

GUIDANCE NOTE FOR TECHNICAL ASSISTANCE SUPPORT FOR GAVI-57 ECONOMIES' PREPAREDNESS AND READINESS FOR COVID-19 VACCINE DELIVERY

BACKGROUND

In July 2020, the Gavi Board approved the establishment of the Gavi COVAX Advance Market Commitment (the "COVAX AMC"), a financing mechanism to accelerate and provide COVID-19 vaccines to ensure that low income and lower middle-income economies, as well as other IDA-eligible economies, have access to COVID-19 vaccines at the same time as wealthier economies.

Gavi's COVAX AMC will allow access to COVID-19 vaccines to a total of 92 low- and middle-income countries and economies (AMC92). The COVID-19 vaccine is expected to be available in the first quarter of 2021.

In September 2020, the Gavi Board approved resources from core funding to focus on urgent technical assistance (TA) needs with priority for 57 Gavi eligible economies and others on a case by case basis. The list of Gavi-57 countries and the list of AMC-92 economies can be found in Annex 1.

The TA support for the Covid-19 vaccine will be administered according to the Partners' Engagement Framework (PEF) principles of country ownership, differentiation, transparency, accountability, adequate partnerships, embracing partnerships beyond immunization and sustainability.

In October 2020, the Partners' Engagement Framework (PEF) - Management Team approved initial seed-funding of \$100,000 to WHO and UNICEF for each Gavi-57 economy to kick-start readiness activities and the development of the National Deployment and Vaccination Plan (NDVP).

In October 2020, the Gavi Secretariat launched a Request for Proposals (RFP) to identify potential expanded partners for providing technical assistance support for the planning and preparation of the Covid-19 vaccine introduction.

FOCUS OF TECHNICAL ASSISTANCE

Focused technical assistance support is available to the Gavi-57 economies for the planning and preparation for the introduction of the COVID-19 vaccine.

To prepare all countries for COVID-19 vaccine introduction, WHO, UNICEF, Gavi, World Bank and partners are working together at global and regional levels: (1) to develop and disseminate adaptable



guidance, trainings, planning and monitoring tools, and advocacy materials, and (2) to provide technical assistance and support to countries.

At the national level, Gavi seeks to engage with Ministry of Health counterparts or other relevant Ministry/body leading COVAX coordination to identify technical assistance needs for the planning and preparation of COVID-19 vaccine introduction in accordance with the Vaccine Introduction Readiness Assessment Tool (VIRAT).

The COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) provides a structured framework for the preparation and planning for the introduction of the COVID-19 vaccine and for self-monitoring readiness progress against key milestones.

This <u>COVID-19 VIRAT</u> may be updated as more information becomes available on the vaccine(s) and timelines for delivery as well as on the National Deployment and Vaccination Plan (NDVP).

Preparation activities include the following:

1. Planning and coordination:

- Establish (or engage an existing committee) a National Coordination Committee (NCC) for COVID-19 vaccine
- 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.

2. Regulatory:

Confirm to WHO the existence of any expedited regulatory pathway for approval of COVID-19 vaccines (i.e. emergency use authorization, exceptional approval/waiver mechanism based on reliance/recognition, abbreviated procedure, fast track, etc.). Timelines and maximum number of days should be mentioned (expected timeline: maximum 15 working days).

3. Prioritizing, Targeting and COVID-19 Surveillance:

o Monitor progress of NITAG working groups on COVID-19 vaccines and interim recommendations focusing on prioritization and risk groups.

4. Service Delivery:

 Update protocols for infection prevention and control measures including adequate personal protection equipment (PPE) to minimize exposure risk during immunization sessions.

5. Training and Supervision:

 Develop a training plan to prepare for COVID-19 vaccine introduction that includes key groups of participants, content topic areas, key training partners and training methods (in-person or virtual). WHO will provide a template for guidance.

6. Monitoring and Evaluation:

 Develop or adapt existing surveillance and monitoring frameworks with a set of recommended indicators (coverage, acceptability, disease surveillance etc.) for COVID-19 vaccine.
 Determine whether registration and reporting will be individual or aggregate, and to what extent existing tools and systems can be re-used.

7. Vaccine Cold Chain and Logistics:

- 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.
- Assess current cold chain capacity through the collection of necessary data (e.g. CC inventory update, operational deployment plan), developing a cold chain and distribution strategy, and



estimating associated gaps and equipment needs. As required, this can include the preparation of support applications to relevant donors.

8. Safety Surveillance:

- 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) are available.
- Assure competent and trained staff to perform vigilance activities.
- Expedite 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.).
- o Identify provisions that require manufacturers to implement risk management plans and collect and report COVID-19 vaccine safety data to the NRA.
- 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.

9. Demand Generation and Communication:

 Design a demand plan (including advocacy, communications, social mobilization, risk and safety comms, community engagement, and training) to generate confidence, acceptance, and demand for COVID-19 vaccines. Must include a crisis communications preparedness planning.

PROCESS FOR COVAX-TA NEEDS FOR GAVI ELIGIBLE COUNTRIES

The TA requirements should be aligned and discussed under the leadership of the Ministry of Health or other relevant Ministry/body leading COVAX coordination and in collaboration with the Gavi Senior Country Manager, and relevant in-country partners (core, expanded and local partners).

The Senior Country Manager(SCM) will share the COVAX TA plan that will include the respective country ceiling.

WHO/UNICEF will indicate activities being conducted from the seed-funding received from Gavi. The outcome of the RFP for expanded partners will be available in mid-November 2020 and the relevant Ministry can consider these results prior to finalizing their COVAX TA plan.

Prior to completing the TA plan template please read the instructions on the first tab.



Gavi-57 Countries: Process for COVAX-TA Needs Identification			
Action	Responsible	Deadline	
Releases of the Vaccine Request, that includes Gavi guidance for support for Technical Assistance and Cold Chain Equipment needs.	Office of the COVAX Facility, Gavi Secretariat	13 November 2020	
COVAX TA plans including country ceilings for Gavi-57 countries shared by SCMs with relevant Ministry and country stakeholders.	Gavi Secretariat	16 November 2020	
EPI, Gavi (SCM), WHO and UNICEF Country Offices and partners complete the COVAX TA plan.	EPI, SCM, Core and expanded partners	27 November 2020	
WHO and UNICEF Country Offices submit country- approved plans to headquarters and Regional Offices for review and approval.	Core Partners	27 November 2020	
Gavi SCMs submit to PEF the COVAX-TA plan.	Gavi Secretariat	Week of 30 November 2020	
Gavi Secretariat will review the submitted Covax TA plan in collaboration with the Office of the COVAX Facility, and the Country Readiness and Delivery Working Group (CRaD).	Gavi Secretariat, CRaD	Week of 30 November 2020	
Compiled plans to be shared with PEF MT. Approved COVAX TA plan shared with each Gavi- 57 country.	Gavi Secretariat	Week of 14 December 2020	
Grant management processes for disbursing additional needs identified completed.	Gavi Secretariat	Week of 14 December 2020	

BUDGET

The budget ceilings for available country-specific TA envelopes will be shared by SCMs with the respective EPI and in-country partners.

This budget ceiling includes the initial seed funding of \$100,000 provided to WHO and UNICEF.

Governments should consider setting aside a portion of the funds for subsequent needs.



REPORTING ON COVAX TA

TA milestones: It is important that the TA plan has strong, logical, and results-focused milestones. For TA planning, a list of predefined milestones is pre-populated in the planning template.

Implementing partners will report on milestones for selected activities on the <u>PEF Partner Portal</u> in June 2021.

Timeline

The expected implementation timeline is December 2020 – June 2021.

Roles and Responsibilities

Stakeholder	Roles & Responsibilities
EPI / MOH/ Relevant	Lead the COVAX TA planning and monitoring process including implementation of activities.
Ministry or body leading COVAX co-ordination	Convene quarterly meetings to review progress on COVAX TA implementation and plan for the following period.
	Proactively raise any concerns with COVAX TA provision to partners, the ICC and Gavi.
In-country Co- ordination Forum	Review quarterly COVAX TA implementation progress and challenges.
Partners: Country Level	Submit progress updates on TA milestone reporting in accordance with the TA planning tool on the PEF Partners' Portal.
	Monitor and discuss progress with other country stakeholders on a quarterly basis.
	Contribute to and submit additional requests as required, subject to available funding.
Partners: Regional Level	Monitor progress on country readiness for receiving of Covid-19 vaccines and support countries in identifying and overcoming challenges or bottlenecks.
	Support dissemination of guidance, tools, and decisions from PEF MT, ACT to country level staff.
	Facilitate lessons learned and best practices from planning, implementation and monitoring of TA in countries.
Partners: HQ	Review submission of TCA milestone reports of priority countries before reporting deadlines and provide reporting feedback via the portal.



	Disseminate guidance, tools, and decisions from PEF MT, ACT, etc. to regional level staff. Core partners to submit HR and financial utilisation reports to Gavi Secretariat twice a year.
Gavi Secretariat	Ensure clarity on process for TA planning and reporting. Engage in review of TA in-country; convene discussions if necessary; review partner reports (milestones, results, and narratives) and provide timely feedback. Ensure robust discussion on planning for TA including link with other Gavi grants and results expected in the country.

Annex 1: List of Gavi-57 countries and AMC-92 economies