

Forum

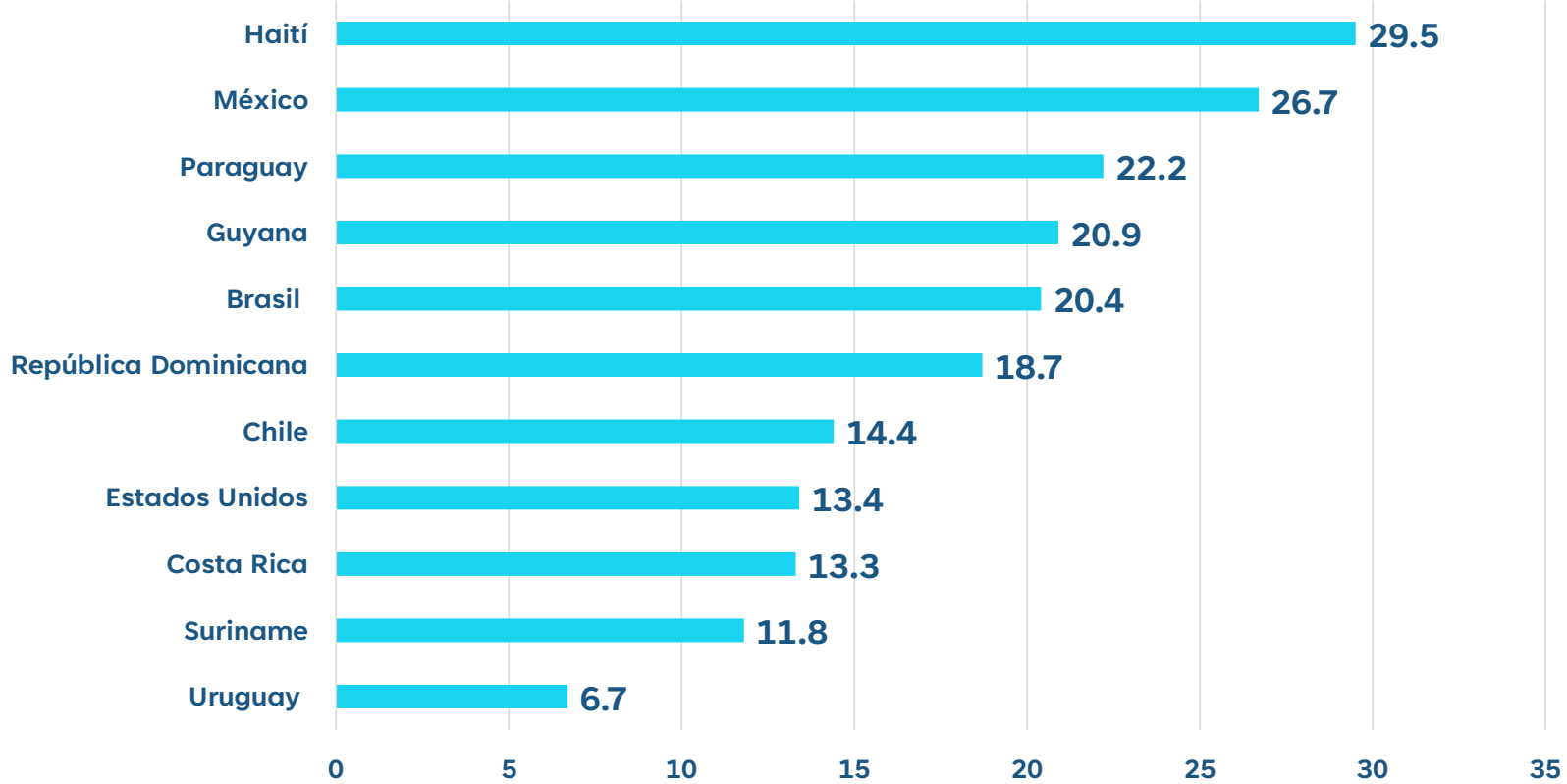
# “Recent Reforms in HTA, Pricing, and Public Procurement Across Latin America: Implications for Access and Sustainability”

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ISPOR Latin America Consortium

Juliana Vallini – IMT | AH  
May 2026

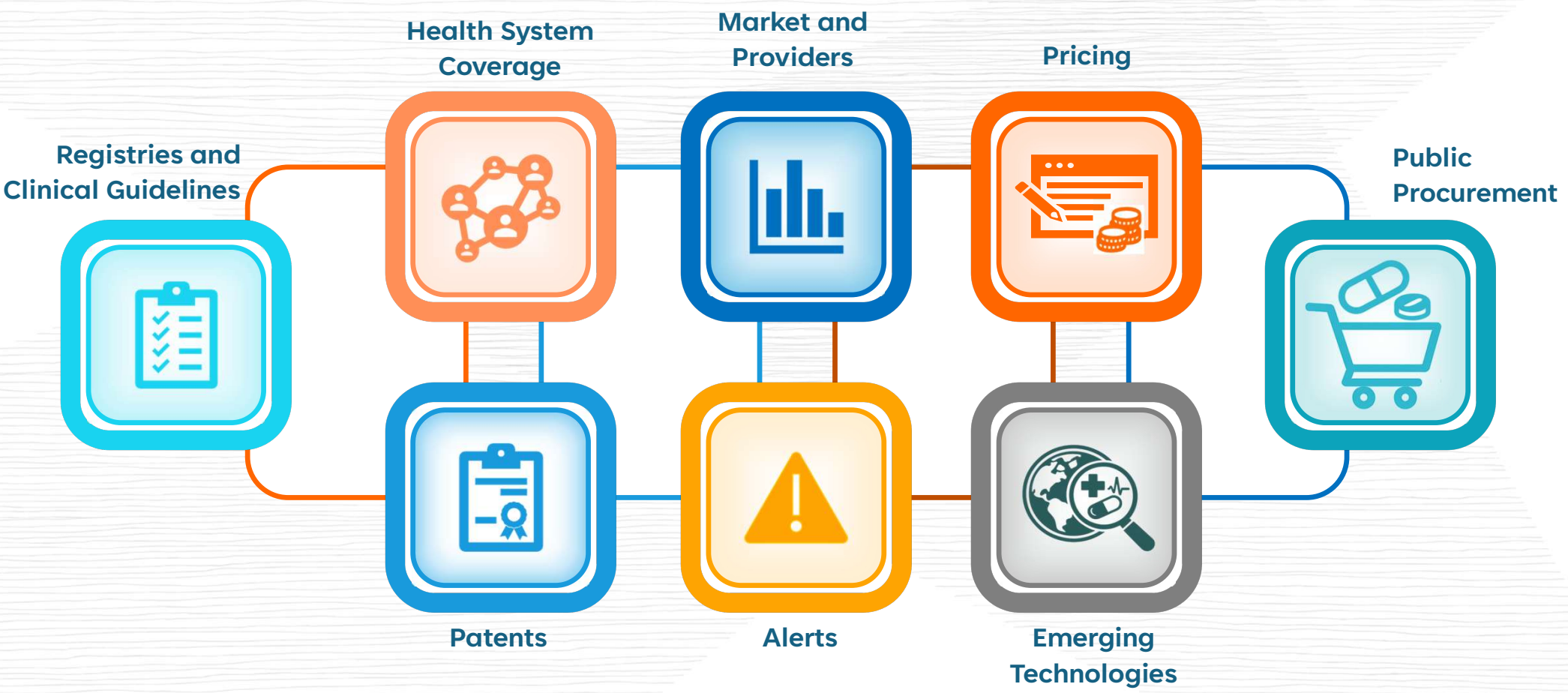
# PHARMACEUTICALS REPRESENT A SIGNIFICANT PROPORTION OF HEALTH EXPENDITURE



Percentage of pharmaceutical expenditure in current health expenditure

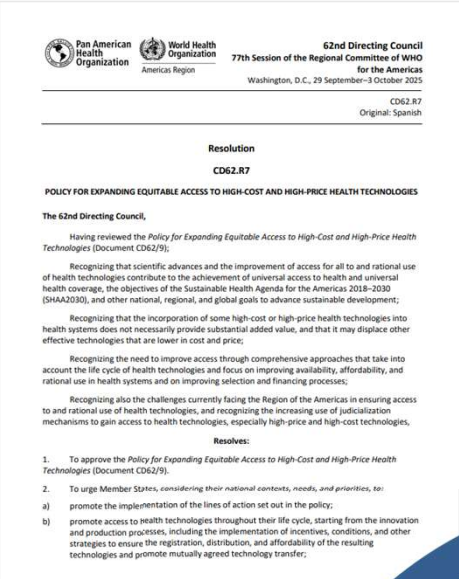
WHO 2019 published by OECD <https://stat.link/lud2g1>

# IDENTIFICATION OF BARRIERS TO ACCESS TO HEALTH TECHNOLOGIES

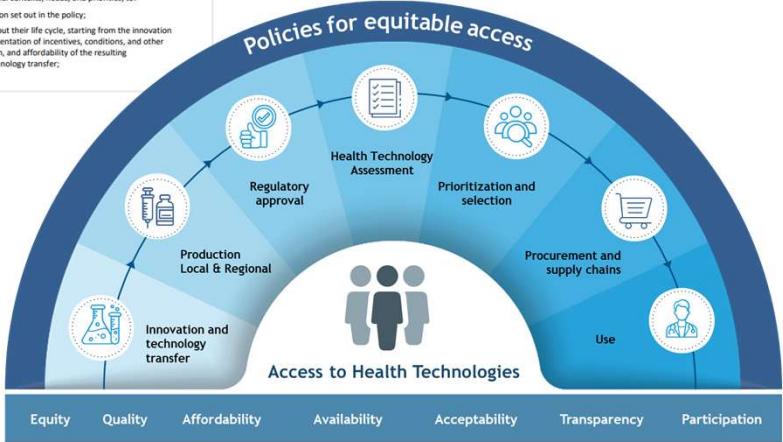


Bottlenecks | Compared Context | Result oriented

# EXPAND EQUITABLE ACCESS TO HIGH-COST AND HIGH-PRICED HEALTH TECHNOLOGIES



Access barriers are found at all stages of the life cycle of technologies



## ACTION LINES

NETWORK

- Innovation, Research and Development, and Production
- Evaluation, Selection and Incorporation of Health Technologies and Litigation
- Regulatory Frameworks and Competition
- PAHO's Regional Revolving Funds
- Strategic Data Monitoring | Use of Evidence

# MARKET STRUCTURE – Biologics and Biosimilars in Selected Countries of Latin America

## The Pharmaceutical Market for Biological Products in Latin America: A Comprehensive Analysis of Regional Sales Data

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**Keywords:** Biologics, Latin America, Market Share, Biosimilars, Innovators, Central America

**Abstract:** The global market for biologics and biosimilar pharmaceutical products is experiencing rapid expansion, primarily driven by the continuous discovery of new molecules. However, information regarding Latin America's biological market remains limited.

**Introduction**  
Global consumption of medicines has increased significantly in recent decades.<sup>1</sup> With the advent of the COVID-19 pandemic, this growth has significantly accelerated in some parts of the world.<sup>2</sup> In addition, technological development, innovation, and rapid advances in biomedicine, genomics, and therapeutics have changed the paradigm of chemical molecules for biological, high-affinity, and highly effective drugs.<sup>3</sup> These drugs are called biologics, a class of very large molecules made from living organisms, such as bacteria, rather than synthetic, chemically developed products.<sup>4</sup> These living organisms are modified to produce the active ingredient of the drug, which is then extracted and placed in a dosage form.<sup>5</sup> The U.S. Food

and Drug Administration (FDA) defines it as a biological product that is highly similar to a reference biological product but has no clinically significant differences from the reference product.<sup>6</sup> Unlike small molecule drugs, biologics are created by living cells. However, since the synthesis pathway of biologics is often patented during development, biosimilar manufacturers may need to engineer a feasible non-infringing synthetic pathway until patents expire.<sup>7</sup>

As of 2022, the European Medicines Agency (EMA) has approved 88 biosimilars, while the FDA has approved 102.<sup>8</sup> In Latin America, approvals were later withdrawn, leaving only 10 biosimilars approved in Europe. By contrast, in Latin America, only 38 biosimilars have been approved to date.<sup>9</sup> Developing a biosimilar has been suggested to cost between 100 to 200 million, in contrast to 80 to 1.3 billion for the development of a new drug.<sup>10</sup> In Europe, biosimilars are commonly sold at a price of roughly 20% to 35% when compared to reference products.<sup>10</sup> This pricing strategy aims to ensure that patients receive treatments that were previously challenging or unattainable. In nations such as Argentina, the Czech Republic, and Romania, the use of biosimilars was particularly limited, with sales estimated to be as high as 50% of the sales of reference biologics, with the use of biosimilars increasing by more than 25% in 2022.

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Table 3  
Listing of Biologics and Biosimilar Producers Categorized by Their Country of Origin

Country	Total Products / Registrations	Total Manufacturers	*Local producers / Local distributors	Multinationals
Argentina	59	32	5	27
Brazil	80	34	7	27
Central America	36	22	4	18
Chile	53	29	6	23
Colombia	37	19	3	16
Dominican R.	22	15	4	11
Ecuador	42	22	2	20
Mexico	71	38	7	31
Peru	27	16	3	13
Uruguay	26	24	6	18
Venezuela	2	2	2	0
Cuba	15	6	3	3
<b>Total</b>	<b>470</b>	<b>259</b>	<b>52</b>	<b>207</b>

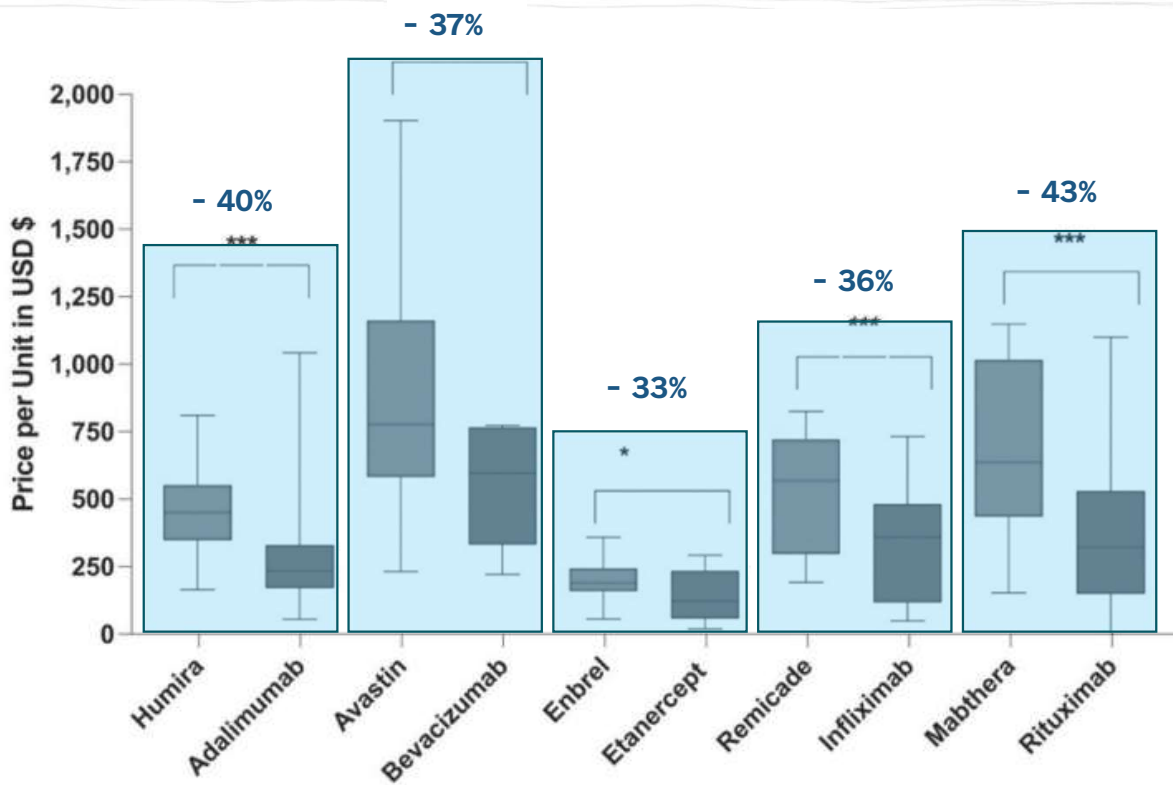
\* In this category, we include manufacturing factories that are established in the region or those regional companies that have registered a biological or biosimilar product made in another country but with an exclusive license for the country where the license was obtained.

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DOI: 10.1017/jlm.2023.112  
<https://doi.org/10.1017/jlm.2023.112> Published online by Cambridge University Press



# AFFORDABILITY - BIOSIMILARS PRICES

## Price of innovative medicines with their biosimilars in Latin American Countries



**Reduction in the Average Price of Biosimilars compared to the Reference Product**

**Key Elements**

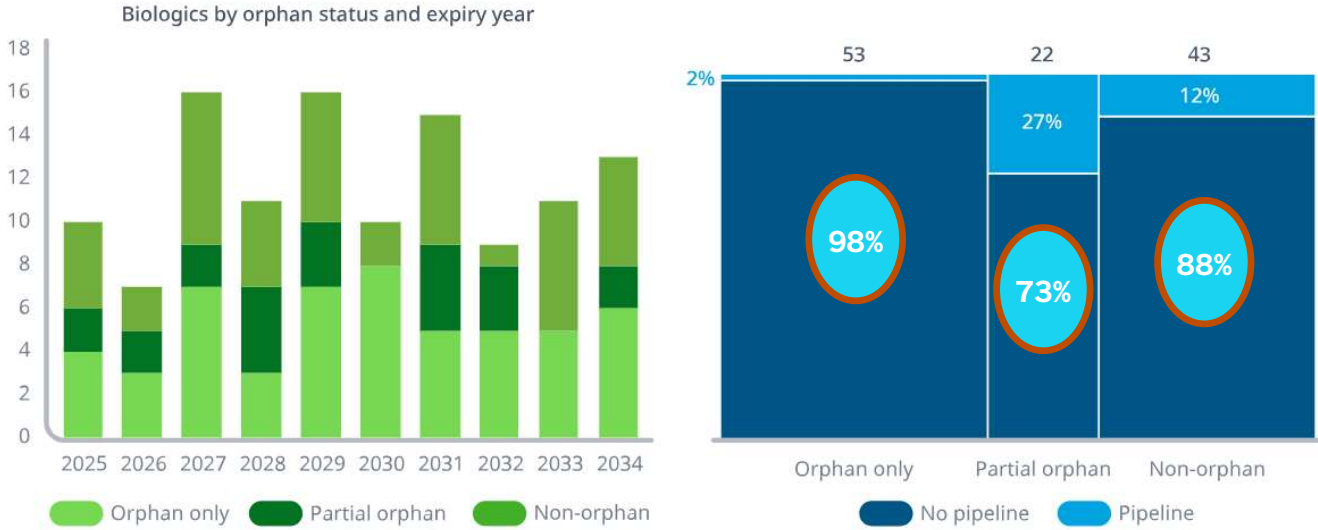
Promotion of competition and use of generic medicines and biosimilars.

Aggregation of demand at national and/or regional level to achieve lower prices.

Fuente: Ortiz-Prado E, Izquierdo-Condoy JS, Vasconez-González JE, Dávila G, Correa T, Fernández-Naranjo R. The Pharmaceutical Market for Biological Products in Latin America: A Comprehensive Analysis of Regional Sales Data. Journal of Law, Medicine & Ethics. 2023;51(S1):39-61.

# AFFORDABILITY – LOSS OF EXCLUSIVITY AND FUTURE ACCESS

Biologic expiries by orphan status and biosimilar pipeline, 2025-2034



**Many biologics that lose exclusivity face little or no competition**

“El pipeline se está estrechando de forma significativa”

El número medio de biosimilares en desarrollo por molécula podría caer de 2,19 para los productos que perderán exclusividad entre 2023 y 2027 a solo 0,43 en el periodo 2028-2032.

Fuente: IQVIA (2024) Evaluación del vacío de biosimilares.

## PROMOTING INNOVATION AND PRODUCTION IN THE AMERICAS

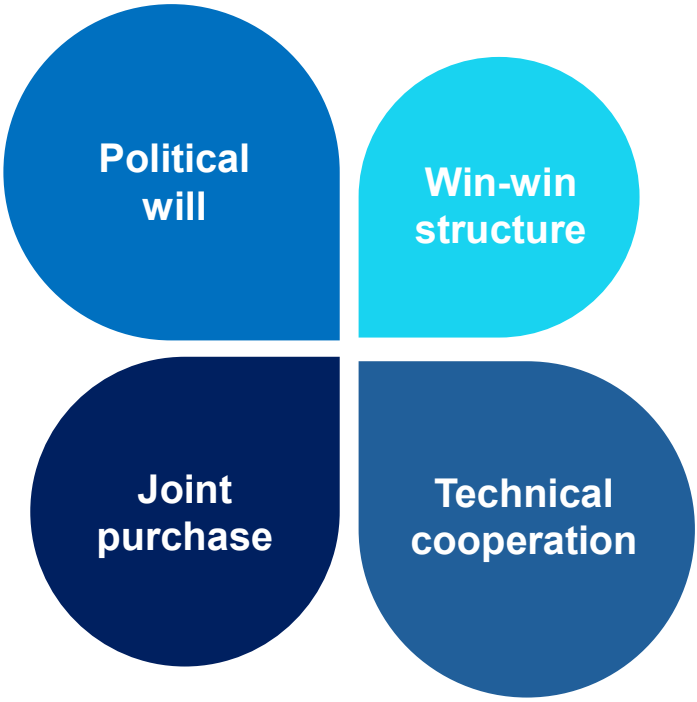
Regional focus on local production of vaccines and health technologies.

- Recent resolutions supporting innovation.
- Ecosystem to cooperate



# KEY POINTS FOR REGINAOL MANUFACTURING

- Creates the conditions and alignment.
- Starts everything up.



- Supports the ecosystem to achieve reliable demand and benefits for all its participants.

- All parties benefit.
- Common goals to achieve collective benefits.

- Aligned with the RRF joint acquisition.

# PAHO REGIONAL REVOLVING FUNDS

**Strategic  
Fund**



**Regional  
Revolving  
Funds**

**Revolving  
Fund** For Access  
to Vaccines

Funds are **technical cooperation mechanisms** of PAHO that allow the Americas to access **quality** vaccines, essential medicines, and public health supplies in a **timely manner**.

Through **regional acquisition and joint demand planning**, Member States obtain the best conditions as well as demand forecasting.



# HIGH PRICE MEDICINES

## Strategic Portfolios



Prostate Cancer



Breast cancer



Multiple Sclerosis



Rare Diseases

## Better Access

Prices between **60% and 90% lower** than national reference prices

**Introduction of informed decision medicines**

## New Mechanisms

Coordination with programmatic actions:  
Global Platform for **Access to Childhood Cancer Medicines +30 medicines**

St. Jude / WHO / UNICEF / PAHO

Working on Innovative financing mechanisms