

**SUBJECT:** COVAX FACILITY OPERATIONALISATION AND VACCINE PROGRAMME

**Agenda item:** 03

**Category:** For Decision

## **Section A: Summary**

### **Context**

In July 2020, the Gavi Board approved Gavi as the legal entity to administer the COVAX Facility (the “Facility”), a global mechanism to pool resources and demand for COVID-19 vaccines with the goal of accelerating the availability of and equitable access to safe and efficacious vaccines. The Board also approved the establishment of the Gavi COVAX AMC (the “COVAX AMC”), a financing mechanism to accelerate and reserve COVID-19 vaccines to ensure that low income and lower middle-income economies, as well as other IDA-eligible economies, have access to COVID-19 vaccines at the same time as wealthier economies.

The COVAX Facility will have global participation of over 170 economies representing over 70% of the world’s population. As this paper is being written, self-financing economies have begun to provide their legally binding agreements which include upfront funding to reserve doses with manufacturers now. This will allow the Facility to build an actively managed portfolio of 10-15 vaccine candidates based upon diverse technologies and geographies to maximise the chance of a successful outcome and accelerate access with up to two billion doses by end of 2021. The COVAX Facility will shape the vaccine market to expand supply and achieve economies of scale through aggregating demand and increasing availability simultaneously in developed and developing countries.

Without a successful COVAX Facility there is a very real risk that lower income countries will be left behind, and the majority of people in the world will go unprotected. This would allow the virus and the pandemic to continue unabated and continue to disrupt the global economy as well as Gavi’s core mission. The Gavi Secretariat, including the Office of the COVAX Facility, under the guidance of the Board, must find the right balance to safeguard the reputation and finances of the Alliance and successfully deliver on the promise of the Facility. To this end, the COVAX Facility is designed to ensure the procurement and governance needs of both Self-Financing Participants (“SFP”) and 92 COVAX AMC-eligible economies (“AMC92”) are adequately addressed whilst minimising risks to Gavi core resources and programmes.

## Questions this paper addresses

- What are the design, funding and financing arrangements for the COVAX Facility to be able to deliver on the commitment of procuring up to 2 billion doses of COVID-19 vaccines, while effectively managing financial risks and liabilities within the Board's risk appetite?
- What Facility governance arrangements have been made to ensure appropriate oversight of the Facility?
- What progress has been made in engaging manufacturers and economies?
- How is the Alliance planning to support eligible economies with COVID-19 vaccine delivery, including the potential need for ultra-cold chain?

## Conclusions

We have set out in this paper: (1) Preliminary Facility funding arrangements; (2) the financial operating model of the Facility; (3) proposed Facility governance structure; (4) a vaccine pipeline and manufacturer engagement update; (5) an update on country engagement in the Facility; (6) the establishment of the Office of the COVAX Facility; (7) cost-sharing with AMC-eligible economies; (8) vaccine delivery and technical assistance support required to deliver COVID-19 vaccines, and; (9) proposed support for India. Related risks and mitigating measures have been highlighted throughout the paper, based on a detailed risk assessment being carried out and to be shared in further detail with the Audit and Finance Committee (AFC) and at the December Board meeting as part of regular risk reporting in the Risk & Assurance Report.

The Board is requested to approve the proposed COVAX Facility governance structure, the proposal for cost-sharing with AMC-eligible economies and a request to allocate US\$ 150 million of core Gavi resources towards the preparation required to deliver COVID-19 vaccines, focusing on urgent technical assistance and cold chain needs. The Secretariat is also seeking guidance on the scope of countries that should be eligible for the US\$ 150 million of support.

## Section B: Update on COVAX Facility Model

### 1. Design and funding arrangements

- 1.1 The Facility accelerates the usual process and timelines for bringing vaccines to market at-scale by enabling investments in a diverse and actively managed portfolio of candidates to maximise the probability of success, facilitates manufacturing capacity expansion, technology transfer and vaccine production in advance of licensure. The Facility is a pass-through mechanism matching limited supply in 2021 with expressed demand. By aggregating global demand, and providing upfront reservations, and commitments to manufacturers through advance purchase agreements and options, the Facility allows economies to have a more diverse portfolio and manufacturers to serve a broad array of economies. In combination, this accelerates the speed and scale of

available vaccines once approved, and the portfolio effect maximises the probability of success.

- 1.2 The Facility's planning assumptions are that by 2021, the maximum availability of doses for the Facility would be around 2 billion; this informed the ambition to attempt to procure that number of doses to end the acute stage of the pandemic. Once the final commitments from SFPs are submitted, and the Facility has visibility to what funds are likely to be available for the AMC, the procurement amount will be adjusted to the demand. In the meantime, the Office of the COVAX Facility is actively negotiating memoranda of understanding with individual manufacturers (see section 4 below) to be able to enter into upfront reservations, advance purchase agreements and future options. To minimise financial liabilities and risk, the Office of the COVAX Facility will only enter into binding agreements with manufacturers once these are backed by legally binding financial commitments<sup>1</sup> with appropriate financial backing for such commitments (in accordance with the July Board decision<sup>2</sup>). Subject to this, to protect against anticipated vaccine candidate failure, the Facility will enter into agreements with manufacturers for additional doses beyond the 2 billion target<sup>3</sup>. Entering into agreements rapidly is critical to the success of the Facility through ensuring sufficient volumes are reserved for Facility Participants to vaccinate the highest priority populations.
- 1.3 Manufacturer agreements will consist of two components: commitments for the purchase of a pre-defined number of doses of COVID-19 vaccine once the vaccine has been approved<sup>4</sup> and the option to purchase a pre-defined number of additional doses. These agreements will require some payments to manufacturers in advance of vaccine approval – to cover scale-out to further increase manufacturing capacity and enable production of vaccine prior to licensure – with these upfront costs converting into initial payment for doses if vaccine candidates are successful. The Facility will also incur costs associated with financing (e.g. insurance, interest costs) – and operating costs. The Participants' arrangements are structured to cover these upfront costs.
- 1.4 There will be two separate and independent sources of funding to cover these costs: COVAX AMC and SFPs. SFPs will have the opportunity to choose between two models: the "Committed Purchase" arrangement or the "Optional Purchase" arrangement (see Appendix 1 for further details).

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<sup>1</sup> Legally binding commitments from SFPs to procure such doses to serve SFPs and from AMC funding to serve the AMC92.

<sup>2</sup> The July Board agreed that "Gavi would not enter into agreements with manufacturers which result in SFPs being distributed doses without having provided a legally binding financial commitment to procure such doses, with appropriate financial backing for such commitment."

<sup>3</sup> Initial planning suggested an average failure assumption of 50% across candidates in the portfolio. Optionality in manufacturing agreements will be structured to mitigate the risk of overshooting the number of procured doses, should the rate of failure (attrition) ultimately be below the current assumption.

<sup>4</sup> An 'approved' vaccine is one that receives WHO prequalification or on an exceptional basis, at minimum, licensure/authorisation from a stringent regulatory authority.

a) **“Committed Purchase” arrangement**

The “Committed Purchase” arrangement commits Participants to purchase allocations of approved vaccines from the Facility. Participants make an upfront payment of US\$ 1.60 per dose (in order to cover a proportion of the pre-approval costs to manufacturers and Facility financing and operating costs) and provide a financial commitment of US\$ 8.95 per dose for the remainder owed, via a guarantee from the Participant’s Ministry of Finance or Central Bank if a country’s long-term credit rating is equal to or greater than B2/B/B from at least one of the indicated rating agencies (Moody’s, Fitch, S&P). If a country does not meet either condition, Gavi will accept a financial guarantee from a multilateral development bank or from a financial institution with a credit rating of Baa2/BBB/BBB (Moody’s, Fitch, S&P).

b) **“Optional Purchase” arrangement**

The “Optional Purchase” arrangement allows Participants to decide whether to purchase any approved vaccine candidate allocated to them. Participants make a higher upfront payment of US\$ 3.10 per dose to reserve options to purchase vaccine doses through the Facility. This amount will cover the full amount of estimated pre-approval costs to manufacturers and Facility financing and operating costs.

Under this arrangement Participants are additionally asked to provide a risk-sharing guarantee of US\$ 0.40<sup>5</sup> per dose to help protect Gavi against the **risk of opt-outs** and any liabilities resulting from Participants deciding not to purchase a particular vaccine candidate after the Facility has already entered into a contract with the manufacturer. Modelling residual liability shows that US\$ 0.40 per dose is sufficient to reasonably cover most scenarios of extent of Participant opt-outs (although the Facility can only enter into supply agreements to the extent that fully committed resources are available). If a Participant opts out of purchasing a vaccine, the Facility could draw from that Participant’s risk-sharing guarantee amount (US\$ 0.40 per dose multiplied by the number of doses the Participant has requested to access through the Facility) to cover any residual liabilities associated with that vaccine.

Participants will also be given the opportunity to opt-out prior to manufacturer deal-signature. This allows the Facility to factor this into the manufacturer agreement and reduces the instances of SFPs under the Optional Purchase arrangement opting out of purchasing doses of approved vaccine allocated to them.

1.5 Under both arrangements, Participants will pay the procurement cost that the Facility has negotiated through bilateral agreements with

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<sup>5</sup> Based on financial liability modelling of different scenarios covering level of optionality in manufacturer deals, opt-out behaviour by economies and level of absorption by other Participants. This model ran a range of scenarios of percentages of economies who would opt for the optional purchase arrangement. Once the true percentage is determined, the model will be rerun to inform the deals with the manufacturers.

manufacturers. This allows the Facility to provide the benefits of economies of scale to Participants while allowing some tailoring to the circumstances of each Participant.

- 1.6 The COVAX AMC will be funded by Official Development Assistance (ODA) (including through contributions through IFFIm (International Finance Facility for Immunisation)) as well as through support from foundations, private donors and concessional funds from multilateral development banks. The AMC will initially reserve doses of vaccines for eligible economies and with respect to upfront payments and procurement it is analogous to the Committed Purchase model.
- 1.7 The Facility's operational planning up to now has assumed a specific proportion of SFPs selecting the Committed Purchase vs Optional Purchase arrangement. The actual data coming in through the signed Commitment Agreements shows a more significant proportion selecting the Optional Purchase arrangement than anticipated. This has implications for the amount of upfront funds the Facility is likely to receive – more than anticipated – as well as the quantity of fully committed doses – less than anticipated. This information will shape the types of deals the Facility intends to negotiate with manufacturers. The Facility will work with industry to match demand with supply in such a way to minimise risk.

## **2. Financial Operating Model and financial risk exposure of the Facility**

- 2.1 A full operations plan is under development and we are seeking risk and financial advice from a number of investment banks and financial experts to feed into the development of a detailed and risk-adjusted operations plan.
- 2.2 The partners of the ACT-Accelerator vaccine (COVAX) pillar (Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, and WHO) have estimated the cost of securing and delivering 2 billion doses of successful COVID-19 vaccines through the Facility by the end of 2021 for AMC and SFP economies based upon a model portfolio of known vaccines. The Facility is being structured as a pass-through mechanism where Participants will pay the actual price manufacturers will be charging (which, manufacturer dependent, may be either a tiered price or a single price for all countries) plus a speed premium for pre-approval payments (for scale up, tech transfer and reservation fees) and a small charge to support the operation of the Facility<sup>6</sup>.
- 2.3 While the Facility will seek to balance the timing of cash outflows with cash inflows, Gavi may seek a debt facility secured against committed resources to ensure that the Facility has access to the necessary liquidity to make upfront cash payments to manufacturers in excess of upfront payments received for SFPs. External legal counsel has confirmed that Gavi can borrow funds should this be deemed necessary and desirable to ensure

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<sup>6</sup> The share of total cost is estimated to be 15-20% for the speed/access premium, 80-85% for ex-factory costs (covering variable costs of manufacturers to produced doses) and <3% for financing and operating costs.

appropriate timing and the overall success of the Facility. This would be presented to and approved by the AFC.

- 2.4 Gavi is seeking to appoint an external Treasury Manager to ensure segregation of, and manage, the SFP funds and expects to issue a Request for Proposals (RFP). The costs related to the Treasury Manager will be covered by upfront payments made by economies, and the oversight of the Treasury will be performed by the AFC. Until the Treasury Manager is in place, funds related to the Facility will be ringfenced in separate Gavi bank accounts.
- 2.5 As per the Gavi Board decision at its meeting in July 2020, Gavi is the legal entity administering the Facility, although Participants will take title to the vaccines and any associated risks. This means that the Alliance will ultimately be assuming the financial risk exposure of the Facility. As described above, in order to protect Gavi's Balance Sheet, Gavi will not enter into any advance purchase agreements with manufacturers until it has legally binding financial commitments for secure funding to procure such doses. This operating principle will considerably limit **financial risk exposure and liabilities** for Gavi, however there is a risk that this results in **delays for deal-making**<sup>7</sup> (due to financial backing being insufficient at the time deals need to be signed), which may pose a risk to the success of the Facility. As set out above, the Facility is therefore looking into additional bridge financing or insurance solutions that can be used to secure these contracts and support deal making and procurement.
- 2.6 To mitigate the **risk of Participants defaulting**, SFPs are asked to provide a guarantee from creditworthy financial institutions (see section 1.4a). Gavi is engaging investment banks and multilateral development banks with relevant financial expertise on sovereign risk to assess robustness of guarantees and guarantors, and limit downside risk.
- 2.7 The Facility will seek to mitigate residual risks of overcommitment due to **higher than anticipated opt-outs** (after deal signature) from SFPs selecting the "Optional Purchase" arrangement or having **more successful vaccine candidates** (lower attrition) than anticipated (and excess doses cannot be reallocated to or absorbed by other Participants), through optionality in manufacturer agreements (whereby Gavi has the option, rather than an obligation to purchase doses), and risk sharing guarantees, as described above.
- 2.8 The AFC, at its meeting on 15 September 2020, discussed the financing operating model and financial risk mitigation steps in place for the Facility, and suggested to explore further steps to better understand and quantify any residual risks and explore innovative ways to further minimise credit and liquidity risk. The Gavi Secretariat is exploring additional insurance products and financial instruments to cover vaccine candidate portfolio

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<sup>7</sup> Delays could be caused by being unable to obtain credible guarantees from SFPs in time, actual prices turning out higher than the estimated weighted average price used for Participant cost calculations, or by a potential AMC funding shortfall.

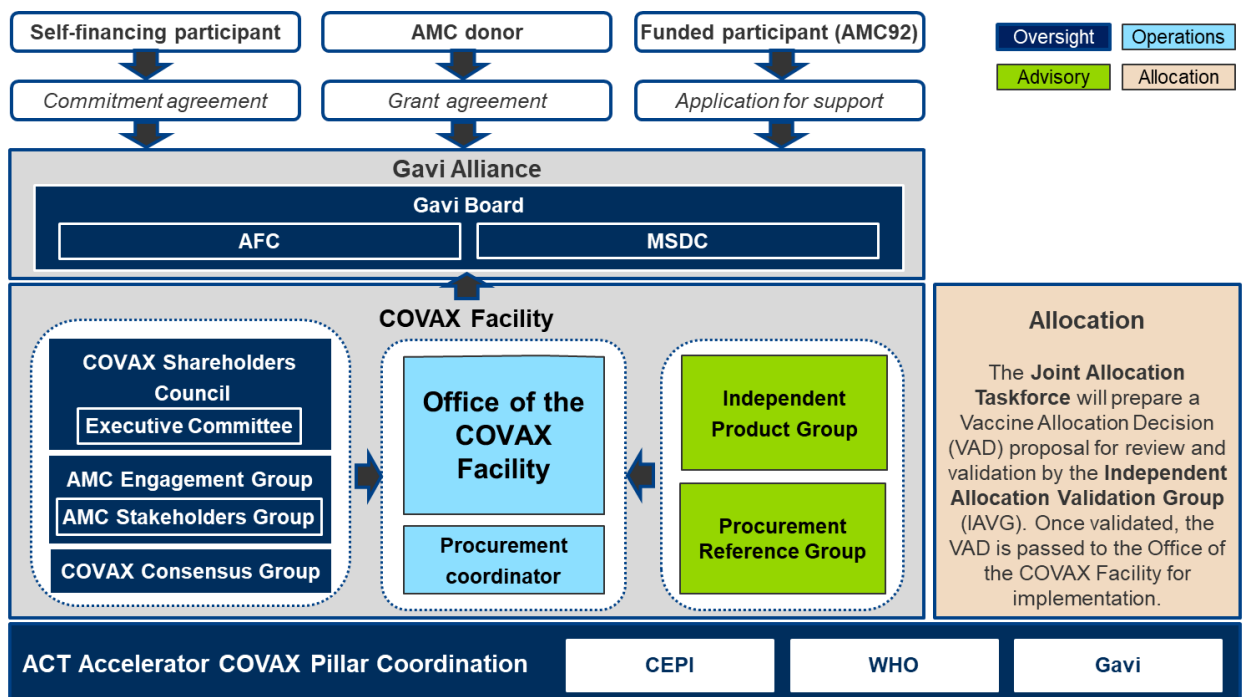
uncertainty, opt-out risks, risk of countries defaulting and other risks of having purchase commitments on vaccine doses in excess of the Facility’s committed resources and guarantees. Gavi is in initial discussions with major insurers who have expressed interest in structuring this instrument for the Facility.

### 3. Proposed Facility governance structure

3.1 The COVAX Facility is being established within the COVAX Pillar of the ACT-Accelerator. As Gavi is the legal entity administering the COVAX Facility, the governance arrangements for the Facility build on the Gavi Board and its Committees, with new bodies established to ensure appropriate oversight and agility to support the functioning of the Facility. The following proposals reflect:

- The Board’s decision that Gavi should host the Facility, therefore giving the Board ultimate responsibility for decisions.
- The need to represent and give a voice to new parties, including new implementing economies and Facility Participants.

#### Schematic of the Proposed Governance Structure



#### Existing Governance Bodies

3.2 The **Gavi Board** will be responsible for overseeing the role of the Gavi Secretariat and the Alliance in the Facility and will have ultimate responsibility for decisions and effective implementation of the COVAX Facility. In this role it will:

- a) Take responsibility to ensure that the Gavi Secretariat operates within the mandate granted to it;
  - b) Provide strategic direction and policy-making;
  - c) Receive regular reports from the Office of the COVAX Facility on operational progress and performance;
  - d) Receive updates from relevant Board Committees (e.g. AFC) on COVAX Facility matters; and
  - e) Provide strategic oversight of the COVID-19 programme and effective implementation including country engagement.
- 3.3 In light of the Board's decision about eligibility for funding through the AMC, the Gavi COVID-19 vaccine programme (see section 8) is available for implementing economies that are not currently represented on the Gavi Board. These economies will need to have a voice when the vaccine programme is considered. It is proposed that:
- a) In order to maintain balance with the existing representation of implementing economies, implementing economies not currently represented on the Board should form new constituencies, and;
  - b) These new constituencies should be invited to attend Board meetings as observers where the COVID-19 vaccine programme is considered.
- 3.4 As agreed by the Board at its meeting on 30 July 2020, Gavi's **Market-Sensitive Decisions Committee (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. For the review of COVAX-related agreements with manufacturers, membership of this body has been expanded to include an additional three representatives nominated by the COVAX Shareholders Council (see section 3.7a).
- 3.5 Gavi's **Audit and Finance Committee (AFC)** will be responsible for: (i) ensuring funding availability for COVAX Facility operations, including review of the financial implications of Facility-related transactions; (ii) ensuring the COVAX Facility is properly represented in Gavi's Annual Financial Report; and (iii) monitoring risk to Gavi, the Alliance, and the COVAX Facility.
- 3.6 Other Gavi governance bodies may request updates from the Office of the COVAX Facility on aspects of COVAX implementation of relevance to the delivery of their mandates. These bodies may also be called upon by the Office of the COVAX Facility to advise on specific issues within their areas of responsibility, as appropriate.

### **New governance and technical advisory bodies**

- 3.7 Whilst the principle of the ACT Accelerator is to not create new governance bodies, effective governance of the COVAX Facility, hosted by Gavi, will



require the establishment of new governance and technical bodies to account for stakeholders that would otherwise be unrepresented. The new bodies are described below:

- a) The **COVAX Shareholders Council** (“the Council”) will represent SFPs in the governance of the COVAX Facility. Membership of the Council will be open to all SFPs in the COVAX Facility. The Council will convene SFPs with the aim of supporting real-time information exchange and providing strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility. Proposed Terms of Reference are attached as Annex B.

As a self-organising body, the Council will determine its own operating procedures and take decisions at its first meeting regarding inviting observers. Draft Operating Procedures, for consideration by the Council are attached as Annex C.

- b) Given the large number of SFPs, it is expected that the Council will decide to establish a smaller **Executive Committee** (“the ExCom”) to prepare and guide its discussions. The ExCom will provide a clear link between the Council and other governance structures to ensure the consolidated advice/view of the Council is considered in relevant deliberations and that the Council is well prepared/briefed to provide advice as issues arise.

Members of the ExCom will be chosen to represent constituencies as determined by the Council. ExCom will take decisions regarding inviting observers, such as representatives of the AMC92 economies, at its first meeting. Draft Terms of Reference for the ExCom, for consideration by the Council, are attached as Annex D.

- c) The **AMC Engagement Group** will be open to representatives from implementing economies, donors and other parties engaged in the financing and operation of the AMC portion of the Facility. This body will represent the AMC in the governance of the Facility. The Group will convene with the aim of supporting real-time information exchange and providing strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility. Proposed Terms or Reference are attached as Annex E.

Within this body, an **AMC Stakeholders Group** will convene representatives from AMC donors, procurement organisations such as UNICEF and PAHO and, the representatives of multilateral development banks or regional banks involved in the financing of the AMC. It will discuss its investments in the AMC, options for additional financing and receive specific reporting on progress achieved against the objectives of the AMC. Proposed Terms or Reference are attached as Annex F.

- d) A **COVAX Consensus Group** will be established to support effective operation of the COVAX Facility through consensus-based decision-making. It will be responsible for ensuring that any disputes or

challenges arising in the governance bodies of the Facility, where all other possible avenues to resolve the matters have been exhausted, can be addressed swiftly and in the best interests of the aims of the Facility. Comprising the Chair and Vice Chair of the Gavi Board; the Co-Chairs of the COVAX Shareholders Council; co-Chairs of the AMC Engagement group ; and – in an ex-officio, non-voting, capacity – the three leads of the ACT-Accelerator COVAX Pillar; the COVAX Consensus Group will be chaired by the Gavi Board Chair. Proposed Terms of Reference are attached as Annex G.

### Technical bodies

- 3.8 Technical bodies of the Facility will make recommendations to the Office of the COVAX Facility on candidate selection and procurement.
- a) **Independent Product Group (IPG)** will provide independent technical advice to the Facility on the prioritisation and inclusion of suitable vaccines and the status of the COVAX portfolio of vaccine candidates, based on information related to clinical development, manufacturing and supply. The IPG will assess all vaccine candidates against a uniform and systematic set of criteria. It will regularly consider the implications of timing/ availability of vaccine on the broader portfolio and review the portfolio for balance. Proposed Terms of Reference are attached as Annex H.
  - b) Once vaccine candidates have been selected to be funded by the Facility, informed by recommendations of the IPG, the **Procurement Reference Group (PRG)** will then be responsible for providing independent advice to the Facility on its procurement strategy and key business terms of proposed advance purchase commitments with the manufacturers of these vaccine candidates. Based on recommendation from the PRG, the Office of the COVAX Facility will advance negotiations with manufacturers and bring recommendations to the MSDC on final deal terms for approval.

### Allocation Mechanism governance

- 3.9 The Facility will apply the WHO Allocation Framework as the basis for vaccine allocation decisions for Facility Participants, operationalised through the Allocation Mechanism. The Allocation Mechanism will comprise the Joint Allocation Taskforce and the Independent Allocation Validation Group:
- a) The **Joint Allocation Taskforce (JAT)**, comprised of WHO and the Gavi Secretariat, will prepare a Vaccine Allocation Decision (VAD) proposal for review and validation by the Independent Allocation Validation Group (IAVG). The VAD proposal will be based on a data-driven allocation model. The JAT will review all the data inputs needed for the allocation model and verify its output. Some flexibility to enable adjustments for clearly defined reasons, such as operational considerations, will be accommodated and fully documented. The JAT will respond to any

requests for clarification from the IAVG, re-running the model if necessary. The JAT will be convened by the Office of the COVAX Facility and WHO, with ToRs jointly defined by WHO, the Gavi Secretariat and CEPI in the coming weeks, aiming for finalisation by end October.

- b) The **Independent Allocation Validation Group (IAVG)** will be established as an independent body to validate the VAD proposal put forward by JAT. Composed of technical experts, the IAVG will validate that the proposed VADs are technically informed, transparent and free from conflicts of interest. They may also request clarifications from the JAT, and for the model to be rerun if needed, before making their final determination. The VAD is characterised as a strong recommendation with any adjustments being made on an exceptional basis for clearly pre-defined reasons, such as specific operational considerations. The VAD, once validated by the IAVG, will be passed to the Office of the COVAX Facility for implementation with support from procuring agencies like UNICEF and the PAHO Revolving Fund.

It is envisaged that the IAVG will be comprised of independent experts jointly nominated by the core COVAX partners (WHO, Gavi Secretariat and CEPI) and other relevant partners and stakeholders, with observers from CSOs and representatives of economies participating in the COVAX Facility. The ToRs for the IAVG will be defined jointly by the core COVAX partners in the coming weeks, according to established existing processes for constituting expert bodies, aiming for finalisation by end October 2020. A nomination process for the membership of the IAVG will be triggered upon finalisation of the ToRs, also in line with existing processes. Areas of expertise for the IAVG will be established based on the final ToRs but will likely include areas such as expertise in immunisation programmes and service delivery; vaccine safety evaluation and monitoring; access to medicines and health products; emergency public health response amongst others.

- 3.10 In addition, work is underway by Gavi and WHO, in consultation with partners, to jointly define the governance and use of the emergency buffer.

### **Civil Society Organisation engagement**

- 3.11 CSOs have expressed a clear recommendation that participation in the COVAX effort through existing governance mechanisms (per ACT-A guidance to limit the creation of new governance bodies) is not sufficient. In support of this view and wanting to be more inclusive of civil society across the broad spectrum of work undertaken by the COVAX Pillar, 10 new CSO representatives are being added, including one each to the Central Coordinating Mechanism (CCM); CEPI's Technical Review, Enabling Science, Manufacturing and Clinical Development and Operations groups; WHO's Vaccine Strategy and Access and Allocation sub-groups, and; the Procurement and Delivery Workstream's country readiness and delivery coordination group and sub-groups.

- 3.12 CSOs were invited to nominate representatives for these positions until 14 September. More than 150 submissions were received. To ensure the best mix of skills and experience on each of the groups, a CCM and CSO co-created nomination process has been agreed. COVAX Pillar leads will shortlist CSOs from the submissions and CSOs will select representatives from that list to join the 10 groups listed above. CSOs are also already engaged in COVAX Pillar decision making bodies such as the Gavi Board, the Strategic Advisory Group of Experts on Immunization (SAGE), the HSS Connector Working Group, and the Gavi MSDC. COVAX Pillar organisations have held a number of CSO updates so far and plan to offer monthly briefings in the future.

### **Section C: COVAX Facility Progress**

#### **4. Vaccine pipeline and manufacturer engagement update**

- 4.1 As of 21 September 2020 across a variety of technology platforms, WHO reports 38 candidates in clinical evaluation and 149 in preclinical development/ discovery. Of the candidates in clinical evaluation, 9 are in Phase III trials of which 3 have been granted 'Limited Use' status by national regulatory authorities. Of the CEPI portfolio, 8 of the 9 initial candidates are in clinical trials and there is an ongoing CEPI/ COVAX call for further candidates.
- 4.2 The Bill & Melinda Gates Foundation (BMGF) has also funded a portfolio of potential second-generation vaccine candidates for the medium-to-long term based on the potential for combining attractive attributes relative to leading COVID-19 vaccine candidates (such as higher potency, existing manufacturing capacity, lower cost of goods, and novel approaches). Except for two candidates which are in Phase I, the majority of these are at discovery/late discovery stages. The Foundation is also supporting technology transfer for selected candidates. It is understood that BMGF funding is conditional on manufacturers' making doses available to the Facility.
- 4.3 Gavi, CEPI and WHO are actively engaging industry as key partners in the success of the COVAX Pillar and the Facility. Representatives of the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) and DCVMN (Developing Country Vaccine Manufacturers Network) have been an integral part of the planning processes including serving on the CCM. Gavi worked with UNICEF on their Expression of Interest in June 2020 which drew submissions from 28 manufacturers. Gavi organised information sessions with partners, UNICEF and WHO about the Facility for the IFPMA, DCVMN and biotech members in June and August which attracted over 100 participants from the three industry associations, to explain the Facility design and benefits of supplying the participating economies through the Facility.
- 4.4 To date, Gavi, on behalf of the Facility, has approved a legally binding agreement with Serum Institute of India and a non-binding MOU with

AstraZeneca for the supply of up to 850 million total doses in 2021, subject to successful development, manufacturing scale up and licensure of the vaccines. There are ongoing discussions with several manufacturers to potentially provide up to an additional 1.6 billion doses in 2021. If successful, these agreements will contribute towards an estimated target of 10-15 agreements by end of 2020 for doses above this number given attrition to obtain up to 2 billion usable doses by end of 2021 for participating economies.

- 4.5 To accelerate the commitments by manufacturers to the Facility, Gavi is:
- a) prioritising promising CEPI and BMGF candidates which already have the commitment to supply the Facility as condition of the R&D and/or manufacturing funding provided by these organisations;
  - b) prioritising vaccine candidates which are relatively advanced in development;
  - c) obtaining support from industry to use streamlined MOUs to gain commitment on key terms, then entering into legal agreements at the next stage.
- 4.6 Although the CEPI deals are attractive as they represent a well planned and diversified portfolio with access provisions, the Facility is open to procuring doses from any manufacturer. Manufacturer commitments will be entered into based on the technical advice of the IPG and PRG and approval of deal terms by the MSDC, as described in section 3.

## 5. Update on funding committed to the Facility and the AMC

- 5.1 To date, US\$ 700 million has been pledged to the COVAX AMC, of which US\$ 0.3 billion has been converted into legal agreements. The European Commission has also recently announced EUR 400 million in guarantees from the European Investment Bank for “low and middle income countries”. The Gavi COVAX AMC is on track to convert 50% of pledges by end of September and the remainder by the end of November. Discussions with donors are intensifying now that the AMC has been legally set up with a view to raise an initial US\$ 2 billion by December 2020. Contributions to IFFIm are encouraged to help frontload much needed resources with ca. 70% of the value of the pledge immediately accessible in cash at signature. A further round of funding is anticipated based on current estimates for an additional sum of at least US\$ 5 billion by end 2021. The rationale for this approach is a) to ensure doses can be accelerated and reserved for lower income economies in the first phase of fundraising; and b) establish better estimates of procurement costs and attrition rates. 28 public and private donors have confirmed intent to pledge to the AMC to date.
- 5.2 Additionally, while we did not initially request AMC-eligible economies to submit an Expression of Interest (EOI), we received voluntary EOIs from 35 economies.

5.3 Since the July Board meeting, the Secretariat has held five consultations with SFP and AMC Participants – three with SFPs and two with AMC-eligible Participants – in addition to numerous individual consultations with at least 37 different economies. Regular updates on the Facility have been provided at weekly WHO member state briefings to ensure maximal provision of information. Given the critical role of continental bodies such as the African Union (COVID-19 Special Envoys, Africa CDC), The Association of Southeast Asian Nations (AESAN), PAHO and the Friends of the COVAX Facility, African Export-Import Bank (Afreximbank), Inter-American Development Bank and the World Bank, the Secretariat has proactively engaged with these groups to provide regular and consistent communication on COVAX Facility and AMC process and progress, leveraging these bodies to support engagement with their economies/participants. We systematically tracked all questions and issued an updated Question & Answer document and other communications to ensure that all Participants received timely access to all information.

## **6. Establishing the Office of the COVAX Facility**

6.1 The Office of the COVAX Facility is currently being established within the Gavi Secretariat to ensure a dedicated team to support the Facility operations and to mitigate disruption to Gavi's core work. Aurélia Nguyen has been appointed as Managing Director of the Office of the COVAX Facility and will move full time to the Facility for a one-year period starting 1 October 2020. Her previous duties at Gavi are temporarily being taken up by other members of the Senior Management Team. The Office will comprise several new, dedicated teams: e.g. design and operations; deal making and vaccine portfolio management; country engagement; and finance. The Office will also leverage dedicated, incremental resources within existing Gavi Secretariat teams (e.g. Resource Mobilisation, Legal, Public Policy Engagement, Governance and other teams) funded in the first instance out of pre-financing approved by the Board.

6.2 Recruitment of individuals both for the dedicated Office of the COVAX Facility teams as well as incremental resources in existing Gavi Secretariat teams is ongoing. In the meantime, surge capacity has been provided through the use of consultants. Gavi anticipates that surge resourcing is required through Q1 2021 to fully setup the Facility, with subsequent reduction to a level of resources for steady state operations beyond that. The Gavi Secretariat is also seeking secondments to ensure that it is fully leveraging the expertise from across Alliance partners and stakeholders.

## **Section D: Gavi COVID-19 vaccine programme**

### **7. Cost-sharing with AMC92 economies**

7.1 The COVAX AMC exists to ensure that all economies, regardless of income level, can participate in the COVAX Facility and have timely, equitable access to COVID-19 vaccines. The Facility and all its Participants represent

an unprecedented show of global solidarity in the fight against COVID-19, and a recognition of the equal role that all economies have in the success of this global effort. Indeed, many AMC economies have indicated their strong commitment to being equal partners in the COVAX Facility, including through contributions to vaccine financing. Contributions to AMC vaccine financing can also help to set a precedent for domestic resource mobilisation for COVID-19 vaccines in the future.

- 7.2 In the medium-to-long term (if long term vaccination programmes will be required), as with all Gavi routine vaccine programmes and in line with Gavi's strong and principled commitment to equity, AMC-eligible economies will be expected to co-finance COVID-19 vaccines with tiered contributions that reflect economies' ability to pay. The unknowns of vaccine efficacy, duration of protection and evolving disease epidemiology have implications on planning for optimal vaccine use, including cadence of vaccination, setting and population. These will be worked out over time and will inform an eventual co-financing approach. The goal of this longer-term co-financing will be to promote financial sustainability.
- 7.3 However, in the acute phase of the pandemic, given the urgency of bringing it under control, the primary objectives of a short-term, exceptional 'cost sharing' model should rather be to promote solidarity and country ownership and to mobilise additional resources for COVID-19 vaccines. In addition, in accordance with the overall principles underpinning the AMC, this cost-sharing approach will ensure that financing is not a bottleneck to any economy's access to, or delivery of, vaccines, thereby promoting equity across economies.
- 7.4 Country cost-sharing contributions may consist of both funding for the purchase of vaccine doses and funding for vaccine delivery (see section 8 below).
- 7.5 For the purchase of vaccine doses, the objective will be to mobilise up to US\$ 1.5 - 2 billion in AMC92 country cost-sharing contributions for the acute phase of the response<sup>8</sup>, equivalent to ~US\$ 1.60-2 per dose<sup>9</sup>. This contribution would be a strong demonstration of global solidarity, mirroring the minimum US\$ 1.60 per dose upfront payment made by fully SFPs, and representing all Participants' equal commitment to and ownership of the Facility, as well as recognition of the Facility's role in ending the acute phase of the pandemic. These AMC92 cost-sharing contributions will be used to fund critical investments such as reservation fees or vaccine procurement, but they will not be used for at risk investments.
- 7.6 Acknowledging the economic situation of many countries that have been heavily impacted by the pandemic, and true to the principle of ensuring that

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<sup>8</sup> Until the end of 2021. Implementation of this cost-sharing approach may be extended if original targets for AMC doses are not fulfilled during this period.

<sup>9</sup> Assumes 2-dose regimen COVID-19 vaccine. Cost-sharing contribution will be adjusted, depending on the number of doses ultimately required for successful vaccines, so that economies pay equally on a per-person basis.

cost does not present a barrier to all economies participating in the Facility, Gavi is actively working to identify ways to support economies to meet their cost-sharing contributions for vaccines. To this end, Gavi is currently in conversation with multilateral development banks to identify resources and structure instruments (including grants, loans, and concessional loans) that could play this vital role. Depending on the modality of funding through this approach, economies that do leverage external financing to meet their cost-sharing contributions would still retain control and ownership of the process, actively choosing to commit funds made available to them either through grants or loans for COVID-19 vaccines over other needs. Leveraging multilateral development bank financing also supports the AMC principle of ensuring equitable access to vaccines, as this financing is structured to reflect an economy's ability to pay, with lower-income economies receiving more grants and more concessional lending terms. The US\$ 1.5-2 billion total in cost-sharing for vaccine doses is a critical investment in both public health and economic security, and amounts to a very small share of total country annual allocations from multilateral development banks.

- 7.7 Should multilateral development bank financing not be available, and should economies express that they are unable to meet the expected cost-sharing contributions for vaccines, it is proposed that Gavi exercise flexibility with economy vaccine dose cost-sharing contributions during this initial acute phase<sup>10</sup>, recognising the fiscal pressures economies are facing and the difficulty of mobilising and budgeting funds in such a compressed timeline. Gavi will work with economies on a case-by-case basis to adjust vaccine dose cost-sharing contributions as needed (i.e. partial or no cost-sharing). This flexibility will help to ensure that cost-sharing for vaccines does not prevent or delay the introduction of the vaccine in any economy, and that economies do not reallocate existing budgets for other routine vaccines towards COVAX cost-sharing, which would undermine both Gavi core programming and broader objectives.
- 7.8 This effort to mobilise additional financing from economies via multilateral development banks does not obviate the urgent need to fundraise additional ODA for the AMC before the end of this year to meet the total cost of vaccine doses. There continues to be a pressing need to accelerate and reserve doses for economies which would otherwise not receive them for several years. Furthermore, while country cost-sharing contributions will help to increase the total resources available for the AMC, these contributions may take some time to structure and process.
- 7.9 All economies will also be expected to contribute to the costs of COVID-19 vaccine delivery: costs will vary by candidate and by economy, and Participants will take heterogenous approaches based on their contexts. Therefore, rather than defining a specific delivery cost-sharing contribution by country at this time, it is proposed that the Gavi Secretariat allocates targeted funds to initially support technical assistance and urgent cold chain

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<sup>10</sup> Until the end of 2021. Implementation of this cost-sharing approach may be extended if original targets for AMC doses are not fulfilled during this period.



gaps, with potential additional support contingent on resource mobilisation efforts (see section 8 below).

## 8. Vaccine delivery and technical assistance support

- 8.1 Across the ACT-A COVAX Pillar, significant efforts are underway to help economies prepare for COVID-19 vaccine delivery, including the development of policy and operational guidance. Based on the current vaccine scenarios, the assumption is that the first batch of vaccines, to cover 3% of their population, will be delivered through facility-based strategies to reach frontline workers in health and social care settings. Subsequent dose volumes are expected to be prioritised for other high-risk groups including >65 year olds or those with co-morbidities but targeting and delivery strategies are still being developed as we better understand the epidemiology of the infection in different settings.
- 8.2 Uncertainties related to the vaccine profiles make it necessary to plan for multiple delivery scenarios to mitigate **equity and delivery risks**. These include, but are not limited to, the recommended dose schedule (1 vs. 2 doses), cold chain requirements (2°C to 8°C, -20°C or -80°C), efficacy/effectiveness, and safety among different populations (e.g. pregnant women, the elderly). The evolution of the epidemic profile may also guide how sub-groups are prioritised (potentially geographically based). Finally, the rate at which doses are made available will also impact delivery strategies and health system capacity needs.
- 8.3 Despite these uncertainties, the Secretariat and Alliance partners will start working with AMC economies to develop end-to-end vaccine delivery plans using available assumptions. To ensure timely distribution of vaccines to those at highest risk, several elements will be critical. These include: the mapping and resolution of regulatory, liability and legal requirements; preparation of supply chains to store, transport and track COVID-19 vaccines (especially given different product profile and risk of diversion); identification and microplanning to reach target populations, which will include sub-populations not traditionally served by immunisation programmes (e.g. healthcare workers (HCWs), and at risk populations including older adults, individuals with underlying co-morbidities); collaboration with other health programmes, across other sectors and ministries, and non-traditional partners; enhanced data systems to track who among the target population has been immunised, and; strengthened surveillance for monitoring vaccine safety and effectiveness of the vaccines. Given increased risks of vaccine hesitancy fuelled by unprecedented rumours around COVID-19 vaccines in some countries, comprehensive demand side interventions will be critical to facilitate trust and acceptance among community members, including social listening and engagement, behavioural interventions, health worker confidence building and interpersonal communication. Open and transparent public communication will be vital at all stages in the process, including communicating the rationale for prioritising high-risk groups including health workers, not least to avoid creating expectations that cannot be met.

- 8.4 As raised to the Board at its June 2020 meeting, one particularly important consideration is **the potential need for a significant and urgent ramp-up of cold chain capacity**. Due to the uncertainties detailed above, additional CCE (cold chain equipment) needs could range from marginal increases to very significant additional investments.
- 8.5 The potential need for ultra-cold chain (-80°C, UCC) storage poses a particular challenge. At present, three of the initial vaccine candidates require UCC for long-term stability, though most manufacturers are indicating their products can be managed with traditional +2°C to 8°C/-20°C storage for up to 4-6 months. However, this could change as more data becomes available or the pipeline evolves. In addition, at least one candidate vaccine is currently expected to have only 24-48 hours of stability, requiring UCC storage nearly to the point of care<sup>11</sup>. If deployed to AMC92 economies, UCC vaccines would impose significant CCE, training and operational requirements. For CCE alone, deploying UCC in a given economy can cost between ~6–15x more than equivalent 2°C to 8°C/-20°C scenarios, which better leverage existing infrastructure.<sup>12</sup> In the medium term, the expectation is that nearly all vaccines will be manageable within a standard cold chain, so any need for UCC infrastructure if provided would be time-limited.
- 8.6 Given the significant cost required, time-limited need, and current indications that nearly all vaccines could be delivered without UCC, Gavi is **not recommending at-scale investment in UCC equipment at this time**, though we will continue to monitor and reassess this position as needed. If several of the first wave of vaccines do turn out to require UCC, this approach **could delay country readiness for vaccine introduction**, given the estimated 4-6 month lead time to procure, install and train HCWs on UCC. To mitigate this risk, Gavi is assessing strategies that would target UCC deployment to a subset of economies and exploring options such as (i) advance procurement of UCC equipment, (ii) contracting third-party logistics provider to provide surge or specialised capacity and (iii) leveraging UCC capacity in other sectors. The Secretariat would welcome Board guidance on whether the proposed approach to UCC appropriately balances cost and access considerations.
- 8.7 If economies can utilise existing 2°C to 8°C cold chain, initial modelling suggests existing facility-level capacity in most economies would be sufficient given Gavi's previous investments through the Cold Chain Equipment Optimisation Platform (CCEOP). Higher-level stores (national, regional) have not historically been targeted by CCEOP and will require meaningful expansion, particularly if economies receive large shipments of vaccine at one time.<sup>13</sup> Significant expansion may also be needed at district

<sup>11</sup> At least until further stability data becomes available in the period after licensure.

<sup>12</sup> This figure compares national/regional storage models for both UCC and 2-8/-20 strategies, at 20% targets; Range accounts for whether UCC-rated transport devices are needed for distribution.

<sup>13</sup> There have been signals from private sector partners and press that air freight for COVID vaccines will be a major constraint. This may lead delivery volumes to be consolidated into larger shipments.

level if economies opt to store significant volume of COVID-19 vaccines at this level to simplify distribution and access to service delivery points.

- 8.8 Across the AMC92 economies, the cost of the cold chain expansion required to reach the first 20% of the population is expected to range between US\$ 35-125 million, of which US\$ 25-80 million is for the 56 currently-eligible Gavi countries.<sup>14</sup> The major swing factor in this range is whether economies decide to store significant vaccine volume at district level. If UCC is required in a subset of AMC economies (working assumption is that this would be deployed in ~15% of economies), it would add an additional US\$ 20-75 million in cost to reach the initial 3% of the population, which is when UCC is most likely to be required.<sup>15</sup>
- 8.9 The Alliance has coordinated with the Therapeutic and Diagnostic pillars of the ACT Accelerator to understand if any CCE needs exist. At present, there is no indication of significant needs from the Therapeutic pillar. Some rapid diagnostic tests are likely to require temperature control in select settings, but the needs are modest and not expected to intersect with EPI (Expanded Programme on Immunization) supply chains. As such, no needs are being flagged for Gavi support at this time, though this will continue to be assessed.
- 8.10 While economies will be expected to contribute to financing of COVID-19 vaccine delivery (see section 7 above), they will require technical and financial support from the Alliance given the unprecedented scale, pace and complexity of COVID-19 vaccine roll-out. The ACT-A investment case includes a preliminary estimate of US\$ 1.5 billion to deliver the first ~1 billion doses to AMC92 economies in 2021 based on an initial costing exercise carried out by Alliance partners. This amount is subject to further refinement (it did not include technical assistance costs, for example) and will depend on the final characteristics and availability of vaccines (e.g. UCC costs are not included).
- 8.11 Funding for delivery is not secured as fundraising has just begun. While ACT-A resource mobilisation efforts are ongoing, initial funding and support will be needed in the coming months to meet the anticipated timelines for in-country delivery (as early as Q2 2021). This is particularly relevant for procurement of CCE, which has long and relatively inflexible lead times, and strategy-oriented/preparatory technical assistance. **The Secretariat recommends Gavi allocate US\$ 150 million from core resources<sup>16</sup>** as initial funding to help economies prepare to deliver COVID-19 vaccine. This funding would be targeted towards TA for economies' planning and addressing urgent cold chain gaps. This level of support can be re-evaluated in the coming months when: (i) bottom up costing is available to

<sup>14</sup> India is excepted from these figures; they are expected to be supported via a dedicated modality.

<sup>15</sup> Figures are sensitive to whether UCC transport devices are needed for distribution. Estimate does not include India, and assumes UCC-receiving economies switch to 2-8 for remainder of vaccine.

<sup>16</sup> Proposal is based on the precedent set by the 2016 approval for core resources to be used to jumpstart the Ebola program while external fundraising was ramped up.

better determine service delivery needs and; (ii) the availability of resources is better understood. Since this funding would be allocated from core resources, the Secretariat is asking the Board for guidance on which countries should be in scope for this funding. In line with previous Board guidance on the use of core Gavi resources, the Secretariat would plan to restrict the use of these funds to the 56 countries which are Gavi-eligible or in accelerated transition. However, this will create a risk to delivery preparation in some of the remaining 36 economies, some of whom may also have significant needs. Broadening the scope of economies also carries risk by stretching Gavi and the Alliance's limited resources.

- 8.12 Taking these factors into consideration, the Secretariat **is asking the Board for guidance on the scope of economies that should be eligible to receive the allocation of US\$ 150 million** from core resources to prepare to deliver COVID-19 vaccines.
- 8.13 Additional resources will need to be mobilised to cover the remaining delivery costs for all AMC92 economies beyond this initial US\$ 150 million. This will likely be funded through both additional donor resources and domestic funding from implementing governments. Multilateral development banks have already expressed interest in supporting countries with COVID-19 vaccine service delivery, and the Secretariat will help to facilitate conversations between countries and multilateral development banks on the nature of this support, which will vary by country based on their allocations.

## 9. Proposed support for India

- 9.1 India is Gavi's largest eligible country and in Gavi's accelerated transition phase. Collaboration with India is important to ensure adequate support for vaccine delivery in the country as the country with the second largest number of cases, and because of the highly important role India plays as a global vaccine supplier. India represents 35% of the total AMC92 population and has at least 24 vaccines in the pipeline/ potential to manufacture, either self-developed or in-licensed by a non-Indian company. Six of these vaccines are in clinical trials, of which two are in phase III.
- 9.2 Given Gavi's existing tailored approach to India and proposed continuing strategic partnership (detailed in *Doc 02 – Recalibrating Gavi 5.0 in light of COVID-19 and successful replenishment*), and India's set transition from Gavi support at the end of 2021, the AMC approach for India will be different than other economies. It will seek to balance equity with constraints on overall doses and AMC funding, while recognising that India is particularly hard hit and is feeling the dramatic economic effects of the pandemic.
- 9.3 The approach to India support will include decisions on the allocation of AMC funding, AMC doses, and vaccine delivery support to the country. AMC funding to India for vaccine doses will likely be capped at a fixed percentage of the overall AMC funds, with additional costs expected to be financed by the country. AMC doses allocated to India will be calibrated to balance the overall availability of doses, the ability to equitably distribute

across the other 91 AMC economies, and India's domestic manufacturing capacity. Vaccine delivery support to India will take into account the country's strong existing capacity for delivery. Conversations with the Government of India and AMC donors on potential packages of support across these three areas are ongoing.

## **Section E: Actions requested of the Board**

The Gavi Alliance Board is requested to:

- a) **Approve** the Terms of Reference of the COVAX Shareholders Council attached as Annex B;
- b) **Approve** the Terms of Reference of the COVAX AMC Engagement Group attached as Annex E;
- c) **Approve** the Terms of Reference of the COVAX AMC Stakeholders Group attached as Annex F;
- d) **Approve** the Terms of Reference of the COVAX Consensus Group attached as Annex G;
- e) **Approve** the proposal for AMC92 economies to cost-share vaccines up to US\$ 1.60- US\$ 2 per dose, assuming a 2-dose regimen, towards the full cost of purchasing a dose of vaccine [bearing in mind that Gavi will exercise flexibility and work with economies on a case-by-case basis to adjust vaccine cost-sharing contributions as needed until end 2021, and with the expectation of additional cost-sharing on vaccine delivery, with targeted Gavi support (see decision point f) to supplement additional resources to be mobilised];

With reference to the discussion on Doc 02 *Recalibrating programmatic priorities for Gavi 5.0 in light of COVID-19 and the successful replenishment: Financial implications*, at the Gavi Alliance Audit and Finance Committee meeting of 15 September 2020:

- f) **Approve** the allocation of US\$ 150 million from core resources [for initial funding] to prepare [*eligible economies subject to Board guidance*] to deliver COVID-19 vaccines, focusing on urgent technical assistance and cold chain needs;
- g) **Request** the Gavi Secretariat to present to the Board in December 2020 the proposed approach for Gavi COVAX AMC support for India for COVID-19 vaccines and delivery;
- h) **Note** the proposed approach to not invest in UCC at this time, and the associated risks regarding access to COVID-19 vaccines; and
- i) **Note** the risks and mitigation measures outlined related to the COVAX Facility.

## **Annexes**

**Annex A:** Implications/Anticipated impact

**Annex B:** Terms of Reference of the COVAX Shareholders Council

**Annex C:** COVAX Shareholders Council Operating Procedures

**Annex D:** Terms of Reference of the Executive Committee of the COVAX Shareholders Council

**Annex E:** Terms of Reference of the COVAX AMC Engagement Group

**Annex F:** Terms of Reference of the COVAX AMC Stakeholders Group

**Annex G:** Terms of Reference of the COVAX Consensus Group

**Annex H:** Terms of Reference of the Independent Product Group

**Additional information available on BoardEffect**

**Appendix 1:** COVAX Facility Explainer- Participation Arrangements for Self-Financing economies

**Appendix 2:** Governance mapping

**Appendix 3:** 15 September 2020 AFC COVAX Paper

**Appendix 4:** 15 September 2020 AFC 5.0 Paper

**Appendix 5:** 30 July 2020 Board Paper - Gavi COVAX AMC

**Appendix 6:** 30 July 2020 Board Paper - COVAX Facility Structure and Governance