



# COMPREHENSIVE PLAN FOR HEALTH SELF-SUFFICIENCY

Strengthening productive and distribution capabilities  
for vaccines and medicines in CELAC countries



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# STRENGTHENING THE PRODUCTION AND DISTRIBUTION OF MEDICINES, ESPECIALLY VACCINES, WITHIN CELAC AND REDUCING EXTERNAL DEPENDENCY

## Components of the Plan

- Mapping of the institutional situation and of supply and demand
- Sector structure and performance in selected countries
- Measures to develop regional chains
- Institutions, standards and regulations, systems of innovation and public procurement
- Formulation of specific lines of action

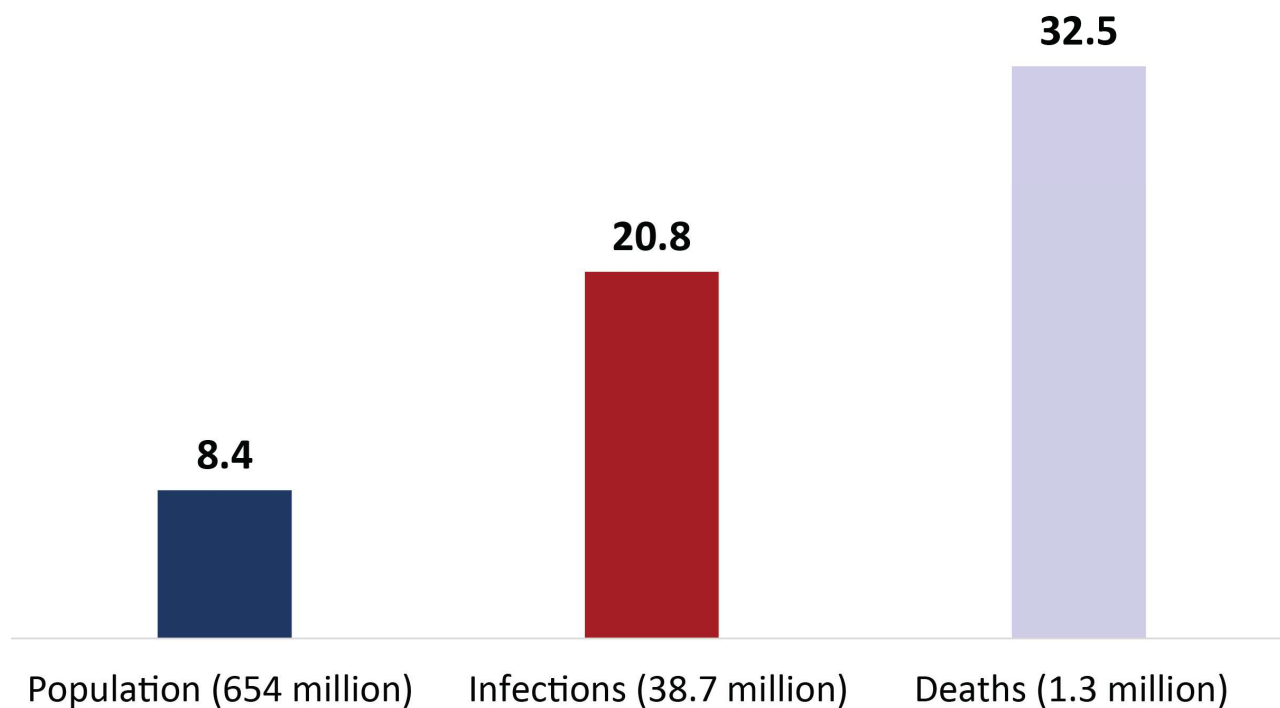
## Progress

- Tracking of progress on vaccination: procurement, inoculation, development and production, scenario estimation
- Creation of a group of 20 experts coordinated by ECLAC, whose findings are included in this presentation
- Expansion of the national and subregional scope of the group
- Identification of institutional implementing capabilities



# A region overrepresented in COVID-19 infections and mortality

**LATIN AMERICA AND THE CARIBBEAN: TOTAL POPULATION AND CUMULATIVE COVID-19 INFECTIONS AND DEATHS, 19 JULY 2021**  
*(Percentages of the global total)*



- Paradox of the recovery:
- Fall of 6.8% in 2020 and growth of 5.2% in 2021
- Higher debt and less fiscal space
- Poverty and extreme poverty have risen: 209 and 82 million
- No improvement in informality and unemployment
- Middle-income traps

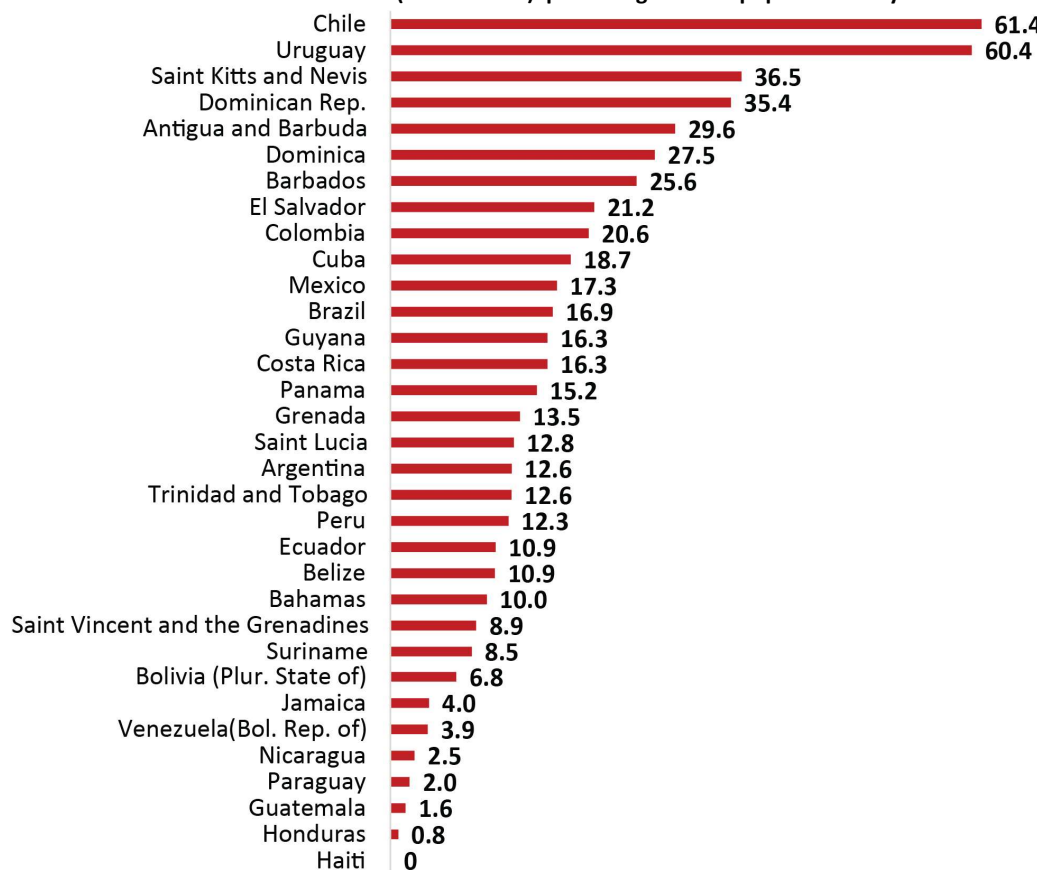


ECLAC

Source: ECLAC, on the basis of WHO, WHO Coronavirus Disease (COVID-19) Dashboard, and United Nations, World Population Prospects.

# Unequal access to vaccination

Latin America and the Caribbean (33 countries): percentages of the population fully vaccinated



***The region will not succeed in vaccinating 80% of its population in 2021***

## ■ Different speeds

### Population fully vaccinated

- United States and Canada: 49.3%
- European Union: 44.6%
- **Latin America and the Caribbean (30 countries): 16.8%**
  - South America (10 countries): 17.2%
  - Central America (without Mexico): 7.4%
  - The Caribbean (12 countries): 10%

## ■ In some countries, procurement exceeds vaccination needs.

The European Union, the United States, the United Kingdom, Canada and Japan **account for 43.9% of purchase commitments**, with only 12.9% of the global population.

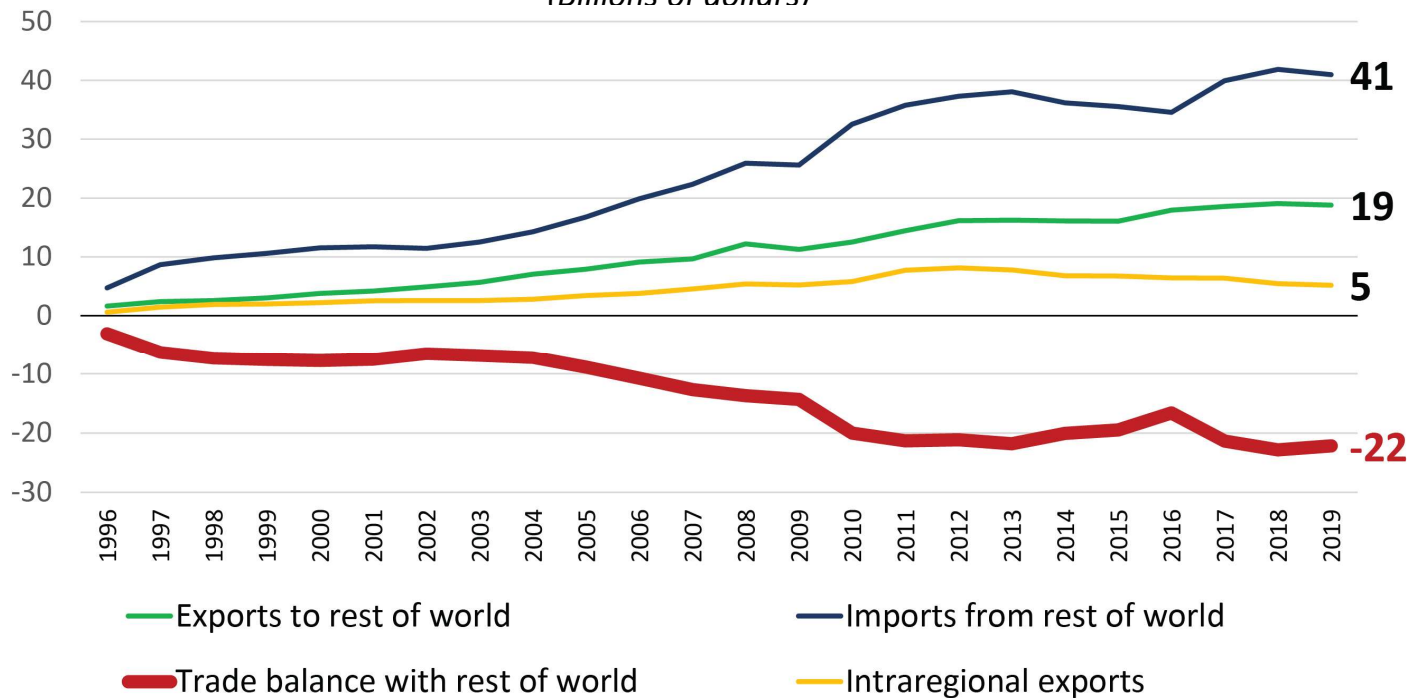


Source: ECLAC, on the basis of *Our World in Data* [online] [www.ourworldindata.org](http://www.ourworldindata.org).

Note: Records for countries that report the breakdown of doses administered (first and second), as of 22 July 2021 or latest date available.

# International trade: high dependency on multinational corporations and growing imports from outside the region

Latin America: pharmaceutical industry trade balance and intraregional trade, 1996–2019  
(Billions of dollars)



In 2019, the region's **imports** were **double** the amount of its **exports**.

The **deficit** was over **US\$ 20 billion**

The rise in imports of innovative biological products has led to **steady rises in trade deficits**.



Source: ECLAC, *Building a New Future: Transformative Recovery with Equality and Sustainability* (LC/SES.38/3-P), Santiago, 2020.

## Low level of technological development and high dependency on imports and on production by multinationals

- The region's strengths in clinical trials has not meant greater access to vaccines.
- Technological development is carried out mainly by public universities and laboratories.
- The larger countries have hubs of high-quality basic research.
- Incipient process of start-ups bringing the outcomes of new research to market.
- Lack of technological business base makes it difficult to scale up production as occurs in highly developed countries.

## Homegrown vaccines: Cuba, Brazil and Mexico

### **Cuba.** The most advanced research

Finlay Institute of Vaccines (IFV) and Centre for Genetic Engineering and Biotechnology (CIGB)

#### **5 vaccines under development**

- 2 in **phase 3** clinical trials
  - *Soberana 2*
  - *Abdala* (effectiveness 92.28%)
- 2 **booster** vaccines (3<sup>rd</sup> dose / convalescents)
- CIGB is working on a nasal vaccine (*Mambisa*)
- *Abdala and Soberana 2*: As of 22 July, **8.4 million doses administered**

### **Butantan in Brazil** (*ButanVac*) and

**Avimex in Mexico** (*Patria*) in collaboration with Mount Sinai and the University of Texas

- *ButanVac* in **phase 1/2** clinical trials
- *Patria* in **phase 1** clinical trials

### **Universities at preclinical stages:**

- University of São Paulo (**Brazil**)
- San Martín National University and La Plata National University (**Argentina**)
- Escuela Superior Politécnica del Litoral (**Ecuador**)
- Pontifical Catholic University (**Chile**)
- Farvet Veterinary Laboratory (**Peru**)
- Autonomous University of **Mexico** is participating in 3 of the 6 vaccines under development.

## Production agreements in Argentina, Brazil, Cuba, Mexico and Venezuela

### AstraZeneca-Oxford (*Vaxzevria*)

**MWXICO-ARGENTINA** / Carlos Slim Foundation

- The Argentine laboratory mAbxience produces the active ingredient (antigen)
- The Mexican laboratory Liomont completes stabilization, manufacture and packaging
- Estimated capacity: 150 million–250 million doses per year
- 4 million doses produced

**BRAZIL** / Oswaldo Cruz Foundation (FioCruz)

- First stage: import of active pharmaceutical ingredient
- At 12 July, 61.9 millions doses delivered

### Sinovac (*Coronavac*)

**BRAZIL** / Butantan Institute

- At 12 July, 53.2 million doses delivered

**CHILE**: in negotiations with SINOVAC

### Gamaleya (*Sputnik V*)

**ARGENTINA** / Richmond Laboratory

- June: production of components 1 and 2 began
- Capacity: ~40 million doses in 2021 and 200 million in 2022 in plant under construction

**BRAZIL** / União Química

- Estimated production: 8 million doses/month.

### CanSino (*Convidecia*)

**MEXICO** / Drugmex

- Packaged in Querétaro
- At 12 July, 4.9 million doses delivered

### CIGB (*Abdala*)

**ARGENTINA/CUBA**

**VENEZUELA** / Espromed Bio Laboratory for phase 3 trials of the vaccine/estimated capacity : 2 million doses/month



# Priority areas and lines of action of the Comprehensive Plan

## Priority areas

1. Pooled procurement by public health systems
2. Financing consortiums for research and production
3. Platform clinical trials
4. Intellectual property
5. Inventory of regional capacities
6. Regulatory standards
7. Supplier development
8. Universal access to vaccines and primary health care

## Lines of action where progress has been made

1. Regional vaccine procurement mechanism
2. Creating consortiums to accelerate vaccine development
3. Platform clinical trials
4. Access to intellectual property
5. Inventory of regional capacities



# Line 1. Regional mechanisms for vaccine procurement

- **Strengthening existing regional mechanisms for joint procurement**
  - PAHO Revolving Fund for vaccines
  - Strategic Fund of PAHO
  - PANDRH Network - Pan American Network for Drug Regulatory Harmonization
- **Coordination of sectors and actors through subregional integration bodies**, in particular their ministerial councils on health matters
  - **Crucial issues:** mechanisms for vaccine price transparency and register of reliable suppliers
  - **SICA and Dominican Republic**, Council of Ministers of Health of Central America and the Dominican Republic (COMISCA)
  - **CARICOM**, Caribbean Public Health Agency (CARPHA)
  - **MERCOSUR**, sub-working group on health (Group 11).
  - **Pacific Alliance**, technical subgroup on regulatory cooperation on pharmaceuticals

## Line 2. Creating consortiums to accelerate vaccine development

- Vaccine development is a long, risky and expensive process.
- Uncertainty over the long-term market potential and testing difficulties.

Approach	Aims	Scope	Highlight
<ul style="list-style-type: none"><li>• Operate as a financier and facilitator</li><li>• Focus on development, licencing and vaccine manufacture</li><li>• Support partners' efforts in vaccine discovery, production and distribution</li></ul>	<ul style="list-style-type: none"><li>• Participate in regional and global R&amp;D bodies</li><li>• Coordinate technology transfer processes at the regional level</li><li>• Diversify technological platforms for vaccine production</li></ul>	<ul style="list-style-type: none"><li>• Regional partnership made up of public, private, charitable and civil society organizations</li></ul>	<ul style="list-style-type: none"><li>• Promote the creation of a regional fund for R&amp;D and production in the framework of PAHO or an ad hoc regional body</li></ul>

## Line 3. Platform clinical trials

- Clinical trials are essential for completing the development of a medicine: they must be a bargaining tool for preferential access to markets and technologies
- The region has the capacity to conduct COVID-19 clinical trials and observational studies (771 up to 15 July), but does so in a fragmented manner: 7% of the global total
- This fragmentation reduces the region's bargaining power: its participation in trials has not secured preferential access to vaccines
- The region can participate as a co-developer of new products by making use these networks
- Creating regional networks of research centres can speed up processes and reduce the costs of clinical trials. For example: the support provided by the HIV Vaccine Trial Network and similar United States government networks (CoVPN) to Moderna, AstraZeneca, Janssen, Novavax and Sanofi Pasteur

# Mechanisms and actors for building regional platforms

## Mechanisms

- Establish centres of excellence in the countries to conduct the different stages of clinical trials
- Develop mechanisms of coordination and governance in the public trials network
- Mutual recognition of clinical trials and regulatory harmonization: for example, regional recognition of clinical trials in level IV countries (Argentina, Brazil, Chile, Colombia, Cuba, Mexico)

## Strengthen mechanisms of regulatory convergence and broaden dialogue among actors

- Authorities for registration of clinical trials: Argentina (ANMAT), Brazil (ANVISA), Chile (ISP), Colombia (INVIMA), Cuba (CECMED), Mexico (COFEPRIS), Peru (INS), WHO and PAHO (Red PARPANDRH Network)
- Chambers of commerce for contract research organizations and the pharmaceutical industry

## Line 4. Making use of regulatory flexibility and joint negotiations to obtain access to intellectual property

- Rules derived from free trade agreements as opportunities or restrictions
- **Coordinate efforts on negotiating waivers at the World Trade Organization (WTO)**
- Share experiences at the regional level. The use of flexibilities available under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in Colombia, Ecuador and Peru led to 30%–90% reductions in medicine prices.
- Explore alternative non-exclusive licensing arrangements according to the market type (public or private)

Flexibility	TRIPS Agreement	Description
Compulsory licensing	Art. 31	Authorization for a non-State party to use an innovation without the consent of the right holder (requirement that efforts have been made to obtain authorization, or in case of a national emergency)
Public non-commercial use	Art. 31	Authorization for a government or contractor to use a patent without the consent of the right holder
Parallel imports	Art. 6	Importation and resale of a product from another country (where that product is sold legally at a lower price) without the consent of the right holder
Exceptions to rights conferred	Art. 30	WTO Members may provide limited exceptions to the exclusive rights conferred by a patent
Bolar exception		Legal exemption from infringement of patents to perform tests to determine the bioequivalence of generic medicines before a patent expires

## Line 5. Inventory of regional capacities

Agreement among ministers of health, production and science and technology and chambers and federations of business associations to gather information on capabilities for COVID-19 vaccine research and production

Consider the results of the survey of companies and technologies performed by the Coalition for Epidemic Preparedness Innovations (CEPI)

Variables to survey:

- Public and private laboratories involved in vaccine production, their technological platforms, value chain capabilities and agreements with transnationals
- Research groups that develop vaccines under the supervision of national research councils or universities
- Vaccine and biotechnology therapeutics production capacities that can be reconverted to vaccine production platforms with business associations and their federations
- Capacity for production of inputs such as syringes, packaging or caps

## In short, the Plan proposes four pillars for joint action engaging national and regional actors

- Governments, academia, national health institutes, biotechnology firms, regulators, R&D consortiums

**Technology development**

- Academia, governments, national health institutes, firms, regulators, PAHO, WHO, private product development partnerships, advanced biomedical R&D authority

**Product development**

- Firms, advanced biomedical R&D authority, contract manufacturing organizations, regulators, governments

**Manufacturing**

**Procurement, delivery and universal access**

- Global Alliance for Vaccines and Immunisation (GAVI), UNICEF, PAHO, WHO, governments, firms, primary health-care system, civil society