COVID-19 national deployment and vaccination plan

SUBMISSION AND REVIEW PROCESS
29 JANUARY 2021
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1. Background

The national deployment and vaccination plan (NDVP) constitutes a country’s overall plan to deploy vaccines and deliver vaccination to identified target populations. The NDVP is considered the “one country plan” and main framework for a country’s COVID-19 vaccine deployment and vaccination efforts in all countries. The plan can be used to work with donors such as the World Bank, other development banks as well as the COVAX Facility for Advanced Market Commitment (AMC) for 92 eligible low- and middle-income economies (AMC 92). The Guidance for developing a national deployment and vaccination plan for COVID-19 vaccines provides advice to countries to develop their NDVP.

In order to avoid two levels of review at the regional and global process, respectively, Gavi Independent Review Committee (IRC) members are included in a regional review committee. This method was selected to shorten the timeline for vaccine allocation recommendations to countries and avoid delays in implementing vaccination. The process described builds directly from the Gavi IRC process and incorporates information, processes, lessons learned and documents developed from the 2009 H1N1 pandemic vaccine deployment, when a similar process was convened. Because of the multiple partners in the COVAX Facility, this process was developed through an iterative process with input from a broad group of stakeholders at the global and regional levels.

This document outlines the submission and review process for the NDVP that applies to the AMC 92 countries, including a step-by-step process for NDVP development, submission and review (Annex 1). To enable a consistent and uniform assessment, an Excel-based NDVP Standard Review Form (SRF) will be used by reviewers. A user’s guide is provided to support reviewers in evaluating each question in the SRF and is attached as Annex 2. This document and the SRF will be posted on the WHO and United Nations Children’s Fund (UNICEF) websites so that countries may also use them to preview or conduct pre-assessments of their NDVP.

A review process will guide vaccine allocation decisions and be used to provide feedback to countries for improving and finalizing NDVPs. A decade ago, during the influenza a(H1N1) pandemic, countries underwent a similar review process to receive donated vaccines. Similarly, countries receiving support from Gavi undergo a similar review for receiving support for introduction of new vaccines and for health systems strengthening.

2. Scope and objectives of the NDVP review

The NDVP serves as the one country plan for COVID-19 vaccine deployment and vaccination as well as the main framework for country support and assistance. The development process is expected to be iterative, with countries and partners working together to finetune the NDVP and fill gaps as the development progresses, until the NDVP is finalized. The 92 AMC countries are required to submit the NDVP so that country vaccine preparedness and readiness can be assessed prior to shipment of the allocated doses of

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1. **Low income:** Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Democratic People’s Republic of Korea, Democratic Republic of the Congo, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Togo, Uganda, United Republic of Tanzania, Yemen.


3. **Additional International Development Association eligible:** Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, Saint Lucia, Saint Vincent and the Grenadines, Tonga, Tuvalu.
COVID-19 vaccines from the COVAX Facility. The NDVP review will support identification of both technical and financial needs which in turn can inform requests to partners.

The purpose of the NDVP review is to:

- Assist all countries in making sure that their NDVP includes all the key elements required to rapidly deploy vaccines and implement COVID-19 vaccination.

- Document and provide awareness of needed actions and support technical improvements, which can be useful for gaining high level support.

Each region will establish a Regional Review Committee (RRC) that will conduct a review of the country plans to gauge preparedness, based on the NDVP submissions. The RRC will determine and shape the final regional review procedure and determine the process for further consultations between the RRC and countries to discuss the recommendations, should these be required.

Once the NDVP is officially submitted by the appropriate national government authority on the COVID-19 Partners Platform, the key responsibilities for the RRC will be to:

- Assess country preparedness in all key areas of the NDVP and provide feedback to countries via existing channels to support country readiness for vaccine introduction.

- Develop recommendations to highlight areas in need of further work or flag any potential technical assistance needs to support improvements in future iterations of the NDVP.

- Confirm adequacy for the 92 AMC countries in the four areas considered to be the minimum criteria that must be met before countries can proceed in a global vaccine allocation exercise (see section 5.1).

The review will form the basis for providing recommendations for allocation of vaccines or improvement(s) to the NDVP for the first target group delivery for up to 3% of the total population (phase 1) and for later target group delivery up to 20% of the total population (phase 2) and beyond.

The review recommendations will be returned to the country with one of three outcomes:

1. The NDVP will be accepted and recommended for the inclusion in the next vaccine allocation round.

2. The NDVP will require minor revisions. Countries will receive written recommendations for revision and requested to submit to the RRC Secretariat, ideally within 2 weeks, an updated NDVP with the respective revisions made. Upon verification by the RRC co-chairs (or other designated regional panel) of the revisions made, the NDVP will be accepted and recommended for inclusion in the next vaccine allocation round. If not, the countries will be further advised on the further revisions required.

3. The NDVP will require major revisions and necessitate a full re-review by the RRC before being recommended for future vaccine allocation rounds. Recommendations for improvement will be provided as well as suggested technical assistance so the countries can address any gaps to enable approval.
The process from development of the NDVP to the allocation and shipment of the allocated vaccine doses is outlined in Fig. 2.1.

* NDVP submission is not a requirement for SFC

**Fig. 2.1 NDVP and review process**
3. NDVP pre-review

**NDVP pre-review** assistance is offered to all countries prior to formal submission of the NDVP for review by the RRC and will be arranged in collaboration with the Regional COVID-19 Vaccine Task Force or Working Group, in accordance with processes established in the respective regions. All NDVP pre-reviews will use the same SRF, which will also be made available to countries to conduct their own self-assessment, if desired. A pre-review is recommended to address any potential gaps prior to official submission of the NDVP.

4. NDVP submission

**KEY TAKEAWAYS**

- Country ministries of health (MoH) (or equivalent authority) will upload NDVPs to the COVID-19 Partners Platform to signal official submission for review by the RRC.

- NDVPs will be accepted starting 25 January 2021 and on a continuing basis; countries should submit their NDVPs for review sufficiently in advance of their intended date of introduction, allowing time for the review and allocation process.

The NDVPs should be developed under the coordination of the National Coordinating Committee (NCC), or similar entity, and submitted by the MoH, or other government body with authority to submit a plan on behalf of the government. The languages for submission will be determined by the RRC. For formal submission, the NDVP will need to be uploaded to the COVID-19 Partners Platform at which time an automated e-mail message will be sent to the respective RRC focal points to notify that the NDVP has been submitted (see Annex 3 for uploading instructions). The NDVPs uploaded on the COVID-19 Partners Platform will be accessible by organizations supporting COVID-19 vaccine rollout. Countries will have the ability to opt out of sharing during the upload process. All users of the COVID-19 Partners Platform must agree to the privacy policy and accept the terms of use (see Annex 3).

By officially submitting the plan, the government is signifying that they approve the country NDVP and are prepared to the best of their ability to receive and deploy COVID-19 vaccines and vaccinate their target populations. The immunization partners at country level, including WHO and UNICEF, can provide support for submission, if requested by the country, through existing structures for technical assistance.

Given the uncertainties in the COVID-19 vaccine product allocation, including product characteristics, dosing schedule and allocation volume, it is understood that countries will need to adjust the NDVP once allocation of a specific product is confirmed. With product-specific information, countries can work with partners to check key assumptions in their plans and make adjustments if needed to enhance readiness.

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1 The coordination mechanism, or NCC, should be presided over by senior-level officials from the MoH, and have a multisectoral representation composed of senior-level officials from relevant ministries (e.g. social welfare, pension service, women’s affairs, communications, finance, transport etc.), external partners, representatives from private sector providers and civil society organizations, with decision-making authority (https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1).

2 Submission by nongovernment authorities will need to be discussed and agreed with the COVAX Country Readiness and Delivery (CRD) team on a case-by-case basis.
5. NDVP review

KEY TAKEAWAYS

- The review should be completed by the RRC within 3 (target) to 5 (maximum) business days after the NDVP has been uploaded into the COVID-19 Partners Platform.
- For all self-financing countries (SFC) and AMC 92 COVAX Facility countries confirmation of completed regulatory procedures will be conducted by UNICEF and the Pan American Health Organization (PAHO) and confirmation of indemnification and liability agreements will be conducted by the COVAX Facility as requirement for shipment of the vaccine.

When NDVPs are submitted, they should be assigned to RRC reviewers within 24 hours. The number of RRC members supporting the review of each NDVP will vary based on the RRC composition.

The RRC will complete the assessment using the NDVP SRF and user’s guide (Annex 2). The review form and guidance are designed to facilitate a standard assessment of all submitted NDVPs to assess country preparedness for vaccine allocation, deployment and administration.

The review process from submission of the NDVP to completion and uploading of the completed review form should ideally take 3 business days, up to a maximum of 5 business days.

Once the review is completed, for those countries accepted for vaccine allocation:

1. The RRC will upload the completed SRF to the COVID-19 Partners Platform. An automated message will notify the global Country Readiness and Delivery (CRD) team and the country that the review is completed and available.

2. For NDVPs that require minor revisions the completed SRF will be uploaded to the COVID-19 Partners Platform and included in the next allocation round, though shipment of vaccine will be conditional on verification that the revisions adequately address the comments.

3. Within 24 hours the global CRD team will confirm submission of the SRF to the RRC and regularly track and notify the Joint Allocation Taskforce of the status of submissions.

4. The Joint Allocation Taskforce will share with the RRC and countries the vaccine product allocation once the allocation exercise is completed.
5.1. NDVP requirements for vaccine allocation for the AMC 92 countries

To be considered for vaccine allocation, AMC 92 countries are required to submit an NDVP that meets minimum requirements of the following four components to signify country preparedness to deliver vaccines from the COVAX Facility. In addition to these four minimum criteria areas, the RRC will take special note of the country plans for regulatory approval and assess if support is needed in order to complete the regulatory processes prior to shipment of vaccines.

1) Target population
Countries will need to provide information on the identification and prioritization of the first 1–3% of the target population, including the rationale and criteria for selecting the target groups, sequencing of target groups, and the role of the National Immunization Technical Advisory Group (NITAG) or equivalent body in identifying priority target populations, especially if they differ from the WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply or product specific recommendations. Strategies for vaccinating each of the target groups should be described, including the potential venues and modalities used.

To foster early introduction, countries have the option to identify the priority groups and develop delivery strategies in phases. For the first phase of submission, all components of the NDVP should elaborate the systems necessary for vaccination rollout. However, countries have the option to focus only on the first priority groups and delivery the strategy for the first 1–3% of the population in phase 1.

While the plans should provide a general indication of the subsequent target groups up to 20% and beyond of the population (phase 2), specific details for vaccination of these groups can continue to be developed while phase 1 priority groups are already being vaccinated. In this case a subsequent review by the RRC will be required to recommend allocation for phase 2 and beyond. However, if the RRC determines that the NDVP provides enough detail to approve allocation for both phase 1 and phase 2, this can be done simultaneously, and the country will remain on the allocation list for future rounds.

2) Supply chain management and logistics
Countries will need to provide confirmation of cold chain capacity in place or planned, with timelines for delivery of vaccine to the priority target populations for each phase of introduction. This includes a description of the supply flow to selected sites consistent with the vaccination strategy and human resource capacity, including training plans for handling the different vaccine products.

3) Costing and funding
Countries will need to provide a budget, including cost estimates for planned activities; description of secured funding sources; and identified funding gaps; and plans to close the funding gaps. Countries can use the COVID-19 vaccine introduction and deployment costing tool to estimate their budget.

4) Vaccine safety
Countries will need to provide evidence that guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities that are compliant with WHO requirements (i.e. adverse events following immunization [AEFI] reporting, investigation, causality assessment, risk communication and response) are available.

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1 This process does not apply to the allocation of doses for the so-called “first wave”, allocating a very limited supply of the Pfizer BioNTech vaccine for which an alternate mechanism is being put in place.
Resources for more information on how to conduct vaccine safety monitoring:


Where the RRC makes recommendations for minor revisions, countries will be requested to submit an updated NDVP, including revisions in response to the recommendations, to the RRC Secretariat within 2 weeks. The SRF will be uploaded to the COVID-19 Partners Platform for inclusion in the subsequent allocation round, though shipment of vaccines will be subject to verification by the RRC co-chairs that the revisions made are adequate.

6. NDVP verification check following vaccine allocation

**KEY TAKEAWAYS**

- Countries will finetune plans to incorporate vaccine product-specific characteristics.
- Prior to vaccine shipment, the following will be verified:
  - documentation of regulatory approval
  - signed indemnification and liability agreements
  - confirmation of refinements made to NDVP due to vaccine product specifications, if needed, especially in the four minimum criteria areas outlined under section 5.1.

Prior to shipment of allocated vaccine, each country will be required to have the following available for verification:

1) **Regulatory** approval paperwork and confirmation of immediate customs clearance upon vaccine arrival. Completion of the regulatory processes will be confirmed by UNICEF and/or PAHO using established mechanisms.

2) **Indemnification and liability** confirmation. The COVAX Facility will confirm that indemnification and liability agreements have been signed.

3) Confirmation that revisions were made to the NDVP to address product-specific characteristics and gaps noted in any of the four critical areas (see Section 5.1.) of the review.¹

Completion of these steps signal readiness to ship product to the country for vaccine deployment and vaccination of target populations for the first phase.

¹ Confirmation will be done by the CRD through the respective regional and country offices.
Annex 1: Step-by-step on NDVP development, submission, review process

1. The country MoH works with WHO and UNICEF country or regional offices and relevant partners to develop an NDVP along projected timelines for submission.

2. Technical assistance needs to support development should be shared with the regional or subregional COVID-19 vaccine task force and regional partners once identified.

3. Periodic progress checks of the NDVP development should be conducted by countries in collaboration with regional/subregional offices and partners to adjust timelines.

4. Support for a pre-assessment review is encouraged and the regional/subregional COVID-19 task force may be requested to support a completeness and quality check prior to submission and provide recommendations for strengthening the NDVP where required. Pre-assessments will be coordinated by the respective regions following regionally established procedures and conducted using the same SRF and user’s guide that will be used for official review process.

5. AMC 92 countries must submit the NDVP to the COVID-19 Partners Platform to signify their plan is complete based on available assumptions. By officially submitting the plan, the government is signalling that they are prepared to the best of their ability to receive and deploy COVID-19 vaccine and vaccinate their target populations. Immunization partners at country level can provide support for submission, if requested by the country.
   a. Upon upload, an automated message will be sent to the RRC Secretariat and co-chairs.
   b. Within 24 hours, the RRC co-chairs will assign review members to review the NDVP.

6. The RRC will use the SRF to review the country’s NDVP submission within 3 (target) to 5 (maximum) business days of receipt.

7. RRC co-chairs will organize a meeting with review team members to consolidate the findings of individual reviewers and finalize the input and recommendations into an SRF final report.
   a. Upon completion, the SRF will be uploaded to the COVID-19 Partners Platform by the RRC Secretariat and an automated message will be sent to the global CRD team.
   b. The completed SRF will also be returned to the country via e-mail at the same time with any recommendations for improvements.

8. In the case of AMC 92 countries, the CRD team, within 24 hours of receipt, will confirm submission of the completed SRF to the RRC. The CRD team will verify that the SFR documents are complete and regularly track and notify the Joint Allocation Taskforce of the status of submissions.

9. Countries will work with the regional working groups or taskforces and partners to use the recommendations from the SRF report to continue improving their NDVP.
10. Once an allocation round is complete, the allocation team (or COVAX Facility) will inform the country and the RRC of the product that will be allocated and the target date for availability. Once informed, countries should:
   a. Check that their NDVP is aligned with product-specific characteristics and make refinements as needed (e.g. cold chain, vaccination strategies, schedules).
   b. Begin implementation of training plan with health workers on product specifications.
   c. Immediately begin regulatory processes for licensure, import and use of the product.
   d. Finalize and submit indemnification agreements as required.

11. As the target due date for shipping the product approaches, a final verification will be conducted by the UNICEF Supply Division or PAHO to confirm regulatory approval and by the COVAX Facility to ensure that the indemnification and liability documents have been submitted. In addition, the CRD will verify whether appropriate adjustments have been made to align the NDVP with the characteristics of the vaccine product allocated.

12. Once all necessary approvals are in place, the product is shipped.
Annex 2: Review of NDVP: user’s guide

JANUARY 2021

Purpose: The purpose of this user’s guide is to facilitate and standardize reviews of NDVPs submitted by countries by providing reviewers general direction on how to assess review components.

Scope: This user’s guide highlights criteria and considerations to be applied by reviewers to each section of the NDVP review. The application of this user’s guide does not assure country readiness but facilitates a structured review of the NDVP and assists in identifying gaps where support may be needed to strengthen readiness for COVID-19 vaccine introduction. During the process of NDVP review, the guide will help reviewers develop recommendations for improvement as appropriate.

User guide structure: This user’s guide is based on the principles in the WHO-UNICEF Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines, COVID-19 vaccine introduction and deployment costing tool, and other relevant technical materials for facilitating readiness and delivery of COVID-19 vaccine introduction.¹⁻³

In the NDVP Standard Review Form (SRF) (Excel workbook) a series of questions are presented to the reviewer for consideration. Each reviewer should consider the issues presented in this user’s guide regarding the relevant NDVP section. If the question is largely addressed and the plan appears complete, the reviewer should score “yes”. If the question is partially addressed, but some areas are missing or not well defined, the reviewer should score “partially”. Lastly, if the information is missing or lacks critical pieces, the reviewer should score “no”.

For each question where the assessment is noted “partially” or “no”, the reviewer should make specific comments in the comments box and formulate recommendations that would help a country strengthen future versions of their NDVP. If gaps are critical and it appears technical assistance might be helpful, the reviewer should also suggest areas for potential support.

Minimum criteria questions for review: For AMC 92 countries, there are four areas that contain minimum criteria questions for vaccines to be allocated, for at least up to 3% of the population. These review questions are listed in red in the Excel workbook and user’s guide. This cluster of questions represents the absolute minimum criteria that must be met before countries can proceed in a global vaccine allocation exercise; if the area is assessed as “no” or “partially”, the issue will need to be rectified before vaccine allocation and/or shipment can proceed.

These minimum criteria questions are 2b to 2e (target populations); 3a to 3d (costing and financing); 4b and 4e (supply chain management); and 7a (pharmacovigilance).

The remaining questions in the NDVP review form are relevant for allocations beyond the initial 3%.

¹ https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1
² https://www.who.int/publications/i/item/10665337553
³ https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery
Section 1.
Regulatory preparedness

KEY ISSUES TO BE CONSIDERED

1a. Does the plan describe emergency or expedited regulatory pathways for approval of COVID-19 vaccines? (Please include comments if technical assistance is needed urgently to support final regulatory approvals.)

☐ Are procedures for authorization of use of the COVID-19 vaccine (mentioning of various regulatory pathways available to fast-track approval/emergency use), importation and customs clearance clearly outlined in the NDVP?

☐ Do procedures include or reference other documents that provide details on the necessary documentation required for these activities and associated timelines?

1b. Do the emergency or expedited regulatory pathways meet at least one of the three objectives below? (Please note in comments all that may apply or if technical assistance is needed.)

1. An exceptional waiver from the appropriate authority (head of national regulatory authority [NRA], executive head of the government etc.) to use the particular vaccine is obtained (copy of such waiver to be present) or

2. National regulations provide special provisions for reliance on one of the following regulatory approvals: (a) WHO prequalification or (b) WHO Emergency Use Listing (EUL) or (c) approved by a third country stringent regulatory authority (such provision in the regulation to be submitted for proof) or

3. A short or fast-track process for emergency approval is in place (in this case each step of the process, estimated time and requirements at each step are to be clearly described with references).

☐ Does the plan indicate which of the processes will be used to secure regulatory approval?

1c. Have barriers or restrictions for issuing an import permit for the specific product been adequately addressed (by legislation or executive order)?

☐ For importation, confirm there is no barrier/obstacle/restriction present by any legislation or any executive order in importing the specific product to the country, or that these barriers have been overcome.
1d. Is there confirmation that local testing of the product is not required prior to introduction?

- Ideally, local testing of the product for lot/batch release should not be required for approval of emergency use of the product.

**IDEAL**
Reliance on lot release certificates from the responsible NCL that are provided with each batch of Emergency Use Listing/Prequalification (EUL/PQ) or Stringent Regulatory Authority (SRA) approved vaccine.

**ACCEPTABLE**
If countries are required by law to review the summary lot protocols, vaccine release should be done quickly and through the review of the minimum documents. The overall release time should not be more than 2 working days. Note: this is essential for self-procured or donated COVID-19 vaccines.

**NOT RECOMMENDED**
Any in-country laboratory testing should require a discussion with the country to ensure they understand the consequences of doing so, and to also understand what testing they propose.

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**Section 2. Planning, coordination, service delivery**

**KEY ISSUES TO BE CONSIDERED**

2a. Does the national coordination mechanism described in the plan adequately meet coordination requirements anticipated for COVID-19 vaccine introduction?

- Has a national coordinating committee (NCC) been established to plan for COVID-19 vaccine introduction?
- Is the NCC chaired by a senior official and is the NCC relationship to the overall COVID-19 response efforts clearly described (e.g. incidence management team)?
- Does the coordinating mechanism cover the key areas for deployment and vaccination (planning/budget, supply/logistics, HR/training, demand/communications, safety/AEFI, monitoring)? Does it describe formation of or use of taskforces or technical working groups (e.g. supply, training, advocacy, communication and social mobilization)?
- Are officers responsible for deployment (e.g. chief of logistics) and vaccination (e.g. chief of vaccination) identified and their relationship and reporting lines to the NCC and the incidence manager outlined in the plan?
- Are key stakeholders included or invited to observe NCC meetings (relevant government sectors, civil authorities, nongovernmental organizations, any funding agencies, e.g. World Bank, regional development banks, other in-country donors), the military and/or other institutions and agencies related to vaccine introduction or special target populations?
2b. Does the plan clearly describe the highest priority categories targeted for vaccination, for up to 3% of the population? (Highest priority categories.)

- Does the plan identify the priority target populations to be vaccinated? Are these target populations clearly defined (no vague terminology)?
- Does the plan indicate the process to be followed when the target groups prioritized for the first phase are below or above the 3% level (e.g. if health workers are only 1% and the next priority groups is more than 2%, how will prioritization be sequenced)?

2c. Does the plan provide a clear rationale and criteria for the prioritization of the first categories to be vaccinated, for up to 3% of the population?

- Does the plan describe the basis and rationale for selecting these priority target groups?
- Does the plan estimate the number of doses needed for each of the target groups?
- Does the plan clarify what data sources are used for estimation purposes?

2d. Does the plan adequately describe the delivery strategy for reaching the highest priority categories to be vaccinated (e.g. venue and modality of delivery) for up to 3% of the population?

- Are the venues, collaborating partners, existing platforms to be used for vaccination described for each of the target population groups?
- Is the mode of vaccinating each group outlined (fixed/mobile/outreach)?

2e. Were the highest priority categories targeted for vaccination for at least up to 3% of the population recommended by the NITAG, other national technical advisory group or equivalent body?

- Are the considerations for decision-making, including the scientific evidence base, described in a transparent manner?
- Does the plan mention confirmation or endorsement of the vaccine recommendations by a NITAG or other equivalent advisory group?
- Is the role of the NITAG (or other equivalent decision-making body) provided, including its functionality and any amendments that were made to accommodate COVID-19 vaccination introduction, such as special working groups formed or increased scope of expertise?
- Are meeting minutes or agenda related to COVID-19 decision-making annexed?

2f, 2g, 2h, and 2i. should be considered the same way as 2b, 2c, 2d, and 2e. above, taking into account larger target populations and planning for beyond 3% of the population.
2j. If applicable, does the plan include reference to vaccinating the highest priority categories targeted for vaccination among special populations in need of humanitarian assistance such as refugees, internally displaced persons or others?

2k. Does the plan adequately describe the infection prevention and control measures established to prevent the spread of SARS-CoV-2, specifically during vaccination sessions?

□ Is there reference to special or targeted strategies required to vaccinate populations such as refugees, internally displaced persons or others in need of humanitarian assistance?

□ Does the plan describe the vaccination strategies that will be used?

□ Does the plan describe the infection prevention and control measures that will be used by providers and patients at vaccination sites to prevent the spread of COVID-19 – e.g. physical distancing, use of personal protective equipment (PPE) including masking, hand hygiene and other procedures?

□ Are the measures described consistent with WHO recommendations?

□ Does the plan adequately explain how the infection prevention and control measures required will be put into place, enforced and financed?

Section 3. Costing and funding

KEY ISSUES TO BE CONSIDERED

3a. Is the plan accompanied by cost estimates and a reasonable budget for planned activities?

□ Is there a budget which accompanies the NDVP and is this in line with proposed activities?

□ Does the budget contain reasonable assumptions either based upon previous vaccination activities or known inputs (based on volume and unit costs)?

Note: Determination of whether the cost estimates are “reasonable” can be made at the regional level, based on delivery costs for vaccination in the region. The costs estimates will merit special consideration if there are large, unmet budget gaps.

3b. Are funding sources clearly described, including secured funding sources?
- Does the estimated budget outline the sources of funding available or projected (e.g. government and external resources)?
- Please note funding sources which have been secured and those that are still being negotiated in the comments section (e.g. World Bank, other development banks, Gavi, other).

3c. Are budget gaps identified?
- Does the budget illustrate and quantify the financing gaps identified?

3d. Does the plan describe a strategy to address the budget gaps identified?
- Does the plan mention strategies and timelines to secure the additional resources that may be needed to close the funding gaps?

Section 4. Supply chain and waste management

KEY ISSUES TO BE CONSIDERED

4a. Has a cold chain assessment or WHO-UNICEF Effective Vaccine Management (EVM) assessment been conducted in the past 12 months?
- Does the plan refer to an EVM assessment or a similar technical review to assess the country cold chain capacity in preparation for vaccine deployment?
- Has the EVM assessment or technical review been conducted in the past 12 months?

4b. Is there a clear description of the cold chain adequacy at different administrative levels that will enable vaccine deployment to the above target groups (refer to 2b, 2f)?
- Please note the temperatures for which this review applies (+2 to +8 °C; -20 °C; -70 °C) and assess whether there is adequate capacity for each based on the questions below.
- Is the procedure for checking the temperature of vaccines on arrival at central, subnational and local cold storage facilities referenced in the NVDP? What evidence will be obtained of compliance to stated temperature ranges at each location?
- Is there mention of the type of inventory management system (manual or electronic/computer-based) available for tracking the reception, storage and distribution of batches of vaccines and related supplies (e.g. syringes, safety boxes)?
- Does the plan detail the approach to cover the health centres or immunization posts not adequately equipped with cold chain equipment (CCE)?
4c. Does the plan address whether there are adequate numbers of trained staff for cold chain management and vaccine handling for COVID-19 vaccine deployment? (interface with question 5a)

- Does the plan describe the vaccine management system and identify those persons responsible for vaccine management and handling at each level?
- Does the plan describe the adequacy of staff to handle and deploy the COVID-19 vaccine to designated distribution points?
- Does the plan make provisions to ensure that each staff member involved in the deployment will be trained and supervised?

4d. Does the plan adequately describe secure distribution and logistics requirements for each stage of vaccine deployment?

- Has the transportation network for vaccine distribution been mapped out?
- Does the NDVP describe the security methods established to protect vaccines and supplies from theft or misuse at the central and/or subnational storage facilities?
- Are methods for ensuring the security of vaccines and related supplies while in transit highlighted in the NVDP? What levels of inventory management are set out?
- Does the plan outline how logistics information management system (LMIS) will be updated to accommodate effective controls for COVID-19 vaccines (could be part of the national LMIS)?

4e. Does the plan adequately describe steps to fill – prior to deployment – any of the gaps potentially identified below (cold chain equipment, human resources for cold chain management, secure distribution and logistics)?

- Are steps outlined to recruit or fill gaps for any areas identified?
- Please note in comments if technical assistance or resource requirements are required.

4f. Does the plan adequately describe the safe handling of waste management?

- Does the plan identify who is responsible for waste collection from the vaccination site up to the point of disposal or does it reference another document that may provide these details?
- Do the current waste facilities in the country have the capacity to process all the medical waste that could be sent to disposal sites in the event of increased numbers of vaccination?
- Have plans been made to address potential shortage of waste facilities and/or lack of capacity to process the volumes of medical waste that will be generated in the event of mass vaccination?
### Section 5. Human resources and training

#### KEY ISSUES TO BE CONSIDERED

**5a. Does the plan adequately outline how to address the human resource implications of supporting COVID-19 vaccine deployment?**

- Are there estimates of staff and health workers highlighted in the NDVP for:
  - vaccination (including supervision and reporting of immunization data and AEFI)
  - advocacy, communications, social mobilization and community engagement
  - supply chain, logistics and waste management
  - immunization monitoring, pharmacovigilance, disease surveillance
  - security issues.

- Is there a list of the type of staff (in terms of skills) needed for deployment and vaccination of target groups? Does the plan mention terms of reference or job descriptions?

- What plans have been made to match the skills of current staff with the skills that will be required by each post during deployment and vaccination?

**5b. Does the plan adequately describe the HR training and supervision plan?**

- Does the plan make provisions to ensure that all staff involved in the vaccine deployment and vaccination (including any partner agencies or private sector) will be trained?

- Does the plan indicate the type of training to be provided and the timelines for conducting training (e.g. in person, online, webinars, etc)?
Section 6.
Demand generation

KEY ISSUES TO BE CONSIDERED

6a. Does the plan adequately describe a demand generation and community engagement plan?

- Does the NDVP outline a demand generation and community engagement plan for optimizing the uptake of the COVID-19 vaccine or refer to a stand-alone plan?
- Does the plan apply social and behavioural data to generate demand and acceptance of COVID-19 vaccine?
- Does the plan outline coordination mechanisms for demand generation and/or advocacy communication and social mobilization (ACSM)?
- Does the plan describe how communities will be engaged in vaccine rollout?
- Does the plan include training of health workers and other stakeholders on demand generation/ACSM and interpersonal communication?
- Does the demand generation and community engagement plan tailor specific messages for different target groups?
- Does the plan outline approaches and timelines to conduct any formative research or rapid assessment to help develop and pre-test messages to promote demand and acceptance and identify the optimal communication channels to reach target populations?
- Does the plan describe any community feedback mechanisms?

6b. Does the plan adequately describe a risk communication strategy (e.g. to respond to misinformation or crisis)?

- Does the plan include monitoring/responding to rumours or misinformation (e.g. social listening)?
- Does the plan describe key elements of crisis preparedness and response (links with AEFI focal points, spokesperson training, established relationships with media, rapid response, worst case scenario mapping, etc.)
- Does the plan describe systems to provide overall geographical coverage for the communications required in all parts of the country?
Section 7. Vaccine safety

KEY ISSUES TO BE CONSIDERED

7a. Does the plan adequately outline the documented COVID-19 vaccine pharmacovigilance procedures, processes or tools for conducting the following activities:
   - AEFI reporting
   - AEFI investigation
   - AEFI causality assessment
   - risk communication and response to serious AEFI.

The goal of COVID-19 vaccine safety surveillance is to detect serious AEFIs rapidly to provide timely data that can be shared with relevant stakeholders for rapid action. This includes identifying, investigating, assessing and validating safety signals and recommending appropriate public health or other interventions to preserve public and stakeholder confidence in immunization.

The description of AEFI reporting should include details of the appropriate mechanism. Information on AEFI investigation should include the investigation of serious AEFI, clusters of AEFI, AEFI of community concern and of programmatic errors. Information on causality assessment should include description of the national AEFI committee.

Refer to COVID-19 vaccine safety surveillance module: (Module_Establishing_surveillance_systems.pdf (who.int).

7b. Does the plan refer to approaches for implementing risk management plans? (refer to 6b)

- Is reference made to a comprehensive approach to respond rapidly to any COVID-19 vaccine-related event (real or perceived)?
- Are the roles and responsibilities of the NRA and the immunization programme described?
- Does the NDVP outline roles and responsibilities of key stakeholders (including the private sector) for the implementation of safety surveillance activities and responding to vaccine-related events?
- Is a system described to keep stakeholders up to date on COVID-19 vaccine safety information?

Refer to COVID-19 vaccine safety surveillance module: (Module_Establishing_surveillance_systems.pdf (who.int).

7c. Is the country considering to set up a monitoring and reporting system of other safety concerns such as adverse events of special interest (AESI)?

- Does the plan contain information or plans for monitoring AESI or other special studies regarding safety or adverse events?
- If yes, does the country need or request guidance from WHO for implementing such a plan? (please remark in comments section)?
Section 8. Monitoring and evaluation system

KEY ISSUES TO BE CONSIDERED

8a. Does the plan adequately describe a mechanism for adapting registers and reporting forms to record COVID-19 vaccination doses?

- Does the plan describe the process for updating the data collection systems and tools to collect COVID-19 immunization data?
- In case of paper-based and aggregate reporting systems, this should include tally sheets, vaccination cards, and registers with the minimum required fields required for reporting.

8b. If applicable, does the plan adequately describe a mechanism for providing dates/reminders to vaccinees for follow-up doses?

- Are the available tools adequate to screen the COVID-19 vaccination status of an individual and complete the vaccination schedule?
- In case of paper-based and aggregate reporting systems, this should include registers and/or home-based records to create an individual record to facilitate follow up.

8c. Does the plan adequately describe the system to monitor and report the required immunization data as defined in the NDVP guidance?

- Does the plan describe the minimum COVID-19 immunization data that will be monitored?
- Are the systems and tools described in the plan adequate to collect the minimum data required for the monitoring indicators?

8d. Does the plan mention the conduct of a programmatic evaluation following introduction of COVID-19 vaccines?

- Does the plan refer to the intent to conduct a full or partial evaluation following introduction of COVID-19 vaccines (post-introduction evaluation)?
- Are the objectives, methods and process for such an evaluation(s) described? (e.g. in phases, after full introduction, etc.)
Section 9. COVID-19 surveillance

KEY ISSUES TO BE CONSIDERED

9a. Does the plan adequately describe a mechanism for adapting case investigation forms to include COVID-19 vaccination status?

☐ Does the plan mention adapting the existing COVID-19 surveillance to collect data on vaccination status, which should include at a minimum the vaccine product used, number of doses, and date of receipt of vaccine doses?

☐ Does the country plan to conduct studies to document vaccine effectiveness or impact? If so, is there a need for technical assistance to design and implement such a study?
Annex 3: Submission of NDVPs and SRFs to the COVID-19 Partners Platform

Foreword and notes

Emergency responses are dynamic by nature. As such, please note that some features of the Platform, as well as this document, will be continuously updated to address new and evolving features and questions on the Platform to improve general user experience.

☐ This document is intended to provide guidance to regional and country-level users engaging with the COVID-19 Partners Platform new Pillar 10 for vaccine introduction (also referred to as “Platform”, “Partners Platform” or “tool”).

☐ The Platform has functionality for country-level users, such as uploading the national deployment and vaccination plan on the Info tab by the World Customs Organization vaccine expert followed by validation by a government official.

☐ The Platform has functionality for regional users, such as reviewing of the NDVP on the Action Checklist tab or uploading a summary of the review of the NDVP on the Info tab and within the NDVP folder.

☐ This document can be used as a reference for all users, with the understanding that some features may differ slightly.

☐ This document is part of a set of materials to guide all users and donors on the Partners Platform. A full User guide, a Resource needs step-by-step and a Resource tracking step-by-step are also available on the Support tab in the Partners Platform. Please contact the Partners Platform support team (covid19-platform-support@who.int) for any questions that do not appear here. There are established administrative focal points in each region that can also provide support.

Access to the COVID-19 Partners Platform and user management

How to register for access to the Partners Platform?

For regional and country-level users for vaccines, an e-mail will be sent to you with a link inviting you to https://covid19partnersplatform.who.int. Please click the “LINK” and follow the next step of the registration process.

Why do I get an error message when try to access the https://covid19partnersplatform.who.int URL?

It may be an internet service provider (ISP) issue. You may try to open the Platform through a different ISP. This may also be a firewall issue. In that case, please contact your IT team to ensure the website is whitelisted. If this does not resolve your issue, please contact covid19-platform-support@who.int.
Why can I not access the full view of the landing page and/or all key functionalities of the Platform?

You might be encountering such complications when using Internet Explorer 11. Please consider using other platform web browsers such as Google Chrome or Firefox.

I have not received the confirmation e-mail responding to my access request, what do I do?

Please search for a confirmation e-mail with subject “Invitation to join COVID-19 Partners Platform” from no-reply@covid19partnersplatform.who.int in your inbox. You may need to refresh your spam folder if you cannot find the e-mail in your inbox. If you still have not found it, you may reach out to your regional admin user or vaccines focal point to ensure you are rightly entitled to have access to the Platform, or alternatively you may contact covid19-platform-support@who.int.

Country and regional users

Country admin users for vaccines have ability to upload NDVPs for Pillar 10 vaccines, ability to view and download information entered in the Platform.

- Generally, country admins for vaccines are invited by the regional admins for vaccines onto the Platform in communication with the WHO representatives (WRs), considering the following criteria:
  - Should have hands-on experience handling the national deployment and vaccination planning for COVID-19.

- Recommend two country admins per country:
  - one WHO or UN member country office COVID-19 vaccine expert to upload the NDVP; and
  - one government official who can validate the NDVP, accepting the NDVP on behalf of the government.

Regional admin users for vaccines are responsible for information entered in the review of the NDVP under the Action Checklist tab, able to upload the summary review of the NDVP, able to view and download information entered in the Platform for vaccine introduction activity for countries in their region and manage user accounts/access requests for country admin users for vaccines.

- Regional admins for vaccines are invited by global admins onto the Platform.

Users must belong to an “approved” organization in order to be invited onto the Platform. An approved organization is one which has previously applied and been approved by a global admin.

- Includes WHO, most multilaterals and UN agencies, many nongovernmental organizations and non-profits.
- Generally, excludes: private companies, universities, media.

Who will have access to the NDVP?

- When countries upload NDVP there will be an automatic opt in to share the NDVP with a limited list of names from our main partners: UNICEF, Gavi, BMGF, US CDC, World Bank, Asian Development Bank and USAID.

- If countries do NOT want to share the NDVP with these partners and donors, they will actively need to limit access partner by partner in a list.
All other stakeholders as global viewers (role already exists in Partners Platform)

- All other vaccine stakeholders (regional and country offices, donors and partners) may register on the Platform as “viewers”. Go to https://Covid19partnersPlatform.who.int and click request access. With a WHO or UN e-mail address, a stakeholder can register as a viewer and be granted access immediately.

- Global viewers in Pillar 10 Vaccines are able to view Technical Assistance and Resource map

Info tab > Country Info – uploading NDVPs and budgets

Action for WHO country admin for vaccines

1. Under the Info tab, select Country Info

2. In the upper right click on the white button labelled Countries, Areas and Territories and select the name of your country, area or territory from the drop-down menu.

3. Scroll down to section 3 titled Country, Territory or Area Plans and Reviews and click on the blue button labelled Add.

4. As available, enter the information for the NDVP including the total budget.

5. Drag and drop the NDVP into the designated area; you can also drag and drop a detailed budget worksheet for the NDVP.

6. Click on the Save button and an e-mail will be automatically sent to the government country admin for vaccines who will be asked to validate the NDVP.
**Action for government country admin for vaccines**

1. Under the **Info tab**, select Country Info.

2. In the upper right click on the white button labelled **Countries, Areas and Territories** and select the name of your country, area or territory from the drop-down menu.

3. Scroll down to section 3 titled Country, Territory or Area Plans and Reviews and click on the folder titled National Vaccine Plan (NVP) and related documents.

4. Under documents, click on the name of the NDVP and it will automatically download for easy reading.

5. Click on the button titled Validate to accept the plan on behalf of the government; an e-mail will be automatically sent to the regional admin for vaccines to begin the process of reviewing the NDVP.
Action Checklist tab – reviewing the NDVPs and uploading summary review forms of NDVPs

Action for regional admins for vaccines

1. Open the Action Checklist tab.

   ![Image of Action Checklist tab]

2. In the upper right, click on the white button labelled **Countries, Areas and Territories** and select the name of your country, area or territory from the drop down menu.

3. Scroll down to the folder titled Pillar 10: Review of NDVP and expand this folder using the downward arrow on the far right side.

4. Record the review of items **included** in the NDVP by ticking boxes next to each item within each technical area as yes, partially, or no; add comments to each.

5. Click the Save button when complete and an automated message will notify the WHO global Country Readiness and Delivery (CRD) team and the country that the review is completed and available.

**Optional feature for uploading Summary Review Form (SRF) of the NDVP**

1. Open Info tab, select Country Info.

2. In the upper right, click on the white button labelled **Countries, Areas and Territories** and select the name of your country, area, or territory from the dropdown menu.

3. Scroll down to section 3 titled Country, Territory or Area Plans and Reviews and click on the blue button labelled **Add**.
4. As available, enter the information for the SRF of the NDVP.

5. Drag and drop the SRF of the NDVP into the designated area.

6. Click on the Save button and an automated message will notify the WHO global Country Readiness and Delivery (CRD) team and the country that the review is completed and available.