

COVAX Facility Terms and Conditions for Participants

These “**Terms and Conditions**” set out the basis on which self-financing economies will participate in the COVID-19 Vaccine Global Access Facility (the “**COVAX Facility**” or “**Facility**”).

It is intended that these Terms and Conditions will be attached to and referenced in the Commitment Agreements relating to the COVAX Facility to be entered into between Gavi and each economy wishing to participate in the Facility.

Each Participant will be expected to sign a Commitment Agreement, specifying its choice between two arrangements: the Commitment Agreement for the Committed Purchase Arrangement or the Commitment Agreement for the Optional Purchase Arrangement. Other than as specified herein, these Terms and Conditions apply to both arrangements. Any differences between the two arrangements are clearly presented in these Terms and Conditions. Capitalised Terms are defined in the document or in the Glossary, attached at Annex 1.

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The COVAX Facility	<p>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 economies. 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 purchase vaccine doses for the COVAX AMC eligible economies through Official Development Assistance funding, as well as through support from foundations, private donors and concessional funds from multilateral development banks. The COVAX AMC helps ensure that the COVAX AMC eligible economies can participate in the Facility and access vaccines through it. The remaining economies are expected to fully self finance their participation in the Facility.</p> <p>Recognising that under a business-as-usual approach it could take years to develop effective vaccines and even more years to ensure these vaccines reach everyone that needs them, the COVAX Facility will accelerate this timeline 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.</p>

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Guiding principles of the COVAX Facility	<p>The implementation of the Facility will be guided by the following principles:</p> <ul style="list-style-type: none"> • Global Access – Protecting global health security means ensuring that all Participants can secure access to a safe and efficacious vaccine. Economies of all financial means can participate with the degree of support for the COVAX AMC eligible economies 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 the Facility 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 with 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.. • 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 the Coalition for Epidemic Preparedness Innovations (“CEPI”) (COVAX partner), Bill and Melinda Gates Foundation (“BMGF”) and other bilateral and philanthropic investments. Manufacturers will be requested to disclose any funding they received from a third party to facilitate R&D or incentivise scale-up. As the Facility enters into manufacturer-specific agreements, the Facility will consider any previous funding received by the manufacturers in contractual conditions.
Goals of the Facility	<p>The goals of the Facility are to:</p> <ul style="list-style-type: none"> • 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

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	<p>are ultimately made available and the supply will be sufficient for highest priority populations globally;</p> <ul style="list-style-type: none"> • deliver at least 2 billion doses of Approved Vaccines by the end of 2021; • guarantee access to Approved Vaccines for every participating economy in the world; and • end the acute phase of the pandemic by the end of 2021.
Host and Administrator	<p>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 COVID-19 vaccines for all Participants, the goals of the Facility are complementary to, and will enhance, Gavi’s mission and strategic goals.</p>
Role of Gavi as administrator of the COVAX Facility	<p>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:</p> <ul style="list-style-type: none"> • enter into Commitment Agreements with the Participants, including tri-partite agreements with multilateral development banks and other parties, as relevant; • enter into agreements 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; • select the most promising vaccine candidates with input from COVAX partners (CEPI, WHO) and informed by the guidance, based on technical assessment, of experts on the COVAX Independent Product Group (“IPG”). Such assessment shall be based on regular assessment of the vaccine development pipeline, 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 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 provide regular reporting to the Shareholders Council on manufacturer transactions, including costs associated with such

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	<p>transactions, as well as administrative fees involved in managing the Facility;</p> <ul style="list-style-type: none"> • share available information with Participants on the quality, safety, efficacy and other characteristics of each vaccine candidate in a timely and efficient manner. Where possible, the Facility will provide to Participants information relevant to the regulatory approval process; • convene the IPG, and with the support of CEPI and WHO, provide regular updates on the pipeline of candidate vaccines, latest policy recommendations and evidence, and assessments of specific candidates to the IPG in order to receive expert advice and enable the Office of the COVAX Facility to include suitable candidates in the Facility's portfolio of vaccine candidates; • convene the Procurement Reference Group (see further below), with the support of UNICEF SD (the procurement coordinator), and provide information on selected candidate vaccines' commercial attributes, such as pricing and timeline of supply availability, to the Procurement Reference Group; • convene the Joint Allocation Task Force, which will have primary responsibility for preparing the allocation proposals based on data-driven considerations in partnership with CEPI and WHO; • provide financial services and, on a 6-monthly basis, prepare a financial report on the use and balance of funds from the Participants, to be independently verified by Gavi's external independent auditors or another recognised accounting firm; • facilitate access and enter into agreements with pooled procurement mechanism (for example, the UNICEF Supply Division and PAHO Revolving Fund) for interested Participants; and • perform all other administrative functions necessary for the proper functioning of the Facility.
<p>Non-Financial Considerations of all Participants</p>	<p>Participants will purchase Vaccine Doses from the manufacturer on the basis of the Advance Purchase Commitments. All relevant national policies, procedures, regulations 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 Vaccine Doses, Participants, where possible under national laws, should enable the following:</p>

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	<ul style="list-style-type: none"> • no interference in movement of Vaccine Doses and medical supplies required for vaccine administration from domestic manufacturers to intended recipient Participants or to the COVAX AMC eligible economies; • regulatory clearance for COVID-19 vaccines supplied through the Facility by making use of collaboration with and reliance upon SRAs to facilitate the pathway to authorisation for emergency use/ licensure; and • contributions of national surveillance, vaccine impact studies, safety data, 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.
Liability & Indemnity	<p>Participants will be responsible for deployment and use of vaccines within their territories and assuming any liability associated with such use and deployment.</p> <p>Prior to shipping vaccines to Participants, it is likely that vaccine manufacturers will require Participants to provide an indemnity against product liability claims. The Facility would expect that indemnification would not apply if an injury associated with the vaccine resulted from wilful misconduct or gross negligence of the manufacturer or from a defect in the vaccine due to non-compliance with terms of the marketing authorization, cGMP, or the like.</p> <p>Some vaccine manufacturers may require other protections against product liability claims, such as, for the Participant to have in place a no-fault compensation scheme or legislative limitations on liability. Understanding that Participants would have different domestic laws with respect to these issues, and that what works for one Participant may not work for another, the Facility will be transparent with Participants on the manufacturer requirements on these issues and will work with Participants on the best approach to liability and indemnity issues.</p>
Participant Cost Structure	<p>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:</p> <ul style="list-style-type: none"> • Ex-factory costs: a pass-through model will apply. The Facility will negotiate a price with manufacturers and this same price will be applied transparently to Participants purchasing the products; prices applied by manufacturers could be tiered or flat. A portion of these ex-factory costs

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	<p>are expected to be paid to manufacturers in advance of licensure through Advance Purchase Commitments and would be applied to the purchase of doses.</p> <ul style="list-style-type: none"> • 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 include for example: <ul style="list-style-type: none"> ○ costs associated with insurance to mitigate risk to enable the Office of the COVAX Facility to enter into Advance Purchase Commitments in excess of the total commitments for doses received from Participants to account for R&D attrition; ○ interest associated with any potential debt financing raised by the Office of the COVAX Facility and backed by financial commitments made by Participants. The financing would be used to make payments to manufacturers before licensure as e.g., manufacturing reservation fees and Advanced Purchase Commitments. The debt financing allows the Facility to reduce the magnitude of down payments required from Participants subscribing to the Committed Purchase arrangement without sacrificing speed/access; ○ Facility operating costs (expected to be ~0.2% of total Facility costs).
<p>Commitments of Participants subscribed to the Committed Purchase Arrangement</p>	<p>Participants subscribed to the Committed Purchase Arrangement will make a binding financial commitment of the Committed Amount. The Committed Amount shall be the Weighted Average Estimated Cost per Dose (as defined below) multiplied by 2 (expected number of doses per person required on average in the regimen) multiplied by the requested share of the Participant's Population to be vaccinated. Participants may commit to purchase doses to cover between 10% to 50% of their Population through the Facility. In return, the Facility will make best efforts to procure the elected number of doses on the Participant's</p>

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	<p>behalf, subject to availability and at the earliest possible opportunity.</p> <p>Each Participant will be required to provide a Financial Guarantee (\$8.95 per dose) equal to the Weighted Average Estimated Cost per Dose net of the Down Payment per dose, which is equal to the total financial exposure the Facility is taking on its behalf. This Financial Guarantee is expected to be received within 21 days following receipt of the signed Commitment Agreement. Each Participant's Commitment Agreement will provide details about the requirement for the financial institutions providing the Financial Guarantees. The Financial Guarantee will decrease over time as the financial exposure decreases through the purchase of Vaccine Doses through the Facility.</p> <p>The all-inclusive "Weighted Average Estimated Cost per Dose", consisting of the three cost components described above, is US\$10.55. The all-inclusive Estimated Costs per Dose 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 and is calculated on an estimated weighted average price across this portfolio. Participants would ultimately purchase Vaccine Doses at the actual price offered by each manufacturer. In some cases, manufacturers may require tiering of prices or offer prices, which may exceed the Estimated Costs per Dose.</p> <p>Execution of a Commitment Agreement by a Participant subscribing to the Committed Purchase option will commit the Participant to purchase Approved Vaccines of a value up to the Committed Amount. Participants will make payments as follows:</p> <ul style="list-style-type: none"> • Participants will be required to provide to the Office of the COVAX Facility signed Commitment Agreements. . • The Participant must make an initial payment of \$1.60 per dose (the "Down Payment"). The Down Payment is made to Gavi and is expected to be received in cash or cash equivalent instruments. It enables the Facility to make payments associated with the access/speed premium, financing/risk mitigation and operating costs. • As Vaccine Doses become available, Participants will be issued allocations of Approved Vaccine and are required to purchase these allocated doses at an "Adjusted Cost per Dose". This is composed of the actual procurement price per dose and if necessary, an adjustment to reflect

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	<p>final access/speed premium, financing/risk mitigation and operational costs. Payment associated with the purchase of Vaccine Doses would be to the procurement agent or manufacturer and subject to the terms therein, while any other payments would be to Gavi;</p> <ul style="list-style-type: none"> • The Adjusted Cost per Dose may be higher or lower than the Weighted Average Estimated Cost per Dose. If the Adjusted Cost per Dose is lower than the Weighted Average 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 Weighted Average Estimated Cost per Dose, Participants will not be required to make payments in excess of the Committed Amount. However, Participants will have the option to purchase the full number of doses envisaged in the Commitment Agreement for the required additional cost; • A Participant will indicate in the Commitment Agreement if it is not willing to receive Approved Vaccine above a price double the all-inclusive Weighted Average Estimated Cost per Dose (i.e., \$21.10). In such a scenario, the Facility would not reserve doses on said Participant's behalf that exceed this price limit. This could delay the time it takes for a Participant to receive Vaccine Doses or a Participant may lose access to a vaccine with characteristics suitable for specific populations; • Participants may have the option to trade allocated Vaccine Doses on the proposed COVAX Exchange . <p>Participants will purchase Approved Vaccines either through their own processes or leveraging existing mechanisms such as UNICEF Supply Division or PAHO Revolving Fund and would be subject to the terms of the arrangement between the Participant and the procurement agent or manufacturer. Any cost associated with utilising such a mechanism is not included in cost estimates and will need to be separately met by the Participant.</p>
<p>Commitments of Participants subscribed to the Optional Purchase Arrangement</p>	<p>Participants to the Optional Purchases Arrangement will be required to indicate the number of doses to be procured through the Facility (the "Number of Doses") expressed as an absolute number of doses corresponding to the percentage of the Participant's Population that the Participant seeks to cover assuming a 2-dose regimen. The Participant's indicated Number of Doses divided by the total number of doses that the Facility</p>

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	<p>intends to procure based on demand from all Participants defines the Participant's "Pro Rata Share". Participants to the Optional Purchases Arrangement may indicate to the Office of the COVAX Facility their willingness to commit to purchase doses to cover between 10% to 50% of their population through the Facility.</p> <p>Participants to the Optional Purchases Arrangement will be required to make an "Upfront Payment" to the Facility equivalent to the Number of Doses multiplied by \$3.10/dose. This payment will fully cover the Participant's pro rata share of the Facility's estimated pre-approval manufacturing costs, which includes the speed/access premium and a portion of the ex-factory costs, as well as a pro rata contribution towards the Facility's operating costs. In return, the Facility will make reasonable best efforts to procure the Number of Doses on the Participant's behalf, subject to availability and at the earliest possible opportunity.</p> <p>Participants to the Optional Purchases Arrangement will also be required to make a "Risk-sharing Guarantee" equal to the Number of Doses multiplied by \$0.40 per dose to cover potential residual liabilities resulting from the unlikely scenario that Gavi's risk mitigation measures have been insufficient to absorb the liability resulting from Participants waiving options for doses that Gavi has committed to purchase from manufacturers. Examples of these risk mitigation measures include agreements with manufacturers that have high proportions of options to purchase doses, the proposed COVAX Exchange, and the ability for Participants to opt-out before deal signature. The Guarantee will be released should Gavi not incur such liabilities during the term of the Facility or once doses have been procured to satisfy the Committed Amount.</p> <p>The Guarantee is expected to be received 21 days following receipt of the signed Commitment Agreement. Each Participant's Commitment Agreement will provide details about the requirement for the financial institutions providing the Guarantees.</p> <p>The cost per dose value for the Upfront Payment 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.</p> <p>Execution of a Commitment Agreement for the Optional Purchase Arrangement will require a Participant to make the Upfront Payment, but the Participant will not be obligated to buy any vaccine subsequently and will have the option to opt-out from</p>

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	<p>specific vaccine candidates that do not align to national vaccination strategies. Terms are as follows:</p> <ul style="list-style-type: none">• On execution of the Commitment Agreement, the Participant must before Friday 9 October make the Upfront Payment to Gavi, which enables it to make payments to manufacturers to enter into Advance Purchase Commitments as well as to cover risk mitigation and operating costs;• Before signature of an agreement with manufacturers, Participants in the Optional Purchases Arrangement will be offered a window in which to indicate their interest in purchasing vaccines from the relevant manufacturer. If a Participant notifies the Office of the COVAX Facility that it is not interested in purchasing vaccines from the relevant manufacturer, it will not be issued any potential options to procure doses resulting from said agreement;• As each agreement with a manufacturer is concluded, Participants will receive options to purchase vaccine corresponding to their Pro Rata Share net of the Participant's pro rata share of vaccine already paid for through payments made to the manufacturer before licensure ("Prepaid Doses"). Together the number of Prepaid Doses and the number of options constitute the Participant's total allocation. Participants may be able to trade these options on the COVAX Exchange (described in more detail below) or exercise them at the actual ex-factory cost per dose;• Exercise of options allocated to a Participant for a certain vaccine candidate will entitle the Participant to also receive any Prepaid Doses from that vaccine candidate. If a Participant does not exercise an option, the Participant may be able to trade the Prepaid doses on the proposed COVAX Exchange. If the Prepaid doses cannot be traded, then the Participant will forfeit these Prepaid doses.• Participants will purchase Approved Vaccines either through their own processes or leveraging existing mechanisms such as UNICEF Supply Division or PAHO Revolving Fund and would be subject to the terms of the arrangement between the Participant and the procurement agent or manufacturer. Any cost associated with utilizing such a mechanism is not included in cost

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	<p>estimates and will need to be separately met by the Participant.</p>
<p>Engagement with manufacturers</p>	<p>The following principles will apply when engaging and contracting with vaccine manufacturers:</p> <ul style="list-style-type: none"> • Volume Commitments: <ul style="list-style-type: none"> ○ 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). 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.). ○ For procurement, the Vaccine must be an Approved Vaccine or have been issued authorisation for emergency use by an SRA based on a national emergency use process or WHO Emergency Use Listing (EUL). ○ Seek options for additional doses (i.e., commitment for X doses with option to buy additional Y doses), especially for more expensive product technologies. • Transparency: manufacturers will be asked to provide transparency to the Office of the COVAX Facility, on technical details of the characteristics, safety, efficacy, and quality data of their vaccine candidates. The Facility will provide this information to Participants in the most timely and efficient manner possible. In addition, manufacturers will be asked to disclose any push funding received and supply agreements it has entered into with other parties. The Office of the COVAX Facility shall take into consideration any such funding in its negotiations with

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	<p>manufacturers. The Facility will strive to provide transparency to Participants on details of agreements with manufacturers to the fullest extent possible.</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <p>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 its investments to directly generate doses and/or reduce the cost of vaccine for distribution by the COVAX Facility, some CEPI-funded projects may fail due to the attrition associated with early stage vaccine development. CEPI will seek to mitigate that risk by supporting development of additional candidates with the potential to meet COVAX goals in terms of speed and scale. Additionally, CEPI will seek access agreements from partners receiving R&D funding that secure commitments of doses or manufacturing capacity for the Facility.</p>
Product Choice	<p>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 product preferences, however, it may not always be possible given the likely supply constraints, as well as other relevant factors. Trading on the proposed COVAX Exchange could allow Participants to further exert product choice.</p>

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	<p>Participants of the Optional Purchase Arrangement would only be allocated doses from vaccine candidates that they have chosen.</p>
Vaccine allocation	<p>Vaccines available through the Facility will be allocated to Participants. There are many unknowns as yet including how many vaccines candidates will succeed, how many countries will sign up to access vaccines through the Facility, what will be the final cost of the vaccines or how ready a Participant will be to take up a vaccine when supplies become available. As a result, for planning purposes, the Facility is targeting to secure 2 billion doses by the end of 2021 to be equally distributed to economies supported with funding from the COVAX AMC and self-financing economies, with a small (5%) buffer to be held for humanitarian emergencies and acute outbreaks.</p> <p>In alignment with the WHO Allocation Framework, initial doses will be offered to all Participants with the intention to enable the rapid immunization of the front-line workers in health and social care settings (estimated to be approximately 3% of the population of Participants). Once all Participants have been offered their initial doses, vaccines will be allocated as they are produced until all Participants receive their indicative amounts. Where Participants have committed to more doses than for 20% of their population, any additional doses shall be offered after other Participants have received their initial 20% or their requested share (if lower than 20%), subject to the availability of funding, from Participants as well as funding for the COVAX AMC-eligible economies. Lack of funding or readiness by a Participant or from the AMC or COVAX AMC eligible economies would not delay the distribution of vaccines to other Participants.</p> <p>The number and type of Approved 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. Allocation will respect the fundamental principle that all Participants and AMC eligible economies should receive doses at the same rate to the extent possible notwithstanding operational considerations, such as minimum shipment size, which will be specified by procurement agents and/or manufacturers.</p> <p>The Facility will allocate vaccines such that all Participants receive a fair and balanced allocation of Approved Vaccines across</p>

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	<p>characteristics (e.g., price, immunisation schedule), acknowledging operational considerations.</p> <p>While Participants are encouraged to develop national policies that align with the SAGE policy recommendations, Participants may use doses according to national policies.</p> <p>The Allocation of additional doses during Phase 2 will also refer 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 may delay receipt of doses if required.</p> <p>Participants would be permitted to swap/trade vaccines which have been allocated to them, subject to operational considerations.</p>
Trading of vaccine	<p>The COVAX Facility intends to support Participants in exchanging and trading their vaccine allocations to optimise each Participant's portfolio in line with national interests. This may be facilitated through a "COVAX Exchange", which would allow Participants to trade their vaccine allocations to the extent possible taking into account regulatory or territorial restrictions. The proposed COVAX Exchange would be co-created with Participants. A Participant may be invited to offer vaccine doses secured through its own bilateral agreements with manufacturers on the proposed COVAX Exchange at the discretion of the Office of the Facility.</p>
WHO Emergency Use Listing	<p>It is envisaged that certain vaccines may be made available if they gain WHO Emergency Use Listing (EUL) or emergency use authorisation from an SRA, 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. If Participants agree to accept EUL vaccine, such doses will be counted against their share under the allocation. In addition, Participants:</p> <ul style="list-style-type: none"> • Commit to comply with WHO SOP on EUL vaccines • Acknowledge that there is no guarantee for these doses to get licensure or PQ

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Participants' bilateral arrangements with manufacturers	<p>Regarding existing deals:</p> <ul style="list-style-type: none"> • The Facility recognises that some Participants will come to the Facility with bilateral deals. The Facility welcomes these Participants to join recognizing that the Facility and Participants all benefit by having the greatest number of Participants involved. • The Facility requests transparency from Participants about bilateral deals (e.g. regarding the volume and manufacturer), subject to any obligations of confidentiality which the Participant is subject to under such bilateral supply agreements. <p>The Facility would also like to coordinate with Participants with existing or future 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. Access to doses from bilateral deals will not impact access to the agreed allocation of doses from the Facility.</p>
Governance, Information and Reporting	<p>The Governance arrangements for the Facility build on Gavi's existing Board and Committees, with new governance bodies established to ensure appropriate oversight of the Facility. The design of these arrangements is guided by the principles of the COVAX Facility and aims to ensure agile, transparent, efficient and responsive governance</p> <p>Existing governance bodies will serve the COVAX Facility as follows:</p> <ul style="list-style-type: none"> • 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. It is proposed that for review of COVAX-related agreements with manufacturers that the MSDC would also include representatives of the 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; (ii) ensuring the Facility is properly represented in Gavi's annual Financial Report;

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	<p>and (iii) appointing an independent financial auditor to ensure an independent financial audit of the Facility's activities.</p> <p>New governance bodies and technical advisory groups will be established as follows:</p> <ul style="list-style-type: none"> • A new Shareholders Council (the "Council"), comprising all Participants, will provide strategic guidance on the administration of the COVAX Facility. The Council will receive regular updates on vaccine development, vaccine allocation, and will be consulted regularly by Gavi leadership. Depending on the size and preference of the Council, it may decide to establish a smaller, representative Executive body to enable close engagement with the Office of the COVAX Facility on administration of the COVAX Facility. As a self-organising body, the Council may establish its own operating procedures – including frequency of meetings, engagement of other stakeholders, and the basis on which members of the Executive body will be agreed. These operating procedures could be agreed at the first meeting of the Council. The Shareholders Council may elect to raise additional funding for the Facility in the event it determines that there is a need.
Advisory Bodies	<ul style="list-style-type: none"> • Independent Product Group ("IPG"): Will be responsible for providing independent technical advice to the Facility to 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 relevant areas. Drawing on the experience of the PCV AMC, it is proposed that these experts are appointed by a selection and oversight panel constituted of representatives from Gavi, WHO, CEPI. The panel would also manage potential conflict of interest issues, dismissal, selection and replacement of IPG members. <p>Procurement Reference Group ("PRG"): Will be responsible for providing independent advice to the Facility on manufacturer offers, taking into consideration the</p>

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	<p>Facility procurement strategy and the state of the market. Membership would comprise 5 – 7 independent experts with expertise in areas important for strategic/public procurement and contracting, manufacturing and delivery, and demand forecasting. The PRG will be co-convened by Gavi and UNICEF SD, and the key procurement agents of the Facility (PAHO Revolving Fund and UNICEF SD) will be observers in the PRG.</p> <p>The Facility will take advice from, and be informed by existing external advisory bodies:</p> <ul style="list-style-type: none"> • 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 making investment decisions.
Costs of administering the Facility	The costs of administering the Facility will be covered as part of each Participants’ commitment. This will be set out in the Commitment Agreements.
Principles of collaboration with other purchasing pools	<p>The Facility would be interested in exploring collaboration opportunities in support of the common goal of equitable global vaccine access.</p> <p>Collaboration would be based on advancing a common set of goals that include:</p> <ul style="list-style-type: none"> • 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.

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Sign-up period	Participants are required to execute Commitment Agreements by 18 September 2020 and provide the Down Payment by no later than 9 October 2020.
Duration	The Facility is envisaged to be operational for an initial period of up to 3 years to enable supply under the Commitment Agreements and an additional timeframe dependent on agreement between the Office of the COVAX Facility and Participants.
Events of termination	The Gavi Board may terminate the Facility if: <ul style="list-style-type: none"> • 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	After the fulfilment of the commitments under the Commitment Agreement, the Office of the Facility will return their share of unutilised funds to the Participants..
Language	The English language version of these Terms and Conditions 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.
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 SRA and/or WHO prequalification.
BMGF	The Bill & Melinda Gates Foundation.
Commitment Agreement	The Agreement between Gavi and economies whiching to participate in the Facility setting out the basis on which the economy 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 the committed percentage of the population of the Participant economy.
COVAX AMC eligible economies	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.
Emergency Use Authorization	A process by which a Stringent Regulatory Authority approves the use of a vaccine under development for use during a public health emergency.
Financial Guarantee	The guarantee of all or part of the Committed Amount.
Office of the COVAX Facility	The Office of the COVAX Facility is a unit within Gavi (unless otherwise decided by Gavi's Board) responsible for administering the Facility
Official Development Assistance	Government aid designed to promote the economic development and welfare of developing countries

Term	Meaning
PAHO	Pan American Health Organization.
Participant	Any party who signs a Commitment Agreement with Gavi.
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.
Population	An economy's total population for 2019 as set out in the World Bank Data Bank.
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 unlicensed 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.