAG, National Immunization Programme, National Regulatory Authority, AEFI committee and other relevant groups such as private sector). The NDVP should be in line with WHO guidance and SAGE recommendations (plan can be developed by adapting the Pandemic Influenza NDVP, if existing).			
B. BUDGETING	B.1 Include COVID-19 vaccine program costs (vaccine, operating costs, HR and capital costs) in government budgetary and/or planning documents approved by the appropriate authority; in addition, include appropriation or allocation (from MOF/treasury) in the cash planning as an additional means to ensure that financing is indeed readily available.			
	B.2 Ensure management aspects of appropriations from the MOF/Treasury are in place.			
	C.1 Confirm the existence of any expedited regulatory pathway for approval of COVID-19 vaccines (i.e. emergency use authorization, exceptional approval/approval mechanism based on reliance/recognition, abbreviated procedure, fast track, etc.). Time lines and maximum number of days should be mentioned.			
C. REGULATORY	C.2 Ensure the national regulatory authority or other concerned authority has clarified the regulatory requirements, and documents needed for regulatory approvals of COVID-19 vaccines and related supplies.			
	C.3 Ensure that regulatory procedures are in place for import permit of COVID-19 vaccines and related supplies, and identify the requirements and documents needed to import COVID-19 vaccines and related supplies, including for taxes and tariffs.			

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	C.4 Confirm to WHO the existence of an expedited import approval from appropriate authorities. Time lines and maximum number of days should be mentioned. (expected timeline: maximum 5 working days).			
	C.5 Ensure COVID-19 vaccines can be released (lot release) in less than two days by reviewing the summary lot protocol only (testing is not required). Identify the requirements and documents needed for NRA lot release for COVID-19 vaccines. Time lines and maximum number of days for lot release/waiver process should be mentioned.			
	D.1 Monitor progress of NITAG working groups on COVID-19 vaccines and interim recommendations focusing on prioritization and risk groups.			
D. PRIORITIZATIO N, TARGETING & COVID19	D.2 Identify potential target populations that will be prioritized for access to vaccines, estimate their numbers, and identify their geographic location, i.e. prepare first to define, identify and estimate no. of HCWs.			
SURVEILLANCE	D.3 Coordinate with national COVID-19 disease surveillance group to ensure relevant epidemiological data will be collected to inform planning of subsequent rounds of COVAX vaccination, if applicable, including outbreak responses.			
	E.1 Update protocols for infection prevention and control measures including adequate personal protection equipment (PPE) to minimize exposure risk during immunization sessions.			
E. SERVICE DELIVERY	E.2 Identify potential COVID-19 vaccine delivery strategies and outreach strategies leveraging both existing vaccination platforms and non-vaccination delivery approaches to best reach identified target groups. Develop a master list and strategy of service providers, points of delivery, including fixed and outreach (e.g. health facilities, community centers, by appointments, house-to-house) and associated medical supplies that could effectively deliver COVID-19 vaccine to target populations, and ensure that the necessary			

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	E.3 Identify implementing agencies and establish			T	
	contractual agreements to prepare for vaccine				
	introduction (e.g., vaccine warehousing, transport, waste				
	management, cold chain capacity, etc.) where applicable.				
	For delivery through private facilities, develop and				
	approve Standard Operating Procedures including				
	service quality and performance and reporting standards				
	and mechanisms for complaints handling, cortification of				
	facilities financing performance monitoring and				
	integrity checks				
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	E.4 Ensure existence of protocols regarding consent to				
	vaccinations, process for agreeing to or refusing to be				
	vaccinated, and measures to protect those that refuse to				
	be vaccinated are in place.				
	F.1 Develop a training plan across all participating				
	that includes you groups of participants contact to at				}
	areas (includes key groups of participants, content topic				
	areas (including sare injection practices), key training				
	partners and training methods (in-person or virtual).			1	
	WHO will provide a template for guidance.				
	F.2 Adapt and translate training materials developed by				
	WHO and develop additional training materials as				
	outlined in the training plan.				
	F.3 Ensure availability of plans to safeguard the security			 	
F. TRAINING &	of staff (e.g. during an emergency or major campaign) as				
SUPERVISION	well as security at the central and/or regional storage			l	
	facilities and for in-transit of products. Ensure				
	regulations are in place regarding personnel who will be				}
	carrying out vaccinations including all				
	staff/nerconnel/consultants atc. engaged in such				
	activities (cover military personnel also if relevant) and				
	include requirements relating to chemical physical and				
	hiplogical substances not engaging in sevual evolutation				
	and abuse and sexual barassment, participation in				
	and asuse and sexual harassment, participation in				
	F.4 Conduct virtual and/or in person trainings as outlined				ĺ
	in the training plan.				
	G.1. Develop or adapt existing surveillance and				
	indicators (covorage, accontability, disease suppoillance)				
	indicators (coverage, acceptability, disease surveillance				
	etc. for COVID-19 vaccine including gathering				
G.	in vaccine delivery, and ensuring necessary human				
MONITORING &	in vaccine delivery, and ensuring necessary numan				Л
EVALUATION	resource capacity is in place. Determine whether				Я
	registration and reporting will be individual or aggregate, [1		11

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	and to what extent existing tools and systems can be	1	1	T	1	1
	used.			1		
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	G.2 Develop or adapt necessary paper-based and/or					
	electronic monitoring tools and appropriate institutional					
	arrangements, including vaccination cards/certificates,					
	facility-based nominal registers and/or tally sheets,					
	vaccination reports, medical records, immunization					
	records, systems entry and analytical tools to monitor					
	progress and coverage among different at-risk categories					
	and facilitate vaccine delivery and timely reporting.					
	G.3 Ensure measures are in place for data protection.		1	1		
	and appropriate data governance regulation is in place to	l	1			
	monitor legitimate, appropriate and proportionate use		1			
	and processing of data which may be routinely collected					
	and managed in health information systems					
		<u> </u>				
	G.4 Produce and distribute monitoring tools to eligible					
	vaccination providers, develop, test and roll-out any					
	changes to electronic systems, provide training for use of					
	these tools and processes to traditional and new					
	providers.					
	G.5 Ensure a mechanism with multiple intake points has					
	been designed and is in place, and is operational for					
	feedback and grievances in relation to the vaccine					
	program.					
	H.1 Establish/strengthen the national logistics working					
	group with appropriate terms of reference and standard					
	operating procedures to coordinate COVID-19 vaccines					
	and ancillary products deployment.					
	H.2 Map key roles and responsibilities needed for					
	vaccine and ancillary products deployment: collect and					
R. VALLINE,	confirm contact information for key personnel and					
COLD CHAIN,	facilities					
LOGISTICS &	100mmc3.					
TUPE	H.3 Create a distribution strategy, including mapping the					
IUKE	potential port(s) of entry, points of storage (stores) and					
	stocking, and fallback facilities in the country with their				l	
	respective cold chain storage (2-8C, -20C, -60/70C) and					
	transportation capacity for vaccines and ancillary					
	products, and ensure necessary human resource capacity					
	is in place.					
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	H.4 Map and develop plan to provide for infrastructure needs, including for energy (primary and back-up power			
	especially in cold chain), IT/communications (including internet connectivity) and water.			
	H.5 Assess dry storage and cold chain capacity and infrastructure needs at all levels with regards to the COVID-19 vaccines characteristics and fill the identified supply and logistics gaps.			
	H.6 Provide COVID-appropriate standard operating procedures (SOPs), protocols, or guidelines for collection and disposal of medical waste, both hazardous and non- hazardous, to the relevant stakeholders. Assure that properly-licensed waste management providers (especially for hazardous waste storage, transportation and disposal) are identified and can be operationalized.			
	H.7 Update and implement systems and protocols for tracking and monitoring the stock management and distribution of vaccines and key supplies through the Government's existing Vaccine Logistics Management and Information System (VLMIS), including operating procedures to reflect the characteristics of COVID-19 vaccines (i.e. vial size, VVM,).			
	H.8 Disseminate delivery and acceptance protocols, ensure monitoring arrangements are in place, and identify supervisory focal points at each facility. Establish security arrangements to ensure the integrity of COVID- 19 vaccines and ancillary products throughout the supply chain.			
	I.1 Ensure that guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities (i.e. AEFI reporting, investigation, causality assessment, risk communication and response), have been developed and disseminated to surveillance facilities/sites.			
I. SAFETY SURVEILLANCE	I.2 Ensure adequate and trained human resources are available to conduct surveillance of events attributable to vaccination.	-		
	I.3 Expedite appropriate representation, well defined ToRs and training the AEFI committee to review COVID- 19 Vaccine safety data (e.g., causality assessment of serious AEFI, clusters of AEFI, emerging safety concerns etc.).			

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•	I.4 Identify provisions that require manufacturers to implement risk management plans and collect and report COVID-19 vaccine safety data to the NRA.			
	I.5 Plan active surveillance of specific COVID-19 vaccine related adverse events. If this is not possible, develop provisions that allow reliance on active surveillance data, decisions, and information from other countries or regional or international bodies.			
	I.6 Define roles and responsibilities and establish a coordination mechanism between relevant stakeholders (NRA, EPI, MAH, MOH, WHO and others) for exchange of COVID-19 Vaccine safety information.			
	I.7 Identify and secure channels of data sharing mechanisms to share COVID-19 vaccine safety data and findings with relevant regional and international partners.			
	I.8 Establish compensation schemes in the event that there are unintended health consequences as result of vaccines, including no-fault liability funds, and ensure that associated policies are in place.			
J. DEMAND GENERATION & COMMUNICA- TION	J.1 Design and distribute a social mobilization and engagement strategy/demand plan and information awareness program (including advocacy, communications, social mobilization, risk and safety comms, community engagement, and training) to generate confidence, acceptance and demand for COVID-19 vaccines, including for engaging with national and local media, NGOs, social platforms, etc. and human resources for community outreach and risk communication management that also explains how complaints may be lodged and how they will be resolved, are available at all levels. Must include crisis communications preparedness planning.			
	J.2 Establish data collection systems, including 1) social media listening and rumor management, and 2) assessing behavioral and social data.			
	J.3 Develop key messages and materials for public communications and advocacy, in alignment with demand plan.			

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