Accelerated Order Management of COVID-19 Diagnostics Products

Approved on: 8 May 2020
Approved by: Executive Grant Management Committee
Process Owner: Supply Operations
Sub-Process Owner: Program Finance and Controlling

Relevant Operational Policies and Guidance:

- COVID-19 Guidance
- COVID-19 Response Mechanism Application Materials
- Grant Flexibilities for Responding to COVID-19
- Interim Guidance on Quality Assurance Requirements for the Procurement of COVID-19 Diagnostic Products
- Guidance on Category and Product-level Procurement and Delivery Planning
- Guidelines for Grant Budgeting
- OPN and OP on Make, Approve and Sign Grants (2020-2022 allocation period)
- OPN and OP on Pooled Procurement Mechanism

1. This document provides procedural guidance on the Accelerated Order Management of COVID-19 Diagnostics Products (AOM). It applies to funding approved through grant flexibilities and through the COVID-19 Response Mechanism (C19RM) for the purchase of products detailed in the funding decision notification consistent with the volume approved within the request detailed in Annex 2 of the C19RM Funding Request Forms for the period defined by the Board decision on Additional Support for Country Responses to COVID-19.

2. The AOM leverages the Global Fund’s existing procurement capacity to maximize market access by engaging industry and negotiating price and volume agreements; it also leverages the Global Fund’s wambo.org transaction platform to efficiently and effectively process orders in a transparent, compliant way.

3. AOM comprises two interlinked components: 1) Demand and Supply Allocation Management and 2) Order Transaction Management.

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1 As of 1 May 2020, this includes COVID-19 test kits and sample collection kits for automated tests manufactured by Abbott Molecular Diagnostics, Cepheid HBDC, Roche and ThermoFisher Scientific and is subject to change over time.
2 B42/EDP11 As of 1 May 2020, this relates to grant flexibilities and C19RM funds approved through 30 September 2020, to be used through 30 June 2021. Dates may be extended by the Board, based on updated information on needs as the pandemic evolves.
4. An overview of key parties and process flow for the Demand and Supply Allocation Management of COVID-19 diagnostic products (C19 Diagnostics) is summarized in Figure 1 below (not including delivery). Section 1 provides additional detail through to order processing.

Figure 1: Overview of Demand and Supply Allocation Management for C19 Diagnostics

Note: C19 Dx in Figure 1 refers to C19 Diagnostics.

5. Following the communication of a funding decision, Order Transaction Management for C19 Diagnostics may advance, as described in Section 2. Figure 2 provides an overview of actors and key steps.

Figure 2: Overview of Order Transaction Management for C19 Diagnostics

Note: C19 Dx in Figure 1 refers to C19 Diagnostics.
SECTION 1. DEMAND AND SUPPLY ALLOCATION MANAGEMENT

6. There is currently a global shortfall in supply of COVID-19 diagnostic products (C19 Diagnostics), requiring a coordinated approach to demand and supply allocation management. Under the leadership of the World Health Organization, the Global Fund is working with partners to implement a C19 Diagnostics allocation model based on country needs, data on national absorption capacity and gap in unmet supply need. This includes reviewing C19 Diagnostics supply requests, mapping available supplies and allocating available supplies to requests.

7. World Health Organization-led COVID-19 Diagnostic Consortium. Key responsibilities of global level coordinating partners include developing and agreeing on C19 Diagnostics allocation model principles, processing C19 Diagnostics allocation model inputs and producing C19 Diagnostics allocation outputs, per country, per platform type (i.e., manufacturer-specific platform for automated tests). This can permit allocation and volume tracking across both Global Fund-eligible and non-Global Fund-eligible countries.


- Management Executive Committee:
  o Confirm the allocation model that will be utilized for COVID-19 diagnostics products

- Strategic Information Department:
  o Contributes to global-level consideration of allocation model approaches
  o Consolidates C19 Diagnostics model inputs for agreed allocation model

- Grant Management Division:
  o Encourages the development of National COVID-19 Response Plans [Country Teams]
  o Receives and processes grant flexibilities, which may include requests to purchase C19 Diagnostics [Grant Management Division]
  o Compiles and shares (with Supply Operations and Finance) grant flexibilities through which orders of C19 Diagnostics can be approved (PR, grant, products, quantities) [Country Teams with approved grant flexibilities for the purchase of C19 Diagnostics]
  o Compiles a list of PRs/grants with potential to submit C19RM funding requests for C19 Diagnostics, including delivery information for those PRs, to facilitate and expedite the start of the Order Transaction Management [Health Product Management Specialist, or Fund Portfolio Manager for Focused Countries]
  o Reviews C19RM funding requests received for C19 Diagnostics [Country Teams]

- Supply Operations Department:
  o Consolidates anticipated and actual C19 Diagnostics demand across Global Fund-eligible countries, as it evolves over time
  o Negotiates with C19 Diagnostics suppliers for pooled volumes

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4 This process step will only be relevant whilst there is supply and demand coordination according to the WHO Diagnostics Consortium allocation model and rules for implementation.

5 It is currently envisaged that the AOM will use the allocation model of the WHO Diagnostics Consortium. If agreement across partners cannot be reached, global level demand and supply allocation of COVID-19 diagnostic products will be managed in line with the allocation model determined by the Global Fund and may evolve over time at the discretion of the Global Fund.
Engages regularly (weekly, bimonthly, monthly) with C19 Diagnostics suppliers to receive updates on supply capacity for volumes of diagnostic products, associated consumables and equipment available for supply, per platform

Assesses feasibility of C19 Diagnostics supply requests received through funding requests against the country- and platform-specific allocation model outputs to inform funding decision

Engages with Principal Recipients, and HPM Specialists/FPMs as needed, to agree delivery schedule for approved order quantities

Facilitates procurement and delivery of the C19 Diagnostics, monitors performance of the Procurement Services Agencies and provides regular order status updates to Grant Management Division colleagues.

C19 RM Secretariat:

Receives and coordinates review of C19 RM funding requests for C19 Diagnostics

Communicates outcome of C19 RM funding decisions for C19 Diagnostics, specifying the PR, grant, diagnostic products and quantities, informed by the allocation model and inputs from Grant Management and Supply Operations

Role of C19 Diagnostics Suppliers. C19 Diagnostics Suppliers negotiate with the Global Fund Supply Operations on pooled volumes, provide dynamic updates to the Global Fund on supply capacity and supply to authorized buyers in alignment with allocation principles agreed by Global Level Coordinating Partners and confirmed purchase orders.

Role of Global Fund-eligible Countries. Global Fund-eligible countries:

- Develop and share with the Global Fund their National COVID-19 Response Plan
- Develop and share with the Global Fund their C19 Diagnostics delivery schedule volumes for automated platforms up to a 16-week allocation model cap
- Submit funding requests to the Global Fund for C19 Diagnostics
- Upon receipt of funding decision, reconfirm Diagnostics delivery schedule, adjusting for funding decision, available supply and roll-out challenges
- Implement grant agreements
- Reconfirm C19 Diagnostics delivery schedule for automated platforms, as these evolve over time, adjusting for funding decision, available supply and roll-out challenges

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6 As per Guiding Principles for Allocation Diagnostics Consortium for COVID-19, countries with access outside the WHO Diagnostics Consortium that have already processed orders, particularly directly from suppliers or through partner procurements, will have their allocations adjusted for volumes already processed, per the equitable proportions/shares for the specific test as listed.
SECTION 2. ORDER TRANSACTION MANAGEMENT

11. Order Transaction Management for the AOM includes four key steps, after fulfilment of pre-requisites. Figure 3 below presents an overview.

Figure 3: Overview of Order Transaction Management Steps

SECTION 2A. PREREQUISITES

12. Approved funding for C19 Diagnostics. Eligible participants are Principal Recipients that submit a request to the Global Fund for C19 Diagnostics, either through grant flexibilities under existing grants, approved by the relevant Grant Management Division authority or through a funding request through the COVID-19 Response Mechanism (C19RM) approved by the C19RM Approvals Committee.

- For approvals based on the decision of the C19 Response Mechanism Approvals Committee, Article 1.4 of the C19 Response Mechanism Funding Request Form will stipulate the PR name and grant. Annex 2 will provide the details on diagnostics-related commodities (quantities and costs) and any related technical assistance. Supply Operations will request confirmation of relevant order details, such as delivery address and incoterm, according to a template that will be shared with Principal Recipients. This will be a precursor for C19 Diagnostics orders to be placed through the AOM for approved C19RM funding requests.

- For requests based on GMD approval of grant flexibilities, the PR name, grant, product details (as noted in the COVID-19 Decision Form and covering the same information as Annex 2 of the C19RM funding request form) and order details such as delivery address and incoterm (as captured in a template that will be shared by Supply Operations) will be made available by the Country Team to Supply Operations and Finance colleagues with review/approve responsibilities for purchase requisitions.

13. Agreement to terms and conditions of participation in AOM.

- Principal Recipients with access to wambo.org. Principal Recipients that have used the wambo.org platform prior to submission of a request for C19 Diagnostics have already signed the Pooled Procurement Registration Letter, the wambo.org Terms of Use and the
wambo.org onboarding form, thus fulfilling key pre-requisites for submission of a request for C19 Diagnostics through the wambo.org platform. 7

- **Principal Recipients without access to wambo.org.** Principal Recipients that have not previously used the wambo.org platform and that intend to use the Global Fund’s procurement mechanism only for procurement of C19 Diagnostics and accessories will agree to the terms and conditions of the Global Fund, wambo.org and the Procurement Services Agents at the time of approving each request by signing an Accelerated Order Management Order Form (as described in Section 2C).

**SECTION 2B. EARMARKING FUNDING**

14. Grant funds are earmarked for AOM procurement in the Global Fund System (GFS) through the Pooled Procurement Mechanism (PPM) ceiling. For the implementation period of the grant, the initial PPM ceiling and increases to it can be based on the approved PPM- or AOM-related procurement budget, following the funding decision, prior to receipt of any order request from the Principal Recipient. Alternatively, the initial PPM ceiling and increases to it can be adjusted over time as each PPM or AOM order request is received from the Principal Recipient, subject to a maximum of the amount defined in the funding decision. Only the unutilized PPM ceiling can be reduced (i.e., the amount that has not been committed for specific orders) if the unutilized PPM ceiling will no longer be required for existing or future PPM or AOM orders.

15. In instances where there are insufficient remaining uncommitted funds under the grant (prior to budget revision) for increasing the PPM ceiling, it is permissible to raise a Purchase Requisition based on the C19 RM Approvals Committee decision. In such instances exclusively, the Supply Operations Financial Controlling Specialist will release the exception manually based on the authorized C19 RM Approvals Committee decision; however, no invoices will be processed until the PPM ceiling has been adjusted.

16. For Purchase Requisitions raised through grant flexibilities, the Supply Operations Financial Controlling Specialist will release the exception manually on the basis of GMD approval captured in the COVID-19 Decision Form; no invoices will be processed until the PPM ceiling has been adjusted. The respective Finance Officer (or PST) will adjust the wambo (or PPM or AOM) ceiling within 2 working days of the Grant Management Division approval of grant flexibilities.

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Timeline</th>
<th>Review and Approval</th>
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<tbody>
<tr>
<td>Establishment of and increases to PPM ceiling</td>
<td>After C19RM funding decision or grant flexibility approval for C19 Diagnostics, either up front or over time as each purchase requisition is raised</td>
<td>• Finance Specialist/Portfolio Services Team (PST) Specialist, in consultation with the FPM, after validating the PPM ceiling establishment or increase against the quantification and estimation of the order value approved by the HPM Specialist (or as specified in the “Country Team Review Group”), (e.g., for approved quantities of C19)</td>
</tr>
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</table>

7 In instances where the Principal Recipient requires any adjustments to its onboarding information, including to revise the Principal Recipient’s approval chain, the transaction process for Principal Recipients without access to wambo.org will be followed (until the onboarding form and system reconfiguration have been completed).
### SECTION 2C. ORDER REQUEST AND APPROVAL

17. **Order Request and Approval.** The order request and approval steps differ depending on whether the Principal Recipient is classified as a Principal Recipient with access to wambo.org or a Principal Recipient without access to wambo.org (as per Section 2A).

- Section 2C1 describes the process steps for Principal Recipients that have previously been onboarded for wambo.org (“Principal Recipients with access to wambo.org”).
- Section 2C2 describes the process steps for Principal Recipients new to the wambo platform (“Principal Recipients without access to wambo.org”).

Process steps align for both classifications of Principal Recipients after the issuance of the Purchase Order by the Procurement Services Agent (PSA).
## SECTION 2C1. PRINCIPAL RECIPIENTS WITH ACCESS TO WAMBO: ORDER REQUEST AND APPROVAL

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Timeline</th>
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</thead>
</table>
| **AOM Purchase Requisition** created by the Supply Operations COVID-19 Support Focal Point through the wambo.org platform, specifying:  
  - COVID-19 Diagnostics product information;  
  - quantities (aligned with C19 Diagnostics allocation model);  
  - requested delivery date;  
  - ship-to-address, consignee, Incoterm; and  
  - logistics costs, according to agreed structure (i.e., pre-agreed fixed breakdown plus any country-specific charges).  
  The amounts entered are aligned with the funding decision for C19 Diagnostics. | After approved funding pre-requisite (Section 2A) | Stage 1 review by:  
  - Principal Recipient Requestors, as defined in the wambo Onboarding Form, who validate that the order products are limited to C19 Diagnostics, order products and quantities (for the full or partial quantity), quantities of associated accessories identified in Annex 2, or any additional critical items required to be able to perform the tests on the automated platform, if any, recipient name, delivery and consignee addresses, incoterm and all other relevant data in the Purchase Requisition (or who fail to validate by declining the allocation)  
  Stage 2 review by:  
  - Any additional PR review groups that appear in the wambo.org Onboarding Form before the Price Quote generation step, who validate the order information  
  - HPM Specialist (or FPM for Focused Countries), who validates order information and that amounts are aligned with the funding decision for C19 Diagnostics and the Principal Recipient’s C19 Diagnostics delivery schedule. The relevant approval document (C19RM Decision Form or COVID-19 Decision Form for grant flexibilities) may be uploaded in wambo.  
  Approval by:  
  - PSA, who approves after reviewing quantities and order information |
| **AOM Price Quotation** issued to the Principal Recipient through wambo.org and attached to the Purchase Requisition | Following approval of an AOM Purchase Requisition | If approved Purchase Requisition is within PPM unutilized ceiling amount:  
Price Quotation is issued to Principal Recipient via wambo.org |
<table>
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<tr>
<th>Requirements</th>
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<tbody>
<tr>
<td>Approval by:</td>
<td></td>
<td>- Principal Recipient according to the process documented in the wambo.org Onboarding Form</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(Approval may be electronic or may require that the Principal Recipient sign the Price Quotation attached to the Purchase Requisition, scan and upload it onto wambo.org)</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Price Quote Checkpoint group, who confirms the Principal Recipient has validly approved</td>
</tr>
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<td></td>
<td></td>
<td>Supply Operations Financial Controlling Specialist, who verifies the availability of funding for the grant in the GFS and ensures that PPM and AOM policies and guidance are adhered to, including but not limited to delivery dates</td>
</tr>
<tr>
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<td></td>
<td>Strategic Sourcing Health Technologies Manager; and</td>
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<td></td>
<td>If the order value exceeds USD 10 million, Strategic Sourcing, Senior Manager</td>
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|              |          | *If approved Purchase Requisition exceeds PPM unutilized ceiling amount:*
<p>|              |          | Review by: |
|              |          | - FPM, who requests Finance Specialist/PST Specialist to increase the PPM ceiling before issuing the Price Quotation to the Principal Recipient |
|              |          | Approval by: |
|              |          | - Principal Recipient according to the process documented in the wambo.org Onboarding Form |
|              |          | <em>(Approval may be electronic or may require that the Principal Recipient sign the Price Quotation attached to the Purchase Requisition, scan and upload it onto wambo.org)</em> |</p>
<table>
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<tr>
<th>Requirements</th>
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<tbody>
<tr>
<td>AOM Electronic Purchase Order</td>
<td>Following approval of Price Quotation as indicated above</td>
<td>Principal Recipient is informed that the Purchase Order has been issued through a system-generated email.</td>
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</table>

### SECTION 2C1. PRINCIPAL RECIPIENTS WITHOUT ACCESS TO WAMBO: ORDER REQUEST AND APPROVAL

<table>
<thead>
<tr>
<th>Requirements</th>
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<tbody>
<tr>
<td>AOM Order Form completed by the Supply Operations COVID-19 Support Focal Point offline, specifying:</td>
<td>After approved funding pre-requisite (Section 2A)</td>
<td>Review by:</td>
</tr>
<tr>
<td>• C19 Diagnostics product information;</td>
<td></td>
<td>- HPM Specialist (or FPM, especially for Focused Countries) who review quantities and order information and send the form to the PR</td>
</tr>
<tr>
<td>• quantities (aligned with C19 Diagnostics allocation model);</td>
<td></td>
<td>- Principal Recipient, who:</td>
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<tr>
<td>• recipient;</td>
<td></td>
<td>- reviews to confirm or adjust quantities (not to exceed allocated quantities of diagnostics);</td>
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<tr>
<td>• grant;</td>
<td></td>
<td>- adds additional accessory products identified in Annex 2, or any additional critical items required to be able to perform the tests on the automated platform,</td>
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<tr>
<td>• requested delivery date;</td>
<td></td>
<td>- confirms or adds recipient name, delivery and consignee addresses, Incoterm and necessary shipping documents;</td>
</tr>
<tr>
<td>• ship-to-address, consignee, Incoterm and necessary shipping documents (which have been provided in advance by HPM Specialist); and</td>
<td></td>
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<tr>
<td>• logistics costs, according to agreed structure (i.e.,</td>
<td></td>
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<tr>
<td>• review by:</td>
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### Requirements

<table>
<thead>
<tr>
<th>AOM Purchase Requisition</th>
<th>After approval of AOM Order Form by Country Team</th>
<th>Review by:</th>
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</thead>
<tbody>
<tr>
<td>issued by the COVID-19 Support Focal Point through the wambo.org platform, specifying all line items in the approved AOM Order Form</td>
<td></td>
<td>• Supply Operations Financial Controlling Specialist, who verifies the availability of funding for the grant in the GFS, verifies the quantities and total requisition value against the signed AOM Order Form and ensures that relevant policies and guidance are adhered to, including but not limited to delivery dates</td>
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Approval by:

- Strategic Sourcing Health Technologies Manager; and
- If the order value exceeds USD 10 million, Strategic Sourcing, Senior Manager

<table>
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<tr>
<th>AOM Electronic Purchase Order</th>
<th>Following approval of Purchase Requisition</th>
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<tr>
<td>issued through wambo.org to the PSA</td>
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### Timeline

- validates all other relevant data in the requisition and
- signs and submits AOM Order Form to the COVID-19 Focal Point and Country Team.

This constitutes the legally binding agreement of the Principal Recipient to the AOM Form, which will be the basis for the creation of the Purchase Order.

Approval by:

HPM Specialist (or FPM, especially for Focused Countries) who approves after confirming quantities and order information and countsigns and submits the AOM Order Form to the COVID-19 Support Focal Point. The relevant approval document (C19RM Decision or COVID-19 Decision Form for grant flexibilities) may be uploaded in wambo.

### Review and Approval

18. **Order changes.** In some instances, the Global Fund may need to make changes to an electronic Price Quotation (for a Principal Recipient with access to wambo.org) or an AOM Order Form after it has been approved by the Principal Recipient. For Price Quotations, material changes
will be made following the same review and approval process as that followed for the original electronic Price Quotation, and the Principal Recipient will receive an updated electronic Price Quotation for review and approval. For AOM Order Forms, a material change will require a new AOM Order Form. For both Price Quotations and AOM Order Forms, the Principal Recipient will only be notified of any non-material changes.

19. A material change results from a price increase of either (a) USD 10,000 and above or (b) 5% or more of the total value of the electronic Price Quotation or AOM Order Form (whichever is less). Increases will be calculated against the price originally authorized by the Principal Recipient (irrespective of any amendment previously processed).

20. Non-material changes include:
   (a) Price increases of less than USD 10,000 or 5% of the total value of the electronic Price Quotation or AOM Form, whichever is less.
   (b) Unplanned costs related to importation (e.g., demurrage, container detention, warehousing, etc.) where delays to address the issue may result in additional costs.

SECTION 2D. ORDER FULFILMENT AND DELIVERY

21. **Order Fulfilment and Delivery.** The PSA is responsible for ensuring that orders are fulfilled and delivered to the Principal Recipient in accordance with the approved order. PSA performance is monitored by the Strategic Sourcing Team.

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<tr>
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<tr>
<td><strong>Orders are confirmed by the PSA with suppliers</strong> (manufacturers and logistics agents) for the quotations approved by the Principal Recipient</td>
<td>Following receipt of the Purchase Order issued through wambo.org</td>
<td>PSA, who undertakes required actions</td>
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<tr>
<td><em>Principal Recipient is responsible for ensuring appropriate waivers are obtained when required and facilitating the import process locally.</em></td>
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<tr>
<td>PSA notifies Principal Recipient and Sourcing Team of any delays in deliveries or changes in products supplied or cost that can trigger additional approvals if the materiality thresholds as defined in paragraphs 19 and 20 above are met</td>
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</table>
### Requirements | Timeline | Review and Approval
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**Quality Control testing of health products completed,** if any, in line with Global Fund Quality Assurance Policy for Diagnostics Products and Quality Assurance requirements approved by the Board ([B42/EDP11])⁸ | Prior to delivery | PSA, who undertakes required actions

**Products are delivered by PSA-engaged logistics service provider** to the Principal Recipient | Following health product manufacture and quality control testing, as applicable | PSA, who undertakes required actions

**Confirmation of receipt of goods delivered and associated costs** by the Principal Recipient (or designated/contracted service provider, as the case may be) | Following delivery | Principal Recipient, who validates quantity and condition of the goods and reports any discrepancy to the PSA within the time limit specified in the PSA’s Terms and Conditions

### SECTION 2E. PAYMENTS AND REPORTING

22. Payments are made to the PSA per payment terms stipulated in its agreement with the Global Fund.

| Requirements | Timeline | Review and Approval |
--- | --- | ---
**Payments to PSA** based on invoices received, which triggers disbursements under the respective grants | Based on PSA agreement | Review by:  
- Supply Operations Financial Controlling Specialist, who verifies invoices not automatically matched in wambo.org⁹  
Approval by:  
- Financial Services, who approves based on final compliance and due diligence review (including Batch Release Approval for execution of the transaction by the Treasury and banking institution)  

The Country Team is informed and sends the Principal Recipient a Disbursement Notification Letter.

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⁸ For example, see [Interim Guidance on Quality Assurance Requirements for the Procurement of COVID-19 Diagnostic Products](#).

⁹ The Supply Operations Financial Controlling Specialist will in particular facilitate the consumption of the cost fluctuation buffer when costs are higher than estimated (this mainly applies to logistics estimates).
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| Periodic performance and financial reports submitted by the PSA to the Global Fund on their procurement activities, including review of the C19 Diagnostics budget and spend by Supply Operations, Grant Management and Finance | Monthly | • Principal Recipient Services Senior Manager, Strategic Sourcing Senior Manager, Regional HPM Managers, HPM Specialists and Regional Program Finance, who triangulate information to monitor expenditure on grants and validate and approve performance information  

• Supply Operations Financial Controlling Specialist, who validates and approves financial information |
| Electronic Purchase Order is closed | Following submission of Invoice Summary Statement by PSA¹⁰ | Review by:  
• Principal Recipient Services Grant Focal Point or Supply Operations COVID-19 Focal Point, who validates and resolves anomalies, if any  
• PR, who validates or notifies the Supply Operations COVID-19 Focal Point of anomalies, if any¹¹  

Approved by:  
• Supply Operations Financial Controlling Specialist, who approves after confirming financial information in the PSA and Global Fund statements are consistent, complete and accurate  

In case of any de-commitment, the Country Team is informed and sends a Commitment Notification Letter to the Principal Recipient. |

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¹⁰ The Invoice Summary Statement is a system-generated report produced from all digitally received, approved and paid invoices. Currently, the Supply Operations Financial Controlling Specialist uploads the Invoice Summary Statement, triggering the review steps, until this step will be automated.  

¹¹ If the Principal Recipient does not respond within 14 days, the Invoice Statement will be considered accepted, in which case the Principal Recipient Services Grant Focal Point or Supply Operations COVID-19 Focal Point will validate the Invoice Statement on behalf of the Principal Recipient.