



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

JAN 12 2021

**ADMINISTRATIVE ORDER**

No. <sup>2021</sup>~~2020~~-9 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

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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:

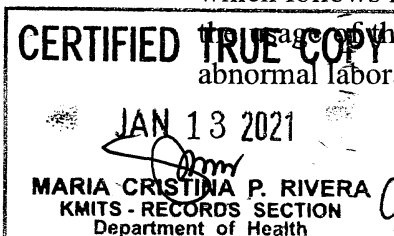
- A. To provide guidance on vaccine delivery strategies, vaccine acceptance, human resource management and training, supply chain, and management of health care waste, safety and surveillance, and immunization monitoring systems
- B. To guide the implementation and provision of a free, safe, and effective, 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.



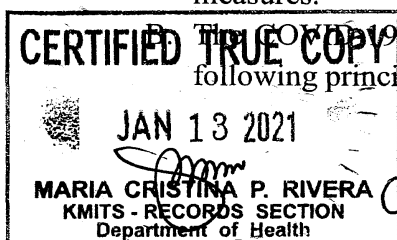
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- C. **Adverse Events of Special Interest (AESI)** - a pre-identified and predetermined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further 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 event 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:

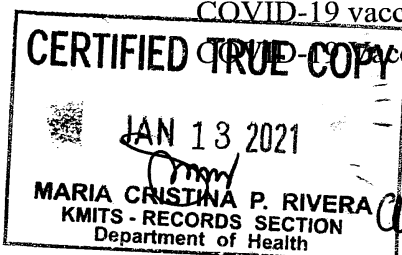


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1. **National Ownership:** the national government shall ensure primary ownership and responsibility for establishing good governance and provision of quality and effective immunization services for all.
  2. **Shared Responsibility and Partnership:** 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

- 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.



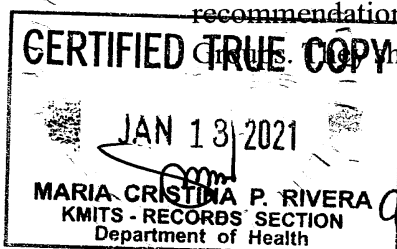
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- D. All immunization interventions and strategies shall be anchored in the principles adhered to by the National Immunization Program (NIP).
- E. A strategic approach in optimizing the deployment of COVID-19 vaccines shall be utilized, without compromising 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

1. In order to protect national interests and to effectively launch the COVID-19 vaccine deployment after rigorous scientific review and considering population safety, a multi-sectoral 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. It 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 COVID-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

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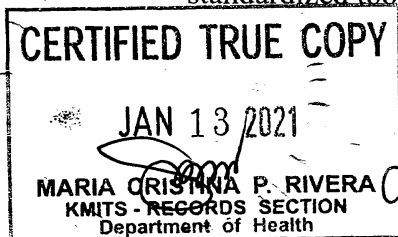
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4. All participating agencies shall develop a three - year budgeted COVID-19 vaccine roadmap, consistent with the NDVP. It shall be annually revised in alignment with standardized budgeting processes and based on the latest updates on COVID-19, COVID-19 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 most-vulnerable 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**

1. The vaccine delivery strategies shall be tailored based on the vaccine characteristics, risk-benefit 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

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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 COVID-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 (PIDS) 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.
7. The Department of Health, upon recommendation from the NITAG and NAEFIC, shall have the authority to suspend the vaccination program following imminent 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**

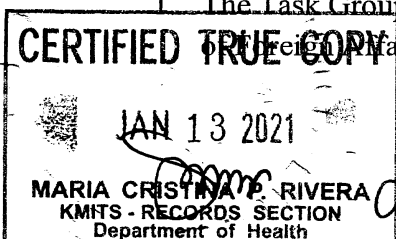
- 1. The roles and responsibilities for the COVID-19 Vaccine Cluster are:
  - a. To provide institutionalize end-to-end vaccines delivery system for COVID-19 vaccines, including, but not limited to:
    - i. Possibility of local production, and participation therein of public or private entities.
    - 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



(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 cost-effective 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**

1. 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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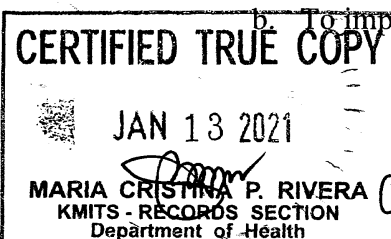
- d. To facilitate and ensure storage, distribution and delivery of vaccines and logistics to target areas.
- e. To monitor cold chain practices and ensure that vaccines are handled and disposed correctly and properly, including reverse logistics.

#### **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.

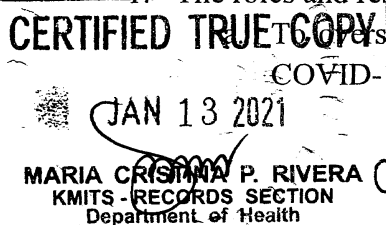
#### **A. National Adverse Events Following Immunization Committee (NAEFIC)**

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:

To oversee and coordinate the health technology assessment process of candidate COVID-19 vaccine.



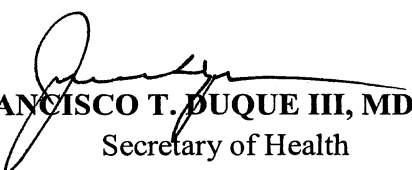
- b. To review and assess existing evidence of COVID-19 vaccines undergoing/undergone clinical trials.
- c. To coordinate and provide recommendations to the TG Vaccine Evaluation and Selection.

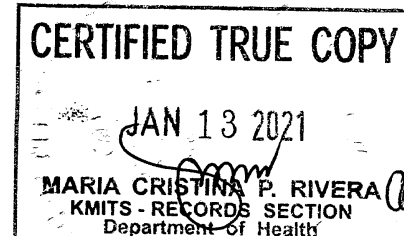
#### **VIII. REPEALING CLAUSE**

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**

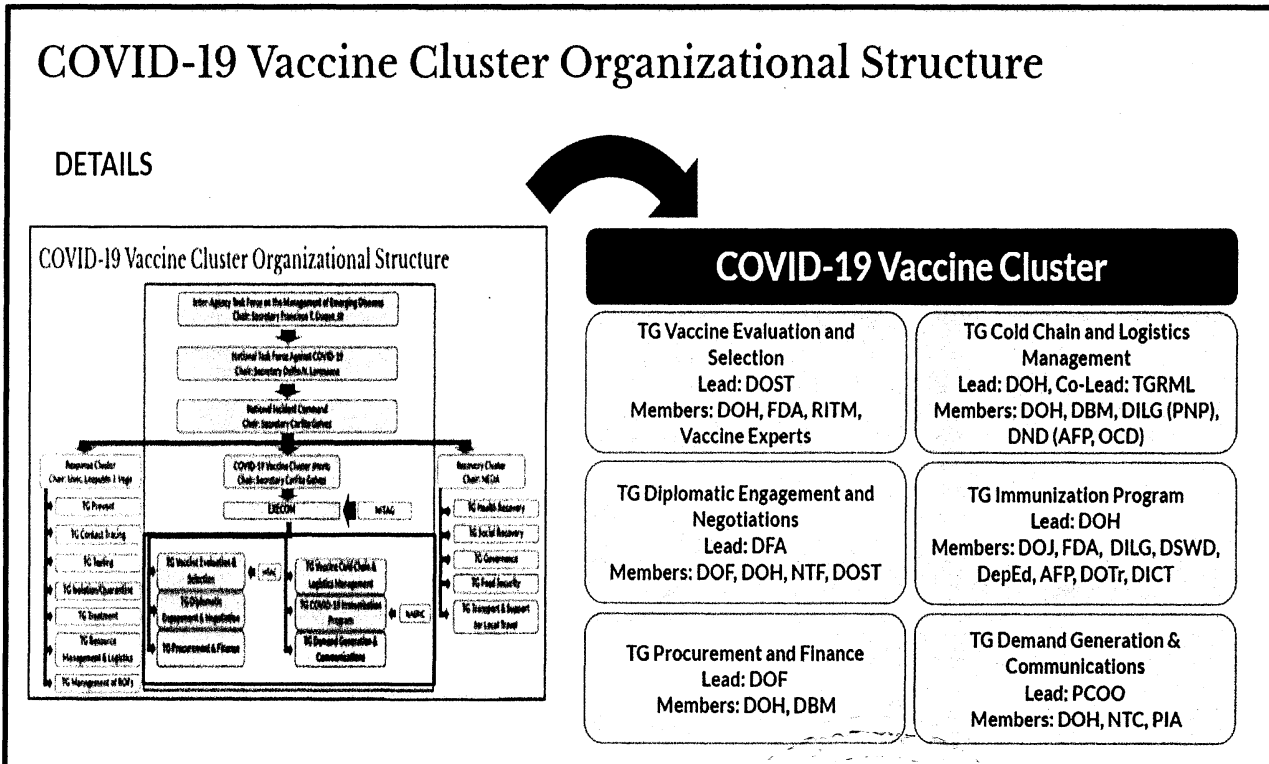
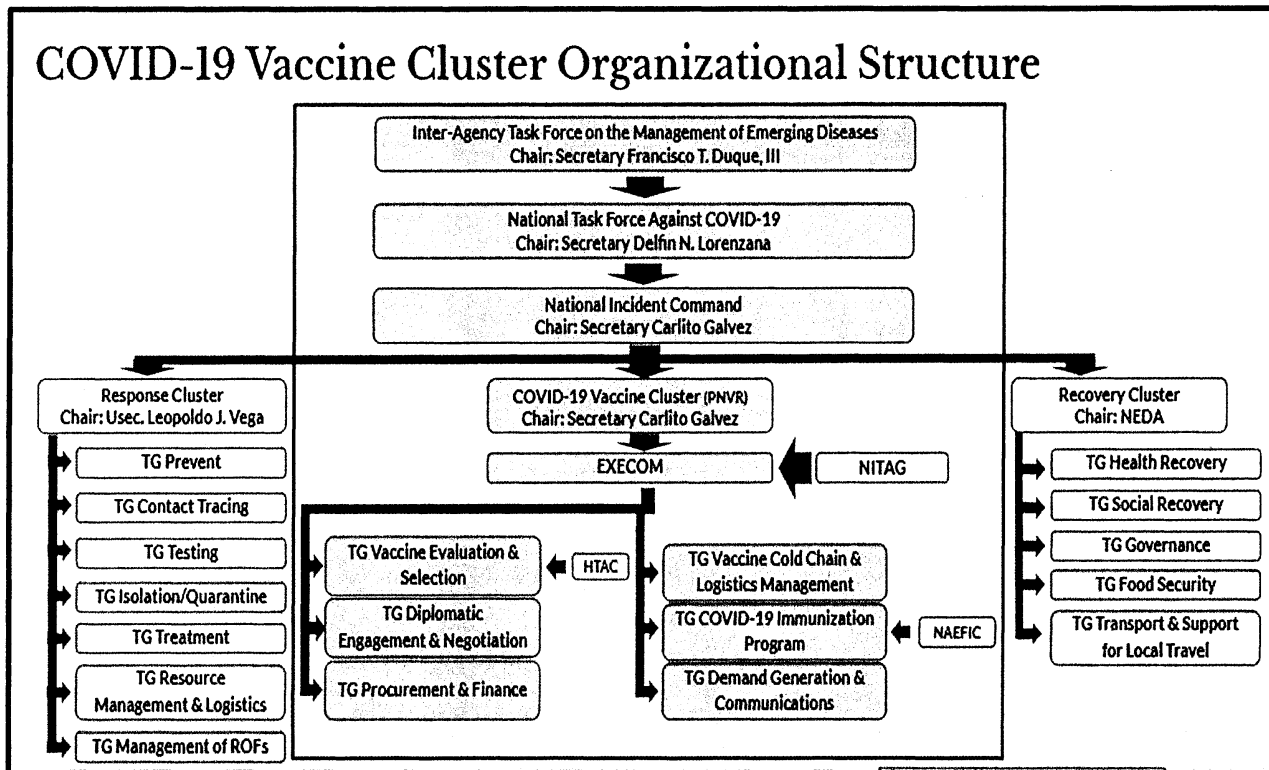
This Administrative Order shall take effect immediately after publication in the Official Gazette or a newspaper of general circulation.

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





## Annex A. COVID-19 Vaccine Cluster Organizational Structure



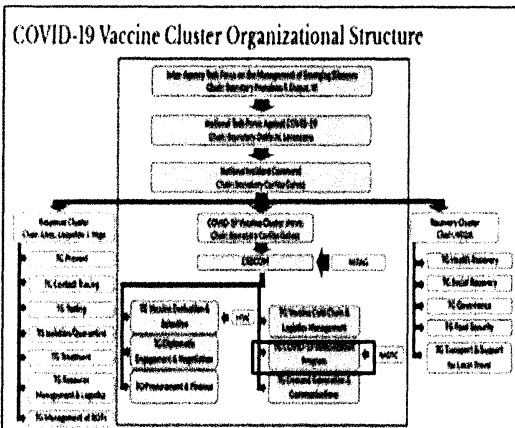
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# COVID-19 Vaccine Cluster Organizational Structure

## DETAILS



### Sub - Task Groups under the TG COVID-19 Immunization Program

**STG Planning, Policy & Technical Support**  
 Lead: DOH (Dir. Arevalo)  
 Member: DOJ, OCPLC, DepEd, DILG  
 STG Sec

**STG Registry, Data Management & M&E**  
 Lead: DOH (Dir. Albornoz, Tayag)  
 Member: DICT, DSWD, DepEd  
 STG Sec

**STG Program Implementation**  
 Lead: DOH (Dir. Alberto)  
 Members: DILG (BFP, PNP, BJMP), DSWD, DepEd, DND (AFP), DOJ (BuCor), DOTr (PCG)  
 STG Sec

**STG Safety Surveillance & Response**  
 Lead: FDA (DG Domingo)  
 Member: DOH (EB, DPCB, FICT)  
 STG Sec

TG Sec

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

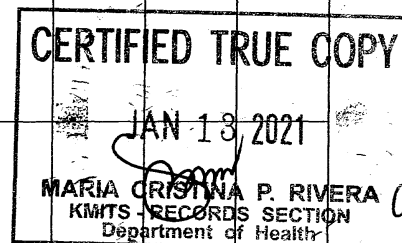
Category	Activities	Status				
		Sep- Oct 20	Nov - Dec 20	Jan 21	Feb 21	Mar 21
<b>A. PLANNING &amp; COORDINATION</b>	A.1 Establish (or engage an existing committee) a National Coordinating Committee (NCC) for COVID-19 vaccine introduction with terms of reference, roles and responsibilities and regular 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.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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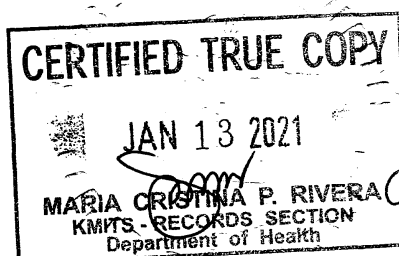
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	A.6 Plan and procure waste management supplies and equipment for appropriate implementation of waste management protocols.					
	A.7 Ensure that program objectives are defined and agreed to by key stakeholders at the central and sub-national levels, 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>B. BUDGETING</b>	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.					
<b>C. REGULATORY</b>	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.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.					



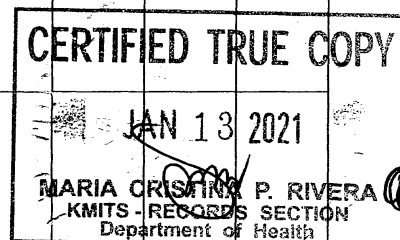
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	C.4 Confirm to WHO the existence of an expedited import approval from appropriate authorities. Time lines and maximum number of days should be mentioned. (expected timeline: maximum 5 working days).					
	C.5 Ensure COVID-19 vaccines can be released (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.					
<b>D. PRIORITIZATION, TARGETING &amp; COVID19 SURVEILLANCE</b>	D.1 Monitor progress of NITAG working groups on COVID-19 vaccines and interim recommendations focusing on prioritization and risk groups.					
	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.					
	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.					
<b>E. SERVICE DELIVERY</b>	E.1 Update protocols for infection prevention and control measures including adequate personal protection equipment (PPE) to minimize exposure risk during immunization sessions.					
	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 planning for locations and logistics is carried out.					

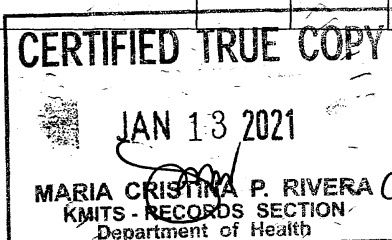


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	E.3 Identify implementing agencies and establish contractual agreements to prepare for vaccine introduction (e.g., vaccine warehousing, transport, waste management, cold chain capacity, etc.) where applicable. For delivery through private facilities, develop and approve Standard Operating Procedures, including service quality and performance and reporting standards and mechanisms for complaints-handling, certification of facilities, financing, performance monitoring and integrity checks.					
	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.					
<b>F. TRAINING &amp; SUPERVISION</b>	F.1 Develop a training plan across all participating facilities to prepare for COVID-19 vaccine introduction that includes key groups of participants, content topic areas (including safe injection practices), key training partners and training methods (in-person or virtual). 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 of staff (e.g. during an emergency or major campaign) as well as security at the central and/or regional storage facilities and for in-transit of products. Ensure regulations are in place regarding personnel who will be carrying out vaccinations, including all staff/personnel/consultants etc. engaged in such activities (cover military personnel also, if relevant), and include requirements relating to chemical, physical and biological substances, not engaging in sexual exploitation and abuse and sexual harassment, participation in training, reporting and non-retaliation.					
	F.4 Conduct virtual and/or in person trainings as outlined in the training plan.					
<b>G. MONITORING &amp; EVALUATION</b>	G.1. Develop or adapt existing surveillance and monitoring framework with a set of recommended indicators (coverage, acceptability, disease surveillance etc. for COVID-19 vaccine including gathering information from facilities and contractors participating in vaccine delivery, and ensuring necessary human resource capacity is in place. Determine whether registration and reporting will be individual or aggregate,					

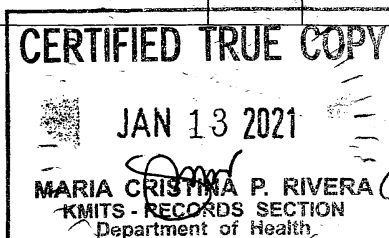


	and to what extent existing tools and systems can be used.					
	G.2 Develop or adapt necessary paper-based and/or electronic monitoring tools and appropriate institutional arrangements, including vaccination cards/certificates, facility-based nominal registers and/or tally sheets, vaccination reports, 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, and appropriate data governance regulation is in place to monitor legitimate, appropriate and proportionate use and processing of data which may be routinely collected and managed in health information systems.					
	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.					
<b>H. VACCINE, COLD CHAIN, LOGISTICS &amp; INFRASTRUCTURE</b>	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 confirm contact information for key personnel and facilities.					
	H.3 Create a distribution strategy, including mapping the potential port(s) of entry, points of storage (stores) and stocking, and fallback facilities in the country with their 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.					
<b>I. SAFETY SURVEILLANCE</b>	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.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.					
<b>J. DEMAND GENERATION &amp; COMMUNICATION</b>	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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