



Plan for self-sufficiency in health matters in Latin America and the Caribbean: lines of action and proposals



UNITED NATIONS

ECLAC

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Economic Commission for Latin America and the Caribbean (ECLAC)

18 September 2021



CELAC

Comunidad de Estados
Latinoamericanos y Caribeños

Towards a plan for self-sufficiency in health matters

Request by the President pro tempore of CELAC to ECLAC for “support for the realization of a comprehensive plan that seeks self-sufficiency in health matters, specifically focused on strengthening capacities for the production and distribution of vaccines and medicines in the CELAC region.”

- For this emergency and future pandemics
- Guarantee equal access to vaccines in the short term
- Inventory and diagnostic of capacities in the health complex: supply and demand
- Seven lines of action for the short, medium and long terms
- Identification of strategic actors and institutions

25 March
2021

**COVID-19
Observatory
Vaccination
observatory:**
acquisitions,
inoculation,
development
and
production,
scenarios

Formation of
a **group of 20
experts**
coordinated
by ECLAC

Analysis
of the the
**pharmaceutical
industry** and
the health
sector

Regional meeting
for the
**strengthening of
capacities in
sanitary
regulation**, with
COFEPRIS, five
other regulatory
agencies of
reference and
PAHO

Road map with
the Ministry of
Foreign Affairs of
Mexico and the
Coalition for
Epidemic
Preparedness
Innovations
(CEPI)

Inventory of capabilities

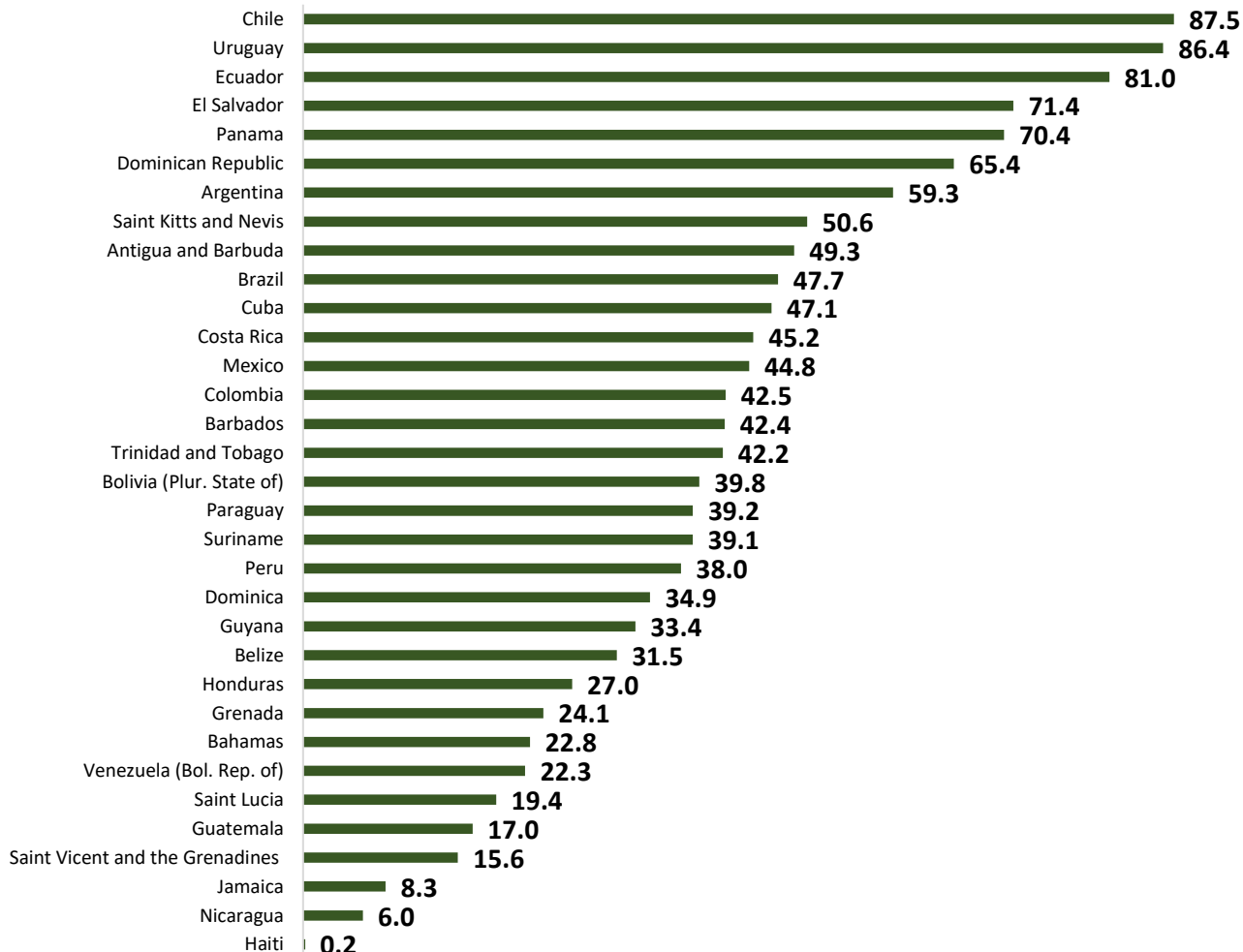
- Vaccines production and development
- Pharmaceutical companies and chambers
- Regulatory systems
- IPR flexibilities
- Sponsors of clinical trials

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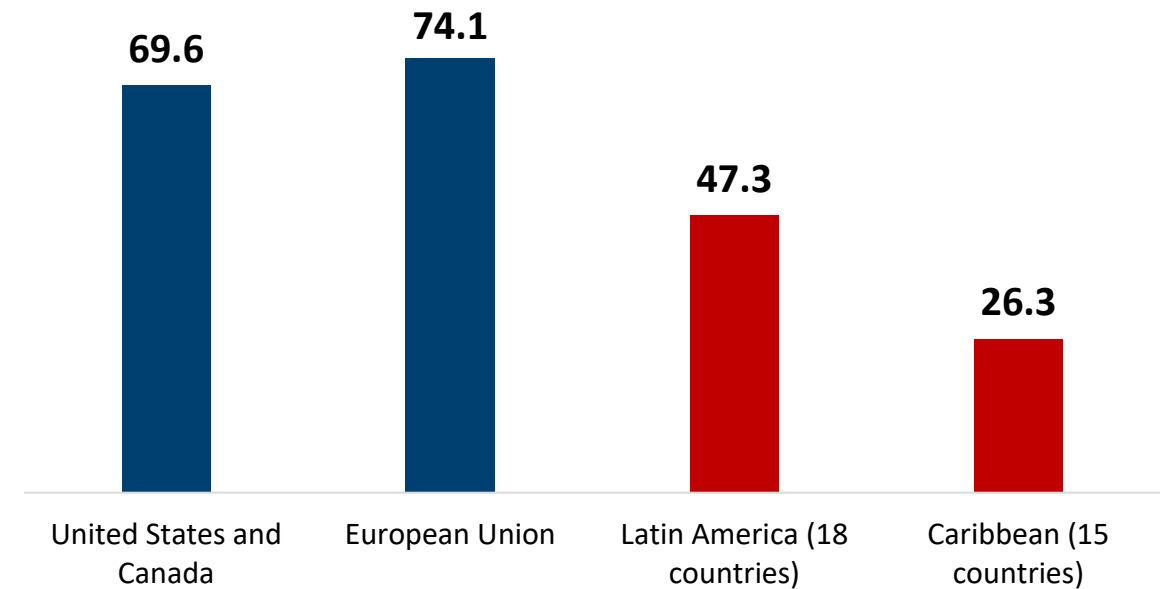
The motivation for the plan: unequal access to vaccines

LATIN AMERICA AND THE CARIBBEAN (33 COUNTRIES): PERCENTAGE OF THE POPULATION OVER 18 YEARS OLD FULLY VACCINATED



The region will not be able to vaccinate 80% of its population in 2021

PERCENTAGE OF THE POPULATION OVER AGE 18 FULLY VACCINATED



Acquisitions in some countries exceed their vaccination needs. European Union, United States, United Kingdom, Canada and Japan account for 39% of purchase commitments, with only 13% of the world population.

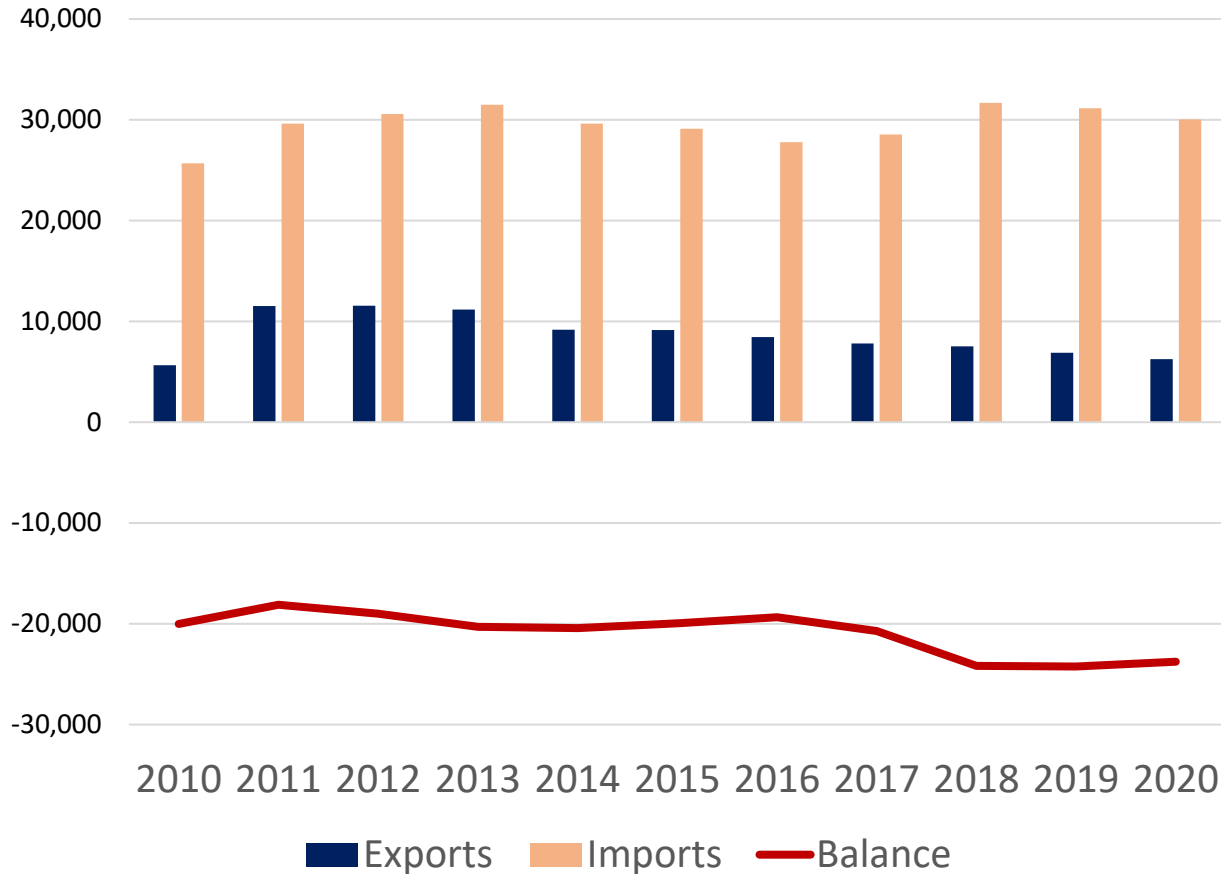
Source: ECLAC, ECLAC COVID-19 Observatory, based on *Our World in Data* [online] www.ourworldindata.org.

Note: Record for countries that report the breakdown of administered doses (first and second), as of 15 September 2021 or latest available date. Purchase commitment data as of 31 August 2021.

Persistent deficit in the pharmaceutical sector

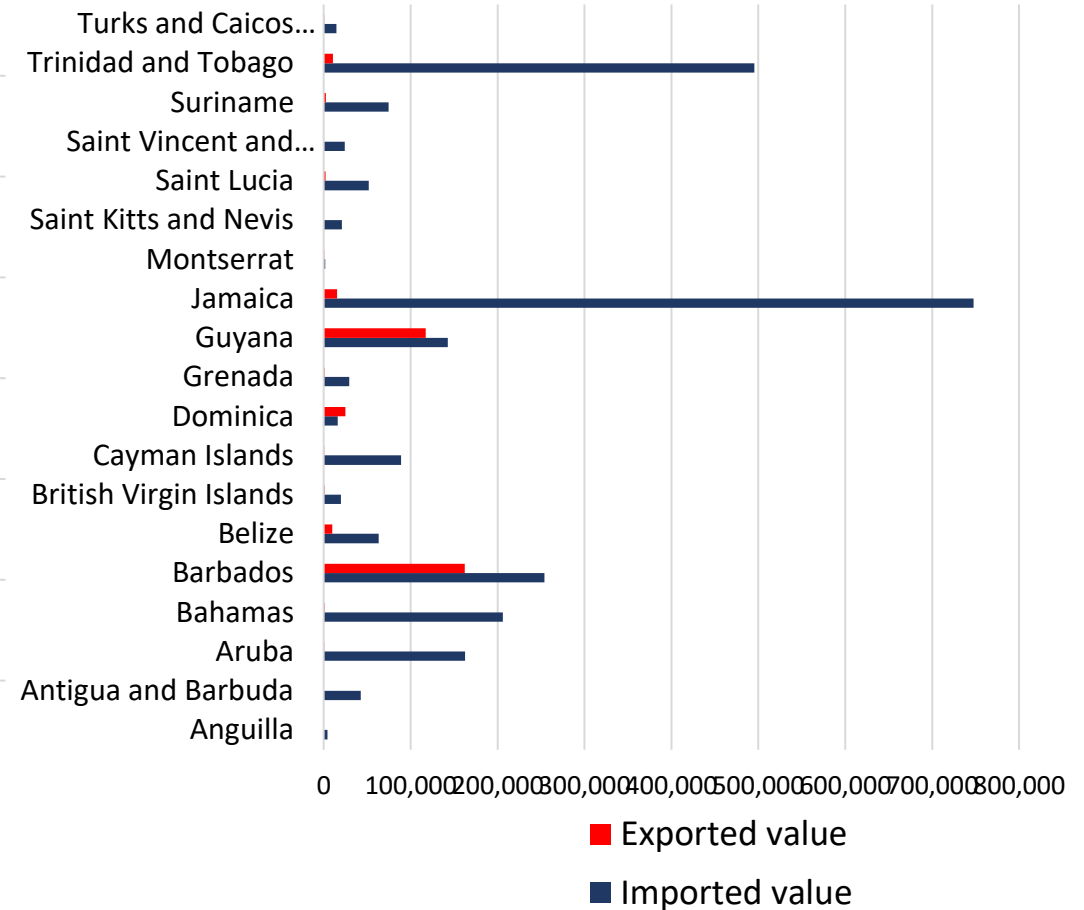
LATIN AMERICA AND THE CARIBBEAN: INTERNATIONAL TRADE IN PHARMACEUTICAL PRODUCTS (MEDICINES AND ACTIVE INGREDIENTS), 2010–2020

(Millions of dollars)



THE CARIBBEAN: VALUE OF EXPORTS AND IMPORTS IN THE PHARMACEUTICAL SECTOR, 2016–2020

(Thousands of dollars)

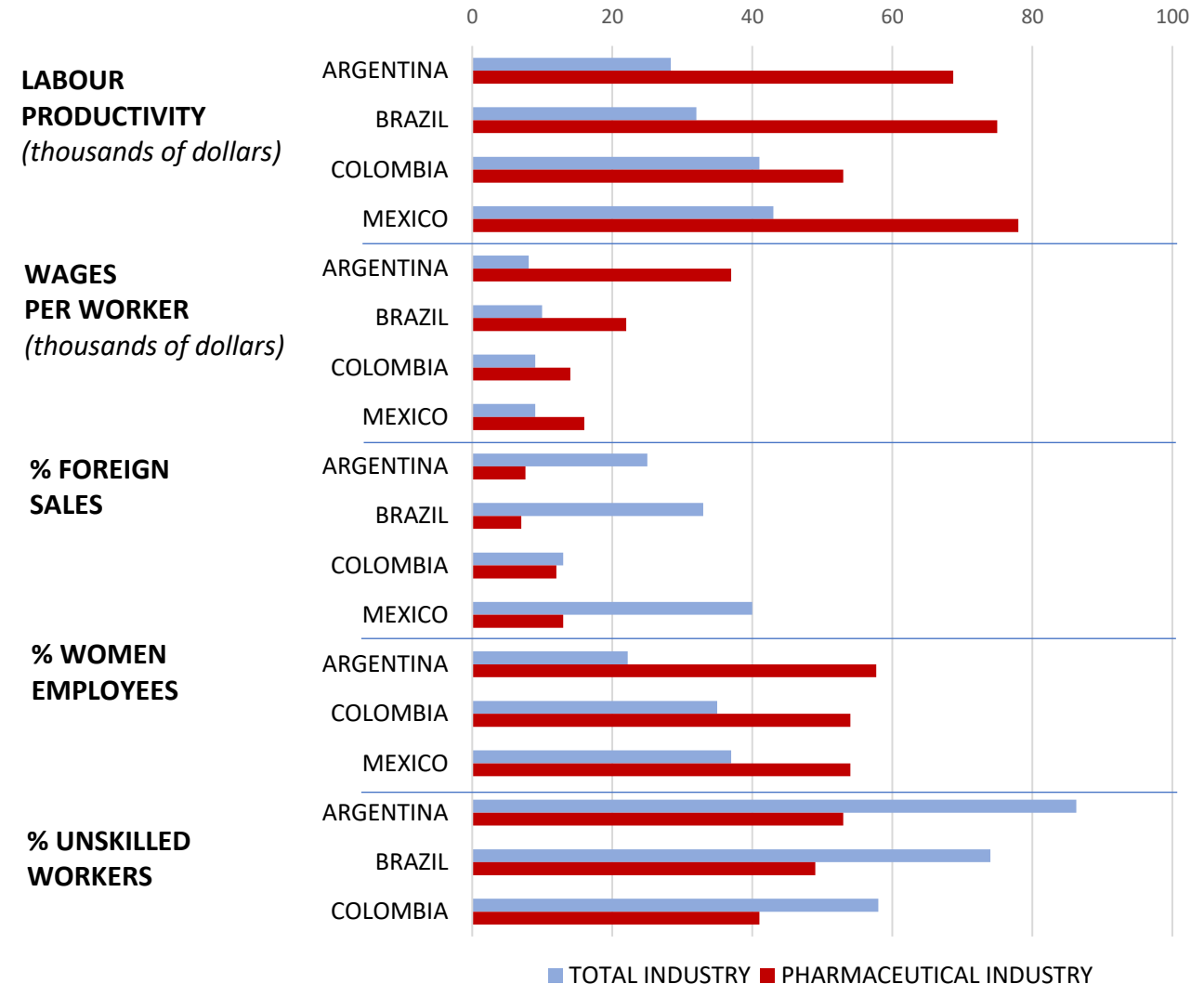


Source: ECLAC on the basis of UN COMTRADE data.

Pharmaceutical industry: a strategic sector for development

- The major pharmaceutical companies are leaders in technological change.
- Represents only 8% in the vs. 51% globally.
- Transnational corporations are concentrated in oligopolistic markets with patents and R&D
- Locally-owned firms have more weight in the generics and biosimilars market
- Lack of transparency in some markets
- **Pharma contributes 1.2% of GDP and close to 0.8% of employment**
- **Higher productivity, more innovative**
- **Higher proportion of skilled workers**
- **Higher wages**
- **Balanced gender composition**

INDICATORS OF THE PHARMACEUTICAL INDUSTRY AND TOTAL INDUSTRY



Current vaccine co-production agreements

AstraZeneca-Oxford (*Vaxzevria*)

MEXICO-ARGENTINA / Carlos Slim Foundation / Liomont / mAbxience

BRAZIL / Oswaldo Cruz Foundation (FioCruz)

Sinovac (*Coronavac*)

BRAZIL / Butantan Institute

COLOMBIA (memorandum of understanding)

CHILE (investment announcement)

Pfizer/BioNTech (*Comirnaty*)

BRAZIL / Eurofarma (announcement)

Gamaleya (*Sputnik V*)

ARGENTINA / Richmond Laboratory

BRAZIL / União Química

CanSino (*Convidecia*)

MEXICO / Drugmex

CIGB (*Abdala*)

CUBA / Argentina / Venezuela (Bol. Rep. of)
(ongoing negotiations)

ReiThera (*Covitar*)

CHILE / University of Chile (announcement)

Urgent need for greater regional coordination for self-sufficiency in health matters

- The pandemic showed the limitations in the supply of vaccines and medicines and the weaknesses of health systems, particularly in primary care.
- Chronic underfunding of technological R&D and the weakness of industrial policy have prevented development of the existing capacities to produce to produce vaccines in a timely manner and the generation of a large-scale market.
- Strategic coordination is urgently needed between: health, economy, industry and finance.
- It is essential to development a pharmaceutical industry, starting by strengthening coordination between regulatory systems.
- A vision of regional and subregional integration is needed that will ensure greater autonomy in production and universal access to vaccines.
- **For these reasons and at the request of CELAC, ECLAC has prepared the lines of action and proposals for a Plan for self-sufficiency in health matters, presented below.**

Plan for self-sufficiency in health matters

OBJECTIVES

Short term

Speed up vaccination processes

Improve access to vaccines

Facilitate the vaccination process

Medium and long terms

Strengthen/generate technological and productive capacities

Ensure a large, stable market

Strengthen regional research and development

Facilitate local production and regional chains

INVENTORY OF CAPABILITIES

- **Ongoing vaccine development and research in the region**
- **Capacities for vaccines production**
- **Pharmaceutical companies**
- **Chambers and associations**
- **Regulatory systems**
- **IPR flexibilities**
- **Primary sponsors of clinical trials**
- **Primary health-care systems**

LINES OF ACTION

- 1. Regulatory convergence and recognition mechanisms**
- 2. Regional clinical trials platform**
- 3. Regional vaccine procurement mechanisms**
- 4. Consortiums for the development and production of vaccines**
- 5. Regulatory flexibilities for access to intellectual property**
- 6. Public procurement mechanisms for regional market development**

Line 1. Strengthen regulatory convergence and recognition mechanisms and broaden stakeholder dialogue

Regional mechanisms and subregional integration agencies

- Red PARF - Pan American Network for the Harmonization of Pharmaceutical Regulations (PAHO)
- SICA and the Dominican Republic, Council of Ministers of Health (COMISCA)
- CARICOM, Caribbean Public Health Agency (CARPHA)
- MERCOSUR, Sub-Working Group No.11 “Health”
- Pacific Alliance, Technical Subgroup on Regulatory Cooperation in Pharmaceutical Matters

National regulatory agencies of reference

- Argentina (ANMAT)
- Brazil (ANVISA)
- Chile (ISP)
- Colombia (INVIMA)
- Cuba (CECMED)
- Mexico (COFEPRIS)

Regulatory entities are key actors in health systems, and could be in competition policy and industrial policy as well

Main actions:

- Virtual repository of clinical data: all companies must enter information on their registration applications and dossiers; regulatory entities can retrieve the information for registration processes.
- Observatory of good regulatory practices.
- Regulatory convergence card to determine equivalence in terms of general requirements for sanitary authorizations of medicines and vaccines.
- Tools to strengthen regulatory systems:
 - Creation or strengthening of laboratories to enable much more expeditious decision-making and risk prevention.
 - Pharmacovigilance and post-marketing programmes with a national and regional vision.
- Programme of visits and exchanges between the different regulatory authorities to gain a better understanding of regional problems.

Next steps:

- Convene technical-political dialogues among the national regulatory authorities.
- Inform regulatory agencies and subregional organizations about this Plan, analyse proposals and coordinate the technical work.

Line 2. Implement a regional clinical trials platform

Create a COVID-19 vaccine clinical trials network

- Starting point for developing platforms that span all stages of clinical research and other diseases
- The region can participate as a co-developer using these networks
- Bargaining tool for preferential access to markets and technology

Broad experience in clinical trials

- **614 clinical trials** and **230 observational studies** related to **COVID-19** (up to 27 August): 7.6% of the global total
- **125 primary sponsors of clinical trials** for vaccines and treatments against COVID-19 in **11 countries** (Argentina, Bolivia (Plur. State of), Brazil, Chile, Colombia, Costa Rica, Cuba, Jamaica, Mexico, Paraguay, Peru)
- However, the region has acted in a fragmented manner, reducing its bargaining power: it has not secured preferential access to vaccines

Line 3. Accelerate regional vaccine and medicine procurement mechanisms in the short term

Coordination and permanent monitoring of vaccine procurement

- Regional dialogue with responsible ministries (health, finance, foreign affairs, etc.)
- Ongoing coordination among the countries to procure COVID-19 vaccines
- Ensure affordable prices for countries that still face issues of availability of COVID-19 vaccines
- Coordinate CELAC efforts with partners such as GAVI, The Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), PAHO/WHO

Strengthen pooled procurement initiatives

- COVID-19 Vaccine Global Access (COVAX) Facility
- PAHO Revolving Fund, as a complement to COVAX
- Subregional procurement platforms:
 - Council of Ministers of Health of Central America (COMISCA) of the Central American Integration System (SICA)
 - CARICOM
 - MERCOSUR Sub-Working Group No.11 “Health”

Line 4. Create consortiums to speed up the development and production of vaccines and medicines

A consortium, is an effective tool for

- **Developing manufacturing capacities**
- **Improving regional and international cooperation** between developers and manufacturers of vaccines, governments, multilateral organizations and financial institutions
- **Facilitating resource mobilization** and the deployment of economic and human resources
- **Diversifying or consolidating technology platforms** to produce vaccines
- Supporting the development, production and distribution of vaccines
- **Increasing regional participation in R&D** in countries within the region and beyond

Experiences in production consortiums:

AstraZeneca-Oxford (*Vaxzevria*)

MEXICO-ARGENTINA / Carlos Slim Foundation

- Argentina laboratory mAbxience produces the active ingredient
- Mexican laboratory Liomont stabilizes, fills and finishes
- Estimated capacity: between 150 and 250 million doses/year
- 22 million doses produced (6 August)

Experiences in vaccine development consortiums:

CHILE. Universities that form part of national COVID-19 consortiums or interdisciplinary research teams for the evaluation of vaccines and therapies to combat SARS-CoV-2: Catholic University of Chile, University of Chile, Universidad de los Andes, Universidad Austral, Universidad San Sebastián, Universidad de Antofagasta, Universidad de Valparaíso and Universidad del Desarrollo

MEXICO. AviMex is developing a vaccine in collaboration with the Icahn School of Medicine at Mount Sinai and the University of Texas.

Line 5. Take advantage of flexibilities in TRIPS and negotiate together in WTO to gain access to intellectual property

Support the updating and implementation of relevant legislation and mechanisms

- Strengthen capacities and promote mutual understanding of the different intellectual property regimes existing in the region
- Create forums to coordinate efforts to negotiate the temporary waiver of intellectual property rights under the TRIPS Agreement in WTO

The TRIPS Agreement offers flexibility in the management of patents on critical goods

1. Compulsory licensing and non-commercial public use (Art. 31)
 2. Parallel imports (Art. 6)
 3. Regulatory and research exemptions (Art. 30)
- **At least 20 countries in the region** have **relevant legislation** with a broad range of provisions
 - Temporary exemption from some of the obligations of the TRIPS Agreement could promote greater production and equal access to vaccines and treatments during the pandemic

Line 6. Coordinate national public procurement systems to create a large-scale and stable regional market

Opportunities for a regional market

- **87%** of medicine imports are sourced outside the region.
- The **scale** offered by an **integrated regional market is vital to the success of a regional production strategy.**

Use public purchasing power as an instrument to develop regional production chains:

- Facilitate intraregional trade
- Foster the development of regional suppliers
- Improve bloc negotiation to gain access to inputs and technology transfer

Subregional mechanisms:

- **COMISCA-SICA** promoted the “Joint Negotiation of Prices and Purchase of Medicines” initiative
- **MERCOSUR** set up a Negotiation Group on the Prices of High-Cost Medicines
- **Organization of Eastern Caribbean States** Pharmaceutical Procurement Service (PPS), established in 1986 to pool funds to procure medicines

Procurement mechanisms in international agencies:

- **PAHO:** Revolving Fund and Strategic Fund

In brief

- I. At the request of CELAC, today ECLAC has delivered an inventory of capabilities and lines of action and proposals for a plan for self-sufficiency in health matters.
- II. **Immediate actions in three areas**
 - Coordination between *national regulatory authorities*
 - Regional *procurement* mechanisms to achieve *universal access to vaccines*
 - Implementation of a *regional clinical trials platform*
- III. **Medium-term actions**
 - Create consortiums to develop and produce vaccines
 - Make use of flexibilities in intellectual property rights
 - Public procurement to develop the regional market
 - Strengthen the health sector with a focus on primary care
- IV. Renew the CELAC mandate to implement the Plan. Each country to appoint a permanent Commissioner to validate proposals, and define a strategy and funding modality



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