

# ***Operating Procedures for the Regional Revolving Fund for Strategic Public Health Supplies***

## ***(Strategic Fund)***

Updated: September 22, 2022

### **General Considerations**

1. The Strategic Fund was created by the Director of the Pan American Health Organization (PAHO), in accordance with the authority conferred to him under PAHO Financial Regulations and at the request of Member States of the Organization, in September 1998 during the 35th session of the Pan American Sanitary Conference. In December 1999 the Director formerly invited all Member States to participate in the Fund.

### **Objectives**

2. The objectives of the Strategic Fund are to:
  - Facilitate the procurement of strategic public health supplies by PAHO Member States at a reduced cost by taking advantage of the potential savings offered by economies of scale;
  - Enhance the continuous and timely availability of supplies in PAHO Member States, especially single- or limited-source supplies;
  - Encourage the Member States to improve supply planning capabilities;
  - Promote the implementation of appropriate quality assurance procedures for the supplies procured;
  - Strengthen Member States' public health programs and application of the pertinent PAHO/WHO regulatory mandates.

### **Country Participation**

3. All PAHO Member States can participate in the Strategic Fund on signature of a Participation Agreement (hereafter "the Agreement"). This Agreement must be signed by PAHO and the government (as represented by the Ministry of Health). The basic purpose of the Agreement is to reflect the commitment of participating countries to addressing common problems and to provide mutual support in managing the supply of quality essential public health supplies, adhering to the Strategic Fund' s operating principles and procedures.
4. The Strategic Fund supports participating countries by:

- Providing technical assistance in procurement planning, product distribution, and estimation of future demand for products;
  - Guaranteeing the supply of quality products;
  - Facilitating communication and coordination among suppliers to improve access to and availability of products.
5. Under said Agreement, other government institutions in participating countries can access the Strategic Fund upon signature of an Annex to the Agreement to be signed by PAHO, the Ministry of Health, and the respective government institution, employing the model agreement approved by PAHO's Office of Legal Council for this purpose.
  6. Furthermore, Principal Recipients of the Global Fund can participate in the Strategic Fund upon signature of a Tripartite Agreement to be signed between PAHO, the government, and the Principal Recipient, employing the model approved by PAHO's Office of Legal Council for this purpose.

### **Strategic Public Health Supplies**

7. Supplies procured through the Strategic Fund must meet the criteria set forth in the Operating Principles of the Strategic Fund and must be included in the Strategic Fund's latest Product List, available on its website ([www.paho.org/StrategicFund](http://www.paho.org/StrategicFund)). The insecticide list is available on the WHO website (<http://www.who.int/whopes/quality/en>).
8. The Product List includes antiretroviral drugs and drugs for the treatment of opportunistic infections associated with HIV/AIDS, first- and second-line malaria and tuberculosis drugs, Chagas' disease and leishmaniasis drugs, antivirals, immunosuppressants and other essential medicines, laboratory reagents for rapid and confirmatory HIV/AIDS testing, and reagents to measure viral load.
9. Pesticides on the Strategic Fund Product List conform to the specifications and formulations indicated by WHO in its Pesticide Evaluation Scheme (WHOPES).
10. The Medicines and Technologies (HSS/MT) within the Area of Health Systems based on Primary Health Care (HSS) periodically updates the Strategic Fund Product List, according to technical criteria and/or in response to requests from Member States.

### **Needs Programming and Procurement of Drugs and Other Strategic Supplies**

11. Each participating country, with cooperation from PAHO, shall annually determine the need for drugs and other supplies to be procured through the Strategic Fund, based on its historical consumption and epidemiological profile. Guided by its procurement plan, the participating country will draw up a list of drugs and other

strategic supplies to be procured, indicating technical and administrative specifications for each product as well as respective quantities required.

12. In so far as possible and when annual needs estimates for products included in the Strategic Fund are available, annual tenders will be executed in order to negotiate long term agreements with suppliers which in turn will ensure availability of products at established prices for the period.
13. In each participating country, the Ministry of Health, in coordination with the PAHO Representation, shall provide a list of supplies to the Procurement and Supply Management Area (PRO) of PAHO in Washington, D.C., so that PRO can proceed and issue a price estimate (PE) for the required supplies. Price estimates may be requested only for medicines and other supplies on the Strategic Fund list.
14. In the case of medicines, the participating country must include in its request the following information:
  - Generic name or international nonproprietary name (INN)
  - Dosage form
  - Concentration
  - Specifications of the primary container (and of the secondary and tertiary containers, when relevant)
  - Units per primary container
  - Available shelf life at the moment of reception
  - Quality control requisites

The form in Annex I, "Official Request of Prices for Procurement of Medicines and Supplies through the PAHO Strategic Fund," should be used in making the above mentioned request.

For further detail in the specifications of medicines, it is recommended that the country completes the medicines technical form of Annex II.

15. The request from the participating country must indicate whether other documents are needed to ensure the quality of medicines to be procured, such as product registration requirements in the country of origin or destination or other documents required in accordance with national regulations. The country must also inform PAHO about products protected by patent in the country of destination.
16. When requesting laboratory reagents, the participating country must provide:
  - The name and description of the reagent;
  - The commercial name;
  - The respective catalogue code;
  - The quantity required and shelf life of the reagent on its arrival in the country;
  - Delivery dates and mode of transport.

17. If the product is a pesticide, the request must include the name of the insecticide/rodenticide/pesticide, using the common name found in the WHO specifications (WHOPES) available at [www.who.int/whopes/quality/en](http://www.who.int/whopes/quality/en), along with the following information:

- Name of the pesticide/insecticide/ rodenticide.
- Percentage required (1%, 20%, etc.).
- Formulation required (aqueous suspension concentrate, emulsifiable, concentrate, sand granules, ultra low volume liquid etc.).
- Size of container (1 kilo, 50 pound bag, 1 liter, etc.).
- Quantity in kilos, pounds, liters, charges, etc.
- Delivery date required.
- Registration requirements in the country of destination.
- Mode of shipment (air or ocean).

18. The procurement specialist at the PAHO country office and PRO shall obtain price estimates verifying that (i) the products requested are included on the Strategic Fund Product List and (ii) the requesting party is an authorized participant in the Strategic Fund. If these two criteria are met, PRO shall include the following statement in the price estimate:

*"The products requested are on the PAHO Strategic Fund Product List, and the requesting party is a Fund participant. The service charge applied to the purchase order generated by an approved purchase authorization shall be credited to the Strategic Fund Capital Account. "*

19. According to the standards and procedures in place, PAHO requests price quotations from its prequalified suppliers and, on receipt of same, selects the best offer. In the case of pesticides, the request for price quotes is sent to suppliers whose products meet the specifications presented in the WHO Pesticide Evaluation Scheme (WHOPES).

20. PRO forwards pro forma invoices or price estimates to the participating country through the PAHO Representation in the country. Pro forma invoices shall explicitly state that the supplies in question will be purchased through PAHO's Strategic Fund. They shall likewise indicate the product for which the price quotation has been obtained, along with technical specifications, unit price, and total cost, including shipping and insurance. The prices in the estimate or pro forma invoice are CIF (Incoterms); that is, they include shipping and insurance to which 4.25% of the value of the supplies will be added. Information will also be provided on the period of validity for the price estimate, the mode of transport, and the conditions of delivery, specifically the date of product shipment and arrival in the country. A copy of this information is issued to the Regional Coordinator of the Strategic Fund.

21. On accepting the price estimate or pro forma invoice submitted by PAHO, the participating country accepts the cost and conditions of delivery indicated by the supplier and formally requests that PAHO place the respective orders, for which it must transfer the necessary funds, in U.S. dollars preferably, to the account that PAHO has set up for this purpose. For this, the country must complete and submit the form in Annex III (Official approval of pro forma invoice or price estimate for the procurement of medicines and supplies through PAHO's Strategic Fund).
22. PRO shall prepare the respective purchase authorizations as requested once the participating country has transferred funds as referenced in point 21 or when there is a sufficient balance in the Strategic Fund account (HD) of the country in question.
23. PAHO shall issue only purchase orders that can be covered with existing unobligated funds in the participating country's Strategic Fund account (HD).
24. In the case of purchase orders that exceed the unobligated balance in the participating country's Strategic Fund account (HD), the country must make the respective deposit, in U.S. dollars preferably, in advance, through a bank transfer or check to PAHO corresponding to the difference between the available balance and the total cost of the supplies, including the cost of the product, shipping, insurance, 4.25% of the total value of the order, 2.5% will be assigned to the capitalization account of the Strategic Fund, and 1.75% to the service charge
25. Based on the purchase authorizations approved by the countries and pursuant to its rules and procedures, PAHO shall issue purchase orders, equivalent to contracts with the suppliers.
26. Once the procurement process is under way, PRO shall convey the conditions and delivery dates to the participating country through the PAHO Representation and shall ensure that documentation necessary for receipt of the product is issued.
27. If a participating country wishes to cancel an order once the purchase order has been issued, it must notify PAHO immediately. Only cancellations made 45 days prior to the delivery date indicated in the purchase order will be accepted. Under the terms of the contract between PAHO and the supplier, any cost connected to the cancellation of an order or a reduction in the quantity purchased will be borne fully and exclusively by the country participating in the Strategic Fund.
28. The participating country shall receive a copy of the purchase order as indication that the order has been placed.

## Country Strategic Fund Account (HD)

29. When the participating country makes a bank transfer to the Strategic Fund for the procurement of supplies, it must reference the pro forma invoice (price estimate) prepared by PRO. Funds received will be allocated to a Strategic Fund account (HD) or budget line for the respective participating country, from which supplier invoices are paid. The country's Strategic Fund account (HD) is used each time the country or recipient institution makes a purchase through the Strategic Fund. The funds in the country's HD are available for purchases under the procedures in place.

## Capital Account

30. PAHO has created a Capital Account for the Strategic Fund, into which a capital contribution of 2.50% of the total cost of each purchase made by the participating countries is deposited.  
The Capital Account is used to procure strategic public health supplies during a declared emergency in a participating country (e.g., an instance in which supplies are out of stock due to an epidemic or other factor jeopardizing public health), facilitating payment for the supplies received. To access funds from the Capital Account, the participating country must make an official request (using the form in Annex IV), confirming that the funds advanced will be reimbursed within 60 calendar days of the date the country receives the supplies. The use of the Capital Account is authorized by PAHO Director, following technical review by the Regional Coordinator of the Strategic Fund.
- 31.
32. The Capital Account may receive donations or financial contributions from regional, global projects or initiatives.

## Billing

33. PAHO bills the country in U.S. dollars for the full cost of each acquisition, which includes the cost of the product, shipping, insurance, and the 2.5% capital contribution and 1.75% service charge. If the PAHO invoice indicates a deficit, it must be paid by the country within 60 days.
34. Payments to the Strategic Fund and advances must be made by bank transfer or check in the following manner:
  - a. ***Payment by bank transfer:*** Transfers shall be made to the Pan American Sanitary Bureau account at CITIBANK (account no. 3615-9769), referencing the number of the pro forma invoice (price estimate) and the Strategic Fund, at the following address:  
**CITIBANK**  
**111 Wall Street**  
**New York, NY 10043**  
**IN FAVOR OF: Pan American Sanitary Bureau**  
**Swift #CITIUS33 ABA #021000089**

b. **Payment by check:** If the participating country wishes to pay by check, the check should be made payable to the Pan American Sanitary Bureau, in U.S. dollars preferably, from a branch of any financial institution in the United States, referencing the number of the pro forma invoice (price estimate) and the Strategic Fund, and sent to:

**Pan American Health Organization**

**525 23rd Street, NW**

**Washington, DC 20037**

**Attn: FMR/FA/TSY**

**RFF: Strategic Fund** (The number of the respective pro forma invoice or price estimate should be indicated)

All advances and payments of Strategic Fund invoices should be made in United States dollars. However, Member States may make payments in local currency using the United Nations Operational Rate of Exchange (UNORE) in effect on the date of payment. The Member State must inform the PAHO country office in advance of the payment in order to ensure that the office can absorb the local currency through normal operations over the next 30 days.

If the PAHO country office cannot absorb the local currency resulting from the payment by the Member State, it must either transfer the funds to another United Nations office in country at the UNORE or sell the funds into US dollars and repatriate them to the PAHO headquarters main corporate bank account. If there is a currency exchange difference from either of these two transfers as a result of timing differences or a difference in the market rate of exchange upon the sale of local currency, the Member State will absorb the gain or loss directly to its accounts receivable balance with the Strategic Fund. The Member State will be notified of any balance remaining due as a result of these transactions.

**Shipment, Delivery, and Receipt of Goods**

35. The Procurement and Supply Management Area (PRO) shall provide information on the shipment, including copies of the shipping documents, to the consignee through the PAHO Representation in the country and on receipt of the information from the supplier and/or its shipping agent. It must also send a copy of this information to the Regional Coordinator of the Strategic Fund.
36. Supplies charged to the Strategic Fund shall be consigned *not* to PAHO but rather to the requesting country, in the name of the officer responsible for customs clearance and the distribution of the supplies in the participating country.

37. The documents sent to the consignee prior to the shipment of the supplies include:
- Airway bill or bill of lading (depending on whether the shipment is by air or sea), commercial invoice, and packing list;
  - Insurance certificate;
  - WHO type certificate of quality for pharmaceutical products circulating in international trade;
  - Certificate of quality for each batch.
38. Payment of charges, fees, or fines relating to customs operations, warehousing, container retention, or other national processes is the sole responsibility of the consignee (Fund participant country).
39. If there are indications that the supplies have been improperly handled or if visible damage is apparent on receipt, the consignee must complete the nationalization process, take possession of the shipment, and immediately notify the airline or shipping company in writing; in addition, the consignee must notify the insurance company in writing and within the timeframe specified in the insurance policy of its intent to file a formal claim. The consignee must also inform the PAHO/WHO Representation in the country so that it in turn can report the problem to PRO. Likewise, if internal damage (e.g., broken bottles or material in questionable condition) is found when the contents of the shipment are checked (a process that should take place as soon as possible), the consignee must report the damage to the insurance company immediately and notify the PAHO Representation in the country.
40. The consignee must retain all evidence of improper handling of the product during transport, such as damaged merchandise and bottles that are broken or in unsatisfactory condition, until the claim has been settled. The consignee is responsible for filing any claims with the shipping and/or insurance company, as applicable, within the timeframes specified in the shipping contract and/or insurance policy.
41. The consignee is responsible for ensuring that medicines and supplies are imported pursuant to national regulations. In addition, the consignee is responsible for conducting the appropriate in-country quality control tests.
42. The consignee must inform the PAHO Representation in the country that the shipment has been received in proper condition as soon as possible, and not exceeding the timeframes indicated in the grid below:

Type of Product	Maximum timeframe
Perishable and Semi-perishable	72 hours after arrival (3 days)

Medicines (and other non-perishable supplies)	120 hours after arrival (5 days)
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43. Upon reception of the products, the consignee must fill out and return to the PAHO country office the reception certification forms in Annex V (for medicines) and/or VI (for other supplies).

### **Quality Assurance of Strategic Supplies**

44. For purchases through the Strategic Fund, PAHO uses a prequalification system to create a basic list of providers and products that meet specific quality criteria.
45. For pharmaceuticals that are multisource and/or are not being evaluated by WHO, PAHO uses suppliers that have been assessed and prequalified, furnishing evidence of compliance with current requirements for good manufacturing practices and adherence to appropriate quality assurance and quality control standards.
46. For pharmaceuticals that are evaluated through the United Nations Prequalification Programme managed by WHO (<http://www.who.int/prequal/>) and that are not multisource, including all antiretrovirals (ARVs) for the treatment of HIV/AIDS, PAHO procures products that have been:
- a) Prequalified by such program; or
  - b) Registered by the regulatory authority of a member of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH).

When relevant, the Strategic Fund Coordinator and Quality Specialist may consider authorization of procurement of products positively reviewed (and approved for procurement on a temporary basis) by the WHO-hosted Expert Review Panel. This authorization will not be made without express discussion and approval from the consignee country.

In the case of medicines for the treatment of tuberculosis ( I st line) and malaria, given that these products are evaluated by the WHO Pre-qualification Program but for the moment such program has only evaluated few -in cases none- suppliers for such medicines, PAHO will prioritize suppliers pre-qualified by WHO or approved by agencies part of the ICH scheme, but -in the absence of adequate options within those categories, and given that these medicines are generally multisource- PAHO may temporarily procure from suppliers without such prequalification or approval but prequalified already by PAHO.

47. In order to ensure the quality of medicines, PAHO requires suppliers to furnish a Certificate of Quality for Pharmaceutical Products Moving in International Trade (WHO type certificate) as well as a certificate of quality for the pharmaceutical product lot, documentation that is sent to the participating country for each product purchased

48. The certificate of quality should indicate the international standards and reference used for testing, including the edition number. Recognized international standards include the United States Pharmacopoeia (USP), the British Pharmacopoeia (BP), the European Pharmacopoeia (EP), the WHO International Pharmacopoeia, and other standards as determined by PAHO.
49. PAHO reserves the right to select the laboratory of its choice to verify the quality of a product before or after delivery and to obtain representative samples of the product or its active ingredients, which the manufacturer shall supply free of charge.
50. Consignees should conduct quality control tests on products within a reasonable time after the receipt of the products, normally within 90 calendar days of arrival at the port of entry or within a timeframe agreed to beforehand by the consignee and PAHO.
51. If quality issues arise related to supplies procured through the Strategic Fund, the consignee must immediately inform the PAHO country office, who will inform AM/PRO and the Strategic Fund Regional Advisor and Coordinator, remitting the information required in Annex VII. On receipt of the respective information, PRO shall contact HSS/MT to make arrangements for quality control testing, including the designation of appropriate reference laboratories. If a quality control report issued by the reference laboratory does not support the respective claim, PAHO (HSS/MT) shall inform the participating country and the respective entities.
52. Under the contract established between PAHO and the supplier, the supplier is normally responsible for removing or replacing rejected lots within 60 calendar days of notification by PAHO, as well as for all related costs.
53. PRO shall conduct an annual evaluation of supplier performance based on indicators established by the Strategic Fund. Using this information, HSS shall reassess prequalified suppliers, imposing sanctions on suppliers for noncompliance.
54. In the case of pesticides, products must be sourced from international suppliers that meet the specifications presented within the WHO Pesticide Evaluation Scheme (WHOPES) and, at the prior request of the receiving country, are registered in that country.
55. For pesticide procurement, a certificate of compliance and testing shall be required that indicates that the product meets the technical specifications found in the monographs of the WHO Pesticide Evaluation Scheme. Pesticides must be subjected to quality control testing prior to their use. Suppliers shall be paid according to the terms and conditions described in the purchase order; providers

will not be paid until the selected quality control laboratory has approved the product.

56. Pesticides rejected during quality assessment shall remain the property of the supplier, which is responsible for their destruction under the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal of the United Nations Environment Programme. The cost of eliminating and replacing the product shall be borne exclusively by the supplier.

### **Strategic Fund Reports**

57. PRO will facilitate access to the Strategic Fund Coordinator to an annual report on the degree to which the countries have used the Strategic Fund, based on the following variables:

- Number of countries that have used the Strategic Fund;
- Number of price estimates issued, by country;
- Number of purchase orders placed, by country;
- Distribution of purchases, by product and country.

58. FMR shall issue an annual report to the Strategic Fund Coordinator, including the financial balance at the beginning of the year, income and expenditures during the year, and the financial balance at the end of the year for each country. It shall also submit an annual report on the funds available in the Strategic Fund Capital Account and movements related to the Fund.

59. The Procurement and Supply Management Area (PRO) maintains an up-to-date listing of average prices for Strategic Fund products:  
<https://intranet.paho.org/AM/PRO/English/AGSPWeb/MAIN.html> (select PRObuy link)

60. Each participating country shall receive a quarterly financial report from FMR indicating the country's procurement activity, income, expenditures, and account balance.

**ANNEX I**

	<b>OFFICIAL REQUEST OF PRICES FOR PROCUREMENT OF MEDICINES AND SUPPLIES THROUGH THE PAHO STRATEGIC FUND</b>
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Country, city, and date

PAHO Representative Office

**Re:** Official price request

I (Indicate full name and identification) \_\_\_\_\_, acting as representative of (name of institution) \_\_\_\_\_, and within the framework of the agreement signed with PAHO to use the Strategic Fund, hereby request that you obtain a price estimate for the medicines and supplies listed below.

**Medicines**

Item no.	Product (INN)	Presentation				Quantity	Delivery date
		Pharmaceutical form	Concentration	Specifications on the primary container	Units by primary container		

List any other technical standards or administrative specifications required by the country (shelf life at time of receipt, quality control requirements, language, etc.).

**Laboratory reagents**

ITEM No.	Generic name	Proprietary name	Description of reagent	Catalog code	Quantity requested	Shelf life required	Delivery date	Mode of transportation

List any other technical standards or administrative specifications required by the country.

**Pesticides**

ITEM No.	Name	Percentage of concentration	Formulation requested	Container size	Quantity (liters, kilograms, loads)	Delivery date	Mode of transportation

List any other technical standards or administrative specifications required by the country (national registration requirements, etc).

Thank you for your assistance.

Sincerely,

Signature and seal Representative of: [institution]

## ANNEX II

 <p>OPS OMS</p>	<h3 style="margin: 0;">MODEL TECHNICAL SHEET FOR MEDICINES</h3>
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### 1. Description

Generic or international nonproprietary name of the medicinal product (INN)	
Pharmaceutical form I Form of administration	
Concentration of the product (mg, g, IU per unit)	
Presentation of the product: units per primary package (blister, bottle, ampoule, etc.)	
Shelf life (minimum required at the time of receipt of the product)	

### 3. Container - Packaging

#### 2.1. PRIMARY CONTAINER

##### 2.1.1. Characteristics and labeling of the primary container

The following data should be *stated at least once.*'

Material (describe the material requested):

Language (specify the language requested):

Generic name or INN
Pharmaceutical form
Concentration of the active ingredient
Lot or code number
Expiration date
Current public health registration number
Name of the manufacturing laboratory or its logo
Legend specified by the institution (free medicinal product, sale prohibited)

#### 2.2. SECONDARY CONTAINER

##### 2.2.1. Characteristics of the secondary container

Box made of cardboard or other substantial material that will protect the product during the handling it will undergo

### 2.2.2. Labeling of the secondary container (external label)

Material (describe the material requested):

Language (specify the language requested):

The labeling on the container should indicate at least the following information:

Generic name or INN
Proprietary name (if appropriate)
Pharmaceutical form
Contents of the container (presentation)
Concentration of the active ingredient
Qualitative and quantitative formulas
Form of administration
Number or lot code
Preparation date
Expiration date
Name of the manufacturing laboratory, city, and country of origin (if applicable, mention any others involved in responsibility for the manufacture, control, and marketing of the medicine)
Storage temperature (specify whether it requires special storage conditions in terms of temperature, light, or any other condition that could influence the stability of the product)
Precautions
Contraindications
Legend specified by the institution, if applicable (free medicinal product, sale prohibited)

### 2.3. PACRAGING (TERTIARY CONTAINER)

#### 2.3.1. Characteristics of the packaging

Box made of cardboard or other substantial material, sealed with strapping tape or other material that protects the contents from being tampered with.

In the event of surpluses, clearly identify the box that contains them

#### 2.3.2. Labeling on the package

Generic nam
Pharmaceutical form
Concentration of the active ingredient
Contents of the container
Batch number
Expiration date
Manufacturer

### **3. QUALITY CONTROL REQUIREMENTS**

At the time the product is delivered from the laboratory, the manufacturer should attach the following documentation:

- Copy of the current public health registration of the medicinal product recorded in the country of origin or destination (as appropriate)-not all countries require this information; some have granted a waiver for purchasing drugs without public health registration.
- Copy of the certificate of analysis of the manufacture lot or lots of the medicinal product being delivered
- WHO-type certificate of quality
- Any other documentation required by the country under its regulations

*ANNEX III*

	<p><b>OFFICIAL APPROVAL OF PROFORMA OR PRICE ESTIMATE FOR PURCHASE OF MEDICINES AND SUPPLIES THROUGH PAHO STRATEGIC FUND</b></p>
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Country, city, and date

PAHO Representative Office

**Re:** Approval of Pro Forma Invoice or Price Estimate

By means of this letter I, (full name and title) \_\_\_\_\_,  
acting as representative of (name of institution) \_\_\_\_\_,  
hereby approve Pro Forma Invoice no. \_\_\_\_\_ and authorize you to proceed  
with procurement of the medicines and supplies indicated.

The corresponding funds have been transferred in (currency) to account no.  
\_\_\_\_\_, at (name of bank) \_\_\_\_\_,  
for: \_\_\_\_\_. A verification copy of the transfer is  
attached.

Thank you for your assistance.  
Sincerely,

\_\_\_\_\_  
Signature and seal of representative of the institution

*ANNEX IV*

	<p><b>OFFICIAL REQUEST FOR LOAN FROM THE CAPITAL ACCOUNT OF THE PAHO STRATEGIC FUND FOR THE PROCUREMENT OF MEDICINES AND SUPPLIES</b></p>
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Country, city and date

PAHO Representative Office

**Re:** Official request for loan from the Strategic Fund capital account

By means of this letter, I (full name) \_\_\_\_\_, Minister of Health of (requesting country) \_\_\_\_\_, within the framework of the agreement signed with PAHO on use of the Strategic Fund, would like to request a loan from the capital account of the Strategic Fund for the procurement-through said Fund-of medicines and supplies in the amounts and at the prices itemized in the attachment to this letter. This request is being made in the interest of protecting public health, given that we are experiencing an emergency, natural disaster, and/or imminent shortage and we do not have sufficient time to raise our own funds.

The details of this situation, the justification for the specific medicines and supplies, and the amounts being requested are provided below.

This Institution hereby assumes the commitment to reimburse the amount of the loan within 60 days of receipt of the products.

Thank you for your assistance.  
Sincerely,

\_\_\_\_\_  
Signature and seal of representative of the institution

**ANNEX V**

 	<p><b>FORM</b></p> <p><b>CERTIFICATE OF SATISFACTORY RECEIPT OF MEDICINES PURCHASED THROUGH THE STRATEGIC FUND</b></p>
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COUNTRY:	CITY:	HEALTH AUTHORITY:
PURCHASE ORDER No.		AIR WAYBILL/BILL OF LADING No.
DATE OF RECEIPT:		DATE OF INSPECTION:
SAMPLING PLAN: take 10% of the units or (1 + n), N being the total number of packages received, and inspect for the elements listed or apply the procedure specified by your institution.		

Name of product	Pharmaceutical form	Presentation	Lot no.	Expiration date	Manufacturer

INSPECT OR VERIFY	COMPLIES (1)
	YES NO
Are the invoice and shipping documents complete?	
Is the lot analysis certificate complete?	
Is there an international trade WHO-type pharmaceutical product quality certificate included?	
If required, is documentation on public health registration included?	
Were the shipping conditions acceptable (temperature, moisture, storage)?	
Does the pharmaceutical form match the form requested in the Purchase Order?	
Do the name and concentration of the active principle or pharmaceutical ingredient match the Purchase Order and the analysis certificate?	
Is the product label written in the language requested?	
Does the name on the primary and secondary containers match what was requested in the Purchase Order?	
Is the product in its primary and secondary container free of any overlabeling or re marking suggestive of adulteration or forgery?	
Do the expiration date and batch number on the primary and secondary containers match what is being declared by the supplier?	
Is the products primary container free of any visible contamination (i.e., dirt showing inside, spots, flakes, mold)?	
Is the product fully covered/sealed/packaged and free of any signs of leakage?	
Do the quantities sent match the amounts on the Purchase Order?	

Comments \_\_\_\_\_

Conclusion: mark with an X: whether the product is approved: Yes No

Responsible officer (full name and position)	Signature	Date

**ANNEX VI**

 	<p><b>FORM</b></p> <p><b>CERTIFICATE OF SATISFACTORY RECEIPT OF SUPPLIES AND REAGENTS PURCHASED BY THE STRATEGIC FUND</b></p>
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COUNTRY:	CITY:	HEALTH AUTHORITY:
PURCHASE ORDER No.		AIR WAYBILL/BILL OF LADING No.
DATE OF RECEIPT:		DATE OF INSPECTION:
SAMPLING PLAN: take 10% of the units or (1 + n), being N the total of received packaging, and carries out the inspection of attributes or applies the procedure stipulated in its entity.		

Name of reagent or supply	Presentation	Lot no.	Expiration date	Manufacturer

INSPECTOR OR VERIFY	COMPLIES <sup>(1)</sup>
	YES NO
Are the invoice and shipping documents complete?	
Is the certificate of analysis/quality corresponding to the lot complete?	
Were the shipping conditions acceptable (temperature, moisture, storage)?	
Does the presentation match what was requested in the purchase order?	
Is the product label written in the language requested?	
Is the product in its primary and secondary container free of any overlabeling or re marking suggestive of adulteration or forgery?	
Do the expiration date and batch number on the primary and secondary containers match what is being declared by the supplier?	
Is the product's primary container free of any visible contamination (i.e., dirt showing inside, spots, flakes, mold)?	
Is the product fully covered/sealed/packaged and free of any signs of leakage?	
Do the quantities sent match the amounts on the Purchase Order?	

(1) A negative response will give rise to a claim

Comments \_\_\_\_\_

Conclusion: mark with an X: whether the product is approved: Yes No

Responsible officer (full name and position)	Signature	Date

## *ANNEXVII*

### **Procedures for Filing a Claim in Connection with the Quality of Pharmaceuticals Procured via the PAHO Strategic Fund**

1. The quality of pharmaceuticals is considered to be compromised when any of the following occurs:
  - a) The pharmaceuticals do not comply with quality standards, as confirmed by a report or certificate issued by the Official Medicines Control Laboratory or a laboratory accredited for this purpose;
  - b) Primary, secondary, or tertiary containers do not meet the stipulated requirements or are received broken and/or damaged, without labels, or missing information on the respective labels;
  - c) The cold chain is interrupted during product transport (in applicable cases).
  - d) A product without corresponding labels or the absence of information on the label
2. When problems with the quality of a pharmaceutical product are reported, the PAHO Representation in the participating country must be informed within 90 days from reception of the product in the port of entry and via an official communication containing the following information:
  - A brief description of the problems detected in the pharmaceutical product (certificate of testing indicating the dates when quality control was performed);
  - Description of the pharmaceutical product: name of the drug (INN), dosage form, concentration, pharmaceutical presentation, trade name of the product, name of the manufacturing laboratory, and, if applicable, name of the distributor, lot number(s), and expiration date;
  - Purchase order number and date of receipt of the pharmaceutical product;
  - Certificate of analysis from the country's official laboratory or the laboratory accredited for that purpose;
  - Certificate of analysis for the lot issued by the manufacturing laboratory;
  - In the case of problems with the container or tertiary packaging of the product, photographs submitted as evidence.
3. In cases where the claim is related to problems with the integrity of the packaging (primary, secondary, or tertiary), the transportation company and insurance company must be informed immediately (within the timeframes specified in the transportation contract and insurance policy), with a copy of the communication forwarded to the PAHO Representation in the participating country annexing the respective certificate of acceptance. PAHO's shipping department will assist with the claims process.

4. In cases where the cold chain is interrupted, as in the previous case, the country must inform both the transportation company and the insurance company, forwarding a copy of the communication to the PAHO Representation in the participating country and attaching appropriate documentation.
5. If the shipment is partial (i.e., units are missing), the PAHO Representation must be informed immediately; if the loss occurred during transport, the transportation company and the insurance company must be informed immediately (within the timeframes specified in the transportation contract and insurance policy), along with the PAHO Representation in the country, with appropriate documentation attached.
6. Claims must be submitted immediately upon arrival of the goods, within the timeframes specified in the transportation contract and insurance policy (normally within 3-5 days)
7. When the claim is related to problems with the quality of the product, whether it is in a solid dosage form such as tablets or capsules (240 tablets/capsules), in the form of an injectable (24 ampoules/ampoule flasks), or in the form of an oral solution (18 flasks), the country may be requested to send a sample of the product to PAHO for subsequent quality control testing, if applicable.
8. Samples must be kept at the PAHO Representation in the participating country until a new quality control test is required. HSS/MT shall select a quality control reference laboratory to which the samples will be sent for further quality control testing.
9. Based on the quality control report issued by the country's official laboratory and the results of further quality control testing at the reference laboratory, PAHO shall if necessary file a claim with the supplier, requesting the supplier to replace the rejected lots within 60 days of notification by PAHO. The supplier bears all costs in connection with the process. If the quality control report from the reference laboratory does not confirm the results in the claim, PAHO (HSS/MT) shall determine the next steps to be taken, informing the Member States and the institutions involved.

**Certificate of Quality (Based on the WHO Model)**

The *Certificate of Quality for Pharmaceutical Products Moving in International Trade* is a document containing validated information issued for a specific product by the competent authority of the exporting country and intended for use by the competent authority of the importing country. The information consists of the name of the product and dosage form; the name and quantity of the active pharmaceutical ingredient(s) by unit dose, using the INN when it exists; the name and address of the owner of the registration and/or the place of manufacture; the formulation (full composition, including all excipients); and an indication that the facility is subject to periodic inspections and complies with good manufacturing practices, that it is authorized to manufacture and/or distribute the product to be exported, and that the product's sale is permitted in the producing country.

**Dosage Form**

Individualized form to which medicinal substances (active ingredients) and excipients (pharmacologically inactive matter) are adapted to create a drug that can be administered to patients. Thus, an active ingredient can be administered in the form of a tablet, capsule, gel cap, syrup, suspension, elixir, oral solution, injectable solution or suspension, gel, cream, ointment, etc.

**Essential Medicines**

According to WHO, these are drugs that meet a population's priority health needs. They are selected on the basis of relevance to public health, testing of their efficacy and safety, and cost-effectiveness. WHO recommends that essential medicines be available in health systems at all times in sufficient quantities and appropriate dosage forms, with quality assurance and information, and at good prices.

**Prequalification**

The process whereby drugs, their manufacturers, and suppliers are vetted to verify that they meet identified standards of quality, following standard procedures; implies preapproval for potential procurement of the drugs.

**Primary Packaging**

Wrapping, container, or any other form of packaging that comes into direct contact with the drug or product.

**Quality Assurance**

A very broad concept that covers all aspects that individually or collectively influence product quality; the measures adopted to ensure that pharmaceuticals are of the quality necessary for their intended use

## **Quality Control**

All measures adopted, including definition of specifications, sampling, testing, and analytical authorization, to guarantee that raw, intermediate, and packaging materials and finished pharmaceutical products meet the specifications established with respect to identity, potency, purity, and other characteristics.

## **Secondary Packaging**

Packing container for primary packaging.

## **Shelf Life of a Product**

The length of time a product can be stored (under the conditions stipulated by the manufacturer) and administered to people before its safety, purity, or potency deteriorates.

## **Single-Source Drug**

A drug that can be obtained from only one manufacturer because it is patent protected or no other manufacturers produce it.

## **Strategic Public Health Supplies**

All supplies used in the prevention, diagnosis, and treatment of diseases of public health concern. Fundamental to the implementation of countries' public health programs, these products meet the following criteria:

- \* They are listed, recognized, and recommended by a WHO Expert Committee or Working Group (e.g., Essential Medicines, WHOPES recommended compounds, HIV Diagnostics).
- \* They are included in WHO recommended protocols or diagnostic algorithms and are considered highly effective in disease treatment or prevention.
- \* When continuously available, they significantly contribute to improvements in mortality rates and patient quality of life and/or minimize possibilities of drug resistance in treatment.
- \* They are subject to particular challenges in areas of product sourcing, pricing, forecasting, and purchasing.
- \* Economies of scale are achievable as volumes purchased increase.

## **Supplier Management**

The entire process of bidding, selection, and ongoing evaluation of the services and products offered by suppliers. The purpose of supplier management is to create a permanent relationship grounded in trust and respect, in which both parties benefit as a result of service and product quality. It requires suppliers to furnish legal, technical, and financial documentation; prepare a Kardex or registry of providers; and evaluate their services and products on an ongoing basis.

## **Technical Specifications**

Precise description of the drug or product, including any special requirements. For drugs and pharmaceutical supplies, the technical specifications include information on compliance with good manufacturing practices (GMP), pharmacopoeia standards, nomenclature, and the description required for each product; shelf life, storage parameters, and expiration date; labeling and packaging instructions; required certificates of GMP and quality assurance; and other information on the quality of the products that must be submitted with the bid and each shipment. Each product must be matched to specific pharmacopoeia standards, and, if any of the standards in a given series are applicable, they should be indicated. The need for special containers or labels, as well as the language on the labels, must be indicated in the list of requirements, but in each case the general technical specifications should include generic information on the packaging and labeling applicable to all products. The instructions for labeling (content and language) and the prospectus can be included along with the technical specifications, unless there are special requirements for a subgroup of products. The latter should be indicated in the list of products to be bid on.

## **WHO Prequalification Programme**

A United Nations prequalification program managed by the World Health Organization; aimed at expanding access by the most affected people to HIV/AIDS diagnostic and treatment supplies, safeguarding quality, and ensuring compliance with existing drug regulations. The process gives manufacturers anywhere in the world the same opportunity to meet international standards and participate in addressing health emergencies. It eliminates or greatly reduces the risk of procuring contaminated or counterfeit drugs or drugs that do not meet standards; accelerates access to quality drugs evaluated through an efficient, standardized process; and facilitates expeditious awarding of contracts through the issuance of a certain number of bidding invitations for the public tender.