

GUIDANCE NOTE ON SUPPORT THROUGH WHO AND UNICEF FOR TECHNICAL ASSISTANCE SUPPORT FOR PREPAREDNESS AND READINESS FOR COVID-19 VACCINE DELIVERY IN AMC-35 ECONOMIES

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 reserve 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) including Gavi eligible economies. 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 and cold chain needs with priority for 57 Gavi eligible economies and other AMC 92 economies on a case by case basis.

The AMC-35 are the non-Gavi eligible economies participating in the Advanced Market Commitment for access to the COVID-19 vaccine. The list of AMC-35 economies can be found in Annex 1.

The Technical Assistance (TA) support for 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 - Management Team approved initial seed-funding worth \$50,000 to WHO and UNICEF for the AMC-35 economies to kick-start readiness activities and the development of the National Deployment and Vaccination Plan (NDVP).



FOCUS OF TECHNICAL ASSISTANCE

Focused technical assistance support is available to the AMC-35 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 the global and regional levels to: (1) develop and disseminate adaptable guidance, trainings, planning and monitoring tools, and advocacy materials and to (2) provide technical assistance and support to countries.

At the national level, Gavi will provide support to WHO and UNICEF 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 Coordinating Committee (NCC) for COVID-19 vaccine introduction with terms of reference, roles and responsibilities and regular meetings.
- 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:

 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 framework 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).
- 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 (includes 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 IDENTIFICATION FOR AMC-35 ECONOMIES

For the AMC 35 economies the WHO and UNICEF are encouraged to reach out to the Ministry of Health or other relevant Ministry/body leading COVAX coordination to discuss their technical assistance needs.

AMC-35 economies: Process for COVAX-TA Needs Identification			
Action	Responsible	Deadline	
The COVAX Facility releases the Vaccine Request Form, which contains the Gavi guidance for support for Technical Assistance, Cold Chain Equipment needs. This Guidance Note contains the link to the planning tool for identifying planning, preparation and readiness needs for the AMC-35 economies.	Office of the COVAX Facility, Gavi Secretariat	13 November 2020	
WHO and UNICEF to reach out to respective Ministries to identify technical assistance needs.	WHO/UNICEF Country/Regional Offices	16 November 2020	
WHO/UNICEF HQ submit the updated needs of the AMC-35 economies to Gavi Secretariat.	WHO/UNICEF HQ	27 November 2020	

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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
Finalized COVAX TA plan available for AMC-35 economies.	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 total envelope to WHO and UNICEF for COVAX-TA support for AMC-35 economies is approximately \$4.8 million. This includes seed-funding of \$50,000 for each AMC-35 economy for WHO and UNICEF.

Additional TA requirements to address key challenges apart from seed-funding activities (such as kickstarting readiness and the development of the NDVP for the AMC-35 economics), should be proposed to WHO and UNICEF from the remaining budget.

Reporting on COVAX TA

WHO and UNICEF will provide updates on progress of the support at the end of January 2021, and every subsequent 2 months.

Timeline

The expected implementation timeline is December 2020 – June 2021.

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