SUBJECT:	**COVAX FACILITY OPERATIONALISATION AND VACCINE PROGRAMME**
Agenda item:	08
Category:	For Decision

Section A: Summary

Context

The COVID-19 pandemic continues to spread across the world, and with over 50 million people infected and 1.5 million deaths, the ongoing crisis is having a profound impact on people's health and livelihoods and their health worldwide. In addition, recent COVID-19 vaccine trial preliminary successes have put an even greater spotlight on vaccines as a solution to the pandemic, and the COVAX Facility ("the Facility") as the mechanism to achieve global access, ensuring that low- and lower middle-income economies, as well as other IDA-eligible economies, have access to COVID-19 vaccines at the same time as all wealthier economies.

Since September 2020, the Secretariat has been working tirelessly to operationalise the Facility, continuing to engage manufacturers, self-financing economies, and AMC-eligible economies, representing the principles of collaboration and solidarity in response to COVID-19. Currently 189 countries are committed or eligible to receive doses through the Facility, representing 90% of the world's population. The COVAX Facility portfolio currently includes three vaccines, and to date the AMC has fundraised US$ 2.1 billion.

The Gavi Board serves as the decision-making body for the COVAX Facility. In September, the Board approved interim terms of reference for COVAX Facility bodies, the allocation of US$ 150 million from core resources to prepare the 92 AMC-eligible participants ("AMC92") to deliver COVID-19 vaccines, and the cost-sharing approach to vaccine procurement for the AMC92.

Following the principle of safeguarding Gavi's assets and reputation, the Facility is being designed to avoid risk where possible, and residual risks are being actively monitored and mitigated. However, it is also understood that operating at this magnitude and speed carries risks, and failure of establishing a successful Facility will also affect Gavi's overall reputation. Some key risks are outlined in this paper and a full overview is included in section 3 of the Risk & Assurance Report (see Doc 06). The Gavi Secretariat, including the Office of the COVAX Facility, under the guidance of the Board, continues to seek the right balance to successfully deliver on the promise of the Facility while minimising risks to Gavi core resources and programmes.

Questions this paper addresses

- What progress has been made in engaging participants, multilateral organisations, and manufacturers in deal-making?
- How has the design of the Facility progressed since September?
- What meetings of Facility governance and advisory committees have taken place to ensure appropriate oversight of the Facility?
- How is the Alliance planning for the delivery of COVID-19 vaccines in AMC92 participants?
- How could a flexible, revolving COVAX Buffer of last resort, housed within the Facility, support the attainment of the Facility's goal to ensure equitable access to COVID-19 vaccines and the Alliance's strategic goal to increase equity in immunisation?
- What are the key Facility risks and how are financial risks being mitigated?
- How will the Office of the COVAX Facility report on its activities?

Conclusions

We have set out in this paper (1) an update on COVAX Facility Participation; (2) an update on the vaccine pipeline and manufacturer engagement update; (3) an update on engagement with AMC-eligible participants; (4) an update on engagement with SFPs (Self-Financing Participants); (5) an update on the COVAX Exchange; (6) an update on the allocation mechanism; (7) an update on delivery planning and preparation; (8) an update on engagement with multilateral development banks; (9) an update on civil society organisation engagement; (10) an update on the Office of the COVAX Facility Structure; (11-16) proposed principles for the COVAX Buffer; (16) Facility risks; (17) financial risk mitigations; and (18) the draft COVAX Reporting framework.

In addition, several other Board Papers are also providing an update on the COVAX Facility: an assessment of COVAX Facility risks is included in section 3 of the Risk & Assurance Report in Doc 06, the AMC Resource Mobilisation Strategy is presented for guidance in Doc 09 and finally the India Strategy is presented for decision in Doc 10.

The Board will be asked to approve the creation and size of the COVAX Buffer and its organising principles, an additional US $150 million to provide exceptional delivery support for AMC92 participants, and an Office of the COVAX Facility Budget of US$ 55 million for 2021.

Section B: COVAX Facility Progress

1. COVAX Facility Participation

1.1 The COVAX Facility has global representation of 189 economies, representing over 90% of the world's population. 68 SFPs have signed

legally binding agreements with Gavi which represents nearly US$ 5 billion for their vaccine procurement. The AMC has to date fundraised US$ 2.1 billion.

2. Vaccine pipeline and manufacturer engagement update

2.1 As of 8 December 2020, WHO reports 52 vaccine candidates in clinical evaluation and 162 in preclinical development, across a variety of technology platforms. Of the candidates in clinical evaluation, 13 are in Phase III trials of which 6 vaccines developed in Russia and China were granted 'Limited/ Emergency Use' status by national regulatory authorities prior to efficacy analysis.[1] Primary efficacy analysis of two mRNA-based candidates and the first interim analysis of one adenovirus-vectored vaccine from Phase III trials suggest potentially high levels of efficacy (ranging from 60-95%). Data to request an Emergency Use Authorization from the U.S. FDA (Food and Drug Administration) and conditional approval from the EMA (European Medicines Agency) have been submitted by the two mRNA-based vaccines, and the UK and Bahrain have now granted emergency use approval to the Pfizer/ BioNTech vaccine. There is currently a debate on how to balance early access to vaccines showing promising Phase III trial results and also enable long-term assessment of safety and efficacy in ongoing trials, which 'Emergency' or 'Limited' Use Authorisations could compromise if clinical trial data is unblinded. Further results from other Phase III trials of the earliest candidates are expected in late 2020 and early 2021. Of the current Coalition for Epidemic Preparedness Innovations (CEPI)-funded COVAX R&D portfolio, 8 of the 9 candidates are in clinical trials and selection of further candidates for the COVAX R&D portfolio is ongoing.

2.2 There are ongoing discussions with several manufacturers to provide up to 2 billion doses to COVAX Facility participants in 2021. The COVAX Facility currently consists of three candidates. Inclusion of the AstraZeneca and Novavax candidates in the portfolio was previously announced through the Memorandum of Understanding (MoU) with AstraZeneca and the deal with the Serum Institute of India Pvt Ltd (SII). SII will supply doses of both the AstraZeneca and Novavax candidates, if they are successful in achieving regulatory approval. In September and October, the COVAX Facility announced additional agreements that would increase the volume of existing deals and introduce an additional candidate from Sanofi-GSK to the portfolio:

2.2.1 An amendment was made to a Pre-Payment and Supply Agreement with the Serum Institute of India Pvt Ltd (SII). This collaboration between SII, Gavi, and the Bill & Melinda Gates Foundation provides upfront capital to SII to help increase and accelerate manufacturing capacity of candidate vaccines licensed from AstraZeneca and Novavax, which can be procured if successful in attaining licensure

[1] According to Linksbridge data: Limited Use for Chinese Military (Cansino); Emergency Use in Bahrain, China and UAE (CNBG Beijing/ Wuhan); Emergency Use in China (Sinovac); Licensure in Russia (FBRI and Gamaleya).

and WHO Prequalification. The Supply Agreement amendment provides the opportunity to purchase an additional 100 million doses of COVID-19 vaccine, bringing the total base number to a total of 200 million doses. The amendment also includes a further Extended Supply Option for up to several hundred million additional doses.

2.2.2 A Statement of Intent was signed with Sanofi and GlaxoSmithKline (GSK) to provide up to 200 million doses of COVID-19 vaccine to the COVAX Facility. The vaccine candidate is based on the recombinant protein-based technology used by Sanofi to produce an influenza vaccine, and GSK's established adjuvant technology. The non-binding statement makes provision for the vaccine, if approved and licensed, to be made available to all economies participating in the COVAX Facility.

2.3 UNICEF and PAHO launched a joint RFP on 11 November 2020 to further identify suitable candidates for the COVAX Facility vaccine portfolio and establish procurement arrangements on the back of COVAX Advance Purchase Commitments. Both the pre-tender consultation on 28 September 2020 and pre-bid meeting on 18 November 2020 received significant interest with close to 130 attendees and 42 manufacturers attending. Manufacturers have until 23 December 2020 to respond. The COVAX procurement process is expected to transition to a standard UNICEF procurement process after the end of the COVID-19 vaccine supply constraint period and as it relates to AMC92 participants.

2.4 The Facility is also discussing with a number of high-income countries how excess doses maybe used to supplement doses in AMC participants.

2.5 The Independent Product Group (IPG), a group of independent scientific and technical experts, held their first meeting on 19 October 2020. The group have since met weekly (8 times), including five manufacturer presentations. Following familiarisation with COVAX and the COVAX R&D portfolio, the IPG has been updated on the latest status of the vaccine candidates included in the COVAX Facility vaccine portfolio and are reviewing other candidates for potential inclusion in the COVAX Facility portfolio, in advance of Market-Sensitive Decisions Committee (MSDC) discussions. Review of vaccines has been prioritised based on anticipating timing and scale of doses available. Discussions are ongoing to ensure ways of working which fully leverage work and expertise of COVAX partners, such as CEPI's understanding of the R&D landscape, and independent scientific review mechanisms.

2.6 The Procurement Reference Group (PRG), a group of independent vaccine supply and procurement experts, will provide independent advice to the Facility on the implementation of the COVID-19 vaccine procurement strategy. The PRG terms of reference are being finalised, and members are in the process of being appointed with the aim to hold the first PRG meeting in January. The PRG is convened by the Office of the COVAX Facility and with UNICEF Supply Division (SD) acting as COVAX Procurement

Coordinator, which mirrors the processes of well-established PRGs for Gavi core programmes.

3. AMC-eligible participants

3.1 Since the September 2020 Board meeting, the Secretariat has engaged with AMC-eligible economies at global, regional, and country- level. The Secretariat held a set of global briefings focused on key topics: cost-sharing, regulatory, procurement, liability & indemnification, available technical support and cold chain equipment (CCE). To ensure broad participation, including across time-zones, the Secretariat held two sessions in English, one in French and one in Spanish with the Pan-American Health Organization (PAHO). 68 of the 92 AMC-eligible economies were represented in this set of briefings, and over 900 participants joined.

3.2 Leveraging regional-level dialogues, the Secretariat has participated in targeted discussions with EPI Managers, Regional Immunization Technical Advisory Groups (RITAGs) and National Advisory Committees on Immunisation in all regions. Health Ministers have also been regularly briefed via presentations at the WHO member state briefings. The COVAX Country Engagement team also developed a targeted approach to engage with the 22 'new to Gavi' economies among the AMC92 to ensure their understanding and engagement with the Facility. Following the publication of the AMC Terms and Conditions and application documents, the country-facing teams have continued and increased bilateral engagement with all eligible economies.

3.3 The AMC application documents released on 13 November 2020 invite AMC92 eligible economies to participate in the COVAX Facility including by agreeing to the terms and conditions, as well as to express preferences on vaccines, technical assistance (TA), cold chain equipment (CCE) and cost-sharing. As of 8 December, TA proposals have been received from 50 of the 57 Gavi-supported countries and we have received Vaccine Request Forms (the main document for signing up to COVAX) from 76 countries. CCE requests will be accepted on a rolling basis from Dec 2020 through Q1 2021.

3.4 Already, in just six months, more than US$ 2 billion has been mobilised in donations to the AMC, from governments, corporations and philanthropies with an additional US$ 5 billion required in 2021. See Doc 09 for further details on the AMC replenishment strategy.

3.5 Fully subsidised donor-funded doses will be distributed across AMC92 participants until donor resources have been fully deployed. AMC92 participants will then have the opportunity to allocate additional funds to receive further doses from the Facility and will have the opportunity to use multilateral development bank funding to support these cost-sharing contributions. Further details on the cost-sharing approach can also be found in Doc 09.

3.6 The first AMC Engagement Group meeting took place on Thursday 19 November 2020 and brought together 670 representatives from the AMC92 participants, the AMC donors and other partners. Agreeing on the group's ToRs, securing guidance on the inclusion of mRNA vaccines in the COVAX Facility vaccine portfolio, and providing information about the AMC applications and cost-sharing programmes were the agenda's top priorities.

3.7 The first meeting of the AMC Stakeholders Group took place on 9 December 2020.

3.8 Additionally, Doc 10 seeks the Board's input and approval into the appropriate level of support for COVAX AMC doses and delivery support for India. Based on the principles of aspirational equity, feasibility, collaboration, and transparency, and recognising the constraints of AMC funding resources and doses, the paper provides the rationale for a proposed package of support to India of **20% of total AMC doses**[2] to cover ~7-9%[3] of India's population and **20% of the overall amount provided for TA and delivery costs** (CCE).

4. Self-Financing Participants

4.1 68 economies have signed Commitment Agreements with Gavi. Of these, 29 have chosen the Committed Purchase arrangement, under which vaccines will be allocated to participants through the Allocation mechanism, and 39 have chosen the Optional Purchase arrangement, under which participants can opt-out of specific vaccine candidates. Together, these participants have committed to upfront payments of US$ 1.3 billion and guarantees with a value of US$ 1 billion.

4.2 The first meeting of the Shareholders Council was held on 2 November 2020. Members discussed the establishment of the Council, and the COVAX vaccine portfolio. Since then, the Council has endorsed its Terms of Reference following minor amendments, and provided guidance on inclusion of early mRNA vaccines in the portfolio. The Optional Purchase participants have had the opportunity to exercise their first opt-outs from the vaccine portfolio and the first opt-out window is now closed.

5. COVAX Exchange

5.1 The Secretariat has also been continuing to advance the design of the 'COVAX Exchange' through early consultations with COVAX colleagues leading the allocation work, and academic and technical experts on exchange systems, manufacturing, and supply chains. A technical group co-hosted with the UK has met with interested economies from the Shareholders Council to vet ideas with the goal to have a finalised design concept by the end of December 2020. The high level objective is to develop a mechanism through which economies can optimise COVAX vaccine preferences through trading while at the same time not interfere with the Allocation Framework or with industry decision making as it relates to

[2] Donor-funded doses. Excludes COVAX Buffer.
[3] Assumes 2 dose regimen. Based on base case and higher price scenarios described in Doc 09.

fill/finish, labelling, and shipping. It will also need to take into account territoriality, tiering of prices and Indemnification & Liability agreements.

6. Allocation

6.1 In addition, the Secretariat is also progressing work with WHO and other partners to finalise the Allocation Model that will analyse the different inputs, including country readiness, to arrive at an initial Allocation calculation. Throughout the development process the team will continuously test the Allocation Model using a mix of real data and scenarios ahead of being used. Once vaccines are available to be allocated, the model will be used to perform the initial calculation. The model's output will be reviewed by the Joint Allocation Taskforce (JAT) who will use it as the basis for developing the Vaccine Allocation Decision (VAD) proposal. The VAD proposal will be reviewed and validated by the Independent Allocation Validation Group (IAVG).

6.2 The COVAX Facility's work with WHO and CEPI to define the terms of reference for the IAVG and the functions for the JAT is ongoing. These bodies will be established in Q1 2021.

7. Delivery planning and preparation update

7.1 As participants **prepare to roll-out a COVID-19 vaccine**, the Gavi Secretariat, World Bank Group, WHO, UNICEF, and others have taken fast actions to align, streamline processes, and develop integrated global frameworks, trainings, assessments, and planning and monitoring tools to guide participants. This includes:

- A COVID-19 vaccine readiness assessment tool that provides a roadmap for planning for vaccine introduction and a framework for monitoring readiness against key milestones;
- A COVID-19 vaccination costing estimation tool to help governments, partners and other stakeholders estimate the marginal cost of vaccination;
- Guidance on Developing a National Deployment and Vaccination Planning for COVID-19 vaccines (NDVP) to elaborate strategies for the deployment, implementation and monitoring of the COVID-19 vaccine(s) in country, and;
- WHO Strategic Advisory Group of Experts values framework for allocation and prioritisation of the COVID-19 vaccination under different epidemiological and supply scenarios.

7.2 In September 2020, the Board approved the allocation of US$ 150 million from core resources to prepare AMC92 participants to deliver COVID-19 vaccines, focusing on urgent TA and cold chain needs with priority for Gavi-supported economies and others on a case by case basis. In line with this decision, the Secretariat and Alliance partners have released application and guidance documents for eligible economies to (i) confirm participation in the COVAX Facility and (ii) request support as part of COVAX. To ensure awareness amongst senior officials about the opening of the application

window and convey key messages on preparedness, a letter of information was also sent to Ministers of Health and Finance signed by Gavi, the Global Fund, UNICEF, World Bank and World Health Organization and committing to help at least 100 countries get ready to deploy new COVID-19 tools within 100 days. Gavi Senior Country Managers, COVAX Facility staff and Alliance partners have also been engaging intensively with COVAX Facility participants to support them to prepare.

7.3 **Cold chain equipment** support will focus on strengthening the regular cold chain to store vaccines at 2-8 degrees, since the vast majority of available doses are expected to require storage at this temperature. It will be targeted primarily at the upper levels of the supply chain (national, regional), which available data suggests is where the biggest constraints are. Investments in district-level equipment and passive devices may be approved on an exceptional basis, and participants also have the option to explore leasing options under some scenarios. In line with the Board decision, funding has been prioritised to the 56 Gavi-eligible participants,[4] who have been allocated an average of 50% more funding than equivalent AMC participants. Significant efforts have been made to expedite the application process, and the first submissions are expected in January 2021, with a rolling process continuing thereafter.

7.4 In addition, the Alliance has continued to evaluate the feasibility of deploying ultra cold chain (UCC) equipment given that one of the leading vaccine candidates requires storage at -70 degrees. While the COVAX Facility has not yet agreed on procurement of this vaccine, it will be important for equity that AMC countries are able to deliver this vaccine if it is available significantly earlier than others. The ACT-A Country Readiness and Delivery group has identified a range of potential models for delivery of UCC vaccines in AMC participants. These would entail significant programmatic complexity, and likely higher risk and cost, but would be feasible if UCC vaccines are available significantly earlier than others. The Secretariat has retained US$ 10 million of the US $150 million approved by the Board to help prepare for delivery of a UCC vaccine if required.

7.5 **Technical assistance** will be administered according to the Partners' Engagement Framework (PEF) principles of country ownership, differentiation, transparency, accountability, adequate partnerships, embracing partnerships beyond immunisation and sustainability. The PEF Management Team approved initial seed-funding of US$ 100,000 to WHO and UNICEF for each Gavi-57 economy and US$ 50,000 each for the remaining 35 AMC-eligible participants to kick-start readiness activities and the development of the National Deployment and Vaccination Plan (NDVP). Additionally, Gavi Secretariat also launched a Request for Proposals (RFP) to identify potential expanded partners for providing TA support in areas of comparative advantage for the planning and preparation of vaccine introduction. The first round of applications for TA support through partners

[4] India is considered separately, in line with its tailored support mechanism

was completed. Subsequent application rounds for TA will be planned subject to funding availability.

7.6 The initial US$ 150 million approved by the Board should address the majority of participants' needs in terms of cold chain and TA for planning introduction. Participants will need to mobilise the additional funding required for delivery support from other sources. The Alliance is coordinating with other donors, especially the multilateral development banks, to help participants secure these resources. However, some AMC participants may not have access to alternative funding, and this may pose a risk to successful vaccine roll-out, especially in poor and fragile settings. The Secretariat therefore proposes to set aside an additional US$ 150 million that could be used in exceptional circumstances to cover critical gaps that cannot be funded from other sources. While the total amount required is uncertain, this envelope (which is approximately 10% of the estimated delivery costs for AMC92 participants in the ACT-A Investment Case) would be adequate to cover the needs of participants which have already been identified as potentially not having access to other sources of financing, as well as those facing challenges of fragility. The Secretariat will include this in its ongoing fundraising efforts (subject to the Board's approval), and define a transparent process with clear criteria for access to this support.

8. Engagement with multilateral development banks

8.1 The Secretariat is working closely with multilateral development banks, which are making financing available to AMC and some self-financing participants to support both vaccine procurement and delivery. The World Bank has made US$ 12 billion in COVID-19 vaccine financing available, half to International Development Association (IDA) and half to International Bank for Reconstruction and Development (IBRD) countries. This funding is highly complementary to the Gavi COVAX AMC, as it can support AMC participants to secure additional doses to supplement those funded by donors via cost-sharing (see further details in Doc 09) and, critically, can support participants to finance vaccine delivery, supplementing the initial targeted funds made available by Gavi to AMC participants for urgent TA and cold chain needs. Other multilateral development banks, such as the Asian Development Bank (ADB) and the Inter-American Development Bank (IADB), are also making financing available. The IADB, for example, is providing guarantees to two self-financing participants, Ecuador and Belize, and discussions are underway for Inter-American Development Bank financial support to AMC participants. In addition, the ADB will send a proposal to its Board in early December for the approval of a financial package of approximately ~US$ 9 billion to support the roll-out of the COVID vaccines, like the World Bank.

8.2 The Secretariat is engaging with multilateral banks at the global and country levels to align processes and parameters of this funding, to ensure streamlined and holistic support for participants. Senior country managers and other country engagement staff are engaging closely with governments,

in-country partners, World Bank Task Team Leaders, and other regional development banks to support budgeting and planning and to allocate multilateral development bank financing as relevant, including for both vaccine doses and delivery. Coordination is enhanced with now regular standing meetings between the Gavi CEO and senior World Bank management as well as at the working level.

9. Civil Society Organisation (CSO) engagement

9.1 The COVAX Pillar has welcomed and onboarded 10 representatives of Civil Society into the remaining major working groups of the COVAX Pillar, including the COVAX Coordination Meeting (CCM), the highest-level coordination body within the Pillar. The Gavi CSO Steering Committee has nominated a representative observer for the COVAX Shareholders Council and the AMC Engagement Group meetings. The latest CSO COVAX Pillar update was held on 8 December 2020 and focused on country readiness and delivery including updates from UNICEF and perspectives from civil society organisations at country level.

10. Update on the Office of the COVAX Facility Structure and Governance

10.1 The Office of the COVAX Facility is rapidly staffing up to meet growing operational demands and a larger scope than expected when initial staffing projections were prepared during the summer. Since September, recruitment for several key roles within the Design & Operationalisation, Deal-making, and Country Engagement teams has gotten under way while a second wave of recruitment is beginning to fill in resourcing gaps on other critical Secretariat teams including Finance, Governance, and Legal. A call for secondments has been issued to both self-financing and AMC-eligible participants and to partners, and the Facility is currently in discussions with several potential candidates. We expect that efforts to build out the team will continue into Q1 2021. A more detailed breakdown of staffing requirements and associated budget has been presented to the Audit & Finance Committee (AFC) on 25 November 2020 and is summarised in Annex B. The AFC has reviewed the budget and recommends to the Gavi Alliance Board to approve a COVAX Facility budget of US $55 million.

10.2 At its meeting in July 2020, the Board meeting approved US$ 7 million seed funding to enable the setting up of the Office of the COVAX Facility. A three-year budget has been prepared for the expected life of the Facility (as outlined in the Terms and Conditions for the SFPs). This budget will be funded by the upfront payments of SFPs and Gavi COVAX AMC funds. Total Facility operating costs are forecast to be US$ 135 million over the three years. The budgeted Facility costs for 2021 are US$ 55 million of which US$ 23 million are staff/ consultants/ professional fees. An estimate has been made to delineate (where possible) and allocate costs of the Facility to SFP and AMC participants. New processes are being introduced and new risk mitigation measures established, many specifically to safeguard against potential risk from SFP liabilities affecting Gavi core financials. It is expected that more of the Facility costs will be funded by SFPs than the AMC. An initial estimated split of costs of 70% SFP and 30%

AMC has been made and a more accurate assessment will be made as the Facility design is finalised and operationalised.

10.3 Since the September 2020 Board meeting, the Office of the COVAX Facility has convened meetings of several new governance/advisory bodies, including the Independent Product Group, the AMC Engagement Group, the AMC Stakeholders Group, and the Shareholders Council, that have been created to provide oversight over and guidance to Facility operations. COVAX Facility body terms of reference are included for Board approval as part of the consent agenda in Doc 01f. These well-attended meetings effectively engaged relevant stakeholders, many of whom are working with Gavi for the first time. Additionally, interagency governance has been managed through a biweekly rhythm of COVAX Coordination Meetings (CCM), which brings the lead technical partners in the vaccine pillar – CEPI, WHO, and Gavi – together with representatives from the World Bank, UNICEF, industry, and Civil Society. Jane Halton and Dr. Ngozi Okonjo-Iweala co-chair the CCM, and the Chair-Elect of the Gavi Alliance Board has been attending as an observer.

Section C: The COVAX Buffer

11. Background

11.1 Gavi currently supports neglected at-risk populations with routine immunisation and outbreak response programmes through its Fragility, Emergencies, Refugees (FER) policy and four emergency vaccine stockpiles[5]. Experience has shown that the FER policy flexibilities facilitate access to vaccines for populations in humanitarian contexts that are otherwise at risk of being left behind, and that stockpiles are an essential and effective mechanism to enable rapid and equitable access to vaccines.

11.2 Since the Facility's inception, there has been a clear intent to explore creating a flexible buffer of doses housed within the Facility to act as a safety net in case needs arise that cannot be serviced through standard processes and which, if left unmet, would undermine both the Facility's goal of ensuring equitable access to COVID-19 vaccines and the Alliance's strategic goal to increase equity in immunisation. Such a buffer is imagined to be 'revolving', i.e. allocating real-time production, given that in the current supply constrained environment it is not appropriate to create a physical stockpile.

11.3 Pursuant to this intent, and in keeping with mentions of a potential buffer in the September 2020 Board papers, the AMC Donors' Terms and Conditions, and the WHO Fair and Equitable Allocation Framework[6], the Secretariat has been working with Alliance partners to consider what the purpose and organising principles of this mechanism of last resort could be, building on prior experience. This section presents, for approval by the Board, a proposed dual purpose and set of organising principles for a

[5] Yellow Fever, Meningitis, Cholera and Ebola
[6] World Health Organisation, September 2020. Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility.

COVAX Buffer (the "Buffer"), and lays out next steps to develop its design, operationalisation and oversight processes.

12. COVID-19 vaccines for high-risk groups in humanitarian situations

12.1 The COVAX Facility is committed to the equitable allocation of future COVID-19 vaccines, realised through the application of the WHO Fair and Equitable Allocation Framework[7] which directs the allocation of doses amongst Facility participants. They in turn are recommended to follow SAGE guidance[8,9] to determine priority high-risk groups for vaccination within their own territories. Prioritised groups vary depending on the epidemiological scenario, but in the two scenarios given where COVID-19 cases are present, they include sociodemographic groups at significantly higher risk of severe disease or death, including "refugees, internally displaced persons, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies [and] vulnerable migrants in irregular situations"[10]. The guidance calls on countries and territories to take action to ensure equal access to vaccines for all prioritised groups.

12.2 National governments are responsible for the vaccination of all high-risk people within their borders and the Alliance, alongside other humanitarian and civil society actors, will advocate for the inclusion of such groups in national vaccine deployment plans through engagements with Facility participants. Experience however shows that despite best efforts, unavoidable gaps arise and at-risk populations in humanitarian settings are often left behind[11]. The 2021 Global Humanitarian Needs Overview estimates there are potentially 235 million people in humanitarian settings[12]. These groups are at risk of being missed by government-led vaccination activities. Within this, and also considering local front line healthcare workers potentially not covered by government-led vaccination activities, an estimated 30 million[13] individuals are considered to be at significantly higher-risk of severe disease or death from COVID-19, as per the SAGE Roadmap, and should therefore be prioritised for early vaccination.

13. Contingency provision

13.1 The first phase of the WHO Fair and Equitable Allocation Framework[14] determines that Facility participants will each be allocated doses at the

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[7] Ibid.
[8] World Health Organisation. September 2020. SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination.
[9] World Health Organization. October 2020. WHO SAGE Roadmap for Prioritizing Uses of Covid-19 Vaccines in the Context of Limited Supply.
[10] Page 14, World Health Organization. October 2020. WHO SAGE Roadmap for Prioritizing Uses of Covid-19 Vaccines in the Context of Limited Supply.
[11] This could include, for example, populations living outside government-controlled areas, populations in conflict settings or those affected by humanitarian emergencies, refugees and asylum seekers, internally displaced people, undocumented migrants, detainees and stateless persons. It should be noted that these different populations often overlap and cannot simply be summed.
[12] Global Humanitarian Needs Overview 2021
[13] It should be noted that these figures are particularly subject to external shocks and statistically significant variability given the volatile nature of conflict and disaster displacement.
[14] World Health Organisation, September 2020. Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility.

same rate to enable them to vaccinate the same percentage of their population in lockstep with each other[15]. However, this approach does not allow for an emergency release of doses. Given the dynamic, unpredictable nature of the pandemic, some participants may need more doses than they have been allocated at that time to address public health needs, such as exceptionally high COVID-19 mortality, including in countries and territories that are not currently participants of the COVAX Facility.

13.2 To more effectively act on the Facility's principles of global solidarity and equity, better prevent unnecessary mortality, support global health security, and implement SAGE guidance, a contingency provision would allow for a limited number of emergency doses to be released to address serious public health needs in exceptional circumstances.

14. Proposed dual purpose, organising principles and funding envelope for the COVAX Buffer

14.1 In light of the above, the Gavi Secretariat proposes the Board **approve the creation of a COVAX Buffer with a dual purpose** to:

a) ensure access to COVID-19 vaccines for high-risk[16] populations in humanitarian settings that are not covered in national vaccine deployment plans, and;

b) provide a contingency provision to enable an emergency release of doses to meet public health needs where normal vaccine allocation timelines may not be sufficient.

14.2 The Secretariat further proposes that the Board **approve six organising principles for the COVAX Buffer**:

a) **Equitable access:** Leaving no one behind by enabling access to vaccines for often missed and at-risk communities;

b) **Targeted deployment:** Reaching the highest-risk population sub-groups in accordance with SAGE guidance and responding to very high incidence of mortality to make best use of a limited supply of doses;

c) **Measure of last resort:** Not an alternative to state responsibility, only deployed where there is an unavoidable gap in coverage and other options have been exhausted;

d) **Contextual Parity:** Sensitive to intra- and inter-country contexts in a supply constrained environment, to avoid any perception of improper[17] prioritisation of any one group above another;

e) **Alignment with overarching principles of the ACT-A COVAX Pillar:** Especially of the COVAX Facility (notably, Global Access, Impact-orientated, and Solidarity) and of the WHO Fair and Equitable Allocation Framework (notably Solidarity, Responsiveness to Public Health Needs, Equity and Fairness, and Collaboration), and;

[15] Notwithstanding some operational caveats, such as country readiness and minimum shipment sizes
[16] As per SAGE recommendations
[17] i.e. outside of WHO and SAGE technical and normative policy and guidance

f) **Adherence to the humanitarian principles** for the oversight and implementation of the humanitarian element of the Buffer: humanity, neutrality, impartiality, independence, and "do no harm".

14.3 Finally, the Secretariat proposes that the Board **approve that 5% of COVAX AMC funding be reserved for the purchase of doses to be deployed via the Buffer**. This will be progressively financed through the Gavi COVAX AMC as its funding increases, with the final amount dependent on dose availability, estimations of need, and fundraising success. The funding envelope for the Buffer will be reviewed at such a time that the Facility is terminated, with a presumption that any unused funds will be returned to the AMC. Additional doses for deployment via the Buffer in non-AMC-eligible participants under the 'contingency provision' element of the Buffer would likely be self-financed by the applicant, pending a review of the implications of this decision. Operational support is still to be defined.

15. Strategic design, effective implementation, and accountability

15.1 The Gavi Secretariat will work closely with Alliance partners through dedicated working groups to elaborate on the Buffer's design, plans for implementation, and oversight, guided by its dual purpose and organising principles. Their development will be in accordance with the normative, technical guidelines developed by WHO and SAGE and humanitarian principles and will leverage existing processes within the COVAX Pillar of the ACT-Accelerator to promote speed, simplicity and efficiency, in particular the newly designed 'Allocation Mechanism' to determine the allocation of Buffer doses. Critical aspects regarding any remaining high-level parameters of the Buffer will be brought back to the PPC and Board for approval in 2021 as necessary.

15.2 The design of the Buffer will also learn from Gavi's prior experience of applying the FER policy and supporting emergency stockpiles. For example, from implementing the FER policy in Gavi 4.0, the Secretariat has identified a clear need to systematically enter into new partnerships with humanitarian actors who have an operational footprint in missed communities and significant experience of implementing vaccination campaigns in humanitarian settings. It is thus expected that effective implementation of the Buffer will entail working systematically with not only countries and territories but also non-state entities including UN agencies, the International Red Cross and Red Crescent Movement and civil society organisations.

15.3 Then, whilst recognising that the proposed Buffer is not a stockpile for outbreak response, there are a number of Board-approved principles that guide how Gavi manages its investment in emergency vaccine stockpiles that still apply. These principles, built on lessons learnt from previous support to stockpiles, are strategic design, effective implementation, and accountability. The lessons also included the need to:

- see stockpiles as part of a comprehensive disease control strategy;

- acknowledge the potential risks of working in unpredictable and fast-moving contexts, particularly in humanitarian non-government controlled settings;
- provide access to stockpiles to all countries and territories, not only Gavi-supported ones, so as to support recovery from epidemics, minimise avoidable morbidity and mortality, and reduce inequities;
- improve processes for implementing emergency vaccine stockpiles to systematically harness the comparative advantage of all Alliance partners and facilitate strong collaboration, and;
- ensure sufficient transparency and accountability, including performance indicators or reporting mechanisms to better enable coordination and visibility on the use and impact of Gavi support.

15.4 These learnings will feed directly into the development of the Buffer. Some of the key issues which require further consideration include:

a) **Territorial scope:** It is intended that the Buffer be open to all countries and territories regardless of participation in the COVAX Facility or prior Gavi-support, pending a review of the implications of this decision. This would build on learning from Gavi stockpiles that non-Gavi supported participants should be eligible to access stockpiles with a principle of reimbursement. Non-COVAX Facility participant access to doses through the buffer will likely be contingent on them joining the COVAX Facility, alongside other requirements that demonstrate solidarity with the participants that already committed to the Facility. It is also intended that non-state entities such as UN agencies and civil society organisations, who are in many instances the primary actors delivering vaccines in humanitarian settings, will be able to apply for doses through the Buffer, but the practical implications of this need to be further assessed, including with regards to regulatory approvals, indemnification and liability, and contracting.

b) **Target populations and threshold for dose release:** The Buffer would only be available as a measure of last resort and its doses will be targeted to high-risk groups as per the SAGE Roadmap. The definition of populations in humanitarian contexts will likely be guided by the Global Humanitarian Needs Overview and relevant inter-agency guidelines and data. A more detailed breakdown of target groups, estimations of population size, risk prioritisation, and the threshold for dose-release for both elements of the Buffer will be developed.

c) **Size of the Buffer:** The total size of the Buffer, to cover both the 'humanitarian' and the 'contingency provision' elements, could be a real-time allocation of up to 5% of doses procured through the COVAX Facility, initially until end 2021. This 'real time' allocation would ensure that doses are not set aside, which would run contra to Facility principles of not letting doses sit idle, but also that such doses would be available from the outset. Making doses available to high-risk populations in humanitarian settings in real time is a core part of the international, collaborative effort to bring the pandemic under control. It is intended

that each element of the buffer will receive a dedicated, ringfenced, portion of doses. The exact number of doses to be made available through the buffer, including the division between the two elements, will depend on the total volumes procured through the COVAX Facility, financing for such doses (including fundraising success), and the results of further data analysis and global needs' assessment. The Buffer could also be open to additional doses donated via the COVAX Facility. The feasibility and modalities for including donations will be further considered.

d) **Allocation and delivery:** Whilst the allocation and delivery mechanisms for the Buffer are yet to be determined, it is expected that the 'humanitarian' and the 'contingency provision' elements will be operationalised as distinct efforts. Recognising that the allocation of COVID-19 vaccines will be high profile and receive a lot of scrutiny, and particularly noting the learnings from previous experience of managing stockpiles, the Secretariat is conscious of the need for independent, impartial, transparent and accountable decision-making processes that can work at speed. The Secretariat also notes the need to ensure that allocation decisions for the humanitarian element of the Buffer are informed by humanitarian context expertise as well as the likely need for a tailored downstream distribution mechanism, coordinated by relevant humanitarian and civil society stakeholders, to support populations in humanitarian settings.

15.5 Other questions include: regulatory, indemnification and liability considerations; roles, modalities of engagement, and responsibilities of implementing partners; the need for a communications and advocacy plan that underscores the responsibility of governments to vaccinate all high-risk individuals within their territory; confirmation of any funding for vaccine delivery support; and oversight and accountability of the Buffer, noting the level and breadth required given its potential financial size.

Section D: Facility Risk Mitigation & Reporting

16. Facility Risks

16.1 Following the principle of safeguarding Gavi's assets and reputation, the Facility is being designed to avoid risk where possible, and residual risks are being actively monitored and mitigated. It is however also understood that operating at this magnitude and speed carries risks, and failure of establishing a successful Facility will also affect Gavi's overall reputation. The Gavi Secretariat, including the Office of the COVAX Facility, under the guidance of the Board, continues to seek the right balance to successfully deliver on the promise of the Facility while minimising risks to Gavi core resources and programmes.

16.2 Some key risks have been outlined in this paper and a full overview is included in section 3 of the Risk & Assurance Report (see Doc 06). The Risk & Assurance Report furthermore highlights the COVAX Facility as a top risk

for Gavi. The risk of a failure to establish a successful COVAX Facility is very high as the COVAX Facility is a large, unique and structurally complex undertaking, is being established in record time, and has to navigate uncharted territory in securing equitable access to potential COVID-19 vaccines. Current risk exposure is deemed outside of risk appetite until there is full clarity on the size of risks and possibilities to mitigate them. It therefore requires intensive mitigation efforts to bring the risk within risk appetite, including by continuing to surge capacity, implementing robust project and risk management and working with external advisors to fill critical skills and capacity gaps.

17. Financial risk mitigation

17.1 The AFC noted that Gavi's role in administering the COVAX Facility must be done with minimal financial risk exposure to Gavi's core resources. To ensure committee members have a clear understanding of the risks to Gavi and to ensure Gavi's assets are effectively protected, the AFC are meeting more frequently to review and advise on financial risk mitigation related to the COVAX Facility.

17.2 Gavi has selected Citigroup to be the financial advisor for the COVAX Facility. In this role it is advising and assisting in finding financial risk mitigation and execution strategies in connection with the Facility. The COVAX Facility Risk Framework, as developed by Citigroup is attached as Annex D.

17.3 Key risks have been identified in the following areas and where Citi are now supporting the team:

17.3.1 **Contract Risk:** Contracts with suppliers and participants and the handover between the two form the foundational layer of risk.

17.3.2 **Long Vaccine Risk:** Gavi is entering into advance purchasing agreements with manufacturers that economies will contract with. There is the risk of supply and demand imbalance that is unlikely to be absorbed by banks or MDBs and that could trigger an economy to not take up its volume commitments with manufacturers and consequently expose Gavi's balance sheet.

17.3.3 **Sovereign Credit Risk:** Gavi is working with over 90 SFPs and needs further mitigation strategies for sovereign credit risk, particularly for sovereigns below Single A credit rating.

17.3.4 **Operational Risk**: the COVAX operating roles and responsibilities are being designed and need to ensure best practice operational risk mitigation strategies for three functional areas including Treasury Operations, Accounting Services and Banking Services.

17.3.5 **Overarching Risk Management Framework:** Gavi should have an operational cash flow/liability model which can inform management in its contractual negotiations, risk mitigation

strategies, and the availability of its cash flow position to act as a residual risk absorption layer.

17.4 The financial risk assessment and mitigation work is ongoing with mitigation measures being built into the design and operationalisation of the Facility. The financial risk framework will also inform the Market-Sensitive Decisions Committee (MSDC) to ensure that manufacturing deals are reviewed with the appropriate financial, legal and other risks in mind. An improved financial, legal and risk appendix is being provided to support all MSDC decisions.

18. COVAX Reporting Framework

18.1 The Gavi Secretariat, in consultation with other stakeholders, is developing a Monitoring, Evaluation and Learning (MEL) approach intended to cover both the COVAX Facility and COVAX AMC. The proposed MEL approach is holistic in nature, spanning from inputs through to impact. A set of topline performance metrics will form the core of the COVAX Reporting Framework, with complementary data, findings and recommendations gathered through other MEL components, such as evaluations, integrated as they are delivered.

18.2 The MEL approach and COVAX Reporting Framework are drafts at present, due in large part to several design and operational aspects of the COVAX Facility and COVAX AMC still under development. Annex C presents the current draft COVAX Reporting Framework.

18.3 The Secretariat has had an initial discussion on future COVAX Facility and COVAX AMC evaluation needs with the Gavi Evaluation Advisory Committee (EAC). The EAC agreed to include the evaluation of COVAX Facility and COVAX AMC on the Gavi 4.0 Evaluation workplan as centralised evaluation topics and that this evaluation(s) should be prioritised. The EAC suggested that the Secretariat proceed with a Request for Proposals that focuses on the design of the COVAX Facility and COVAX AMC evaluation(s).

Section E: Actions requested of the Board

The Gavi Alliance Board is requested to:

a) **Approve** the creation of the COVAX Buffer with the dual purpose to (i) ensure access to COVID-19 vaccines for high-risk populations in humanitarian settings that are not covered in national vaccine deployment plans, and (ii) provide a contingency provision to enable an emergency release of doses to meet public health needs where normal vaccine allocation timelines may not be sufficient.

b) **Approve** the six organising principles of the COVAX Buffer of equitable access, targeted deployment, measure of last resort, contextual parity, alignment with overarching principles of COVAX and, in addition for the humanitarian element, adherence to the humanitarian principles.

c) **Note** that the total size of the Buffer, to cover both purposes, could be a real-time allocation of up to 5% of doses procured through the COVAX Facility, initially until end 2021, and **approve** reserving 5% of total funding received or pledged for the COVAX AMC at any point in time for doses to be deployed via the Buffer, **noting** that this will be progressively financed as AMC funding increases, with the final amount dependent on dose availability, estimations of need for target groups eligible for Buffer doses once confirmed, and fundraising success. The funding envelope for the Buffer will be reviewed at such a time that the Facility is terminated with a presumption that unused funds will be returned to the AMC.

d) **Note** that critical aspects regarding any remaining high-level parameters of the Buffer will be brought back to the PPC and Board for approval in 2021 as necessary.

e) **Approve** US $150 million to provide exceptional support, if required and on a case-by-case basis, to AMC92 participants to address critical vaccine delivery gaps for which no other funding is available, subject to this funding being mobilised by Gavi.

f) **Note** the Reporting Framework.

The Gavi Alliance Audit and Finance (AFC) Committee recommends to the Gavi Alliance Board that it:

Approve an Office of the COVAX Facility Budget of US $55 million for 2021.

Annexes

Annex A: Implications/Anticipated impact

Annex B: COVAX Budget 2021- and three-year forecast

Annex C: COVAX Draft Reporting Framework

Annex D: Citigroup COVAX Facility Risk Framework

Additional information available on BoardEffect

Appendix 1 (in September 2020 Board meeting book): Document 03 *COVAX Facility Operationalisation and Vaccine Programme*