Q&A from the COVAX Procurement & Delivery Workshop, 14 January 2021

Question	Answer
1. What are the next steps in the process for Self-Financing Participants (SFPs), including Self-Procuring Participants (SPPs)? **2. When should SPPs contact the manufacturer(s)?** **3. What reporting is required to COVAX?**	After COVAX signs an Advance Purchase Commitment (APC) with a manufacturer, **all SFPs, with either an Optional Purchase agreement or a Committed Purchase agreement**, will receive an information pack (as part of Window 2 for the former group and around the same time for the latter group), which includes key APC terms and specific supply terms as shared by the manufacturer. In addition to the above, **SFPs with an Optional Purchase agreement** will need to indicate to COVAX if they want to opt-in or opt-out of receiving the specific vaccine. If **SPPs with an Optional Purchase agreement** opt-in by the close of Window 2, they will then receive the manufacturer contact details to initiate early engagement to settle any Participant-specific terms (such as supply arrangements and Indemnification and Liability agreement) in advance. However, they are not to issue Purchase Orders (PO) until they receive their allocation. **SPPs with a Committed Purchase agreement** will receive manufacturer contact details together with their allocation. **SFPs that want to procure via UNICEF or PAHO** should inform COVAX and UNICEF and PAHO of such as soon as possible, if they have not already done so. Otherwise, the next step for **all COVAX Participants** will occur when they are informed of their allocation. All Participants will be informed of their allocation by the Office of the COVAX Facility in coordination with the COVAX Procurement Coordinator (UNICEF). Upon receiving their allocation, **SPPs** should: • **Contact the manufacturer** of the allocated vaccine and settle any Participant-specific terms, agree on delivery date(s) and place their PO directly with the manufacturer within the designated allocation period (4-6 weeks). *(Note: SPPs should give the manufacturer permission to share data on orders/deliveries/batches with COVAX Procurement Coordinator (UNICEF) in order to facilitate the*

	work of the COVAX facility.) A Summary Term Sheet will be provided with the allocation, as reference for finalizing these agreements with the manufacturer (see **question 18** below). • In case of any major delay beyond the designated period (4-6 weeks) in settling terms with the manufacturer or issuing the PO(s), the SPP should reach out to the COVAX Procurement Coordinator (UNICEF) for support. In case of delays in delivery, the COVAX Procurement Coordinator (UNICEF) should be informed. • Participants will need to sign an indemnification and liability agreement, obtain regulatory approval or waiver, import license placement and finally place the PO(s) within the designated allocation period (4-6 weeks). If there are delays beyond this period, the allocated quantities may be subject to reallocation. **All SPPs** then **report** the following to COVAX: • Once the PO(s) are issued, the SPP should inform the COVAX Procurement Coordinator (UNICEF) of the quantities (which should be identical to the allocations received) and requested delivery dates of their PO(s), factoring in manufacturer lead times. • Upon receipt of the doses, the SPP should inform the COVAX Procurement Coordinator (UNICEF) of the quantities and date(s) delivery. • Once the SPP has paid the manufacturer(s) invoice they should inform the Office of the COVAX Facility (Gavi) of the price per dose, total payment amount, and date of payment. **All SPPs should inform the COVAX Procurement Coordinator (UNICEF) of their Procurement Focal Point.** Following notification of allocation, **SFPs and AMC Participants procuring through UNICEF or PAHO** should plan the delivery schedule(s) (based on supply availability) with UNICEF and PAHO. SFPs will receive an estimated price (cost estimate or price estimate) and expected availability to facilitate transfer of funds to UNICEF or PAHO, which will trigger their issuance of POs (also following confirmation of regulatory acceptance, import license (as required), and indemnification and liability agreement between the Participant and the manufacturer). (*Note: If a country is not able to make funds available during the specified allocation round time period, there will be at risk of losing allocated doses and have to wait for the next round. In order to ensure timely availability of funds and to minimize risk of not processing allocated doses for*

	countries due to insufficient availability of funds, PAHO is requesting participating countries to consider to make advances based on financial projections). SFPs procuring through UNICEF should contact UNICEF (Alekaw Tegegne, Procurement Services Specialist (ategegne@unicef.org)) to receive an overview of the process and provide Participant-specific information in advance of procurement. SFPs procuring through the PAHO Revolving Fund should contact Oscar Vargas, Procurement Specialist (vargasos@paho.org).
4. When will vaccines be available to COVAX participating economies?	Vaccines in the COVAX portfolio are expected to be available starting in February with availability scaling up throughout the year. The COVAX Global Supply Forecast is available here, and Participant specific forecasts will be shared at the end of January and updated regularly. (*Note: caveats apply to the Global Supply Forecast that could impact actual timing and scale of availability, including vaccine candidate attrition, regulatory approval, manufacturing scale up, delivery readiness at country level, actual allocations, etc*.) The COVAX portfolio currently includes agreements (APCs) with five manufacturers; active negotiations with others are ongoing. Additionally, Long Term Arrangements (LTAs) with UNICEF and PAHO, which operationalize the APCs for Participants procuring through UNICEF and PAHO, are still under negotiation. The current status of APCs by manufacturer is as follows. (*Note: approval of products is manufacturing site-specific for all regulators. This is why in some cases a product may appear approved by a certain national regulatory authority but if the offered product to COVAX is from a manufacturing site that is not yet approved, the product is not yet approved*.) • **Pfizer / BioNTech**: The vaccine that will be provided to COVAX will be produced in Europe. The vaccine has received emergency approval by the U.S. Food and Drug Administration (FDA), the UK Medicines and Healthcare Products Regulatory Authority (MHRA), European Medicines Evaluation Authority (EMEA), and other NRAs. The WHO EUL was granted on 31 December 2020. Doses are expected to start being available from February. Note that doses during 1Q will be minimal.

	• **AstraZeneca (AZ)**: The vaccine that will be supplied to COVAX will be manufactured in multiple locations and therefore is under review by the European Medicines Evaluation Authority (EMEA), the China National Medical Products Association (NMPA), and the Korean Ministry of Food and Drug Safety (MFDS), as well as WHO. It is expected that the first reviews could be completed by end February, with vaccines available thereafter. • **Serum Institute of India (SII) / AZ**: The vaccine that will be supplied to COVAX will be manufactured in India. It has been approved by the Drugs Controller General of India and is currently being reviewed by WHO. It is expected that the review will be concluded and vaccine available in February, however based on the nature of SII/AZ licensing agreements, only a subset of AMC Participants are eligible to this vaccine under COVAX. • **SII / Novavax**: The vaccine that will be supplied to COVAX will be manufactured in India. It is expected that the outcome of regulatory reviews of this vaccine will conclude in Q2, with supply available from mid-year. • **Janssen** / **J&J**: The Phase III trial of the vaccine is underway and the expected outcome of regulatory reviews for this vaccine is expected in Q2, with supply available from mid-year. • **Sanofi / GlaxoSmithKline (GSK)**: The vaccine that will be supplied to COVAX will likely be manufactured in Europe and the U.S. The Phase I/II trial of the vaccine is underway and the regulatory reviews for this vaccine are expected towards end of the year.
5. What is the role of UNICEF and PAHO?	UNICEF and PAHO are the COVAX designated procurement agencies. In addition, UNICEF is appointed as the COVAX Procurement Coordinator. While PAHO will purchase on behalf of all interested Member States from the Region of Americas, UNICEF will serve other Regions. UNICEF and PAHO support SFPs with procurement through their normal procurement services. They are establishing LTAs with manufacturers that operationalize the COVAX APCs and from which subsequent purchase orders will be placed for Participant deliveries. For more information about procuring through UNICEF or PAHO, please see:

	UNICEF: https://www.unicef.org/supply/procurement-services PAHO: https://www.paho.org/en/resources/paho-revolving-fund
6. How is the COVAX portfolio of vaccine being established?	The portfolio of COVAX is being developed by the Office of the COVAX Facility with expert advice at two key moments of the process in order to have a portfolio that ensures rapid and equitable access: the selection of products and the establishment of commercial terms of COVAX APCs. An Independent Product Group (IPG) advises on the selection of products. The IPG reviews data and information relating to vaccine candidates and provides independent technical advice to COVAX that informs the selection of candidates to be prioritized for deal making in the COVAX portfolio. Building on the technical advice of the IPG, the Procurement Reference Group (PRG) provides advice to COVAX on commercial aspects to ensure an appropriately risk managed COVAX portfolio considering vaccine candidate probability of success, timelines for delivery, commercial terms and broader market conditions. Negotiations for APCs build on the advice from the IPG and the PRG. The final proposed terms for APCs are submitted for review and approval by the Market Sensitive Decisions Committee (MSDC) of the Gavi Board prior to contracting.
7. What are the main challenges and how will these be mitigated for meeting the ambitious timelines for procurement and delivery?	As of 18 January, COVAX has agreements in place to access nearly two billion doses of several promising vaccine candidates. At least 1.3 billion donor-funded doses will be made available to 92 economies eligible for the Gavi COVAX AMC, targeting at least 20% population coverage by the end of the year. This represents a major scale-up in terms of vaccine manufacturing, participant capacity, as well as the COVAX ecosystem. Scaling up of manufacturing is a technical process that always has some level of risk. This, along with progress with achieving regulatory approvals, will be monitored closely and any issues will be communicated. The scale up capacity of manufacturers included in the COVAX portfolio has been assessed so that the risks can be better managed and mitigated. Given the scale and speed, it is not possible to eliminate all risks.

	Preparation and early action at participant level for procurement and delivery will also ease the roll-out (for example, streamlining national registration processes and ensuring legislation for countries to take on indemnification and liability). All actors working together to ensure efficient processes is also key. The COVAX facility has mapped the critical path and will work closely with the COVAX Procurement Coordinator (UNICEF) and main procurement agents, UNICEF and PAHO, to ensure timely access.
8. How is the allocation process done? **9. Will we receive more than one allocation?** **10. What is the current status of allocations?**	WHO is leading the allocation process for the COVAX Facility. There are two phases of the allocation process: • Phase 1: proportional allocation up to 20% of the population. **It is expected that we will be in Phase 1 for most of 2021.** • Phase 2: weighted allocation beyond 20%, based on vulnerability and COVID-19 threat (to be applied if supply is still severely constrained) Participant information, including requested number of doses, and the vaccine supply availability will be input into the WHO Allocation Algorithm, along with various other criteria. The main objective of the allocation process is to ensure equity and efficient/timely use of available doses considering country readiness and programmatic considerations/preferences. The output of the Allocation Algorithm will then be reviewed and assessed by the Joint Allocation Taskforce (JAT) which will come up with Vaccine Allocation Decision (VAD) Proposal for recommendation by the Independent Allocation Vaccine Group (IAVG). Participants will be notified in due course. Information on the COVAX allocation process is available here: https://www.who.int/publications/m/item/allocation-mechanism-for-covax-facility-vaccines-explainer Participants will receive allocations, based on supply availability and rounds of the Allocation Algorithm execution, until they have received all the doses they requested. WHO will try to allocate from the same manufacturer, but this may not always be possible. All allocations assume vaccine quantities for a fully vaccinated allocated target population (e.g. 2 dose regimen). WHO, together with COVAX partners, is finalizing the Allocation Algorithm.

	COVAX is cognizant of Participants' need for information to plan in-country delivery of vaccine, and hence are aiming to run an interim allocation to provide participants with more certainty.
11. What information will be included when allocations are shared?	The following information will be shared with each Participant's allocation. • Number of doses allocated • Name of vaccine • Name of vaccine manufacturer • Manufacturing sites for doses allocated • Time window available for each participant to place a PO (4-6 weeks) In addition, SPPs will receive a Summary Term Sheet developed by the COVAX Procurement Coordinator (UNICEF) that includes APC contract provisions and LTA supply terms agreed to by the manufacturer for the product allocated as well as Point of Contact with the manufacturer. The COVAX Facility anticipates the Summary Term Sheet can be leveraged by SPPs in the establishment of Supply Agreements / POs. If Participants need documentation for national registration, this information should be requested from the manufacturer.
12. When will SFPs receive technical information on the vaccine to support programmatic planning?	**SFPs with an Optional Purchase agreement** will receive technical information on the vaccine at Windows 1 and 2. **SFPs with a Committed Purchase agreement** will receive technical information on the vaccine at similar times as SFPs with an Optional Purchase agreement.
13. Can Participants state their preference for a vaccine, manufacturer or a manufacturing site?	AMC Participants and some SFPs have provided information on the preferred characteristics of vaccines. However, due to limited availability of supplies, product preferences may not be able to be accommodated. Optional purchasers can opt out of a specific vaccine and committed purchasers had the opportunity to opt out of vaccines costing over $21.10. These opt-outs will be upheld. Opting out of a vaccine may delay access timelines, depending on actual availability of other products.

14. If there is excess supply available, can a SFP opt for a higher percentage of vaccines than originally requested?	If a COVAX SFP is interested in increasing the quantities in their agreement, they should inform their COVAX focal point and covax@gavi.org. A mechanism for offering additional doses has not yet been decided but is under review. Any additional quantities would be allocated per the WHO Allocation Algorithm.
15. What information is available about the WHO regulatory approval process for COVID-19 vaccines?	Information on WHO regulatory processes is available here: **General information** Prequalification: https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/about/en/ Emergency use listing for vaccines: https://www.who.int/teams/regulation-prequalification/eul/ Additionally, WHO maintains a list of prequalified vaccines: https://extranet.who.int/pqweb/vaccines/list-prequalified-vaccines **COVID-specific information** Considerations for the assessment of covid-19 vaccines: https://www.who.int/publications/m/item/considerations-for-the-assessment-of-covid-19-vaccines-for-listing-by-who Product eligibility under the COVAX Facility: https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process (as of 11th Jan – to be regularly updated): https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX.pdf *(Note: In case a vaccine supplied to COVAX is produced in a different manufacturing site than the one that has achieved regulatory approval, then additional regulatory review is needed.)*
16. What information will be available to SPPs with Optional Purchase agreements at Window 2?	At Window 2, SPPs with Optional Purchase agreements will receive key APC terms, such as ex Factory vaccine price, indemnification & liability terms, and any other supplier specific terms as shared by the manufacturer, as well as manufacturer contact details. Additionally, they will receive information regarding their share of the overall volume (quantity) of the APC.

17. What information will be available to SPPs with Committed Purchase agreements prior to allocation?	Around the same time as Window 2, SPPs with Committed Purchase agreements will receive key APC terms, such as ex Factory vaccine price and indemnification and liability terms as well as any other supplier specific terms as shared by the manufacturer.
18. What documents will be provided to SPPs to support direct discussions and contracting with manufacturers?	SPPs will be provided with the following information to support direct discussions and contracting with manufacturers: - Key APC terms, by manufacturer, which include information such as ex Factory vaccine price, indemnification and liability terms (at Window 2) - Specific supply terms that apply to SPPs as indicated by manufacturer (at Window 2) - A Summary Term Sheet, by manufacturer, that summarizes key terms in UNICEF and PAHO Long Term Arrangements (LTA), such as incoterms for shipment, shipping documentation, etc. (with the Allocation) If a participant has questions or needs support in their discussion with the vaccine manufacturer, they can contact the COVAX Procurement Coordinator (UNICEF).
19. What happens if a SPP does not reach agreement with a manufacturer?	In case a SPP has a challenge in settling terms with the manufacturer, they can reach out to the COVAX Procurement Coordinator (UNICEF) for support. If there is significant delay and a PO is not placed within the time period indicated in the allocation decision, the allocated quantities may be subject to reallocation.
20. How will payments be made to manufacturers?	SPPs will make payments to manufacturers directly. SFPs procuring through UNICEF or PAHO will transfer money to UNICEF or PAHO in accordance with standard provisions to settle payment to manufacturers.
21. How will the upfront participation fee to COVAX be applied?	The upfront participation fee is used to fund upfront payments for manufacturers as well as overhead costs (including partner costs such as UNICEF's role as a COVAX Procurement Coordinator). Every deal will have a different percentage of upfront payments. For SFPs with Optional Purchase agreements, the COVAX Facility will use the upfront costs as a rolling fund to backstop the gap between Gavi signing commitments with manufacturers and individual Participants signing contracts with the manufacturers. Gavi will track and report to each SFP on the use of their funds.

	If at a point in time there is a requirement for more upfront participation fees the Facility will contact Participants. If at the end of the Facility term there is a balance remaining, the Facility will contact Participants and agree whether to return funds or procure more doses.
22. What is included in the APC vaccine price? What other costs do SFPs need to cover?	The APC terms include the ex Factory vaccine price. SFPs agree to pay the price established in the APCs (and per the LTA terms for Participants procuring through UNICEF and PAHO) for agreed volumes as per allocation decisions. The actual price may be different for a specific SPP, depending on the INCOTERMS agreed with the manufacturer. Operational and other supply costs (such as shipping, insurance, in-country distribution, syringes, etc.) are also to be covered by the SFP, whether procuring directly or through UNICEF or PAHO.
23. Delivery: Will there be any specific logistics / freight forwarding arrangements for COVAX, or is the expectation that SPPs need to arrange their own shipments?	Depending on the INCOTERMS agreed between the SPP and manufacturer, SPPs are responsible for organizing their shipments, either with the manufacturer or a Freight Forwarder. For SFPs procuring through either UNICEF or PAHO, deliveries will be organized via their standard practices.
24. What documents will accompany vaccine shipments?	Standard documentation should accompany vaccine shipments, such as Air Way Bill (AWB), Invoice, Packing List, National Release Certificate, Certificate of Analysis, Certificate of Origin, Summary Protocol, Certificate of Quality Assurance, and Batch Release Certificate.
25. Can a Participant request for later shipment if they have bilateral deals that can supply the vaccines earlier?	A Participant can defer their allocation if they are able to access vaccines earlier through bilateral deals. This will help other Participants that do not have bilateral channels access their vaccines earlier. The Participant should inform the Office of the COVAX Facility as early as possible. It should be noted that such a Participant will then be considered in later allocation rounds.
26. How will COVAX support Indemnification & Liability agreements between SFPs and manufacturers?	All COVAX Participants need to enter into a direct contractual relationship with respect to indemnity and liability with manufacturers, whether they procure directly from a manufacturer or indirectly through UNICEF or PAHO. If a SFP has negotiated a bilateral deal with a manufacturer outside of COVAX, the terms relating to indemnity in that bilateral agreement will apply to vaccines procured through the COVAX Facility from that same manufacturer.

	If a SFP does not have a bilateral agreement in place, manufacturers will present their standard terms to Participants to sign up to. For SPPs it is likely that the indemnity provisions will be set out in a broader supply agreement. For SFPs procuring via UNICEF/PAHO a separate indemnity agreement directly with the manufacturer will be required. If no agreement is reached between a SFP and a manufacturer, the manufacturer may delay or refuse to deliver allocated doses. Eventually, if no agreement is reached within the window of 4-6 weeks noted above, the vaccine will need to be reallocated.
Contact Information	Office of the COVAX Facility: covax@gavi.org COVAX Procurement Coordinator: procurement_coordinator@unicef.org UNICEF Procurement Services: Alekaw Tegegne, Procurement Services Specialist (ategegne@unicef.org) PAHO Revolving Fund: Oscar Vargas, Procurement Specialist (vargasos@paho.org)
Definitions	APC = Advance Purchase Commitment AMC = Advance Market Commitment EUL = WHO Emergency Use Listing I&L = Indemnification & Liability IAVG = Independent Allocation Vaccine Group IPG = Independent Product Group JAT = Joint Allocation Taskforce LTA = Long Term Arrangement MSDC = Market Sensitive Decisions Committee NRA = National Regulatory Authority OCF = Office of COVAX Facility PO = Purchase Order PQ = WHO Pre-Qualification PRG = Procurement Reference Group

	SFP = Self-financing Participant SPP = Self-procuring Participant VAD = Vaccine Allocation Decision