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ACT Accelerator Facilitation Council

Vaccine Manufacturing Working Group

Report to the G20

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Executive Summary and Recommendations

Extensive COVID-19 immunization is a global public good. While the speed of the development of COVID-19 vaccines is unprecedented in history, this extraordinary achievement has not yet been sufficient to stop the COVID-19 pandemic. This disease is still destroying lives and livelihoods across the globe, exposing structural weaknesses and deepening inequities.

Access to COVID-19 vaccines remains highly inequitable. Despite a predicted total global COVID-19-vaccine production of 11 billion doses in 2021, sufficient to vaccinate 70% of the world population, currently available vaccine doses are particularly lacking in sufficient quantity in low- and lower-middle-income countries. Only 20% of people in low- and lower-middle-income countries have received a first dose of vaccine compared to 80% in high- and upper-middle income countries. In Africa, merely 5% of the population is fully vaccinated.

At the beginning of the pandemic, the main focus was on research and development of vaccines. However, it soon became evident that **scaling-up global production capacities and supply chains**, **restrictive trade measures,** as well as the **lack of regional vaccine manufacturing capacities, and inputs and ancillary supplies are key bottlenecks for equitable access**. Only 1% of vaccine production is currently located on the African continent. To remedy inequitable access to safe and effective WHO-approved[1] vaccines and to increase security of supply worldwide in accordance with the goals formulated by the WHO is of the highest priority.

Against this background the **Access to Covid Tools Accelerator (ACT-A) Facilitation Council Vaccine Manufacturing Working Group** (VMWG)[2] was set up and politically mandated by G20. Its objective is to provide political support the COVAX Manufacturing Task Force led by the WHO, Gavi and CEPI, that has elaborated short-, medium and long-term measures to address COVID-19 vaccine manufacturing challenges.

To address the acute phase of the pandemic, which is currently mainly a vaccination crisis, the VMWG, in line with the request of the G20 Global Health Summit on 21 May and its mandate to politically guide and support the work of the COVAX Manufacturing Task Force led by Gavi, CEPI and the WHO, presents the **following recommendations to the G20 with regard to vaccine manufacturing and closely related topics to optimize and strengthen supply chains**.

The recommendations were developed **based on VMWG's close engagement with relevant stakeholders** working towards increasing global production capacities and achieving equitable access, like the COVAX Task Force, WTO, WCO, WB, other major vaccine initiatives, manufacturers, and pharmaceutical associations. These recommendations reflect the three workstreams of the Work Plan adopted by the VMWG. While the workstreams 1 and 2 aim at improving short-term supply towards the global vaccination target of 70% set by WHO, the third workstream endeavours to facilitate longer-term vaccine production sustainability.

[1] Please note that this definition applies for the rest of the text.
[2] VMWG members include: South Africa and Germany (Co-Chairs), China, Brazil, India, Indonesia, Republic of Korea, Norway, Rwanda, Saudi Arabia and the United States of America.

Recommendations of the ACT Accelerator Facilitation Council Vaccine Manufacturing Working Group Report to the G20

Workstream 1

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

- With a view to improving transparency on demand and supply of critical and essential inputs and equipment for vaccine manufacturing worldwide and at regional level, the COVAX Task Force set up a Marketplace on vaccine input supply. The VMWG welcomes this important step and **calls on G20 to increase industry awareness and encourage local manufacturer and supplier communities to participate in the Marketplace.**

- To increase transparency on supply of vaccines, including dose sharing, **G20 members should encourage accountability in vaccine donations and deliveries and use COVAX as the primary mechanism for such donations,** including by expediting the delivery of approximately 2.0 billion already committed doses of COVID-19 vaccines. **G20 countries should urge manufacturers to fulfill and prioritize their contracts to COVAX and other relevant regional initiatives**. It is essential to share with COVAX and recipient countries well in advance details on supply forecasts and **delivery schedules** for all vaccine shipments, and to speed up the **negotiations of contract models** for vaccines both for resale and for donations. The VMWG calls on G20 members, wherever possible, **to promote earlier delivery of doses including swaps to low- and lower-middle-income countries through COVAX and fully exploit their potential for dose donations**, clearly prioritizing unearmarked upfront deliveries to COVAX and ensuring doses are available in larger and more predictable volumes, with longer shelf lives.

- **G20 should support WTO and WCO Member States and Secretariat** to drive forward deliberations and, as appropriate, to implement recommendations to improve coordination and information sharing. In order **to reduce unnecessary barriers at the border, address relevant supply chain vulnerabilities, improve regulatory cooperation and compatibility, and accelerate implementation of the Trade Facilitation Agreement best practices need to be developed; moreover, undue export and import restrictions and tariffs, customs and regulatory bottlenecks, or other political and legal barriers to facilitate trade need to be addressed** in favor of the provision of safe and effective COVID-19 vaccines and the raw materials and supplies required for the production and timely distribution of vaccines.

Workstream 2

INCREASE MANUFACTURING CAPACITY

- To ensure equitable global access to vaccines and input supplies (1) the **shift from multi dose vials to single dose containers should be postponed until global equitable access to vaccines is achieved,** in order to avoid multiplication of demand for already critical Fill & Finish capacity and scarce raw materials; (2) **Stockholding of vaccines and input supplies should be limited** to prioritize delivery to those who are most in need; (3) **Boosters should only be administered on the basis of valid clinical evidence**, especially for vulnerable populations, taking into consideration WHO recommendations and not at the expense of fair and equitable access to vaccinations at national, regional and global level. (4) In order to expand vaccine supply by increasing vaccine manufacturing capabilities, the **supply of comparator vaccines should be facilitated and cooperation on production** such as CMO, CRMO agreements through bilateral and multilateral cooperation with organizations like CEPI should be encouraged.

Workstream 3

NEW AND EXPANDED SUSTAINABLE CAPACITY IN LMICS

- **G20 should call on manufacturers, suppliers and other pharmaceutical and international stakeholders and organizations to engage proactively with partners globally** to jointly define targets to accelerate and ramp up regional vaccine and input supply production**. G20 should support the use of flexible cooperation models** such as building up **fill & finish capacities**, **technology partnerships and licensing activities** as well as **joint ventures for production and innovation** in the global pharma and vaccines sector, including through support for regulatory strengthening, consistency and standardization. In terms of **financial engagement, public and private stakeholders should combine their efforts,** also including concessional and capital-based instruments.

- **G20 should support the mRNA technology transfer hub in South Africa as a flagship project** for the transfer of technology and for the development of knowledge, skills, and networks in vaccine manufacturing, take note **and support current discussions on other regional mRNA manufacturing Hubs for the LAC region**. G20 should also encourage technology holders, economic players, and governments to **constructively engage with the mRNA technology transfer hub** and the regulatory, training and institutional **ecosystems** in which it is embedded. **Market shaping aspects** should be taken into account to ensure the long-term sustainability of the project, especially the demand side and the involvement of key representatives such as Gavi, UNICEF and the GFATM as well as relevant regional initiatives. Lessons learnt and outcomes of the hub operational model should be made available quickly and transparently to **benefit other initiatives** (including bio training initiative for LMICs).

OVERARCHING RECOMMENDATION

Recognizing a multitude of multilateral (such as MLT) and bilateral initiatives that currently address vaccine manufacturing issues, the VMWG recommends to the **G20 to support close coordination to ensure complementarity.**

Next steps

The following next steps are proposed to be monitored by VMWG and ACT-A Hub in coordination with other multilateral and bilateral vaccine manufacturing initiatives:

- The VMWG will organize a **follow-up meeting between the VMWG, the COVAX Task Force, and major manufacturers and pharmaceutical associations** in November 2021 to deepen the exchange on immediate priorities and challenges and to promote good practices, related to all workstreams of the work of COVAX Task Force.

Workstream 1: Improve supply inputs to vaccine manufacturing and increase supply of vaccines to COVAX

- The VMWG members will **continue to promote the COVAX Marketplace** and to further increase awareness; a newsletter is expected to be published by CEPI in the coming weeks.
- Based on the indicative list of barriers issued by WTO and WCO, the VMWG members will **continue to address identified chokepoints and advocate for easing import-export** of relevant COVID-19 input supplies.

Workstream 2: Increase manufacturing capacity

- The VMWG will **continue to monitor the risk of moving to single dose vials** and consider promoting alternative solutions.
- With regard to **boosters**, the aim is to identify and implement mitigation measures as required to minimize risks to a fair and equitable access to COVID-19 vaccinations worldwide.
- To support the COVAX TF in building capacities for F&F service providers in developing countries, the VMWG will **continue to reach out to bilateral and multilateral development cooperation partners** in order to find sufficient financing.

Workstream 3: New and expanded sustainable capacity in LMICs

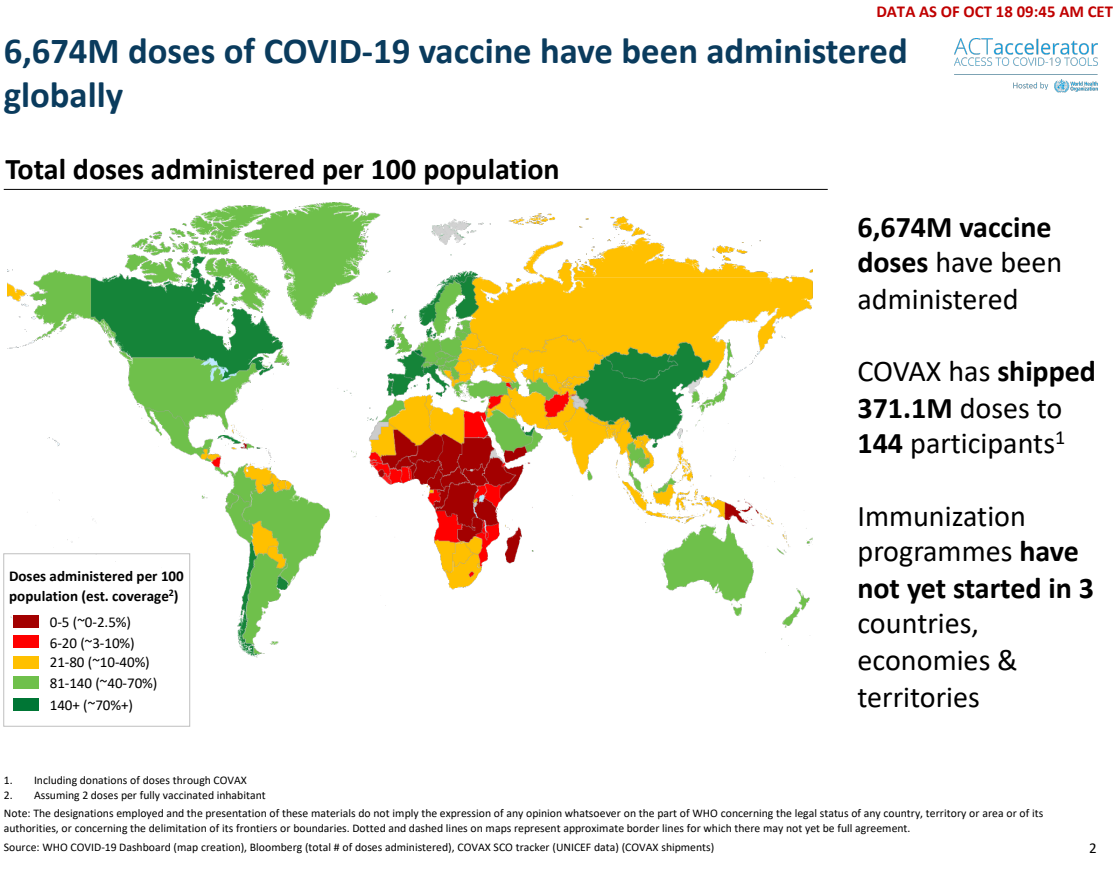
- The VMWG will work to **improve coordination between local, regional, and global initiatives** related to expanding sustainable capacity in LMICs.
- To support in-country programs and resourcing needs, the working group 6 “Workforce development” under workstream 3 of the COVAX TF will **identify workforce training needs** for both the hub(s) and recipients.
- The VMWG will **continue promoting the establishment of regional collaboration hubs** and will assess in cooperation with the Covax Task Force what resources are required by countries once the infrastructure for technology transfer hubs has been established.

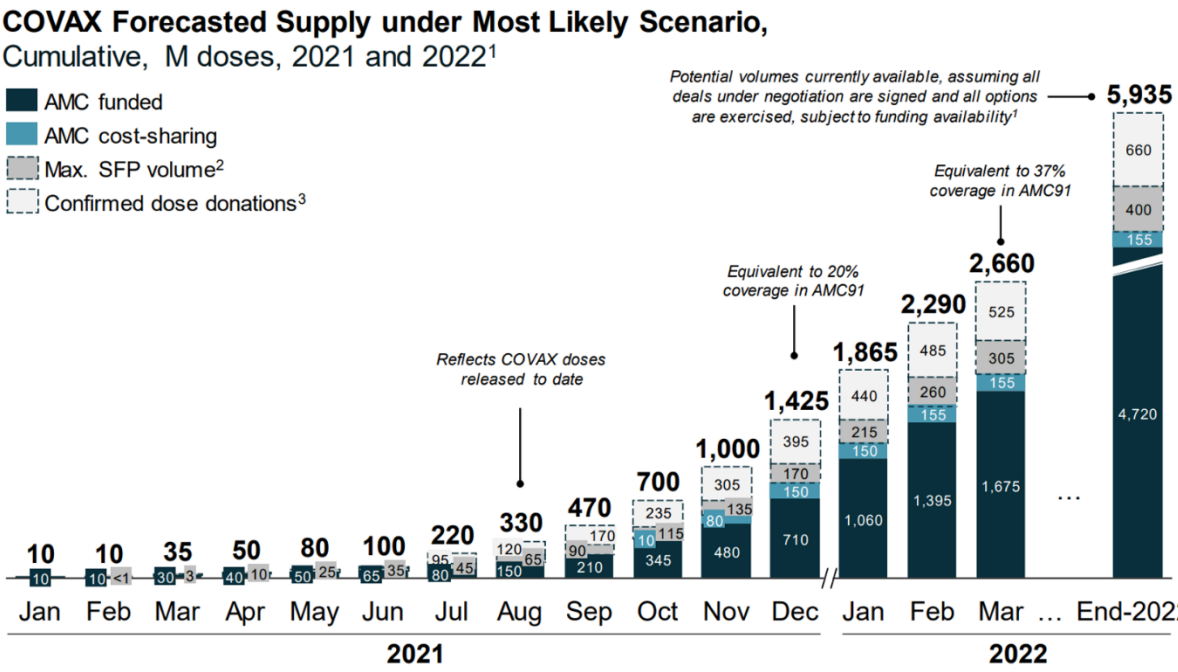
Background - ACT Accelerator Facilitation Council Vaccine Manufacturing Working Group

The ACT-A, launched in spring 2020 following a G20 commitment, is a collaboration between governments, scientists, businesses, civil society, philanthropists, and global health organizations to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. The ACT-A is organized into four pillars of work: diagnostics, treatment, vaccines, and the health system connector.

The ACT-A Facilitation Council provides advice and guidance to ACT-A pillars, principals, and partners, as well as global leadership and advocacy for the initiative. The Council consists of diverse representation of global leaders and partners and includes ACT-A members and donors, market shapers, and regional cooperation groups. It is co-chaired by Norway and South Africa and hosted by the WHO.

Ending the acute phase of the pandemic will require global equitable access COVID-19-vaccines and other life-saving therapies, diagnostics, and medical tools.





Supply shortages due to difficulties in scaling-up production capacities, access to vaccines heavily concentrated in high-income countries as well as export restrictions, and other setbacks forced the COVAX Facility to reduce its original goal of distributing 2 billion doses of COVID-19 vaccines by the end of 2021 to just over 1,4 billion doses. The VMWG was set up by the Facilitation Council and is mandated by the G20; it aims to address political bottlenecks and barriers to increase vaccine supply through COVAX. It provides high level political support to the COVAX Vaccine Manufacturing Task Force, led by the WHO, Gavi and CEPI, in its mission to increase the supply of COVID-19 vaccines to COVAX as well as to set up long term sustainable vaccine manufacturing capabilities in LICs and LMICs.

The membership of the VMWG was determined by the Facilitation Council discussions. The Co-Chairs of the Facilitation Council selected countries from different regions, based on expressed interest, including both vaccine manufacturing countries and countries intending to advance this agenda. With Germany and South Africa acting as co-chairs, the VMWG is comprised by eleven members: Brazil, China, India, Indonesia, Republic of Korea, Norway, Rwanda, Saudi-Arabia, and the United States.

The VMWG has met biweekly for two sessions, respectively, since its inception meeting in June. After thorough consultations and with the aim to provide efficient, swift and impactful support to the COVAX TF, the VMWG has developed and started to implement activities under a comprehensive work plan with short-, medium- and long-term measures, based on input from COVAX TF and further stakeholders:

- Short-term: Improve supply inputs to vaccine manufacturing and increase supply of vaccines to COVAX
- Medium-term: Increase Manufacturing Capacity
- Long-term: New and expanded sustainable capacity in low- and middle-income countries

Since its launch, the VMWG has been supported intensively by the ACT-A Hub at the WHO. To monitor progress, VMWG members and the COVAX TF provide regular updates on the implementation status of the work plan; collective inputs are consolidated in a dashboard.

The implementation of the VMWG Work Plan comprises a wide range of actions and activities. With the aim of improving input supply availability, the VMWG is promoting the COVAX Marketplace launched by CEPI, which matches suppliers of critical inputs with vaccine manufacturers and thereby accelerates the global production of COVID-19 vaccine doses for COVAX. Other activities focus on identifying and addressing trade-related barriers as well as easing import-export of required input supplies to address short-term supply constraints. The VMWG has also implemented measures to maximize medium-term manufacturing capacity, including the facilitation of "fill and finish" (F&F) matchmaking as well as regulatory, funding and workforce interventions. Moreover, key measures are being taken to build new and expanded production capacity in low- and middle-income countries. These include support to the creation of a global mRNA vaccine Technology Transfer Hub in South Africa as well as raising awareness among the vaccine industry of the work of the COVAX TF and the VMWG and encouraging technology holders in the hub network. Moreover, efforts have been made to support the integration of parallel initiatives in order to maximize the impact of the COVAX TF's work and to harness synergies. The COVAX TF and the VMWG also support the sustainable development of manufacturing ecosystems, including harmonization of regulations and certification, research, development, and education.

Key Deliverables – COVAX Manufacturing Task Force and Vaccine Manufacturing Working Group

To address challenges to equitable access to vaccines, the COVAX TF has the following vision and objectives:

- Support COVAX's mission to end the acute phase of the pandemic by the end of 2021,
- Optimize short-term vaccine dose manufacturing,
- Prioritize doses for COVAX with an emphasis on AMC92 to ensure greater equity,
- Mitigate any unintended impact on other vaccines and health products,
- Reinforce regional health security through establishment of sustainable regional long-term manufacturing of vaccines.

To support this mission, three workstreams were organized to improve the availability of input supply in the short term (workstream 1), maximize mid-term manufacturing capacity (workstream 2), and support new and expanded sustainable capacity in LMICs in the long term (workstream 3). The political support of the VMWG is oriented toward these workstreams. This chapter reports on the progress made by each workstream to date.

Workplan of the Vaccine Manufacturing Working Group (VMWG)

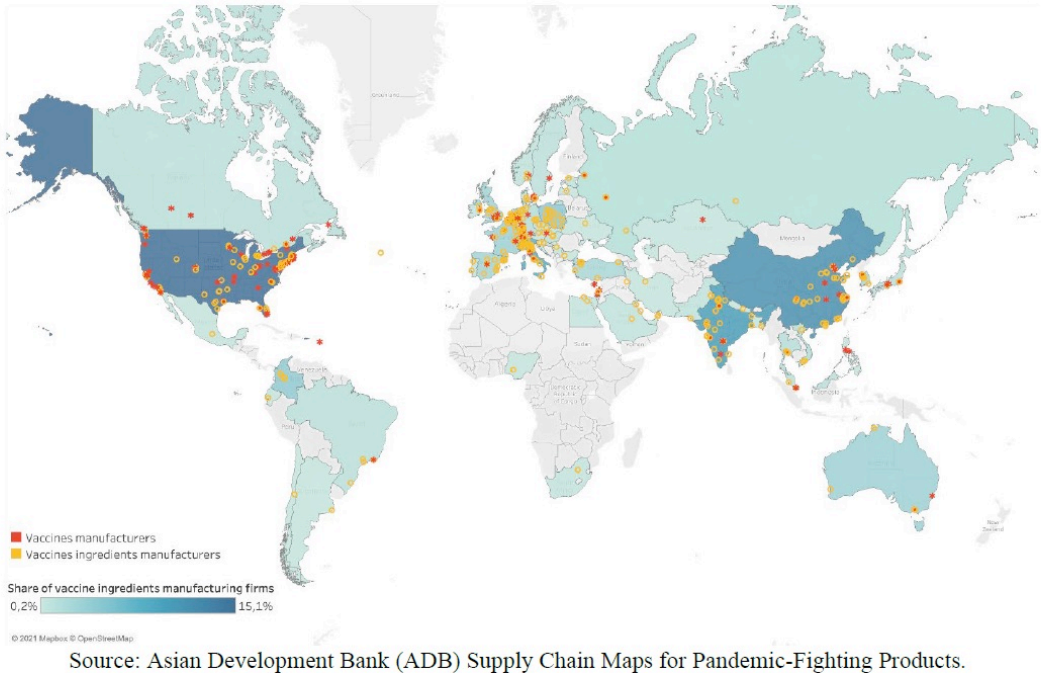
WORKSTREAM	AREA OF WORK
1 - Improve Supply Inputs to Vaccine Manufacturing and Increase Supply of Vaccines to COVAX	**(1)** Create awareness within local manufacturer and supplier communities to join COVAX input supply Marketplace
	(2) Advocate for deliberations in in WCO and WTO governance/ Member States meetings to introduce/revise policies that would significantly accelerate expediting customs processes on critical vaccine manufacturing input supplies for vaccines and biologicals manufacture
	(3) 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
	(4) 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 to provide input supplies to other COVID-19 vaccine manufacturers as possible, e.g. in case of failed vaccines
2 – Increase manufacturing capacity	**(1)** Postpone shift to single dose vials until the acute phase of the pandemic is over
	(2) Create awareness and advocate for within local vaccine manufacturer community to reach out to CEPI with their Fill & Finish capacity needs and underutilized capacity
	(3) Lift any travel restrictions for critical workers and address their COVID-19 vaccine requirements to support accordingly
	(4) Streamline clinical trial stages of vaccine development

3 - New and expanded sustainable capacity in LMICs	**(1)** 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)
	(2) support to integrate parallel initiatives that could benefit from this effort (to receive technology, benefit from sustainable intra-pandemic support, etc.)
	(3) Support in-country programs and resourcing needs

Workstream 1: Improve supply inputs to vaccine manufacturing and increase supply of vaccines to COVAX

The first workstream focuses on improving short-term supply inputs. Its aim is to introduce a **marketplace** for the supply of critical inputs, to facilitate the global unrestricted flow of critical supplies for vaccine production, and to expand the medium-term availability of input supply capacity. It is led by the Coalition for Epidemic Preparedness Innovations (CEPI) and has a timeline of 1 to 6 months with activities expected to be finalized by the end of 2021.

Distribution of vaccine and vaccine ingredient manufacturers



Source: Asian Development Bank (ADB) Supply Chain Maps for Pandemic-Fighting Products.

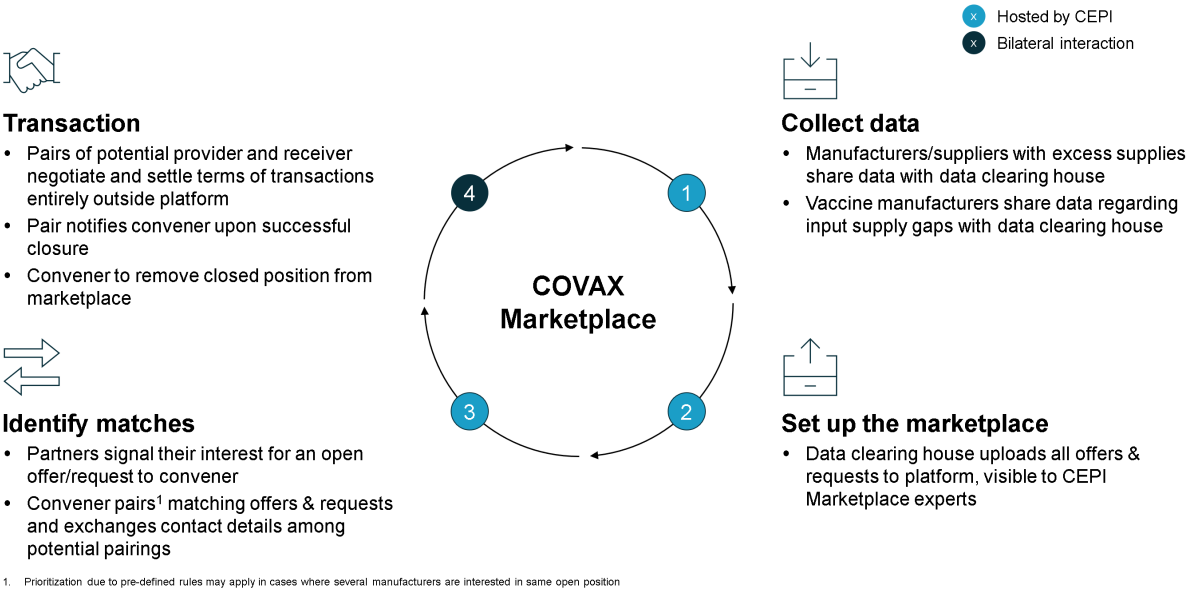
Area of work: Create awareness within local manufacturer and supplier communities to join the COVAX input supply Marketplace

Expanding manufacturing capacity requires managing intricate cross-border supply chains, which frequently involve more than 100 components. The past year has seen unprecedented efforts by vaccine manufacturers and suppliers of vaccine components to triple previous annual vaccine output. According to latest estimates, 11 billion doses of COVID-19 vaccine

will be produced by the end of 2021.[3] Restrictive trade measures and the infrastructure pressures created by this rapid upscaling have created bottlenecks in the availability of critical input materials which affect the global supply chain and cause acute shortages of vital supplies. Resulting delays in production restrict COVAX's ability to ensure rapid and equitable access to COVID-19 vaccines.

In response, CEPI and COVAX partners launched the COVAX Marketplace on July 19th, 2021, under the first workstream of the COVAX Task Force to accelerate the global production of COVID-19 vaccine doses for COVAX by matching suppliers of critical inputs with vaccine manufacturers. The COVAX Marketplace provides suppliers with a platform to allocate and reallocate unused materials and mobilize idle stock from vaccines, unsuccessful candidates, and potential surplus stock from manufacturers with non-vaccine activities. The Marketplace operates based on a lean, circular logic that starts with vaccine manufacturers sharing input supply gaps and consumable suppliers sharing excess supplies and ends with a successful matchmaking between potential provider and recipient.

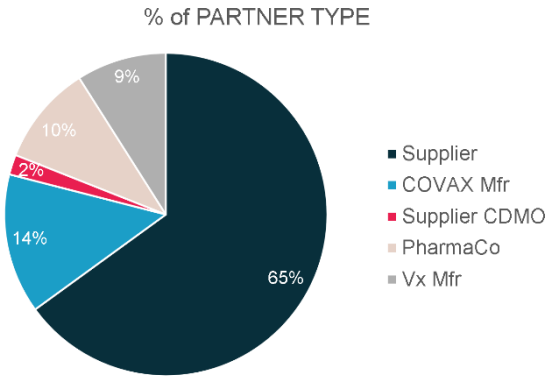
The input supply marketplace runs by a lean circular logic



In support of the COVAX TF, the **VMWG held a roundtable with industry on September** 1st, 2021, to increase awareness among manufacturers; in addition, VMWG members like China, Germany, India, Norway, South Africa, Republic of Korea, and the United States, promoted and advocated for the Marketplace in different fora to local manufacturer and supplier communities. For example, the VMWG co-chairs Germany and South Africa used the WTO-WHO High Level Dialogue on "Expanding COVID-19 Vaccine Manufacture to Promote Equitable Access" on July 21st, 2021, to raise awareness about the newly launched COVAX Marketplace.

[3] https://www.airfinity.com/insights/how-much-vaccine-will-be-produced-this-year

As of September 15th, 2021, fifteen active partners – suppliers and manufacturers – have joined the Marketplace, with an additional thirty-five partners under review. To expand the Marketplace to more partners, its legal terms and conditions were recently broadened to allow for the participation.

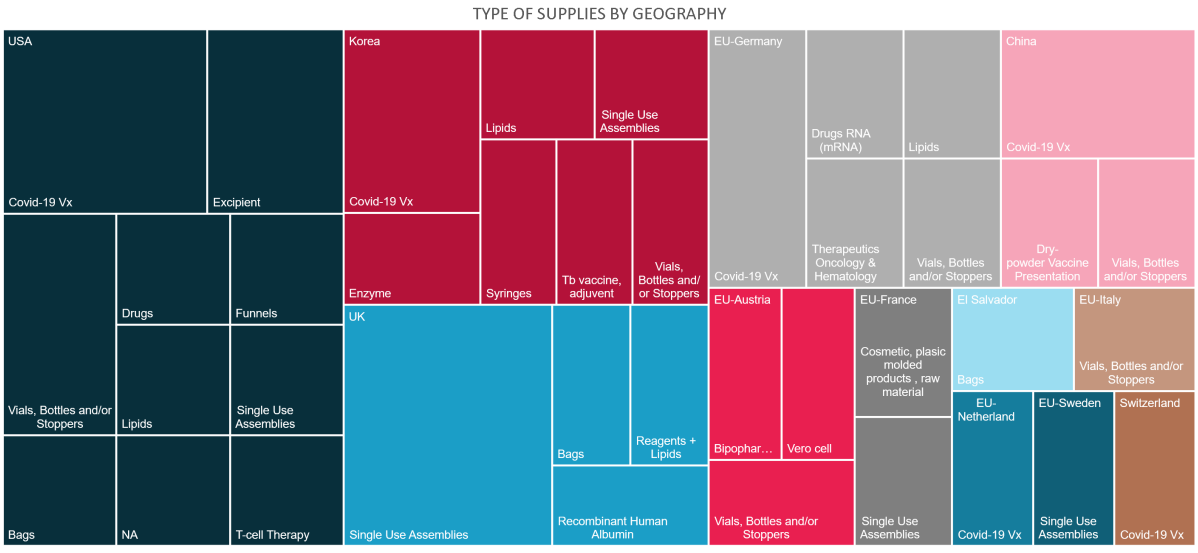


The **first and second successful matches** concluded the week of September 13th, 2021 and enabled:

- 3.3 million stoppers to produce an estimated 33 million vaccine doses,
- Cell media growth that will result an estimated 45 million vaccine doses.

These matches are expected to produce approximately 78 million vaccine doses, of which 45 million will be prioritized for COVAX.

Interest in the Marketplace spans the globe and includes companies from countries such as Republic of Korea, Germany, China, the United States, and Sweden, among others. The graphic below contains type of supply by geography for both signed and pending partners. Outreach continues through industry and governments to increase participation; the first Marketplace "newsletter" is expected to be published in the coming weeks.



The next phase of the Marketplace will be to find a new home so that the legal terms and conditions can be further broadened to allow for partners that manufacture or supply other human vaccines and therapeutics and so that there is a standing structure to manage future shortages and crisis

Area of Work: Advocate for deliberations in WCO and WTO governance and Member States meetings to introduce and revise policies that could significantly accelerate expediting customs processes

Manufacturers have brought attention to restrictive trade measures and several constraints they are facing in their efforts to scale up existing production capacities. These include issues related to border clearance and regulatory approval procedures, import/export restrictions, and tariffs. These issues have also been identified and discussed during a roundtable with major vaccine manufacturing initiatives and relevant stakeholders organized by the VMWG on August 18th, 2021 (see section 3.3.2 for details). The VMWG members address these issues through their advocacy work in various fora of the World Trade Organization (WTO), the World Customs Organization (WCO) and partners to facilitate exchange on how to address these challenges with the goal of expanding vaccine production in LMICs. Particular attention was put on addressing trade-related barriers and travel restrictions for critical vaccine workers. These fora were also used to advocate for the COVAX Marketplace and to encourage approved technology holders to participate in the hub network being created by the COVAX TF (see section 3.3.1 for details). To this end, the Permanent Missions of VMWG member states in Geneva facilitated an exchange between the VMWG Co-Chairs with WTO Secretariat on manufacturing and supply issues. In addition, the COVAX TF has explained its work and shared its findings on supply chain bottlenecks in outreach activities with WTO and its Members, including a briefing for the Facilitator appointed by the Chair of the WTO General Council to take forward consideration of WTO's response to COVID-19 pandemic. In parallel, the COVAX TF is continuing to provide to WTO market intelligence on Marketplace supply chain challenges.

Area of Work: Facilitate rapid creation of needed bilateral and multilateral agreements to ease import-export of needed input supplies

To further facilitate rapid border clearance, the WTO Secretariat has issued an indicative list of trade-related barriers impacting critical inputs for the manufacturing, distribution and administering of COVID-19 vaccines.[4]

The list has been prepared and updated by the WTO Secretariat based on contributions by other key organizations (especially in the context of the Multilateral Leaders Task Force) and other stakeholders (including the WCO), and consultations with the private sector. Together with the WTO's work in collaboration with the WCO on improved, more granular statistical tools, this enhances transparency by affording a more focused, timely and more precise information base on the impact of trade policy settings on the production and distribution of vaccines.

Building on this, the VMWG members advocated for easing import-export of these input supplies. The United States, for example, provided regular updates and facilitated discussions on import-export challenges in the “Joint COVID-19 Manufacturing and Supply Chain Taskforce” between the United States and the European Commission. Advocacy at the political level by the VMWG members also led to the introduction of regulation that

[4] https://www.wto.org/english/tratop_e/covid19_e/vaccine_inputs_report_e.pdf

facilitates import duty and tax exemptions for vaccines, as well as for vaccine-related materials and equipment in Indonesia.

Workstream 2: Increase Manufacturing Capacity

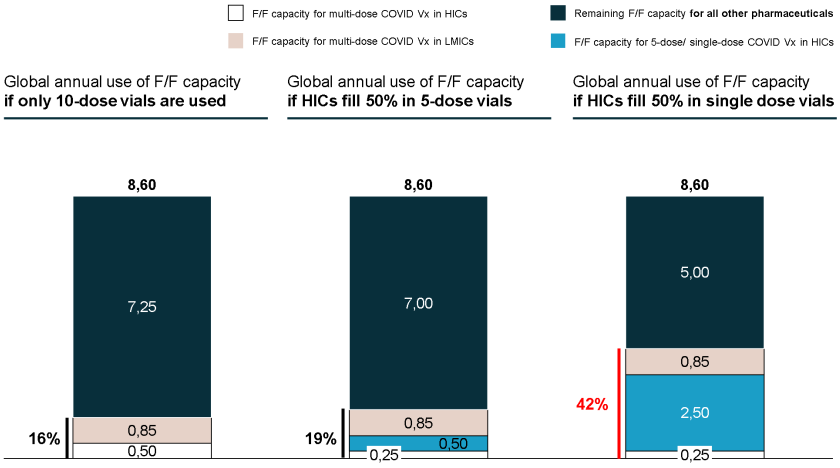
The second work stream is jointly led by CEPI and Gavi and focuses on increasing medium-term manufacturing capacity. It aims to maximize the expansion of medium-term manufacturing capacity through measures like the facilitation of F&F matchmaking as well as regulatory, funding, and workforce interventions. It also aims to create a consolidated overview of manufacturing capacities.

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

To better understand influencing factors to fill and finish match making, the COVAX TF conducted a strategic analysis on vaccine drug product containers (e.g., vials, syringes). It noted that, as the demand for vaccines is decreasing in countries with higher vaccination rates, vaccine manufacturers are currently evaluating moving to single-dose containers where the vaccine is delivered in a vial meant for the use for a single patient. However, this shift could heighten supply constraints for several reasons: first, containers for COVID-19 vaccines occupy a significant portion of global glass manufacturing capacity, which are fully utilized until end of 2022. Due to limited production capacity and raw materials, glass manufacturers can either produce multidose or single dose vials. Secondly, single dose containers would multiply the demand for F&F capacity, which is already in critical shortage. It would also constrain the testing capacity for vaccine releases at vaccine manufacturers and health authorities, as it would result in five to ten times more batches to be released for the same total number of doses. Thirdly, single dose vials require significantly more cold chain space leading to possible negative impacts on the cold chain distribution.

If HICs start to fill only half their Vx as single-dose, F&F capacity occupation increases from 16% to 42%

ILLUSTRATIVE – SCENARIO ANALYSIS



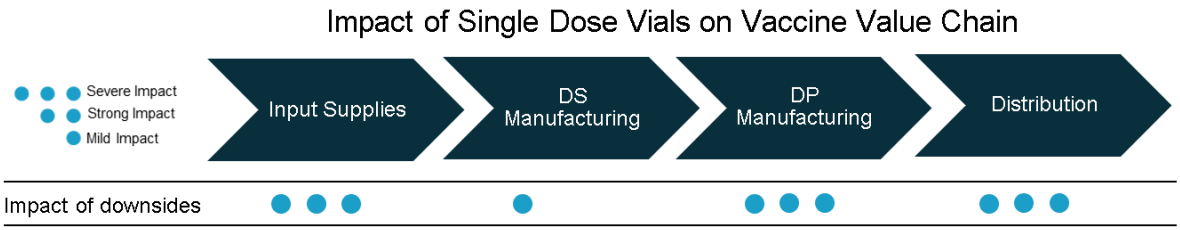
Assumptions: 1. 8,5bn doses/year for LMICs; 2. 5bn doses/year for HICs; 3. Average 10 doses per multidose vial; 4. Only vial capacity considered, other process implications such as duration not considered; 5. Prefilled syringes will not be of relevance for overall volumes; 6. Similar vial volumes in 2022 full year as in 2021 full year

Source: Global market benchmark for pharmaceutical vials; Scenario analysis

HICs may consider the introduction of single-dose vials as they move from mass vaccination to more targeted efforts once their population's majority has received the first round of Vx

Single-dose vials **multiply the demand for fill/finish capacity and input supplies** (e.g., vials), **aggravating** their **critical shortage**

This has the potential to **significantly impact available fill/finish capacities for COVID-19 vaccine doses and all other vial-filled pharmaceuticals for other countries**



To ensure that existing manufacturing capacities are used in the most efficient way, the VMWG is therefore advocating to postpone a shift to single dose vials until the acute phase of the pandemic is over. Some VMWG members like China and the United States have already stated that they are not pursuing single-dose vials at this time, while others plan to further discuss this issue with their local manufacturer and supplier community. The VMWG will continue to monitor the risk of moving to single dose vials and consider promoting potential alternative solutions, including new technologies. The Manufacturing Taskforce recommends that countries and manufacturers hold off transiting to single-dose containers until the WHO recommendation of 70% fully vaccinated coverage by mid- 2022 is met. It is particularly important for countries that are, or are anticipating, third dose vaccinations for their populations to contribute to equitable global access by holding off on single-dose containers. The downside for moving to single-dose containers not only impacts the COVID-19 landscape. It could also significantly impact other human vaccines and therapeutics that require mass volumes of vials (e.g. measles-mumps-rubella (MMR), pentavalent, polio, etc.).

Due to recent studies which indicate waning efficacy of COVID-19 vaccines over time and reduced effectiveness against the Delta variant[5], some countries decided to offer booster shots for certain population groups in Q3 2021, mainly those at higher risk. While these decisions aim at safeguarding accomplished efforts to end the pandemic, the VMWG is aware of their possible impact on the global vaccine supply and equitable access to COVID-19 vaccines, especially for LMICs. Therefore, the VMWG advocated that booster shots for fully vaccinated people should only be administered based on valid clinical evidence and not at the expense of fair and equitable access to vaccinations worldwide. Several countries – also member countries of the VMWG – had discussions within its government on this issue. At the EU-level, discussions are ongoing.

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

While there are no accurate estimates of worldwide F&F capacity, industry observers believe there is a need for over 10 billion vials. Therefore, additional F&F capacity is needed for all COVID-19 vaccines as well as for many other vaccines to accelerate the process to meet the global demand. The VMWG is working closely with CEPI to support this need.

CEPI has close relationships with local vaccine manufacturing communities. Assessments to identify available local manufacturing with F&F capacity have been conducted in Indonesia and Republic of Korea which led to the identification of several local manufacturers with F&F capacity (for example, KoreaVaccine Co., Ltd., LG Chem). Brazil also evaluated unit

[5] https://www.ndm.ox.ac.uk/files/coronavirus/covid-19-infection-survey/finalfinalcombinedve20210816.pdf

operations and productive operational capacities installed in animal health laboratories with the potential to perform upstream, downstream as well as F&F steps of human vaccines production to make more production capacities available. This is additional to already ongoing licensed production of COVID-19 vaccines by the Bio-Manguinhos Institute of Technology in Immunology (FIOCRUZ) (AstraZeneca's Vaxzevria) and the Butantan Institute (Sinovac-CoronaVac) in Brazil. Korea has proposed to increase vaccine manufacturing capabilities by cooperation between vaccine developers and CMOs and CRMOs through multilateral cooperation with organizations like CEPI and bilateral partnerships. This is in line with the WHO goal of vaccinating 70% of the global population before the 2022.

The VMWG members support the establishment or upgrading of vaccine manufacturing facilities, particularly in LMICs by leveraging appropriate mechanisms and business processes. Indonesia, for example, is conducting discussions with multilateral development cooperation partners for technical assistance for F&F service providers in developing countries. India reports that efforts are being made under the Indo-United States Vaccine Action Program and the Indo-CEPI initiative to support in-country vaccine development and manufacturing efforts. These efforts are leveraged through the Quad Cooperation, an alliance between including the United States, Australia, India, and Japan. Germany reports on investment in expansion of F & F capacity e.g. in South Africa and possibly Senegal.

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

At the beginning of the pandemic, travel restrictions were enforced as a public health measure to contain the further spread of the SARS-CoV-2 virus. These were critical to slow down the pace of the pandemic, especially as therapeutics and vaccines were not available at the time. However, travel restrictions and border closures have severely affected sectors which are dependent on global value chains and on international travel. These restrictions are still largely in place and also affect critical workers in the field on vaccine manufacturing. This constrains efforts to increase manufacturing capacities, for example because trainings cannot take place. Thus, the VMWG has been supporting discussions to exempt essential and technical staff from travel restrictions. This issue was also highlighted by the Co-Chairs to the WTO and further discussed at the ACT-A Facilitation Council in mid-October.

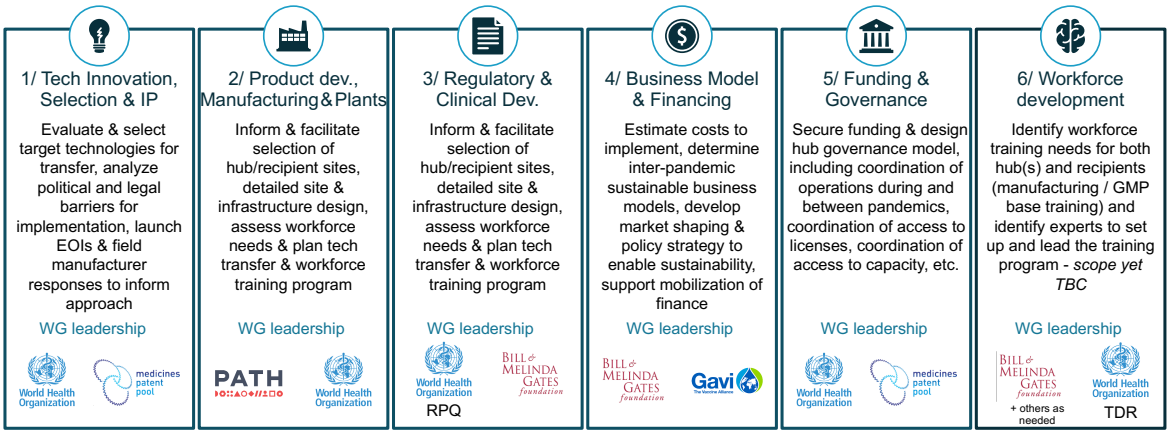
Area of work: Streamline clinical trial stages of vaccine development

The VMWG supports comparative clinical trials by utilizing political advocacy to facilitate obtaining approval from vaccine developers for comparator vaccines. Through bilateral and multilateral engagement support, vaccine development will be enabled to respond to variants and solve global vaccine shortage issues. Clinical trial collaboration with various vaccine developers has beneficial outcomes, such as capacity building in clinical trial management and establishing a gateway for further collaboration, such as procurement deals and F&F collaboration. For this reason, bilateral outreach to mRNA vaccine developers and manufacturers (industries and universities) has been conducted.

Workstream 3: New and Expanded Sustainable Capacity in LMICs

The third workstream aims at expanding capabilities of existing manufacturers in low- and middle-income countries; in addition, it supports the creation of sustainable capacity in regions that do not have significant existing manufacturing capacity to date. This is critical both to ensure regional health security and to empower LMICs. The workstream is led by WHO and the Medicines Patent Pool (MPP) and designed with a long-term perspective that goes beyond the COVID-19 pandemic.

Successfully achieving these objectives will require identifying and implementing manufacturing innovations that will permit cost-effective production and facility maintenance; moreover, normative frameworks to accelerate product development and approval across technology recipients need to be developed. Six working groups have been established:



Area of Work: Encourage approved tech holders to participate with their technology in the hub network being created

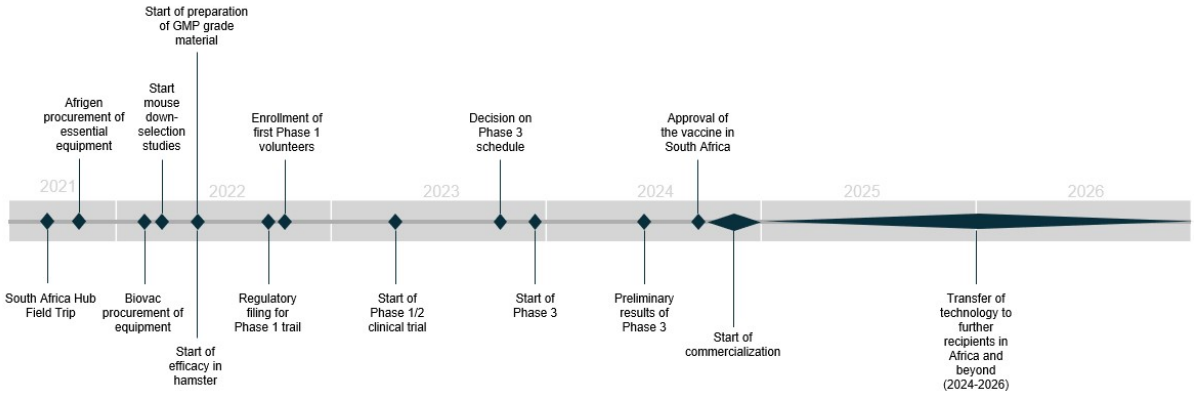
Technology transfer is key to expanding production capacities in LMICs and thereby to contributing to ending the acute phase of the pandemic. Manufacturing license agreements between technology holders and other manufacturers from the beginning of the pandemic have enabled the rapid increase in vaccine production the world has witnessed over the past months. However, further production increases are needed to address current supply constraints. The roundtable with industry on September 1st 2021 (see below) highlighted opportunities and examples, but also stressed the complexity of building production capacities in LMICS which are related to a series of challenges and prerequisites, especially the mRNA supply chain. Thus, F&F can be understood as a starting point and as "host facilities" with the view to gradually build up workforces, supply, quality, and knowledge. Subsequently, the COVAX TF and the VMWG have been actively working on facilitating technology transfer.

In April 2021, WHO as co-leader of Workstream 3 issued a global call for Expression of Interest to establish mRNA vaccine technology transfer hubs to scale up production and access to COVID-19 vaccines. On June 21st 2021, WHO and its COVAX partners announced their cooperation with a South African consortium comprising Biovac, Afrigen Biologics and

Vaccines, a network of universities, and the Africa CDC to establish its first COVID mRNA vaccine technology transfer hub. A Letter of Intent (LOI) was signed on July 30th, 2021, to establish an mRNA technology transfer hub in South Africa and a site visit to kick-off the hub was organized by invitation from WHO and supported by the Department of Science and Innovation of South Africa on September 6th to 9th. The visit provided opportunities for high-level political engagement, technical discussions, and visits to the pilot plant at Afrigen and manufacturing plant at Biovac. This field trip was accompanied by delegations of the VMWG members Germany and South Africa. The South African Co-Chair of the VMWG also expressed the VMWG's commitment to advocate for the project at the Facilitation Council, with national government, and possibly at the UN level.

The Afrigen and Biovac teams, supported by experts, developed an integrated GANTT chart for the project. This GANTT chart incorporates all foreseen activities allowing Afrigen to develop a robust mRNA vaccine production process, which will be transferred to Biovac and other, yet to be selected, technology recipients. The key milestones are presented below:

South Africa Hub Milestones



The mission also informed a more detailed outline for the design of the hub, including its governance structure, budget, and the timeline for the commercialization of the first African COVID-19 vaccine, which is envisioned for the end of 2024. PATH (Seattle, USA) will provide product development support to the project and will be setting up meetings with the Afrigen/Biovac teams to refine the GANTT chart, incorporate target product profiles, and assist with the establishment of an integrated project management system.

There was consensus that the Hub consortium was fit for purpose and that the project had a high chance of success. Therefore, the decision was made that the South-African Hub would be a global mRNA vaccine technology transfer hub in view of its research capacities. A donor meeting organized by WHO and MPP took place on 22 September to present the overall 5-year budget and gather support from already committed and potential funders. Following this process, WHO issued a Call for Expression of Interest for manufacturers interested in receiving technology transfer and training at the mRNA vaccine technology transfer hub by end of September 2021, as well as a Call for Expression of Interest to host technology transfer hubs for other technologies.

In addition, Republic of Korea proposed to be designated as a multitech hub to transfer vaccine technology to LMICs in the Asia-Pacific region as well as a "Global Vaccine Training

Hub" for relevant professionals from the region. Republic of Korea started a bio workforce training program (K-NIBRT) in September 2021 and aims to include 60 professionals supported by the Asian Development Bank (ADB) from LMICs in the program in 2022.

On 21 September PAHO announced that it has selected two centres for development and production of mRNA vaccines for COVID-19 through a competitive selection process. One is the FIOCRUZ in Brazil, which will receive assistance from PAHO in handling various aspects of vaccine development and production and in adhering to complex regulatory processes. The other one is the Sinergium Biotech based in Argentina, which will work jointly with Abxience in the development and manufacturing of the active ingredient. Both centres will form the basis of regional collaboration and will liaise with the mRNA technology transfer hub in South Africa for the purpose of expanding production capacity in Latin America. MPP was mentioned as one of the key partners in this initiative.

The COVAX TF and the VMWG have also encouraged approved technology holders to participate in the hub network. To this end, the VMWG members reached out bilaterally to individual companies and relevant governments with proven technology to advocate for them to join mRNA technology transfer hubs and facilitate contact between WHO and manufacturers. These activities increased awareness among the vaccine industry about the work of the COVAX TF and the VMWG, particularly with the regard to their efforts to increase production capacities. Moreover, this engagement also stimulated discussions on private-public solutions to effectively tackle bottlenecks and barriers that constrain the availability of COVID-19 vaccines in short-term and increasing manufacturing capacity in the mid- and long-term. Germany, for example, has been in close exchange with international manufacturers and pharmaceutical associations on the issue of promoting local manufacturing capacities through a series of roundtable discussions which kicked-off in April 2021. Indonesia reached out to mRNA vaccine developers and manufacturers which is expected to lead to a cooperation for mRNA F&F technology transfer, starting in the middle of 2022. As a result of China's bilateral outreach, Chinese manufactures China National Biotec Group and Sinovac have also announced their willingness to participate in the mRNA technology transfer hubs. In addition, the VMWG Co-Chairs, Germany and South Africa, invited 15 major manufacturers and pharmaceutical associations to a roundtable with the COVAX TF and VMWG on September 1st. This process has supported the identification of immediate priorities and challenges such as increasing country readiness and absorption capacities, sensitizing on the issue of boosters as well as the need for dose-sharing and for revisiting delivery schedules of vaccines by manufacturers and buyers with a view to prioritizing deliveries to COVAX and AVAT (swaps). It was also stressed that, given the series of prerequisites for increasing sustainable local production capacities, long-lasting partnerships are key to address these in a joint matter, such as between the public and the private sector. The ability and willingness of national governments to sustain business engagement in the long term has also been highlighted as vital for its sustainability. A follow-up meeting is planned for the November 2021 to deepen the exchange and to promote good practices for participating companies and technology holders.

Area of Work: Support to integrate parallel initiatives that could benefit from this effort

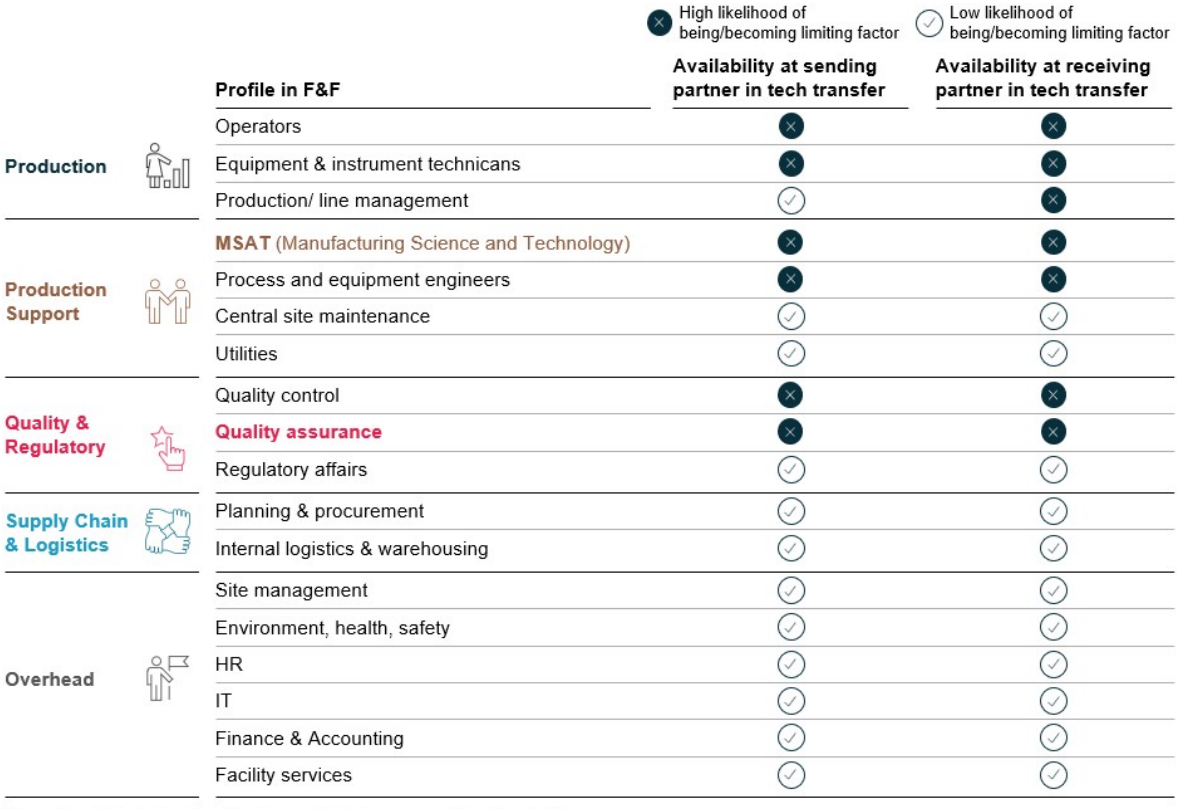
The world is currently witnessing an unprecedented level of support and collaboration between governments, international organizations, the private sector, and public health institutions to build and expand local production capacities. These efforts do not only aim at increasing the availability of COVID-19 vaccines, but also at enabling LMICs to react to locally predominant diseases and epidemics beyond COVID-19. A mapping by the COVAX TF in May 2021 identified about 130 initiatives by about 30 different organizations that aim to address input supply, tech transfer, enhanced regulatory convergence to international norms, free flow facilitation as well as coordination and agenda setting. Particular support has been given to strengthening manufacturing capacities. For this reason, the VMWG supports the integration of parallel initiatives to maximize the impact of the COVAX TF's work and to harness synergies with initiatives supported by other relevant actors. In particular, the VMWG members are advocating for the sharing of information across major initiatives in vaccine manufacturing programs and mRNA technology transfer hubs. Germany and South Africa co-chaired a roundtable with major vaccine manufacturing initiatives and relevant stakeholders like Partnerships for African Vaccine Manufacturing (PAVM), the European Commission (Team Europe), the World Bank, International Monetary Fund (IMF), and WTO on August 18th to discuss ongoing and planned efforts, lessons learnt, and immediate priorities and barriers in this field. The issue of needed coordination between local, regional, and global initiatives has also been discussed at this meeting. Accordingly, it was proposed to continue the engagement between the VMWG and other initiatives on a regular basis, also at the bilateral level. South Africa is also discussing the establishment of laboratory and production facilities for further vaccine research beyond COVID-19, e.g. on malaria and Tuberculosis vaccines with relevant stakeholders. Further work on coordinating the various initiatives is needed.

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

In addition to knowledge exchange and alignment of already established initiatives, in-country support for sustainable, long-term manufacturing capacity building is crucial as it alleviates global vaccine production bottlenecks and strengthens resilience towards future health threats in LMICs and globally. Therefore, VMWG members have been promoting and advocating the establishment of national and regional collaboration hubs and initiatives among governments, vaccine manufacturers, development banks, and other relevant supporting stakeholders in LMICs. Emphasis has been set on supporting capacity expansion for manufacturers of vaccine inputs that are certified by regulatory agencies. The VMWG members support, among others, sustainable manufacturing ecosystems, including regulation and certification, research and development, education, and training. These issues have also been identified as crucial by the roundtable with the industry on September 1st, 2021. Further, the expansion of already existing production capacities has been promoted. For example, the VMWG members, the United States and Germany together with the European Investment Bank (EIB), France and the International Finance Corporation (IFC) are investing in vaccine production in Senegal through the Institut Pasteur de Dakar (IPD). This support is a first step to raise the facility's long-term capacity to produce vaccines. The United States, France, and Germany are also working with the IFC to support COVID-19

vaccine and pharmaceutical manufacturing in Africa by providing financing to South Africa's Aspen Pharmacare and other partners with the objective to increase the number of doses from 300 to 600 million. DFC is also working with Indian manufacturer Biological E to finance increased capacity. This effort will support Biological E's effort to produce at least 1 billion doses of COVID-19 vaccines by the end of 2022. China has also carried out international production capacity cooperation with eleven countries via technology transfer or technical guidance. As a result of these efforts, the United Arab Emirates, Egypt, Indonesia, and Brazil were the first countries in their regions, respectively, to establish production capacity for COVID-19 vaccines. Following this, emphasis should be set on undertaking a needs assessment to understand what resources are required by countries once the infrastructure has been established.

Industry and expert interviews on workforce training, conducted by the COVAX TF between May-July 2021, revealed a shortage of specific workforce profiles. In particular, there is a high demand for qualified quality assurance staff and Manufacturing Science and Technology experts which creates challenges for "sending" and "receiving" partners in technology transfers who have to stretch their existing workforces and/or are unable to find enough qualified staff.



Source: Manufacturing Taskforce Workstream 2 Industry and expert interviews (n=9)

While some positions could be filled with adjacent profiles, others require pharma manufacturing experience.

Scarce Profile	Min FTE required to fill 100mn vials/yr[1]	Adjacent Profiles	Training Needs
Operators	102	Equipment operators in the **food processing** (e.g., beverages, dairy, meat) and **cosmetics industry**	Biopharmaceutical, GMP, and Vx knowledge **Technical** training on equipment
Equipment & instrument Technicians	12	**Outsourced service** from OEM When insourced, **equipment technicians from other sectors** (other pharma, food, cosmetics)	**Technical training** on specific equipment (e.g., by OEM)
Production/line management	10	**Engineers with experience** in pharma or biologicals industry (>2 years)	**On-site experience** with specific equipment and processes, incl. GMP certification
Process Engineers	9	Experienced on-site **technical staff**	**Limited value-add** from external training (on-site experience required)
MSAT (Manufacturing Science and Technology)	3	n/a	n/a
Quality Control	26	**Laboratory** workforce (e.g. medical diagnostics, biotech, food and cosmetic industry)	**GMP processes & documentation** **For supervisors**: **Experience** in distinguishing critical vs. tolerable deviations
Quality Assurance	24	People with **experience in quality management** against stringent standards and with biomedical/-technical background	**GMP process documentation** Deviation management processes under GMP and local regulatory environment

1. Assumption: 1 filling line can produce 40mn vials/yr and requires 100FTE of workforce

Source: POBOS Benchmark

For established COVID-19 licensed manufacturers, the issue is no longer the availability of training but rather the access to technical process experts to help ramp up and trouble shoot their COVID-19 vaccine process. For new manufacturers, training needs vary according to their starting point. Therefore, most training organizations recommend to first assess the gaps and the training needs. Most – if not all – manufacturers and some training organizations find that generic training will only cover a small share of the training needs and hold that training specific to the manufacturing processes will be essential. These identified training gaps present a crucial challenge to the goal of providing resources for manufacturing hubs in developing countries. The working group 6 “Workforce development” under workstream 3 of the COVAX Task Force will identify workforce training needs for both the hub(s) and recipients.

In addition to supporting sustainable, long-term local manufacturing capacity, activities which support market shaping also need to be taken into account by the VMWG and the COVAX Task Force as steady demand is key for the sustainability of emerging production capacities. Accordingly, political and financial support for the demand side is essential to ensure that locally developed and manufactured vaccines will also be purchased, delivered, and administered within the region. At the regional level, countries could agree to primarily purchase from emerging manufacturing facilities - if circumstances allow, considering supply constraints and other factors. Against this background, these issues should be continuously brought forward by VMWG members in high-level fora.

Index of Abbreviations

ACT-A	Access to COVID-19 Tools Accelerator
AFD	The French Development Agency
Africa CDC	Africa Centres for Disease Control and Prevention
AU	African Union
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX	COVID-19 Vaccines Global Access
COVAX TF	COVAX Manufacturing Task Force
DEG	Deutsche Investitions- und Entwicklungsgesellschaft
DFC	United States International Development Finance Corporation
EIB	European Investment Bank
EU	European Union
F&F	Fill-and-finish
FIOCRUZ	The Bio-Manguinhos Institute of Technology in Immunology (Brazil)
HICs	High-income countries
IFC	The International Finance Corporation
IMF	International Monetary Fund
IPD	Institut Pasteur de Dakar
LICs	Low-income countries
LMICs	Low- and middle-income countries
LOI	Letter of Interest
MLTF	Multilateral Leaders Task Force on COVID-19 vaccines, therapeutics and diagnostics
MMR	Measles-mumps-rubella vaccine
MPP	Medicines Patent Pool
PAHO	Pan American Health Organization
PAVM	Partnerships for African Vaccine Manufacturing
VMWG	ACT-A Facilitation Council Vaccine Manufacturing Working Group
WCO	World Customs Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Annex

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Annex 1: Context & Terms of Reference for the ACT-A Facilitation Council Vaccine Manufacturing Working Group

1. Introduction

The Facilitation Council of the Access to COVID-19 Tools Accelerator (ACT-A), co-chaired by South Africa and Norway, provides high-level advice and guidance to ACT A pillars, principals and partners, as well as global leadership and advocacy for ACT-A.

ACT-A operates with four main Pillars: i) COVAX for vaccines, with the overarching goal of ensuring equitable distribution of vaccines across the world, particularly to low and lower middle-income countries; ii) Diagnostics pillar for work related to the evaluation, procurement, allocation and uptake of tests; iii) Therapeutics pillar for leading the landscaping, policy and regulatory work, as well as procurement and distribution of therapeutics; and iv) Health Systems Connector for work across these pillars to support product uptake and use.

This document provides the Terms of Reference (ToR) for the Vaccine Manufacturing Working Group (VMWG). The need for either expanding these ToRs or creating an additional Working Group will be kept under review in case production and/or supply issues are found to be constraining access to other ACT-A products.

2. Context for the ACT-A Council's Vaccine Manufacturing Working Group

a. As the COVID-19 pandemic ravaged people and economies in 2020, global solidarity was agreed to be critical in ensuring an effective response. However, at mid-2021 that solidarity is at risk, with deeply inequitable access to key products. Most alarming, less than 1% of COVID-19 vaccines have reached the world's lowest income countries, particularly in Africa. This inequity is at risk of becoming even worse if policy decisions in high income countries extend vaccination to pediatric populations and to booster doses in advance of scaling up doses for low income countries through COVAX.

b. The urgent need to address this crisis of equitable access to vaccines, diagnostics and therapeutics is reflected in various proposals including the proposal of South Africa and India for a temporary waiver of certain TRIPS requirements in order to facilitate access to and application of IP, technology and know-how.

c. Rapidly expanding access to vaccines for low income and lower middle-income countries (LICs/LMICs) also requires high income countries to scale-up their support to expand existing manufacturing capacities and to share or donate vaccines in real-time to COVAX. Such actions would complement but not replace the work needed towards systemic changes to ensure equitable access to life saving medical products for all on a sustainable basis. The current crisis demonstrates that philanthropy-centered approaches is not a long-term solution;

it requires increasing production capacities for vaccines, therapeutics and diagnostics in LIC/LMICs.

d. Urgent action in this area is needed to ensure implementation of the G20 commitment of extensive immunization as a global public good, including by seeking to address inequities in the production and consumption patterns.

e. ACT-A's support for country-driven proposals to reshape global public health could facilitate the systemic change needed for all countries to be better prepared for the next pandemic.

f. The participation of the ACT-A Council Co-Chairs and a number of Council Members in the Vaccine Manufacturing Working Group in support of COVAX can ensure that country views are represented and can strengthen the resolve of countries to remove barriers to access and produce vaccines. This Working Group will help ensure increased and equitable access to vaccines and, if necessary, could later consider diagnostics and therapeutics. ACT-A's leadership in addressing inequitable access to medicines and vaccines must be premised on the understanding that this requires tackling the root causes of the deep structural inequalities that currently hamper access.

3. Principle & Objectives of the ACT-Accelerator

a. In the pursuit of its two major objectives, ACT-A operates under the principle of global solidarity, knowing that no one is safe from COVID-19 until everyone is.

b. Adherence to the principle of global solidarity has facilitated the substantial progress that has been made in achieving the first objective of ACT-A – the accelerated development of new tests, treatments and vaccines against COVID-19. However, ACT-A's second objective – ensuring global access to and equitable allocation of these tools – is at real risk without a new and deeper commitment to this principle.

c. The increasing COVID-19 vaccine equity gap is now driving calls to leverage under-utilized and idle manufacturing capacity also in developing countries, especially in Africa, including through the removal of barriers in order to facilitate the sharing and usage of IP and access to production technology and know-how for vaccines, diagnostics and therapeutics on mutually agreed terms. Such technology transfer and capacity building could in turn enhance resilience in the response to the COVID-19 pandemic through diversification of production, while promoting and improving product affordability as well as the manufacturing capacity of countries and regions.

The ToRs for the Vaccine Manufacturing Working Group will focus on the actions needed to enhance supply of vaccines through COVAX, from the evolving supply chain issues to unleashing capacities in developing countries, such as in the African region, where there is no or limited production capacity.

4. Terms of Reference for VMWG

COVAX, the vaccines pillar of ACT-A, has established a Task Force which aims to address production and supply issues that impede equitable access to vaccines. The ACT-A Facilitation Council Co-Chairs endorsed this initiative in their Outcome Statement from the 5th Council meeting. In support of this COVAX initiative, the ACT-A Facilitation Council Co-Chairs are establishing a Vaccine Manufacturing Working Group (VMWG). The VMWG will aim to support the COVAX Task Force on Manufacturing by addressing political bottlenecks and barriers to increase vaccine supply through COVAX. The overarching goal is to ensure equitable distribution of vaccines across the world, particularly in LMICs.

VMWG's primary objective is to ensure the success of COVAX, specifically by providing political support for the work of COVAX's Manufacturing Task Force, which has the following aims:

- *to optimize, and prioritize for COVAX, the number of vaccine doses manufactured in the short term, with a special emphasis on the AMC92 countries to ensure greater equity,*
- *to kickstart the establishment of sustainable regional manufacturing of vaccines with a view to build long-term regional health security, and*
- *to mitigate the unintended impact of COVID-19 vaccines on other vaccines and health products*

4.1 Objectives

The VMWG will provide support to:

- increase supply of vaccine doses to COVAX to ensure equitable distribution by addressing supply chains of raw material and vaccines
- identify and address all barriers, including legal and political barriers to fully **utilizing existing** capacities and incentivizing greater and new production in developing countries
- facilitate the identification of potentially under-utilized/idle capacity for vaccine manufacturing for viral vector, mRNA and other vaccine technologies in all regions
- facilitate mutually agreeable solutions for technology transfer from vaccine manufacturing companies with approved products
- unlock political barriers for implementation of increased manufacturing at the regional level by stimulating regulatory, manufacturing workforce development
- increase information availability on vaccine production and deliveries to countries, ensuring more transparency of distribution of vaccines
- increase transparency on the affordability of vaccines, and encourage that vaccines supplied to COVAX AMC are priced at the cost of goods and production (i.e. not for profit pricing)
- increase political dialogue and build global political consensus around the above, particularly focusing on the G20 Global Health Summit, World Health Assembly and the G7 and G20 processes.

5. Operations and Representation

a. The VMWG will include a representative from South Africa and Norway and will be supported by relevant technical units from the COVAX co-convening agencies Gavi, CEPI and the World Health Organization, as well as the ACT-A Hub. South Africa and Norway will, as ACT-A Facilitation Council Co-Chairs, be participating in (Norway) or co-leading (South Africa) the Working Group. These Co-Chairs will ensure that the Working Group reports back to the Facilitation Council and that consultations are held with Council Members and countries, as needed, so that they are kept abreast of developments and are afforded their right to make inputs given the importance of countries in driving the global health agenda. The perspectives of countries could be facilitated by WHO Regional Offices which could submit brief reports related to vaccines, diagnostics, and therapeutics for their Regions.

b. ACT-A Facilitation Council Members who will be invited to participate in the Working Group include:

   i. Germany (as co-chair of the Working Group)
   ii. Brazil
   iii. China
   iv. India
   v. Indonesia
   vi. Republic of Korea
   vii. Rwanda
   viii. Saudi Arabia
   ix. USA

c. The Working Group will be co-chaired by South Africa and Germany.

d. Working Group co-chairs and representatives may meet with members of COVAX (including CEPI, GAVI, WHO, UNICEF) and relevant private sector organizations to ensure that blockages to access emanating from any sector are dealt with expeditiously when identified.

e. The COVAX pillar will be asked to support and complement the work and reports of the Working Group by providing updates on relevant areas such as:

   - the quantities of vaccines being procured or received as donations by COVAX,
   - COVAX allocation targets per country and the target timelines for distribution,
   - progress towards achieving targets,
   - challenges and remedial actions to address challenges,
   - measures to address key barriers identified in regional reports, and

- insights on the pricing of COVID-19 vaccines globally.

f. The Working Group will meet fortnightly to consider information and reports received from COVAX partners, WHO Regional Offices and other relevant public or private sector organizations and prepare a situational analysis and recommendations for the Facilitation Council through the Co-Chairs.

Annex 2: 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.

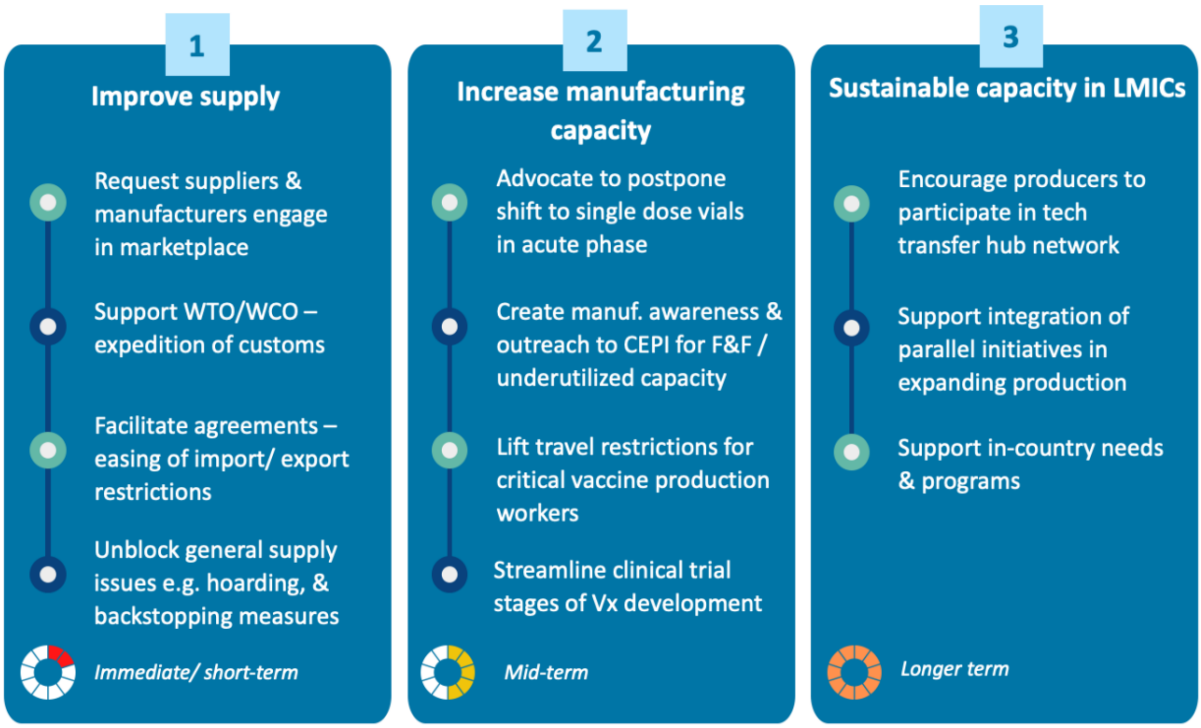
Based on concrete 'asks' from the TF, through an iterative consultative process, the WG have articulated in this document, core areas of work and key actions that the WG can take to advance the agendas of these workstreams. Prospective accountable owners and timelines are projected to deliver are outlined.

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**.

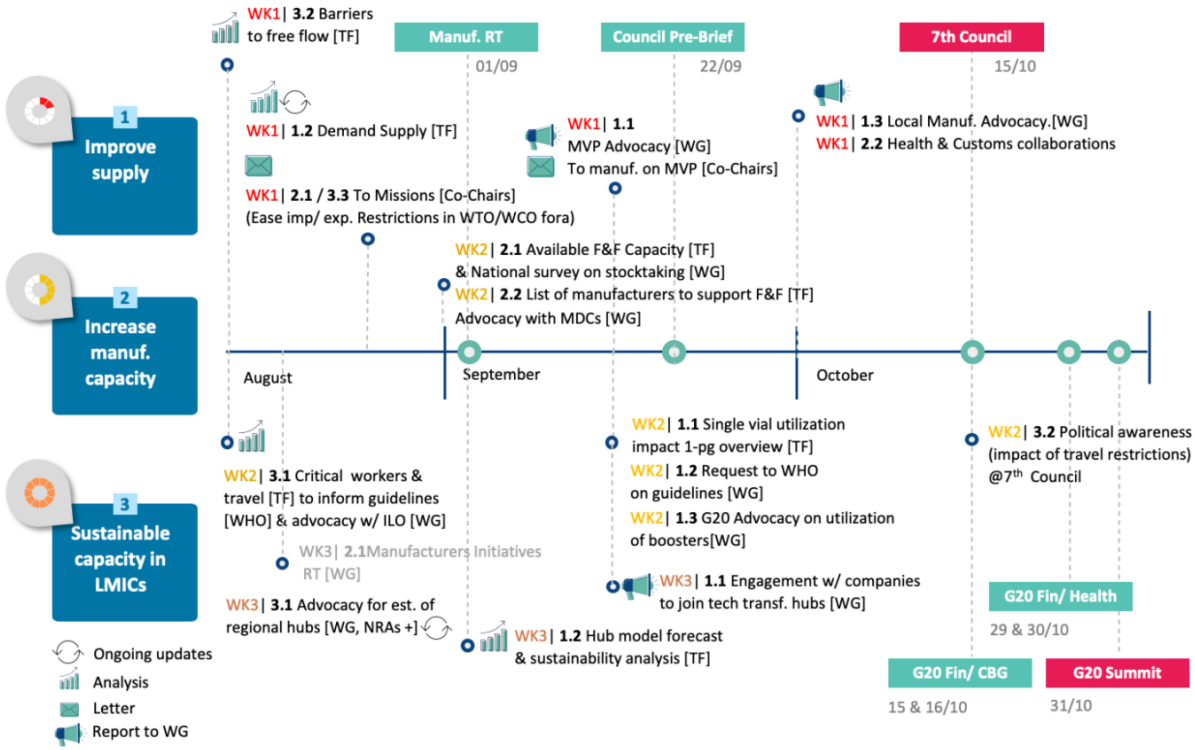
This progress and outcomes of the work articulated in this document will be reported to the G20 in upcoming meetings in October 2021.

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

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

- **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:**
  - 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

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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.

(1.4) 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

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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

- **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

(2.2) 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

Annex 3: Members' contributions to Workplan: Brazil

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(2.1) Advocate in various fora of WTO and partners (e.g., WCO, IMF, WB, WHO).	N/A	Brazil is a cosponsor of the Trade and Health Initiative at the WTO.	Draft WTO General Council Declaration circulated among WTO Members (document WT/GC/W/823, entitled "Covid-19 and Beyond: Trade and Health") on 15 July 2021.
(2.1) Advocate in various fora of WTO and partners (e.g., WCO, IMF, WB, WHO).	N/A	Brazil is a cosponsor of the proposal on accelerated implementation of the WTO Trade Facilitation Agreement as a response to the Covid-19 pandemic.	Communication G/TFA/W/25/Rev.7, circulated among WTO Members on 21 June 2021, entitled "Supporting the Timely and Efficient Release of Global Goods through Accelerated Implementation of the WTO Trade Facilitation Agreement".
(2.1) Advocate in various fora of WTO and partners (e.g., WCO, IMF, WB, WHO).	N/A	Brazil endorsed the decision by the Trade Facilitation Committee at the WTO to compile trade facilitation measures taken as a response to the Covid-19 pandemic.	Compendium of measures circulated among WTO Members on 8 July 2021 (document G/TFA/W/40/Rev.1, entitled "Compendium: Sharing Experiences Related to the Covid-19 Crisis").
(2.1) Advocate in various fora of WTO and partners (e.g., WCO, IMF, WB, WHO).	N/A	Brazil cosponsored the WHO resolution strengthening local production of medicines and other health technologies to improve access, adopted at the 74th World Health Assembly	The resolution established the legal framework for WHO action regarding local production.

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(2.1) Identify available F&F capacity in LMICs and HICs, incl in WG member countries	Completed	Evaluation of unit operations and productive operational capacities installed in animal health laboratories with the potential to perform upstream, downstream, Fill & Finish steps of human vaccines production.	Specific legislation was adopted in Congress that allows the use of animal health laboratories for the production of human vaccines in Brazil, thus allowing progress in the regulatory steps concerning the National Health Surveillance Agency (ANVISA)
(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.	Ongoing	Covid-19 vaccine technology transfer agreement signed between Fiocruz and pharmaceutical company AstraZeneca,	Fiocruz currently performs the Fill & Finish steps with monthly capacity of approximately 30 million doses of AstraZeneca vaccine per month. Laboratory is in the process of installing and qualifying new filling lines towards to increase the Fill & Finish capacity and the production of the API will be the next step.
(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.	Ongoing	Coronavac vaccine technology transfer agreement signed between the Butantan Institute and Chinese pharmaceutical company Sinovac Life Science.	Butantan Institute currently performs the Fill & Finish steps, with capacity of approximately 30 million doses per month. The API facility building is ongoing.
(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.	Ongoing	Development of BuntanVac based on Viral Vector technology through an agreement at the Butantan Institute and the Icahn School of Medicine of Mount Sinai, New York.	Clinical trial is ongoing.
(2.2) Support the COVAX TF in building capacities for F&F service providers and manufacturing to get Emergency Use Listings or Authorizations from WHO Regulatory Bodies for approved and match-making vaccine regimens where appropirate.	Ongoing	Production of Pfizer vaccine through an agreement between Eurofarma and Pfizer.	The Memoradum of Understanding between the two companies establishes the local production of mRNA vaccine ComiRNAty for distribution in Latin America. Production should start in 2022 with approximately 100 million doses annualy.

(3.1) Promote and advocate for government and IO/IFI- supported initiatives/collaboration between vaccine manufacturer, development banks and supporting industries in LMIC and regional capacity.	Ongoing	Brazil was an early supporter of WTO's initiative to promote equal access to vaccines and to encourage voluntary tech transfer from innovative companies to partners in developing countries	The mechanism held its first virtual meeting in April and remains active.
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(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	Ongoing	WHO COVID-19 mRNA vaccine technology transfer hub. S..	WHO and PAHO announced decision to facilitate the establishment of technology transfer hub in Fiocruz, in Brazil, which will be able to receive a comprehensive technology transfer package and provide appropriate training to interested manufacturers in LMIC
(2.1) Facilitate scoping exercise and map of different initiatives on local vaccine production, gap analysis, and identification of parallel initiatives	Ongoing	Project for Scaling Up Immunization Capacities in PROSUR Countries.	Diagnosis and a pre-feasibility study to identify the necessary requirements to scale the vaccine production capacity in South America; identify governance arrangements, articulating the public and private sectors, to manage the new production facilities; define a strategic roadmap for scaling up immunization technical, economic and regulatory capacities in the region.

Annex 4: Members' contributions to Workplan: China

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(1) Create supplier & Manufacturer awareness for MVP: ▪ Report to WG on bilateral / multilateral/ regional group engagement on advocacy	Mid-September	We have advocated local supplier & manufacturer to participate with market place.	Participation to be confirmed.
(2) Advocate for deliberations in WCO / WTO meetings - expedite customs processes Reportto WG on activities to facilitate necessary collaborations on customs (expedited border clearances) between authorities of affected countries	End of Sep	The electronic customs declaration system has been used for manufacturers to get approved online.	Effectively shorten the time required for customs clearance.
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(1)Postpone shift to single dose vials until the acute phase of the pandemic is over	Mid-September	The local manufacturers have been producing two-dose vial vaccine since they got regulatory evaluation.	The output is stable.
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(1)Encourage approved tech holders to participate with their technology in hub network Conduct bilateral outreach to individual companies and relevant governments with proven technology to join tech transfer hubs, facilitating contact between WHO & global network/ manufacturers report to wg	Mid-September	Got in touch with relevant manufacturers to confirm their intention.	CNBG & sinovac would like to participate.

Annex 5: Members' contributions to Workplan: Germany

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(1) Create supplier & manufacturer awareness for MVP: • Co-Chairs to write a letter to industry associations and multilateral actors advocating for them to call for increased participation.	Mid-September	Roundtable with German Industry in (April), July and on 1 October	Market-place announced and promoted, follow-up with German Industry ensured
(2) Advocate in various fora of WTO and partners • WG members to reach alignment amongst states on recommended policy changes at relevant WTO/WCO fora (e.g., process simplification, ease of restrictions) • WG Co-Chairs to develop a letter advocating for these issues to be circulated with ambassadors in Geneva missions (and dispatched to countries)	3rd week of August	• WTO in VMWG meetings • Letter to Geneva missions of member states and WTO DG Ngozi Okonjo-Iweala was sent on 8 September to raise awareness on WTO-related actions in the VMWG workplan and to invite WTO to further discussions on trade and supply chain related issues and how to address them • PermMission Geneva facilitating exchange with WTO Secretariat on manufacturing and supply EU	Stronger Involvement of WTO, increased awareness of challenges as well as of possible approaches and closer coordination.
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
Postpone shift to single dose vials until the acute phase of the pandemic is over		Discussion of implications of shift with German industry on 1 October (planned)	
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.		Discussion within German government; Decision to offer booster vaccination to vulnerable people and health workers in line with WHO recommendation Discussion at EU-level (planned)	
Create awareness and advocate for within local vaccine manufacturer community to reach out to CEPI with their F&F capacity needs and underutilized capacity		(CEPI is already in close and good contact with the local vaccine manufacturing community. Manufacturers are thus already sensitized with regard to F&F needs and underutilized capacities)	

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(1) Encourage approved tech holders to participate with their technology in the hub network • Conduct bilateral outreach to individual companies	Mid-Sep 2021	Roundtable with German Industry in April and July; Follow up roundtable with German industry planned for the 1st of October	Increased awareness within German industry, follow-up ensured
		Held a roundtable with international manufacturers and pharmaceutical associations on the 1st of September; presentation on work and objectives of COVAX TF and VMWG (co-chaired by GER).	Increased awareness among the Industry for work of COVAX TF and VMWG; identification of immediate priorities and challenges (to be reflected as recommendations in report to G20); follow up ensured, next meeting tbd.
		GER bilaterally exchanging ideas with tech holders about cooperation potentials related to global hub network, German development cooperation and beyond; ongoing discussion with Hub-Team and Local Production Team of WHO on possible technical support.	increased awareness of potentials and challenges as well as of possible approaches.
• Support TF to conduct a forecast analysis for hub's long-term sustainability	1st week of September	German Participation in donor dialogue with WHO and in the WHO South Africa Hub field trip (6th-9th of September) to develop a budget and to discuss governance, regulatory aspects as well as technology and product development.	Success criteria and challenges identified, more concrete outline on design of technology transfer hub
(2) WG to convene the major actors (donors/investors/industries) with established or evolving programs in the vaccine manufacturing ecosystem • WG to share information across major actors in vaccine manufacturing programs and tech transfer hubs	August 2021	Roundtable with major Vaccine manufacturing initiatives (PAVM, EU COM, CHN, WBG, IMF, WTO) was held on 18th of August (co- chaired by GER).	Exchange on ongoing and planned efforts, lessons learned as well as immediate priorities and barriers; bilateral follow ups (e.g. WTO)
(3) Support in-country programs and resourcing needs • Promote and advocate for government and 10/IFI-supported collaboration between vaccine manufacturer, development banks and	Ongoing *German support in total: appr. 500 Mio. EUR for vaccine manufacturing in Africa:*	German support by BMZ through KfW and GIZ to South Africa for sustainable manufacturing ecosystem (e.g. regulation and certification, research and development, education and training), German contribution: grant/	Ongoing appraisal missions, project outlines to be expected in Q4

supporting industries in LMIC to strengthen national and regional capacity		technical support 51 million EUR as part of the Team Europe Initiative	
		Partnership between German DEG, IFC, Proparco and DFC to support vaccine manufacturing in Africa through a joint loan for the South-African manufacturer Aspen; German contribution: Loan 144 million EUR	Estimated additional vaccine output: for Aspen - additional of 300 mio. doses per year, mainly for South Africa and Africa (via AVATT)
		German support by BMZ through KfW by Strengthening and expanding production capacities of the Institute Pasteur Dakar (Senegal): establish a "fill-and- finish" facility and develop production capacities; German contribution: Grant 20 million EUR as part of the Team Europe Initiative	Follow up: preparation of the appraisal for Financial Cooperation funding (KfW), currently exploring private-sector solutions
		Advisory support of the GIZ to the Ghanaian Presidential Vaccine Manufacturing Committee (VMC) to set up a local vaccine production in Ghana, particularly setting-up of a F&F-plant and development of a national and international framework; German contribution: 5 million EUR via GIZ for technical support	10-year roadmap for vaccine development and manufacturing (with support of the GIZ); ongoing exchange with vaccine manufacturers; a market analysis and a technology options analysis for vaccine production to be expected in Q4
		Regional/Africa-wide support: 1. Support of Africa CDC in establishing the African Medicines Agency (AMA) to facilitate the harmonisation of medical regulation throughout the African Union; 2. Consulting the Partnership for African Vaccine Manufacturing (PAVM) at Africa CDC; 3. Training for skilled workforce; German contribution: 8 million EUR via GIZ for technical support	Ongoing preparation for planned activities in close coordination with other actors engaged in promoting vaccine production

		PTB (National Metrology Institute of Germany) support to AMA, Ghana, and South Africa to expand the African Quality Infrastructure in the pharmaceutical and healthcare sector, particularly improvement of quality assurance and regulation such as the harmonisation of standards and the application international guidelines (e.g. WHO GMP); German contribution: 3 million EUR via PTB for technical support	Ongoing preparation for planned activities
		kfW Loan (250 million EUR) to the Afreximbank to strengthen local production vaccine COVID-19 vaccines; accompanying project preparation facility (12.2 million EUR) to improve access to financing for African companies	Financing of feasibility studies on companies along the vaccine production (supply) chain to identify bankable investment opportunities

Annex 6: Members' contributions to Workplan: India

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(1) Create supplier & Manufacturer awareness for MVP: • Letter to industry associations and multilateral actors call for increased participation	Mid-September	Details on CEPI's Marketplace shared through with Biotechnology Industry Research Assistance Council BIRAC, a PSU Department of Biotechnology for due communication to the Indian vaccine manufacturers.	2 Manufacturers connected to COVAX Tf MVP contacts and committed to joining MVP
2) Create manufacturer awareness & advocate for outreach to CEPI for F&F /underutilized capacity. Report on programs to support financing for technical assistance for F&F service providers in developing countries,	End-Aug,	Efforts being leveraged under the lndo-US Vaccine Action Program (VAP) and the lnd-CEPI initiative, to support in-country vaccine development and manufacturing Efforts leveraged through the Quad Cooperation, an alliance between four countries including the United States, Australia, India, and Japan.,	Financing by US Development Finance Corporation (DFC) for three fill-finish lines to produce 1 billion doses of J&J Vaccine till end of 2022, for export to the lndo-Pacific region, under consideration
(3) Support in-country programs and resourcing needs Promote establishment of regional collaboration hubs/constellations between governments, vaccine manufacturers, development banks and relevant supporting industry representatives in LMICs,	Ongoing,	Under "Mission COVID Suraksha-The Indian COVID-19 Vaccine Development Mission", efforts undertaken for enhancement of capacities for augmented vaccine production. Technology transfer facilitation being provided. Provision of at -risk manufacturing support for indigenous vaccine candidates in advanced stage of development, under consideration,	Enhanced production of Covaxin, India's indigenously developed inactivated vaccine for COVID-19

Annex 7: Members' contributions to Workplan: Indonesia

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
1.3. Advocate for actions that increase supplies and equipment to regional/local manufacturing facilities	Mid-Sep	• The use of the Indonesian National Single Window (INSW) platform to facilitate expedition of licensing/port/export/import documents release. • Regulation to facilitate import duty and tax exemptions for vaccine, as well as for vaccine materials, and vaccine related equipment needed for vaccine development. • Procedural facilitation to expedite import goods handling in port-of-entry	• Significant time reduced for the release of licensing/port/export/import documents, as well as the release of the imported goods.
2.2. Facilitate effective collaboration between health and customs authorities to mitigate additional delays in export/import of critical supplies, including for APIs	End-Sep		
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
2.1. Identify available F&F capacity in LMICs and HICs, including in WG member countries	Early Sep	Have conducted assessment to identify available local manufacturing with F&F capacity	6 local manufacturers with F&F capacity have been identified (one state-owned company and five private industries).
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	Early Sep	Conduct discussion with multilateral development cooperation partner for technical assistance for F&F service providers in developing countries.	Further discussion needed.
4.1. Obtain approval from vaccine developers for comparator vaccines as comparative clinical trials are needed to accelerate the development of vaccines.	TBD	Collaborate with and involved in several multi-centre phase 2 and 3 clinical trials for vaccine development with different platforms.	Clinical trial collaboration with various vaccine developers has beneficial outcome, such as: • Capacity building inclinical trial management • Gateway for further collaboration, such as procurement deals and F&F collaboration

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
1.1. Conduct bilateral outreach to individual companies and relevant governments from the WG and in addition to WG members.	Mid Sep	Conducting bilateral outreach to mRNA vaccine developers and manufacturers (industries and universities).	Planned cooperation for mRNA vaccine F&F tech transfer with mRNA vaccine developer, started Mid 2022.

Annex 8: Members' contributions to Workplan: South Africa

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(1) Encourage approved tech holders to participate with their technology in hub network Conduct bilateral outreach to individual companies and relevant governments with proven technology to join tech transfer hubs, facilitating contact between WHO & global network/ manufacturers Advocate for government supported initiatives and for relevant industry support to hubs in LMICs Conduct a forecast analysis for hub's long-term sustainability.	Mid-September	• Expressions of Interest (EOI) process for tech recipients was initiated in mid-April for mRNA technology. • Advocacy work is ongoing. A funders' meeting is currently in preparation. It will take place on 22 September 2021. • Performing of forecast analysis is ongoing.	• IP review to ensure FTO and licensing pathways are being conducted to finalise selection (time consuming).
(2) Support to integrate parallel initiatives that could benefit from this effort WG to support TF in conducting scoping exercise and analysis and sharing results with member states WG to share information across major initiatives in vaccine manufacturing programs and tech transfer hubs WG to promote joint support for setting up global multilateral forum focused on this	Ongoing	• PAHO has issued EOIs for PAHO - due diligence is being conducted by HQ and PDVAC-expect announcement next week on PAHO network of manufacturers and producers of reagents. • Discussions with kENUP and BioNtech on the establishment of mRNA production facilities in Africa for malaria and TB vaccines are ongoing.	
(3) Support in-country programs and resourcing needs Promote establishment of regional collaboration hubs/constellations among governments, vaccine manufacturers,development banks and relevant supporting industry representatives in LMICs Request TF to undertake a needs assessment exercise for what is required by countries once the tech transfer hub has been established	Ongoing	• Field trip to South Africa was held in the week of 6 September 2021.	• High-level, 5-year project budget and timeline • Granular workplan for the next • 18 months • See NFTR

Annex 9: Members' contributions to Workplan: Norway

Norway			
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(2) Create manufacturer awareness & advocate for outreach to CEPI for F&F /underutilizedcapacity • VMWG to preform national survey/stocktakingon available/idle F and F capacity by early Sep • Report on programs to support financing for technical assistance for F&F service providers in developing countries • Identify and list available vaccine manufacturing related industries in each LMIC to support the F&F match making mechanism	Sept 2021	• There is no F and F capacity in Norway. • Suggest to survey all countries; with capacity, not limit this to WG members. Who would be the most appropriate actor to conduct such a survey? WHO/ACT-A hub? CEPI? Others? • Could link to survey above; Could then aim to link those with capacity and financing programs • Should be a priority for the VMWG	
(3) Lift any travel restrictions for critical workers and address their COVID-19 vaccine requirements to support accordingly • Bring forth discussions in ACT-A Facilitation Council (7th Meeting) on provisions for countries to include essential workers (incl. technical vaccine workers)	Sept 2021	• Norway and South Africa to bring this to the ACT-A meetings (with the Hub) as an agenda item	• Consider agenda item to be added to the agenda for the 7th meeting of the council or in briefing (pending on action on other items)

Annex 10: Members' contributions to Workplan: Republic of Korea

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(1) Create awareness within local manufacturer and supplier community to join COVAX input supply marketplace	8.17	• Promoted participation in COVAX Marketplace to Korean companies related to raw and sub materials for vaccines (Jul.) • Korea-CEPI Marketplace cooperation meeting (Aug.SJ • Notified CEPI that 7 Korean companies on the list of raw and sub material supply and demand companies want to participate (Aug.17)	• 16% of the CEPI Marketplace-listed companies are Korean; Two Korean companies have signed an agreement with CEPI (Aug.31)
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(2) Create awareness and advocate for within local vaccine manufacturer community to reach out to CEPI with their F&F capacity needs and underutilized capacity	8.25	• Promoted participation in COVAX Marketplace to vaccine-related Korean companies (Jul.) • Korea-CEPI Marketplace cooperation meeting (Aug.SJ • Notified CEPI that 6 Korean companies capable of F&F want to participate (Aug.25)	• follow up
(4) Streamline clinical trial stages of vaccine development	End 2021	• Discussed the relevant subject with WHO, CEPI (Jun~Jul.) • Consulted with the UK government (twice in Jul.)	• Secured AZ vaccines for comparison, regarding the Covid- 19 vaccine SK bioscience is developing supported by CEPI • Comparative clinical trial is underway (Aug. ~)
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(1) 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)	End 2021	• Proposed that Korea be designated as Multi tech Hub in the Asia-Pacific region, for transferring the vaccine technology to the LIMCs region (Joint meeting of VMWG-COVAX Manufacturing TF on Jul.20, Korea-WHO bilateral meeting on Jul.30) • Consultation with WHO is underway, regarding the	

		proposal for designating Korea as "Global Vaccine Training Hub", for nurturing vaccine-related professionals of LMICs. (Korea-WHO bilateral meeting on Jul.30, Sep.14) • Pushing the inclusion of the workforce of LMICs in the Asian region in Korea's vaccine workforce training program ('22); consultation with ADB (Asian Development Bank) is underway (meetings on Jul.7, Sep.2, Sep.8) • Korea started its bio workforce training program {K-NIBRT) in September 2021, pushing the inclusion of 60 people of LMICs in the program in 2022. (Consultation with ADB is underway regarding the selection of trainees and cost sharing)	

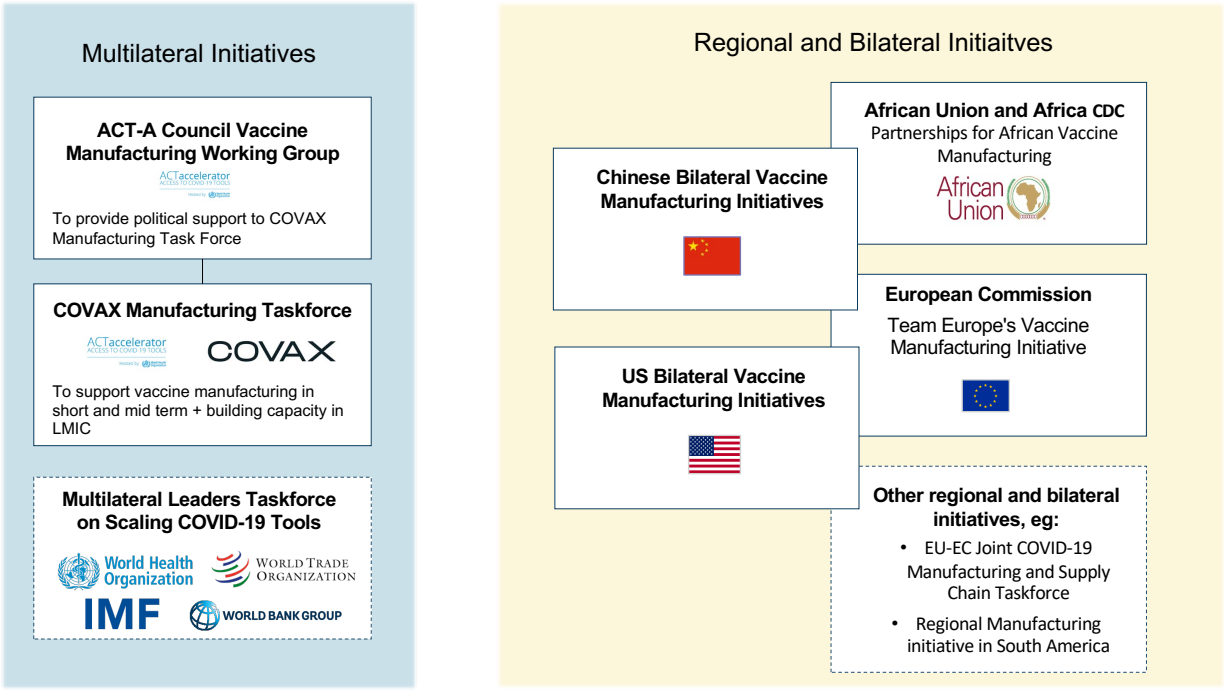
Annex 11: Members' contributions to Workplan: United States of America

ACTIVITIES PER WORKPLAN	DUE DATE	ACTIVITIES DONE	OUCTOMES
(1.1) Create supplier & Manufacturer awareness for MVP: • Report to WG on bi lateral / multilateral/ regional group engagement on advocacy	Mid-September	Encouraged COVA'X Marketplace participation on call with U.S. CEOs regarding global COVID-19 response	16% of the CEPI Marketplace- listed companies are Korean; Two Korean companies have signed an agreement with CEPI (Aug.31)
(1.1) Create supplier & Manufacturer awareness for MVP: • Report to WG on bi lateral / multilateral/ regional group engagement on advocacy	Mid-September	Discussed COVA'X Marketplace bilaterally as part of "KORUS Vaccine Partnership" between the U.S. and the Republic of Korea, and encouraged select suppliers to join	At least one supplier signalled interest in Joining as a result of this outreach
(1.1) Create supplier & Manufacturer awareness for MVP: • Report to WG on bi lateral / multilateral/ regional group engagement on advocacy	Mid-September	Discussing COVAX Marketplace bilaterally as part of "EU-U.S. COVID-19 Manufacturing and Supply Chain Taskforce" between the U.S. and the EU	Ongoing; we will share updates as we hear of additional companies joining the Marketplace
(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	Immediatel y	We provide regular updates on import-export challenges in the "EU-U.S. COVID-19 Manufacturing and Supply Chain Taskforce" between the U.S. and the EU	Ongoing import-export updates and action where needed to alleviate bottlenecks
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(1.1) Monitor the risk of moving to single dose vials and consider promoting potential alternative solutions, including new technologies.	Ongoing	The U.S. continues to monitor this potential trend. The U.S. is not pursuing single-dose vials at this time.	
(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.	Ongoing	The U.S. International Development Finance Corporation (DFC), the European Investment Bank (EIB), the French Development Agency (AFD), and the International Finance Corporation (IFC) are investing in vaccine production in Senegal through the Fondation Institut Pasteur de Dakar {IPD). The support is a first step to grow the facility's long-term capacity to produce vaccines.	This support will help expand F&F capacity on the continent, including for COVID-19 vaccines.

(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.	Ongoing	DFC, France's Proparco, and Germany's Deutsche Investitions-und Entwicklungsgesellschaft (DEG) are also working with the IFC to support COVID-19 vaccine and pharmaceutical manufacturing in Africa by providing financing to South Africa's Aspen Pharmacare and other partners.	This financing helps support Aspen's ongoing efforts to produce COVID-19 vaccines, including F&F for the Janssen vaccine.
(2.2) Support the COVAX TF in building capacities for F&Fservice providers and manufacturers to get Emergency Use Listings or Authorizations from WHO Regulatory Bodies for approved and match-making vaccine regimens where appropriate.	Ongoing	In September, the U.S. announced nearly $3 billion in investments in expanded manufacturing capacity of critical vaccine inputs and supplies, including vials, needles and syringes, consumables, fill-finish capacity, and more	By expanding manufacturing capacity for vaccine inputs and fill-finish capacity, these investments will help alleviate global vaccine production bottlenecks
ACTIVITIES PER WORKPLAN	**DUE DATE**	**ACTIVITIES DONE**	**OUCTOMES**
(3.1) Promote and advocate for government and IO/IFI-supported initiatives/collaboration between vaccine manufacturer, development banks and supporting industries in LMICto strengthen national and regional capacity. Particularly support capacity expansion for manufacturers of vaccine inputs that are certified by regulatory agencies	Ongoing	In September, the U.S. announced nearly $3 billion in investments in expanded manufacturing capacity of critical vaccine inputs and supplies, including vials, needles and syringes, consumables, fill-finish capacity, and more	By expanding manufacturing capacity for vaccine inputs and fill-finish capacity, these investments will help alleviate global (including LMIC) vaccine production bottlenecks
(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	Ongoing	The U.S. International Development Finance Corporation (DFC), the European Investment Bank (EIB), the French Development Agency (AFD), and the International Finance Corporation (IFC) are investing in vaccine production in Senegal through the Fondation Institut Pasteur de Dakar {IPD). The support is a first step to grow the facility's long-term capacity to produce vaccines.	This support will help expand F&F capacity on the continent, including for COVID-19 vaccines.
(3.1) Promote and advocate for government and IO/IFI-supported initiatives/collaboration between vaccine manufacturer, development banks and supporting industries in LMICto	Ongoing	DFC, France's Proparco, and Germany's Deutsche Investitions-und Entwicklungsgesellschaft (DEG) are also working with the IFC to support COVID-19 vaccine and pharmaceutical manufacturing in Africa by providing financing to	This financing helps support Aspen's ongoing efforts to produce COVID-19 vaccines, including F&F for the Janssen vaccine.

strengthen national and regional capacity. Particularly support capacity expansion for manufacturers of vaccine inputs that are certified by regulatory agencies		South Africa's Aspen Pharmacare and other partners.	
(3.1) Promote and advocate for government and IO/IFI-supported initiatives/collaboration between vaccine manufacturer, development banks and supporting industries in LMICto strengthen national and regional capacity. Particularly support capacity expansion for manufacturers of vaccine inputs that are certified by regulatory agencies	Ongoing	The U.S. International Development Finance Corporation (DFC) is working with Indian manufacturer Biological E to finance increased capacity	This effort will support Biological E's effort to produce at least 1 billion doses of COVID-19 vaccines by the end of 2022

Annex 12: Meetings Convened by ACT-A Facilitation Council Vaccine Manufacturing Working Group

Meeting Date	Meeting Type
26 May	VMWG co-chairs and COVAX Leadership
22 June	VMWG and COVAX MFTF
30 June	VMWG
6 July	VMWG and COVAX MFTF
20 July	VMWG and COVAX MFTF
22 July	VMWG
10 August	VMWG and COVAX MFTF
18 August	VMWG with other Vx Manufacturing Initiatives
23 August	VMWG and COVAX MFTF
31 August	VMWG and COVAX MFTF
1 September	VMWG Industry Roundtable
15 September	VMWG and COVAX MFTF
29 September	VMWG
13 October	VMWG
26 October	VMWG

Annex 13: Key Vaccine Manufacturing Initiatives Engaged with VMWG