

## **COVAX Facility**

### **Terms and Conditions for Self-Financing 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 the Gavi Alliance (“**Gavi**”) and each self-financing economy wishing to participate in the Facility. The Commitment Agreement sets out which of these Terms and Conditions shall be binding on the Participant and Gavi and enforceable against one another.

Each Participant will sign one of two forms of the Commitment Agreement, specifying its choice between two types of purchase arrangements; there is a different form of Commitment Agreement for the Committed Purchase Arrangement and for the Optional Purchase Arrangement. Other than as specified herein, these Terms and Conditions apply to both purchase arrangements. Any differences between the two arrangements are presented in these Terms and Conditions.

Capitalised terms not otherwise defined in these Terms and Conditions shall have the meaning given in the glossary, attached at Annex 1.

No.		Terms and Conditions
1	<b>The COVAX Facility</b>	<p>The <b>COVAX Facility</b> 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 “<b>COVAX AMC</b>”, 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 longer 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</p>

No.		Terms and Conditions
		future vaccine procurement to increase the speed and scale of available vaccines once approved.
2	<b>Guiding principles of the COVAX Facility</b>	<p>The implementation of the Facility will be guided by the following principles:</p> <ul style="list-style-type: none"> <li>• <b>Global Access</b> – Protecting global health security means ensuring that all Participants and COVAX AMC Eligible Economies 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 by the COVAX AMC.</li> <li>• <b>Impact-oriented</b> – 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.</li> <li>• <b>Transparency</b> – The Facility promotes visibility into cost and fees and, therefore, the costs associated with the Facility will be made available to all Participants and COVAX AMC Eligible Economies.</li> <li>• <b>Solidarity and collective ownership</b> – 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.</li> <li>• <b>Complementarity with other funding</b> – The pull mechanisms used by the Facility will complement the push funding for R&amp;D provided by other stakeholders, such as the Coalition for Epidemic Preparedness Innovations (“<b>CEPI</b>”) (COVAX partner), Bill and Melinda Gates Foundation and other bilateral and philanthropic investments. Manufacturers will be requested to disclose any funding they received from a third party to facilitate R&amp;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.</li> </ul>
3	<b>Goals of the Facility</b>	The goals of the Facility are to:

No.		Terms and Conditions
		<ul style="list-style-type: none"> <li>• 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 for all Participants and COVAX AMC Eligible Economies;</li> <li>• deliver at least 2 billion doses of Approved Vaccines by the end of 2021;</li> <li>• guarantee access to Approved Vaccines for every participating economy; and</li> <li>• end the acute phase of the pandemic by the end of 2021.</li> </ul>
4	<b>Host and Administrator</b>	<p>The COVAX Facility will be administered by 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 and COVAX AMC Eligible Economies, the goals of the Facility are complementary to, and will enhance, Gavi's mission and strategic goals.</p>
5	<b>Role of Gavi as administrator of the COVAX Facility</b>	<p>As administrator of the Facility, Gavi will allocate human resources to support the Facility, which will be known as the “<b>Office of the COVAX Facility</b>”. The responsibilities of the Office of the COVAX Facility will be as follows:</p> <ul style="list-style-type: none"> <li>• enter into Commitment Agreements with the Participants, including tri-partite agreements with multilateral development banks and other parties, as relevant;</li> <li>• enter into agreements with individual vaccine manufacturers and developers to: (i) guarantee the purchase by Participants of; and/or (ii) provide for the option for Participants to purchase, a pre-defined number of doses of COVID-19 vaccines from each manufacturer or developer;</li> <li>• select the most promising vaccine candidates for Advance Purchase Commitments with input from COVAX partners (CEPI, WHO) and informed by the guidance, based on technical assessment, of experts on the IPG (as defined below). 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,</li> </ul>

No.		Terms and Conditions
		<p>geographic location of production, supplier) and to manage development and supply risks;</p> <ul style="list-style-type: none"> <li>• convene the Council (as defined below), and provide regular reporting to the Council on manufacturer transactions, including costs associated with such transactions, as well as administrative fees involved in managing the Facility;</li> <li>• share available information with Participants and COVAX AMC Eligible Economies on the quality, safety, efficacy and other characteristics of each vaccine candidate in the portfolio in a timely and efficient manner. Where possible, the Facility will provide Participants and COVAX AMC Eligible Economies with information relevant to the regulatory approval process;</li> <li>• convene the IPG and, with the support of CEPI and WHO, provide the IPG with regular updates on the pipeline of candidate vaccines, latest policy recommendations and evidence, and assessments of specific vaccine candidates in order to receive expert advice from the IPG and enable the Office of the COVAX Facility to include suitable vaccine candidates in the Facility's portfolio;</li> <li>• convene the PRG (as defined 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 PRG in order to receive expert advice from the PRG on procurement strategy for those vaccine candidates selected for inclusion in the Facility's portfolio based on advice of the IPG;</li> <li>• jointly with WHO, establish the Joint Allocation Taskforce which will operationalise the Allocation Mechanism by preparing allocation proposals based on data-driven considerations and aligned with the Allocation Framework;</li> <li>• provide financial services and, on a 6-monthly basis, prepare a financial report on the use and balance of funds from the Participants and COVAX AMC Eligible Economies, to be independently verified by Gavi's external independent auditors or another recognised accounting firm;</li> <li>• facilitate access and enter into agreements with pooled procurement mechanism (for example, the UNICEF SD and PAHO Revolving Fund) for interested Participants and COVAX AMC Eligible Economies; and</li> </ul>

No.		Terms and Conditions
		<ul style="list-style-type: none"> <li>perform all other administrative functions necessary for the proper functioning of the Facility.</li> </ul>
6	<b>Non-Financial Considerations of all Participants</b>	<p>Participants will, or will have the option to, purchase Approved Vaccine doses from manufacturers on the basis of the Advance Purchase Commitments. All relevant national policies, procedures, regulations and laws of the Participant shall remain matters for the individual Participants.</p> <p>To enable the smooth operation of the Facility and prevent undue delay in the shipment of Approved Vaccine doses, Participants, where possible under national laws, should ensure the following:</p> <ul style="list-style-type: none"> <li>no interference in movement of Approved Vaccine and medical supplies required for vaccine administration from domestic manufacturers to intended recipient Participants or to the COVAX AMC Eligible Economies;</li> <li>marketing authorisation approval 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</li> <li>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.</li> </ul>
7	<b>Liability &amp; Indemnity</b>	<p>Participants will be responsible for deployment and use of Approved Vaccines within their territories and assuming any liability associated with such use and deployment.</p> <p>Prior to shipping Approved 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 Approved Vaccine resulted from wilful misconduct or gross negligence of the manufacturer or from a defect in the Approved Vaccine due to non-compliance with, for example, terms of the marketing authorisation or cGMP.</p> <p>Some vaccine manufacturers may require other protections against product liability claims, such as, for the Participant to have a no-fault compensation scheme in place 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</p>

No.		Terms and Conditions
		these issues and will work with Participants on the best approach to liability and indemnity issues.
8	<b>Participant Cost Structure</b>	<p>The total cost which Participants will incur has three main components: ex-factory costs (i.e., the purchase price of Approved Vaccines charged by manufacturers); access/speed premium; financing/risk mitigation and operating costs. All Participants are expected to pay the same total cost per dose whether subscribing to the Committed Purchase Arrangement or the Optional Purchase Arrangement though the timing of payments differs between the two arrangements.</p> <ul style="list-style-type: none"> <li>• <b>Ex-factory costs (the “Actual Procurement Price”):</b> 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 are expected to be paid to manufacturers in advance of licensure through Advance Purchase Commitments and would be applied to the purchase of doses.</li> <li>• <b>Access/speed premium:</b> 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 and COVAX AMC Eligible Economies 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.</li> <li>• <b>Financing/risk mitigation and operating costs,</b> which include for example: <ul style="list-style-type: none"> <li>○ 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&amp;D attrition;</li> <li>○ interest associated with any potential debt financing raised by the Office of the COVAX Facility and backed by financial commitments made by Participants of the Committed Purchase Arrangement. The financing would be used to make payments to manufacturers before licensure as e.g.,</li> </ul> </li> </ul>

No.		Terms and Conditions
		<p>manufacturing reservation fees and Advance Purchase Commitments. The debt financing allows the Facility to reduce the magnitude of Down Payments (as defined below) required from Participants subscribing to the Committed Purchase Arrangement without sacrificing speed/access; and</p> <ul style="list-style-type: none"> <li>○ Facility operating costs (expected to be ~0.2% of total Facility costs).</li> </ul>
9	<p><b>Commitments of Participants subscribed to the Committed Purchase Arrangement</b></p>	<p><b>Participants of the “Committed Purchase Arrangement”</b> will be required to indicate the number of doses they wish to procure through the Facility (the “<b>Total Participant Doses</b>”). The Total Participant Doses will be 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. Participants may commit to purchase doses to cover between 10% to 50% of their Population through the Facility. Participants will make a binding financial commitment of the Committed Amount. The “<b>Committed Amount</b>” shall be the All-Inclusive Weighted Average Estimated Cost per Dose (as defined below) multiplied by the Total Participant Doses. In return, the Facility will endeavour to procure the elected number of doses on the Participant’s behalf at the earliest possible opportunity, subject to availability.</p> <p>Participants to the Committed Purchase Arrangement will be required to provide an initial Down Payment of \$1.60 per dose for the Total Participant Doses and a Financial Guarantee of \$8.95 per dose. This Financial Guarantee amount is equal to the All-Inclusive Weighted Average Estimated Cost per Dose net of the Down Payment per dose and is the estimated total financial exposure the Facility is taking on the Participant’s 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 Approved Vaccine through the Facility.</p> <p>The “<b>All-Inclusive Weighted Average Estimated Cost per Dose</b>”, consisting of the three cost components described under section 8, is \$10.55. The All-inclusive Weighted Average Estimated Cost per Dose is determined by the Office of the COVAX Facility based on proxy data and the latest available pricing information from manufacturer engagement for the portfolio of vaccines under</p>



No.		Terms and Conditions
		<p>consideration and is calculated on an estimated weighted average price across this portfolio. Participants would ultimately purchase Approved Vaccine at the actual price offered by each manufacturer. In some cases, manufacturers may offer tiering of prices. Manufacturers may also offer prices which may exceed the All-Inclusive Weighted Average Estimated Cost per Dose.</p> <p>Execution of a Commitment Agreement by a Participant subscribing to the Committed Purchase Arrangement will commit the Participant to purchase Approved Vaccines of a value up to the Committed Amount. Terms are as follows:</p> <ul style="list-style-type: none"> <li>• The Participant will be required to provide to Gavi a signed Commitment Agreement.</li> <li>• The Participant must make an initial payment of \$1.60 per dose (the “<b>Down Payment</b>”). The Down Payment is made to Gavi and is expected to be paid in cash. It enables the Facility to make payments associated with the access/speed premium, financing/risk mitigation and operating costs.</li> <li>• As doses of Approved Vaccine become available, Participants and COVAX AMC Eligible Economies will be issued allocations of Approved Vaccine and Participants are required to purchase these allocated doses at an “<b>Adjusted Cost per Dose</b>”. This is composed of the Actual Procurement Price and if necessary, an adjustment to reflect final access/speed premium, financing/risk mitigation and operational costs. Payment associated with the purchase of Approved Vaccine would be made to the procurement agent or manufacturer and subject to the terms therein, while any other payments would be to Gavi.</li> <li>• The Adjusted Cost per Dose may be higher or lower than the All-Inclusive Weighted Average Estimated Cost per Dose net of the Down Payment per dose. If the Adjusted Cost per Dose is lower than the All-Inclusive Weighted Average Estimated Cost per Dose net of the Down Payment per dose, Participants will purchase doses at the Adjusted Cost per Dose and would not need to pay their full Committed Amount. If the Adjusted Cost per Dose is higher than the All-Inclusive Weighted Average Estimated Cost per Dose net of the Down Payment per dose, Participants will not be required to make payments in excess of the Committed Amount. However, Participants will have the option to purchase additional doses up to the full number of doses</li> </ul>



No.		Terms and Conditions
		<p>indicated in the Commitment Agreement for the required additional cost.</p> <ul style="list-style-type: none"> <li>• A Participant will indicate in the Commitment Agreement if it is not willing to receive Approved Vaccines above a price that is equal to or greater than 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 that Participant's behalf that exceed this price limit. This could delay the time it takes for a Participant to receive doses of Approved Vaccines or a Participant may lose access to a vaccine with characteristics suitable for specific populations.</li> <li>• Participants may have the option to trade allocated doses of Approved Vaccines on the proposed COVAX Exchange (as defined below).</li> </ul> <p>Participants will purchase Approved Vaccines either through their own processes or leveraging existing mechanisms such as UNICEF SD or the 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>
10	<b>Commitments of Participants subscribed to the Optional Purchase Arrangement</b>	<p>Participants to the “<b>Optional Purchase Arrangement</b>” will be required to indicate the number of doses they wish to procure through the Facility (the Total Participant Doses). The Total Participant Doses will be 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. Participants may commit to purchase doses to cover between 10% and 50% of their Population through the Facility. The Participant's indicated Total Participant Doses divided by the total number of doses that the Facility intends to procure based on demand from all Participants (across the Committed Purchase Arrangement, the Optional Purchase Arrangement and the COVAX AMC) defines the Participant's “<b>Pro Rata Share</b>”.</p> <p>Participants to the Optional Purchase Arrangement will be required to make an “<b>Upfront Payment</b>” to the Facility equivalent to the Total Participant Doses multiplied by \$3.10/dose, which is equivalent to \$6.20/person. 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</p>

No.		Terms and Conditions
		<p>contribution towards the Facility's operating costs. In return, the Facility will endeavour to procure the Total Participant Doses on the Participant's behalf at the earliest possible opportunity, subject to availability. A regional organisation could provide payments on behalf of its Member States.</p> <p>The cost per dose for the Upfront Payment has been determined by the Office of the COVAX Facility based on proxy data and the latest available pricing information from manufacturer engagement for the portfolio of vaccines under consideration. While the Upfront Payment for the Optional Purchase Arrangement is larger than the Down Payment for the Committed Purchase Arrangement, the All-Inclusive Weighted Average Estimated Cost per Dose is expected to be the same for both arrangements. Any unspent portion of a Participant's Upfront Payment will be refunded to the Participant (see "Return of any surplus funds" below).</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 obliged to purchase any vaccine subsequently and will have the ability to decide which specific vaccine candidates it will purchase, for example, based on alignment to national vaccination strategies. Terms are as follows:</p> <ul style="list-style-type: none"> <li>• The Participant must make the Upfront Payment to Gavi by no later than 9 October 2020, which enables Gavi to make payments to manufacturers to enter into Advance Purchase Commitments as well as to cover risk mitigation and operating costs.</li> <li>• Before signature of an Advance Purchase Commitment with a manufacturer, Participants in the Optional Purchase Arrangement will be offered a window in which to indicate their interest in purchasing Approved Vaccine from the relevant manufacturer. If a Participant notifies the Office of the COVAX Facility that it is interested in purchasing Approved Vaccine from the relevant manufacturer, it will be issued Purchase Options to procure Approved Vaccine that result from the relevant Advance Purchase Commitment. If a Participant notifies the Office of the COVAX Facility that it is not interested in purchasing Approved Vaccine from the relevant manufacturer, it will not be issued any potential options to procure doses resulting from said Advance Purchase Commitment. A decision in respect of one vaccine will not impact a Participant's Pro Rata Share for allocation of subsequent Approved Vaccine.</li> </ul>

No.		Terms and Conditions
		<ul style="list-style-type: none"> <li>• After each agreement with a manufacturer is executed, Participants will receive from Gavi a <b>“Purchase Option”</b> to purchase vaccine corresponding to their Pro Rata Share net of the Participant’s Pro Rata Share of Approved Vaccine already paid for through payments made by Gavi to the manufacturer before licensure (<b>“Prepaid Doses”</b>). The timeframe in which Participants will receive Approved Vaccine under the Purchase Options and the Prepaid Doses will be determined by Gavi acting in accordance with the Allocation Framework. Together the number of Prepaid Doses and the number of doses to be purchased pursuant to the Purchase Options constitute the Participant’s total allocation. Participants may be able to trade these Purchase Options and Prepaid Doses on the proposed COVAX Exchange (described in more detail below) or exercise them at the Actual Procurement Price. If the Participant does not exercise its Purchase Options, it will not be obliged to purchase the associated vaccine doses.</li> <li>• These Purchase Options provide Participants of the Optional Purchases Arrangement a second window to decide on a certain vaccine candidate, which coincides with the point at which the Facility confirms orders with manufacturers (the <b>“Option Exercise Window”</b>). If after attempting to trade on the proposed COVAX Exchange, a Participant chooses not to acquire any doses from a vaccine candidate during the Option Exercise Window, then the Participant will also forfeit their allocation of Prepaid Doses from such candidate. Likewise, exercise of Purchase Options for a certain vaccine candidate will entitle the Participant to also receive any Prepaid Doses from its allocation with no additional payment.</li> <li>• The Facility will seek to ensure Participants of the Optional Purchase Arrangement are still able to be allocated their Total Participant Doses (less the Prepaid Doses which, as set out above, are forfeited if a Participant exercises an option not to purchase a vaccine during the Option Exercise Window) even where they have exercised an option not to purchase a vaccine, but Participants recognise that in this case there may be a delay in receiving their doses of Approved Vaccine.</li> <li>• Participants of the Optional Purchase Arrangement will also be required to provide a <b>“Risk Sharing Guarantee”</b> for the Risk Sharing Guarantee Amount to cover potential residual</li> </ul>

No.		Terms and Conditions
		<p>liabilities resulting from the waiver of Purchase Options for doses that Gavi has committed to purchase from manufacturers. The scenario would only materialize should Gavi's risk mitigation measures prove insufficient to absorb these liabilities. Examples of these risk mitigation measures include: (i) entering into agreements with manufacturers whereby Gavi has the option rather than an obligation to purchase doses, (ii) the proposed COVAX Exchange (see further details below); and (iii) the ability for Participants to decide whether to be included in a manufacturer agreement before deal signature (i.e. before allocation of Purchase Options). Should a Participant exercise its Purchase Options such that it has received its Total Allocated Doses (i.e. refrain from exercising its ability to decide not to purchase a vaccine during the Option Exercise Window), the Facility would release its Risk Sharing Guarantee without drawing upon it. The Facility would only draw upon a Participant's Risk Sharing Guarantee if Gavi incurred a liability resulting from that Participant's decision to exercise an option not to purchase a vaccine.</p> <ul style="list-style-type: none"> <li>• The Risk Sharing Guarantee shall be provided by Participants within 21 days of executing the Commitment Agreement. If a Participant does not provide its Risk Sharing Guarantee within the deadline, then Gavi may either: (i) following an assessment of the Participant's risk profile and creditworthiness, terminate the relevant Commitment Agreement; or (ii) elect that the Participant will not receive Purchase Options and therefore the ability to decide whether to purchase vaccine during the Option Exercise Window from any agreement with manufacturers that it is party to. Instead, that Participant will be committed to purchase its Pro Rata Share of Approved Vaccine resulting from any manufacturer agreement that it is party to.</li> <li>• Participants will purchase Approved Vaccines either through their own processes or leveraging existing mechanisms such as UNICEF SD or the 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 estimates and will need to be separately met by the Participant.</li> </ul>
11	<b>Engagement with</b>	The following principles will apply when engaging and contracting with vaccine manufacturers:

No.		Terms and Conditions
	manufacturers	<ul style="list-style-type: none"> <li>• <b>Volume Commitments:</b> <ul style="list-style-type: none"> <li>○ 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 of the Committed Amounts received from Participants subscribing to the Committed Purchase Arrangement and the Upfront Payments received from Participants subscribing to the Option Purchase Arrangement (acknowledging the likelihood that a number of vaccine candidates will be unsuccessful). In all cases the liability of each Participant subscribing to the Committed Purchase Arrangement 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.).</li> <li>○ For procurement, the Vaccine must: (i) be an Approved Vaccine; or (ii) if agreed by a Participant or COVAX AMC Eligible Economy, have an Emergency Use Authorisation or WHO Emergency Use Listing (see further detail below).</li> <li>○ Seek options for additional doses (i.e., commitment for X doses with option to buy additional Y doses), especially for more expensive product technologies.</li> </ul> </li> <li>• <b>Transparency:</b> 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 at the time Gavi enters into Advance Purchase Commitments and on an ongoing basis as additional data becomes available. The Facility will support the provision of relevant information to Participants and COVAX AMC Eligible Economies in the most timely and efficient manner possible. In addition, manufacturers will be asked to disclose details of any push funding received and any supply agreements it has entered into with other parties. The Office of the COVAX Facility shall</li> </ul>

No.		Terms and Conditions
		<p>take into consideration any such funding in its negotiations with manufacturers. The Facility will strive to provide transparency to Participants and COVAX AMC Eligible Economies on details of agreements with manufacturers to the fullest extent possible.</p> <ul style="list-style-type: none"> <li>• <b>Intellectual property:</b> 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.</li> <li>• <b>Indemnification:</b> the Facility acknowledges that manufacturers may require Participants and COVAX AMC Eligible Economies to provide a form of indemnity or certain other protections against product liability claims (see “Liability and Indemnity” above). The Facility will seek to manage the protections that Participants and COVAX AMC Eligible Economies are required to provide as part of the negotiations with manufacturers.</li> <li>• <b>Tailored agreements:</b> the Facility will develop agreements tailored to individual negotiations with manufacturers that optimise outcomes for the Facility, Participants and COVAX AMC Eligible Economies.</li> </ul>
12	<b>Engagement with CEPI</b>	<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&amp;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 typically 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</p>



No.		Terms and Conditions
		agreements from partners receiving R&D funding that secure commitments of doses or manufacturing capacity for the Facility.
13	<b>Product Choice</b>	<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> <p>Participants in the Optional Purchase Arrangement would only receive doses from vaccine candidates that they have chosen.</p>
14	<b>Vaccine allocation</b>	<p>Recognising that the Facility will be operating in a supply constrained environment for some period of time, a consistent methodology is required to decide how available vaccine supply is allocated to Participants and COVAX AMC Eligible Economies. The Facility will apply the Allocation Framework as the basis for allocation decisions, subject to periodic review by Participants and COVAX AMC Eligible Economies. While the Allocation Framework helps sequence the allocation of Approved Vaccines during a period of supply constraint, it does not influence the total quantity of Approved Vaccine allocated to a Participant as agreed in its Commitment Agreement nor does it redistribute Approved Vaccine from one Participant to another. Though a core objective of the Allocation Framework is to promote fair and equitable access for all, no dose will go idle and a lack of funding or readiness on the part of one Participant, COVAX AMC or COVAX AMC Eligible Economy will not delay the allocation of doses to other Participants or COVAX AMC Eligible Economies.</p>
15	<b>Trading of Approved Vaccines / Proposed COVAX Exchange</b>	<p>The COVAX Facility intends to support Participants in exchanging and trading their Approved Vaccine allocations, for example, to optimise each Participant's portfolio in line with national vaccine strategies. 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 COVAX Facility.</p>
16	<b>Emergency Use Authorisation or WHO</b>	<p>It is envisaged that certain vaccines may be made available if they gain WHO Emergency Use Listing or Emergency Use Authorisation, prior to licensure and prequalification, with the ultimate goal of expediting the availability of these vaccines to people who need them. The WHO Emergency Use Listing process</p>



No.		Terms and Conditions
	<b>Emergency Use Listing</b>	<p>would take into consideration the WHO target product profile and SAGE recommendations. If Participants and COVAX AMC Eligible Economies agree to accept a WHO Emergency Use Listing vaccine, such doses will be counted against their share under the allocation. In addition, Participants:</p> <ul style="list-style-type: none"> <li>• Commit to comply with WHO Standard Operating Procedures on WHO Emergency Use Listing vaccines; and</li> <li>• Acknowledge that there is no guarantee for these doses to get licensure or prequalification.</li> </ul>
17	<b>Participants' bilateral arrangements with manufacturers</b>	<p>Regarding existing and future deals:</p> <ul style="list-style-type: none"> <li>• The Facility recognises that some Participants and COVAX AMC Eligible Economies will come to the Facility with bilateral deals. The Facility welcomes these Participants and COVAX AMC Eligible Economies to join recognising that the Facility, Participants and COVAX AMC Eligible Economies all benefit by having the greatest number of Participants and COVAX AMC Eligible Economies involved. The Facility has a duty to ensure that the founding principles of solidarity and equity remain intact for all Participants and COVAX AMC Eligible Economies so that together, we bring the pandemic under control as quickly as possible.</li> <li>• While access to doses from bilateral deals will not impact a Participant's or COVAX AMC Eligible Economy's access to the agreed allocation of doses of Approved Vaccine from the Facility, the Facility requests transparency from Participants and COVAX AMC Eligible Economies about bilateral deals – existing and future – (e.g. regarding the volume and manufacturer), subject to any obligations of confidentiality which the Participant or COVAX AMC Eligible Economy is subject to under such bilateral supply agreements. The Facility would not disclose this information to any other parties.</li> </ul> <p>The Facility would also like to coordinate with Participants and COVAX AMC Eligible Economies with existing or future bilateral deals on an individual basis:</p> <ul style="list-style-type: none"> <li>• To ensure they, all other Participants and COVAX AMC Eligible Economies, can benefit from the speed, scale, and access to COVID-19 vaccines that the COVAX Facility provides;</li> <li>• To explore opportunities to partner for mutual benefit, i.e. fungibility in complementary deals.</li> </ul>

No.		Terms and Conditions
18	<b>Governance, Information and Reporting</b>	<p>The governance arrangements for the Facility build on Gavi's existing board (the "<b>Gavi Board</b>") 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>A new <b>Shareholders Council (the "Council")</b>, comprising representatives of all Participants, will provide strategic guidance on the administration of the 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 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 Council may elect to raise additional funding for the Facility in the event it determines that there is a need.</p> <p>Existing governance bodies will serve the Facility as follows:</p> <ul style="list-style-type: none"> <li>• <b>Gavi Board:</b> Will be responsible for overseeing the role of Gavi in the implementation of the Facility to ensure consistency with the mandate given to it</li> <li>• <b>Gavi Alliance Market Sensitive Decisions Committee ("MSDC"):</b> 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.</li> <li>• <b>Gavi Alliance Audit and Finance Committee:</b> 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; and (iii) appointing an independent financial auditor to undertake an independent financial audit of the Facility's activities.</li> </ul>

No.		Terms and Conditions
19	Advisory Bodies	<ul style="list-style-type: none"> <li data-bbox="523 253 1396 817"> <b>Independent Product Group (“IPG”)</b>: Will be responsible for providing independent technical advice to the Facility to inform the selection of vaccine candidates in respect of which the Facility will pursue supply agreements. The IPG will review 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. </li> <li data-bbox="523 831 1396 1272"> <b>Procurement Reference Group (“PRG”)</b>: Will be responsible for providing independent advice to the Facility on the procurement strategy for those vaccines that are selected for inclusion in the Facility’s portfolio based on the advice of the IPG. 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. </li> </ul> <p data-bbox="523 1285 1396 1361">The Facility will take advice from, and be informed by existing external advisory bodies:</p> <ul style="list-style-type: none"> <li data-bbox="523 1391 1396 1630"> The governance structure for the <b>Allocation Mechanism</b> 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 Allocation Framework. </li> <li data-bbox="523 1644 1396 1803"> <b>“SAGE”</b>: 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. </li> <li data-bbox="523 1816 1396 1928"> <b>CEPI Research, Development &amp; Manufacturing Investment Committee</b>: Will be responsible for advising CEPI on portfolio strategy and making investment decisions. </li> </ul>

No.		Terms and Conditions
20	<b>Costs of administering the Facility</b>	The costs of administering the Facility will be covered as part of Participants' commitments or Upfront Payments. This will be set out in the Commitment Agreements.
21	<b>Principles of collaboration with other purchasing pools</b>	<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"> <li>• supporting and advocating for open flow of information and vaccine products (including raw materials) across borders; and</li> <li>• promoting establishment of diverse and broad portfolios of vaccine candidates through transparency in respective investments.</li> </ul>
22	<b>Sign-up period</b>	Participants are required to execute Commitment Agreements by 18 September 2020 and provide the Down Payment or Upfront Payment (as applicable) by no later than 9 October 2020.
23	<b>Duration</b>	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.
24	<b>Events of termination</b>	<ul style="list-style-type: none"> <li>• The Gavi Board acting together with the Council may terminate the Facility if there are no Approved Vaccines manufactured by December 2023; or</li> <li>• The Gavi Board may terminate the Facility if all Participants have been allocated their Total Participant Doses and there is no demand for further doses.</li> </ul>
25	<b>Return of any surplus funds</b>	After the fulfilment of the commitments under the Commitment Agreements, the Office of the COVAX Facility will return their share of unutilised funds to the Participants.
26	<b>Language</b>	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
<b>Advance Purchase Commitment</b>	An agreement between Gavi and a vaccine manufacturer, whereby Gavi commits to the purchase of a defined number of Approved Vaccines, if developed.
<b>Allocation Framework</b>	The rules which govern the allocation of vaccines to Participants and COVAX AMC Eligible Economies, as developed by WHO, subject to periodic review by Participants and COVAX AMC Eligible Economies.
<b>Allocation Mechanism</b>	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 and COVAX AMC Eligible Economies.
<b>Approved Vaccine</b>	A vaccine against COVID-19 in respect of which Gavi has entered an Advance Purchase Commitment and which has WHO Prequalification or on an exceptional basis, at a minimum, licensure/authorisation in place from an SRA.
<b>cGMP</b>	Current good manufacturing practices.
<b>Commitment Agreement</b>	The Agreement between Gavi and economies wishing 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.
<b>COVAX</b>	The vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator.
<b>COVAX AMC Eligible Economies</b>	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.
<b>Emergency Use Authorisation</b>	A process by which a Stringent Regulatory Authority approves the use of a vaccine under development for use during a public health emergency.
<b>Financial Guarantee</b>	The guarantee of all or part of the Committed Amount.
<b>Office of the COVAX Facility</b>	The Office of the COVAX Facility is a unit within Gavi (unless otherwise decided by the Gavi Board) responsible for administering the Facility.

<b>Term</b>	<b>Meaning</b>
<b>Official Development Assistance</b>	Government aid designed to promote the economic development and welfare of developing countries.
<b>PAHO Revolving Fund</b>	The revolving fund of the Pan American Health Organization.
<b>Participant</b>	Any party who signs a Commitment Agreement with Gavi.
<b>PCV AMC</b>	The pneumococcal conjugate vaccine advance market commitment.
<b>Population</b>	An economy's total population for 2019 as set out in the World Bank Data Bank as of 27 August 2020.
<b>Risk Sharing Guarantee Amount</b>	An amount equal to the product of USD 0.40 and the Total Participant Doses.
<b>SRA</b>	A stringent regulatory authority as defined by reference to WHO's list of stringent regulatory authorities, as updated from time to time.
<b>UNICEF SD</b>	UNICEF Supply Division
<b>WHO Emergency Use Listing</b>	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 United Nations procurement agencies and national regulatory authorities of relevant WHO member states.
<b>WHO Prequalification</b>	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 United Nations and international procurement to developing countries.