COVID-19 Vaccine Global Access (COVAX) Facility

Preliminary technical design

DISCUSSION DOCUMENT – 11 June 2020

Table of Contents

1. Context and issue

The world urgently needs safe and efficacious COVID-19 vaccines to protect the most vulnerable, stop transmission and prevent resurgence of COVID-19. Although other interventions, including therapeutics and diagnostics, have critical roles to play and should continue to be development priorities, vaccination is considered the linchpin intervention to sustainably restore health and societal stability. Through vaccination, we can mitigate the need for repeated rounds of distancing measures and associated negative social and economic impacts which would be significant.

COVID-19 vaccine development is advancing at an unprecedented pace; as of June 9th, there are at least 126 candidates across at least nine different technology platforms[1] in preclinical development and ~10 candidates already in early stage human clinical trials. **However, developing vaccines quickly is not enough. It is critical that there is sufficient supply of the most suitable (safe, efficacious, quality assured and appropriate) COVID-19 vaccines as soon as possible**, and that when available[2], supply is accessible globally for an effective public health response.

In April, WHO with the support of the European Commission and other global stakeholders, launched the **Access to COVID-19 Tools (ACT) Accelerator** to coordinate the activities of global actors toward addressing the challenge of equitable access to new COVID-19 therapeutics, diagnostics and vaccines. For COVID-19 vaccines, a number of activities are underway. **CEPI, which is leading the Development and Manufacturing Workstream** within the Accelerator's Vaccine Pillar, is making direct financial investments to support R&D and manufacturing expansion of promising candidates. To date, CEPI has entered into agreements to support 9 candidates, with equitable access conditions for vaccine developers/manufacturers as part of its funding. In addition, **WHO, which is leading the Policy and Allocation Workstream**, is developing global policy recommendations on use of vaccines via the Strategic Advisory Group of Experts (SAGE) on Immunisation. Building on these policy recommendations, WHO is also developing a global allocation framework to guide future allocation of limited vaccine supply toward public health goals based on transparent criteria.

To complement these activities, a mechanism is needed to incentivise manufacturers to expand production capacity, while they are still developing their vaccines. The **global vaccine requirements to control the pandemic are vast,** and achieving the scale of vaccine production needed, as quickly as possible, requires providing manufacturers with certainty of future **financing and procurement.**

Individual countries and groups of countries are already trying to address this challenge and secure vaccine for their domestic or regional needs by entering into bilateral agreements with manufacturers. However, going down this pathway with a **siloed and disaggregated approach will not be effective or efficient**. The competition for vaccine candidates would lead to a global bidding frenzy, driving up pricing as countries 'panic buy'. **As some vaccines are successfully developed, and most others are not, access to vaccine candidates would be limited to a privileged few countries that selected the successful candidates.** Research suggests that historically, vaccine programmes that have not yet entered human trials have just a 7% probability of succeeding, which rises to only 17% once they enter human trials. Furthermore, because supply of vaccines is likely to be constrained for at least the first 12-18 months, countries will find it difficult to obtain supply of other vaccines if the one(s) they contracted fail or aren't as effective. The **outcomes for lower income countries would be particularly dire**. Without the necessary financing or the ability to take risks with domestic resources during the pandemic, they would not be able to enter into supply agreements and would be left behind. Apart from potentially devastating consequences at national level, there will be associated global health security risks as the virus continues to circulate between countries.

To avoid this outcome a globally coordinated solution for financing and procurement is required. By working together, countries can jointly manage the uncertainty of which vaccine candidates will succeed by

[1] e.g., Candidates encompassing DNA, Inactivated, Live Attenuated, mRNA, Non-replicating Viral Vector, Replicating Viral Vector, Protein Subunit, Virus-like Particle (VLP), and OMV vaccine platforms

[2] i.e., when a proven safe and effective product (ideally to prevent COVID-19 infections meeting some agreed standards, TBD) is licensed, WHO prequalified and recommended for use.

pooling demand and resources and collaborating across individual investments. A **collective approach allows for a much larger portfolio of vaccine candidates than can be reached independently** and increases each country's chance of accessing sufficient supply. Countries can also **share technical expertise and knowledge** on vaccine candidates and investments, increasing the likelihood of supporting the most promising candidates and using manufacturing facilities most effectively as the portfolio matures. In addition, this globally coordinated approach, whereby demand and resources are pooled across countries, would be a **more efficient way of investing** and would allow countries to leverage benefits of economies of scale and reduced transaction costs. Given that upfront certainty on demand and financing will be required to incentivise manufacturing expansion, acting urgently is essential.

2. Solution in brief

The **COVID-19 Vaccine Global Access (COVAX) Facility** is proposed as a mechanism to enable such collaboration. This name has been chosen as it highlights the **importance of global coordination and cooperation** and **equitable access** to vaccines. This Facility is **focused on COVID-19 vaccines and associated supplies** and not other COVID-19 tools or vaccines for other infectious diseases. The COVAX Facility will be **time-limited**, focused on addressing supply requirements for reaching agreed priority populations to control the pandemic and to create a healthy vaccine market to support vaccine requirements beyond this[3]. In particular, it aims to ensure developing countries are not left behind in terms of access to vaccines, and the global pandemic is contained in the shortest time possible.

2.1. Objectives

The primary objective of the Facility is to **accelerate equitable access to appropriate, safe and efficacious vaccines**. To achieve this, two **supporting objectives** have been identified:

- **Secure supply rapidly** through resilient expansion of manufacturing
- **Reduce uncertainty and lack of predictability of demand and financing** as a barrier to manufacturing expansion

The Facility should **adapt to an evolving situation and set of needs**, **while balancing predictability to countries and manufacturers**. Some of the drivers of adaptation include the evolution of disease epidemiology, candidate pipeline, country needs and policy. These factors introduce uncertainties, which will need to be considered and/or managed in the Facility's engagement with manufacturers, countries and stakeholders (see Annex A).

[3] The exact timeframe of the COVAX Facility will be determined once there is greater clarity on policy recommendations regarding target populations and supply availability to meet global demand for these groups.

2.2. How the Facility works

The COVAX Facility is the umbrella financing and procurement mechanism through which demand and resources are pooled to support procurement of and equitable access to COVID-19 vaccines. All countries are invited to participate in the Facility and all participating countries would benefit by securing affordable access to vaccine supply through the Facility. Countries with less purchasing power as well as fewer resources and capacities to enter into their own agreements with manufacturers would benefit by entering into a joint pool for securing and procuring vaccine doses. Even those countries who do have the resources to enter into bilateral agreements with manufacturers, or have already done so, would benefit as the Facility provides access to a wide portfolio of vaccine candidates, insuring against the risk that the candidates they have invested in are unsuccessful.

At its core, the COVAX Facility is a risk-management mechanism – *reducing risk for countries concerned about failing to secure access to vaccines and reducing risk for manufacturers concerned about investing without assured demand*

To ensure participation in the Facility – and access to the vaccines secured through it – is possible for all countries, it is envisaged that some participating countries will receive financial support, where needed, to secure the predictability and timeliness of the Facility's financing. This is likely to include **support from Gavi to low and lower middle-income countries through Official Development Assistance (ODA) funding from donors**. These countries could potentially receive support for example, for contributions to the Facility, vaccine procurement, delivery and technical assistance. Other middle-income countries could potentially be eligible for specific financing or credit enhancement support to enable their participation in the Facility.

Countries can participate in the Facility in two ways, depending on whether they self-finance or are donor supported. **Fully self-financing countries (HICs, UMICs) contribute directly to the Facility by committing to purchase the doses to vaccinate the highest priority populations**. These countries confirm this commitment by making **upfront financial contributions to the Facility**, proportional to the number of doses they will receive. These contributions will act as down-payments against future vaccine delivery and will enable the Facility to enter into advance purchase commitments for future vaccine supply. As supply becomes available, **a ring-fenced proportion of that real-time vaccine production will be directed to the fully self-financing countries to be used by these countries according to the guidance provided by their national bodies**. The exact amount of ring-fenced real-time production still needs to be determined, but could be a proportion of population. Self-financing countries that engage in bilateral deals would be encouraged (but not required) to donate any doses they may not require to the Facility. Timing of commitment to the Facility will make a difference. Fully self-financing countries that join the Facility before early deals with manufacturers are concluded (date to be determined) will be able to access the ring-fenced volume for self-financing countries, while those that commit after this point would not have this assurance.

Funded countries (LICs and LMICs) are those whose financial commitments for participating in the Facility are covered by official development assistance (ODA). They also get access to volumes as soon as it becomes available to meet requirements to vaccinate the highest priority populations. The volumes specifically directed to these funded countries would be **allocated across them using guidance from the global allocation framework** under development by WHO, which builds on WHO's policy recommendations on priority target populations.

Within the COVAX Facility, an innovative finance instrument – the Gavi COVAX Advance Market Commitment (AMC) – will be used to secure access to timely and sufficient supply of vaccines for LICs and LMICs, including IDA-eligible Small Island Economies. The use of the AMC term leverages an innovative finance concept familiar to many stakeholders, in particular donors, while noting the COVAX AMC will not be identical to other previous AMCs. The Gavi COVAX AMC was launched on 4 June and is the first building block of the COVAX Facility. It has received seed funding of over US$ 500m at its launch – primarily ODA from OECD countries. The Gavi COVAX AMC will be supplemented by additional innovative finance building blocks to enable joint investment in the advance purchase commitments on behalf of HICs and UMICs that choose to participate in

the Facility and would not be financed through ODA. While there will be separate sources of financing, advance purchase agreements will be integrated.

The COVAX Facility will utilise pull mechanisms, which are instruments to incentivise manufacturer product development and installment of capacity through the assurance of future procurement at a pre-determined volume and price of a successful candidate. Two types of pull mechanisms will be used. Gavi will enter into **manufacturer-specific contingent volume guarantees** to procure vaccines that meet the agreed WHO Target Product Profile[4], so as to de-risk and incentivise timely investment in expansion of manufacturing capacity. The Facility will also rely on a **market-wide demand guarantee**, which could provide continued incentives and assurances to manufacturers to expand production capacity and to bring products to market meeting e.g. preferred characteristics of the WHO target product profile (TPP) or with enhanced characteristics based on country needs.

Direct financial support done at risk prior during product development to facilitate expansion of manufacturing capacity (sometimes referred to as 'push' funding) is being led by ACT Accelerator partners (CEPI, BMGF and other stakeholders) outside the COVAX Facility. The effectiveness of the Facility pull incentive mechanisms will rely on **close collaboration and sharing of information** with those financing push investments to enable both sets of investments to be complementary and synergistic. This collaboration will take place within the ACT Accelerator Vaccines Pillar.

The Facility may issue an Expression of Interest (EOI) process to provide itself with some level of visibility and ensure the volumes and prices intended support the Facility objectives. **Vaccine pricing will be negotiated under the expectation that manufacturers seek minimal returns in the near term for supply to vaccinate priority populations and control the pandemic and will take into consideration any other direct financial support received by manufacturers**[5]. For the short-term period, depending on the manufacturer proposals received, there could be a flat price from manufacturers with a cross-subsidization mechanism to establish differential pricing for countries to account for varying ability to pay. The Facility may accommodate manufacturer requests for tiered pricing if the price levels offered for each tier are considered appropriate. Beyond the near term, pricing would evolve to a traditional tiered pricing approach. Upon availability of doses, vaccines will be procured via **existing procurement mechanisms** (e.g., UNICEF Supply Division, PAHO Revolving Fund, EC, individual country procurement mechanisms).

Given the previous successful experiences with similar advance purchase and market commitments, the Gavi Secretariat would coordinate the activities of the COVAX Facility and implement the Gavi COVAX AMC, working closely with other ACT Accelerator partners. **Roles and responsibilities, the financing structure and legal agreements for the COVAX Facility will be further defined**. **A tailored governance mechanism will also need to be defined**, ensuring representation of Facility investors and recipients, including a combination of fully self-financing and funded countries. The figure below provides a simplified schematic description of the participation of countries in the COVAX Facility, including both LICs/ LMICs supported by ODA and other participating countries (UMICs and HICs), and the Gavi COVAX AMC as the initial innovative financing instrument for LICs and LMICs.

[4] Target Product Profiles for COVID-19 vaccines: https://www.who.int/who-documents-detail/who-target-product-profiles-for-covid-19-vaccines

[5] For example, national R&D grants or subsidies

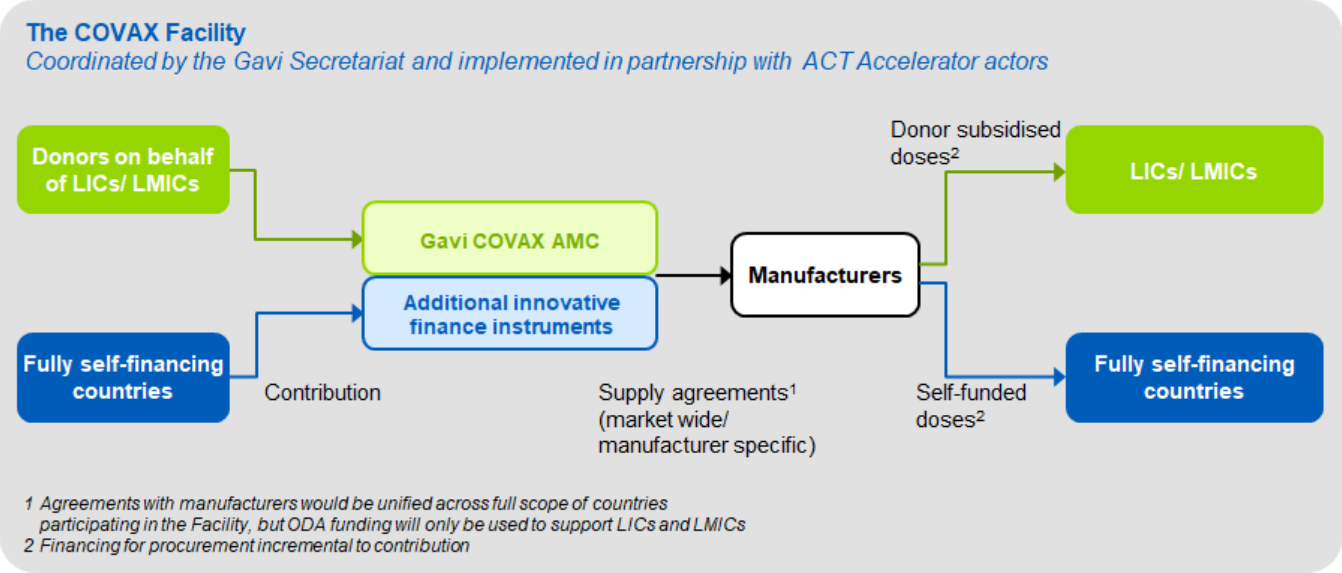

***Figure 1**: Schematic representation of COVAX Facility*

2.3. The COVAX Facility within the ACT Accelerator

The COVAX Facility sits within the overarching **ACT Accelerator Vaccines Pillar as part of the Gavi-led Procurement and Delivery At-Scale Workstream.** It will be **complementary to other Vaccine Pillar efforts**. CEPI is leading the Development and Manufacturing Workstream, which includes facilitating direct financial investments for the support to R&D and manufacturing expansion of the most promising candidates. The COVAX Facility pull incentive mechanisms will build on and be synergistic with these CEPI investments towards accelerating availability of COVID-19 vaccines at scale. WHO is leading the Policy and Allocation Workstream which is developing policy recommendations on vaccine use and a framework for allocation of limited supply. This allocation framework will serve as the basis for allocating supply secured through the COVAX Facility for the donor-supported country participants, in a fair and equitable manner. Within the Accelerator Vaccines Pillar, and Independent Product Group, comprised of independent experts, will also advise on the technical assessment of candidate vaccines to inform investments. The Alliance – including the Gavi Secretariat, WHO, UNICEF and other partners – will additionally focus on supporting developing countries to prepare for deployment of COVID-19 vaccines as soon as they are available as part of the Procurement and Delivery At-Scale Workstream. In combination, these three Vaccine Pillar workstreams will support equitable access to COVID-19 vaccines globally. The figure below outlines the COVAX Facility within the Vaccine Pillar of the ACT Accelerator.

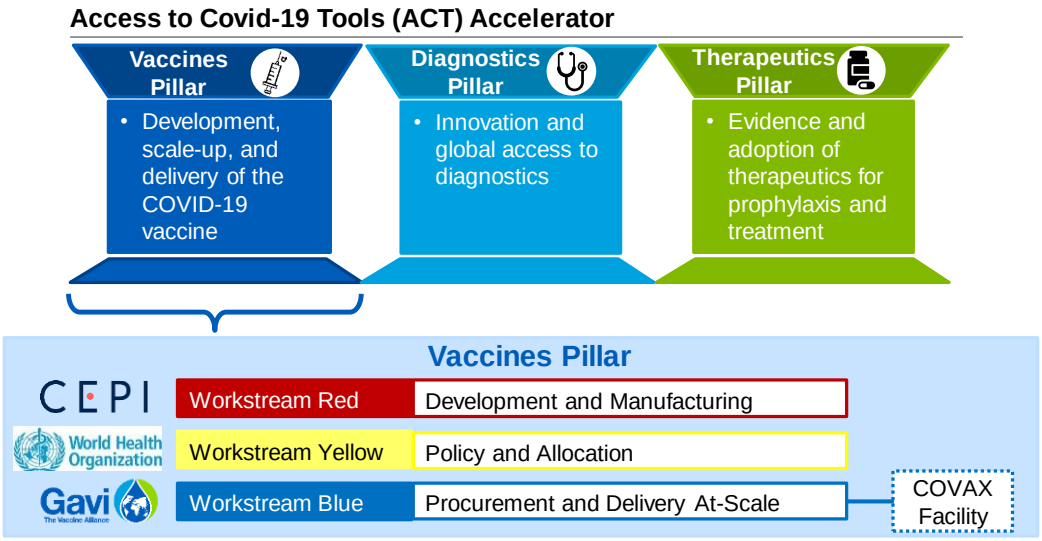

***Figure 2**: The COVAX Facility within the ACT Accelerator*

The preliminary technical design of the COVAX Facility was developed on an accelerated timeline over a ~4 week period given the urgency of addressing the challenges described. The Gavi Secretariat worked closely with technical partners – BMGF, CEPI, UNICEF, World Bank, WHO – to perform analyses and identify design concepts. Rapid consultations were conducted with civil society organisations, developing and donor countries, manufacturers, think tanks and other subject matter experts to help inform the design. Annex B provides a list of stakeholders consulted. The Gavi Secretariat will continue engaging closely with stakeholders to finalise the design of the COVAX Facility and begin operationalisation.

3. Country participation

3.1. A global aspiration

COVID-19 is the biggest threat to global health security in a century, and the pandemic has shown that disease has no borders. Countries have seen that the health of their people is inextricably linked to the health of the world's people. Without a global effort that focuses on vaccinating the world's key priority populations across all countries and quickly tackling disease outbreaks, the pandemic will continue to spread, within and between countries, with significant and ongoing health, economic and social ramifications for all.

The devastating depression of the global economy caused by the pandemic gives another clear incentive for an international response to mitigate these economic consequences. Until the pandemic is brought under control, limitations to social and economic activity, even if only targeted lockdowns and restrictions in movement and cross-country travel, will continue to impede economic recoveries. According to IMF estimates, the cumulative loss of the global economy in 2020 and 2021 could be around US$ 9 trillion[6]. With the IMF currently projecting that advanced economies are being particularly hard hit, compared to other countries they will have the worst recession and will experience the greatest negative impact on trade volumes. In today's globalized economy, only a global solution will provide the stability required for individual economies to go back to pre-pandemic growth projections.

Countries cannot solve this problem alone. The reality is that the vast majority of countries will not be able to secure access to a vaccine by entering into early stage bilateral agreements with manufacturers, neither able to

[6] IMF Blog https://blogs.imf.org/2020/04/14/the-great-lockdown-worst-economic-downturn-since-the-great-depression/

raise the necessary financing nor to take the risk with limited state resources, already stretched by the COVID-19 pandemic response. But even for countries that can invest in these bilateral agreements, the outcomes are far from certain. Countries will be limited in the number of deals they can enter into given their fiscal constraints, and there is no guarantee that any that they do enter into will be successful, with potentially significant associated financial loss if not: research suggests that historically, vaccine programmes that have not yet entered human trials have just a 7% probability of succeeding, and still only 17% even once they have entered human trials[7]. Achieving an ~80 per cent chance of success would require investing in up to 15-20 candidates[8]. But even if countries are fortunate enough to back a vaccine candidate that proves to be both efficacious and safe, they cannot isolate their populations and their economies from a continuing global pandemic. As cross-border transmission fears remain a very real threat, and movement and transport restrictions remain in place, countries will see slow, lengthy national recoveries with potential lockdowns and uncertainties coming back at any time. Large reservoirs of virus circulating among humans also risks continued evolution of the virus which may lead to better adapted, more lethal strains.

A disjointed, non-collaborative approach, where individual countries or groups of countries continue to pursue siloed vaccine strategies and each invests to scale-up specific vaccines, will lead to an **inefficient use of resources** and the **inequitable allocation of eventual vaccines**, with damaging outcomes to the detriment of national and global health and economies. The competition for vaccine candidates and manufacturing capacity could lead to a global bidding frenzy, driving up pricing as countries 'panic buy' with poorer countries left behind. Competing funds could 'cannibalise' each other and give very confusing market signals. Finite manufacturing inputs and capacity would also end up being locked into individual agreements, not available to support production of the vaccines that end up with the most appropriate characteristics, and even countries with successful candidates may subsequently find themselves without sufficient manufacturing capacity to rapidly produce the required quantities. Furthermore, due to the global nature of supply chains, a lack of international coordination could prevent materials crossing borders to where they are most needed, further paralysing vaccine production. It is an unfortunate reality that vaccine nationalism could result in export controls over needed components or vaccines.

Access to vaccine candidates that successfully emerge from the R&D process would be limited to a privileged few countries who had been able and fortunate enough to have entered into bilateral agreements with vaccine manufacturers whose vaccines proved efficacious and safe. Countries that had supported unsuccessful vaccine candidates, or those unable to enter into bilateral agreements, would be left without access to vaccines (alongside losing any investments).

Equitable access to COVID-19 vaccines is therefore a global problem that calls for a global, coordinated solution. The global community took the first step towards answering this call by passing the COVID-19 resolution at the World Health Assembly, a landmark achievement cementing the commitment of all 194 countries towards controlling the pandemic and making immunisation against COVID-19 a global public good.[9]. **The COVAX Facility, designed to ensure equitable access to a safe and efficacious COVID-19 vaccine, embodies that commitment, and represents the next step in this global endeavour. All countries are invited to participate.** By working together, countries can jointly manage the uncertainty of which vaccine candidates will succeed by collectively investing and pooling their risk, reaching a larger pool of vaccine candidates than they could have reached independently. Even for countries with the financial ability to enter into bilateral agreements with manufacturers, the Facility could be viewed as a form of insurance policy, diversifying their risk to increase their eventual chances of accessing a vaccine. And by joining the Facility, countries that would previously have been competing with each will now be working together. For those countries that don't have the ability to independently make bilateral deals, without the COVAX Facility they will almost certainly be left behind.

---

[7] Pronker ES, Weenen TC, Commandeur H, Claassen EH, Osterhaus AD. Risk in vaccine research and development quantified. PLoS One. 2013;8(3):e57755. doi:10.1371/journal.pone.0057755

[8] "Accelerating a COVID-19 Vaccine" Athey, S. et al. May, 2020. *In preparation.*

[9] Resolution WHA 73/1 on 19 May, 2020. https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf

Being part of a pool **increases countries' chances of access as time reveals efficacious and safe vaccines**. Investing in just one or two vaccine candidates is a high-risk strategy but the Facility would have the ability to invest in many more. The more countries that participate in the Facility, the greater the Facility's ability to invest in a greater number of deals, increasing both the chances of success and the ultimate availability of supply. Being part of a pool is also a more efficient way of investing and would bring countries **more sustainable vaccine prices**, thanks to economies of scale and reduced transaction costs. Together, countries can achieve a global view of demand and pool resources together, allocating and investing in manufacturing capacity that can be flexibly deployed to produce vaccines with the most appropriate characteristics at scale to meet that demand.

When COVID-19 vaccines become available, the Facility will work to support the equitable distribution of vaccines across countries, striving to ensure that **key priority populations across all countries can be protected** by assured access to COVID-19 vaccines, that disease hotspots can be brought quickly under control to limit the risk of outbreaks spreading and cross-border transmission, and the global economy can start to reopen.

The sections below introduce the overarching design of the Facility, whilst recognising that there are still details to be refined. They present a set of operating principles for the Facility, describe what the benefits are for participating countries, and outline what countries will be asked to contribute in return.

3.2. Operating principles

The COVAX Facility is designed to **accelerate equitable access** to appropriate, safe and efficacious vaccines. It is an ambitious undertaking. And for such an ambition to succeed, it needs to operate in line with a set of clearly defined principles that are agreed by all participants:

- **Global access:** Protecting global health security means ensuring that everyone can secure access to a safe and efficacious vaccine. The Facility is open to all countries, and no country will be prevented from participating due to income. Pricing principles will reflect manufacturers' commitment to seek minimal returns during the short-term acute phase of the pandemic, with potential evolution over time to, for example, tiered pricing to support longer term sustainability and affordability of the vaccines for all countries.

- **Impact-oriented and transparency:** The COVAX Facility is single minded in its goal to ensure equitable access to a COVID-19 vaccine. Recognising that in the short-term, demand for vaccines will outstrip supply, a coordinated strategy for vaccination is needed to reduce the spread of the virus and its impact on lives, health systems and economies.

- **Solidarity and collective ownership:** Countries will need to work together to overcome the pandemic, committing to this collaborative global effort. Everybody contributes so that everyone can benefit. This principle will be realised through clear political and financial commitments, and all countries will be asked to contribute to the Facility based on their capacities in the form of financial contributions and potentially vaccine doses.

3.3. Benefits for country participants

The COVAX Facility encourages and enables as wide a participation as possible for all countries in pursuit of reaching a globally coordinated solution. It is designed to deliver **affordable access to enough supply of efficacious and safe vaccines needed by participating countries to vaccinate their highest priority populations** against COVID-19. Every country has a unique set of needs, and different countries will find the various benefits of the Facility especially pertinent for different reasons.

Countries that have not entered into any bilateral agreements with vaccine manufacturers will benefit from the Facility's assured access to affordable vaccines. This is particularly true for **low and lower middle-income countries** (LICs and LMICs) who, with less purchasing power and fewer resources and capacities to enter into bilateral agreements with suppliers, are likely to struggle on their own and may find themselves paying very high prices to secure supply. LICs and LMICs that participate in the Facility will additionally benefit from targeted Gavi financing and programmatic support through the Facility, combining access and financing in a seamless,

coordinated mechanism[10]. **Upper middle-income countries** (UMICs) will also be attracted by timely, affordable access to vaccines, keen to avoid feeling forced into 'panic buying' uncertain vaccine candidates at high prices, or to only receive supply after the demand of wealthier countries is met.

High-income countries (HICs), despite having greater purchasing power and therefore greater ability than lower income countries to independently secure bilateral deals with manufacturers, still face the challenge of not knowing which vaccine candidates will be successful, potentially being left without a vaccine, or trying to hedge that risk by entering into multiple agreements but carrying a high level of financial exposure. The Facility gives them access to a portfolio of vaccine candidates, insuring against the risk that the candidates they invest in are unsuccessful. Joining the Facility also removes the need to compete with other countries for any individual supplier, possibly resulting in higher prices and putting capital at risk, an inefficient use of government resources. HICs have also called for greater global engagement and collaboration against the pandemic. Participating in the Facility is a concrete way of implementing this resolution, demonstrating global goodwill whilst protecting domestic interests. Many countries have already made announcements to this effect, recognising the role of extensive immunization against COVID-19 as a global public good.

The Facility brings **countries that have entered into bilateral agreements with vaccine manufacturers** a 'portfolio approach', insuring them against the risk that the vaccine candidate they have invested in fails, leaving them without any effective doses. The Facility enables these countries to insure against this risk, diversifying their portfolio through reasonable investments to increase their eventual chances of accessing safe and efficacious vaccines and to ensure the protection of their highest priority populations.

Countries that 'house' vaccine developers and manufacturers that are working to develop successful vaccine candidates and appropriate manufacturing capacity could see these enterprises benefit from the agreements that the Facility will make with manufacturers, bringing investment to their countries. Middle-income countries with emerging vaccine production and regulation capabilities would particularly benefit if vaccine manufacturers in their countries were to sign contracts with the Facility, given the visibility such a deal would bring with longer term benefits for their vaccine industries. Countries may also have access to tech-transfer opportunities and the potential over time to gain additional manufacturing capacity if manufacturing is quickly 'globalized'.

Certain **regional groupings** of countries, such as the Pan American Health Organization or the European Union, are created under the principle of solidarity amongst its members and include countries with varying country characteristics (i.e. a range of needs, financial strengths, and differing vaccine capabilities). These regional groupings already often procure as a group (e.g. PAHO's Revolving Fund) and would benefit by joining the Facility as a bloc to secure reliable and affordable vaccine supply for their countries, as well as demonstrating their commitment to the global effort. These groupings would also bring a clear added value to the Facility in the form of a strong, existing organizational ability to represent a large number of countries as a single entity, as well as their experience of uniting self-financing member states around a common goal.

The benefits for countries accrue as more and more countries join the Facility. The Facility will rely on countries' financial commitments and upfront financial contributions to enter into agreements with manufacturers to secure future vaccine doses for participating countries. The greater the number of countries that join the facility, the larger the number of agreements that the Facility can enter into, both securing more doses and more effectively spreading the risk of failure across a greater number of vaccine candidates. As more and more countries join the Facility, this also reduces competition both between these countries, and between the Facility and these countries, reducing panic buying, leading to better prices and a more effective pooling of risk.

Over and above these immediate country benefits**, participating countries will reap the rewards of global solidarity**: protecting **national and global health security** by achieving higher global vaccine coverage as more

[10] Some targeted support, for example for technical assistance, could also be considered for selected upper middle-income countries and Small Island States as per the World Bank's IDA definition. The scope of technical assistance is still to be determined.

and more countries are able to access a vaccine; the subsequent **positive impact on national economies and the global economy**; and the knowledge that they have set a **historic precedent on how the world can work together** to tackle a global pandemic, setting an example of how to respond to threats to global health security knowing that COVID-19 will not be the last threat of its kind.

3.4. How will doses from the Facility be allocated?

The Facility will allocate doses from the Facility to participating countries through a clear and transparent process, recognising that there will be, at least initially, a limited supply of vaccines[11]. This process ensures that available vaccines through the Facility are designated to participating countries in a fair and equitable manner.

The process collects countries into two groups: countries that are fully self-financing their participation in the Facility, and countries whose participation is supported by donor funding. Each group of countries will have a ring-fenced proportion of real time vaccine production[12]. The criteria to determine the size of this ring-fenced proportion is still to be determined but could be calculated based on proportion of population. Within each group of countries, doses from this ring-fenced proportion will then be allocated in the following way:

- **Fully self-financing countries:** The Facility will work to secure enough vaccine doses to enable all countries in this group to vaccinate e.g. 20% of their populations, to ensure that every country can immunise their highest priority populations[13]. Ring-fenced doses for this group will be distributed evenly amongst all countries in the group until each country has received enough doses to vaccinate this proportion of their population. Whilst the Facility will determine the number of doses that a country receives, it will not interfere with a country's sovereign right to follow guidance from their own national bodies about how they use any fully self-financed allocated doses once they receive them.

  In line with the principle of solidarity, if a country in this group successfully concludes a bilateral deal and receives enough doses to cover e.g. 20% of their population, the Facility requests that these countries delay receipt of any additional doses from the Facility until all other Facility country participants have received enough supply to also cover their highest priority populations. The Facility requests that countries be open and transparent about their supply agreements. This requirement matches the condition placed on manufacturers to also be open and transparent about their bilateral deals with countries.

  Once all countries in this group have received sufficient supply from the Facility to cover e.g. 20% of their population, any additional supply of vaccines would be offered to countries in line with a needs-based allocation framework[14].

- **Funded countries (supported by ODA):** The Facility will work to secure enough doses to enable all countries in this group to vaccinate at least their highest priority populations. Ring-fenced doses for this group of countries will be allocated to, and distributed across, countries according the WHO Allocation Framework, which is based on transparent ethical and public health criteria. This will require a **clear picture of applicable demand from countries**. In addition, WHO will provide policy recommendations to countries on use of vaccines, which will be particularly important for developing countries which may have limited capacity to conduct a robust epidemiological assessment.

---

11 The successful execution of push and pull incentives, procurement and allocation of vaccine could result in sufficient supply to meet priority vaccination needs by end of 2021 – as illustrated in a simulation (Annex C).
12 Note that these two ring-fenced proportions will not add up to 100% of available doses, as a proportion of doses will be held by the Facility in reserve as a buffer to be deployed against severe outbreaks and to address the most urgent public health issues.
13 Countries will have access to enough supply to vaccinate either e.g. 20% of their population, or all of their highest priority populations (as determined by WHO policy recommendations on target populations), whichever is the lesser.
14 In line with the WHO Allocation Framework

Timing of commitment to the Facility is critical. Fully self-financing countries that join the Facility before early deals with manufacturers are concluded (date to be determined) will be able to access the ring-fenced volume for self-financing countries and will receive doses in the manner described for this group of countries. **Committing early assures full self-financing countries of a secured allocation and the benefit of their contributions.** Other fully self-financing countries would potentially still be able to participate in the Facility beyond this point but would only receive available volumes from existing and additional supply agreements without the assurance of the ring-fenced distribution. For those who commit early to support time-sensitive advance purchase commitments, this provides reassurance that they have a secured allocation and will realise the benefits from their contributions.

Countries will realise doses allocated to them by the Facility through **existing procurement mechanisms**, such as UNICEF Supply Division, PAHO Revolving Fund and those of self-financing countries. By leveraging existing procurement structures, the Facility avoids the significant time and effort required to establish a 'new' single procurement mechanism and also avoids requiring countries to adapt to a new process, which also carries that risk of creating a barrier to country participation. Using existing mechanisms also ensures that procurement, shipment and delivery of COVID-19 vaccines can be harmonised with other vaccines and commodities, to ensure efficiency and minimise disruption in those countries and regions. The details of operationalising procurement across multiple procurement agencies within the Facility will be further explored.

3.5. Obligations for country participants

Being an active participant in the Facility implies benefits but also obligations. In line with the principle of solidarity and collective ownership, all countries will be asked to make **a binding financial commitment to purchase doses for the first year from the Facility**[15]**.** Countries will make an **upfront financial contribution** to the Facility, proportional to the size of their overall financial commitment, which is itself proportional to the required number of doses. These contributions will act as down-payments against future vaccine delivery and will be paid by countries to the Facility according to a payment schedule[16]. The Facility will use the financial commitments and upfront financial contributions to enter into advance purchase commitments with manufacturers. Once doses are available, countries will realise their initial commitments to purchase doses and will receive doses in return[17]. Further procurement or "calls" for larger volumes of doses could be coordinated through the Facility. The future price of vaccines secured through the Facility is considered in **Section 5**.

In line with the principle of global access, to ensure the Facility and access to vaccines is accessible for all countries it is envisaged that financial institutions will support some countries, where needed, with predictable and timely financing.

Low- and lower-middle income countries will have their participation in the Facility supported by ODA towards, for example, the initial financial contribution and subsequent vaccine procurement and vaccine delivery support. These countries may also receive additional support for **targeted technical assistance from Gavi** to ensure that countries are ready to implement effective and efficient vaccination strategies. There is also the potential for **Multilateral Development Banks** (MDBs) to provide financing support for fully self-financing countries, such as UMICs, towards ensuring the ready availability of financial resources, consistent with their programming capacities.

---

15 Fully self-financing countries would commit to purchasing enough doses to cover e.g. 20% of their population. Countries supported by the Gavi COVAX AMC would commit to purchasing enough doses to cover their highest priority populations, e.g. healthcare workers and the elderly.

16 Countries may have financial commitments backed, and upfront financial contributions met, by alternative funding arrangements, for example: Gavi financing for low income countries, lower middle-income countries, and potentially also for Small Island States as per the World Bank's IDA definition; or from financing institutions like Multilateral Development Banks (MDBs). See Section 7 for more details. It is critical that countries do not face financial barriers to participation.

17 Doses will be allocated to participating countries in line with the WHO Global Allocation Framework

Participating countries that 'house' vaccine manufacturing capacities used to produce COVID-19 vaccines would be required to demonstrate their commitment to the principles by agreeing to not impose embargoes or any impediments to access, and to quickly resolve or prevent any bottlenecks such as timely National Regulatory Authority (NRA) release, import/export requirements, and prioritisation of cargo space for vaccine shipments. Finally, participating countries would be expected to contribute data (e.g. epidemiological and virological) to global information repositories[18] to build the overall body of knowledge (e.g. to inform vaccine development and vaccination strategies) to the benefit of all countries. Once vaccines are distributed and used, results from country pharmacovigilance will be shared for the benefit of all.

Countries that wish to sign up to the principles of the Facility, to make financial contributions, to donate vaccine dose contributions from bilateral agreements, or to agree to ensure unrestricted movement of vaccine doses produced inside their borders, are welcome to participate, regardless of whether or not they seek to access doses through the Facility.

3.6. Examples

Four examples help to demonstrate how participating countries will interact with the Facility.

Example 1: A low income country, supported by ODA, with no capacity to make bilateral deals with manufacturers seeks to participate in the COVAX Facility to obtain access to a COVID-19 vaccine. The country determines the number of doses they need to vaccinate their high-risk populations, such as healthcare workers and the elderly, in line with the allocation framework. The country approaches the Facility and, because of their low-income status, receives financial support from ODA to make the necessary financial commitment and associated upfront financial contribution, guaranteeing their demand for vaccine doses. The Facility includes this country's demand in the COVAX Facility's forecasts, entering into sufficient agreements with manufacturers to secure enough eventual supply of successful vaccine candidates. When an efficacious and safe vaccine is available, the WHO Allocation Framework determines the number of doses the country will receive and the country finalises the procurement through a procurement agency, such as UNICEF Supply Division (SD). The initial financial contributions count as down payments against these doses, and only the remainder is due. Gavi supports the country to pay this remainder by providing vaccine financing to procure the doses through UNICEF SD.

Example 2: An upper middle-income, fully self-financing Latin American country that has not been able to secure any bilateral deals with manufacturers is concerned that they will not be able to vaccinate their highest priority populations. They want to participate in the Facility to ensure they can meet their priority needs. The country makes a financial commitment to the COVAX facility to purchase enough doses to cover e.g. 20% of their population and a multilateral development bank or financial institution provides the upfront financial contribution and financial guarantee on behalf of the country. When an efficacious and safe vaccine is available, thanks to their agreement with the COVAX Facility, the country is able to procure the determined number of vaccine doses through the Pan American Health Organization Revolving Fund. The country fully finances the vaccine doses from domestic resources.

Example 3: A fully self-financing country had previously entered into a bilateral agreement with a manufacturer but does not know if the vaccine candidate they have invested in will be successful. The country sees participating in the COVAX Facility as a form of insurance policy to ensure the vaccination of at least their highest risk groups, given the Facility's broader pool of vaccine candidates. The country makes a financial commitment to purchase enough doses to cover e.g. 20% of their population and makes the necessary upfront payment. Unfortunately, the vaccine candidate from the bilateral deal fails in clinical trials. However, when an efficacious and safe vaccine becomes available through the COVAX Facility, the country finalizes the procurement through the relevant procurement mechanism, makes the remaining necessary payments, and receives their doses as they become available.

[18] Including, for example, the WHO Global Health observatory data repository (https://apps.who.int/gho/data/node.main), as well as potentially other systems especially for surveillance, lab data etc.

Example 4: A fully self-financing country participating in the Facility has a bilateral agreement with a manufacturer whose vaccine candidate proves successful. This bilateral deal has produced sufficient doses for the county to vaccinate e.g. 20% of their population and so, in line with the principle of solidarity, the Facility asks them to wait to receive additional doses from the Facility until all the other fully self-financing countries have also been able to do the same. In fact, the country no longer requires the doses they committed to purchase through the Facility, and so decides to donate these to low income countries within the Facility as an ODA contribution.

4. Demand scenarios

WHO and its Strategic Advisory Group of Experts (SAGE) on Immunisation will define the vaccination recommendations and strategy for COVID-19 vaccines based on disease epidemiology, vaccine characteristics, public health impact, and other considerations. While these recommendations will only be available once specific vaccines can be considered, the Gavi Secretariat, in consultation with partners, has identified **potential COVID-19 vaccination scenarios to inform planning assumptions and forecasts** of dose and funding requirements. These do not constitute a presumption of the eventual vaccination recommendations from WHO and SAGE.

Three potential vaccine programme objectives, with associated target populations, are considered, which could be addressed as supply becomes progressively available. First, **protecting the most vulnerable** by preventing infection, serious illness and deaths among **healthcare workers and older adults** (65+ year olds) and maintaining a **buffer** to stop uncontrolled outbreaks or vaccinate other target groups such as those with co-morbid health conditions. Second, **minimizing societal and economic disruption by immunizing the general workforce**. Third, subject to such data on transmission dynamics, **stopping transmission by immunizing additional virus spreading populations**. The indicative planning scenario for the COVAX Facility assumes that the highest priority populations will serve the first objective, consisting of vaccinating healthcare workers and older adults and maintaining a buffer of doses. This would need to be confirmed with additional data and policy recommendations.

As our understanding of disease epidemiology, immunity following exposure/infection, transmission dynamics, and specific vaccine characteristics evolves, the relative priority, specific target cohorts and the sequencing of vaccinating these segments might shift. Country participation in the Facility will be defined over time with the aim of as broad global participation as possible. As an indicative example of a potential eventual scope of country participation, a scenario was modelled which includes LICs, LMICs, and a number of UMICs/HICs. Focusing on the most immediate term to protect the most vulnerable as described in the first scenario above, an estimated ~1.7 bn doses (which is not an implausible amount) from 2021-2022 would be needed. The total demand for all three scenarios described above would sum up to around 9 bn doses for these countries from 2021-2026. These estimates assume a two-dose regimen and would be halved for a single-dose vaccine. The total demand needed to be addressed by the COVAX Facility will be dependent on the number of countries ultimately participating. More detailed modelling of this is underway.

5. Incentive mechanisms

In order to serve the Facility's primary and supporting objectives, it will be important **to identify the appropriate levers to influence suppliers towards these goals**. Supplier behaviour in vaccines markets is, to an important extent, driven by their perception of risk: development risk, demand risk and competition risk – all critical factors affecting the potential return on their investments in R&D and capacity establishment.

Therefore, interventions to guide supplier behaviour towards desired outcomes of the COVAX Facility will be focused on sharing risk with suppliers of vaccines and administration commodities through the use of targeted financial instruments. **Given that risks are expected to vary over time, the instrument mix may vary**

accordingly. Through the instruments deployed, in addition to securing supply, the COVAX Facility intends to support a continued pipeline of improved products coming to market.

There are two types of instruments which can optimally address these risks. Push incentives seek to make vaccine development more attractive to firms by sharing their costs and hence, share the risk on their upfront investments in R&D and manufacturing capacity. In contrast to push funding, pull incentives generally encourage manufacturers' investments in R&D and manufacturing expansion by focusing on addressing commercial risk. As each instrument shares different manufacturer risks, a combination of complementary push and pull incentives is likely to be most effective in securing manufacturers' commitments to deliver sufficient and timely supputily, and in achieving equitable access objectives. Manufacturers benefiting from the funding attached to these instruments will also be expected to adhere to a principle of transparency to ensure the instruments' complementarity and to maximise value for money.

ACT Accelerator partners – in particular CEPI and BMGF – are currently making push investments in COVID-19 vaccine candidates through the Development and Manufacturing Workstream within the Accelerator's Vaccine Pillar. These investments serve as a starting point for securing timely and sufficient supply of vaccines. Push investments are out of scope for the COVAX Facility, which will focus on pull mechanisms to incentivise suppliers to come to market at the maximum speed and scale possible. In order to ensure complementarity with and effectiveness of the COVAX Facility's pull incentives, it is expected that partners doing push funding will share information with the Facility to avoid double paying and in general Gavi will align efforts with the providers of push funding, **inclusive of other providers outside the ACT Accelerator where feasible.**

5.1. Pull instrument

Pull mechanisms[19] **with strong guarantees on demand could provide suitable global vaccine candidates with incentives both for vaccine development and manufacturing capacity investment, and to allocate doses to the COVAX Facility and its participating countries**, even in a very supply-constrained environment.

The COVAX Facility will provide two types of pull incentives:

- **Manufacturer-specific volume guarantee**: this incentive mechanism mitigates demand risk for an individual supplier by providing it with greater certainty on cash flows and sales volume prior to their product being on the market. Although the Facility may take on risk by executing volume guarantees for products that are still in development, this can be mitigated by designing conditions to limit financial exposure e.g., procurement conditional on regulatory outcomes or WHO Prequalification. To secure the required volumes and early supply (2021-2022) for participating countries, especially in a context where the Facility needs to 'compete' with ongoing capacity reservation by individual countries, volume guarantees can play an important role. As these volume guarantees are manufacturer-specific they may include differential terms, reflecting a diverse COVID-19 vaccine manufacturer base and needs. Collectively, they aim to secure sufficient supply across a set of manufacturers to ensure equitable access and support country preferences and specific needs. This incentive mechanism could also be used to secure volumes for administration commodities (e.g., syringes).
- **Market-wide demand guarantee**: this incentive mechanism can provide assurance on the overall demand for COVID-19 vaccines, but gives a lower level of demand risk mitigation for individual suppliers and hence, may not be sufficient alone to secure volumes in the immediate term for the pandemic context. Nevertheless, this incentive mechanism can bring visibility and a level of assurance on the mid to longer term demand to suppliers, beyond the short-term, incentivizing manufacturers with varying development timelines and product profiles to come to market while providing some flexibility for the Facility to accommodate evolving insights in changing epidemiology, product preferences, market conditions and supplier needs.

[19] Instruments to incentivise manufacturer product development and installment of capacity through the assurance of future procurement at a pre-determined volume and price of a successful candidate

The pull instrument will be structured as a market-wide demand guarantee, out of which multiple manufacturer-specific volume guarantees will be made. For the initial period (2021-2022), the majority of this market-wide demand guarantee will be issued as volume guarantees on specific products to individual suppliers. For the later phase (after 2022), it is expected that the majority of the guarantee would remain unallocated, allowing introduction of improved products over time. Guarantees made through the Facility will be subject to mechanisms supporting transparency and on-going monitoring for accountability of funds spent. As a condition of entering into supply agreements, manufacturers will be required to provide transparency into the volumes they have committed to through any push funding they have received and supply agreements they have entered into.

The following section expands on the design elements of the pull incentive, covering the mix of manufacturer specific vs. market-wide volume guarantees, timing, volumes, pricing and conditions.

5.2. Pull incentive mechanism mix, timing and volumes

The **size of demand to be guaranteed aims to strike a balance** between:

- The **effectiveness of the incentive** in de-risking demand uncertainty to accelerate manufacturing capacity expansion;
- The **level of financial exposure** given the demand uncertainty and product risk as guarantees need to be issued prior to full licensure of the products.

The **mix of incentive mechanisms will be adjusted to the level of benefit vs. risk for different time periods**:

- The benefit of vaccination is likely to be greatest in 2021-22 given that cohorts with greater COVID-19 risk will be prioritised for vaccination (e.g. healthcare workers, older adults).
- Conversely, demand uncertainty is higher in later years when capacity investments come onstream (due to lead times) leading to higher volumes reflected in the global supply forecast[20] (2023-2024).
- Comparatively, demand for 2021-22 will be less risky due to:
    - The possibility of vaccinating additional groups of people earlier than planned if demand for vaccination by the priority groups is less than projected or
    - The option to store vaccines for later utilisation if lower initial demand is due to programme introduction delays or if the profiles of products coming early to market will be more suitable or indicated for target populations which are planned to be vaccinated later (e.g. younger age groups) over 2021-22.

The initial target volume for the manufacturer-specific volume guarantees is the doses required to vaccinate the highest priority populations (see Section 3.4). However, given the early phase of development of current vaccine candidates, the Facility will need to guarantee more than this target volume in order to account for candidate attrition. The Facility may also over time seek to guarantee more than this target volume, subject to countries placing calls for larger volumes. This would also account for demand in early years potentially being underestimated.

Manufacturer-specific guarantees are particularly relevant for the short-term and aim to address the immediate 'access to supply' issues. The market-wide demand guarantee (remaining unallocated to suppliers) will further stimulate competition and the development of improved products over time. In addition, the mechanism will avoid potential double-payments to suppliers having benefited from a dedicated volume guarantee. However, given the uncertainty today on the need for a longer-term market for COVID-19 vaccines, the **design elements of the appropriate market-wide demand guarantee beyond 2021-22 are challenging to define at this time.** Flexibility is needed to allow for refinement of the mechanism as new information becomes available on epidemiology and market conditions. An initial market signal, however, could be considered by allocating some portion of funding for procurement for the 2023-24 period, for example, providing some visibility to manufacturers

[20] Preliminary global demand forecast as developed recently by WHO and partners as of 4th May

over potential longer-term demand. It should be noted that push funding has been made available by others, such as BMGF, to support and incentivise the development of vaccines expected to come to market in this timeframe.

5.3. Additional pull mechanism design elements

In addition to the pull funding design elements described above, there are **other critical design elements of manufacturer-specific volume guarantees**, in the form of contractual conditions, to be considered, which may include:

- Meeting minimal and/or preferred characteristics of normative WHO standards for COVID-19 pandemic response vaccines
- Regulatory approval by a maturity level (ML)3/ML4 regulatory authority and WHO prequalification
- Desirability of vaccine profile potentially influencing size of volume guarantee (e.g. if some product presentations are unsuitable for LICs / LMICs e.g. intravenous administration or large below-freezing cold chain requirements)
- Confirmed ability to export from supplier and host government
- If the supplier also produces routine life-saving antigens, agreement that disruption of supply of other vaccines to Gavi / LICs / LMICs will be minimised
- Agreement with conditions of liability / indemnity mechanisms being created

5.4. Principles of portfolio design

In applying pull incentive mechanisms, a number of portfolio-level principles should be considered.

Complementarity of push and pull investments:

As mentioned above, there is urgency to enter into manufacturer-specific guarantees to secure sufficient volumes of vaccines for participating countries. These guarantees may be made concurrently with push contracts aiming to fund clinical trials and manufacturing capacity expansions. The sequencing of push and pull funding needs to be well coordinated, as per explicit and compatible contractual conditions, where push funding helps secure at risk inventory build, and pull funding provides a commitment on the procurement of vaccines that successfully meet certain conditions , such as regulatory approval and WHO Prequalification. The figure below illustrates an example of how pull incentives through the COVAX Facility could complement push funding investments made within the broader Accelerator.

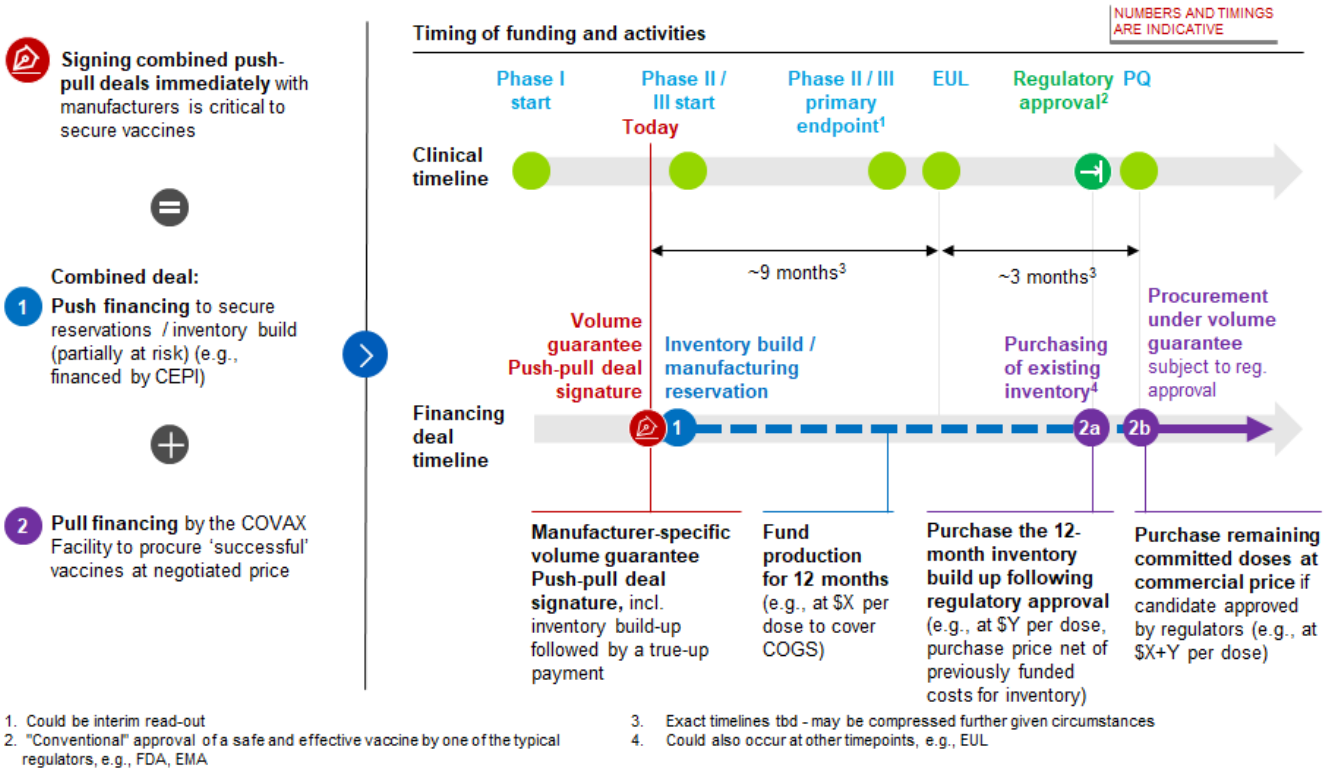

Figure 3 *Illustrative approach to coordinated push and pull*

In order to ensure complementarity with and effectiveness of the COVAX Facility's 'pull' incentives for those which have benefited from push funding, **tailoring pull incentives and complementing efforts of the providers of push funding will be important, and will require transparency from all actors.** This will necessitate information exchange and coordination across push and pull providers, particularly on the following aspects:

- **Priority access to most suitable candidates:** The COVAX Facility design and governance mechanism should have the ability to ensure that, **as data on the respective merits of vaccine candidates emerge, its pull investments can be flexibly allocated to the most suitable candidates, based on agreed upon criteria** (e.g. efficacy, adherence to normative WHO standards, etc.).

- **Coordinated contracting or visibility on key push funding requirements and features,** such as**:**
    - **Concessions and contractual obligations that are a precondition of push funding** e.g. providing volumes and prices for global access
    - **Timing/trigger** of the push funding (e.g. milestones)
    - **Size and structure of the push funding** – i.e. scope of push funding and contract terms to ensure complementarity of the potential pull mechanisms

Supply security and portfolio diversification strategy: To ensure supply security and equitable access to COVID-19 vaccines during and after the pandemic, and in line with Gavi's Supply and Procurement Strategy 2016-20 and the Healthy Market Framework, the Facility will embed a portfolio diversification strategy in its investment choices:

- **Vaccine platform diversity** is best achieved through push mechanisms based on a portfolio investment approach. There is a need to consider candidates globally to support this diversification.

- **Geographic diversity** of supply is best achieved through push funding, but can be reinforced by pull mechanisms. Geographic diversity reduces national regulatory authority (NRA) risk and the potential impact of trade embargoes/export controls on vaccines or related inputs and supplies. Moreover, when push funding investments are made, political assurances should be sought to ensure the host country will comply with global access rules, as well as to ensure the NRA will prioritize COVID-related reviews to accelerate time to market.
- **Supplier diversity***:* In the current environment, the focus needs to be supply security, with supplier diversity as a means to this end. For those manufacturers commercializing other life-saving vaccines, the Facility should seek assurance from suppliers benefitting from its pull investments that these manufacturers' supply of other vaccines will not be disrupted, through stipulations embedded in manufacturer contracts.

It will be important that providers of push investments, such as CEPI and BMGF, together with Gavi regularly monitor and assess gaps in the supply value chain to identify bottlenecks and the appropriate mix of interventions to address supply security. This will help ensure complementarity and synergy between push and pull investments. An initial assessment of supply security and bottlenecks is summarised in Annex C.

The successful execution of push and pull incentives, procurement and allocation of vaccine could result in sufficient supply to meet priority vaccination needs by end of 2021 – as illustrated in a simulation in Annex D.

5.5. Pricing approach

The Facility's approach to pricing intends to support the achievement of its primary objective: to accelerate equitable access to appropriate, safe and efficacious vaccines. There is broad acknowledgement that the **unique issues and priorities in the context of this pandemic require both buyers and suppliers to consider exceptional approaches to pricing.** Specific considerations that inform the Facility's pricing approach are the following:

- The Facility **prioritizes time-to-market and sufficiency of volumes for its members** as primary objectives, with affordability as a secondary objective. Although price is an important factor affecting equitable access, the Facility will consider multiple strategies, beyond just pricing, to ensure all its members are able to afford and access COVID-19 vaccines.
- Considering the wide **diversity of actors involved in COVID-19 vaccine development and manufacturing**, reflected in size, existing portfolio and customer base, geographic location, funding base and structure and type of innovation partnership models, the facility **acknowledges the diversity of pricing-related considerations**.
- There are still **significant epidemiological uncertainties**, e.g. on whether the disease may gradually shift from a pandemic to an endemic disease and under which timelines. The Facility acknowledges that emerging changes in market conditions and hence, commercial prospects, may require/justify changes in pricing approach over time.
- The Facility recognizes that, particularly in light of the unique scope of this effort covering high-, middle- and low-income countries, it is critical to preserve the **long-term health of the COVID-19 vaccine market and more broadly, other epidemic vaccines.**

Based on these considerations and the current exceptional circumstances, the Facility will adopt the following **pricing principles**:

- Vaccine prices may reflect **the range of cost of goods (COGS), vaccine profiles, developer and manufacturer profiles,** levels of **support received and risk incurred** during development.
- Vaccine prices may reflect different **time periods in the disease evolution and associated variations in market conditions and commercial opportunity.** This acknowledges the broad willingness from suppliers to consider the vaccine as a global public good in the short-term, to meet global requirements

for priority populations, and to evolve later to a more market-based approach. Given the pressing public health need, it is expected that manufacturers would seek **minimal returns**. Such a model could provide incentives to as wide a range of countries as possible to join the COVAX Facility for the short-term period, while establishing a blueprint for a future lower price for LICs/LMICs.

- Vaccine prices may be tiered, reflecting countries' varying **ability to pay**.
- Both the Facility and suppliers are expected to adhere to **transparency principles.** The Facility will expect from manufacturers to provide full visibility on other external funding received and will provide countries with the pricing of all participating vaccine candidates' (to the extent that such information can be shared).

Based on these pricing principles, the Facility proposes a **mixed pricing approach that will evolve over time:**

- Short-term period to reach priority populations and control the pandemic: A **flat pricing strategy (with firms able to set their own price, which then applies across countries participating in the Facility) will be encouraged**, given existing bilateral agreements between a number of countries and manufacturers and broad expectations to price the vaccine as a global good during the short-term period. Such a pricing structure should incentivize broad country participation in the Facility. However, some manufacturers may prefer tiered pricing; **the Facility will accommodate that request** if the price levels offered for each tier are considered suitable. If a flat pricing strategy is proposed by manufacturers, a **cross-subsidization mechanism may be applied** to establish differential pricing charged to countries to account for varying ability to pay.
- **Beyond this initial short-term period, the market is expected to evolve towards a traditional, market-led, tiered pricing approach** (noting that the Facility, itself, will be time-limited).

In practice, the expectation that supply will be constrained in 2021-2022 means that pricing models will need to be discussed in the context of contingent volume guarantees (VGs), negotiated prior to these vaccines reaching market. To execute on the pricing approach described above and to provide some level of competition and transparency, the Facility **would consider issuing an Expression of Interest** (EOI), inviting manufacturers of vaccine candidates for procurement discussions in the context of future VGs being issued. This would allow each manufacturer to express their interest in participating in the Facility, pricing-related considerations and supply volumes, and facilitate a negotiation process. Moreover, through an EOI process, the Facility may be able to better take into account how differences in vaccine profile (e.g. course schedule, efficacy, etc.) may be reflected in pricing considerations.

6. Financing

6.1. Financing instruments within the COVAX Facility

The COVAX Facility is composed of both an access component (i.e., including both manufacturer-specific volume guarantees and market-wide demand guarantees) as well as a procurement component (i.e., payment and delivery of vaccine doses made available through the manufacturer agreements).

Each of these components have distinct, though linked financing needs, hence the need for different financing instruments to be leveraged sequentially.

The initial focus will be on the access component as this innovative finance structure will be critical to the success of the COVAX Facility by securing reliable supply of COVID-19 vaccines for participating countries once these vaccines are available. This access component is also time sensitive given the urgent need to enter into agreements with manufacturers to enable manufacturing expansion and reservation of capacity for the Facility's participating countries. Successful design and execution of the access component is therefore of the utmost priority and should by itself largely condition the proper financing and execution of the procurement component, which will rely mostly on existing financing structures that have already demonstrated their effectiveness and efficiency for the procurement of other Gavi-supported vaccines.

6.1.1. Financing access

Access to doses will be ensured by Gavi providing the appropriate incentive mechanisms through leveraging innovative finance instruments as described in Section 5 above. These will take the form of specific agreements with manufacturers aiming at securing supply of doses to be made available for purchase to participating countries.

The financing of these agreements will rely on two complementary financing instruments: one that will be capitalised by ODA funding (Gavi COVAX AMC) and another capitalised through domestic resources of some participating countries (additional innovative financing instrument to be defined). The ODA funding will need to cover the needs of LICs and LMICs, while all other participating countries not eligible under the Gavi COVAX AMC would need to cover their funding share of agreements separately. This twofold structure would also create a clear distinction between ODA funding and funding coming from domestic health budgets.

These two financing instruments will be aimed at ensuring that:

- The COVAX Facility is capitalised appropriately to allow for potential upfront payments before doses are available to recipient countries as required in the manufacturer agreements;

- All COVAX volume guarantees offered by the Facility to manufacturers under the agreements are back-stopped by secured capital and do not create a financial exposure for Gavi;

- All participating countries, either externally or self-funded, hold the adequate financial exposure to each manufacturer agreement.

These conditions imply that the COVAX Facility will seek capitalisation from contributions of all countries in the form of (i) upfront payment in cash and (ii) secured future payments.

6.1.2. Financing procurement

Once made available through the manufacturer agreements, doses will be available for procurement through existing procurement mechanisms. Each participating country would therefore be able to procure COVID-19 vaccines either with domestic resources or with financial support, should they be eligible, according to the dose allocation as defined in Section 6.2. The amounts to be disbursed for the procurement of vaccines will be netted, as the case may be, from any upfront payment having already been made by Gavi to the manufacturers under the agreements.

6.2. Financing the COVAX Facility

While ODA contributions (for ODA eligible countries) and health budgets (for self-funded countries) are natural options in terms of financing of the COVAX Facility, the potential magnitude of financial commitment makes it necessary to consider other financing tools to allow a broad country participation. In addition, given the context in which the Facility will have to operate, namely one in which AMC agreements would have to be entered into prior to having full knowledge of the success of the vaccine candidate, it may be the case that volume guarantees cover volumes in excess of the targeted demand in order to hedge the Facility against failure of certain vaccine candidates. Appropriate financing instruments or risk transfer solutions will need to be considered to ensure that no unfunded liabilities arise from this approach and that financial losses would be minimised should vaccine candidate success rates be significantly different from their anticipated levels.

The Gavi COVAX AMC was launched on 4 June and is the first building block of the COVAX Facility. It has received seed funding of over $500m at its launch – primarily ODA from OECD countries. The Gavi COVAX AMC will be supplemented by additional innovative finance building blocks to enable advance purchase commitments for HICs and UMICs that choose to participate in the Facility and would not be financed through ODA. The Gavi Secretariat has identified different financing instrument options for the Facility to explore and the Secretariat plans to engage in the following weeks with various stakeholders to gauge their interest. The primary focus over this summer will be placed on securing financing and participation for Gavi-supported (Gavi COVAX AMC) and other

financially supported or credit enhanced countries while more standard solutions leveraging existing financing instruments could be offered to other self-funded participating countries on a case-by-case basis.

7. Governance and Legal Structures

7.1. Governance

A **representative governance structure is under development**. The tailored governance body will include representatives from Facility investors and recipients, including a combination of self-financing and funded countries, and will shape how the Facility may evolve as conditions change.

7.2. Legal structures and contracting

It is anticipated there would need to be an **overarching document setting out the obligations and benefits of the participants** and defining **Gavi's role and the role of other organisations** (e.g., WHO, UNICEF, World Bank, etc.) in the COVAX Facility. The form this document takes would be determined based on the ease of countries to agree to it in a short time frame.

Countries would also be required to enter into binding commitments to make upfront payments to Gavi to address the immediate funding need through the Facility. Some countries may make their commitment through loans or other types of support from Multilateral Development Banks. As the case may be, appropriate financial guarantees will also need to be concluded to backstop volume guarantees committed under AMC deals.

Countries may also provide direct ODA funding to Gavi in the form of grant agreements to assist with aspects of the COVAX Facility related to LICs and LMICs.

Gavi would enter into **bilateral agreements with manufacturers** for manufacturer-specific volume guarantees to procure vaccines that meet the agreed WHO Target Product Profile. Gavi may also enter into agreements with manufacturers related to a market-wide demand guarantee.

Procurement would be done under countries' existing arrangements (UNICEF Supply Division, PAHO Revolving Fund, individual country procurement mechanisms) where applicable.

Gavi's support to LICs and LMICs would be done under Gavi's normal grant agreements.

Annex A: List of uncertainties

Significant uncertainties will influence vaccine developers' investment decisions and as such, may affect development, timely expansion of manufacturing capacity, as well as availability and access. Uncertainties include:

- **Research and Development (R&D) uncertainties**, e.g. with so many candidates under development yet the high risk of failure[21], which will succeed to become safe and efficacious vaccines that are approved by a regulatory body?
- **Manufacturing uncertainties,** e.g. what will the yield of specific vaccine candidates be? Will all manufacturing be scalable? How can public and private sector actors work together to scale up manufacturing of the most suitable vaccines rapidly (i.e. in parallel to clinical development) and sufficiently (i.e. such that there are hundreds of millions / billions of doses available soon after licensure)?
- **Epidemiologic uncertainties**, e.g. will the disease become less severe over time, or even disappear altogether? Or will there be mid-long term need for vaccination if natural infection does not confer sustained immunity? Will our increasing understanding of the disease and its impact strengthen or weaken the case for vaccination? Could vaccination only be recommended for sub-populations? How will the availability of therapeutics or diagnostics affect the case for vaccines? How will demand for a vaccine evolve going forward? Will vaccines be effective in older or immunocompromised populations? Given the different disease risk across populations, how should the risk-benefit profile of different interventions be considered?
- **Political uncertainties,** e.g., will governments work together on a coordinated, multilateral pandemic response as they committed to in World Health Assembly (WHA) 73/1 or pursue diverging, unilateral strategies (e.g. bilateral agreements that countries enter into with vaccine developers/manufacturers to secure exclusive vaccine supplies)?
- **Financing uncertainties**, e.g. given the high risks driven by the above mentioned uncertainties, economic impacts of COVID-19 in all countries around the world and the stringent public health measures to control the disease in the absence of a vaccine, will all countries have the available funds to convert need into demand for vaccines and will financiers (sovereign governments, public and private institutions and multilateral banks) be willing to take such risks? If so under which circumstances?
- **Lack of clarity on access/allocation**, e.g. how can governments and multilateral institutions ensure equitable access across countries based on public health need (e.g., controlling major outbreaks, mitigating health impact, interrupting transmission) rather than vaccines going to countries with the greatest willingness/ability to pay?
- **Public perception uncertainty,** e.g. how will vaccine hesitancy fuelled by misinformation campaigns impact the uptake of COVID-19 vaccines?

[21] Pronker ES, Weenen TC, Commandeur H, Claassen EH, Osterhaus AD. Risk in vaccine research and development quantified. PLoS One 2013; 8: e57755

Annex B: List of stakeholders engaged in the preliminary design

We would like to thank the following individuals and organisations who participated in, or were consulted on, the preliminary design of the COVAX Facility. Note that this list may not be exhaustive.

Name	Organisation
Rabih Abouchakra	Office of Strategic Affairs, Crown Prince Court of Abu Dhabi
Al Anood Al Abdool	Ministry of Foreign Affairs and International Cooperation, United Arab Emirates
Eng. Ahmed Al Baiz	King Salman Relief
Hnid Al Barwani	Ministry of Foreign Affairs, Oman
Ali Abdullah Al Dabbagh	Qatar Fund for Development
Rashed Al Hemeiri	Ministry of Foreign Affairs and International Cooperation, United Arab Emirates
Yahya Al Shammari	King Salman Relief
Abeer AlFouti	Alwaleed Philanthropies
Faisal Alkahtani	Saudi Fund for Development
Ibrahim Alsugair	Saudi Fund for Development
Phyllis Arthur	BIO
Susan Athey	Stanford University
Lamia Badarous	Sanofi Pasteur
Abdulredha Bahman	Kuwait Fund
Haja Bally	CEPI
Teresa Barba Cornejo	Ministry of Europe and Foreign Affairs, Spain
Subir Basak	International Finance Corporation
Joan Benson	Merck
Julie Bernstein	Bill & Melinda Gates Foundation
Laetitia Bigger	IFPMA
Pierre Blais	Global Affairs Canada
Maureen Boer	UNICEF
Sophie Bracken	Department for International Development, UK
Thomas Breuer	GSK
Emma Brigham	UNICEF, Sri Lanka
Megan Cain	Global Affairs Canada
Ben Carcani	World Bank
Miguel Casado	Ministry of Foreign Affairs and Cooperation, Spain
Tania Cernuschi	WHO
Joe Cerrell	Bill & Melinda Gates Foundation
Indrani Chakma	UNICEF, Bhutan
Kalipso Chalkidou	Center for Global Development
Mukesh Chawla	World Bank
Mickey Chopra	World Bank
Diego Cimino	Ministry of Foreign Affairs & International Cooperation, Italy
Thomas Cueni	IFPMA
Mahima Datla	Biological E
Heather Deehan	UNICEF
Bernard Derebergue	Permanent Mission of France to the UN
Lindsey Dietschi	Pfizer
Ruxandra Draghia Akli	Johnson & Johnson
Naomi Dumbrell	Permanent Mission of Australia, Geneva
Christopher Egerton-Warburton	Lion's Head Global Partners
Susan Elden	Department for International Development, UK
Kate Elder	MSF Access Campaign
Raches Ella	Bharat Biotech
Stan Erck	Novavax
Dorothy Esangbedo	Union of National African Paediatric Societies and Associations, Nigeria
Irfan Farid	CHIP Training & Consulting (Pvt) Ltd
David Fidler	Council on Foreign Relations

John Fitzsimmons	PAHO
Alexander Freese	Federal Ministry of Economic Cooperation and Development, Germany
Katarina Fried	Ministry of Foreign Affairs, Sweden
Kenji Fujita	Ministry of Foreign Affairs, Japan
Deepa Gamage	Ministry of Health, Sri Lanka
Gian Gandhi	UNICEF
Henriette Geiger	Directorate General for Development and Cooperation, European Union
Samitha Ginige	Ministry of Health, Sri Lanka
Dimitrios Gouglas	CEPI
Sarah Goulding	Department of Foreign Affairs and Trade, Australia
Lynda Grant	Ministry of Health & Sanitation, Sierra Leone
Danny Graymore	Department for International Development, UK
Eman Hableel	Ministry of Foreign Affairs and International Cooperation, United Arab Emirates
Ilse Hahn	Federal Ministry of Economic Cooperation and Development, Germany
Mona Hammami	Office of Strategic Affairs, Crown Prince Court of Abu Dhabi
Lubna Hashmat	Civil Society Human and Institutional Development Programme – CHIP
Richard Hatchett	CEPI
Mariko Hayashi	Ministry of Foreign Affairs, Japan
Danielle Hoegy	Global Affairs Canada
Fergal Horgan	Department of Foreign Affairs and Trade, Ireland
Ingrid-Gabriela Hoven	Federal Ministry of Economic Cooperation and Development, Germany
Sjoerd Hubben	AstraZeneca
Marjeta Jager	Directorate General for Development and Cooperation, European Union
Aurélie Jousset	Ministry of Foreign Affairs, France
Etleva Kadilli	UNICEF
Judith Kallenberg	Johnson & Johnson
Karrar Karrar	Save the Children
Mishal Khan	Chatham House / LHSTM
Noor Khan	Norwegian Ministry of Foreign Affairs
Burcu Kilic	Public Citizen
Salman Kirmani	Agha Khan University, Karachi
Lea Knight	Johnson & Johnson
Irene Koek	USAID
Michael Kremer	Harvard University
Anja Langenbucher	Bill & Melinda Gates Foundation
Emilie Larese-Silvestre	Ministry of Foreign Affairs, Monaco
Ramanan Laxminarayan	Centre for Disease Dynamics, Economics & Policy
Diane Le Corveq	International Federation of Red Cross and Red Crescent Societies
Jean Lee	World Bank
Sarah Lendon	Department of Foreign Affairs and Trade, Australia
David Loew	Sanofi Pasteur
Orin Levine	Bill & Melinda Gates Foundation
Mimi Lhamo	National Immunization Technical Advisory Group Bhutan
Alvin Liu	Pfizer
Lene Loethe	Norwegian Agency for Development Cooperation
Nicole Lurie	CEPI
Frank Mahoney	International Federation of Red Cross and Red Crescent Societies
Rohit Malpani	Independent Consultant
Laura Manno	AstraZeneca
Francesca Manno	Ministry of Economy and Finance, Italy
John Markels	Merck
Daniel Markovits	Yale University
Peter Maybarduk	Public Citizen
Ariane McCabe	GSK
Diarmaid McDonald	Just Treatment
Sharon McHale	CSL/Seqirus

Violaine Mitchell	Bill & Melinda Gates Foundation
Jonathan Mitchell Weiss	UNICEF
Chandralal Mongar	UNICEF, Bhutan
Phillipe Mores	Ministere des Affaires Etrangeres et Europeennes, Luxembourg
Simon Moss	Global Citizen
Sana Mostaghim	Takeda
Michael Newman	Department of Foreign Affairs and Trade, Australia
Freddy Nkosi	VillageReach DRC
Elizabeth Noonan	USAID
Anders Nordström	Ambassador for Global Health, Sweden
Hanke Nubé	Ministry of Foreign Affairs, Netherlands
Kate O'Brien	WHO
Steven Okin	Merck
Andrea Ordóñez	Southern Voice
Murat Ozturk	PAHO
Jan Paehler	International Cooperation and Development, European Commission
Sonia Pagliusi	DCVMN
Muhammad Pate	World Bank
Harriet Pedersen	Ministry of Foreign Affairs, Sweden
Razia Pendse	WHO, Sri Lanka
Dan Peters	Bill & Melinda Gates Foundation
Sonam Phunthso	Bhutan Health Trust Fund
Sangay Phunthso	EPI, Bhutan
Timothy Poletti	Permanent Mission of Australia, Geneva
Adar Poonawalla	Serum Institute of India
Sai Prasad	Bharat Biotech
Olivier Praz	Swiss Agency for Development and Cooperation
Shirmila Ramasamy	World Bank
Cinthya Ramirez	Pfizer
Kent Ranson	World Bank
Ferdinando Regalia	Inter-American Development Bank
Matthias Reinicke	International Cooperation and Development, European Commission
Laila Rizvi	The Health Foundation, Pakistan
Jim Robinson	CEPI
Eduard Salakhov	Russia Geneva Mission
Rodrigo Salvado	Bill & Melinda Gates Foundation
Sudath Samaraweera	Ministry of Health, Sri Lanka
Bill Savedoff	Inter-American Development Bank
Soleine Scotney	Clinton Health Access Initiative
Tom Sesay	Ministry of Health & Sanitation, Sierra Leone
Anant Shah	Merck
Sheetal Sharma	Safari Doctors, Kenya
Lora Shimp	John Snow Institute
Dasom Shin	Ministry of Foreign Affairs, Korea
Jenny Shum	AstraZeneca
Jeffrey Silsbee	Merck
Viacheslav Smolensky	Rospotrebnadzor, Russia
Christopher Snyder	Dartmouth
Pascal Soriot	AstraZeneca
Angela Specht	Johnson & Johnson
Julia Spencer	Merck
Nine Steensma	Clinton Health Access Initiative
Preeti Sudan	Ministry of Health and Family Welfare, India
Manabu Sumi	Ministry of Foreign Affairs, Japan
Vegar Sundsbø Brynildsen	Norwegian Ministry of Foreign Affairs
Tshewang Tamang	EPI, Bhutan

Naveen Thacker	International Pediatric Association
Anne-Laure Theis	Ministere des Affaires Etrangeres et Europeennes, Luxembourg
Thomas Triomphe	Sanofi Pasteur
John Trizzino	Novavax
Carmen Tull	USAID
Joan Valadou	Ministry of Foreign Affairs, France
Anna Valkova	Ministry of Finance, Russian Federation
Rajeev Venkayya	Takeda
An Vermeersch	GSK
Jaume Vidal	Health Action International
Lionel Vignacq	Ministry of Foreign Affairs, France
Sonam Wangchuk	Ministry of Health, Bhutan
Sonam Wangdi	WHO, Bhutan
Karin Westerberg	Ministry of Foreign Affairs, Sweden
Greg Widmyer	Bill & Melinda Gates Foundation
Prashant Yadav	INSEAD
Gavin Yamey	Duke University
Xu Ye	China National Biotec Group Company
Makiko Yoneda	Ministry of Foreign Affairs, Japan
Niloofar Zand	Global Affairs Canada

Annex C: Supply risks and gaps along the vaccine supply value chain

With regard to COVID-19 vaccine supply, across the vaccine manufacturing and supply value chain, **three potential areas of risk have been identified**:

- **Shortages of specific raw materials** could slow down or interrupt manufacturing of promising COVID-19 vaccines at scale, which could put equitable access at risk or adversely impact the production of other essential vaccines or treatments which share these materials.
- **Adequate drug substance (DS) availability** might become a challenge, as COVID-19 vaccine candidates span a wide range of technologies and fungibility of manufacturing facilities is limited by their suitability to and the specificities of different platform technologies. The scale up and scale out of vaccine candidates could be restricted if adequate DS capacity is not in place – in particular for the less established platforms. For established platforms (e.g. inactivated), bottlenecks in drug substance manufacturing could force manufacturers to make trade-offs between which vaccines and/or treatments to produce. Manufacturing of existing low margin vaccines or treatments – some of them potentially critical for low- and middle-income countries – could be deprioritized.
- **Fill-Finish capacity** globally could present a risk to timely and sufficient vaccine supply, however greater fungibility as well as implementation of operational improvements, use of larger multi-dose vials and utilization may increase capacity availability for fill-finish. This fungibility comes with the potential risk of manufacturers making trade-offs between which vaccines to produce and this needs to be managed – particularly existing low margin vaccines which are potentially critical for low- and middle-income countries.

While there are many potential bottlenecks across the vaccine supply value chain, a number of efforts are under way to address these gaps. Based on inputs from BMGF, CEPI and UNICEF and their current projections, a **preliminary assessment of product needs along the manufacturing chain did not identify any immediate bottlenecks and shows that risks can be mitigated**. However, as global scale-up efforts occur in parallel, there remains a significant risk of shortages especially as candidates turn out to be successful and supply/manufacturing capacity needs to be allocated to specific programs. For this reason, close **market monitoring and coordination is needed to identify and act on potential emerging bottlenecks as more information becomes available in the next 6 months** (e.g., manufacturing yields, down-selection outcomes, their specific manufacturing needs) and demand scenarios. The figure below summarizes potential capacity gaps that might arise over time.

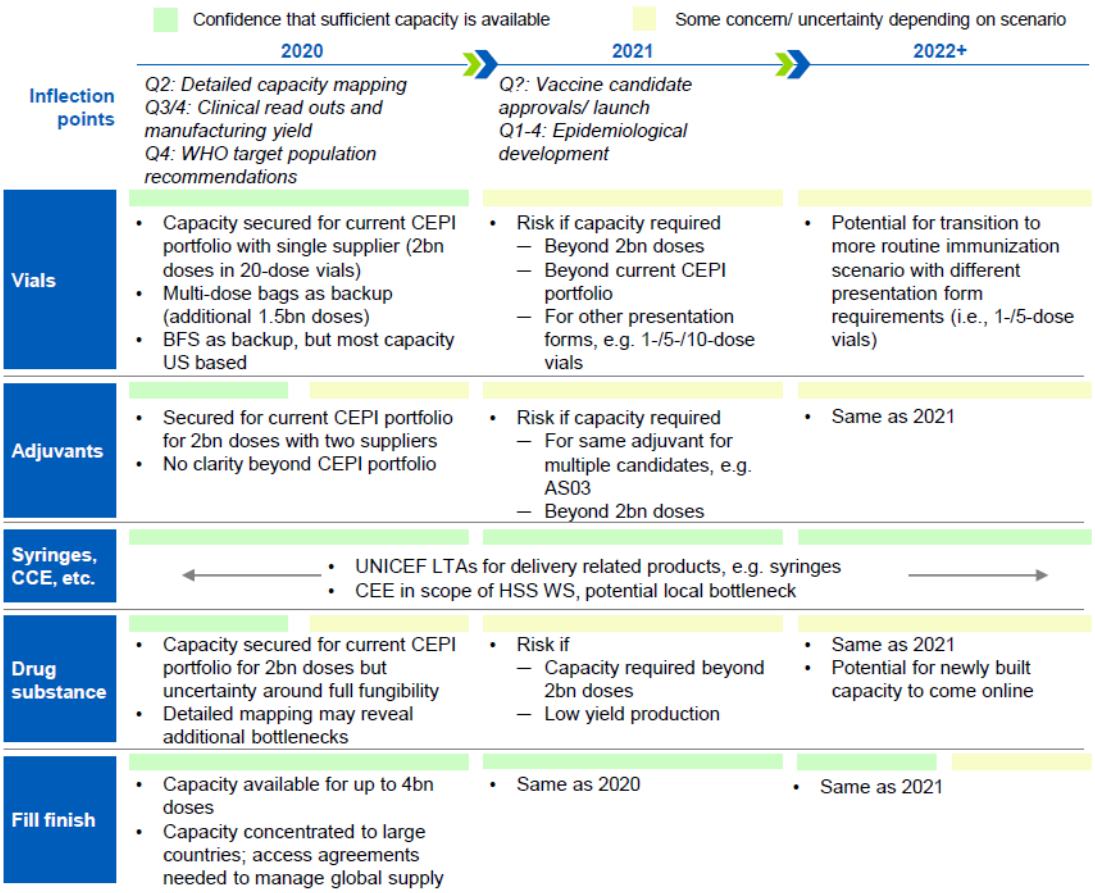

***Figure 4**: Summary analysis of gaps in the supply value chain*

Key milestones for monitoring and coordination that will drive further insights include completion of a detailed mapping of potential bottlenecks per product type (Q2 2020); collecting information on candidate success and manufacturing productivity (Q3 2020) and increasing visibility on epidemiology and target populations recommended by WHO (Q4 2020).

Annex D: A simulation illustrating COVAX Facility approach

By aggregating demand and supply via pull incentives, the COVAX Facility will help manage vaccine supply as a common resource shared among participating countries. Treating vaccine as a shared resource, with allocations to individual countries under WHO's guidance, countries might pursue the objective of first vaccinating specific high-risk groups (e.g., health care workers, older adults, those with medical co-morbidities). Interruption of disease transmission by targeting persons in occupational or other settings with heightened outbreak risk might be prioritized. A portion of the total pool of vaccine may be reserved centrally as a buffer for deployment to stop uncontrolled outbreaks or vaccinate other high-risk target groups. If multiple vaccines become available, some may be preferred in certain settings – due to cold chain requirements, the number of doses required to immunize, and appropriateness for use in different segments of the population – and be allocated in a way that maximizes their utility, informed by the WHO global allocation framework.

CEPI conducted an analysis of its portfolio of supported vaccines, for which COVAX Facility complementary pull investments could help secure access to future supply. CEPI's analysis estimates the number of successful candidates and volumes that could be achieved over time. The simulation presented below presents anonymized data from a Monte Carlo analysis of 10,000 simulations run on a putative portfolio of COVID-19 vaccines using estimates of yield, dose, and projected timing of production for one anticipated and nine existing CEPI-funded candidates. The yield, dose and timing were varied over ranges specified for each product based on the probability of various outcomes and by applying CEPI's calculations of the R&D probability of success. The base-case scenario presented below is drawn from an illustrative mid-range scenario.[22]

For the base case, 2 of 10 projected candidates in the CEPI portfolio are predicted to result in licensed vaccines.[23] Scale out includes two manufacturing sites per successful vaccine. The operational expenditure and capital expenditure costs for each scenario were estimated but are not presented, with costs for failed programs committed early and considered sunk. The projected supply is derived exclusively from programs within CEPI's investment portfolio and does not contemplate supply by other vaccine manufacturers. The dose estimates provided are for drug product (filled and finished vaccine available for distribution), presented as millions of doses available for shipping per month.

Summary findings

	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
Base case scenario – 2.4BN doses by end 2021	30.4	48.6	48.6	79.0	187.8	187.8	187.8	277.1	277.1	277.1	277.1	277.1	277.1
Upside scenario – 3.5BN doses by end 2021	30.2	48.4	48.4	165.9	275.0	275.0	298.6	387.6	387.6	387.6	387.6	387.6	387.6
Downside scenario – 1.4BN doses by end 2021	21.3	21.3	21.3	41.2	103.4	103.4	103.4	165.3	165.3	165.3	165.3	165.3	165.3

Figure 5: *Simulation summary results (million doses of vaccine per month)*

[22] More details about the modeling methodology can be provided upon request
[23] The upside scenario projects three successful candidates, the downside one.

Under the assumption of COVAX Facility participation of 78 LIC/LMICs supported by Gavi and a number of UMICs and HICs, there is a total population of 3.8b persons and 740m persons respectively with around 21 million healthcare workers and 355 million persons ≥ 65 years old. Assuming immunization requires two doses, the base case scenario above provides sufficient vaccine for approximately 1.2 billion people (26% of the total population across participating countries).

In a best case scenario, assuming the Facility successfully incentivises procurement of 100% of the production of these 2 candidates across their 4 manufacturing sites, an allocation scheme prioritizing first healthcare workers and then persons ≥ 65 years old could result in shipping of sufficient vaccine to immunize health care workers in all participating countries by mid-January, and of persons ≥ 65 years old by the end of June, assuming that no vaccine is reserved for other applications (such as for outbreak control or for vaccinating high-risk critical workforce personnel or residents of refugee camps or other high-risk settings). Reserving one third of monthly production for such applications, up to the total of 10% of the population across the 109 countries, beginning after the vaccination of health care workers, would result in a delay of completing shipping for persons ≥ 65 years old by approximately 6 weeks (due to the accelerating supply beginning in July 2021) and completion of the outbreak control reserve by early September.

Annex E: Acronyms and abbreviations

ACT Accelerator – Access to COVID-19 Tools Accelerator

AMC – Advance Market Commitment

BMGF – Bill and Melinda Gates Foundation

CEPI – Coalition for Epidemic Preparedness Innovations

COGS – Cost of Goods Sold

COVAX Facility – COVID-19 Vaccine Global Access Facility

EC – European Commission

EUL – Emergency Use Licensure

HIC – High Income Country

IDA – International Development Association

IFFIm – International Finance Facility for Immunisation

IMF – International Monetary Fund

LIC – Low Income Country

LMIC – Lower-Middle Income Country

MDB – Multilateral Development Bank

MIC – Middle Income Country

NRA – National Regulatory Authority

ODA – Official Development Assistance

OECD – Organisation for Economic Cooperation and Development

PAHO – Pan-American Health Organisation

PAHO RF – Pan-American Health Organisation Revolving Fund

PQ – Prequalification

R&D – Research and Development

SAGE – Strategic Advisory Group of Experts

SRA – Stringent Regulatory Authority

TPP – Target Product Profile

UMIC – Upper-Middle Income Country

UNICEF – United Nations Children's Fund

WHO – World Health Organization