

## **COVID-19 Vaccine Global Access (COVAX) Facility: Key considerations for Gavi's new global financing mechanism**

Médecins Sans Frontières/Doctors Without Borders (MSF) has been following the development of Gavi, the Vaccine Alliance's new COVID-19 vaccine financing mechanism. As an international medical humanitarian organisation, MSF seeks to ensure that the medical tools urgently needed to respond to COVID-19 are accessible, affordable and available to all countries and vulnerable populations equitably. Overwhelmingly, global health leaders have agreed that potential future COVID-19 vaccines must be considered a "global public good",<sup>1</sup> with more than 140 world leaders and experts uniting in a call for "a people's vaccine" for COVID-19.<sup>2</sup>

This briefing document presents some of MSF's concerns around access for future COVID-19 vaccines and Gavi's new initiative, known until recently as an Advance Market Commitment (AMC),<sup>3</sup> and now renamed the COVID-19 Vaccine Global Access (COVAX) Facility. The COVAX Facility is also being developed within the context of the World Health Organization (WHO)'s Access to COVID-19 Tools (ACT) Accelerator initiative,<sup>4</sup> in which Gavi and the Coalition for Epidemic Preparedness Innovations (CEPI) are the leading implementers of the vaccines pillar. This document offers MSF's perspective on key considerations and next steps that Gavi, partners and potential funders of the COVAX Facility should undertake to support the development and delivery of COVID-19 vaccines that are accessible and affordable for everyone.

### **Landscape for COVID-19 vaccines**

Given that the entire world needs a COVID-19 vaccine, a shortage of vaccine supply is likely if and when a vaccine is successfully developed and regardless of which candidate is first to market. Global actors are trying to plan ways to secure vaccines in advance, particularly for countries and populations typically marginalised by the global research and development (R&D) system. These populations are usually last in line for the fruits of medical innovation because they do not represent an attractive commercial market.

Using the example of pneumococcal conjugate vaccine (PCV) access, 25% of the world's countries still have not introduced this lifesaving vaccine, largely due to its high price.<sup>5</sup> This is driven by the lack of competition in the market (until recently only Pfizer and GlaxoSmithKline made the vaccine). PCV on average represents 34% of the vaccine budget of middle-income countries (not receiving Gavi assistance), and can account for as much as 66% of vaccine spending, placing a particular burden on these countries.<sup>6</sup> We must learn from this and ensure COVID-19 vaccines are available to all at cost.

Fortunately, the pipeline of COVID-19 vaccine candidates is robust, with more than 100 candidates in preclinical development and 10 in human trials, on eight different vaccine platforms.<sup>7</sup> Many vaccine candidates are benefitting from the more than US\$4.4 billion of public and philanthropic funding allocated so far for COVID-19 vaccine R&D.<sup>8</sup> This includes grants of nearly US\$1 billion from the US Biomedical Advanced Research and Development Authority (BARDA) to just two companies, Johnson & Johnson and Moderna. It also includes some of the nine candidates funded by CEPI, which invests in vaccine development for diseases with epidemic potential and has recently expanded its mandate to include financing for producers in their manufacturing preparations.<sup>9,10</sup>

Despite these massive sums of R&D money invested largely by the public, requirements for accessibility or affordability of any new COVID-19 vaccines have yet to be clearly seen. Little to no information is available from the major funding agencies or government funding schemes about institutional policies or individual

agreements on global vaccine access. CEPI has a very loose equitable access policy,<sup>11,12</sup> and how this has been interpreted and implemented in its grantee R&D agreements for COVID-19 is not publicly known.

Furthermore, despite the current rhetoric on “global public goods” and “the people’s vaccine”, public funders have thus far failed to ensure that public entities retain the rights to the vaccines to determine adequate production, supply and allocation. How intellectual property (IP), such as patents, related to the COVID-19 vaccine will be dealt with remains unclear. MSF experience has shown that by holding and enforcing patents on lifesaving vaccines, pharmaceutical corporations maintain overall control of the scale of production, competition, price and supply of their vaccines.<sup>13</sup> Important technologies and know-how would also be controlled by companies, or simply kept as trade secrets. A “business as usual” approach to IP and technology sharing will likely not deliver a “people’s vaccine” because the resulting vaccine will be proprietary, and pharmaceutical corporations will retain decision-making power as to who does or does not get access, based on control of pricing and supply. Permitting industry to retain ownership and control of “the people’s vaccine”, and the associated lack of planning for public access to future vaccines, is problematic.

## **Gavi’s new initiative**

Gavi is now designing a finance mechanism – the COVAX Facility - to raise massive funding, in addition to the public monies already committed, to attract industry to scale up manufacturing of a new vaccine and reserve supplies for developing and other participating countries.

Among the global actors responding to the need for equitable, affordable access to future COVID-19 vaccines, Gavi appointed itself to design this global funding mechanism. Despite the staggering stakes, little has been shared about Gavi’s plans with this new mechanism, and only a few organisations and academics were involved in the planning process. The information presented here on the COVAX Facility mechanism is based on informal communications received as of 30 May 2020, and one consultation with civil society.

Regarding the role of the COVAX Facility within WHO’s ACT Accelerator, little is known on how the nominations and decisions were made on ACT’s implementing parties, and whether Gavi obtained official designation from the WHO or its member states to work on the proposal. Thus far the COVAX Facility seems to be the first step towards operationalising the ACT Accelerator’s vaccine pillar work.

### ***What is the COVAX Facility?***

Gavi published a two-page “Proposal for an Advance Market Commitment for COVID-19 Vaccines” on 1 May.<sup>14</sup> At the European Commission Coronavirus Global Response Pledging Conference on 4 May, Gavi CEO Dr Seth Berkley noted that Gavi was developing this initiative. Gavi intends to officially launch their COVAX Facility at their 4 June funding replenishment meeting.

The mechanism was designed by an invited group of organisations and individuals. The core group of decision-making partners are Gavi’s Secretariat, the World Bank, CEPI, the Bill & Melinda Gates Foundation, UNICEF, and WHO. This core group and invited experts participated in a process led by the consulting firm McKinsey & Company to design this initiative, with four working clusters: country scope; supply; mechanisms; and financing. Aiming to determine perhaps one of the biggest global health mechanisms in the coming decade, notably missing from this design process were the legitimate designation by the WHO’s member states through a formal and transparent process; and the perspectives and participation of Gavi-eligible and other affected countries, as well as civil society organisations, who have only recently received a briefing of Gavi’s plans via one consultation.

Details of any decisions taken on what the COVAX Facility will ultimately entail have hardly been shared. However, based on information shared thus far, it may have up to three different elements:

1. A facility open to all countries wanting to procure COVID-19 vaccines. The facility will design various financial tools – “pull mechanisms” – which may include AMCs, advance purchase commitments, pre-payments or volume guarantees, to attract pharmaceutical companies to engage with the platform.
2. A fund to pay for COVID-19 vaccines for certain eligible low- and middle-income countries.
3. Based on the global equitable allocation framework under development by WHO, arbitration of potentially limited vaccine supplies to participating countries.

An additional element of “push” incentive funding for R&D and scale-up of manufacturing capacity is considered outside the scope of the COVAX Facility, but alignment is necessary. Whether the Facility will provide financing for broader manufacturing scale-up is not clear.

Also unclear is which countries will be included in the scope of this mechanism; Gavi is calling for all countries to join. Countries may be encouraged to participate in a number of ways. All countries may be invited to join the procurement pool and to contribute to the financial mechanism or to “pull incentive” funding intended to entice pharmaceutical companies to supply their future vaccines to the Facility. Certain developing countries may be offered financing support via the second element of the Facility; this could include all current and former Gavi-eligible countries, and potentially some middle-income countries (MICs) that were never Gavi-eligible (approximately 78 countries have been proposed to Gavi’s Programme and Policy Committee [PPC] for Gavi financing). Donor countries may also participate in the mechanism by contributing funding to Gavi to finance this set of developing countries for their COVID-19 vaccine introductions.

The only document that Gavi has made public thus far about the COVAX Facility stipulated a US\$2 billion initial financial need as “seed funding” for future COVID-19 vaccines for 20 million healthcare workers in low- and lower-middle income countries.<sup>14</sup>

### ***The Facility constitutes a large expansion of Gavi’s current mandate***

The nature of this mechanism and the breadth of countries that Gavi seeks to include raises questions as to *why* it is Gavi that has assumed the lead on this initiative. Gavi is a Swiss-based foundation with a mandate to finance vaccines for the world’s poorest countries – currently 58 eligible countries (of an original 73 eligible countries). That Gavi would play a role in pooling procurement and negotiating prices for Gavi-eligible countries is logical, but the proposal that Gavi should be the host of a truly global “facility” for COVID-19 vaccines is beyond the organisation’s mandate and expertise. Gavi has no experience working with most MICs nor any high-income countries (HICs) on procuring for the countries’ vaccine needs. Gavi also does not have experience negotiating with pharmaceutical companies on behalf of these countries. Meanwhile, the WHO Pandemic Influenza Preparedness (PIP) Framework is an example of WHO’s global normative and operational role to develop public health instruments that help to prepare for and respond to global pandemics.<sup>15</sup> The PIP Framework includes requirements from manufacturers that they set aside specific quantities of medicines or vaccines in the case of a global influenza pandemic, with WHO determining the equitable allocation of those medical tools.

Additionally, vaccine procurement mechanisms already exist that serve country needs through a pooled approach. These include the UNICEF Supply Division (SD) (which is the procurement agent for Gavi) and the Pan American Health Organization (PAHO) Revolving Fund, which are the largest vaccine procurement groups currently in operation; as well as the Gulf Cooperation Council.<sup>16</sup> The need for a new global superstructure to procure future COVID-19 vaccines has not been established, and no analysis has been made available on the needs, advantages or disadvantages of such a global mechanism. Certainly, some countries are currently left out of the existing procurement process and need support, but whether a new global

procurement mechanism is the most efficient and effective way is not clear. Supporting regional groups and coordinating between them to ensure no country is left out may be a more expedient approach. This would not require creating new global organisational infrastructure, nor risk costly and time-consuming duplication of already existing mechanisms.

### ***The Facility and the current global context differ substantially from Gavi's past experience***

Gavi has previously played a role in designing financial mechanisms, such as their AMC for PCVs and their Advance Purchase Commitment (APC) for Ebola vaccines. However, in contrast to these initiatives, which specifically focused on Gavi-eligible countries where Gavi has a mandate and expertise, the current context of the global COVID-19 pandemic is dramatically different because the vaccine will be needed by every country in the world at the same time.

#### **Advance market commitment for pneumococcal conjugate vaccine (PCV)**

Gavi points to the success of its AMC for PCV, highlighting the performance of the AMC in scaling up manufacturing capacity to accelerate the introduction of PCV into Gavi countries. The AMC for PCV was designed over a five-year period (late 2005-2010) and included a US\$1.5 billion subsidy from six donors. The AMC had four objectives: 1) accelerate the development of PCVs for developing-country needs; 2) increase PCV availability for Gavi countries by supporting scale-up of manufacturing capacity; 3) accelerate PCV uptake with predictable vaccine pricing and binding commitments from companies on number of doses; 4) pilot the effectiveness of an AMC as an incentive and learn lessons for possible future AMCs.

Independent evaluations of the AMC found it did not deliver on the first objective in a timely way, and failed to fully accomplish the second objective.<sup>17</sup> Supporting scale-up of manufacturing capacity so that companies could meet the volume needs of Gavi countries, and pulling in new manufacturers and PCV products into the market for developing countries, were only partially successful. PCV supply shortages occurred a few times throughout the AMC. Additionally, a PCV product designed for developing countries finally entered the market only at the tail end of the AMC (December 2019). At the time of writing, this manufacturer still has not been publicly awarded any of the AMC funding.

The evaluation also indicated that Gavi may have paid more per dose of PCV than was necessary, to incentivise pharmaceutical-company participation in the AMC. This was based on a deliberately cautious approach and because they did not have the information regarding the actual costs incurred by pharmaceutical corporations. Based on the last objective of the PCV AMC, the lessons learned from the AMC's limitations for stimulating new vaccine development, stable supply and affordable prices should be addressed in the design of the new COVAX Facility.

#### **Advance purchase commitment for Ebola vaccine**

The APC for Ebola was launched in 2015 with an agreement between Gavi and Merck whereby Gavi paid Merck US\$5 million towards the development of its Ebola vaccine, and Merck agreed to submit the vaccine for marketing approval by the end of 2017. Merck also committed to maintain a stock of 300,000 doses for emergency use and/or expanded-use clinical trials. The US\$5 million pre-payment was supposed to be deducted from Gavi's future Ebola vaccine purchases.

Ultimately, Merck did not submit for marketing approval until March 2019 in Europe (approved November 2019)<sup>18</sup> and September 2019 in the US (approved December 2019).<sup>19</sup> Despite this delay in fulfilling one of the major commitments of the APC, Gavi was not in a position to take any punitive action, since the pre-payment to Merck had already been made. Importantly, the US government alone invested US\$176 million to help develop Merck's vaccine, including US\$23 million to Merck to boost production,<sup>20</sup> dwarfing Gavi's US\$5 million APC. To date, Gavi has not received any Ebola vaccine from Merck despite the US\$5 million pre-payment.

## **Key questions and considerations for the COVAX Facility**

While much of the purpose and modality of the COVAX Facility is still unclear, at a minimum the following questions need to be answered in Gavi's next steps:

### ***How will the initiative ensure equitable access?***

Vaccine manufacturers will be challenged with making enough vaccines for every country of the world despite anticipated supply shortages. There is currently no global plan for how to equitably allocate initially scarce supplies of future COVID-19 vaccines. This is one of the most important tools currently needed and is under way in the form of a global allocation framework in development by WHO, but even more important will be encouraging solidarity to get governments to adhere to such a plan.

These challenges are further underscored by the competition that countries will face from much wealthier HICs, which have already signalled to manufacturers they will pay high prices to secure large volumes. Gavi may raise a lot of money for the COVAX Facility, but it will likely not be able to compete with the budgets of HICs. For example, one proposal promotes an AMC for the US government, calling for a US\$70 billion upfront funding commitment, as well as a guaranteed high price for a certain number of doses.<sup>21</sup> New deals are being announced by HICs that would tie up supply for their countries.<sup>22,23</sup>

In addition to the competition that Gavi price negotiations will face from wealthy countries seeking access to the same vaccine supply, information asymmetries put Gavi at a distinct disadvantage when negotiating prices with pharmaceutical corporations. Companies are not transparent about their costs, including total R&D investment, publicly funded R&D, cost investments into manufacturing scale-up/capacity, cost of goods, or cost of manufacturing future COVID-19 vaccines. Governments have a priority to protect their populations and therefore may be expected to ask for more vaccines than they currently need, an objective that may be at odds with a global allocation framework for equitable access.

Also unclear is what kind of affordable price requirements, pricing structure, or other access safeguards Gavi will seek in their procurement mechanism and in exchange for funding to manufacturers. Open licenses for IP and technology transfer agreements that could expand manufacturing capacity and scale up supply have not been discussed.

### ***Which countries will actually participate?***

Gavi has expressed an interest in bringing in as many countries as possible, yet Gavi has no experience negotiating on behalf of most MICs nor any HICs, nor does it have experience procuring for these countries. Certain MICs and HICs may consider participating if they don't have domestic manufacturing capacity, or lack negotiating power due to limited budgets and small populations. However, no mapping or information has been shared with regards to which countries are expected to join or could find joining advantageous.

Additionally, no analyses have been shared on volumes of doses and/or number of people needing vaccines for Gavi to meaningfully engage pharmaceutical companies, when the US and other HICs are already committing to pre-purchase future doses. A modelling of different scenarios based on volume and market attractiveness for industry to come to the negotiation table would help predict how effective the COVAX Facility will be in delivering vaccines.

### ***What procurement mechanism will be used?***

No global procurement mechanism exists for vaccines. Setting up the legal and technical framework for such a mechanism would be highly complicated. Many existing domestic procurement routes are legislated through domestic law with specific requirements. The UNICEF SD procures for ~100 countries, the PAHO Revolving Fund for ~40 countries, and the Gulf Cooperation Council for 6 countries. Given these existing mechanisms for procurement, if Gavi's new initiative required participating countries to procure COVID-19

vaccines through a new platform, this could be complicated, burdensome and regressive for countries that already have their own capacity.

***What are the projected costs of financing such a mechanism?***

Gavi suggests it may provide financing for its original 73 eligible countries, in addition to some low- and middle-income countries never previously eligible and potentially some upper-middle-income countries, bringing the proposed scope of countries to ~78. Although no firm prices have been set yet, indications from companies such as Johnson & Johnson suggest the corporation would charge ~US\$10 per dose,<sup>24</sup> which is currently more than double the price of the most expensive vaccine in Gavi's portfolio. Projecting a budget to finance vaccines in 78 countries with this proxy price yields extraordinarily high sums, and this would be the cost of just one component of what Gavi is proposing. No analyses have been shared on forecasted costs for the "pull incentives" planned, nor administrative costs of the COVAX Facility. Recent Gavi planning for the Facility would provide manufacturer-specific volume guarantees and milestone-based upfront instalments. This is a potentially expensive and risky use of funds for products so far away from licensure.

***What regulatory approvals will be needed for vaccine eligibility?***

No information has been shared as to the regulatory approval status required for vaccines to be eligible for the Facility. It is unclear if the Facility only applies to licensed vaccines, requiring full regulatory approval from the country of origin of the manufacturer, as well as WHO prequalification; or if Gavi may consider including non-licensed vaccines approved under the WHO's Emergency Use Listing Procedure.<sup>25</sup>

***How will Gavi work with other "push funding" initiatives to ensure coordination and efficiency?***

Gavi seems to be designing the COVAX Facility primarily around "pull" funding mechanisms but acknowledges other organisations are providing "push" funding for R&D and manufacturing investments. Some of these push investments are from governments directly to developers, and some are through CEPI (which has provided grants to nine COVID-19 vaccine developers).

How will Gavi assess how much public and philanthropic funding has already been received by manufacturers and use this information to inform their negotiations with industry? While the links between Gavi and CEPI seem close, of the ten COVID-19 vaccines in human clinical trials, only four have received CEPI funding. Tracking public and philanthropic funding already invested in the other candidate vaccines is far more difficult.

Additionally, if Gavi wishes to have a role in funding manufacturing capacity scale-up prior to licensure, what will happen with the funds and the additional manufacturing capacity awarded to individual companies that may ultimately not have a successful candidate? Would this funding function as a conditional loan or would companies be mandated to transfer that capacity, if technologically feasible, to another company that has been successful?

## Recommendations

In a pandemic that is characterised by control measures restrictive of people's movements and normal social activities (quarantines, social distancing), the ultimate global control may only be achieved once an effective vaccine is widely available. With such an urgent need for these vaccines, decisions on supply and pricing of a successful vaccine against COVID-19 must be based on public health needs rather than narrow political or commercial interests.

If Gavi intends to play a constructive role in delivering a COVID-19 vaccine that meets these requirements, the following recommendations are key:

1. **Negotiate an “at cost” price:** With such a dramatic need for vaccines in all countries and with so much public funding invested in bringing forth new vaccines, a tiered pricing model is not appropriate. Gavi has a responsibility to hold pharmaceutical corporations at their word and enforce no profiteering off a pandemic. An at-cost price should be set for any COVID-19 vaccines. The COVAX Facility should not be instrumentalised to advance industry's longer-term pricing strategy goals.
2. **Ensure equitable vaccine distribution:** Predicting that initial demand will outstrip supply for COVID-19 vaccines, a global equitable allocation system led by WHO must be followed. The global allocation framework needs to be based on ethical principles and be transparent in terms of which groups are prioritised. At the very least, access must be prioritised for frontline healthcare workers and people at greatest risk of severe illness and death worldwide. Governments must demonstrate global solidarity and adhere to the global allocation system.
3. **Safeguard affordable access long term by overcoming intellectual property barriers:** Gavi must help safeguard affordable access to COVID-19 vaccines more sustainably by also advocating for open licenses and requiring technology transfer and other measures that can ensure more manufacturers can participate. Gavi's previous AMC approach failed to address this issue, and IP remained a barrier to diversifying the PCV manufacturer base. Helping to address IP obstacles will result in more stable supply and lower prices. Gavi publicly communicated that its mechanism will help with “funding the expansion of manufacturing capacity, securing critical raw materials and equipment, and helping to transfer technology from developers to manufacturers.”<sup>14</sup> However, the most recent plans by Gavi do not include an element of technology transfer nor pushing for open licensing or better treatment of IP. COVAX Facility funding should come with “strings attached” that require companies to participate in technology transfer to broaden the manufacturer base, helping improve supply availability.
4. **Do not undermine existing functional procurement mechanisms:** Gavi's work to negotiate a mechanism should not undermine existing, well-functioning procurement initiatives run by governments. Gavi is a foundation created to serve as a financing instrument that funds vaccine introduction in the poorest countries of the world. It is not owned by governments, nor does it have the credibility with governments that regional governmental bodies do. It should therefore not undermine efforts of government-backed initiatives, such as the PAHO Revolving Fund or the Gulf Cooperation Council.
5. **Include the humanitarian community and NGOs as eligible purchasers:** Besides governments, other vaccination service providers such as humanitarian organisations and non-governmental organisations (NGOs) will need access to future COVID-19 vaccines. Oftentimes these organisations are able to reach the most vulnerable people such as internally displaced and refugee populations. Past initiatives led by Gavi left out NGOs who were ultimately paying a higher price for the same vaccine being administered in the same Gavi-eligible country. To avoid repeating this mistake, Gavi must include non-governmental purchasers in their COVAX Facility; a platform for all NGOs that administer vaccinations must be established in the Facility architecture.



6. **Be transparent:** Gavi, and governments that provide funding to Gavi, must insist on transparency from pharmaceutical corporations. A “not for profit” price already claimed by some companies such as Johnson & Johnson and AstraZeneca must be substantiated by a review of pharmaceutical companies’ accounting. Corporations should be held to their word, and this expectation should be extended to all companies with successful COVID-19 vaccines. Corporations should also be mandated to substantiate their pricing; Gavi should require that any company receiving funding from the COVAX Facility be transparent with its costs. Gavi already publicly communicated that “...manufacturers will be asked to commit to transparency regarding their costs, and pricing could be based on validated costs of production plus a small margin.”<sup>14</sup> Governments must insist that any money given to Gavi for the Facility has product cost information as a requirement. Additionally, Gavi must operate transparently in the development and plans for the Facility, including the agreements made with industry; all contracts must be public.
7. **Include developing countries and civil society organisations in the process:** Some institutions and selected individuals have had an outsized influence on the design of the Facility so far, while affected countries and civil society partners have had little to no opportunity to participate in its design. The COVAX Facility could greatly impact their ability to serve people’s health needs in the face of COVID-19, so the right voices must be at the table to ensure the Facility is appropriately designed to serve the needs of the most vulnerable populations. In the next steps of its design process, Gavi must include representatives from its list of traditionally eligible countries and civil society.

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