

SUBJECT: COVAX FACILITY STRUCTURE AND GOVERNANCE**Agenda item: 04b****Category: For Decision**

Section A: Summary

Context

Following the launch of the ACT Accelerator with the goal of achieving equitable access to new COVID-19 therapeutics, diagnostics and vaccines, Gavi has led on the preliminary technical design of the COVAX Facility (the “**Facility**”), a global mechanism to pool resources and demand for a COVID-19 vaccine with the goal of accelerating the availability of and access to safe and efficacious vaccines, and on the design of the COVAX Advance Market Commitment (the “**COVAX AMC**”), a financing mechanism to ensure access to COVID-19 vaccines.

To realise the objectives of the Facility, a legal entity is required to enter into agreements with high income economies and upper middle-income economies wishing to participate in the Facility and potential manufacturers of a COVID-19 vaccine. A number of legal options for the Facility were explored; however, given the urgency for the Facility to be operational quickly in order to enter into advance purchase contracts with manufacturers and considering Gavi’s unique experience in accelerating access to vaccines in low income economies and credibility with high income economies as well as manufacturers, it is proposed that Gavi administer the Facility. Administrative costs, including resourcing needs, would be covered by incremental funding. If the Board approves Gavi as administrator of the Facility, a governance mechanism is proposed that builds on Gavi’s existing structures as much as possible, while recognising the need for certain new bodies and advisory functions.

Questions this paper addresses

- 1) Given the urgency to operationalise the Facility, should Gavi serve as the administrator of the Facility?
- 2) What are the risks and challenges of Gavi serving as administrator for the Facility and how can these risks and challenges be managed?
- 3) What governance arrangements should be in place to ensure that responsibilities to oversee the Facility and decision-making sit with the appropriate governing bodies, for example, should the MSDC be expanded to include representatives of self-financing countries for the purpose of reviewing the business terms of COVAX agreements with manufacturers?

Conclusions

While there are risks to Gavi serving as the administrator for the Facility, these can be mitigated by robust policies and procedures that ensure a clear line for decision-making, segregation of funding, transparency and a focus on and oversight over the delivery of Gavi 5.0. We have set out in this paper: (1) the impetus behind the Facility; (2) the high level terms of the Facility; (3) an analysis of options for the legal personality for the Facility; (4) risks and opportunities of Gavi serving as the legal personality; (5) a proposed governance approach; (6) the role and responsibility of the “Office of the COVAX Facility”; and (7) relationship between the COVAX AMC and Facility. The Board will be asked to approve Gavi serving as the legal entity to administer the Facility and to approve amendments to the MSDC Charter with respect to the review of COVAX agreements with manufacturers.

The COVAX AMC is presented in a separate paper (Doc 04a) and the interplay between the AMC and Facility is further covered under Section 6 of this paper.

Section B: COVAX Facility Structure and Governance

1. **ACT-Accelerator and the impetus behind the COVAX Facility**
 - 1.1 As of 23 July 2020, according to the Johns Hopkins University COVID-19 map, there are more than 15 million confirmed COVID-19 cases worldwide and more than 600,000 confirmed deaths. The virus has spread to nearly every territory and region, with growing or stagnant numbers across the globe. Although a number of regions have been able to control the virus spread in some cases through quarantine, social mobilisation and contact tracing, these measures have taken a toll on economies and often as precautions relax cases tend to trend upwards. A vaccine provides the best chance of any return to normality.
 - 1.2 COVID-19 vaccine development is advancing at an unprecedented pace; as of 23 July 2020, there are at least 142 vaccine candidates in preclinical evaluation and ~24 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 prequalified and available, supply is accessible globally for an effective public health response.
 - 1.3 At the end of April 2020, at an event co-hosted by the President of France, the President of the European Commission, the Director General of the World Health Organization, and the Bill and Melinda Gates Foundation, WHO launched the Access to COVID-19 Tools (ACT) Accelerator, an initiative bringing together governments, scientists, businesses, civil society, and philanthropists and global health organisations towards addressing the challenge of equitable access to new COVID-19 therapeutics, diagnostics and vaccines.
 - 1.4 Gavi was charged with co-leading, along with the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO, the Vaccines Pillar of the

ACT-Accelerator. Within the Vaccines Pillar, CEPI, as lead for the Development and Manufacturing Workstream, is making direct financial investments to support R&D and manufacturing expansion of promising COVID-19 candidates. WHO, as lead for the Policy and Allocation Workstream, is developing global policy recommendations on use of vaccines via the Strategic Advisory Group of Experts (SAGE) on Immunization and an Allocation Framework.

- 1.5 As Gavi is the lead for the Vaccine Procurement and Delivery at Scale Workstream, the Secretariat collaborated with a range of technical partners¹ and consulted with low income economies, civil society, Gavi donors and at least 170 experts to design a mechanism to pool global demand and resources to provide manufacturers with certainty of future financing and procurement as an incentive for manufacturers to expand production capacity, while still developing their vaccines. All three partners in the Vaccine Pillar (the “**COVAX partners**”) have committed to working together closely to support a seamless effort towards the rapid development and equitable delivery of COVID-19 vaccines.
- 1.6 Recognising that a global solution is the best solution for a global problem the COVAX partners launched the COVID-19 Vaccines Global Access (COVAX) Facility.

2. The COVAX Facility

- 2.1 The key principles and design features of the Facility are described in the following sections. The Secretariat is continuing to engage with stakeholders to complete the design of, and begin to operationalise, the Facility.
- 2.2 The **COVAX Facility Goals** are to:
- develop the largest and most diverse actively managed portfolio of COVID-19 vaccine candidates to maximise the probability of success so that the best vaccines are ultimately made available;
 - deliver 2 billion doses of an approved COVID-19 vaccine (“**Doses**”) by the end of 2021;
 - satisfy the needs of Participants and offer a compelling business case to participate in the Facility;
 - guarantee fair and equitable access to COVID-19 vaccines for every economy in the world; and
 - end the acute phase of the pandemic by the end of 2021.

¹ Including WHO, CEPI, Bill & Melinda Gates Foundation, UNICEF, World Bank

- 2.3 High Income Economies and Upper Middle-Income Economies² will be self-financing participants (“**Self-financing Participants**”) in the Facility and will be required to pay for their doses. Each Self-financing Participant will be required to commit the following:
- to enter into a legally binding commitment to purchase through the Facility enough doses to immunise 20% of its population (“**Commitment Amount**”). The Commitment Amount will be calculated based on an indicative price.
 - to provide a payment of 15% of the Commitment Amount to enable Gavi, acting on behalf of the Facility, to enter into manufacturer agreements to scale up vaccine production at risk for future vaccine supply as well as to support the administrative costs of the Facility. If it is not used any remaining amounts will be returned. Although they are not currently planned, additional payments may be required in advance of procurement to ensure adequate scale up.
- 2.4 Based on a Participant’s credit rating profile and its ability to provide financial commitments both as an upfront down payment and over time, a guarantee may be required either from the Participant’s central bank (for those Participants rated AA by a rating agency, for example) or for the Commitment to be backed by a financial institution (such as a multilateral development bank).
- 2.5 Participants will also be asked to agree to non-financial commitments such as:
- **Ensure unrestricted movement of vaccine doses from domestic manufacturers.** Participants agree to not impose embargoes or any impediments to access, support timely National Regulatory Authority (NRA) release, import/export of vaccines, and prioritize cargo space for vaccine shipments.
 - **Facilitate regulatory clearance.** Participants are encouraged to promote and leverage regulatory convergence, collaboration and reliance as much as possible to fast-track the path to vaccine licensure.
 - **Contribute to global information repository.** Participants agree to contribute data (e.g. epidemiological and virological) to global information repositories to build the overall body of knowledge (e.g. to inform vaccine development and vaccination strategies) to the benefit of all.
 - **Provide transparency on bilateral supply agreements.** Participants commit to being open and transparent about their own COVID-19 vaccine supply agreements with the Facility, which will help the Facility optimising its portfolio of investments to the benefit of all.

² Except for the additional 12 IDA eligible economies in scope for the COVAX AMC, subject to Board Approval under the COVAX AMC paper, Doc 04a, Board Meeting 30 July 2020

- 2.6 As part of the deliberations to take place as part of the COVAX AMC, the Board is expected to define which economies will receive assistance through the AMC; however, the current assumption is as follows: low income and lower middle-income economies, plus other World Bank IDA-eligible economies, would participate in the Facility with support from the AMC donors through the COVAX AMC (collectively, the “**Funded Participants**” and together with the Self-financing Participants, the “**Participants**”).
- 2.7 Gavi, on behalf of the COVAX Facility, will enter into agreements with selected manufacturers to secure access to vaccine supply on the following basis:
- Only appropriately approved vaccine doses will be procured through the Facility (this will include licensing by a stringent regulatory agency, WHO prequalification or WHO Emergency Use Authorization until it has completed the full registration).
 - Manufacturers will be expected to seek minimal return during the acute phase of the pandemic.
 - Manufacturers will be required to provide transparency on any push funding received.
 - The financing provided to the manufacturers will be complementary to, and synergistic with, the direct financial support to vaccine developers/manufacturers being provided by other ACT Accelerator partners (e.g. CEPI and BMGF).
 - The Facility will commit to procure a pre-defined number of doses that meet the agreed WHO Target Product Profile, so that the manufacturers will be able to quickly supply reserved doses to the Facility upon licensure.
- 2.8 Doses will be allocated to Participants in accordance with an Allocation Framework and Allocation Mechanism to be developed by WHO, which has made a preliminary determination that, at the outset, Participants would receive doses proportionate to the total population as follows:
- All Participants will initially receive Doses to cover 3% of their population. This would be intended to be enough to cover all workers involved in health and social care work.
 - All Participants will then receive additional doses beyond the 3% up to a total of 20% of their population (in tranches). This could cover the elderly, adults with co-morbidities or others depending on locally relevant risk factors.
 - After this phase one period, Participants could receive vaccines to cover more than 20% of their population and allocation timing for these additional vaccine doses would be based on the need of the economy, vulnerability and COVID-19 threat.

- 2.9 On behalf of the Facility, UNICEF Supply Division has issued an Expression of Interest process with manufacturers in order to provide the Facility with some level of visibility and ensure the volumes and prices intended to support the Facility Goals.
- 2.10 Upper middle-income and high income economies have been invited to participate in the Facility and there is already a high level of interest, with 75 Expressions of Interest received.
- 2.11 The Facility is an ambitious undertaking and, as such, to succeed, will require clearly defined principles and these have been set out below:
- a) **Global access:** Protecting global health security means ensuring that everyone can secure access to a safe and efficacious vaccine. No economy will be prevented from participating due to GNI (Gross National Income) disparities.
 - b) **Impact-oriented:** The Facility is single-minded in its goal to ensure equitable access to COVID-19 vaccines. 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.
 - c) **Transparency:** The Facility promotes visibility into cost and fees and as such the costs associated with R&D and advance purchase commitments will be made available to all Participants.
 - d) **Solidarity and collective ownership:** The world 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 economies will be asked to contribute to the Facility based on their capacities in the form of financial contributions.
 - e) **Complementarity with other funding:** The vaccine pillar is designed to be an end to end solution. The pull mechanisms used by the Facility would operate in complementarity with the push funding provided by other stakeholders, such as CEPI, and other bilateral and philanthropic investments. Manufacturers will be requested to disclose any funding they received from a third party to facilitate R&D or incentivise scale-up. As the Facility enters into manufacturer-specific guarantees to secure sufficient volumes of vaccines for the Participants, the Facility will consider any previous funding received by the manufacturers in contractual conditions.
3. **Legal Entity for the Facility**
- 3.1 Given the requirement to enter into commitment agreements with the Self-financing Participants and agreements with manufacturers for the advance purchase of doses, the Facility will require legal personality.

- 3.2 The Facility's legal status needs to be determined as soon as possible so that the Facility is operational and able to carry out its activities, to quickly to start entering into volume guarantee agreements with manufacturers to ensure equitable distribution of vaccine when they are first available. Economies all over the world are exposed to the massive impact that the COVID-19 pandemic has on their population and economies. To mitigate such impact, some high income and upper middle income and regional blocks are seeking opportunities to secure, and in some cases are already securing, vaccines for their domestic needs by entering into bilateral or regional agreements with manufacturers. As some vaccines are successfully developed, and most others are not, access to vaccine candidates might then be limited to a privileged few economies that select the successful candidates. Consequently, there would be insufficient supply for most economies, and, in particular, Gavi-supported economies as they would be unable to financially compete with high income economies.
- 3.3 Moreover, manufacturing investments in capacity and raw materials should happen now alongside research and development to accelerate vaccine availability, compressing the development timeline to 12-18 months, from the typical 7-20 years.
- 3.4 Gavi serving as the legal personality of the Facility is recommended over several alternative options given an assessment of advantages, disadvantages and risks. Notably, this is not an assessment carried out by an independent party, looking at advantages and disadvantages of particular entities. Given the urgency, the Secretariat has conducted the analysis.
- 3.5 A more detailed analysis of these alternative options is set out in Annex A. In summary, Gavi is recognised as a key global stakeholder with established expertise, track record and credibility in areas that are relevant for the COVAX Facility (immunisation, market shaping, innovative finance applied to global health programmes). Moreover, having led the design of the Facility, Gavi is well positioned to move to the next phase of implementation.
- 3.6 Alternative options would lead to significant delays in entering into transactions with manufacturers and jeopardises the achievement of the Facility's Goals. Indeed, it is highly likely that the majority of early vaccines would already be gone by the time some of the other options would be operational. Assuming the Board approves that Gavi should implement the AMC, some of the alternative options would be structurally complex and entail high transaction costs to set up and achieve the level of cooperation required between the COVAX AMC and the Facility.
- 4. Risks and opportunities of Gavi serving as the legal personality for the COVAX Facility**
- 4.1 It is proposed that Gavi serve as the administrator/legal personality of the COVAX Facility with immediate effect until the earlier of 31 July 2023 or the date that the Participants have been allocated enough doses to immunise 20% of their population (which is expected to be by Q2, 2022). At such point,

the Participants would decide whether to extend the term of the Facility, and the Gavi Board would decide whether Gavi should continue in the role or hand over responsibility to a different entity(ies).

A. The Facility aligns with the Mission and Strategic Goals of Gavi

4.2 Gavi's purpose as set out in its Statutes is as follows:

“to promote health by: (i) providing vaccines and the means to deliver such vaccines to people in the poorest countries; (ii) facilitating the research and development of vaccines of primary interest to the developing world; and (iii) to provide support in connection with achieving the foregoing purposes by helping to strengthen health care systems and civil societies supporting such purposes in the developing world.

Within this broad purpose, the Gavi Alliance will focus its work in support of improvement of vaccination and immunisation in the poorest countries. To this effect, the Gavi Alliance works as an innovative international public-private partnership, which brings together various organisations and constituencies actively engaged in supporting immunisation in implementing countries – such as Governments, United Nations organisations, vaccine manufacturers, foundations, nongovernmental organisations and research institutes, as well as individuals with private sector and other experience, which together provide legitimacy, credibility and technical expertise. Recognising and drawing on the mandates and responsibilities of all constituencies represented on the Gavi Alliance Board, the Gavi Alliance provides public and private finance and a broad diversity of perspectives, experience and skills.”

4.3 The goals of the Facility as set out in Section 2.2 of this paper are aligned with Gavi's mission and strategic goals.

4.4 Equitable access to COVID-19 vaccines is a global problem that calls for a global, coordinated solution. While the Facility would be open to all economies, regardless of GNI, the Facility is seen as the best means to ensure that low income economies have access to vaccines at the same time as high income economies as opposed to waiting years for supply to materialise.

4.5 In particular, the Facility goal **to develop the largest and most diverse actively managed portfolio of vaccine candidates so that the best vaccines are made available** increases the chance that Funded Participants will access vaccines when they are first approved and made available. With pooled resources and demand of all Participants, the Facility will be able to benefit from a larger portfolio of COVID-19 candidate vaccines, produced by a wider group of manufacturers, with a bigger market to provide security of demand – in each case with greater scope than any government or regional group can support on its own. This significantly improves the likelihood of accessing successful candidate vaccines, as well as vaccines that will meet the specific needs of populations around the globe.

- 4.6 The Facility goals **to deliver 2 billion doses by end of 2021, to guarantee fair and equitable access to COVID-19 vaccines for every economy in the world and end the acute phase of the pandemic by the end of 2021** benefits Gavi eligible economies by ensuring that all economies can access vaccines for their most vulnerable populations and not just the lucky few. If there is a significant delay in setting up the Facility, and high income economies and upper middle-income economies do not participate in the Facility and instead continue to strike their own bilateral deals with manufacturers, there is a risk that the majority of global COVID-19 vaccine supply will be tied up and there will be little left for Gavi-supported economies. Gavi supported economies would have no options, as early availability will have been already taken by high income economies.
- 4.7 If we consider just the US and EU, they represent a combined population of 750m individuals, which would translate into ~1.5 billion doses of vaccines (assuming a 2-dose regimen). This would likely be the vast majority of available global COVID-19 vaccine supply through the end of 2021. The Facility, by allowing the participation of high-income economies and upper middle-income economies, with allocation for all, addresses this issue.
- 4.8 Even if Gavi-supported Participants have access to vaccines through the AMC, without the combined buying power of the Self-financing Participants, reaching critical populations will be complicated and will take time because of weak health systems in many economies. If the virus continues to circulate in those high-income economies and upper middle-income economies that have not secured early deals with manufacturers, it will continue to spread worldwide with lower income economies with weak health systems particularly vulnerable to continued spread of the virus.
- 4.9 External Swiss counsel has confirmed that the COVAX Facility as proposed in this paper and in the preliminary technical document is consistent with Gavi's mandate. Therefore, because of the alignment of the goals of the Facility with Gavi's mission and strategic goals and the benefits to Gavi supported economies, Gavi administering the COVAX Facility would not require an amendment of the Statutes. Further, we have confirmed with external US counsel that Gavi's administration of the Facility would not impact Gavi's status as a public charity in the US.

B. Risks and Opportunities

- 4.10 To inform the Board's decision on whether Gavi should be the administrator of the COVAX Facility, a risk analysis is presented in Annex B, which includes the risks of Gavi not being the administrator and the risks of Gavi being the administrator along with general risks that apply to both the COVAX Facility and AMC. As part of operationalising the Facility, the Secretariat will conduct a risk assessment to be shared at the Board's December meeting.
- 4.11 In addition to benefits to Gavi eligible economies already stated above, consideration should be given to the following opportunities to Gavi in hosting the Facility: (1) the positive impact of the early availability of a

vaccine to deploy globally on the economies of the world, in particular low-income economies; and (2) the potential for Gavi's engagement with HICs and UMICs with whom Gavi currently does not have a relationship to be leveraged to directly benefit the COVAX AMC and Gavi strategic goals more broadly.

C. Principles for the Administration of the Facility

4.12 If Gavi is to play a role in the Facility's administration, it is proposed that overarching principles frame its course of action in order to mitigate against the risks that have been highlighted and safeguard resources and the capacity of the Secretariat to deliver on existing programmes and Gavi 5.0. These principles would serve as red lines from which the Secretariat would not deviate:

- Facility funds will be segregated from Gavi's core financing, and funding provided by the Self-financing Participants will be tracked separately from the funds received by the AMC donors under the COVAX AMC.
- Expenses associated with the administration of the Facility will be paid for with administrative fees provided by Self-Financing Participants and AMC funding in accordance with an appropriate allocation methodology.
- Gavi would not enter into agreements with manufacturers which result in Self-Financing Participants being distributed Doses without having provided a legally binding financial commitment to procure such Doses, with appropriate financial backing for such commitment.
- Additional staff would be hired to ensure capacity and bandwidth for the set-up and, ultimately, implementation of the Facility.

D. Board and Committee Decision Timeline

4.13 Recognising the speed and urgency with which the decisions on the Facility need to be taken to be successful, the Secretariat proposes to come back to the Board at its meeting in December with: (i) a reporting framework and (ii) a risk assessment and risk mitigation plan for the COVAX Facility; (iii) detailed TORs for the new governance and advisory bodies mentioned below in Section 5.

5. Potential governance approach if Gavi administers the Facility

5.1 The governance mechanism outlined in this paper builds on Gavi's existing mechanism to the greatest extent possible, while recognising that the Facility will require separate bodies to ensure appropriate oversight.

A. Existing Governance Bodies

5.2 Following are the roles and responsibilities of the Gavi Board, Market-Sensitive Decisions Committee ("**MSDC**") and Audit and Finance Committee ("**AFC**") with respect to the Facility. It is not contemplated at this time that the other Gavi governance bodies would have a role in the

administration of the Facility, although they would continue to carry out normal activities with respect to the COVAX AMC.

- a) **The Gavi Board** will be responsible for overseeing the role of Gavi in the implementation of the Facility to ensure consistency with the mandate given to it.
- b) **The MSDC** will be responsible for reviewing business terms of proposed agreements with manufacturers to ensure: (i) reasonableness of terms and acceptable level of reputational risks; and (ii) availability of resources to back proposed agreements. The current members of the MSDC include Board Chair, the Board Vice Chair, the Audit and Finance Committee Chair, the Programme and Policy Committee Chair, representatives of multilaterals, a representative of BMGF, representatives of implementing country governments (2), representatives of donor country governments (3), a representative of the Civil Society Organisations. It is proposed that for review of COVAX-related agreements with manufacturers that the MSDC would also include representatives of Self-financing Participants.
- c) The **AFC** will be responsible for: (i) ensuring funding availability for COVAX Facility operations, including review of the financial implications of Facility-related transactions; and (ii) ensuring the COVAX Facility is properly represented in Gavi's annual Financial Report.

B. New governance and technical advisory bodies

- 5.3 A new oversight body would be established to oversee operational aspects of the Facility as related to Self-Financing Participants. Following is a proposal for a Shareholders Council, established to represent the interest of Self-Financing Participants. Depending on the number of shareholders, some type of steering committee or executive committee may be required to facilitate quick work and to liaise with the Gavi Board to take key decisions with respect to the Facility.
- 5.4 The **Shareholders Council** will include representation from all Self-Financing Participants and could also include members from the AMC Stakeholders Group, which is defined in the paper on the COVAX AMC to include representation from Funded Countries and AMC Donors. Self-Financing Participants in collaboration with Gavi would agree and establish the final Operating Procedures. The Shareholders Council will provide strategic guidance on the activities of the COVAX Facility, in particular on areas related to the status of vaccines under development. The Council will also have an overview of the Facility's processes on dose allocation in alignment with the WHO Allocation Mechanism. Information would be provided to the Council on a real-time basis and the Council will be updated on regular basis.

- 5.5 It is also anticipated that the following advisory bodies will be established to accommodate the specific technical requirements of the Facility.
- 5.6 **The Independent Product Group** will be responsible for providing independent advice to the MSDC and the COVAX Facility on vaccine candidates, informing on the selection of candidates for inclusion in transactions funded by the COVAX Facility, provide an assessment as to whether selected candidates have met threshold criteria for eventual purchase, reviewing the overall COVAX portfolio on a rolling basis, taking into consideration updates related to clinical development, manufacturing and supply. Membership would comprise 5–7 independent experts with expertise in areas important to vaccine discovery and delivery. Drawing from the experience of the PCV AMC, it is proposed that these experts are appointed by a selection and oversight panel constituted of each of Gavi, WHO, CEPI in consultation with IFPMA and DCVMN. The panel would also manage potential conflict of interest issues, dismissal, selection and replacement of IPG members.
- 5.7 The governance structure for the **WHO Allocation Mechanism** will be responsible for reviewing and analysing data and documentation, providing technical input and making dose allocation assessments in accordance with the final technical design, approved by Member States, of the WHO Allocation Framework. The governance of the WHO Allocation Mechanism and the interplay with the governance of the COVAX Facility is under development.
- 5.8 In addition, consideration will need to be given as to whether there is a requirement for a treasury manager function.

6 **The role and responsibilities of the “Office of the COVAX Facility”**

- 6.1 As set out in more detail in the following sections, if Gavi is to administer the Facility, there will be resources fully dedicated to support the Facility as well as resources allocating time in support of the Facility. These resources will be referred to as the **“Office of the COVAX Facility”**. The Office of the COVAX Facility will be responsible for carrying out the following activities:
- a) negotiate legally binding agreements with the Self-Financing Participants, including tri-partite agreements with multilateral development banks, as relevant;
 - b) negotiate with manufacturers to achieve volume availability at an affordable price for Participants;
 - c) enter into volume guarantees with a range of vaccine manufacturers on the best terms possible for the Facility, taking into consideration any CEPI or other push funding;
 - d) actively manage the portfolio of vaccine candidates, along with experts from CEPI and WHO and other technical experts and advisors;

- e) convene the Shareholders Council and provide regular reporting to the Council on manufacturer transactions, including costs associated with such transactions as well as administrative fees;
 - f) convene the Independent Product Group; and
 - g) all administrative functions.
- 6.2 While over the last ~2.5 months, Secretariat staff have been flexibly deployed to support the design of the Facility, going forward it is critical that the right resources and capabilities are mobilised to both finalise the set-up and operationalise the Facility. This is necessary in order to: (i) ensure adequate resources are available to do this well, (ii) allow Gavi to deliver on its regular activities and Gavi 5.0 goals, which include major adjustments due to COVID-19, and (iii) help protect staff and their well-being.
- 6.3 The overall resource needs for COVID-19-related activities include: (i) resources for a dedicated Facility team; (ii) Facility dedicated resources that are deployed from the current Secretariat departments; (iii) resources in the Secretariat for other COVID-19 vaccine-related activities (e.g. delivery); and (iv) resources to drive core Gavi programmes “in the COVID-19 world.” This paper focuses on defining the high-level resource needs and considerations for (i) and (ii), while (iii) and (iv) will require an integrated analysis with Gavi’s broader scope of activities and will be considered as part of the Organisational Review for Gavi 5.0, which was paused in the context of the pandemic and will resume later in the summer.
- 6.4 To successfully deliver on the mandate of the Facility, a range of functions and capabilities, as well as appropriate management, are needed. While the majority of these capabilities already sit within the Secretariat (hence Gavi’s leadership of the Facility under the Procurement and Delivery At Scale workstream within ACT-A), there are some specific areas where existing capabilities may need to be supplemented – for example, deal making for vaccines that are still in the R&D stage, as well as engaging with economies that are new to Gavi. To ensure Gavi’s core work is not impacted and a strong focus remains on the Facility, resources will be fully dedicated either in the existing functional teams or in new ones.
- a) **Resources for a dedicated team within the Office of the COVAX Facility:** these resources form the core of the Office of the COVAX Facility given the benefit for those resources to “sit together” to deliver their tasks and mission to launch and operationalise the Facility. This may include, for example, the activities of coordination with the ACT-A Vaccine Pillar, deal-making and Self-financing Participant account management.

- b) **Resources deployed from the current departments:** while still working on aspects of the Facility, these resources would still sit in their respective Departments due to strong synergies (e.g. stakeholder engagement) and economies of scale, or in cases where activities are not meaningfully different from traditional/'non-Facility' activities or need to provide a second line of defence (e.g. legal). This may include, for example, resource mobilisation, legal, monitoring and evaluation, advocacy, IT and human resources. Similar to the allocation methodology used for the IFFIm Company, where IFFIm is charged and reimburses Gavi for administrative support, time spent on the Facility would be apportioned to the Facility.
- 6.5 The Gavi Secretariat is currently performing set-up activities for both the Facility and the AMC. From March through the end of July 2020, the Secretariat will have spent from within its existing budget ~US\$ 1.4 million on consultant support and external legal counsel to support the design and initial implementation of the Facility and AMC. If the Board approves the Facility, it is anticipated that the costs attributed to the Facility will be reimbursed through fees paid by Self-financing Participants to cover operating costs to administer the Facility including overheads and through Gavi funding mobilised for procurement and delivery of COVID-19 vaccines for Gavi-supported economies (subject to Gavi Alliance Board approval).
- 6.6 Looking ahead, additional dedicated resources will be required to successfully operationalise the AMC and the Facility. The extent of resourcing will ultimately depend on the number of Participants and manufacturer transactions required to fulfil the dose supply. It is envisioned that surge capacity will be needed in the next ~6 months, followed by a more "steady state", implementation mode (as illustrated in Annex D). To ensure that the right level of support is provided to the core Gavi activities and that staff wellbeing is not compromised, launching the recruitment of these additional resources as soon as possible will be critical.
- 6.7 The Secretariat is asking for an initial "seed funding" to support the activities to set up the Office of the COVAX Facility and start implementing the Facility and the AMC, in the amount of US\$ 7 million for the next 12 months, inclusive of external legal fees and other expenses. Travel expenses should be in line with Gavi's Travel policy. These resourcing needs are dependent on the final scope of the Facility (e.g. coverage, number of deals, final demand / supply level etc.) – but also on the evolution of the pandemic, how successful the manufacturers will have been in developing vaccines. It will be critical to reassess the needs for the Office of the Facility over time. The Secretariat is seeking approval from the Board to pre-finance these costs at risk through Gavi funds to enable operationalisation of the Facility and AMC.
- 6.8 These costs would ultimately be substantially funded through the Facility participation fees for Self-Financing Participants and through Gavi funding mobilised for procurement and delivery of COVID-19 vaccines for Gavi-supported economies (subject to Board approval). The AFC and Board would be regularly updated on evolving needs.

7. Relationship with the COVAX AMC

- 7.1 The COVAX AMC, as described in Doc 04a of this meeting of the Board, is a financing instrument aimed at accelerating access by lower income economies to COVID-19 vaccines as soon as they are available for procurement. It is proposed that the COVAX AMC supports access by lower income economies for a period of ten years, while the Facility is anticipated to be active for up to three years.
- 7.2 Should the Board approve Gavi serving as administrator of the Facility, the COVAX AMC would become a financing tool enabling the participation of lower income economies to the Facility. The AMC would continue to support access to COVID-19 vaccines once the COVAX Facility has ended.

Section C: Actions requested of the Board

Building on the approvals and guidance provided by the Board at its meetings of 11 May and 24 and 25 June 2020, the Gavi Alliance Board is requested to:

- a) **Recognise** that the global fight against the COVID-19 pandemic and the nature of the disease call for the creation of a global mechanism to ensure rapid, fair and equitable global access to a safe and efficacious COVID-19 vaccine to as broad a population as possible.
- b) **Note** that, given the supply constraint environment and ongoing bilateral initiatives to secure availability of vaccine candidates, the timing for such a mechanism to become effective is of the essence.
- c) **Acknowledge** that, across several options presented to the Board, Gavi being entrusted with the task to administer the COVAX Facility is the fastest way to have an established and credible legal entity working towards the objective of ensuring global and equitable access of COVID-19 vaccines and that the benefits of Gavi administering the COVAX Facility outweigh the risks.
- d) **Note** that administering the COVAX Facility is aligned with Gavi's mission given the expected benefits it will yield for low income economies.
- e) **Approve** Gavi as the legal entity to administer the COVAX Facility with immediate effect; provided that:
 - i. Gavi's role will be reassessed by the Board on the earlier of: (a) the Board meeting taking place between June and September of 2023, and (b) the first Board meeting taking place after the Participants have been allocated enough Doses to vaccinate at least 20% of their population pursuant to the WHO's Allocation Mechanism; and

- ii. The Secretariat will, at all times, ensure that:
- (i) Facility funds will be segregated from Gavi's core financing, and funding provided by the Self-financing Participants will be segregated from the funds received by the AMC donors under the Covax AMC
 - (ii) Expenses associated with the administration of the Facility will be paid for with administrative fees provided by Self-Financing Participants and AMC funding in accordance with an appropriate allocation methodology.
 - (iii) Gavi would not enter into agreements with manufacturers which result in Self-Financing Participants being distributed Doses without having provided a legally binding financial commitment to procure such Doses, with appropriate financial backing for such commitment.
 - (iv) Additional staff would be hired to ensure capacity and bandwidth for the set-up and, ultimately, implementation of the Facility.
- f) **Request** the Secretariat to present to the Board in December 2020: (i) a reporting framework and (ii) a risk assessment and risk mitigation plan for the COVAX Facility.
- g) **Request** the Secretariat to convene a Board meeting by no later July 2021 to assess Gavi's continued role in the administration of the Facility.
- h) **Note** the establishment of a COVAX Shareholders Council to provide strategic guidance on the administration of the COVAX Facility, which body shall be self-organising and will operate in accordance with its operating procedures.
- i) **Approve** the amendments to the Market-Sensitive Decisions Committee Charter as set out in Annex C to Doc 04b to allow for review and approval of COVAX transactions with manufacturers to include members of the COVAX oversight body.

With reference to the discussion on Doc 03 *Financial Forecast*, the Gavi Alliance Audit and Finance Committee **recommends** to the Gavi Alliance Board that it:

Approve the pre-financing of the COVAX Facility initial costs through Gavi funds to enable operationalisation of the COVAX Facility, which includes the COVAX AMC mechanism. The estimated amount is US\$ 8.4 million, of which US\$ 1.4 million has already been incurred and an incremental US\$ 7 million is forecasted for the next 12 months. These costs will ultimately be funded through the COVAX Facility participation fees for Self-financed Participants and through Gavi funding mobilised for procurement and delivery of COVID-19 vaccines for Gavi-supported Participants).

Annexes

Annex A: Table outlining options for the administration of the COVAX Facility

Annex B: Risk analysis

Annex C: Proposed amended Charter of the MSDC

Annex D: Facility resourcing needs over time