

# Operating Manual

of PAHO's Regional Revolving Funds

**PAHO**

Pan American  
Health  
Organization

World Health Organization  
Americas Region



# Operating Manual

## Of PAHO's Regional Revolving Funds

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# Abbreviations

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<b>SF</b>	Regional Revolving Fund for Strategic Public Health Supplies (Strategic Fund)
<b>RRF</b>	Regional Revolving Funds
<b>RF</b>	Revolving Fund for Access to Vaccines (Revolving Fund)
<b>WHO</b>	World Health Organization
<b>PAHO</b>	Pan American Health Organization

# Introduction

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**The Regional Revolving Funds (RRF or “the Funds”) of the Pan American Health Organization (PAHO) serve as technical cooperation mechanisms, supporting countries and territories in the Americas in accessing quality vaccines, essential medicines, and public health supplies at affordable prices in a timely and transparent manner. They are based on joint procurement and the use of economies of scale to obtain better conditions for participating Member States.**

The RRF plays a crucial role in the fight against vaccine-preventable diseases, such as poliomyelitis, rotavirus infection, and yellow fever, as well as other diseases, including HIV/AIDS, malaria, and tuberculosis. Since their creation, the RRF have contributed to achieving elimination targets for these diseases in the Region of the Americas.

The Funds have continuously operated under the principles of solidarity, Pan-Americanism, equity, quality, and transparency. Today, they remain an essential tool for improving health and well-being in the Americas, helping countries ensure equitable access to health products (vaccines, essential medicines, and public health supplies) under the best possible conditions.

In 2024, the RRF procured health supplies for 41 countries and territories in the Americas. PAHO’s support is two-fold: reducing the administrative burden for these countries and territories, while also providing programmatic and technical guidance on products aligned with PAHO/WHO recommendations.

# History of the Regional Revolving Funds: Strategic Fund and Revolving Fund

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In 1977, the PAHO Directing Council adopted Resolution CD25.R27,<sup>1</sup> Through this, the Expanded Immunization Program was established to reduce morbidity and mortality caused by preventable diseases through vaccination. To facilitate the timely supply of quality vaccines at the lowest possible cost, in 1979, the Organization was asked to create the Revolving Fund for Access to Vaccines (RF) as a technical cooperation mechanism for the supply of vaccines, syringes, and other immunization supplies for PAHO Member States, associated states, and territories (collectively referred to in this document as Member States).

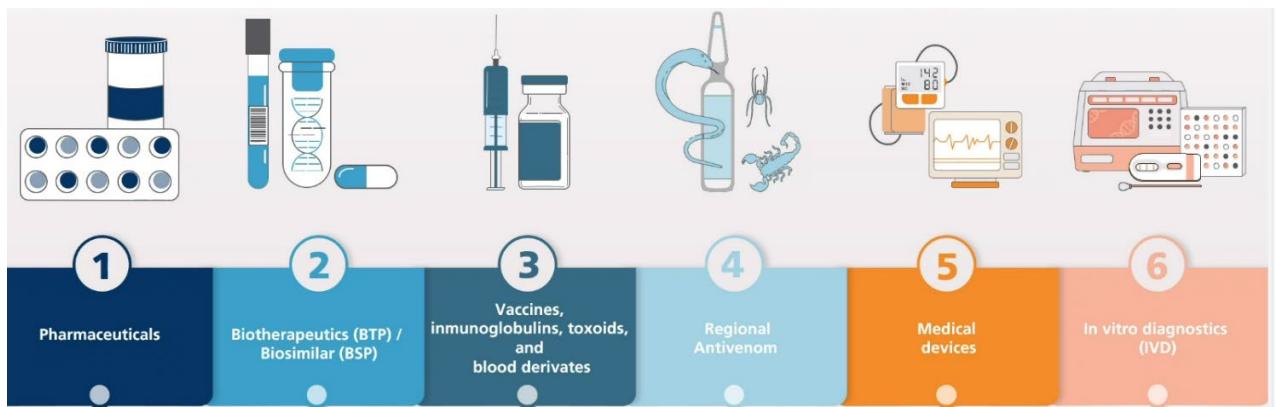
In 2000, the Regional Revolving Fund for Strategic Public Health Supplies, also known as the Strategic Fund (SF), was established to improve the health and well-being of people and promote universal health in the Americas. It aims to strengthen health systems and improve equitable access to safe, effective, and quality medicines, as well as other priority public health supplies.

In April 2023, both funds were reorganized under a single management. The goal of this change was to create opportunities for synergy and the integration and optimization of processes, and they now form the new Regional Revolving Fund Special Program (RRF).

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<sup>1</sup> Pan American Health Organization. Expansion and strengthening of the immunization program in the Americas [resolution CD25.R27]. 25th Pan American Health Organization Directing Council, 29th session of the WHO Regional Committee for the Americas; from September 27 to October 6, 1977. Washington, D.C.: PAHO; 1977. Available at: <https://iris.paho.org/bitstream/handle/10665.2/2381/CD25.R27sp.pdf?sequence=2>.

**Figure 1. The Regional Revolving Funds and their scope**



## **Purpose of this document**

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This document provides an overview of the processes involved in technical cooperation to support Member States and territories in estimating their needs and purchasing vaccines, medicines, and other essential public health supplies through the Regional Revolving Funds. It offers essential information to strengthen operational capacities and improve procedures related to the joint procurement of vaccines, medicines, and other health supplies, as well as the administration of the RRF.

## **Who is this document intended for**

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This operational manual is intended for the national authorities of Member States, such as Ministries of Health and other participating institutions of the RRF. It will be especially helpful for decision-makers and support staff involved in resource management within the health sector. Its content emphasizes processes to provide a clear and practical guide that aids the effective implementation and use of the RRF.

# Objectives of the Regional Revolving Funds

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**The main objective of the Regional Revolving Funds (RRF) is to support Member States in improving timely access to vaccines, essential medicines, and other strategic health supplies at affordable prices. To achieve this goal, the RRF:**

- They consolidate demand for products, allowing Member States to benefit from economies of scale (lower prices) and transparency in the processes.
- They support the strengthening of national capacities in supply chain management, including demand planning and forecasting.
- They help reduce the risk of shortages due to inadequate planning, in line with technical and programmatic recommendations.
- They support Member States interprogrammatically in the selection and rational use of health supplies.
- They manage bids and establish agreements with suppliers to facilitate timely deliveries.
- They offer and manage a capitalization fund that provides short-term credit to Member States for their acquisitions through the RRF.
- They collaborate with regional and global alliances and associations to strengthen access to health products.
- They strengthen horizontal cooperation among Member States, including the exchange of knowledge and information to improve the availability of health supplies.

# List of products offered through the Regional Revolving Funds and quality assurance

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## **Inclusion of health technologies in the listings of the Regional Revolving Funds**

The RRF maintain close coordination with the technical departments of PAHO and with Member States to establish their list of products<sup>2, 3</sup> defining the inclusion and exclusion criteria. The products included in the Funds' portfolio are incorporated into the World Health Organization (WHO) List of Essential Medicines, the WHO Model List of Essential In Vitro Diagnostic Tests, or in the treatment and diagnostic guidelines of PAHO and WHO.

In cases where Member States request the inclusion of health technologies in the funds that are not listed in the WHO lists or guidelines, PAHO may accept them if the technology has been integrated into the benefits package of countries in the Region. This is achieved through a rigorous evaluation process that assesses the available scientific evidence on the effectiveness, safety, and cost-effectiveness of such technologies, known as **health technology assessment**.

Additionally, it should also be reviewed whether there is available economic evidence about the technology. The goal is to assess whether it provides better, similar, or worse clinical outcomes compared to the comparator or comparators (clinical effectiveness). Whenever possible, a comparison of the relative clinical benefits with the relative costs involved in using the technology and other comparators should be conducted, known as cost-effectiveness analysis.

The recommendation to include or not include a technology is based on the available evidence (clinical effectiveness and cost-effectiveness, if available). Still, factors such as unmet needs, whether other treatments are already available or included in the HTA, equity and social factors, the rarity of the

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<sup>2</sup> For a list of Revolving Fund products, see Pan American Health Organization. Revolving Fund Prices. Washington, D.C.: PAHO. Available at: <https://www.paho.org/es/tag/precios-fondo-rotatorio>.

<sup>3</sup> The list of products covered by the Regional Revolving Fund for Strategic Public Health Supplies (Strategic Fund) is available at: <https://www.paho.org/es/fondo-estrategico-ops>.

disease, and urgent needs in a specific country are also considered. This process is crucial to supporting informed decision-making that is transparent and consistent, thereby helping to achieve the best possible outcomes.

## **Quality Assurance**

PAHO relies on its mandates, policies, and procedures to acquire only quality health technologies.<sup>4</sup> This process involves accurately, promptly, and thoroughly obtaining and reviewing product information. Additionally, all products on the RRF list meet international standards for quality, safety, and efficacy or performance (according to the relevant health technology), supported by the WHO Prequalification Program and collaboration with national regulatory authorities that operate at an advanced level of performance and are recognized regionally or globally by WHO and/or PAHO.

The PAHO procurement strategy aims to optimize product selection through a rigorous evaluation that varies according to the following product categories:

- Pharmacists or drugs of chemical synthesis.
- Biologicals or biosimilars.
- Vaccines, immunoglobulins, blood derivatives, antivenoms, and toxoids.
- Medical devices, including those used for in-vitro diagnosis.

The eligibility criteria for these products are dynamic and adapt to advances in regulatory sciences and updates in international standards related to their quality, safety, efficacy, or performance. Once an offered health technology meets these criteria, it undergoes a quality assurance process that includes a detailed technical evaluation. This evaluation considers the following major categories of technical aspects:

- Product regulatory status and manufacturing sites.
- Quality management system.
- Therapeutic equivalence.
- Product description and composition, and batch formula.
- Stability studies.
- Product quality specifications.
- Product artwork, insert, or labeling.
- Product safety requirements and information.
- Impurity characterization (when applicable).

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<sup>4</sup> Quality assurance is a broad concept that encompasses all matters that, individually or collectively, influence the quality of a product. It is the totality of activities performed to ensure that products are of the quality required for their intended use.

- In the case of medical devices, information related to the offering (including warranty, technical service availability, accessories, and consumables, as applicable), risk management for medical devices, and clinical performance or efficacy studies, among other relevant details.

According to PAHO procedures, products should be supplied with the maximum shelf life achievable with current production technology, as recommended by WHO. If the product requires a diluent, it should have a shelf life at least as long as that of the corresponding product. Unless PAHO provides prior written authorization (followed by approval from the Member State), the remaining shelf life at the time of dispatch should be at least 75% of the total shelf life of the pharmaceutical and biological products. For vaccines, the recommended storage period is at least 18 months, except for the seasonal influenza vaccine, which should have a remaining shelf life of at least six months. Additionally, other vaccines may have a total shelf life of 12 to 18 months at the time of shipment.

# Eligibility for the Regional Revolving Funds

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**In principle, the Ministries of Health of all Member States can participate in the Regional Revolving Funds (RRF), provided they meet specific requirements. In the case of the Revolving Fund for Access to Vaccines (RF), the participation requirements include having:**

A specific allocation in the national budget is intended to cover the costs of vaccines, syringes, and vaccination supplies.

A manager or coordinator of the national immunization program who has been appointed and authorized to develop and implement the program.

A comprehensive and realistic national operational plan that covers at least five years and aligns with the general policies of the Expanded Immunization Program in the Americas, as recommended by the Technical Advisory Group for vaccine-preventable diseases and the applicable resolutions of the PAHO Governing Board.

Regarding the Regional Revolving Fund for Strategic Public Health Supplies (Strategic Fund), all Ministries of Health are eligible to participate by signing a **Participation Agreement**.<sup>5</sup>

In addition to the Ministries of Health, other government institutions recognized by the national health system (such as specialized and subnational institutions) can participate in the Strategic Fund through the signing of an annex to the agreement, along with the Ministry of Health, and PAHO.

Government authorities other than the Ministry of Health seeking to access vaccines and related supplies through the RF must contact the RRF, and this request will be reviewed on a case-by-case basis.

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<sup>5</sup> A model participation agreement for Member States is available at the following address: <https://www.paho.org/es/node/45330>.

# Operational processes of the Regional Revolving Funds

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**The RRF follows standardized operational processes that enable the consolidation of demand for vaccines, essential medicines, and other health technologies through needs assessment and planning, ensuring the necessary supplies through joint procurement. The RRF aims to ensure better conditions for Member States to obtain high-quality products in a transparent and timely manner. Below, the functioning of these operational processes is specified.**

## Demand Planning and Consolidation

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For the RRF to consolidate demand, participating entities, including Ministries of Health and other agencies within the national and subnational health systems of Member States, must annually estimate their requirements for types and quantities of products. It is essential to note that accurate regional demand consolidation lays the foundation for establishing long-term agreements with producers, thereby facilitating timely supply to the Region at an affordable price. This process includes the following steps:

1. Every year, the Revolving Fund and the Strategic Fund send notifications to Member States and their participating entities<sup>6</sup>, allowing them to complete their plans for vaccine demand and essential medicines (as well as other health technologies) for the following year on the RRF Member States' portal.<sup>7</sup> Each fund manages the demand planning process independently.
2. Participating health entities must complete demand plans within the established deadlines for each fund (six weeks for the RF and one month for the SF). The demand plans must be approved by the competent authority of each entity, which will serve as the approver for the entity in the RRF Member States' portal. In the case of the SF, participating health entities can request their products by specifying the generic name,

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<sup>6</sup> Hereinafter, the terms "participating entities" and "Member States" are used interchangeably in this manual to refer to those who participate in and purchase inputs through the Regional Revolving Funds.

<sup>7</sup> Starting in 2023, a new online tool called the RRF Member States portal has replaced the old PAHO-173 form for collecting annual estimates of vaccination supplies. It is available at <https://ms-portal.paho.org/#/home> for Member States, upon authentication.

concentration, dosage form, presentation, required quantity, and requested regulatory requirements. Member States can request support in quantifying needs, including access to the QuantMET tool<sup>8</sup> to quantify the demand for specific products.

3. Once the plans are entered and approved on the RRF Member States' portal, each Fund analyzes and consolidates the demand for the following year.

In the RF, a **reconfirmation** process is in place that allows Member States to modify their initial demand. Until 2025, this process was carried out twice a year:

- Before the end of the current year, to reconfirm the demand for the first half of the following year (Q1/Q2).
- In the first quarter of the following year, to reconfirm the demand for the second semester (Q3/Q4).

The reconfirmed amounts were used to issue price estimates for the corresponding semester.

To streamline the planning process and results, the reconfirmation for T1/T2 has been simplified, focusing on stock information collection. The supply quantities used for issuing price estimates for the first semester will be those included in the annual plan for that period. The reconfirmation for the second semester will remain unchanged. This change will be implemented starting with the 2026 demand planning exercise.

In the SF, needs estimates are analyzed with the respective technical departments at PAHO, and once reviewed, they are returned to the country to proceed with the official request for price estimates of the products with which there is a long-term agreement in force. For products without a long-term agreement, the consolidated demand is analyzed to inform the launch of an international tender, taking into account the number of countries and the requested volume.

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<sup>8</sup> QuantMET tool, which Member States can access via the following link: <https://quantmet.paho.org/>.

# Financial planning for the line of credit

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Once the demand plan is submitted, the RRF Member States' Portal provides an estimate of its cost<sup>9</sup>, allowing participating health entities to plan the necessary funding to cover these needs. The RRF offers two payment options:

- **Prepaid** payment: Participating entities deposit funds into their prepaid accounts, from which reserves are established for the issuance of purchase orders.
- **Line of credit:** allows participating entities to access a line of credit to proceed with purchase orders while finalizing the payment release processes.

If the Member State anticipates the need to use the line of credit, it will request it by sending a letter signed by the highest authority of the Ministry or the Health entity or the officially accredited delegate; each fund will provide the requesting entity with a draft of this letter through the respective PAHO Representation in the country, which will include an annual limit amount for the line of credit.

The annual limit amount of the line of credit is the amount that the Ministry or the Health entity can use during the year for requisitions, purchase orders, and pending invoices at any time during the calendar year. The health entity may use the line of credit to meet its planned needs until it reaches the approved limit amount. Once this limit is reached, the participating entity must reimburse the line of credit to free up capacity for future use.

The limit amount will be determined based on the entity's planned demand, the availability of funds, and other relevant factors.

Payments are due within 60 days from the date the invoice is issued. PAHO will closely monitor debts that are more than 60 days and will implement an escalation system that may include formal communications, meeting convocations, or other communication interventions.

If, when applying, the participating entity has outstanding obligations, additional requirements will apply depending on the amount and age of the invoices, which could range from requesting a payment plan for the debt to

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<sup>9</sup> This estimate is a general projected value for the entire demand plan, different from the price estimates mentioned in the section "Price Estimation Process."

immediate payment. Any unpaid debt counts as use of the credit line and, therefore, reduces the available limit.

Each Fund (Revolving and Strategic) will approve credit line requests separately, ensuring that debt from one Fund does not impact the other, thereby speeding up the approval process.

Unpaid invoices from an entity within the same country do not directly affect the ministry, and vice versa. However, they limit the credit balance available for other Member States and health entities, so timely repayment is critical to continue supporting regional access to health technologies.

## Bidding process

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Once the demand for a product is consolidated, PAHO typically issues an international tender to establish long-term supply agreements. The selected suppliers must meet the eligibility criteria outlined in the 'quality assurance' section, as well as all technical requirements. Additionally, among other factors, the quality-price ratio, previous performance, and quarterly availability are considered.

Once the offers are selected, and according to the consolidated annual demand by the Funds, PAHO signs supply agreements with providers to meet the needs planned by the Member States.

Throughout the entire purchasing process, PAHO maintains clearly defined standards of ethics, transparency, and integrity in its internal procedures.

## Price estimation process

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1. The RF issues price estimates according to the demand plan of the Member States
2. For the SF, participating health entities will send an official request to the country office, confirming the products for which they require a price estimate.
3. An **estimated price or proforma invoice** contains relevant details such as the product description and price,<sup>10</sup> freight and insurance estimate, service charges,<sup>11</sup> the validity of the estimate, the mode of transportation, the language of the label and insert, the expiration date of the batch, and the estimated delivery time, among others.
4. Exceptionally, the RRF may process requests for unplanned purchases (products or quantities beyond those included in the demand plan). However, this approach is not optimal, as it does not allow Member States to benefit from demand consolidation advantages, such as obtaining better prices, and may also lead to longer delivery times. If there are no

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<sup>10</sup> This price is published at <https://www.paho.org/en/regional-revolving-funds> and will be the same as that invoiced to the Member State.

<sup>11</sup> The service charge is 4.25% of the cost of the products, of which 2.5% goes to the capitalization account and 1.75% to the cost of the Funds.

existing long-term agreements that can meet these needs, PAHO may conduct a competitive process. Requests in response to declared emergencies are exempt from this process.

5. The PAHO sends the participating entity the price estimate for its review and approval. In some instances, PAHO will inform the participant about special terms and conditions, allowing them to consider and, if applicable, accept them.
6. The entity reviews and approves the price estimate, and if necessary, confirms the source of funding. Price estimates must be approved within the validity period to avoid delays.
7. With the approval of the estimated prices, it is considered that the participating entity agrees for PAHO to proceed with the purchase and accepts all the conditions and procedures established by PAHO.

# Purchase, shipment tracking, and delivery

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- Once the participating entity approves the price estimate, PAHO issues a purchase **order, a binding legal** document that formalizes the contractual relationship between PAHO and the supplier. It contains details about the quantity of products, as well as their descriptions, costs, and estimated delivery dates and delivery conditions. Purchase orders **cannot be canceled**, neither by PAHO nor by the participating entities, once issued. PAHO, in coordination with the supplier or freight forwarder and the requesting entity, supports international logistics and monitors the delivery.
- PAHO shares the documents for the dispatch of the products included in the purchase order with the health entity. Before dispatch, some of these documents are shared:
  - Air waybill or bill of lading, depending on whether the shipment is by air or sea.
  - Commercial invoice.
  - Packing list.
  - Insurance certificate.
  - Certificate of origin.
  - Good manufacturing practices certificate for the finished product and diluent (if applicable).
  - A pharmaceutical product certificate issued for the recipient country or annexed with the list of importing countries.
  - Analysis certificate or test reports for each batch of finished product and diluent (if applicable).
  - Batch release certificate from the national regulatory authority for the finished product and plasma reserve, if applicable.
  - Brief manufacturing and control protocol, if applicable<sup>12</sup>
  - A declaration letter indicating whether the manufacturing process includes any raw material of bovine origin in the offered product that transmits animal spongiform encephalopathy, if applicable.
  - List of spare parts, accessories, and consumables related to the equipment, if applicable.
  - Certificate of compliance with the quality management system for

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<sup>12</sup> This document summarizes all manufacturing steps and test results for a vaccine batch, and is certified and signed by the person responsible at the manufacturing company. The batch summary protocol applicable to United Nations agencies is used, employing the format recommended by the WHO with the information required according to Table A2.1 of Annex 2 [https://cdn.who.int/media/docs/default-source/biologicals/vaccine-standardization/lot-release -of-vaccines/trs\\_978\\_annex\\_2.pdf?sfvrsn=35394428\\_3&download=true](https://cdn.who.int/media/docs/default-source/biologicals/vaccine-standardization/lot-release -of-vaccines/trs_978_annex_2.pdf?sfvrsn=35394428_3&download=true)

medical devices.

- Analysis certificates, test reports, or other documentation related to the application of standards in accordance with the medical device.

Any request for non-standard documentation must be submitted prior to the approval of the price estimate.

- Before the shipment arrives, the requesting entity, as the consignee, is responsible for obtaining and managing all import licenses and other documents required by local regulatory authorities.
- The entity, as the consignee, is responsible for receiving, customs clearing, and distributing the product within the country.

### **Instructions for the receipt of shipments**

Once the product has been delivered, the entity is responsible for the following:

- Confirm the arrival of the shipment at the PAHO Representation within 24 hours of the date and time of arrival.
- Ensure that the shipment is cleared through customs and transferred from the airport or port to the central warehouse immediately.
- If the shipment does not arrive as scheduled, immediately inform the PAHO Representation and initiate local tracking with the responsible airline or shipping company.
- The cargo tracking should be checked at <https://www.track-trace.com/>. If there is no update, immediately call the airline or local transportation company for the latest information on the arrival.
- If the product is perishable and requires temperature control, the participating entity will contact the airline to have the shipment transferred immediately to refrigerated chambers, according to the instructions contained in the shipping documents.
- Send confirmation of arrival (PAHO form 183) within the first 24 hours of the shipment's arrival, acknowledging only the arrival of the products in the country.
- Completing and sending this **PAHO 183 form** does not prevent subsequent claims for defects, damages to the cargo, incorrect quantities, or other issues.
- Pay the expenses related to customs clearance and transportation (according to the negotiated international trade terms or Incoterms) from the port or airport of arrival to the recipient's facilities or distribution center.
- Immediately after unloading and customs clearance, return the

containers to the transportation, air, or shipping company to avoid fines.

- In the event of penalties, the consignee will pay these expenses promptly.
- If the entity requires quality control of the received products, the Member State will perform and finance it.
- The participating entity will verify the shipments within seven days after delivery.
- Verification involves opening boxes, checking if the quantity is correct, ensuring the presentation and batch numbers match, and verifying that the contents are in good condition and stored and transported according to the manufacturer's recommendations.
- If any irregularity is suspected in the shipment, the entity may file a claim within seven days of receiving the product.
- Any affected part of the shipment must be isolated from the rest, without discarding any damaged packages.

## Billing and payment

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- Once the participating entity confirms receipt of the product, PAHO will issue the invoice corresponding to the purchase order. If a line of credit is used, this invoice must be paid within 60 days of its issuance (see the section "Financial Planning of the Line of Credit" in the previous paragraphs of this chapter).
- The transfers will be made to the Pan American Health Office account at Citibank, account **number 3615-9769**, at the following address:

CITIBANK  
111 Wall Street  
New York, NY 10043  
IN FAVOR OF: Pan American Sanitary Bureau SWIFT #CITIUS33  
ABA #021000089

- Member States must pay all advances and payments to PAHO in U.S. dollars and cover any bank commissions and any gains or losses resulting from currency exchange.
- Member States shall include in their transfers to PAHO the cost of the applicable bank fee, if any, in addition to the total amount they wish to transfer to PAHO.
- PAHO provides participating entities with quarterly statements to monitor their financial situation. Additionally, the RRF Member States Portal provides financial reports to facilitate fund monitoring by participating entities.
- Whenever the participating entities send funds to PAHO, it is necessary to specify the destination account for these funds, and if applicable, the proforma invoice(s), purchase order(s), or invoice(s) number that the transfer is

intended to cover.

If the invoice, proforma, or purchase order for which the transfer is made is not specified, PAHO will apply the payment to the oldest outstanding invoices.

## Claims

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**Claims can arise from quality deviations, temperature excursions, or external or internal physical damage.**

**Quality deviation:** It is defined as the occurrence when a product exhibits quality attributes that differ from those specified by the manufacturer, and these attributes may impact the product's quality characteristics and pose a risk to its efficacy or patient safety. In case of suspected quality deviation, the participating entity must contact the PAHO representation office and send the following information:

- Purchase order number.
- Product description.
- Batch number.
- Date and location of the event.
- Storage conditions throughout the supply chain.
- Current storage location.
- Applicable evidence, such as reports issued by the official laboratory or responsible entity for receipt, the number of samples analyzed, attached photographs, description of the deviation or malfunction observed, physical characteristics of the product, and any other relevant information.
- The quantity of products received and the remaining quantity of products.
- Visual inspection of remaining products (when applicable). It will indicate how many present the same problem.

If the product requires reconstitution before use, the materials and solution used for reconstitution will be specified, along with any changes observed during the process.

- A clear and detailed written description of the issue observed. The product must be kept in quarantine and stored within the temperature range recommended by the manufacturer at all times.

**Temperature excursion:** an event in which a thermosensitive product is

exposed to temperatures outside the range established by the manufacturer for storage or transportation conditions. In case of suspected temperature excursion during international transportation, the participating entity will follow the basic guidelines below and contact the PAHO office, providing the following information:

- Purchase order number.
- **Readings** from all electronic monitors are available in PDF and TXT formats (for Qtag) or PDF and TTV formats (for Temptales), which are mandatory in both formats.
- Photographs of the 3M cards or freezing indicators, if applicable.
- For the vaccine with vial monitors (VVM), send photographs of the vials showing the development of the VVM indicator.
- Complete the temperature excursion notification form (NTE, by its acronym in English) if required by the provider.

The following must be considered:

- Monitors with activated alarms should not be handed over to suppliers or third parties without prior approval from PAHO.
- No monitor will be discarded. None of the original packages will be discarded until PAHO provides the technical guidance for the product's use.
- Undamaged products should be separated from questionable ones to prevent further damage.
- The product must be kept in quarantine and stored within the temperature range recommended by the manufacturer at all times.

**Physical damages (external or internal)**, claims related to incorrect quantities received, loss of products, incorrect products received, broken boxes, missing items, spills, etc. The ministry or health authority of the Member State will follow the basic guidelines below, submit the claim with all the requested information, and contact the PAHO office to provide the following information:

- Purchase order number.
- Product description.
- Batch number or serial number, as applicable.
- Date of arrival, photographs showing the damage, and those that display the brand, batch, product, manufacturer, and box number, among other information.
- Event description.
- Total number of affected units.
- Storage conditions throughout the supply chain.
- Current storage location.

It is important to note that claims will **not** be considered in the following cases:

- Broken or damaged units after the deadline for filing claims.
- Damages caused during transportation from the airport to the warehouse.
- Damages caused by forklifts at the destination.
- Cases in which there is no alarm registered on the temperature control monitors.
- Unused products whose shelf life has expired.

It is important to highlight that if the Member State is the direct beneficiary of the cargo insurance policy, it must immediately contact the insurance representatives in the country and provide the relevant information. The insurance policy establishes the deadlines that must be met. If necessary, at the request of the PAHO technical unit, the health entity will support the claim by sending samples for evaluation by WHO for prequalified products, or by reference laboratories of that Organization.

### **Claims resolution**

- Once all the information has been received from the entity and the reference laboratory's assessment, if applicable, PAHO will issue a final technical statement on the use of the product in question.
- If the technical statement issued by PAHO concludes that the product, in whole or in part, cannot be used and the responsibility falls on the manufacturer, the necessary actions will be coordinated with the suppliers or freight forwarders. It should be noted that invoices cannot be canceled.
- If PAHO's technical evaluation determines that the product, in whole or in part, can be used, the country will be informed to proceed with using the product according to the manufacturer's specifications.
- If the supplier, the Ministry, or the health entity disputes PAHO's technical statement, PAHO reserves the right to select a laboratory, at the expense of the disputing party, to conduct its own evaluation. The decision of this laboratory will be final.

### **Destruction or de-naturalization of rejected products**

- The Member State, in its capacity as consignee, assumes full responsibility for the handling, storage, disposal, and, when applicable, decontamination or destruction of supplies that have not been approved during the technical

reception.

- In the event of claims regarding deliveries made by suppliers according to established procedures, whose assessment concludes responsibility lies with the supplier, PAHO will coordinate with said suppliers to have them assume the costs associated with defective products, if any, including, when applicable, the costs of local destruction.
- In this context, it is recommended that the Ministry or health entity incorporate into their national protocols the applicable procedure for the final disposal of pharmaceutical and medical products, specifically for the destruction of supplies supplied through Regional Revolving Funds when such products are rejected after technical reception.
- Additionally, it is recommended that this preventive consideration be considered in national logistics planning to anticipate operational and budgetary needs related to the final disposal of supplies that do not pass technical reception standard control.
- It should be noted that the Member State must obtain PAHO's approval before proceeding with the destruction of the products. PAHO will only approve the destruction once coordination with the suppliers has been completed.
- The Member State must allow PAHO and/or the supplier access to the goods to verify if there is damage or a defect. Without such access, PAHO cannot guarantee reimbursement or replacement from the supplier.
- To facilitate a possible reimbursement request to the supplier, it is recommended that the Member State document the destruction process with a

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report and an invoice reflecting the costs incurred, as well as include the destruction certificate, if applicable.

The Regional Revolving Funds (RRF or “the funds”) of the Pan American Health Organization (PAHO) are mechanisms of technical cooperation that support countries and territories in the Americas in accessing vaccines, essential medicines, and quality public health supplies at affordable prices, in a timely and transparent manner. To achieve this, they rely on joint purchasing and leverage economies of scale to obtain better conditions for participating Member States.

In line with the principles of solidarity, Pan-Americanism, equity, quality, and transparency that have always characterized them, the RRFs play an essential role in the fight against vaccine-preventable diseases such as poliomyelitis, rotavirus infection, yellow fever, as well as others, including HIV/AIDS, malaria, and tuberculosis.

In 2024, the RRFs acquired health supplies for 41 countries and territories in the Americas. In this regard, PAHO’s support is twofold. On the one hand, it helps reduce the administrative burden on these countries and territories. On the other hand, it supports them with recommendations for supplies aligned with technical and programmatic specifications.

This operational manual has been designed for national authorities of the Member States, such as Ministries of Health and other participating institutions of the RRFs. In particular, it will be very useful for decision-makers and resource management staff in the health sector.

It provides an overview of the processes related to technical cooperation in supporting Member States and territories in estimating needs and purchasing vaccines, medicines, and other essential public health supplies through the RRFs. It offers the necessary information to strengthen operational capacities and optimize procedures related to the joint procurement of vaccines, medicines, and other public health supplies, as well as the administration of the RRFs.