

STRATEGIC FUND

Access to high-quality medicines and health
technologies in the Americas

ANNUAL REPORT 2016



Pan American Health Organization, 2017

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To find out more about the Strategic Fund, to place an order, or to get help in estimating demand for the products you need, contact the PAHO office in your country or e-mail us at:

strategicfund@paho.org

Preface



Dr. Carissa F. Etienne
DIRECTOR
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Organization

Access to medicines and other health supplies is essential if we are to achieve universal access to health and universal health coverage. Rising costs, lack of availability, and substandard quality of medicines constitute some of the challenges that our Member States face in ensuring equitable access to medical products throughout health systems and services.

The Strategic Fund was created in 2000 by the Pan American Health Organization (PAHO) as a mechanism to improve equitable access to safe, efficacious, and quality medicines and supplies in the Americas. Through the Strategic Fund, participating countries join together in solidarity to pool needs and collectively procure quality health supplies at affordable prices.

I am pleased to present **The 2016 Annual Report of the Strategic Fund**, which summarizes the activities of the Fund during this period. The Strategic Fund is an innovative cooperation model that seeks to strengthen the management of the regional and national supply chain for essential medical products, so that everyone throughout the Region can enjoy the benefit of timely access to medicines and other strategic health supplies. The achievements of 2016 reflect the advances that have been made collectively by our Member States as they continue to expand access to medicines and other essential supplies, and move progressively towards the achievement of universal health.

The Strategic Fund:

A collective mechanism supporting Universal Health in the Americas

Equitable access to medicines and other health technologies is a requirement to achieve universal access to health and universal health coverage. Despite the significant progress being made by the countries of the Region of the Americas in moving towards universal health, equitable access to medicines and other products continues to be a major challenge due to rising costs, the lack of availability and substandard quality of certain supplies.

The Regional Revolving Fund for Strategic Public Health Supplies, best known as the Strategic Fund, was established in 2000 by the Pan American Health Organization to improve access to quality, safe, and efficacious medicines and other health supplies in the Americas, while ensuring the efficiency and sustainability of health systems.

Taking advantage of economies of scale and promoting competition through open tenders for generic drugs*, the Fund provides an innovative platform for countries in the Americas to collectively impact market dynamics for key medicines and other health technologies.

*The World Health Organization (WHO) uses the term "multisource pharmaceutical product," defined as a pharmaceutical equivalent or pharmaceutical alternative that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent to the comparator product are regarded as interchangeable.



The Strategic Fund: a mechanism to promote Universal Health

In 2014, PAHO Member States adopted the Strategy for Universal Access to Health and Universal Health Coverage (Resolution CD53.R14). In 2016, PAHO Governing Bodies approved the Resolution CD55.R12, Access and rational use of strategic and high-cost medicines and other health technologies. Together, these resolutions provide a policy framework and present a vision and strategic guidance to countries to promote access to medicines and other health technologies in support of universal health. PAHO has since scaled up the capacity of the Strategic Fund to provide the necessary cooperation and services that countries require on the road toward universal access to health and universal health coverage.

Vision Improve the health and well-being of peoples and contribute to the advancement of universal health in the Americas, by strengthening health systems and improving the equitable access to safe, efficacious, and quality medicines and other priority public health supplies.

Mission Develop a regional platform for PAHO Member States that facilitates collective action to improve the affordability, availability and quality of strategic health supplies in the Americas.

Values Solidarity, quality, transparency, equity, efficiency, Pan-Americanism.

Objectives

- 1 Increase access to quality health products that improve health outcomes in PAHO Member States.
- 2 Improve the efficiency of expenditures and availability of quality strategic supplies for national priority health programs.
- 3 Work jointly with participating countries to boost national capacities in demand planning and supply chain management, including the appropriate use of procured products.
- 4 Consolidate demand and apply innovative procurement and negotiation strategies that promote transparency and international competition in order to achieve significant price reductions for strategic public health supplies.



2016

more than

150

products for
the Region

An innovative cooperation model

to meet the needs and demands of health systems

Since its launch, the PAHO Strategic Fund has evolved to become an internationally recognized mechanism that provides comprehensive technical and financial support to countries, centralizing procurement to maximize economies of scale and international competition in the procurement of health supplies.

The Fund offers more than 150 products including medicines from the World Health Organization (WHO) Model List of Essential Medicines, vector control supplies, diagnostics for priority public health programs, and other medicines considered of high importance for the Region. In all cases, the Fund applies criteria to measure the impact of the portfolio of products in participating countries in terms of efficiency, equity, and cost-effectiveness.

A list of products that can be purchased through the Strategic Fund is available on its website www.paho.org/strategicfund

More than
15
years working
for health

Providing the best scientific evidence to inform selection of supplies

WHO Model List of Essential Medicines

Diagnostics for priority programs

Vector control supplies

Other strategic medicines

Seeking significant impact on public health outcomes

Fostering efficiency in allocation of resources

Prioritizing reductions in inequity and vulnerability

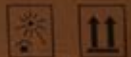
Providing care in emergency situations

OPS



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The Strategic Fund has been structured so as to:

- Support high-impact public health programs.
- Ensure the delivery of interdisciplinary and collaborative technical cooperation to the Fund's signatory countries.
- Maximize joint actions across the Region for the benefit of all participating countries.

Ensuring access to medicines and other health technologies requires the adoption and implementation of comprehensive policies, strategies, and interventions within health systems. Thus, PAHO, through the Strategic Fund and complementary technical programs of work, promotes improved stewardship and the development of supply chain management capacity at the national level, from the selection and incorporation of cost-effective products in health systems, through quality assurance, distribution and appropriate use.

More than
60 long-term
agreements:
**QUICK and
TIMELY
delivery**



**Increased availability
of high-quality
essential supplies**

**Comprehensive
strengthening of supply
management**



Facilitation of strategic cooperation between countries

Quality assurance

ACCESS

Collective funding

Economies of scale, transparency, and incentives for competition

Strengthening supply management:

promoting efficiency to ensure timely access to essential health supplies

The lack of availability of certain health supplies within national markets, quality problems, and product expirations due to overstock, among others, threaten the supply chain and jeopardize the efficiency of national health systems. Weak information systems affect planning and demand estimation, and impact the capacity of health systems to ensure access to safe, efficacious, cost-effective, and quality supplies.

To meet the needs and demands of countries in the Region, the Strategic Fund expanded its response in the area of supply chain management, relying both on its own resources and on strategic partnerships, leading to a tangible strengthening of capacity within countries. The characterization of national supply chains combined with the analysis of their strengths and weaknesses has resulted in the design of country specific strategies that seek to strengthen management processes and increase efficiencies.



24

Technical cooperation missions



14

Work plans



13

Countries visited



3

National strategies for strengthening supply-chain management

Strategic partnerships:

the Global Fund and USAID

In 2015, PAHO and the Global Fund signed an agreement to strengthen supply chain systems, and reduce the risk of medicines shortages in a number of key countries. In 2015-2016, technical cooperation was provided to six participating countries within the framework of this agreement. The application of new methodologies to improve antiretroviral (ARV) demand forecasting combined with capacity building in supply management resulted in a significant improvement in the availability of medicines for patients.

The United States Agency for International Development (USAID) and PAHO signed a 5-year agreement aimed at strengthening health systems in the Region. The agreement aims, amongst other things, to improve access to medicines and health technologies with a particular emphasis on vulnerable populations in the Americas. The project, launched in 2016, will strengthen national information systems to monitor and evaluate the quality, delivery, access to, and use of medicines in populations living in conditions of vulnerability in remote geographical areas.



2

New tools
for supply chain
management



0

Stock-outs in
participating
countries

Budgetary impact*

Local procurement cost
\$16,50 million

Strategic Fund procurement cost
\$3,04 million

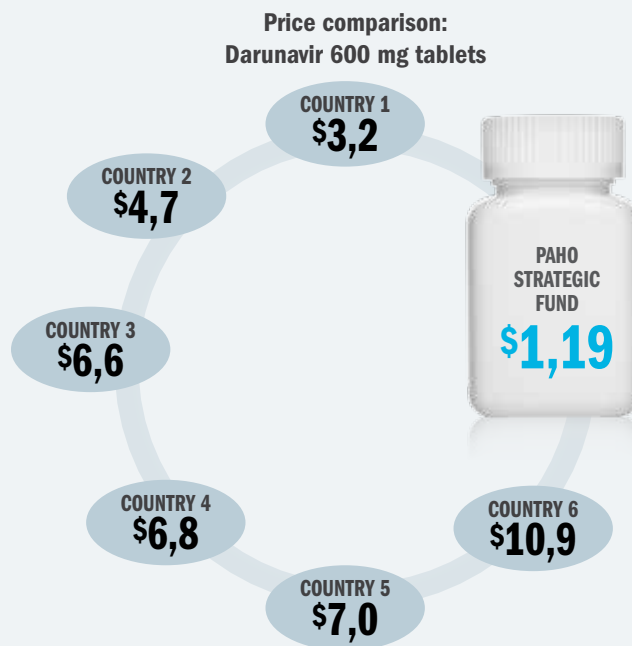
Country savings
\$13,40 million

Local procurement cost
\$7,98 million

Strategic Fund procurement cost
\$1,14 million

Country savings
\$6,84 million

*Example based on the annual budgets of two signatory countries for HIV/AIDS and TB programs



2000

Launch of Strategic Fund

The Strategic Fund was launched in September 2000: Member States were invited to participate in the Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund)

2013

Inclusion of medicines for chronic diseases

Creation of the Expert Committee for the Selection and Inclusion of Medicines in the Strategic Fund

2015

Process for the use of the Capital Account simplified

The Fund begins to procure antiretrovirals

2006

Creation of the Distribution Center in Panama

2014



As of December 2016,
30 Member States
 and territories
 have signed
 agreements to
 use the Fund.

Support for negotiation
 of high-cost medicines
 with countries

New eligibility criteria
 for procurement

2016

Procurement through the Strategic Fund:

greater efficiency in the allocation of health resources

In 2016, more than 150 strategic health supplies were acquired from more than 100 quality-assured suppliers. In many cases, due to the consolidation of demand, a procurement process that takes advantage of economies of scale and the use of competitive international tenders to stimulate competition between quality-assured manufacturers, Fund prices represent a significant saving in relation to national market prices. Moreover, procurement through the Fund also includes individualized logistic support and follow-up for each shipment.

For several products of high interest to countries, the Fund signs **long-term agreements** (LTAs) with suppliers, establishing fixed prices for the products for the length of the agreement. LTAs improve the efficiency of purchases, set predictable prices, and help ensure quick and timely delivery of quality-assured products. In 2016, the Fund established more than 60 LTAs covering medicines for HIV/AIDS, tuberculosis, malaria, and Guillain-Barré syndrome (Zika), among others, and more than 30 LTAs for diagnostic kits.

Critical areas of Strategic Fund cooperation include supporting the procurement of supplies during emergencies and disasters and ensuring the availability of medicines and supplies that are hard to find or available in limited quantities. In 2016, the Fund supported regional efforts in the control and elimination of neglected infectious diseases by procuring over \$4,3 million of essential medicines for entities such as Chagas disease and Leishmaniasis- and issued purchase orders for more than \$20 million for vector control products.

The Fund forged strategic partnerships with United Nations agencies and international organizations, making it possible to establish cooperation agreements, share information and lessons learned, identify potential suppliers and carry out joint bidding processes.



2016
Procurements through
the Strategic Fund reached

\$81,9
million

16%

more than 2015

800%

cumulative increase in
the last 10 years

\$188 million

price estimates

150

products

30

LTAs for diagnostic kits

\$4,3 million

in products for Chagas disease
and leishmaniasis

388

purchase orders

60

LTAs for medicines

\$40 million

ARV medicines

\$20 million

in purchase orders for vector control

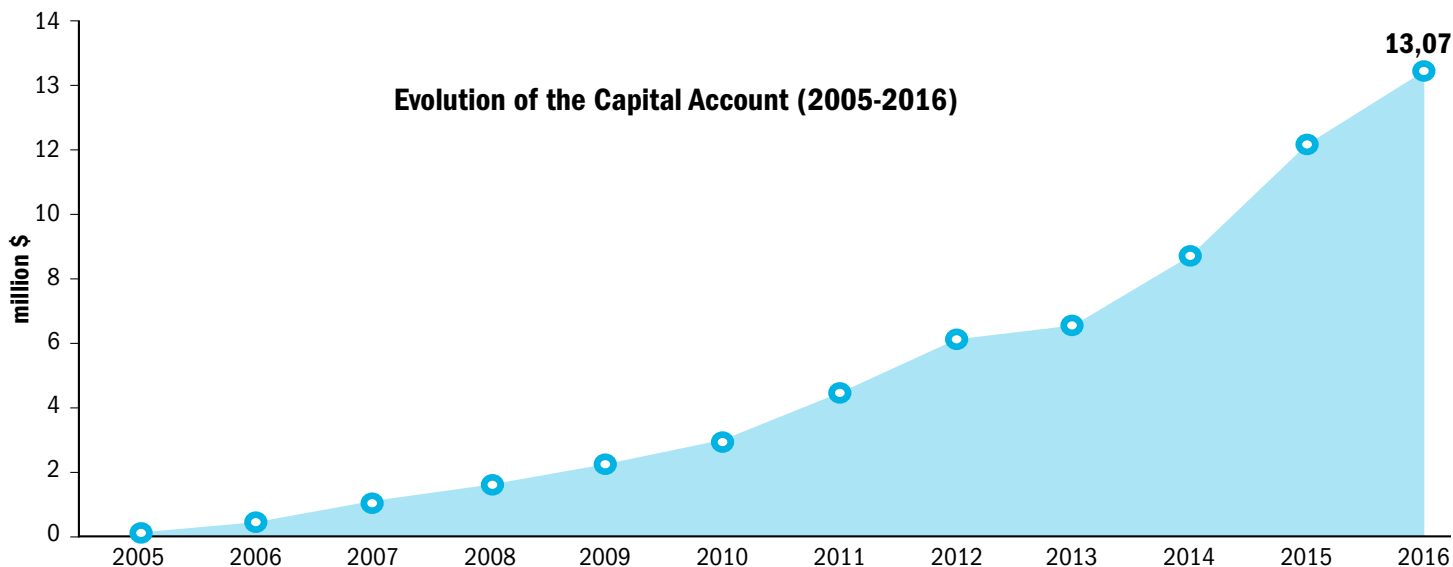
A funding mechanism based on solidarity:


the Strategic Fund Capital Account

The Strategic Fund Capital Account provides interest-free lines of credit to countries that need to ensure the continuity of supplies and prevent shortages, and to facilitate the procurement process. The Capital Account is an example of solidarity and Pan-Americanism: countries contribute a 3% surcharge over every purchase. These funds accrue in the Capital Account, which is managed by PAHO, allowing the Organization to grant lines of credit to its signatory countries, which

must be paid within 60 days of having received the product. Also, a fee of 1.25% of the total price of the products purchased is charged to countries to cover administrative costs.

The streamlining of the mechanisms for credit-line authorization completed in 2015 significantly facilitated the credit-granting process and improved the use of funds by countries. In 2016, PAHO granted 17 lines of credit amounting to a total of \$9,049,985.





12 countries used lines of credit* for a total of

\$9,05
million

*17 approvals

Capital Account balance as of 31 December 2016

\$13,07 million

Expanded access

to quality care and treatments

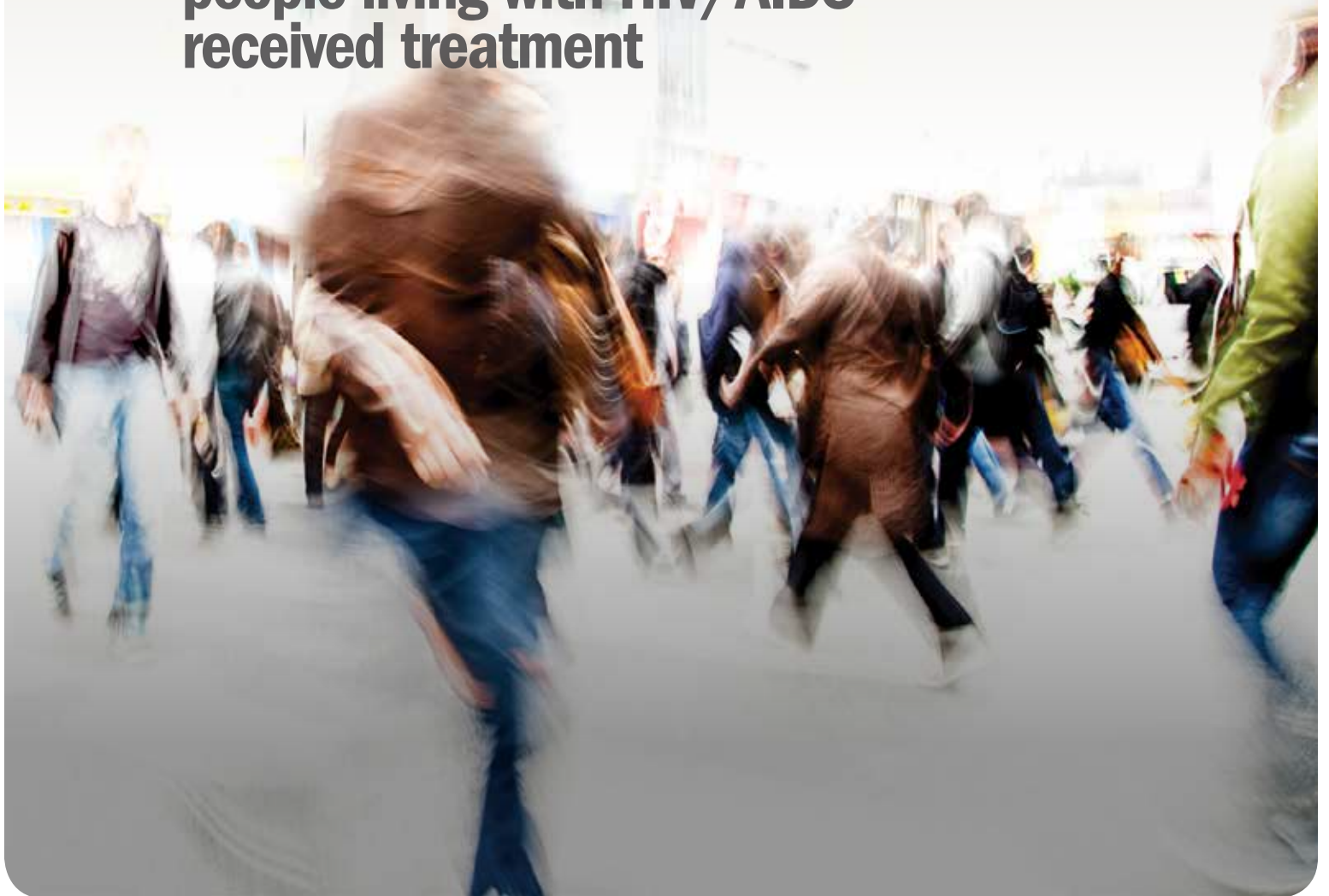
Among the objectives of the Strategic Fund is to work together with countries to expand access to quality care and treatments and to ensure the sustainability of national health systems. The budgetary impact of medicines procurement is a growing concern for countries in the Region, which largely depend on their own resources to purchase medicines and other essential supplies.

In recent years, the Strategic Fund has served as a transparent and efficient mechanism for cost reduction without compromising the quality of the products. Member States have thus managed to expand access to and rational use of essential medicines that save lives and improve the quality of life of the peoples of the Americas. For example, more than 607,000 people living with HIV/AIDS have received the preferred first-line treatment with medicines acquired through the Strategic Fund.

Units of preferred ARV first-line treatment procured through the Strategic Fund



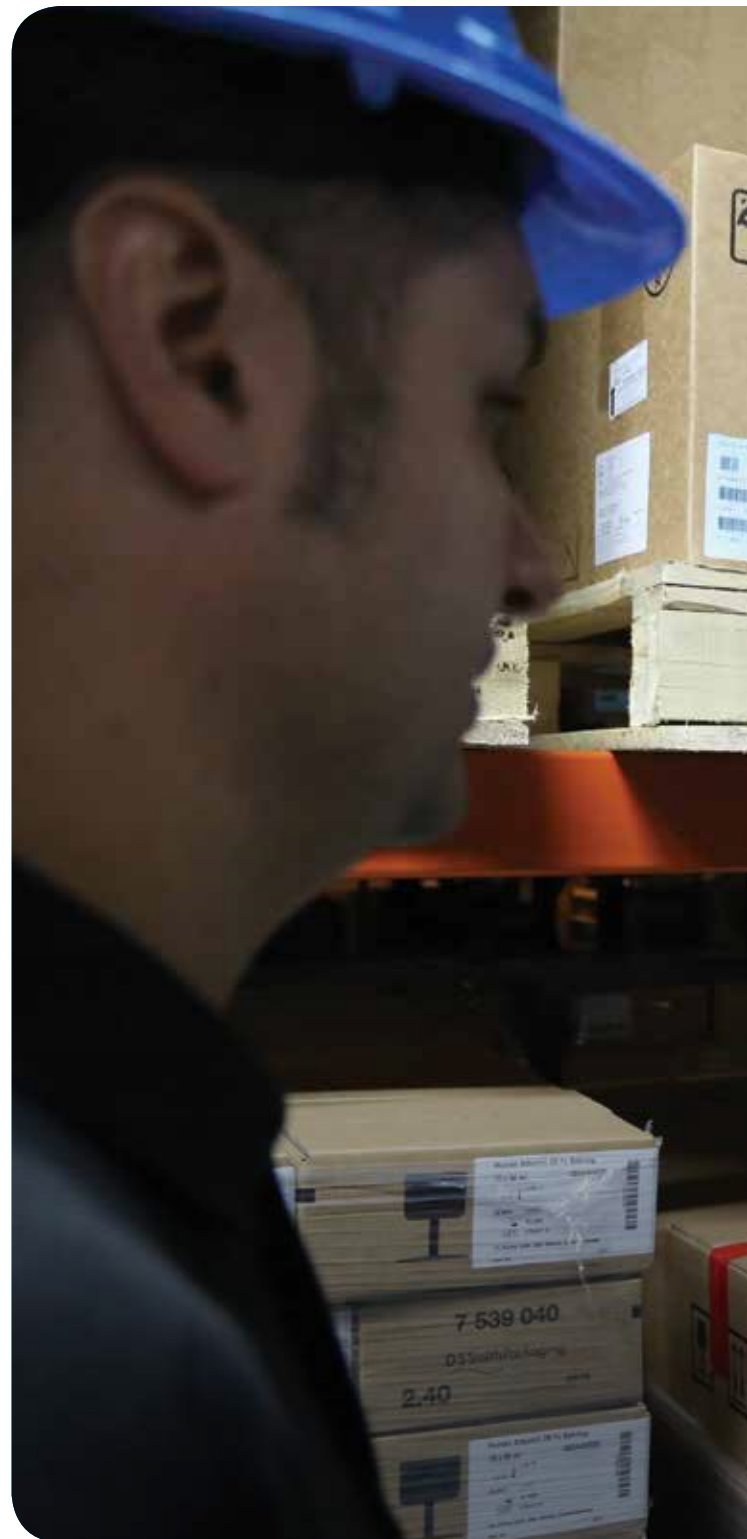
More than
607,000
people living with HIV/AIDS
received treatment



Small warehouse, big impact

In recent years, the countries of the Americas have made tangible progress toward the elimination of neglected and vector-borne infectious diseases such as malaria, Chagas disease, and leishmaniasis. However, this success has created another problem: while the number of affected people has declined, medicines to treat them have become scarcer. To ensure a rapid response when the countries of the Americas need these medicines, since 2014 PAHO has operated a regional distribution center for supplies to treat such diseases –located in Panama– within the framework of an interprogrammatic project. The center stores, distributes, and seeks to improve the efficiency and sustainability of management for medicines that are available in limited quantities or with limited access on the pharmaceutical market.

In 2016, the regional warehouse managed the storage and delivery of 12 medicines, including anti-Chagas, antimalarial, antileishmanial, and antiparasitic. Overall, 162,108 treatments were distributed to 25 countries across the Region. Furthermore, the distribution center shipped human immunoglobulin (IgG) treatments to patients in remote areas who had developed Guillain-Barré syndrome as a result of Zika virus infection.





+5,000
treatments for
Chagas

+160,000
treatments for neglected infectious diseases were made
available to **25** countries in the Region

Quality, safety, and efficacy assurance

for supplies in compliance with the strictest international standards

Based on the WHO Prequalification Program and through collaboration with national regulatory authorities (NRA) in countries across the Region, PAHO assures the quality, safety, and efficacy of the products acquired through the Strategic Fund. PAHO has internal quality assurance processes for the continuous monitoring of products acquired through its procurement mechanisms, to ensure that the products that reach member countries meet strict international standards.

In 2016, PAHO expanded its eligibility and technical criteria for product procurement through the Strategic Fund. Thus, signatory

countries can have access to WHO-prequalified products as well as to medicines approved and marketed in countries whose regulatory bodies have been designated as reference authorities (NRA of Regional Reference) through PAHO's capacity evaluation processes (Resolution CD50.R9). The expansion of the eligibility criteria allowed access to a larger number of sources for procurement and improved the availability and competitiveness of the mechanism without compromising quality standards. Furthermore, a review of the quality assurance criteria and processes has made the evaluation of technical offers more efficient and means the results of bids and tenders now become available faster.



Quality, safety and efficacy

International recommendations on production and control



Eligibility

WHO pre-qualification processes
Registration and commercialization in a NRAs
of Regional Reference



Performance

Supplier performance evaluation



Better access to critical supplies: the Essential Medicines Program in Haiti

The Essential Medicines Program (PROMESS) is the main source of essential medicines and medical supplies in the Republic of Haiti. PROMESS relies on PAHO's technical support and procurement services to ensure that Haiti receives safe, quality, efficacious and affordable health products.

Comprehensive technical cooperation

Thanks to the comprehensive technical cooperation mechanism offered to the countries of the Region, the Fund has had an impact on national programs for communicable diseases, vector control, and noncommunicable diseases, extending beyond the procurement of health supplies. Technical cooperation through the Strategic Fund is based on a comprehensive perspective that takes into account all aspects that can influence timely access to safe, efficacious, quality supplies: rational use, the application of clinical practice guidelines based on the best available evidence, efficient allocation of resources, and improvement of the equity and quality of access to services and treatment, all of which constitute critical elements of this integrated, comprehensive approach.

Integrated cooperation reveals itself in the daily work of country offices, which provide technical support and procurement assistance at the request of the health authorities. At the regional level, joint

missions are a concrete expression of interprogrammatic work. For example, the Fund collaborates in the strengthening of programs for tuberculosis, malaria, and HIV/AIDS in the Region through joint interprogrammatic missions. In 2016, PAHO supported 11 member countries within the framework of regional antimalarial monitoring to prevent shortages and improve the efficiency in the management of these supplies. Likewise, PAHO provided cooperation for training to improve tuberculosis treatment regimens in 10 countries of the Region. The Fund helped countries in Central America devise treatment migration plans for patients with HIV/AIDS, with a view to optimization of treatment regimens. A financial impact assessment for the English-speaking Caribbean found that these countries could save up to 80% of their budgets on HIV/AIDS medicines if they purchase these supplies through the Strategic Fund. A line of cooperation was created for member countries in this subregion to optimize their supply-chain management and estimation of needs.

2016

Joint missions for HIV/AIDS, tuberculosis, and malaria

Measures to address chronic kidney disease from nontraditional causes with a special focus on Central America

PAHO supports antimalarial monitoring in 11 countries

www.paho.org



Pan American
Health
Organization



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