

# Operational Policy Note

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## Implementing the Quality Assurance Policies for Pharmaceutical, Diagnostics and Other Health Products

**Issued on:** 10 November 2014

**Purpose:** To define the monitoring process for compliance with requirements of the Quality Assurance Policies for Pharmaceutical, Diagnostics and other health products, including corrective measures to address non-compliance.

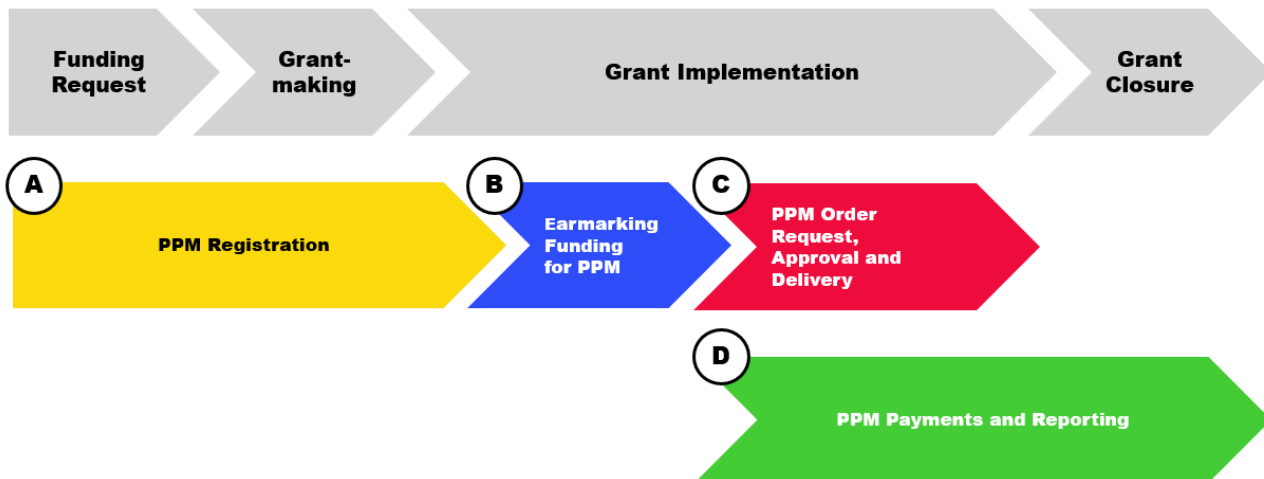
### Process Objective

1. The Global Fund's Pooled Procurement Mechanism (PPM) is a key tool used to drive equitable access to quality-assured health products, equipment and other non-health products and services in support of the [Global Fund Strategy](#). Wambo.org is a digital online procurement platform that facilitates the order management of Global Fund pooled procurement transactions from requisition to delivery. PPM enables the Global Fund Secretariat to aggregate order volumes from participating Principal Recipients<sup>1</sup> to leverage the Global Fund's market spend aiming to:
  - a. secure quality-assured products;
  - b. obtain better value for money<sup>2</sup> through optimal sustainable pricing and delivery conditions;
  - c. reduce lead times for critical health products by engaging with manufacturers using framework contracts; and
  - d. contribute to sustainable markets for core products as defined in paragraph 4 (i) below.
2. The framework below provides a summary overview of the PPM process.

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<sup>1</sup> Unless otherwise defined, all capitalized terms used in this Operational Policy Note shall have the same meaning as set forth in the Global Fund Grant Regulations available on the [Governance & Policies](#) web page.

<sup>2</sup> Value for money as defined under the [Global Fund Procurement Policy \(2008\)](#) as amended from time to time.



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3. This Operational Policy Note (OPN) defines the rules and requirements for implementation of PPM. Detailed procedural guidance to implement these rules are provided in the Pooled Procurement Mechanism Operational Procedures.

### Eligible Health Products

4. Health products (and associated Procurement and Supply Management (PSM) costs) that may be procured by Principal Recipients through the PPM are categorized as PPM core or non-core products. The list, which may be updated from time to time, is as follows:
  - (i) **Core products:** antiretrovirals (ARVs); HIV rapid diagnostic tests (HIV RDTs); and viral load tests; Artemisinin-based combination therapy (ACTs); long-lasting insecticide treated nets (LLINs); anti-malarial pharmaceutical products (other than ACTs); and malaria rapid diagnostic tests (malaria RDTs).
  - (ii) **Non-core products:** drugs for opportunistic infections and sexually transmitted infections; other diagnostic products and laboratory supplies; post-exposure prophylaxis kits; condoms; insecticides for indoor residual spraying (IRS) and related equipment/consumables; and other products and PSM costs<sup>3</sup> agreed with the Procurement Transaction Management Team.

### Procurement Services Agents and Suppliers

5. Through the PPM, Principal Recipients procure eligible health products using the services of Procurement Services Agents (PSAs). PSAs are external service providers contracted by the Global Fund to perform procurement and delivery services on behalf of PPM-participating Principal Recipients, including order and logistics management, while ensuring quality assurance and timely deliveries.

The selection of PSAs is done by the Global Fund through a competitive process, and their performance is managed through long-term performance-based agreements.<sup>4</sup> The Global Fund facilitates the procurement of such eligible health products. However, the Global Fund is not a party to the procurement contract (Purchase Order), which is exclusively concluded between the Principal Recipient and the PSA.

6. As part of the PPM, the Global Fund also manages the selection of suppliers for certain core

<sup>3</sup> Only logistic costs ancillary to the delivery of products.

<sup>4</sup> For certain product categories, the Global Fund may use partner organizations, acting as agents of the Principal Recipients.

products. Supplier performance is managed by the Global Fund through long-term performance-based agreements which are signed according to the Global Fund [Delegation of Signature Authority](#) (which may be amended from time to time). Supplier-specific prices negotiated by the Direct Sourcing Team for health products are uploaded onto the wambo.org platform and are updated from time to time.

## A. Principal Recipient Registration

7. Principal Recipients may wish, on a voluntary basis, to take advantage of the benefits (e.g., reliable delivery) and negotiated PPM prices which may provide better value for money. In the event that a Principal Recipient does not volunteer, the Country Team may require a Principal Recipient to use this mechanism for some or all Global Fund-financed health products as a risk-mitigating measure where the Principal Recipient or the designated procurement entity has demonstrated inadequate capacity to procure health products effectively and efficiently. At its own discretion, the Global Fund may for any Principal Recipient, regardless of their participation in PPM, limit health product budgets to the negotiated PPM unit prices to ensure that the Global Fund will not pay for health products purchased by non-PPM participating Principal Recipients more than the PPM negotiated prices for similar commodities.<sup>5</sup>
8. To participate in PPM, Principal Recipients must comply with defined PPM registration requirements. A registration application may be submitted and processed at any time during grant-making or implementation.
9. Participation in PPM is, in principle, for the duration of the grants managed by the same Principal Recipient. Registration remains effective until they cease to be Principal Recipient or the Principal Recipient's participation in PPM ends. The Principal Recipient's participation in PPM may be ended through written notice only, at least ninety (90) calendar days prior to the desired end date.<sup>6</sup>
10. Only PPM-registered Principal Recipients are allowed to use PPM, including the Rapid Supply Mechanism (RSM).

## B. Earmarking Funding for PPM

11. PPM-related funding is committed outside of the grant-based annual funding decision process. From the grant signed amount, Grant Funds are earmarked for PPM orders directly in Global Fund systems by setting the PPM ceiling amount, which, for orders processed through wambo.org, is automatically interfaced with wambo.org.
12. The PPM ceiling amount is based on the approved detailed budget (aligned with the Health Product Management Template (HPMT) requirements as described in the [OPN on Make approve and Sign Grant](#)), after grant signature for PPM-related procurement for the grant implementation period (i.e., cumulative 3-year ceiling). It can be adjusted (increased or decreased) as needed during grant implementation based on approved changes to the budget. Only the unutilized PPM ceiling can be reduced (i.e., the amount that has not been committed for specific orders). Such reduction shall be processed only if the unutilized PPM ceiling will no longer be required for existing or future PPM orders.
13. The sum of all Grant Funds committed through annual funding decisions and wambo.org orders, for the full implementation period and closure period of a grant must not exceed the total Grant Funds amount (including C19RM where relevant) as it appears in the relevant Grant Agreement.

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<sup>5</sup> Reference prices per product category are updated from time to time and are available at: <https://www.theglobalfund.org/en/sourcing-management/health-products/>.

<sup>6</sup> The end of participation in PPM would apply to new Price Quotations not yet approved; any Price Quotations approved by the Principal Recipient prior to the desired end date would be fulfilled as per contractual agreements triggered by Principal Recipient approval of the Price Quotation.

## C. PPM Order Request, Approval and Delivery

14. PPM Purchase Requisitions are raised electronically through the wambo.org platform.
15. A request for procurement is only initiated by the Principal Recipient and only validated by the Country Team and the Procurement Transaction Management Team after grant signing if:
  - a. Principal Recipient registration to participate in PPM has been completed;
  - b. the quantification and budget have been approved by the Global Fund (e.g., as per the Health Product Management Template or assumptions informing health product budgeting);
  - c. Grant Funds are available in accordance with the signed Grant Agreement and the associated approved detailed budget; and
  - d. all relevant grant requirements for the procurement have been fulfilled, or otherwise waived or postponed.<sup>7</sup>
16. PPM Purchase Requisitions shall include a need by delivery date. To achieve better value for money and timely delivery of products under PPM, Principal Recipients must place orders taking into account a minimum procurement lead time as defined in the [Category and Product-level Procurement and Delivery Planning Guide](#) (as amended from time to time). If the requested lead time is below the defined minimum lead time, additional costs may be incurred by using air freight instead of the standard sea freight.
17. When the order request is submitted less than three months from the expected delivery date, the Procurement Transaction Management (PtM) Team may recommend the use of the RSM. The RSM is an approach that has been agreed with selected suppliers to help mitigate against the risk of stock-outs of certain health products.

Through agreements with selected suppliers, suppliers implement Vendor Managed Inventory (VMI) of certain health products to permit increased responsiveness and reduced delivery times compared to the standard order process. Through the RSM, certain health products can be delivered to the port of entry within four to six weeks from order approval.

Products available through the RSM include select anti-retroviral medicines and antimalarial medicines through VMI. This product selection may be reviewed from time to time and amended as deemed necessary by the Direct Sourcing Team.
18. All order requests<sup>8</sup> are submitted and planned as per standard lead times to ensure that final deliveries take place no later than the implementation period end date stipulated in the Grant Agreement. In certain instances, deliveries may span between two implementation periods, in which case relevant guidance should be consulted.<sup>9</sup>
19. Following review and approval of the Purchase Requisition as per the PPM Operational Procedures, a Price Quotation is submitted to the Principal Recipient for electronic approval and, if required under the Principal Recipient's national laws, manual signature. The Price Quotation may include a buffer amount, which can be used for potential increases in cost. The buffer, if any, is set as described in the PSA's terms and conditions. Following electronic approval and, if applicable, manual signature by the Principal Recipient of the Price Quotation and the Global Fund's review and clearance process, a Purchase Order is issued on wambo.org, which becomes the legally binding agreement between

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<sup>7</sup> In accordance with the [OPN on Oversee Implementation and Monitor Performance](#) or future OPN providing guidance on management of requirements.

<sup>8</sup> An order request on the wambo.org platform is called a Purchase Requisition.

<sup>9</sup> See [Guidelines for Grant Budgeting](#)

the PSA and the Principal Recipient.

20. Approval limits for purposes of PPM Purchase Orders, including RSM orders, issued to PSAs are broken down into two categories (as outlined in the table below):

	APPROVAL AUTHORITY	
	Up to (and including) US\$10 million	Above US\$10 million
PPM Purchase Orders, including Rapid Supply Mechanism orders	<ul style="list-style-type: none"> <li>• Manager, Global Sourcing, Supply Operations Department</li> </ul>	<ul style="list-style-type: none"> <li>• Senior Manager, Direct Sourcing, Supply Operations Department</li> </ul>

21. The issuance of a PPM Purchase Order on wambo.org triggers grant liability recognition in the accounts of the Global Fund. Once committed, PPM funds will no longer be available for other purposes (e.g., disbursement to the Principal Recipient or third parties) until the order is finalized and all payments for the relevant PPM Purchase Order are made to the PSA. The Principal Recipient will be notified of every PPM-related commitment made.
22. Under certain circumstances, a Price Quotation for a previously approved order may need to be updated. For Material Changes (as defined in the PPM Operational Procedures), an updated Price Quotation will be issued to the Principal Recipient for electronic approval and, if applicable, manual signature. For Non-material Changes, Unplanned Costs and Cancellation Costs (as defined in the PPM Operational Procedures), the Principal Recipient will be notified of the changes.
23. PSAs are responsible for issuing Purchase Orders (or their equivalent) and other requested information to suppliers and logistics providers for the fulfilment of PPM Purchase Orders and delivery of the health products to the Principal Recipient. PSAs are also responsible for ensuring that health products meet the quality standards of the Global Fund.<sup>10</sup>
24. Principal Recipients are responsible for ensuring appropriate waivers, exceptions and exemptions (e.g., product registration, import duty, tax exemptions, etc.) are obtained when required and facilitating the import process locally. Principal Recipients must confirm receipt of each order to the corresponding PSA, within the timeline specified in the PSA’s terms and conditions, indicating the products received and any discrepancies.

## D. PPM Payments and Reporting

25. Payments to PSAs for the procurement and delivery of health products and their services under the PPM shall be made from available Grant Funds of PPM-participating Principal Recipients.<sup>11</sup> Payments are made to PSAs by the Global Fund on behalf of Principal Recipients upon approval of invoices in accordance with the payment terms stipulated in their respective agreements. All payments made will be charged as disbursements under the respective grants, and the Principal Recipient will be informed of every PPM-related disbursement made.
26. For the purposes of procurement management, planning and performance, the PSAs will send to the Global Fund comprehensive reports capturing required financial and operational details on a regular basis as agreed with the Global Fund. Reports received from PSAs feed into Global Fund organizational reporting.
27. PPM Purchase Orders are closed after products have been received by the Principal Recipient and all PSA payments have been made. As described in the PPM Operational Procedures, confirmation of the receipt of products is made by the Principal Recipient to the PSA within the timeline specified

<sup>10</sup> See [OPN on Implementing the Quality Assurance Policies for Pharmaceuticals, Diagnostics and Other Health Products](#).

<sup>11</sup> If a grant is suspended or terminated, no disbursements shall be made without due consideration and relevant authorization in accordance with Global Fund policies and procedures relating to the suspension and termination of grants.

in the PSA's terms and conditions for the order, after which time the products are considered received. Once all payments have been made to the PSA, an Invoice Summary Statement is issued to the Principal Recipient, who is granted fourteen (14) calendar days within which to review and to object, or approve the statement.<sup>12</sup> The Invoice Summary Statement details the actual costs incurred, and if applicable, any unutilized Grant Funds relating to the procurement transaction are de-committed to the PPM ceiling. In case of no response within fourteen (14) calendar days, the Invoice Summary Statement is automatically approved in wambo.org on behalf of the Principal Recipient<sup>13</sup>, and the Purchase Order is closed.

## Annex 1. Requirement Levels by Portfolio Category

Note that the requirements are applicable for each portfolio category (High Impact, Core and Focused) and for Focused portfolio management models (Aligned, Targeted, Light, Legacy) for country and Multicountry portfolios.

Outputs per Sub-process	Requirement by Portfolio Category			
	High Impact & Core	Focused		
		Aligned	Targeted	Light
<b>A. Register in PPM</b>	R	R		
PR Registration Approved				
<b>B. Earmark funds for PPM</b>				
PPM Ceiling Increased or Decreased				
<b>C. Submit, approve and deliver PPM orders</b>				
Purchase Requisition approved				
Price Quotation approved				
Purchase Order approved and Grant Funds are committed				
Import waivers (e.g. product registration, import duty, and tax exemptions, etc.) completed				
Products picked up from supplier and delivered to PR				
Delivery confirmed by PR				
<b>D. Process PPM payments in wambo.org</b>				
PSA invoices and payments approved and processed				

<sup>12</sup> PSA accountabilities are captured in the PSA terms and conditions available at <https://wambo.azurewebsites.net/user/home/terms-conditions>.

<sup>13</sup> A non-response by the Principal Recipient after 14 days will be considered concurrence with the Invoice Summary Statement, in which case the system will automatically approve the Invoice Summary Statement on behalf of the Principal Recipient.

Report on PPM transactions in wambo.org		
Grant Account Statement(s) issued to PR		

**Level of Requirements:**

R Required

## Annex 2. Definition of Terms

- Health Product Management Template (HPMT):** A grant document that captures key information pertaining to the procurement and supply management of health products funded by the grant. HPMT is the source document which is used – once it has been approved – to populate the Detailed Budget Template (DB).<sup>14</sup> This is required for grants in Core and High Impact portfolios.
- Purchase Requisition:** A procurement request submitted by the Principal Recipient to the Procurement Services Agent containing product information, quantities, requested delivery date, ship-to address, consignee, Incoterm and special requests, if any.
- Price Quotation:** A legally binding offer by the Procurement Services Agent to the Principal Recipient to supply and deliver products in accordance with the terms set out therein, specifying the Incoterm applicable to the order, which is either signed manually or approved through wambo.org by the Principal Recipient.
- Purchase Order:** The legally binding agreement between the PSA and the Principal Recipient, issued by wambo.org resulting from the Price Quotation approved, and, if required by the Principal Recipient’s local laws or other regulations, signed by the Principal Recipient and the completion of the Global Fund’s review and clearance process.
- wambo.org:** The electronic purchasing platform through which PPM transactions are processed. More information is available at <https://www.theglobalfund.org/en/sourcing-management/procurement-tools/>
- Invoice Summary Statement:** A final statement summarizing all invoices issued through wambo.org detailing actual costs and expenses incurred relating to the procurement after all payments to the PSA have been processed for a Purchase Order.
- Incident:** An event where a shipment deviates in any way from the scheduled service, including, but not limited to, a shipments’ temperature excursion, routing changes and/or service level changes. Such situations may lead to Unplanned Costs.<sup>15</sup>
- Unplanned Costs:** As defined in the PPM Operational Procedures.

<sup>14</sup> See [User Guidelines for Health Product Management Template](#)

<sup>15</sup> Policies and procedures related to the management of quality assurance including the management of incident are currently under review (Q3/4 2023) and any necessary updates to policies and procedures will be captured as part of that review.

