



**Pan American
Health
Organization**



**World Health
Organization**

REGIONAL OFFICE FOR THE **Americas**

Operating Procedures of the PAHO Revolving Fund

for the Purchase of Vaccines, Syringes,
and Other Related Supplies

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Operating Procedures of the Revolving Fund for the Purchase of Vaccines, Syringes, and Other Related Supplies through the Pan American Health Organization

1. Background

- 1.1 The establishment of the PAHO Revolving Fund (RF) was authorized by Resolution CD25.R27 of the 25th Meeting of the Directing Council (1977). The RF is a procurement mechanism for essential vaccines, syringes, and other related supplies of immunization programs for Member States and Institutions.
- 1.2 Based on consolidated forecasting requirements received from participating Member States and Institutions, the Pan American Health Organization, Regional Office of the World Health Organization (hereinafter PAHO or PAHO/WHO), extends an annual arrangement with selected suppliers that fulfill the requirements for the purchase of vaccines and syringes. It is understood that PAHO acts as a procurement agent, through these annual arrangements with the suppliers, on behalf of the Member States and Institutions, after bidding process has been completed.

2. Purpose

- 2.1 The primary purpose of the RF is for the purchase of PAHO/WHO prequalified vaccines and syringes. The RF provides participating Member States and Institutions with the assurances of a constant flow of vaccines and related supplies for their immunization programs. The RF offers the following advantages to participating Member States:
 - 2.1.1 Vaccine and syringe requirements from all participating Member States and Institutions are consolidated and annual arrangements are established by the PAHO Procurement Services Area (PRO) with various suppliers based on country requirements.
 - 2.1.2 Bulk purchasing options offered by suppliers result in the lowest prices for vaccines, syringes, and other related supplies. This is especially beneficial to smaller, less developed countries that otherwise would have to pay higher prices for small quantities.

3. Participation

- 3.1 Participation in the RF is limited to those PAHO Member States or Institutions meeting each of the following criteria:
- 3.1.1 Allocation of a national budget item with a specific line item for the cost of vaccines and syringes.
 - 3.1.2 Appointment of a national EPI (Expanded Program on Immunization) program manager with the authority to develop and implement the program.
 - 3.1.3 Formulation of a comprehensive and realistic national program plan of operations covering at least a 5-year period and conforming to the general policies of the EPI in the Americas as recommended by the Technical Advisory Group (TAG) on vaccine-preventable diseases and PAHO's Directing Council Regulations.
- 3.2 Through the PAHO country offices (PWRs) the Comprehensive Family Immunization Project in the Area of Family and Community Health (FGL/IM) at PAHO is responsible for contacting participating PAHO Member States or Institutions in order to identify those who meet the criteria for participation as outlined above, and who would like to make purchases through the RF. As a result, the RF is a component of FGL/IM's overall technical support to participating Member States and Institutions.

4. Capitalization.

- 4.1 The RF is capitalized through the allocation of the 4.25% service charge that is applied to the net cost¹ of each order to the RF capital account.
- 4.2 The RF may also receive lump sum contributions from Member States or other partners. With the continuing support of Member States and Institutions, the capitalization of the fund will continue to increase. This will facilitate participation of more countries and the introduction of new vaccines into national immunization programs.

¹ As approved by the Directing Council in Resolution CD52.15 (2013), it was established an applicable charge for purchase of public health goods, including vaccines, syringes and other related supplies of 4.25% of the net cost of the goods (excluding freight and insurance). The 3.0% goes to the common capital fund to be used by PAHO as working capital to provide a line of credit to participating Member States, and a 1.25% contributes towards the administrative and purchasing activity costs.

5. Forecasting Vaccine and Syringe Requirements

- 5.1 Member States and Institutions participating in the RF prepare PAHO Vaccine Form 173-1 and Syringe Form 173-1 project their annual vaccine and syringe requirements. These forms are submitted to FGL/IM no later than 15 July of the prior year. Information provided must also include updated delivery addresses and a schedule of national holidays for the coming year. With the intent to ensure sustainability of supply, Member States and Institutions prepare a projection of vaccine and syringe requirements for one additional year through PAHO Form 173.
- 5.2 Upon receipt of PAHO Form 173 from Member States or Institutions, FGL/IM consolidates requirements by country, vaccine type, and vial size (1 dose, 10 dose, 20 dose, etc), and for syringes into a regional forecast. This information is forwarded in summary form to PRO to initiate the bid process in August.
- 5.3 FGL/IM will ask the Member State or Institution to confirm quarterly requirements and/or changes five months in advance of the quarter in question; e.g. faxes/e-mail confirming vaccine and syringe requirements for the third quarter (Jul-Sep.) will be sent out on 15 February to be returned by the Member State or Institution no later than 15 March. This will help to ensure a reliable and sustainable procurement of vaccines and syringes on a timely basis as suppliers require a minimum lead time of three months to adjust their production plan. If a Member State or Institution does not confirm quarterly requirements in a timely manner, the supplier's response may be limited. In the event of such a situation, the RF will attempt to identify alternative sources of supply.

6. Quality of Vaccines, Syringes, and Related Supplies

- 6.1 Vaccines purchased through the RF shall be processed in a manner that meets the minimum quality criteria agreed with international standards. For vaccines included in the United Nations prequalified vaccines system, only vaccines that are prequalified and agree with the last updated version of the WHO list of vaccines for purchase by UN agencies (http://www.who.int/immunization_standards/vaccine_quality/pq_suppliers/en/index.html) will be purchased through the RF. Since not all vaccines that the RF offers are included in the United Nations prequalification system, for vaccines out of this system, registration and lot release by the

following National Regulatory Agencies will be acceptable: United States Food and Drug Administration (FDA, USA), European Medicines Agency (EMA, Europe), Biologics and Genetic Therapies Directorate (BGTD, Canada), Therapeutics Good Administration (Australia), or Korea Food and Drugs Administration (KFDA). In addition, participant Member States or Institutions may request the registration of the product by the country's Regulatory Agency.

- 6.2 Disposable and AD syringes and needles purchased through the RF shall be processed in a manner that products meet quality criteria based on ISO Standards (International Standardization Organization) for Syringes and Needles. PAHO requests certificates of Good Manufacturing Practice, Quality Systems, Protocols of Production and Quality Control, Certificate of Sterility. Random tests on selected samples will be conducted in a Reference Laboratory to verify conformity with standards.
- 6.3 Cold chain equipment purchased through the RF shall be processed in a manner that products are in accordance with International Electrotechnical Commission standards for Electromechanical and Electromedical equipment. The products also should follow the WHO recommendations for cold chain equipment. PAHO will conduct performance evaluation and laboratory tests to verify conformity with the standards. The equipment should be subject to a preventive maintenance program.

7. Vaccine and Syringe Procurement

- 7.1 Once the bidding process has been completed (see paragraph 5.2), PRO establishes annual arrangements with suppliers for the forthcoming year. These arrangements will provide terms, conditions, and prices for the coming year and will guide placement of individual orders to meet the specific quarterly needs of each participating Member State or Institution.
- 7.2 FGL/IM along with PRO will place each quarterly order for the forthcoming calendar year in accordance with the submitted PAHO Form 173 or as indicated by the country if changes to a quarterly order are received as mentioned in Section 5.3. Individual orders will be placed against the established arrangements, for example, supplier X is instructed to ship Y number of doses in a specified vial size (S) to country (Z).
- 7.3 As part of the procurement ordering process for those Member States in good financial standing (i.e., those Member States with no invoices overdue

for greater than 60 days), FGL/IM will refer the order to the PAHO Area of Financial Resources Management (FRM). FRM will certify that the funds are available and then obligate the estimated cost of the order. It should be noted that the orders using financial resources from the RF are assigned to the Revolving Account (PQ001), while pre-paid (advance) orders from the Member States or Institutions will be assigned to the Pre-paid (advance) Account (PQ002). The maximum amount available per Member State or Institution in the Revolving Account (PQ001) is normally US\$ 3 million.

- 7.4 Vaccines will be supplied with an expiration date no less than 12 months unless otherwise specified by Member States or Institutions on their PAHO form 173.² If any shipment does not meet this expiration date guideline, the Member State or Institution would be asked to authorize the shipment, prior to the order being placed.
- 7.5 Participating Member States and Institutions will be charged for any vaccine or syringe orders placed by PAHO on their behalf pursuant to PAHO Form 173. If a participating Member State decides to cancel or reduce a requirement, after the orders have been placed with the supplier, **it must notify PRO 45 days** before the vaccine or syringe is scheduled to be shipped. If notification is not received on time by PRO to cancel/amend the order, then the Member State requesting the vaccine or syringe will be responsible for any charges up to the full value of the order.

8 Vaccine, Syringe, and Related Supplies Delivery

- 8.1 PRO will make the necessary arrangements with the suppliers and their freight forwarders to ship and deliver, on a timely basis, all vaccine and syringe requests specified by Member States on a properly submitted PAHO 173 Form.
- 8.2 PAHO does not allow partial shipments from suppliers unless prior authorization is obtained from PRO/SE. Depending on the circumstances, PAHO may request written authorization from the Member State or Institution to proceed with such a shipment.
- 8.3 PRO will send copies of each vaccine, syringe and/or related supplies' purchase order to each Member State or Institution concerned.
- 8.4 Depending on the product, the following documents will be provided to the

² Seasonal Influenza vaccines normally have a limited shelf life of 6 months

Member State or Institution, as Consignee, prior to shipment:

- Air waybill or bill of lading, commercial invoice and packing list;
- Insurance certificate;
- License from the National Regulatory Authority of the country of origin;
- Certificate of release per lot from the National Regulatory Authority;
- Certificate of analysis per lot;
- Free sale certificate;
- Summary protocol of production and quality control based on WHO standards.

8.5 Upon arrival of the vaccines, syringes, or any related supplies to the final destination, the Member State or Institution is solely responsible for completing customs clearance procedures.

9 Acknowledgment of Receipt and Claim Process

9.1 The Member State or Institution should formally notify acknowledgment of receipt to the local PWR within 3 working days of arrival of the product.

9.2 When goods arrive at destination with visible damages, the consignee must complete customs clearance, take possession of the cargo while at the same time report to the airline the damages in writing. The consignee should also inform the insurance company and PRO of its intention to file a formal claim and proceed with the claim according to the instructions specified in the insurance certificate.

When goods arrive at destination with hidden (not visible) damages, the consignee must complete customs clearances and immediately upon arrival at their warehouse inspect the goods. The consignee should also inform the insurance company and PRO of its intention to file a formal claim and proceed with the claim according to the instructions specified in the insurance certificate.

In both instances, it is imperative to report the damages immediately and send written notice to the insurance company of the intent of filing a formal claim. Most insurance policies establish very short periods of time for filing a formal claim. If the claim is not reported within the time limits set by the insurance company, the claim may be denied.

The consignee should evaluate, based on the total value of the goods damaged, whether or not filing a formal claim justifies the time and efforts

required to comply with the specifications set forth by the insurance company to accept a claim.

PAHO cannot file a claim on behalf of the consignee.

- 9.3 In the case of specific problems reported by the Member State or Institution (short expiration date, broken product, mislabeling, instability, etc.) with the receipt of vaccine flasks or any related supplies (needles, syringes, cold boxes, and thermos), the PWR will contact PRO/SE when it is informed of the problem by the Member State or Institution and PRO/SE will address the problem with the supplier and proceed accordingly.
- 9.4 Otherwise, the PWR should notify PRO within 3 working days after receiving the formal acknowledgment of receipt from the Member State or Institution. Upon receipt of the acknowledgement, PRO authorizes payment to the supplier and closes the order. PRO must pay the supplier upon presentation of a commercial invoice and a transport title as proof of shipment within the time limit stated in the purchase order.
- 9.5 Final acceptance of vaccine shipments shall be subject to technical clearance of production and control protocols by the receiving country's National Regulatory Authority and/or PAHO. Upon receipt of the product at destination, the Member State or Institution shall have ninety (90) days to inspect and test products and to reject all products that do not conform to the specifications, terms, and conditions of the order.
- 9.6 PAHO will notify the supplier in case of discrepancies between laboratory results from the National Regulatory Authority and the supplier. Thereafter, for a prequalified product, PAHO will request WHO to have the product re-tested in a WHO reference laboratory; the expenses will be covered by the WHO prequalification budget. For vaccines not included in the WHO prequalification system, PAHO will arrange to have the product re-tested in a reference laboratory designated by PAHO; these expenses will be covered by the supplier. PAHO may also request the supplier to furnish additional samples to the reference laboratory for testing. The decision of the reference laboratory will be considered final. Upon notice of rejection, and destruction or return certificate, the supplier will either replace the shipment, or refund the payment, as requested by PAHO, and pay all laboratory expenses.

10 Invoicing, Payment, and Collections

- 10.1 PRO reviews the commercial invoices and supporting documents for accuracy and approves them if everything is in order. When there are discrepancies, PRO requests additional information, clarification, or corrections from the suppliers. After approval of the commercial invoice, PRO sends it to FMR for payment and invoicing the Member State (see paragraph 8.2).
- 10.2 When all the charges for a particular purchase order have been made (cost of vaccine, freight, 4.25 % service charge, etc.), FMR will prepare an invoice for submission to the Member State or Institution concerned. The invoice will be issued in US dollars with the following sentence clearly stated on the invoice: "IF BALANCE IS DUE, PLEASE PAY WITHIN 60 DAYS VIA INTERNATIONAL WIRE TRANSFER TO: CITIBANK, 111 WALL STREET, NEW YORK, NY 10043 ON BEHALF OF THE PAN AMERICAN SANITARY BUREAU, SWIFT CITIUS33, ABA # 021000089, ACCT # 3615-9769 OR MAKE CHECKS PAYABLE TO THE "PAN AMERICAN SANITARY BUREAU" IN US DOLLARS FROM A BANK DOMICILED IN THE U.S.A"
- 10.3 Payments require proper identification in order for the invoices to be paid properly. If this information is not received, payments will be credited to the oldest invoices.
- 10.4 All payments from Member States or Institutions should be made in US dollars.
- 10.5 On an exceptional basis, payments may be received in local currency, in consultation with the PWR, by exclusively applying the official rate of exchange issued by the United Nations System for the date the funds are actually received by PWRs. As per Imprest guidelines, prior written authorization from the Chief of Treasury at PAHO to the PWR must be obtained before accepting any payment in local currency. PWRs will be responsible for informing Member States or Institutions the equivalent amount in US dollars for all payments received in local currency.
- 10.6 PWRs have to consider their Imprest cash flow before accepting payments for the RF in local currency in order to manage their Imprest account properly.
- 10.7 Exchange rate differences originating from the value on a remaining balance of one exchange rate converted to another for a payment received in local currency will be debited/credited to the variance account

of the RF.

- 10.8 To maintain the financial health of the RF, Member States and Institutions are required to reimburse the RF within a 60-day period after the invoice date in order to maintain good financial standing for further procurement support from the RF.
- 10.9 FMR prepares daily PAHO invoices for the Member States and Institutions.
- 10.10 FMR prepares quarterly statements of accounts for all Member States or Institutions indicating funds received and charges incurred for each purchase order and refund, if applicable. Member States or Institutions may request an updated statement of accounts at any time.

11. Special Financing Arrangements

- 11.1. In some instances when the value of a Member State's vaccine requirement is in excess of available funds, PAHO will ask the Member State to prepay part or the total cost of the order. To facilitate the prepayment process, pro forms are often provided. See 7.3 on accounting control.
- 9.7 International organizations, funding agencies, international financial organizations, and/or other donors may provide financial support through loans, grants, or contributions to Member States and Institutions in order to support their immunization programs. In such cases, FMR will open specific accounts. If necessary, PAHO will establish an agreement directly with the donor organization in order to define payment terms directly to PAHO. Whenever possible, funds available through these agreements should be paid in advance. If an agreement with PAHO is required, PAHO's Area of Legal Affairs (LEG) will prepare and/or review the arrangement. PRO will coordinate internal clearance process with the PWR, LEG, FGL/IM, FMR, and other concerned offices. Once approved by PAHO's Director, the executed agreement will be provided to the relevant PWR with copies to PRO, FMR, and FGL/IM.

12. Reporting

- 12.1 Reports and indicators are monitored by FGL/IM, PRO, FMR, and PWR on an ongoing basis to help manage and measure the operation and performance of the RF. This information is shared with the Member States, Institutions and suppliers accordingly.