How to Cooperate with Global Health Organizations in the field of Medicines & Diagnostic Products

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PAHO/WHO

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PAHO

PAHO/WHO

Agenda

MISSION	About PAHO
	Acquisition mechanisms
	Product catalog
STRATEGIES FOR ACQUISITIONS	Shared Responsibility Model
	Strategy for product Acquisition
	Opportunities & Benefits
OPPORTUNITIES FOR SUPPLIERS	Doing business with PAHO
	Upcoming tenders
	Eligibility and technical proposal



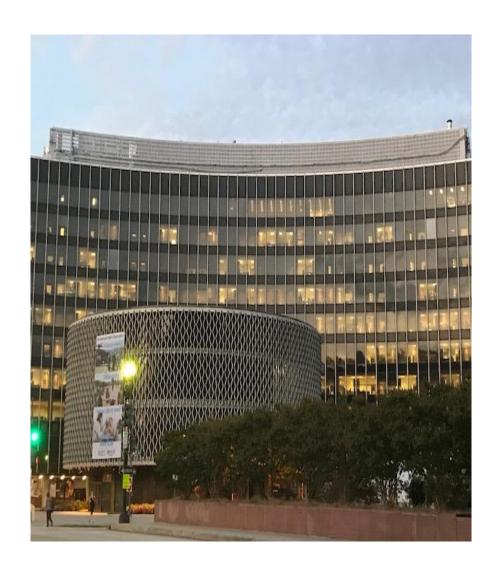
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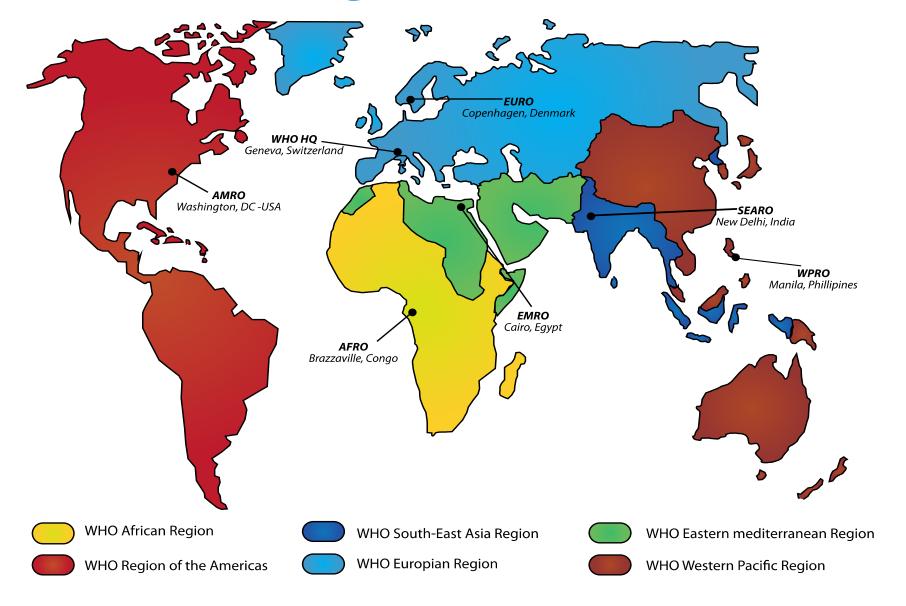
PAN AMERICAN HEALTH ORGANIZATION -PAHO



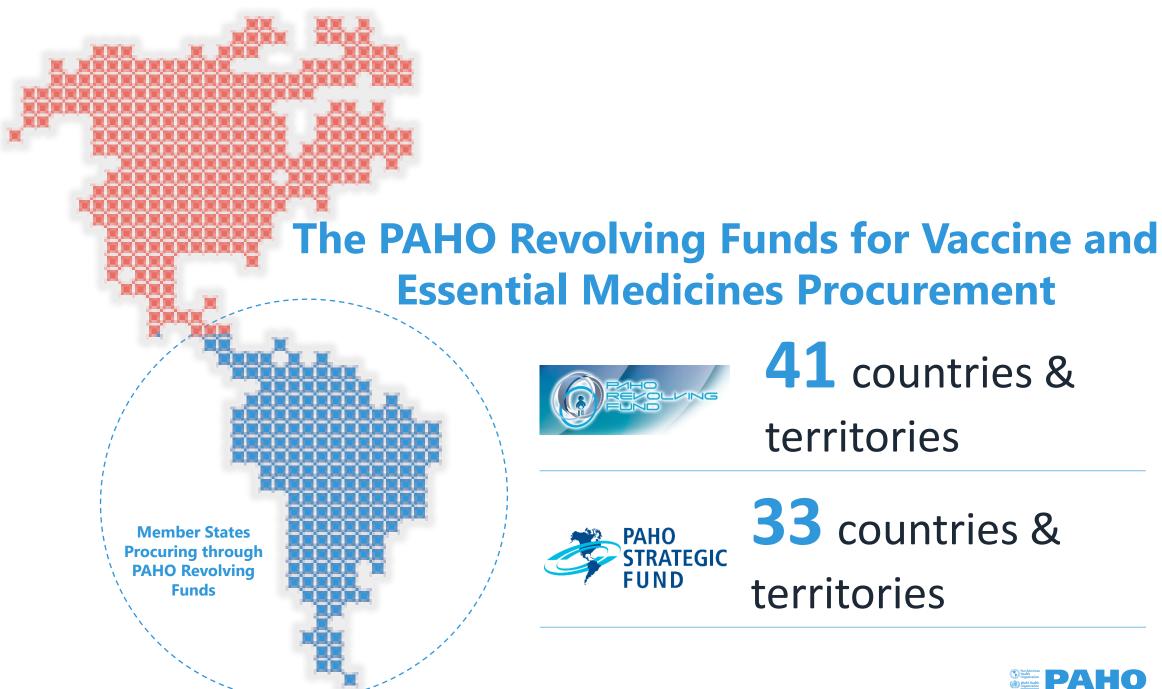
- ❖ The Pan American Health Organization is the oldest international public health agency in the world, founded in 1902.
- Serves as Regional Office for the Americas of the World Health Organization (WHO) since 1949.
- Is a technical cooperation agency for health development.
- Today it is lead by and serves to 52 member countries and territories.



WHO Regional structure









ANNUAL STATISTICAL REPORT ON UNITED NATIONS PROCUREMENT

PAHO is #7 of 40 UN Agencies (US\$ Value)

Table 1.3 – Procurement by UN organization

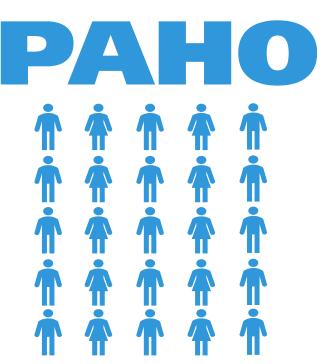
Organization	Total 2017 (USD m)	Total change 2016-2017 (%)	Share of procurement from developing countries, countries with economies in transition and LDCs 2017 (%)
UNICEF	3,428.7	-1.6%	56.9%
WFP	3,075.3	3.8%	73.0%
UNPD	2,746.7	-15.0%	61.3%
UNDP	2,117.0	24.7%	71.5%
UNHCR	1,239.4	5.1%	70.3%
UNOPS	1,068.9	18.7%	64.3%
PAHO	919.4	16.4%	47.1%
WHO	666.6	-11.9%	51.5%
IOM^	617.6	18.2%	N/A
FAO*	371.4	17.2%	74.9%
UNFPA	316.8	12.4%	49.4%
IMF	272.3	N/A	0.0%
UNRWA	243.7	-15.5%	83.4%
IAEA	219.8	49.2%	14.0%
ILO*	214.7	32.0%	65.6%
UNIDO	178.4	44.6%	52.7%
JNESCO	129.0	5.0%	63.4%
WIPO	114.8	0.4%	6.2%
UNOG	109.7	16.6%	5.6%
UN Women	104.2	-17.3%	59.2%
UNOV	84.9	28.1%	71.0%
UNAIDS	49.4	45.1%	57.3%
IFAD	48.7	3.3%	18.9%
ITU	47.7	0.1%	13.0%
UNON	40.9	42.8%	77.2%
UNFCCC	24.4	230.8%	5.8%
UN-ICTY/MICT	19.2	43.1%	17.9%
UNECA	18.9	43.5%	52.6%
OPCW	18.4	-60.8%	1.8%
UPU	16.7	-24.0%	10.5%
IMO	16.4	6.5%	17.8%
ITC	14.3	53.6%	27.9%
WMO	14.1	-19.7%	2.7%
ECLAC	13.9	146.2%	62.3%
ESCAP	13.5	73.8%	70.3%
UNV	9.1	8.5%	2.0%
UNU	7.4	0.1%	14.0%
ESCWA	6.7	43.1%	87.1%
UNWTO	3.0	-3.0%	2.3%
UNAKRT	1.1	-43.0%	69.5%
UN total	18,622.7	5.1%	60.9%

Calculation of share of procurement from developing countries, countries with economies in transition and LDCs excludes data where the supplier country is unknown.

countries in 2017. https://www.unops.org/news-and-stories/publications/annual-statistical-report-on-un-procurement-2017

^{*} Supplier country known for only part of data (FAO 94%, ILO 95% by volume). ^ IOM did not report on supplier countries in 2017.





25 million people are protected in The Americas with at least one vaccine procured through the PAHO Revolving Fund



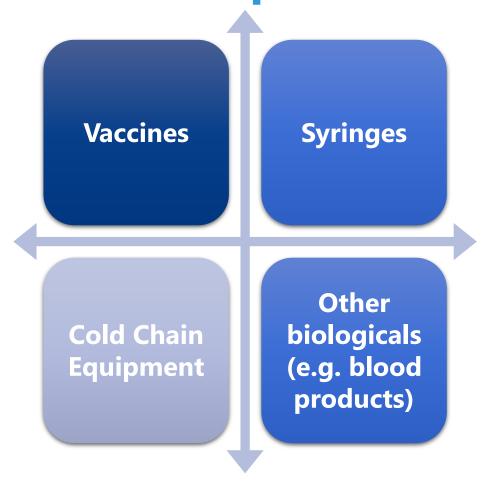
117 LTAS including vaccines, immunoglobulins, syringes, and safety boxes



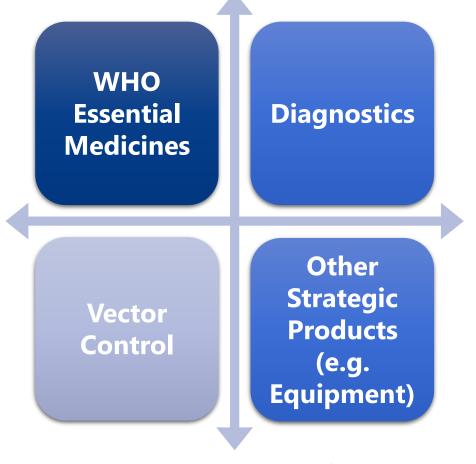
74 LTAS Including HVI/AIDS, TB, Malaria, Antineoplastic, Antivirals (HCV), Immunosuppressive drugs, Hematologic, Surfactant Diagnostic kits



PAHO Revolving Fund – Products portfolio



PAHO Strategic Fund – Products portfolio

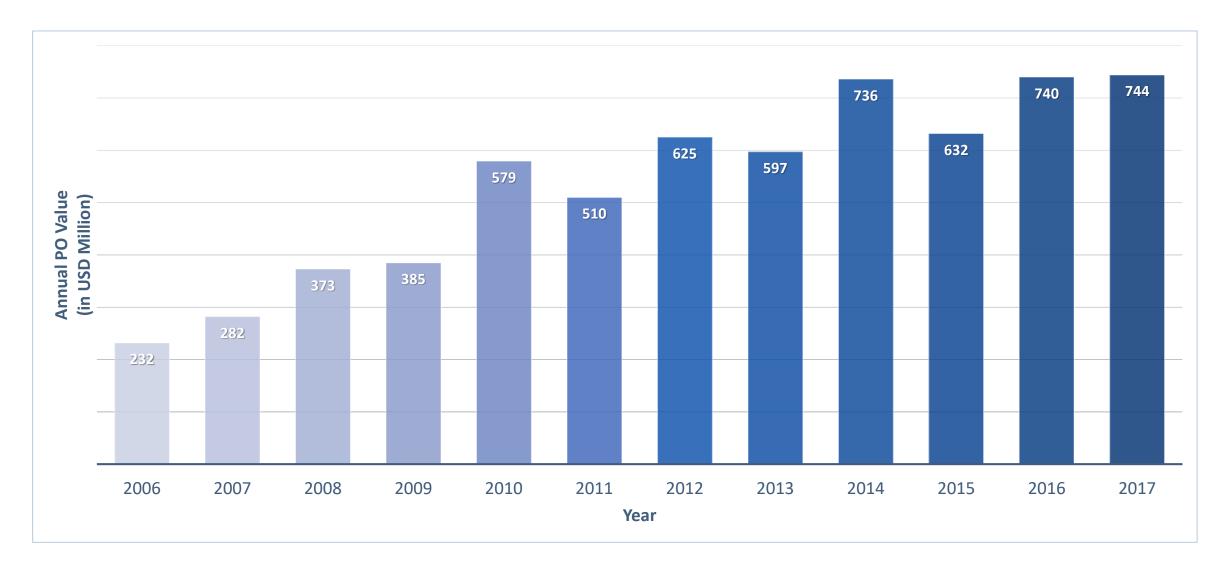


www.paho.org/strategicfund





HQ Procurement 2006 - 2017





TOP COMMODITIES (USD MILLIONS during 2017)



USD\$566.1 M

Vaccines, antigens and toxoids



USD\$37.7 M

Antiretroviral medicines



USD\$3.8 M

Laboratory & Scientific Equipment



USD\$5.2 M

CCE, syringes & safety boxes



USD\$3.0 M

Hematologic medicines



USD\$6.0 M

Anti-Tuberculosis medicines



USD\$11.1 M

Disease vector mngt. & control



USD\$2.6 M

Bio-technology/chemistry, genetic & microbiology and related materials



USD\$8.0 M

Antiviral medicines (HCV)



USD\$1.0 M

Amebicides trichomonacides



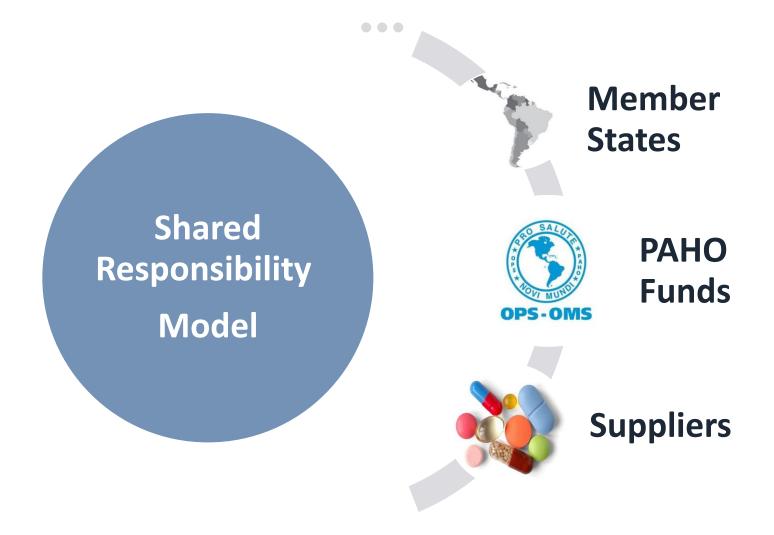
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Strategies for Product Acquisition







Strategy for Product Acquisition

Understan d the regional needs and demand Planning and consolidati ng demand (when possible)

Key
negotiations
with
exclusive
sources

Continually explore new market opportunities and new sources

Maximize the use of long-term agreements

Joint tenders - with other internation al agencies





The PAHO Revolving Funds Benefits for Stakeholders

For Manufacturers

• Efficiency:

- **✓** Direct access to 41 countries and territories
- ✓ Pooled quantities
- **✓** Contract Management support

Risk reduction:

- **✓** Fair and transparent relations
- **✓** Forecasts and Long Term Agreements
- ✓ Prompt payments
- ✓ Post-market surveillance

For Countries

Access to safe, quality products

Timely and continuous supply

Technical cooperation mechanism

Supports financial sustainability

Access to a credit line or "capital fund" (60 days)

"Catalyst" for a sustainable uptake of new products

Fast emergency response



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Doing Business with PAHO

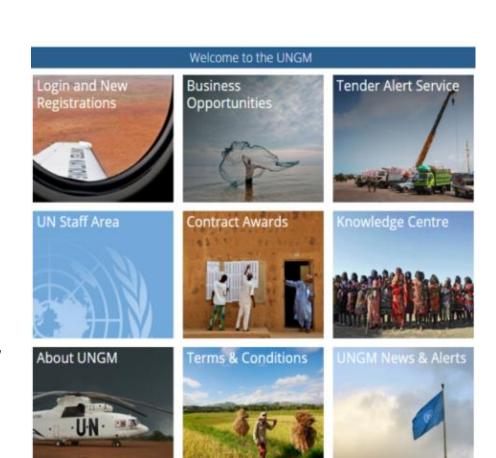
Integrated System:

UNGM (Vendor registration)
In-Tend (e-tendering system)

Over 25 UN Agencies use UNGM as their supplier roster

PAHO procurement:







Doing Business with PAHO

Search UNGM English ▼ Register • Log in



Welcome to the UNGM

















Help (?)

UNGM Registration





Subscribe to the **Tender Alert Service**. Only **USD250** per year for this value-added service. Save time. No need to search through the more than 200 active notices on the site Create a UNGM account and subscribe today. Don't miss an opportunity!

Public

Home

Code of conduct

Contract awards

Knowledge centre

About UNGM

Registration process

UNSPSC Tender alert service

For more information on the UNGM vendor registration process, please click here,

It should take approximately 5 to 10 minutes to complete the Basic level of registration.

If you need any assistance or require more information, please do not hesitate to use the Help? button in the right-hand corner of the page.

Registering with the relevant UN organizations

During the online registration process, vendors are automatically matched with the UN organizations which buy the products and services the vendor offers. You are able to deselect any of these UN organizations, should you wish to do so. If your company is unable to register with a particular UN organization, it is because that organization does not buy the goods or services

After completion of your registration

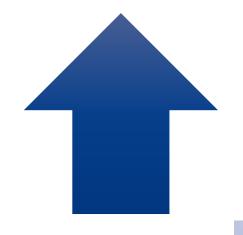
Once the required information has been provided, you will be able to submit your registration for review. Some UN organizations automatically accept submissions, while others review and evaluate each submission based on specific criteria. This process can take up to 10 working days. Once a vendor has been accepted by at least one (1) UN organization, the vendor's profile is visible to all UN staff.

Please click the Help? button. From here you are able to get in touch with our HelpDesk who will assist you with your query. We try to answer all queries within 48 hours. For the most efficient service, please ensure that you are logged in. Provide a detailed comment and screenshot where possible.

Continue to registration



Eligibility Criteria for PAHO's funds



a) Products Prequalified by WHO-PQ

A bidder is eligible if it offers products that have been pre-qualified by WHO/Geneva at the time the bids for this solicitation are opened.



Eligible if you offer a product that is registered and has a marketing authorization and a batch release (if applicable) by one of the following ARNs

- Pharmaceuticals: ANMAT (Argentina), ANVISA (Brazil), BGTD (Canada), COFEPRIS (Mexico), CECMED (Cuba), INVIMA (Colombia), ISP (Chile) or FDA (USA), or a stringent regulatory authority (SRA) as defined in WHO's "Guidelines on Submission of Documentation for Prequalification of Finished Pharmaceutical Products Approved by Stringent Regulatory Authorities

- Biologicals: ANVISA (Brazil), BGTD (Canada), CECMED (Cuba), COFEPRIS (Mexico), ANMAT (Argentina), EMA (Europe), FDA (USA), KFDA (Korea) or TGA (Australia).



1- WHO Prequalification letter

If the product is prequalified by WHO

2. Certificate of Pharmaceutical Product (CPP)

According to the WHO certification scheme issued by the relevant RNA

3. Proof of therapeutic equivalence reviewed by the NRA of the country of product manufacture

For pharmaceuticals only:

Bioequivalence /
Bioavailability
studies, when
applicable, or
comparative in vitro
dissolution tests,
when applicable,
according to
conditions described
in the latest edition
of the WHO
Multisource



4. Declaration by the bidder indicating the NRA responsible for lot release

For biological products only:
declaration of the finished product. In addition, when the offered product is a human derived blood product the formal declaration must also include the NRA responsible for plasma pool release.

5. Manufacturing sites requirements

List of all sites and their responsibilities involved. For each site(s), the GMP certificate(s) issued by the NRA of the country of manufacture. If a diluent is required, corresponding GMP certificate must be submitted if different manufacturing site from finished product.

6. Insert and packaging (primary and secondary)

A PDF of the insert (pamphlet) and Packaging (primary, secondary and tertiary) for the product presentation offered and its diluent, if applicable, in all available languages



7. Finished product specifications

current finished
product
specifications,
including diluent (if
applicable),
approved by the
corresponding NRA.
A certificate of
analysis or a
summary of
manufacturing and
control (as
applicable) may also
be submitted.

8. Stability studies

Summary of stability studies for natural and accelerated storage conditions performed according to international recommended standards for 3 different lots-including the results tables and the final conclusions

9. PSUR

The latest Periodic Safety Update Report (PSUR)



10. Annex I - Global Regulatory Status

List of countries
where the
product is
registered and has
been granted a
marketing
authorization.

11. Annex II - Checklist

The checklist of the technical documents included in the proposal, completed and signed by the corresponding quality assurance representative



Process for evaluating offers



Not just the choosing the lowest price when multiple sources were available.



- ✓ Performance & experience
- ✓ Availability & flexibility
- ✓ Language labels and instructions
- ✓ Minimum order quantity (MOQ)
- ✓ Logistical support
- **✓** Price







Practical "Tips" for tenders

Respond to bid invitations - if you are unable to submit an offer inform accordingly

Review all the bid documents, conditions and requirements carefully

Comply the eligibility and Technical requirements

Prepare bid accordingly to the instructions to facilitate the evaluation – complete and accurate information and supporting documents.

Ask for clarification if necessary



Upcoming Tender Exercises



Human Coagulation Factor

On-going



Antiretrovirals

Q2-2021



Oncologics

Q4- 2018

Mental Health

Antihypertensive

Q1 - 2019

Q2 - 2019



Canine Rabies

Q2-2020

Vaccines 2020-2022

Q2 - 2019

Vaccines 2021-2022

Q2 - 2020

Seasonal influenza

Q1-Q2- 2019 (NH)

Q3-2019 (SH)

Syringes / Safety boxes

Q2- 2019

Immunosuppressive

Q4- 2018

Antidiabetics

Q1 - 2019



Cold Chain Equipment

Ad-Hoc depending Member State's identified requirements



Micronutrients **Dic 2019**



In vitro Diagnostic Products

Q4 2018 – Joint tender

(UNICEF, UNDP, UNFPA, WHO, PAHO)



