

PAHO – Regional Regulatory Systems and Innovation and Production Agenda

Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers

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PAHO



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas

Regional Revolving Funds

Improving Access to Vaccines, Medicines and Health Technologies

Revolving Fund For Access to Vaccines

Strategic Fund

Regional Revolving Funds

The RRFs are **technical cooperation mechanisms** that enable the Americas to equitably access quality **vaccines, essential medicines**, and public health supplies on time.

Through **pooled procurement**, Member States obtain affordable prices and better conditions by **planning their demand together** to obtain benefits plus **reliable demand predictability**.

Goals



Affordability



Accessibility



Availability



Quality Assurance

Revolving Fund

- Vaccines
- Injection Devices
- Cold-chain Equipment

Strategic Fund

- Treatments
- Diagnostics
- Medical Devices
- Vector Control



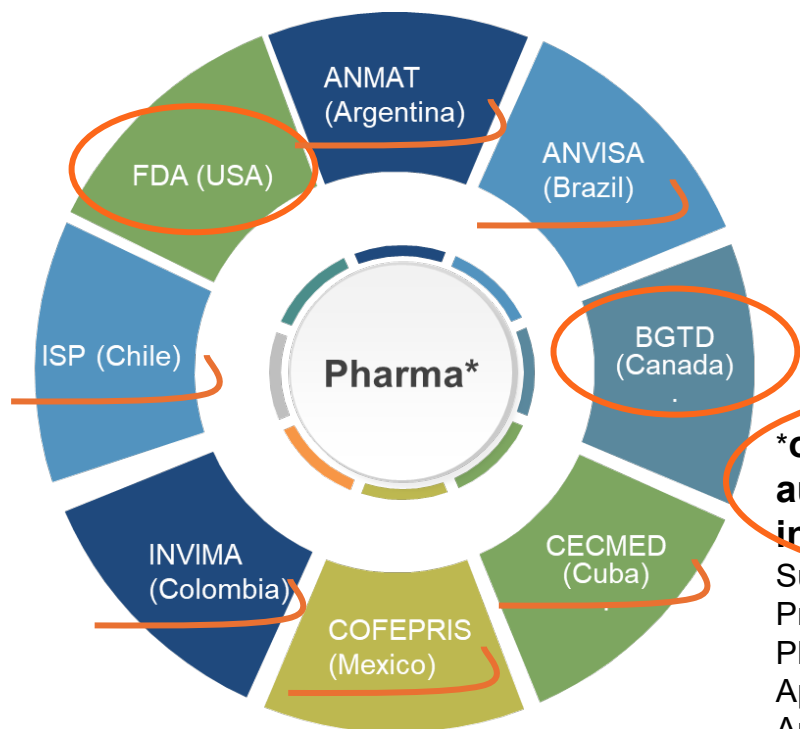
Quality Assurance

Reliance

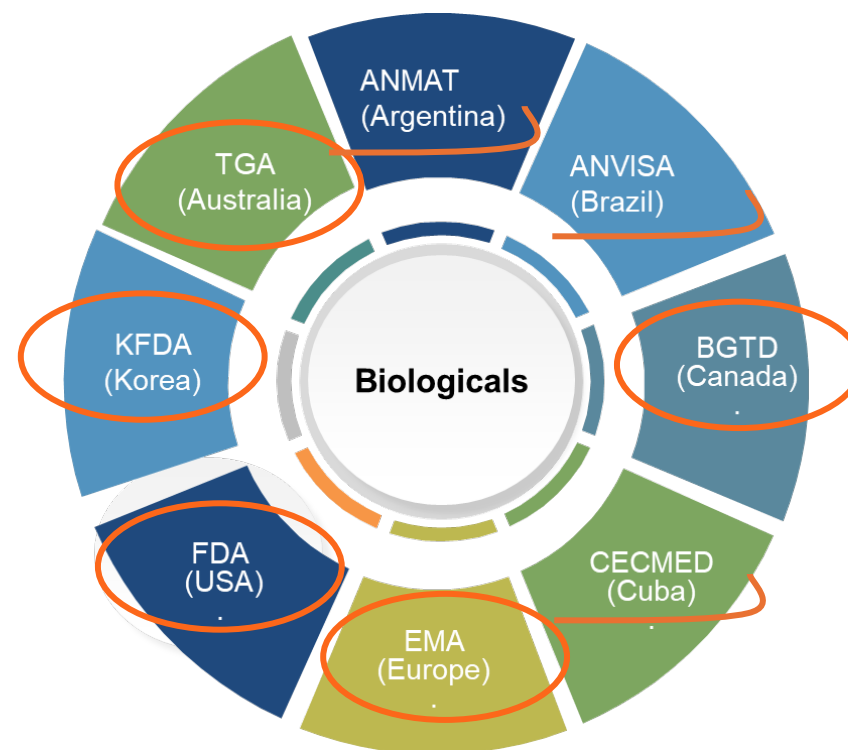
Harmonization

Regional RS Strengthening

Current eligibility criteria > WHO PQ or marketing authorization and batch release (if applicable) by:



***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"**



Department of Innovation, Access to Medicines and Health Technologies (IMT)



Structure

Access to Medicines and
Health Technologies
(IMT/AH)

Quality and Regulation of
Medicines and Health
Technologies
(IMT/QR)

Special Program,
Innovation and Regional
Production Platform
(IMT/RP)

Quality
Assurance

Mission

- ❖ IMT was created in 2023 and is responsible for promoting, coordinating, and implementing the Organization's technical cooperation in **innovation, access and rational use** of medicines and other health technologies.
- ❖ IMT works across **all categories of medicines and health technologies**, including medicines, vaccines, diagnostics, medical equipment, radiology, blood products, and organs for transplantation, and the strengthening of pharmaceutical services
- ❖ It supports countries in addressing **barriers to access** and promote access throughout the full health technology **lifecycle**, e.g. **strengthening regulatory capacity**, supporting **evidence-based decision making and rational use**, promoting **competition and transparency**, as well as strengthening regional **innovation and production capacity**.

Background: Creation of the IMT Department

Quality and Regulation Unit within IMT

Structure

Access to Medicines and
Health Technologies
(IMT/AH)

Quality and Regulation of
Medicines and Health
Technologies (IMT/QR)

Special Program, Regional
Innovation and Production
Platform (RP)

Resolution CSP30.R12 endorsed in 2022

Policy to strengthen national regulatory systems for medicines and other health technologies

QR's strategic **lines of action**:

- **Adopt** the new evaluation systems based on the **WHO Global Benchmarking Tool (GBT)** and related mechanisms.
- Strengthening regulatory **harmonization and convergence**
- **Promote efficient regulatory systems**, and, where the context permits, encourage the production of health technologies that promote health and well-being, as well as economic and social development.
- **Ensure the quality of medical products procured** by PAHO's Revolving Funds on behalf of Member States.

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Sept 21 - Resolution CD59.R3

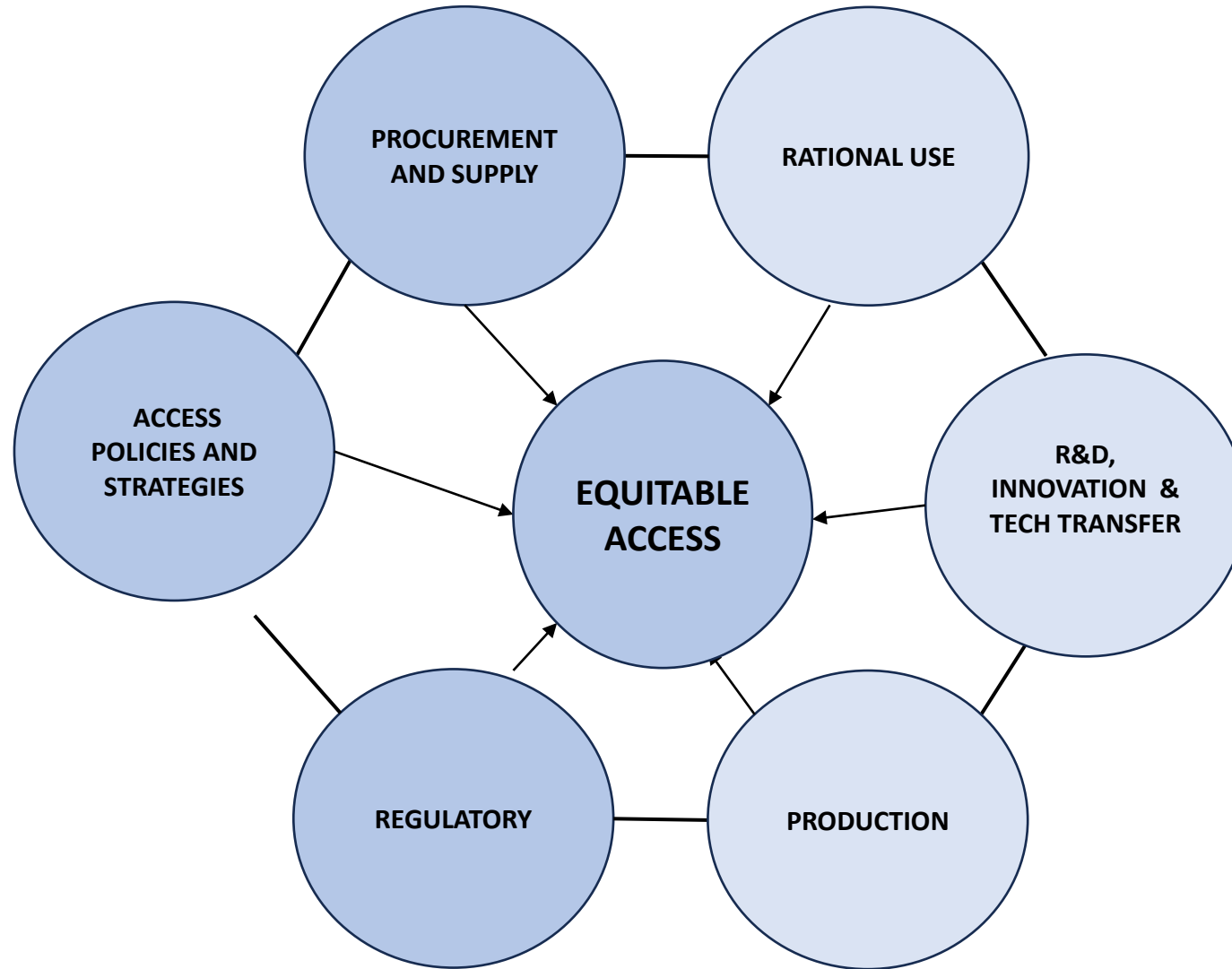
Increasing Production Capacity for Essential Medicines and Health Technologies

The objective of RP is to increase the capacities of innovation and production of medicines and other essential health technologies to contribute to equitable access.

RP has 4 **lines of work**:

- Promote **research**, **development** and **production** initiatives
- Strengthening of **regional ecosystems** conducive to development, production and access
- Provide **information and technical cooperation** for decision-making
- Facilitate **dialogue and promote regional coordination** and cooperation

ACCESS THROUGH THE ENTIRE TECHNOLOGY LIFECYCLE: OUR APPROACH



Special Program, Regional Innovation and Production Platform (PR)

Lines of Work

I. Strategic initiatives

II. Ecosystems of innovation and production

III. Information for decision-making

IV. Regional dialogue and cooperation



Promote strategic research, development and production initiatives

Support for mRNA vaccine development and production capacities

In coordination with



Public-private partnership to produce mRNA vaccines and strategic inputs (lipids for nanolipid particles);



Bio-Manguinhos / FIOCRUZ preclinical studies to develop a proprietary self-amplifying mRNA COVID-19 vaccine

Collaboration for the R&D vaccines relevant for the region

- Promote **R+D** capacities of technologies relevant to the region.
- Provide **technical cooperation** to identify opportunities and promote the implementation of innovation and productive projects, including South-South collaboration projects.
- Joint collaboration projects in LAC:
 - Lesihmaniasis
 - Influenza
 - Lipids



R&D meeting at mRNA, in BioManguinhos/Fiocruz, Oct-2024

Regional Revolving Funds

Strategic priorities for the next biennium

Strengthening Innovation with a Regional approach



Integrate added value initiatives with a Regional perspective to increase access to essential health products and supply chain.

Establishment of global/regional supply agreements for rapid response



Improve preparedness and response capacities through early access to medical countermeasures.

Creation of a regional hub



Alleviate supply chain disruptions in emergency situations and reduce transportation costs

Specific initiatives



Focus support on the Elimination Initiative, Better Care for Noncommunicable Diseases, the digital agenda, and high-cost medicines.

IMT and RRF collaborate to support regional production and innovation projects

This year, the **61st Directing Council** approved **Res. CD 61.R14** "Review of the Applicable Charge for the Purchase of Public Health Supplies for Member States"

15% of the capitalization accounts to encourage regional innovation and production:

- Implement innovative procurement strategies
- Negotiating pre-pandemic agreements
- Formulate financing initiatives

Exempt capitalization accounts from the charge applicable to the purchase of inputs, when the products are produced in the Region

Special Program, Regional Innovation and Production Platform (PR)

Lines of Work

I. Strategic initiatives

II. Ecosystems of
innovation and production

III. Information for
decision-making

IV. Regional dialogue and
cooperation



Promote the strengthening of regional ecosystems conducive to development, production and access

- Technical cooperation to Member States to develop multisectoral policies and enabling ecosystems

- Identification of **gaps and development of national roadmaps**
- Support for **cross-sectoral** work
- Identification of **opportunities for collaboration**, including **South-South** cooperation
- **Technical Support** for Manufacturing

- Strengthening of National Regulatory Systems for production

- Strengthening human resource capacities to develop and produce health technologies

- Course on **Vaccine Development and Production** for MERCOSUR with Fiocruz and Butantán
- Collaboration for the creation of a **Regional Center for Training** in Vaccine Development and Production (in process)

- Strengthening regional value chains

- **Workshop** on Regional Vaccine Manufacturing Capacities in Latin America and the Caribbean (Oct, 2024).
- **Analysis of strategic information** on capabilities and opportunities for collaboration to strengthen vaccine innovation and production.

Special Program, Regional Innovation and Production Platform (PR)

Lines of Work

Generation of strategic information in priority areas to support decision-making and policy design

I. Strategic initiatives

II. Ecosystems of innovation and production

III. Information for decision-making

IV. Regional dialogue and cooperation



Provide information and technical cooperation for decision-making

- ✓ Strategic information generation for decision-making; conduct studies and policy analysis, identify opportunities, and share national experiences.
- ✓ Foster collaborations and sharing of best practices and common challenges, providing guidelines, and recommendations for action.

Studies (selection)



Overview of mRNA vaccines patents for COVID-19 in Argentina and Brazil.



Manufacturing opportunities for healthcare technologies: biologicals, chemical synthesis, healthcare, and PPE.



Analysis of the role of women in the vaccine industry and the regulatory system.



Technology transfer models for developing and manufacturing vaccines in LAC.



Analysis of productive ecosystems for policy design. Case studies in 6 countries.



Supply chain management during COVID-19: national experiences.

Special Program, Regional Innovation and Production Platform (PR)

Lines of Work

I. Strategic initiatives

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IV. Regional dialogue and cooperation



Facilitate dialogue and promote regional coordination and cooperation

Alliances / Partnerships



• **United States (HHS/OGA)**

Canada

• **Canada (GAC)**



• **European Commission**

Cooperation and Articulation



CELAC 2022
Argentina



PROSUR



CEPI



Multisectoral Dialogues

- **Strategic Advisory Group** on Innovation and Production
- **Multinational dialogues** with government representatives of Health, Industry, Science and Technology, manufacturers and researchers



- **Technical Webinar Series:** Production, Intellectual Property, Public Policy, Gender, among others.
- **Workshop** on Policies for Strengthening the Production Capacity of Vaccines and Other Health Technologies



Key messages



Innovation and production for access: Strengthening regional capacities in innovation and production is driven by the goal of improving equitable access to health technologies.



Ecosystem Strengthening with quality at the center: Robust ecosystems, grounded in strong regulatory and quality systems, are essential for sustainable innovation and equitable access.



From providers to partners: PAHO sees manufacturers in the Americas not just as providers, but as strategic partners, working collaboratively to advance innovation and production for access.