

ACT-Accelerator Facilitation Council Vaccine Manufacturing Working Group

Consolidated Workplan

Finalized (30/08/2021)

Context and background:

The objective of the [Facilitation Council Vaccine Manufacturing Working Group](#) (WG) **is to support the COVAX Manufacturing Taskforce (TF) by addressing political bottlenecks and barriers.**

The COVAX Manufacturing TF, in previous meetings, have shared a number of shared political challenges and bottlenecks that are crucial to the scaling up global manufacturing.

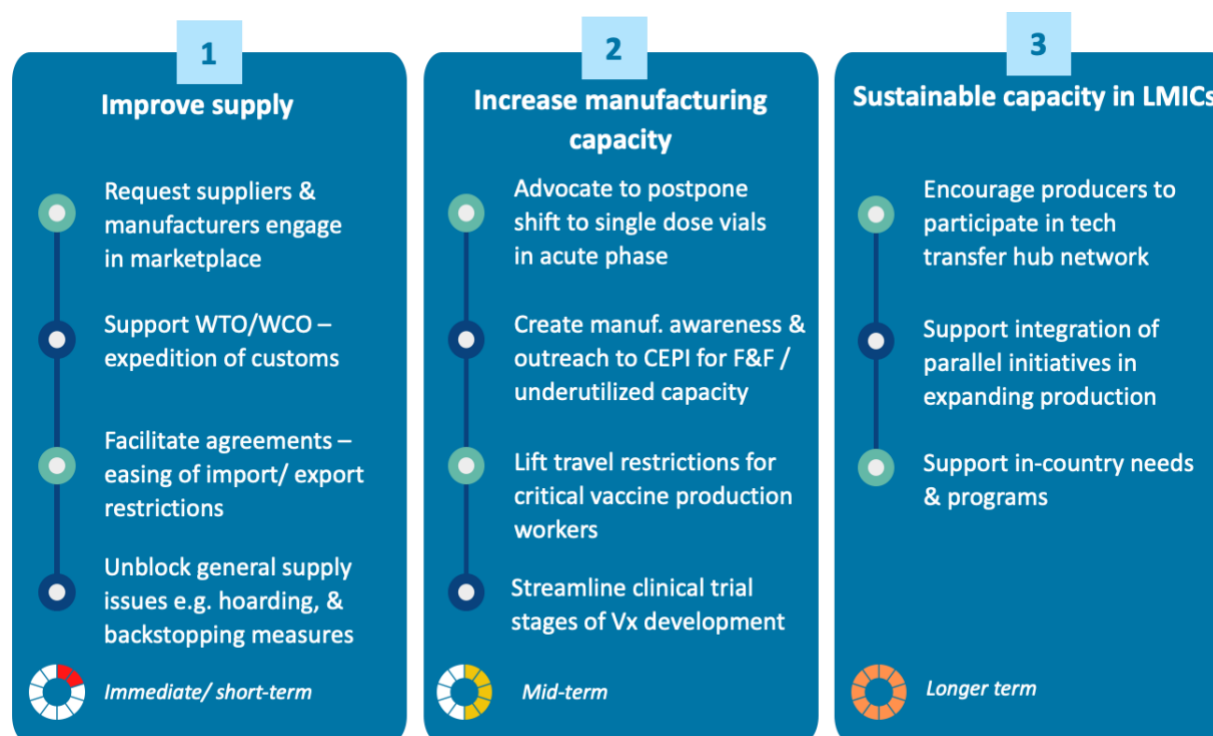
Based on concrete ‘asks’ from the TF, through an iterative consultative process, the WG have articulated in this document, core areas of work and key actions that the WG can take to advance the agendas of these workstreams. Prospective accountable owners and timelines are projected to deliver are outlined.

To drive this work described in the proceeding sections below, the WG will employ the following **tools**:

1. **Information sharing & consensus building** - e.g., consultations & fora with other ACT-A Council members & key actors (e.g., manufacturers, suppliers etc.) on matters of concern
2. **Demarché** – signaling & requesting political positions and support (e.g., through letters or bilateral meetings)
3. **Leveraging political leadership at diplomatic and political fora (e.g., ministerial or head of state level engagement.**

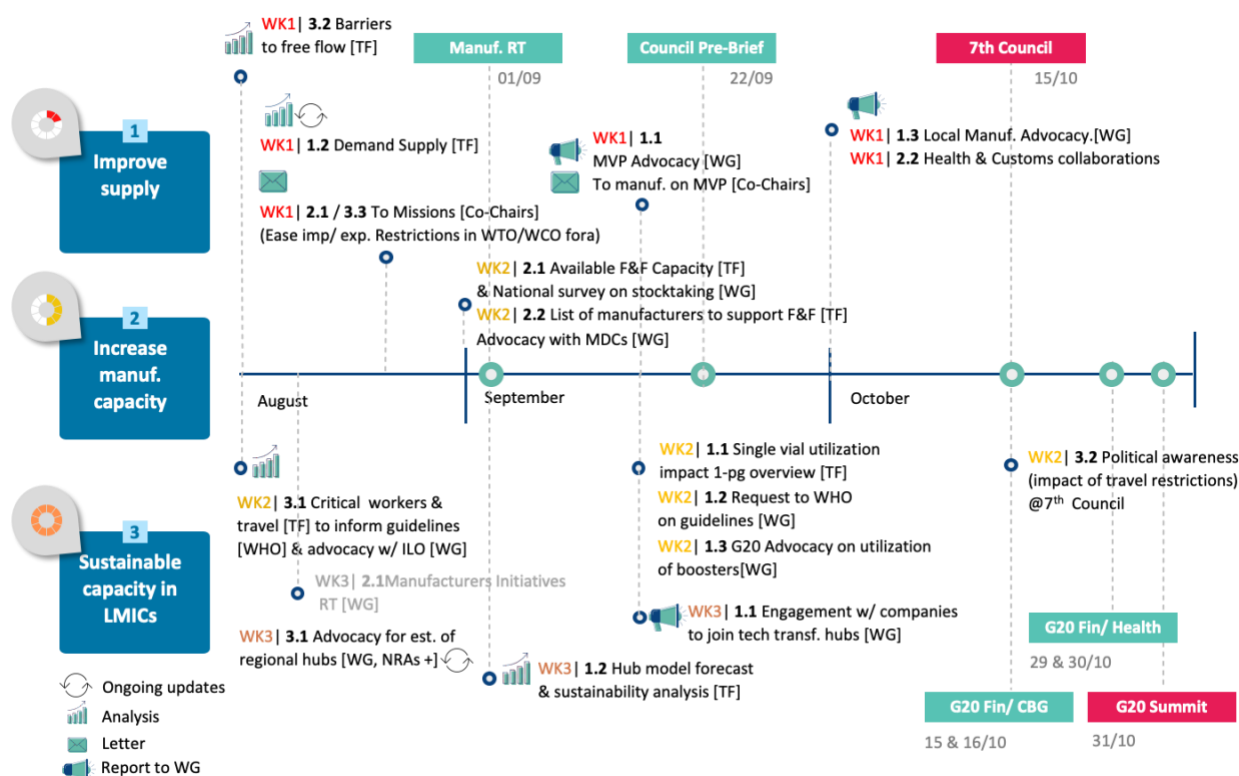
This progress and outcomes of the work articulated in this document will be reported to the G20 in upcoming meetings in October 2021.

***Workplan at a glance: Core Workstreams and Area of Work**



* Workplan executed in collaboration with COVAX Manufacturing Taskforce

High-level timeline to G20 (Oct 2021): *[Numbers reference activities detailed in workplan]*



COVAX Manufacturing Taskforce Workstream 1:

**IMPROVE SUPPLY INPUTS TO VACCINE MANUFACTURING AND INCREASE SUPPLY
OF VACCINES TO COVAX**

Time horizon: Immediate

1. Area of work: Create awareness within local manufacturer and supplier community to join COVAX input supply marketplace

(1.1) Create awareness and advocate for global human biopharma manufacturers and single use/raw material consumable suppliers to join COVAX supply marketplace

Note: Need to promote transparency and articulate incentives for manufacturers and suppliers to join and reduce the practice of safety stocking (for duration of pandemic)

- **Action(s) needed:**
 - i. For countries with suppliers and manufacturers, engage bilaterally, multilaterally (e.g. ACT-A, G7, G20) and through regional platforms (e.g., EU, AU, ASEAN).
 - ii. Co-Chairs to write a letter to industry associations and multilateral actors advocating for them to call for increased participation.
- **Timeline:** Mid-Sep [Report to WG]
- **Owner (s):** Individual WG members and Co-chairs

(1.2) Articulate the demand and supply of critical/essential inputs for vaccine manufacturing at the regional level

Note: to address potential blockages to securing essential supplies and consequently to vaccine production

- **Action (s) needed:**
 - i. Leverage the 08 – 09 March 2021 “Global C19 Vaccine Supply Chain and Manufacturing Summit” and subsequent activities mapping of demand and supply in collaboration with COVID-19 vaccine manufacturers consumables and suppliers and identify chokepoints and mitigations. List of “chokepoints” should be prioritized and contextualized by regional environment and a master list of sources and access to essential raw materials required for various products should be compiled. TF to drive.
 - ii. WG to determine critical political actions members can take (jointly or individually) to address identified chokepoints in regional fora (e.g., EU, AU) particularly those may potentially lead to consumable supply shortages of vaccines and essential inputs for vaccine manufacturing for and in LMICs
- **Timeline:**
 - i. Analysis: ongoing updates

- ii. WG to discuss and align on approaches to address barriers (early Sept)
- **Owner (s):** TF/WTO and WG

(1.3) Advocate for actions that increase supplies and equipment to regional or local manufacturing facilities

- **Action (s) needed:**
 - i. WG to advocate with governments to adopt policies to ease regional/local manufacturing, e.g., utilizing incentives and schemes as needed
- **Timeline:** Mid- Sep [Report to WG]
- **Owner (s):** WG members

2. Area of Work: Advocate for deliberations in WCO and WTO governance/ Member States meetings to introduce/ revise policies that would significantly accelerate expediting customs processes on critical vaccine manufacturing input supplies for vaccines and biologicals manufacture

(2.1) Advocate in various fora of WTO and partners (e.g., WCO, IMF, WB, WHO) to:

- include issues related to customs, procedures, import/export restrictions and tariffs supporting expansion of vaccine production in LMICs, in the various intergovernmental processes of WTO; and
- support efforts for development of standard protocol on custom clearance
- **Action (s) needed:**
 - i. WG members, through bilateral engagements to promote information sharing between countries most affected (as supported by analysis by COVAX allocation group on countries with lowest coverage), to reach alignment amongst states on recommended policy changes at relevant WTO/WCO fora (e.g., process simplification, ease of restrictions)
 - ii. Leverage political leadership to advocate for agreements option of standard protocols for custom clearance of critical supplies including support of new Harmonized System coding
 - iii. WG Co-Chairs to develop a letter advocating for these issues to be circulated with ambassadors in Geneva missions (and dispatched to countries)
- **Timeline:** 3rd week of Aug (letter sent to missions), meeting with missions ASAP
- **Owner (s):** WG members and Permanent mission representatives in Geneva who would discuss this with WTO and WCO

(2.2) Facilitate effective collaboration between health and customs authorities to mitigate additional delays in export/import of critical supplies, including for APIs

- **Action(s) needed:**

- i. WG members to facilitate necessary collaborations on customs between authorities of affected countries. Especially for essential materials and speeding up landing permits for operations carrying essential COVID-19 tools
- **Timeline:** End Sep. [Report to WG by members]
- **Owner (s):** WG members

3. Area of Work: Facilitate rapid creation of needed bilateral and multilateral agreements to ease import-export of needed input supplies (e.g., raw materials, intermediates, or final vaccine products)

Note: To prevent additional export hurdles on key routes, particularly where export delays have been identified

(3.1) Promote development of a model utilizing bilateral and multilateral agreements with aligning guidelines to ease import-export of critical input supplies at all stages *(noting that multilateral agreements take longer to finalize)*

- **Action (s) needed:**
 - i. WG to request WTO to facilitate the drafting of such model bilateral and multilateral agreement(s)
- **Timeline:** Tentatively End 2021
- **Owner (s):** WTO /WCO *(Meeting with both parties still to occur to get feedback). Can be joint activity under 2.1*

(3.2) Facilitate identification of all political and legal barriers, that are hindering free flow of critical supplies and work to prevent these and additional export hurdles on key routes

- **Action needed:**
 - i. WG to request WTO/TF to identify barriers hindering free flow of critical supplies. Based on report from WTO/TF, WG to agree on recommendations to address in consolidated statement to be shared with member states
- **Timeline:** Immediately
- **Owner (s):** WG Members

(3.3) Facilitate Country encouragement of WTO members to expedite forming a longer-term system with supply transparency and oversight

- **Action(s) needed:**
 - i. WG to release statement to WTO on rationale to expedite longer-term system and promote member states to follow-up
 - ii. WG Co-Chairs to develop a letter advocating for these issues to be circulated with ambassadors in Geneva missions (and dispatched to countries) *(Same letter referenced in 2.1)*
- **Timeline:** Letter to be sent 3rd week of August, meeting with missions ASAP
- **Owner (s):** WG members and Permanent mission representatives in Geneva

4. Area of Work: Facilitate the unblocking of general supply issues particularly in bolstering incentives and backstopping measures to encourage manufacturers and suppliers to reduce safety stocking during pandemic and provide input supplies to other COVID manufacturers as possible (e.g., in the case of failed vaccines)

(4.1) Identifying ways to backstop companies that are willing to reduce safety stocks and guarantee supply of consumables if unexpectedly needed (e.g., in future pandemics, surge demand requests).

- **Action (s) needed:** TBD
- **Timeline:** TBD
- **Owner (s):** WG Members

(4.2) Explore possible emergency measures in the interests of public health to compel non-hoarding of essential inputs for the duration of the pandemic if voluntary measures fail.

- **Action needed:** TBD
- **Timeline:** TBD
- **Owner (s):** WG Members

COVAX Manufacturing Taskforce Workstream 2:

INCREASE MANUFACTURING CAPACITY

Time horizon: Mid-term

1. Area of Work: Postpone shift to single dose vials until the acute phase of the pandemic is over

(1.1) Monitor the risk of moving to single dose vials and consider promoting potential alternative solutions, including new technologies.

- **Action (s) needed:**
 - i. Ask TF to provide one page overview articulating the impact of this change in national immunization programs, and impact on global capacity of manufacturing inputs and final goods production, and continue to monitor this action.
 - ii. WHO to engage HIC countries and manufacturers in prioritizing their orders for countries most in need of vaccines to get to sufficient coverage.
- **Timeline:** Mid-End September (TF and WG to report on interactions with respective national industries).
- **Owner (s):** WG members and TF

(1.2) Advocate for multilateral approach to build consensus on postponing shift to single-dose vials acute phase of the pandemic is over, and equitable access to vaccines are achieved globally

- **Action(s) needed:**
 - i. Consensus to be made in multilateral forums like WHO Governing Bodies proceedings, G20 with support of other organisations for WHO to develop global guidelines to delay move to single dose vials given current context.
- **Timeline:** Mid-September
- **Owner (s):** WG to request WHO to create guidelines on this issue.

(1.3) Advocate that boosters for fully vaccinated people should only be employed when there is valid clinical evidence for doing so and not at the expense of fair and equitable access to vaccinations worldwide.

- **Action (s) needed:**
 - i. Build consensus within multilateral and plurilateral forums that booster shots are doses that could be reallocated to LMIC for initial vaccinations.
 - ii. Identify and implement mitigation measures linked to the risk of demand for boosters.
- **Timeline:** Mid-September
- **Responsible:** WG

2. Area of Work: Create awareness and advocate for within local vaccine manufacturer community to reach out to CEPI with their F&F capacity needs and underutilized capacity

(2.1) Identify available F&F capacity in LMICs and HICs, incl in WG member countries

- **Action (s) needed:**
 - i. Commit to disseminate findings (generated by CEPI) through ACT-A, G7, G20 and regional governing bodies (e.g., EU, AU, ASEAN). CEPI to inform WG about how much amount of untapped existing capacity they have identified for F&F and engage collaboration/initiatives with vaccine manufacturers from LMICs to improve underutilized capacity.
 - ii. Ask TF to evaluate costs of retrofitting and constructing new facilities
- **Timeline:** CEPI to inform VMWG by end August, VMWG to preform national survey/stocktaking on available/idle F and F capacity by early Sep.
- **Owner (s):** TF and WG

(2.2) Support the COVAX TF in building capacities for F&F service providers and manufacturers to get Emergency Use Listings or Authorizations from WHO Regulatory Bodies for approved and match-making vaccine regimens where appropriate.

- **Action (s) needed:**
 - i. Ask TF to identify and list available vaccine manufacturing related industries in each LMIC to support the F&F match making mechanism
 - ii. WG to reach out to bilateral and multilateral development cooperation partners in order to find financing for technical assistance for F&F service providers in developing countries.
- **Timeline:**
 - i. TF to inform VMWG by End-Aug.
 - ii. WG to report on programs to support F and F by End-Aug.
 - iii. WG to advocate to multilateral development cooperation (MDCs) partners by 1st week of September.
- **Owner (s):** TF and WG

3. Area of Work: Lift any travel restrictions for critical workers and address their COVID-19 vaccine requirements to support accordingly

(3.1) Promote/propose through UNCTAD, WTO, ILO, WHO & WTO intergovernmental processes to develop guidelines for movement of critical workers

Note: Guidelines should include criteria of critical workers that need prioritization with regards to travel leeway and vaccination

- **Action(s) needed:**
 - i. WG to request TF produce analysis of validating need for this prioritization and informing discussions on criteria development

- ii. WG to utilize analysis to advocate for consensus at a multilateral level on criteria of critical workers needing prioritization.
- iii. WG to foster discussions at ILO and WHO to draft recommendations.
- iv. WG to address this nationally or through regional fora
- **Timeline:** Immediate
- **Owner (s):** TF and WG.

(3.2) Ensure political awareness of unintended effects of travel restrictions and promote international collaborations to minimize such to the extent possible

- **Action (s) needed:**
 - i. Bring forth discussions in ACT-A Facilitation Council (7th Meeting) on provisions for countries to include essential workers (incl. technical vaccine workers) that are vaccinated through WHO EUL'd vaccines to travel.
- **Timeline:** Mid- October
- **Owner (s):** WG co-chairs and ACT-A Hub

4. Area of work: [Streamline clinical trial stages of vaccine development](#)

(4.1) Obtain approval from vaccine developers for comparator vaccines as comparative clinical trials are needed to accelerate the development of vaccines.

- **Action (s) needed:**
 - i. WG to support comparative clinical trials by utilizing political advocacy to facilitate obtaining approval from vaccine developers for comparator vaccines
 - ii. Through bilateral and multilateral engagement support vaccine development to respond to variants and solve global vaccine shortage issue
- **Timeline:** TBD
- **Owner (s):** WG

COVAX Manufacturing Taskforce Workstream 3:

NEW AND EXPANDED SUSTAINABLE CAPACITY IN LMICS

Time horizon: Long-term

1. Area of Work: Encourage approved tech holders to participate with their technology in the hub network being created (and facilitate mutually agreed tech transfer licensing to all LMIC regions)

(1.1) Conduct bilateral outreach to individual companies and relevant governments from the WG and in addition to WG members. Drive political mobilization to set expectations and promote good practice for participant companies and tech holders

i. Action needed:

- i. WG to conduct bilateral outreach to individual companies and relevant governments with proven technology to join tech transfer hubs.
- ii. Facilitate contact between focal points of global network and relevant manufacturers and WHO.
- iii. Promote and advocate for government-supported initiatives/coordination and collaboration between vaccine manufacturers and supporting industries in LMICs to lend tech to hub network.

- **Timeline:** Mid-Sep [Report to WG on engagement with companies]
- **Owner (s):** WG members

(1.2) Better understand the hub model, including a forecast analysis for outcomes of the hub and measures to ensure long term sustainability and support hub operational model

▪ **Action needed:**

- i. Support TF to conduct a forecast analysis for hub's long-term sustainability.

- **Timeline:** 1st week of September
- **Responsible:** TF with support from WG

2. Area of Work: Support to integrate parallel initiatives that could benefit from this effort (to receive technology, benefit from sustainable intra-pandemic support, etc.)

(2.1) Facilitate scoping exercise and map of different initiatives on local vaccine production, gap analysis, and identification of parallel initiatives

▪ **Action needed:**

- i. WG to support TF in conducting scoping exercise and analysis and sharing results with member states (building on existing work by WG/ Hub in this area).

- **Timeline:** TBD

- **Owner (s):** WG and TF

(2.1) WG to convene the major actors (donors/investors/industries) with established or evolving programs in the vaccine manufacturing ecosystem and promote participation in mutually agreed licensing agreements for tech transfer hubs

- **Action needed:**
 - i. WG to share information across major actors in vaccine manufacturing programs and tech transfer hubs. Establish global multilateral forum for vaccine manufacturing and setting up mutually agreed tech transfer licensing agreements. Promote joint support.
- **Timeline:** 18 August WG roundtable w/ major Vx manufacturing initiatives.
- **Owner (s):** WG / WHO/ WTO / Hub

3. Area of Work: Support in-country programs and resourcing needs

(3.1) Promote and advocate for government and IO/IFI-supported initiatives/collaboration between vaccine manufacturer, development banks and supporting industries in LMIC to strengthen national and regional capacity. Particularly support capacity expansion for manufacturers of vaccine inputs that are certified by regulatory agencies

- **Action needed:**
 - i. WG to promote establishment of regional collaboration hubs/constellations between vaccine manufacturers, development banks and relevant supporting industry representatives in LMICs.
 - Note: Vision is to have a global network of technology transfer multi-regional hub(s) / recipients dedicated to LMIC uptake. First hub will be in South Africa, which will serve South Africa and beyond. Intent behind hub model is to replicate learnings and successes in creation of any subsequent hubs.
 - ii. WG to advocate with governments, development banks and other relevant stakeholders to support capacity expansion measures for vaccine inputs manufacturing.
- **Timeline:** Ongoing
- **Owner (s):** WG, National Regulatory Agency (NRA), and others to identify as the work progresses.

(3.2) Identify the nature of resources required once hubs transfer the tech to any country.

- **Action needed:**
 - i. WG to Request TF to undertake a needs assessment exercise for what is required by countries once tech transfer hub has been established, and report back to WG for further recommendation
 - ii. WG to act upon recommendations from TF.
- **Timeline:** TBD
- **Responsible:** WG and TF