



COVAX REDEPLOYMENT POLICY

POLICY OVERVIEW

Redeployment is defined as the movement of COVAX distributed vaccine doses after they have been received in country, from one Participant to another Participant, for example due to the inability of the original receiving Participant to use the vaccine doses in question before their expiry.

With every effort made to coordinate with Participants on readiness and capacity before allocations, COVAX strongly discourages redeployment. Even with careful planning, transferring doses in accordance with international shipping protocols and with proper continuous temperature control is challenging and may expose the vaccines to unnecessary quality risks.

Nevertheless, COVAX and its partners stand ready to support Participants to ensure effective use of all received vaccines. WHO and UNICEF country-level technical support, as well as multiple funding approaches (e.g., Gavi bridge funding and Gavi COVID Delivery and Systems Strengthening funding), are available to help overcome implementation bottlenecks.

If all reasonable efforts to utilise the doses are not successful, COVAX will work with a Participant to explore the possibility for redeployment.

It is important to note that both the re-deploying and receiving Participant will face implications for allocations, eligibility for upcoming donations and redeployments, financial requirements and possibly, for the applicability of the COVAX No-Fault Compensation Program (“**NFC**”), depending on the contractual arrangements with the COVAX Facility and applicable circumstances. These are outlined in the section “Implications for Participants”, below.

POLICY STATEMENT

In order to effectively support Participants with absorption, Participants are requested to routinely monitor their utilisation rates of COVID-19 vaccines and regularly report to WHO through regional dashboards and e-JRF.

Furthermore, Participants are requested to abide by the following timelines:

- No later than 8-10 weeks prior to expiry date of any COVAX distributed vaccine doses, Participants are strongly encouraged to alert COVAX in writing of any risk of inability to fully absorb such doses before their expiry and potential possibilities for redeployment, in order to jointly identify solutions to accelerate utilisation with in-country and regional partners.
- No later than 6 weeks prior to the expiry date of any COVAX distributed vaccine doses, if it is likely that despite all efforts, such doses cannot be utilised prior to their expiry, Participants are required to formally communicate a written request to redeploy the quantity of doses in question through a formal letter to the Office of the COVAX Facility.

Provided that such alerts and requests are received in accordance with the above timelines, COVAX will make every effort to support the redeployment of doses in question but with no guarantees. Receipt of redeployment requests no later than 6 weeks prior to expiry is critical in order to ensure sufficient time to identify potential suitable recipients and allow at least one month of remaining shelf life at the time of receipt of the redeployed doses by the recipient Participant.

COVAX approval for redeployment will be dependent on a deploying Participant’s efforts to accelerate utilisation of all doses received through COVAX prior to their expiry, and on necessary steps having been taken to avoid wastage. Approval for redeployment is contingent on the following requirements:

- Redeployment will only be considered for a minimum of 10,000 doses
- Participants will need to obtain Gavi’s (on behalf of the COVAX Facility) approval for the redeployment, sign a tripartite agreement between the re-deploying Participant, the recipient Participant and Gavi, and COVAX Facility Terms & Conditions must be respected¹
- *Note: UNICEF Product Manager / Procurement Coordinator is responsible for informing the manufacturer of the pending redeployment. The decision to approve a redeployment is also dependent on the manufacturer’s approval*

¹ T&Cs make clear that exportation and resale are prohibited for COVAX distributed doses. COVAX distributed doses exported and redeployed without COVAX approval in accordance with this Redeployment Policy will be counted against the allocation of both deploying and receiving Participants. Redeployment of COVAX distributed doses to AMC Participants without prior approval of the COVAX Facility will make it impossible for the Claims Administrator of the COVAX NFC Program to determine whether a serious adverse event resulting in permanent impairment or death is associated with the administration of a redeployed dose. Hence, COVAX distributed doses redeployed without COVAX Facility’s approval shall not be covered by the COVAX NFC Program.

- Participants cannot earmark doses for redeployment to a specific recipient Participant
- Note: COVAX will aim to support the deploying Participant to redeploy doses to recipient Participants that have received the same vaccine, to limit the need for additional regulatory and I&L processes.*
- UNICEF/PAHO will be responsible for coordinating transport and logistics of approved redeployed doses in their capacity as procurement agencies of the COVAX Facility.
- Participants requesting redeployment will be required to provide the associated injection materials and commodities [such as needles and safety boxes] to the agreed recipient Participant, with doses being redeployed, unless the recipient Participant declines the need for materials.
- Doses being considered for redeployment must have been maintained in accordance with Good Storage and Distribution Practices (GSDP) and have remained stored at the redeploying Participant's central warehouse.
- Note: COVAX country partners (UNICEF, WHO and PAHO) will support the redeploying Participant to gather the relevant data to help assess the quality of the cold chain storage of the doses. Should the quality check highlight problematic temperature excursions, then WHO Performance Quality and Safety Team (PQS) will be informed to make a decision about the remaining shelf-life.*
- Recipient AMC Participants of redeployed doses must confirm that they have not received doses with the same batch number through other channels than COVAX [bilateral agreements or donations], in order for the Claims Administrator of the COVAX NFC Program to be able to determine whether a serious adverse event resulting in permanent impairment or death is associated with the administration of a COVAX distributed dose.

IMPLICATIONS FOR PARTICIPANTS

Implications for both the redeploying and receiving Participant depend on whether they are an AMC-eligible Participant or Self-Financing Participant (SFP). The different implications for Participants' allocation, eligibility for donations through the Gavi-administered COVAX Facility,

financial requirements and applicability of the COVAX NFC Program are outlined for each of the varying scenarios described below.

For COVAX-approved redeployments from one AMC Participant to another AMC participant, the implications are as follows:

- The allocation for the deploying Participant will be adjusted to account for redeployed doses (i.e. the deploying Participant's allocation is adjusted **downwards** by the number of redeployed doses going to another Participant). Furthermore, the deploying Participant will **not be caught up** in the next round (the round minimum will be allocated, but shipments will be sequenced later in the queue so long as utilisation issues remain). The allocation of the receiving Participant will also be adjusted to account for the redeployed doses (i.e. the recipient has their allocation adjusted **upwards** to reflect the additional doses received). This means the recipient will be allocated less in the next allocation round, again to align with other participants.
- In order to avoid potential wastage, in the short term, the deploying Participant will **not be eligible** for near-term dose donations and other redeployments of the same product until utilisation issues have been resolved. In order to ensure equity of allocation across Participants, in the short term, the receiving Participant will be **deprioritised** for near-term donations and other redeployments given receipt of the redeployed doses, but near-term donations and other redeployments will be considered if urgent needs remain.
- There will be no financial implications for the deploying or receiving Participant, and the COVAX NFC Program will continue to apply to the redeployed doses.

For COVAX-approved redeployments from an AMC Participant to a SFP, the implications for allocation and eligibility for donations or other redeployments will be as follows:

- The allocation for the deploying Participant will be the same as COVAX-approved redeployments from one AMC Participant to another AMC Participant (as noted above).
- The allocation of the receiving Participant (SFP) will **not** be adjusted to account for redeployed doses.

The financial requirements and implications for the applicability of the COVAX NFC Program are as follows:

- The COVAX Facility needs to be reimbursed for the cost of the doses, freight and devices by the AMC participant.²
- The SFP may need to also pay any price differential to the manufacturer.
- The SFP will need to fund any other costs that arise as no AMC funds are available to support SFP costs.
- The COVAX NFC Program, which only covers COVAX distributed doses administered within AMC-eligible economies, will not apply to redeployed doses in this circumstance.

If an AMC Participant redeploys to another AMC Participant or an SFP **without COVAX approval,** the implications for allocation and eligibility for donations or other redeployments will be the same as COVAX-approved redeployments from one AMC Participant to another AMC Participant (as noted above), with the following modifications:

- If the receiving Participant is an SFP, the allocation of the receiving Participant will not be adjusted to account for redeployed doses. Furthermore, the COVAX NFC Program will not apply to redeployed doses, as the COVAX NFC Program only covers COVAX distributed doses administered within AMC-eligible economies.
- If the receiving Participant is AMC-eligible, the COVAX NFC Program will not apply to redeployed doses, as it will be impossible for the Claims Administrator of the COVAX NFC Program to determine whether a serious adverse event resulting in permanent impairment or death is associated with the administration of a redeployed dose.

For COVAX approved SFP redeployments to an AMC Participant, this will be considered as a donation to COVAX under a dose-sharing arrangement. The implications on allocation and eligibility for donations or other redeployments will be the same as COVAX-approved redeployments from one AMC Participant to another AMC Participant (as noted above).

However, financial requirements are as follows:

- The deploying SFP will be responsible for any ancillary costs (e.g., transport).
- There will be no cost to the receiving AMC Participant.

The COVAX NFC Program will apply to the redeployed doses

If an SFP redeploys to another AMC Participant **without COVAX approval,** the implications on allocation and eligibility for donations or other redeployments will be the same as COVAX-approved redeployments from one AMC Participant to another AMC Participant (as noted above). However, financial requirements and implications for the applicability of the COVAX NFC Program are as follows:

- The COVAX Facility **will not** provide funding for the redeployment of doses.
- The COVAX NFC Program **shall not** apply to redeployed doses.

If an SFP redeploys to another SFP, this will be considered a bilateral sale or donation to the SFP Participant, and therefore COVAX will not be involved in the transaction. Noting the position that COVAX strongly discourages redeployments and that certain manufacturers have agreed to make doses available to the COVAX Facility on the basis that they cannot be transferred or exported, Participants should be aware of any constraints expressed in the supply agreement with the relevant manufacturer or with UNICEF or PAHO regarding redeployment, sale or exportation (e.g. restriction on transfer/export of the doses that the relevant proposed deploying country has in its agreement with either the manufacturer or UNICEF/PAHO).

In exceptional circumstances where an AMC Participant or SFP redeploys to another Participant of any type without consent from the receiving Participant, the following implications will apply:

- The allocation for the deploying Participant will be adjusted to account for redeployed doses. Furthermore, the deploying Participant will **not be caught up** in the next round

² The AMC participant may agree with the SFP that the SFP will bear such costs

(the round minimum will be allocated, but shipments will be sequenced later in the queue so long as utilisation issues remain). The allocation of the receiving Participant will **not** be impacted.

- The deploying Participant will **not be eligible** for near-term dose donations or other redeployments of the same product until utilisation issues are resolved. The receiving Participant will **continue to be considered** for donations / redeployments despite receipt of the redeployment.
- The deploying Participant is responsible for any costs (including costs of wastage

if doses not accepted by recipient country). If an AMC Participant redeploys to SFP, the COVAX Facility needs to be reimbursed for the cost of the doses by the AMC Participant³, and the SFP may need to also pay any price differential to the manufacturer. There are no financial implications on the receiving Participant.

- NFC **shall not** apply to redeployed doses.

In all redeployment scenarios involving an SFP, the allocation of the SFP will not be adjusted to account for redeployed doses.

³ The AMC participant may agree with the SFP that the SFP will bear such costs.

