Annex A: Key details on allocation, procurement, pre-requisites, supply and delivery (AZ AMC)

Allocation process

Overview of the process

Participant information, including requested number of doses, and the vaccine supply availability is an 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 Participant readiness and programmatic considerations/ preferences. The output of the Allocation Algorithm is then reviewed and assessed by the Joint Allocation Taskforce (JAT) which will come up with the Vaccine Allocation Decision (VAD) Proposal for recommendation by the Independent Allocation Vaccine Group (IAVG). Participants will be notified in due course. 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).

First Allocation Round of AstraZeneca (AZ) AZD1222 vaccine

The first allocation round of AZD1222 vaccine doses follows the WHO fair and equitable allocation mechanism, and is subject to the validation of the Independent Allocation of Vaccine Group (IAVG).

The first round of AZD1222 vaccine doses are allocated from February to May. The timespan of the first allocation round does not include the month of June and thus covers only a portion of Participants' expected allocation for the first half of 2021 (H1) and that of the indicative allocation communicated on 29th January.

We invite you to consult the following link for more information on how COVAX vaccines are allocated amongst Participants.

Procurement

This first allocation round allows for the procurement process to be planned and implemented for phased deliveries. UNICEF and PAHO will be placing purchase orders, provided Participants have completed all pre-requisite steps noted below.

Pre-requisite steps

All of the following pre-requisite steps have to be completed in order to enable the delivery of AZD1222 doses.

- **Sign an Indemnification and Liability agreement** with AstraZeneca and forward a copy to the COVAX Facility. Confirmation that it is in place should be provided to COVAX support (covaxsupport@gavi.org). The COVAX Facility is helping to facilitate the process of getting these agreements executed between the supplier and Participant, in particular by supporting the signing process for AMC Participants. Please reach out to your Gavi Senior Country Manager or focal point if you have questions about this process, or need support in preparations to be able to sign these indemnity agreements, for example to **ensure that the required in-country legislative frameworks are in place to be able to enter into indemnity agreements with manufacturers.** AMC Participants can further refer to the slides and FAQ shared in December, following the AMC briefing on indemnity, compensation and cost sharing.

- **Issuing (and proof of issuance) of any national regulatory authorisation,** or proof of recognition or reliance on another type of regulatory approval, as well as an **import license provision** for relevant vaccine products to your respective procurement agency (PAHO Revolving Fund for the Region of Americas and UNICEF Supply Division for all other regions). The use of reliance on WHO PQ EUL in issuing a regulatory authorisation is also strongly encouraged.
- **For AMC Participants, ensure the completed NDVP has been uploaded** to the COVID-19 Partners Platform **and validated** by the Ministry of Health. Participant-specific feedback will be provided through the Partners Platform and WHO, UNICEF and technical partners will work with Participants to support further refinement of the NDVP if needed. A webinar overview of NDVP and allocation processes is available in English, French, and Spanish. Participants can connect, ask follow-up questions and share their views via a forum post and a Telegram channel dedicated to COVID-19 vaccine introduction.

Regulatory

COVAX Participants are encouraged to expedite their national regulatory processes, if additional steps are required in addition to WHO's Emergency Use Listing (EUL), by leveraging as much as possible the assessments done in the context of the Emergency Use Listing. The public reports are available here, and WHO is available to provide support to National Regulatory Authorities to issue the necessary regulatory authorisations. This support can be either accessed to the detailed assessment and the dossier stored on WHO's secured platform, in which case Participants need to sign a confidentiality agreement prior to accessing the platform, and/ or through specific sessions organised at the regional level. For any enquiries on accessing EUL assessments, Participants can reach out here: WHOEUL@who.int and for any enquiries on confidentiality agreements or any additional documentation needed, countries can reach out here: Luther Gwaza gwazal@who.int and Elisabeth Pluut pluute@who.int

Safe Injection Devices (Syringes and Safety Boxes)

Procurement of syringes and safety boxes may require a specific action, dependent on Participants' standard practices and procurement channel. Device procurement is separate to that of the vaccines and dependent on the procurement agent (UNICEF or PAHO RF).

For AMC Participants procuring through UNICEF SD/PAHO RF, devices will be shipped separately from the vaccines. For UNICEF countries indicating a need for shipment of devices by air for the first wave, provisions have been made based on the associated vaccine quantity. UNICEF will schedule shipments in accordance with vaccine allocations and will follow up directly with countries. Countries in the Americas should indicate their requirements and coordinate with PAHO RF for injection devices needs.

Supply & delivery timelines

The original indicative allocation of the AstraZeneca and the SII-AZ AZD1222 vaccines are firming up, with more than 80 million doses currently in pipeline for availability in Q1.

Once allocation is complete and required documents have been submitted to place a purchase order, the expected lead time is 3 weeks for AstraZeneca to process logistical preparation and have the vaccines ready for pick up, and export authorization to be processed. Shipping prioritization and additional logistics lead times must also be considered, which vary based on airline capacity availability and location of the Participant, among other factors.

Tax

The COVAX Facility will not cover the costs of any import duties or taxes applicable to these vaccines. Please note that by applying for these doses you have agreed to bear any tax liabilities and to ensure that vaccines allocated pursuant to the COVAX Facility can enter the country free of tax.