COVAX Facility
Principles of Participation for Participants

These "**Principles of Participation**" set out the basis on which Self-Financing and Funded economies will participate in the COVID-19 Vaccine Global Access Facility (the "**COVAX Facility**" or "**Facility**"), which includes the COVAX Advance Market Commitment ("**COVAX AMC**" or "**AMC**").

It is intended that these Principles of Participation will be attached to, and referenced in: (i) the Commitment Agreements relating to the COVAX Facility to be entered into between Gavi and each Self-Financing Participant; (ii) the Grant Agreements to be entered into between Gavi and the COVAX AMC Donors; and (iii) the applications from the COVAX AMC Group for support from the COVAX AMC.

FOR DISCUSSION: There remains opportunity to optimise these Principles of Participation, recognising the extremely fast-moving environment, the different needs of Paricipants and the objective of the COVAX Facility to develop the most compelling investment opportunity for Participants possible.

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The COVAX Facility	The **COVAX Facility** is a mechanism through which demand and resources are pooled to support availability of, and equitable access to, COVID-19 vaccines for all. Therefore, all economies are invited to participate, and all participating economies will benefit by securing access to vaccine supply made available through the Facility. The **COVAX AMC**, has been established to raise funding to enable Gavi to subsidise vaccine dose purchase for eligible economies through Official Development Assistance funding from donors, as well as through support from private foundations. The AMC helps ensure that eligible economies can participate in the Facility and access vaccines through it. The remaining economies are expected to self-fund their participation. Recognising that under a business-as-usual approach it could take years to develop effective vaccines and even more years to ensure they reach everyone that needs them, the COVAX Facility will accelerate this time line by enabling investments in a diverse and actively managed portfolio of candidates, manufacturing capacity expansion, technology transfer and vaccine production in advance of licensure and provide commitments of future vaccine procurement to increase the speed and scale of available vaccines once approved.
Guiding principles of the COVAX Facility	The implementation of the Facility will be guided by the following principles: • **Global Access** – Protecting global health security means ensuring that all economies can secure access to a safe

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	and efficacious vaccine. Economies of all financial means can participate with the degree of support for economies of limited means determined by the resources raised. • **Impact-oriented** – The Facility is single-minded in its goal to ensure equitable access to COVID-19 vaccines. Recognising that in the short term, demand for vaccines will outstrip supply, a coordinated strategy for managing vaccine as a scarce resource is needed to reduce the spread of the virus and its impact on lives, health systems and economies. • **Transparency** – The Facility promotes visibility into cost and fees and, therefore, the costs associated with manufacturing capacity expansion, production at risk and advance purchase commitments will be made available to all Participants. • **Solidarity and collective ownership** – The world will need to work together to overcome the pandemic, and the Facility will work best when as many economies as possible committing to this collaborative global effort. Everybody contributes so that everyone can benefit. This principle will be realised through clear political and financial commitments, and economies will be asked to contribute to the Facility based on their capacities in the form of financial contributions. • **Complementarity with other funding** – The pull mechanisms used by the Facility will complement the push funding for R&D provided by other stakeholders, such as CEPI (COVAX partner), BMGF and other bilateral and philanthropic investments. Manufacturers will be requested to disclose any funding received from a third party to facilitate R&D or incentivise scale-up. As the Facility enters into manufacturer-specific agreements, the Facility will consider any previous funding received by the manufacturers in contractual conditions.
Goals of the Facility	The goals of the Facility are to: • develop a large and diverse actively managed portfolio of COVID-19 vaccine candidates to maximise the probability of success of several candidates, so that the best vaccines are ultimately made available and the supply will be sufficient for highest priority populations globally; • deliver 2 billion doses of an approved COVID-19 vaccine by the end of 2021;

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	• guarantee fair and equitable access to COVID-19 vaccines for every participating economy in the world; and • end the acute phase of the pandemic by the end of 2021.
Host and Administrator	The COVAX Facility will be administered by the Gavi Alliance ("**Gavi**"), a Swiss-based non-profit foundation, granted privileges and immunities by the Swiss authorities. By accelerating access to a COVID-19 vaccine for all economies, the goals of the Facility are complementary to, and will enhance, Gavi's mission and strategic goals.
Role of Gavi as administrator of the COVAX Facility and COVAX AMC	As administrator of the Facility, Gavi will allocate human resources to support the Facility, which will be known as the Office of the COVAX Facility. The responsibilities of the Office of the COVAX Facility will be as follows: • enter into Commitment Agreements with the Self-Financing Participants, including tri-partite agreements with multilateral development banks, as relevant; • enter into Grant Agreements with COVAX AMC Donors; • enter into Advance Purchase Commitments with individual vaccine manufacturers and developers to guarantee the purchase of, or have the option to purchase, a pre-defined number of doses of COVID-19 vaccines from each manufacturer or developer, contingent on the vaccine achieving at minimum licensure/authorisation from a Stringent Regulatory Authority ("**SRA**"), as defined by reference to WHO's list of SRAs which is regularly updated, and/or WHO prequalification. Vaccines may also be purchased based on national emergency use processes or WHO Emergency Use Listing ("**EUL**"). Reliance on WHO prequalification and EUL processes would be informed by the WHO target product profile and SAGE recommendations; • facilitate the participation of Funded Participants through an application process for financial support through the COVAX AMC; • select the most promising vaccine candidates with input from COVAX partners (CEPI, WHO) and the guidance, based on technical assessment, of experts on the COVAX Independent Product Group. Such assessment shall be based on regular assessment of policy recommendations, the latest evidence from clinical development (e.g., safety, efficacy), the pathway to regulatory approval and considerations regarding vaccine delivery and use and

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	vaccine production, in order to create a portfolio that is diversified (e.g., vaccine technology platform, geographic location of production, supplier) and to manage development and supply risks; • convene the Shareholders Council and Shareholders Executive Committee (see further details below), and provide regular reporting to the Shareholders Council on manufacturer transactions, including costs associated with such transactions, as well as administrative fees involved in managing the Facility; • convene the Independent Product Group (see further below), and with the support of CEPI and WHO, provide regular updates on the pipeline of candidate vaccines and assessments of specific candidates for potential Advance Purchase Commitments to the Independent Product Group in order to receive expert advice and enable the Office of the COVAX Facility to develop and oversee the Facility portfolio of vaccine candidates for supply agreements; • appoint a Treasury Manager for the administration of the commitments provided by Self-Financing Participants; • provide financial services and, on a 6-monthly basis, prepare a financial report on the use and balance of funds from the Self-Financing Participants, to be independently verified by Gavi's external auditors or another recognised accounting firm; • facilitate access to a pooled procurement mechanism (for example, the UNICEF Supply Division) for Funded Participants and interested Self-Financing Participants (if applicable); and • perform all other administrative functions necessary for the proper functioning of the Facility.
Non-Financial Considerations of all Participants	Participants will purchase Approved Doses from the manufacturer on the basis of the Advance Purchase Commitments. All relevant national policies, procedures and laws of the Participant shall remain matters of the individual Participants. To enable smooth operation of the Facility and prevent undue delay in the shipment of Approved Doses, Participants, where possible under national laws, should enable the following:

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	• no interference in movement of vaccine doses and medical supplies required for vaccine administration from domestic manufacturers to intended recipient economies; • regulatory clearance for COVID-19 vaccines supplied through the Facility by making use of collaboration with and reliance upon Stringent Regulatory Authorities to facilitate the pathway to authorisation for emergency use/ licensure; • contributions of national surveillance and laboratory data on COVID-19 and SARS-CoV-2 to global information repositories such as the WHO Global Health Observatory Data Repository or other systems; • transparency to the Office of the COVAX Facility, on bilateral supply agreements entered into with manufacturers in relation to COVID-19 vaccines, including the identity of the manufacturer, the overall volume committed and timing of delivered doses (for coordination with distribution of doses from the Facility), subject to any obligations of confidentiality which the Participant is subject to under such bilateral supply agreements. Participants will be expected to seek to ensure that, in any future bilateral deals which they enter into, they are not prevented from providing transparency to the Office of the COVAX Facility by confidentiality obligations in those bilateral agreements; and
Liability & Indemnity	Participants will be responsible for deployment and use of vaccines within their territories and assuming any liability associated with such use and deployment. Participants should expect for vaccine manufacturers to require Participants to indemnify them against product liability claims, which normally can include carve outs for negligence, wilful misconduct and manufacturing defect.
Commitments of the Self-Financing Participants	The total cost which Participants will incur has three main components: ex-factory costs (i.e., the purchase price of vaccines charged by manufacturers); access/speed premium; financing/risk mitigation and operating costs: • **Ex-factory costs**: a pass-through model will apply. The Facility will negotiate the best possible prices with manufacturers and this same price will be applied transparently to Participants purchasing the products; prices applied by manufacturers could be tiered or flat.

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	• **Access/speed premium**: non-recoverable portion of payments made in advance of licensure to accelerate manufacturing or secure access to a vaccine (technology transfers, reservation fees, Advance Purchase Commitments); payments made in advance of licensure are aimed at ensuring Participants can access more doses faster as soon as approval is granted, and a proportion of these are likely to be non-recoverable as some vaccine candidates will not be successful. • **Financing/risk mitigation and operating costs**: which includes for example: o costs associated with insurance to mitigate risk, for example to enable the Office of the COVAX Facility to make Advance Purchase Commitments in excess of the total commitments for doses received from Participants to account for R&D attrition; and o interest associated with debt financing to cover the expected recoverable portion of the speed/access costs, which reduces the magnitude of down payments required from Self-Financing Participants. o Facility operating costs. Given the current uncertainty in prices that will be charged by manufacturers and in the other cost elements mentioned above, Participants are required to make a financial commitment on the basis of estimated costs. **Self-Financing Participants** will make a binding financial commitment of the Committed Amount. The "**Committed Amount**" shall be the Estimated Cost per Dose (as defined below) multiplied by 2 (expected number of doses per person required on average in the regimen) multiplied by a number equal to 20% of the Participant's population. Self-Financing Participants may be required to secure a financial guarantee to cover the Committed Amount depending on their credit rating. Self-Financing Participants may indicate to the Office of the COVAX Facility their willingness to commit to purchase doses to cover more than 20% of their population through the Facility. In such a case, the Committed Amount shall be determined with reference to the percentage of the population actually being covered. The exact percentage will be confirmed prior to a Participant entering into a Commitment Agreement. It is envisaged that additional commitments will be subject to an upper limit, by

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	reference to the size of the Participant's population and associated vaccine will be provided after other Participants have been provided their allocations up to 20% of their population. The all-inclusive "**Estimated Cost per Dose**", consisting of the three cost components described above, is determined by the Office of the COVAX Facility based on proxy data and latest available pricing information from manufacturer engagement for the portfolio of vaccines under consideration. **FOR DISCUSSION**: The all-inclusive Estimated Costs per Dose is $10-11 USD. This is an estimated weighted average price across a portfolio of potential candidate vaccines for the Facility to maximise the probability of success and based on best available data from engagement with manufacturers. Participants would ultimately purchase vaccines at the actual price offered by each manufacturer. In some cases, manufacturers may requiring tiering of prices, which may exceed the Estimated Costs per Dose for some income tiers. Execution of a Commitment Agreement will commit a Self-Financing Participant to purchase Approved Vaccines of a value up to the Committed Amount. Self-Financing Participants will make payments as follows: • On execution of the Commitment Agreement or bank guarantee, whichever is later, the Self-Financing Participant must, within 15 business days, make an initial payment of 15% of the Committed Amount (the "**Down Payment**"). The Down Payment is made to the Office of the COVAX Facility and enables it to make payments associated with the access/speed premium, financing/risk mitigation and operating costs; • Self-Financing Participants may also be requested to make further payments of the Committed Amount beyond the Down Payment in advance of vaccine purchase should additional upfront funding be required. The amount of such further payments would be agreed with the Shareholders Council based on review of costs of transactions and administration; • As doses become available, Participants will be required to purchase doses of Approved Vaccine at an adjusted cost per dose. This is composed of the actual procurement price per dose and if necessary, an adjustment to reflect final access/speed premium, financing/risk mitigation and operational costs which may

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	be lower or higher than estimated costs covered in prior payments. Payment associated with vaccine purchase would be to the manufacturer, while any other payments would be to the Office of the COVAX Facility; • The adjusted cost per dose may be higher or lower than the Estimated Cost per Dose. If the adjusted cost per dose is lower than the Estimated Cost per Dose, Participants will purchase doses at the adjusted cost per dose and would not need to pay its full Committed Amount. If the adjusted cost per dose is higher than the Estimated Cost per Dose, Participants will not be required to make payments in excess of the Committed Amount. However, Participants will have the opportunity to purchase the full number of doses envisaged in the Commitment Agreement for the required additional cost, subject to availability of supply; • On a case by case basis, other forms of direct funding or in-kind commitments from Participants could be considered. Self-Financing Participants will acquire Approved Vaccines either through their own processes or leveraging existing mechanisms such as UNICEF Supply Division or PAHO Revolving Fund. The cost associated with utilizing such mechanism is not included in the Committed Amount and will need to be separately met by the Participant. **FOR DISCUSSION**: An alternative approach would be for the Facility Participants to pay upfront the costs for the at-risk investments and not amortize this to the doses; although it would be simpler, it requires a larger upfront commitment. Another possibility is to increase the level of investment into at-risk manufacturing capacity expansion in return for a larger proportion of optioned doses relative to doses the Facility has committed to buy. This would require a higher upfront payment from Participants, but would reduce the Committed Amount that Participants are required to make.
Commitments of the COVAX AMC Donors	**COVAX AMC Donors**: each donor will enter into a Grant Agreement with Gavi, to provide a schedule of committed financing (which can be provided through innovative financing instruments such as IFFIm) to the COVAX AMC. The financing will be utilised by the Office of the COVAX Facility to cover the four components of the total cost described above for the Funded Participants.

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Commitments of the Funded Participants	The **COVAX AMC Group** may submit a request to Gavi to receive financing support through the COVAX AMC towards a specified number of doses of COVID-19 vaccines made available through the Facility. Participants approved for support will: • deploy vaccines in accordance with the Gavi vaccine request process and requirements therein; • may be responsible for co-financing a portion of the vaccine dose costs in accordance with policies on such matters approved by the Gavi Board from time to time • will be expected to procure vaccines through UNICEF Supply Division or PAHO Revolving Fund; and • will be required to report on use and coverage of vaccine.
Engagement with manufacturers	The following principles will apply when engaging and contracting with vaccine manufacturers: • **Volume Commitments**: o The total indicative value of the doses for which the Office of the COVAX Facility commits to purchase through Advance Purchase Commitments will likely exceed the total Committed Amounts received from Participants under the Facility (acknowledging the likelihood that a number of vaccine candidates will be unsuccessful). The Office of the COVAX Facility can ask Participants to increase the Committed Amounts, but Participants shall not be obliged to do so. In all cases the liability of each Participant in respect of the Advance Purchase Commitments shall be no more than the Participant's Committed Amount. The Office of the COVAX Facility may obtain insurance and/or alternative funding to protect against the risk that the value of purchase requirements of the Advance Purchase Commitments it enters into are in excess of the total Committed Amount from Participants (e.g., due to higher than anticipated price, higher than anticipated success rate of vaccine candidates, etc.) o the Vaccine must be an **Approved Vaccine**. o Seek options for additional doses (i.e., commitment for X doses with option to buy additional Y doses) without risking timely access to doses, especially for more expensive product technologies.

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	○ Seek termination rights which allow: ▪ the volume commitments to be terminated by Gavi where the demand for vaccine reduces, on fair and reasonable terms, to protect the interests of the Facility and the Participants; and ▪ Gavi to require the manufacturer to transfer vaccine materials (e.g. unused raw materials) which have been financed by Gavi to another manufacturer which Gavi has an agreement with. ○ To protect Participants and the Facility from being required to purchase vaccines that exceed pricing expectations by a large margin, seek the ability to allow Gavi to opt-out of purchasing vaccine in the event that the actual procurement price per dose is more expensive than the estimated procurement price per dose by more than a certain amount. • **Transparency**: manufacturers will be asked to provide transparency to the Office of the COVAX Facility, on any push funding received and supply agreements it has entered into with other parties and the Office of the COVAX Facility shall take into consideration any such funding in its negotiations with manufacturers. • **Intellectual property**: the Facility will respect existing IP rights and will be supportive of IP licencing and knowhow transfer rights (including, if appropriate, rights to facilitate tech transfer for third party manufacturing) to support the manufacturing and distribution envisaged by the Facility. • **Tailored agreements:** the Facility will develop agreements tailored to individual negotiations with manufacturers that optimise outcomes for the Facility and its Participants.
Engagement with CEPI	Gavi and CEPI are partners within COVAX and are collaborating on the design and operation of the COVAX Facility. This collaboration includes, but is not limited to, engagement with manufacturers, active management of a portfolio of vaccine candidates, and a coordinated approach to incentivizing and securing supply. As part of this collaboration, Gavi and CEPI have implemented a set of complementary supply, development, and access agreements and incentives.

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	As stated above, Gavi will seek to enter into Advance Purchase Commitments. CEPI provides R&D funding to vaccine candidates selected through a rigorous review process and will partner with Gavi and others, such as multi-lateral development banks, to facilitate financing for manufacturing capacity expansion, inventory build, and technology transfers before licensure to accelerate dose availability. While CEPI expects to directly generate doses and/or reduce the cost of vaccine for distribution by the COVAX Facility, many CEPI-funded projects may fail due to the high rates of attrition associated with early stage vaccine development. CEPI will seek access agreements from partners receiving research and development funding that secure commitments of doses or manufacturing capacity for the Facility.
Product Choice	Participants will be invited to express preferences in respect of the various vaccines / vaccine candidates which may be available. The Facility will endeavour to meet Participant product preferences, however, it may not always be possible given the likely supply constraints, as well as other relevant factors. **FOR DISCUSSION**: If the alternative approach focused on enhanced options contracts with manufacturers is pursued, once the mandated contracted vaccines are distributed, a Participant could communicate to the Facility which vaccine candidates it would or would not be interested in purchasing. The Facility would execute options to purchase doses based on such communications and would allocate to the Participant doses of Approve Vaccines that it has expressed an interest in purchasing. As there will likely be supply constraints for some time and demand for a particular Approved Vaccine may exceed supply, an allocation mechanism will be needed to distribute each Approved Vaccine fairly and equitably to those Participants that have chosen to purchase it if it is available.
Vaccine allocation	Vaccines available through the Facility will be allocated to Participants. It is not yet known how many vaccines will succeed, how many countries will sign up, what will be the final cost of the vaccines or what Participant readiness will be like as vaccine supply becomes available. As a result, for planning purposes, the Facility is targeting 2 billion doses by the end of 2021 to be equally distributed to Funded Participants (supported by funding from the COVAX AMC) and Self-Financing Participants, with a small (5%) buffer to be held for humanitarian emergencies and acute outbreaks.

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	In alignment with the WHO Allocation Framework, initially doses will be provided to all Participants with the intention to cover health and social care workers (estimated to be approximately 3% of the population across Participants). Vaccines will continue to be rolled out as they are produced until all Participants receive their indicative amounts. Where Participants indicate to Gavi that they are willing to commit to more doses than for 20% of their population, any additional doses shall be allocated after other Participants have been allocated their initial 20% (Phase 1), subject to the availability of funding, from Self-Financing Participants as well as funding for AMC-supported Participants. The total amount allocated to each Participant over time may be more or less than 20% depending on the funding that is made available as the provision of doses from the two financing streams are separate. Lack of funding or readiness by a Participant or set of Participants would not delay the distribution of vaccines to other Participants in alignment with the WHO Allocation Framework. The number and type of vaccine doses that Participants will receive will be implemented through the Allocation Mechanism. Recognising that sufficient doses will not be immediately available to cover all Participants' commitments, Participants will receive doses gradually, thereby covering subsets of high risk and priority groups. Notwithstanding operational considerations, such as minimum shipment size, allocation will respect the fundamental principle that all Self-Financing Participants and Funded Participants should receive doses at the same rate to the extent possible. The Facility will allocate vaccines such that all Participants receive a fair and balanced allocation of Approved Vaccines across characteristics (e.g., price, immunisation schedule), acknowledging operational considerations. Whilst Participants are encouraged to develop national policies that align with the SAGE policy recommendations, Participants have the flexibility in the use of these doses according to national policies formulated on the basis of needs and context, provided that Funded Participants must use vaccines in accordance with requirements set out in the Gavi vaccine request form. Should there be demand and financing from Participants for additional vaccine to cover a higher share of their population than the initial indicative amount, this will be considered but not until all Participants have received their allotted doses in Phase 1. The Allocation of additional doses during Phase 2 will also have regard

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	to the WHO Allocation Framework, which in Phase 2 applies a 'weighting' to dose allocation timing, taking into account the latest and best evidence regarding public health need, disease epidemiology, and understanding of transmission and risk. As in Phase 1, lack of funding or readiness by a Participant or set of Participants would not delay the distribution of vaccines to other Participants in Phase 2 and transition to Phase 2. Participants would be permitted to swap/trade vaccines which have been allocated to them, subject to operational considerations.
WHO Emergency Use Listing	It is envisaged that certain vaccines may be made available if they gain WHO Emergency Use Listing (EUL) or emergency use authorisation from a Stringent Regulatory Authority, prior to licensure and prequalification, with the ultimate goal of expediting the availability of these vaccines to people who need them. The WHO EUL process would take into consideration the WHO target product profile and SAGE recommendations.
Emergency buffer	An emergency buffer of vaccine (equivalent to 5% of the total number of doses of Approved Vaccine available to the Facility) shall be maintained. The buffer will be funded by the COVAX AMC and will be accessible to both Participants and economies not participating in the Facility and humanitarian actors. Access to doses from the buffer will be determined by an independent decision-making body. There will be an expectation of reimbursement of the cost of vaccine except for where the receiving economies are Funded Participants.
Participants' bilateral arrangements with manufacturers	Regarding <u>existing deals</u>: • The Facility recognises that some economies will come to the Facility with bilateral deals. The Facility welcomes these economies to join the Facility, recognizing that the Facility and Participants all benefit by having the greatest number of economies. • The existence of prior bilateral deals should not deter economies from joining the Facility and such economies would not have their allocation of vaccine from the Facility reduced. The Facility, however, has a duty to ensure that the founding principles of solidarity and equity remain intact for all Participants so that together, we bring the pandemic under control as quickly as possible.

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	• As a result, the Facility will work with Participants with bilateral deals on an individual basis to ensure they, and all other Participants, can benefit from the speed, scale, and access to COVID-19 vaccines that the COVAX Facility provides. As an example, the Facility and Participant could agree that if the Participant is receiving, or has received, vaccine from its own bilateral agreement, its allocation from the Facility would be delayed until other Participants have received a minimum amount of vaccine in order to support the principle of equity. Alternatively, for a Participant that may have an option to access additional vaccine from a manufacturer beyond what it needs, the Facility could collaborate to make this available to other Participants. The Facility welcomes and encourages such individual discussions. • The Facility requests transparency from Participants about any existing bilateral deals, e.g. regarding the volume and manufacturer. Regarding <u>future deals</u>: • The Facility discourages bilateral deal making by Participants, requesting that Participants work through the Facility. • Where a Participant does pursue a bilateral deal after joining the Facility, the Facility requires transparency from Participants about any new deals to enable a coordinated approach and (a) ensure that parties are not working at cross-purposes and (b) that benefits are maximised for all parties. • The Facility has a duty to ensure that the founding principles of solidarity and equity remain intact for all Participants so that together, we bring the pandemic under control as quickly as possible. As a result, the Facility will work with Participants who enter into a new bilateral deal on an individual basis to ensure they, and all other participants, can benefit from the speed, scale, and access to COVID-19 vaccines that the COVAX Facility provides.
Governance, Information and Reporting	The Governance arrangements for the Facility build on Gavi's existing Board and Committees, with new governance bodies established to ensure appropriate oversight. The details of the governance arrangements, including terms of engagement with civil society and other non-funded/non-funding participants, are still being refined as the Facility is established. However, the

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	principles and structures outlined in this section of the Principles will provide the framework for COVAX Facility governance. Existing governance bodies: • **Gavi Board**: Will be responsible for overseeing the role of Gavi in the implementation of the Facility to ensure consistency with the mandate given to it • **Gavi Alliance 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. The MSDC would receive scientific advice from the IPG. It is proposed that for review of COVAX-related agreements with manufacturers that the MSDC would also include representatives of Self-Financing Participants. • **Gavi Alliance Audit and Finance Committee:** Will be responsible for: (i) ensuring funding availability for Facility operations, including review of the financial implications of Facility-related transactions; and (ii) ensuring the Facility is properly represented in Gavi's annual Financial Report. New governance bodies and technical advisory groups: • A new oversight body would be established to oversee operational aspects of the Facility as related to Self-Financing Participants. Depending on the number of Self-Financing Participants, the Shareholders Council may establish a form of steering committee or executive committee to facilitate quick work and to liaise with the existing governance bodies to take key decisions with respect to the Facility. • **Shareholders Council (the "Council")**: Will include representation from all Self-Financing Participants and could include other stakeholders such as from the AMC Stakeholders Group. Self-Financing Participants in collaboration with Gavi would agree and establish the final terms of reference and operating procedures. At a minimum, the Council will provide strategic guidance on the activities of the Facility, in particular on areas related to the status of vaccines under development. The Council will also have an overview of the Facility's processes on dose

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	allocation in alignment with the WHO Allocation Mechanism. Information would be provided to the Council on a real-time basis.
Advisory Bodies	• **Independent Product Group ("IPG")**: Will be responsible for providing independent advice to the MSDC and the Facility on vaccine candidates, which will inform the selection of candidates to be funded by the Facility. The IPG will provide an assessment as to whether selected candidates have met threshold criteria for eventual purchase, reviewing the overall COVAX Facility portfolio on a rolling basis, taking into consideration updates related to clinical development, manufacturing and supply. Membership would comprise 5 – 7 independent experts with expertise in areas important for vaccine discovery, clinical trials, manufacturing and delivery. Drawing on the experience of the PCV AMC, it is proposed that these experts are appointed by a selection and oversight panel constituted of each of Gavi, WHO, CEPI in consultation with IFPMA and DCVMN. The panel would also manage potential conflict of interest issues, dismissal, selection and replacement of IPG members. The Facility will take advice from, and be informed by existing external advisory bodies: • The governance structure for the **WHO Allocation Mechanism** will be responsible for reviewing and analysing data and documentation, providing technical input and making dose allocation assessments in accordance with the final technical design, approved by Member States, of the WHO Allocation Framework. • **SAGE**: Will be responsible for advising WHO on vaccination policies and strategies for COVID-19 vaccines. In turn, WHO policies and recommendations will inform the Facility. • **CEPI Research, Development & Manufacturing Investment Committee ("RDMIC"):** Will be responsible for advising CEPI on portfolio strategy and investment decisions.
AMC Stakeholders Group	The AMC Stakeholders group will be established pursuant to an AMC stakeholders agreement, setting out the rights and obligations in relation to the AMC funds. The AMC Stakeholders Group will have representatives from AMC Donors, from

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	procurement organisations such as UNICEF and PAHO, from the COVAX AMC Group and multilateral development banks or regional banks involved in the financing of the AMC. It will include private sector and philanthropic donors that have provided at least US$10m in funding to the COVAX AMC. All AMC donors will receive additional and specific reporting relating to progress achieved against the objectives of the AMC and AMC Donors will participate in the Gavi Board through existing donor representation.
Costs of the Facility	The costs of administering the Facility will be covered as part of each Self-Financing Participants' commitment and through contributions from the AMC. This will be set out in the Commitment Agreements and Grant Agreements respectively.
Principles of collaboration with other purchasing pools	The Facility would be interested in exploring collaboration opportunities in support of the common goal of equitable global vaccine access. Collaboration would be based on advancing a common set of goals that include: • supporting and advocating for open flow of information and vaccine products (including raw materials) across borders; and • promoting establishment of diverse and broad portfolios of vaccine candidates through transparency in respective investments.
Sign-up period	Participants are required to join the Facility by 31 August 2020, the initial sign-up period. Where potential Participants cannot obtain financing within the initial sign-up period, the potential Participant may join the Facility by signing a Commitment Agreement which is conditional on the potential Participant obtaining adequate financing by 15 September.
Duration	The Facility is envisaged to be in place: • for the Self-Financing Participants: up to 3 years for Phase 1 and an additional timeframe for Phase 2 dependent on agreement between the Office of the COVAX Facility and Participants; and • for the COVAX AMC Group: to be defined with AMC stakeholders and based on need but could be ~10 years.
Events of termination	The Gavi Board may terminate the Facility if:

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	• there are no Approved Vaccines manufactured by December 2023; or • all Participants have been allocated their initial Committed Amounts and there is no demand for further doses.
Return of any surplus funds	At the end of Phase 1 and the end of Phase 2 (and on termination of the Facility), Gavi will redistribute unutilised funds to the Self-Financing Participants and COVAX AMC Donors who do not wish to continue to participate in the Facility, taking into account the Participants' level of commitment.
Language	The English language version of these Principles of Participation shall prevail if there is a conflict between the English language version and a translated version.

Annex 1: Glossary of Terms

Term	Meaning
Advance Purchase Commitment	An agreement between Gavi and a vaccine manufacturer, whereby Gavi commits to the purchase of a defined number of Approved Vaccines, if developed.
Allocation Framework	The rules which govern the allocation of vaccines to Participants, as developed by WHO.
Allocation Mechanism	The Allocation mechanism is the means by which the Allocation Framework becomes operational. Whilst still undergoing development, it will include an independent body that considers a variety of inputs relevant to the allocation of doses and makes an assessment of dose allocation for Participants.
API	Active Pharmaceutical Ingredient.
Approved Vaccine	A vaccine against COVID-19 in respect of which Gavi has entered an Advance Purchase Commitment and which has, at minimum, licensure/authorisation in place from a Stringent Regulatory Authority, WHO prequalification or has been issued authorisation for emergency use based on a national emergency use process or WHO Emergency Use Listing (EUL).
BMGF	The Bill & Melinda Gates Foundation.
Commitment Agreement	The Agreement between Gavi and Self-Financing Participants setting out the basis on which the Participant is joining the Facility and the legally binding commitments which it is making.
Committed Amount	The amount of money which a Participant commits to the Facility, which is equal to the Estimated Cost per regimen multiplied by a number equal to 20% of the population of the Participant economy.
COVAX AMC Donors	Economies and private individuals / institutions who make donations to the COVAX AMC.
COVAX AMC Group	80 low income and lower middle-income economies based on 2018 and 2019 World Bank GNI data and the 12 other World Bank IDA eligible economies (92 economies in total) eligible for AMC support.
DCVMN	Developing Countries Vaccine Manufacturers Network.
Funded Participant	A COVAX AMC Groupeconomy an approved request for funding support for a COVID-19 vaccine.

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Grant Agreement	The Agreement between Gavi and COVAX AMC Donors setting out the basis on which donors are contributing to the COVAX AMC.
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations.
Official Development Assistance	Government aid designed to promote the economic development and welfare of developing countries
PAHO	Pan American Health Organization.
Participant	Any: • party who signs a Commitment Agreement with Gavi; or • a Funded Participant.
PCV AMC	The pneumococcal conjugate vaccine Advance Market Commitment.
Phase 1	The phase up until each Participant has been allocated their initial indicative amounts.
Phase 2	The point after each Participant has been allocated their initial indicative amounts, at which point Participants may have the option to make further commitments.
Stringent Regulatory Authority or SRA	A stringent regulatory authority as defined by reference to WHO's list of stringent regulatory authorities, as updated from time to time.
WHO Emergency Use Listing	An extraordinary process in the case of a public health emergency for the review of quality, safety and efficacy of vaccines to provide guidance to interested UN procurement agencies and national regulatory authorities of relevant WHO member states.
WHO Prequalification	Prequalification is a service provided by WHO to assess the quality, safety and efficacy of medical products for priority diseases and which are intended for UN and international procurement to developing countries.