

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



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Latinoamericanos y Caribeños

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Contents

Foreword	7
Chapter I	
The health complex in Latin America and the Caribbean: capacities and constraints	9
A. Analytical framework: linkage of production and demand	9
B. Vaccination: the focus of the regional situation	11
1. Inequality of access to vaccines	11
2. Local vaccine development and production	13
C. Structure and performance of the pharmaceutical industry: stylized facts	14
1. The pharmaceutical industry is highly innovative	14
2. The structure of the pharmaceutical industry is that of an oligopoly and research and technological development activities are concentrated in large transnational companies	15
3. Ongoing trends in the pharmaceutical industry envisage a patent “cliff”, the rise of digital health and the growth of biotech drugs	17
4. On average, the pharmaceutical industry is more productive, more innovative, has a higher proportion of skilled workers and a more balanced gender composition, pays higher wages, and is less export-oriented than the manufacturing industry	17
5. The pharmaceutical industry directly contributes 3.1% of manufacturing gross domestic product (GDP) and 0.4% of total GDP in Latin America	18
6. The pharmaceutical industry accounts for 1.5% of jobs in the manufacturing sector and 0.2% of total employment	19
7. The pharmaceutical industry contributes 1.2% of the region’s GDP (direct, indirect and induced effects)	20
8. The differences in the total contribution of the pharmaceutical industry to GDP between one country and another is due to imports and the distribution of production between intermediate consumption and final demand	21
9. The pharmaceutical industry’s share of employment is around 0.8% (direct, indirect and induced effects)	21
10. The stock market value of health economy companies in 2021 shows a rise in private health care and a relative decline for health technology and biotech firms	22
D. International trade in pharmaceuticals	22
1. Increasing reliance on imports	22
2. Significance of intra-regional trade	24
3. Local production of medicines in the framework of free trade agreements	27
E. Firm size, ownership and specialization	30
F. Fragmentation, segmentation and insufficiency of resources in the health sector	32
G. Policy formulation and implementation: the big picture	37
1. The importance of the time dimension	37
2. The key role of science and technology policies and boards	37
3. The advantages of a strategic approach to intellectual property	38
4. The important role of the regulatory agencies	38
5. The need for competition policies	38

6. The overlap of sectoral regimes	38
7. The lack of coordination among national strategies	39
8. The interdependence with health plans	39
9. The incentives	39
10. Resources and institutional development	40
11. Planning and prioritization in the health sector vary	40
12. Interaction with other plans	40
Bibliography	41
Chapter II	
Components of the plan for self-sufficiency in health matters	43
A. Considerations, scope, objectives and structure	43
1. Strategic considerations	43
2. Scope of the plan	44
3. Objectives and lines of action	44
B. Lines of action	46
Bibliography	67
Annexes	69
Tables	
I.1 Patents granted to the pharmaceutical industry in the United States, 2011–2015	17
I.2 Latin America, United States and European Union: stylized facts on the pharmaceutical sector, 2019	18
I.3 Latin America, United States and European Union: direct economic contribution of the pharmaceutical industry to GDP, 2014	18
I.4 Latin America, United States and European Union: direct share in employment of the pharmaceutical industry	19
I.5 Latin America, United States and European Union: contribution of the pharmaceutical industry to GDP, 2014	20
I.6 Imports, final demand, intermediate consumption and value added of the pharmaceutical industry, 2014	21
I.7 Employment multiplier for the pharmaceutical industry	21
I.8 Latin America and the Caribbean: 10 leading intraregional exporters of pharmaceutical products, 2019	26
I.9 Latin America and the Caribbean: 10 leading importers of pharmaceutical products, 2019	27
I.10 Provisions included in modern trade agreements with possible effects on national pharmaceutical policies	28
II.1 Flexibilities in the Agreement on trade-related aspects of intellectual property rights (TRIPS Agreement)	58
Figures	
I.1 Grouping and selected countries: population and COVID-19 vaccines committed under bilateral contracts	11
I.2 Latin America and the Caribbean: population fully vaccinated against COVID-19, as of 31 August 2021 or latest available date	12
I.3 Spending on research and development relative to global sales, by sector, 2019	15
I.4 Region or grouping: share in revenues of global pharmaceutical market, 2019	15
I.5 Value added by region, 2014	16
I.6 Selected countries and groupings: number of research and development firms in the pharmaceutical industry as a share of the world total, 2020	16
I.7 Latin America and the Caribbean: sectoral structure of the health economy, 2019 and 2021	22

I.8	Global exports of pharmaceutical products, 2007–2020	23
I.9	Ten leading global medicine exporters, 2009 and 2020	23
I.10	Latin America and the Caribbean: trade in pharmaceutical products, 2010–2020	24
I.11	Latin America and the Caribbean: exports of pharmaceutical products, total and intraregional, 2015–2020.....	25
I.12	Latin America and the Caribbean: intraregional share in total pharmaceuticals trade, 2015–2020	25
I.13	Subregional groupings: distribution of intraregional trade in pharmaceuticals, 2019.....	26
I.14	Latin America (4 countries): share of the pharmaceutical industry in domestic market sales, by firm ownership, latest available year.....	31
I.15	Latin America and the Caribbean: health expenditure relative to GDP and its composition, 2018.....	34
I.16	Latin America and the Caribbean: out-of-pocket spending on health relative to total health expenditure and incidence of poverty caused by effect of household out-of-pocket health expenditure.....	36

Diagrams

I.1	Structure of the health complex: services and production	10
II.1	Plan for self-sufficiency in health matters	45

Map

I.1	Latin America and the Caribbean: vaccination scenarios and year in which 70% of the population could be fully vaccinated.....	13
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Foreword

The pandemic caused by the coronavirus disease (COVID-19) has highlighted the unprecedented vulnerabilities and challenges facing Latin American and Caribbean countries in the health, economic, social and productive spheres.

This region has been one of the hardest hit by the COVID-19 crisis. Despite the fact that it is home to just 8.4% of the world's population, it accounted for 20.1% of COVID-19 infections and 32% of deaths by end-August 2021. This has placed the region in a critical situation, prompting it to re-evaluate strategies and public policies and to shift priorities related to productive, technological and health capacities.

In view of the extent of the challenges facing the countries of the region, Mexico, in its capacity as Pro Tempore Chair of the Community of Latin American and Caribbean States (CELAC), requested the Economic Commission for Latin America and the Caribbean (ECLAC) to prepare a plan for self-sufficiency in health matters for the region, not only assessing and analysing the situation but also advancing lines of action for strengthening capacities to produce and distribute vaccines and medicines in CELAC countries.

To this end, ECLAC conducted an in-depth review of vaccination progress (procurement, inoculation, development and production, scenario estimation), established a working group of over 20 experts from different countries in the region, assessed the region's capacities, highlighting institutional capabilities for policy design and implementation, and developed recommendations for strategies and lines of action.

In a changing and uncertain global and regional scenario, the lines of action and proposals presented herein call for reflection and action on short-term constraints (access to and administration of vaccines) as well as long-term needs (investment driven by industrial policies). Moreover, the plan recognizes the key role of science and technology policies and boards, as well as the substantial financing that is urgently needed to move towards self-sufficiency in health matters. It also highlights the important role of regulatory agencies and competition policies, and the advantages of a strategic approach to intellectual property. This all calls for an analysis of the institutional capacities of governments, with particular attention to organizational weaknesses in institutions, with a view to improving coordination in national strategies and drawing useful and practical lessons for CELAC countries.

The lines of action and proposals included in the plan for self-sufficiency in health matters Latin America and the Caribbean had to take into account the specificities of the pharmaceutical industry and supply- and demand-side issues. The supply-side analysis covered all links in the industry chain, from research and development to the production and distribution of vaccines and medicines. On the demand side, the plan affords special consideration to the public primary health-care system and its role in the access to vaccines and medicines and their efficient distribution, given their potential for driving new activities.

The ultimate goal of regional self-sufficiency in health matters will require substantial investment in resources in the medium and long terms, especially to build capacity in weak sectors or creating capacity where there is none, as in the case of messenger RNA vaccines. However, the region also needs to finance responses to immediate or very short-term emergencies, such as the need to source COVID-19 vaccines on the international market to cover its population.

The plan for self-sufficiency in health matters and the initiatives it contains are regional in spirit, with proposed lines of action that can be implemented at regional or subregional level. While a plan of this nature requires capacity-building in each country—and recognizes the importance of national policies—its focus is not on domestic proposals but on regional cooperation and integration.

Pursuant to the mandate given by CELAC and based on the work of the group of experts established for this purpose, ECLAC has defined and prioritized seven lines of action:

- (i) Strengthen mechanisms for pooled international procurement of vaccines and essential medicines
- (ii) Use public procurement mechanisms for medicines to develop regional markets
- (iii) Create consortiums for the development and production of vaccines
- (iv) Implement a regional clinical trials platform
- (v) Take advantage of regulatory flexibilities to gain access to intellectual property
- (vi) Strengthen regulatory convergence and recognition mechanisms
- (vii) Strengthen primary health systems for equitable distribution of vaccines and universal access to them

These lines of action are supported by an exercise to identify key stakeholders and assess regional capacities in research, development and production in the pharmaceutical industry. The progress associated with this supporting exercise is presented under the heading “Inventory of capabilities”.

ECLAC wishes to thank the countries of CELAC for the opportunity to propose a plan that is a call to action and sets a clear regional agenda. We firmly believe that to fully benefit from the hard lessons learned from the COVID-19 pandemic, greater regional integration, cooperation and solidarity are of the essence.

Alicia Bárcena

Executive Secretary
Economic Commission for
Latin America and the Caribbean (ECLAC)

The health complex in Latin America and the Caribbean: capacities and constraints

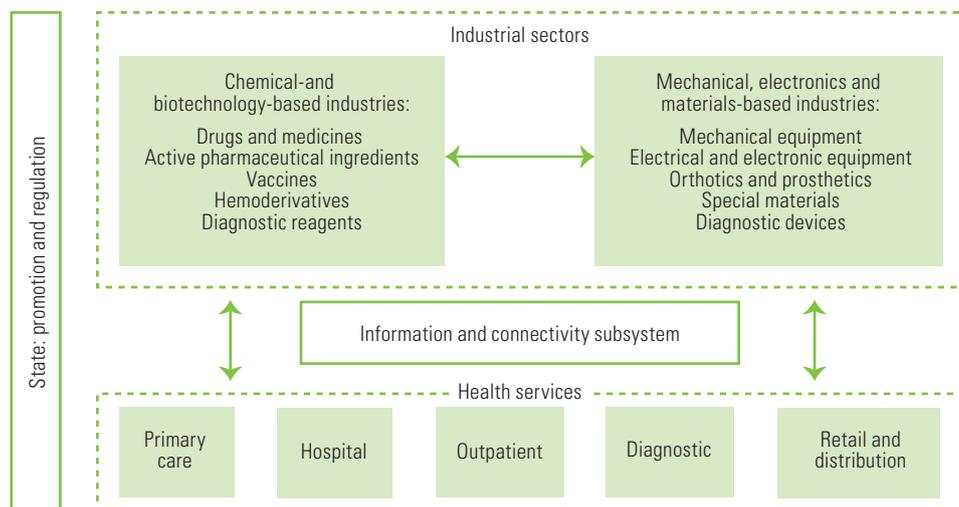
A. Analytical framework: linkage of production and demand

The coronavirus disease (COVID-19) pandemic presented every country in Latin America and the Caribbean with the unprecedented challenges of finding, formulating and implementing systematic responses to a set of closely interrelated health, economic and social problems. While the pandemic has laid bare the health vulnerabilities of the region, it has also been an opportunity to re-evaluate its productive and technological capacities, and to reformulate strategies and policies for strengthening local manufacturing and innovation systems for components of goods and services linked to the health complex. It has also made more pressing the need for national policy initiatives to be complemented by regional actions, coordinated by means of a plan.

As summarized in diagram 1, the health economic-industrial complex is a distinct institutional, political, economic, industrial and social space in which there are notable complementarities (for example, between productive capacities and research, development and innovation) and contradictions (such as between the social objectives of universality at the lowest possible cost and the business interests of profitability). Production encompasses a broad spectrum of industrial activities associated with technological paradigms with varying degrees of dissemination that fall into two groups: on the one hand, there are sectors that are built on consolidated chemical-based technological paradigms and new biotechnology-based paradigms and, on the other, sectors in which innovations are founded on mechanical, electronic and materials-based technological paradigms. The output from this set of segments converges in a closely interlinked productive space for the provision of public and private health services that includes basic care, diagnostic and treatment, and outpatient and inpatient services, which, in turn, shape its competitive and technological dynamics. The technological progress associated with the spread of digital technologies and the consequent changes in the modalities of production and consumption of health services and products also lead to the formation of an information and connectivity subsystem that links relations between the industrial sectors and the provision of health services and is characterized by a pronounced asymmetry in terms of access to information. This has resulted in the expansion of digital platforms that open up opportunities for personalized medicine, while at the same time increasing vertical competition with industry sectors for the appropriation of revenues and health budgets.

Diagram I.1

Structure of the health complex: services and production



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of C. A. Grabois Gadelha, "O Complexo Econômico-Industrial da Saúde 4.0: por uma visão integrada do desenvolvimento econômico, social e ambiental", *Cadernos do Desenvolvimento*, vol. 16, No. 28, Rio de Janeiro, International Celso Furtado Center for Development Policies, 2021.

The health industry encompasses productive activities that harness biology and technology for improving health, including biopharmaceutical products, medical technology, genomics, diagnostics and digital health. This definition places an emphasis on products that are applied or used in preventive or curative medicine, are produced and distributed on an industrial scale and have systematized processes of research, development and innovation of processes and products. The health industry is divided into three categories: the pharmaceutical industry, production of medical equipment and devices, and activities carried out by entities dedicated to health-related research, be they companies or non-profit organizations.

The systemic approach to the health complex in this document contemplates the perspective of health as an inherent right of the population and, at the same time, as a strategic space for the development of the productive and technological base, the creation of value and the generation of investment, income, employment, knowledge and innovation. Within that framework, the State performs a fundamental role, both in guaranteeing the formation of productive and technological capacities, and in ensuring universal access to health. Within the health complex, this document focuses on the pharmaceutical industry to respond to the request from the Community of Latin American and Caribbean States (CELAC) to move forward with the preparation of a plan to strengthen vaccine and medicine production and distribution capacities in the region.

To address that request, this document is divided into two chapters. The first, contains a diagnostic assessment of the region's capacities, providing a basis for recommendations on strategies, policies and lines of action set out in the second. This analysis emphasizes that the formulation and implementation of the plan presented here is based on the interaction between the supply of goods and services generated by the industry and the demand arising from the needs of the health sector in order to move towards the provision of universal healthcare coverage. After examining the issue of vaccination in the regional context, the study analyses the structure of production and the behaviour of the main economic agents that impact the sector's performance, before exploring in detail the characteristics of the health sector. It also includes a section specifically devoted to the dynamics of international trade, given its importance to a plan that aspires to regional self-sufficiency in the pharmaceutical industry.

B. Vaccination: the focus of the regional situation

1. Inequality of access to vaccines

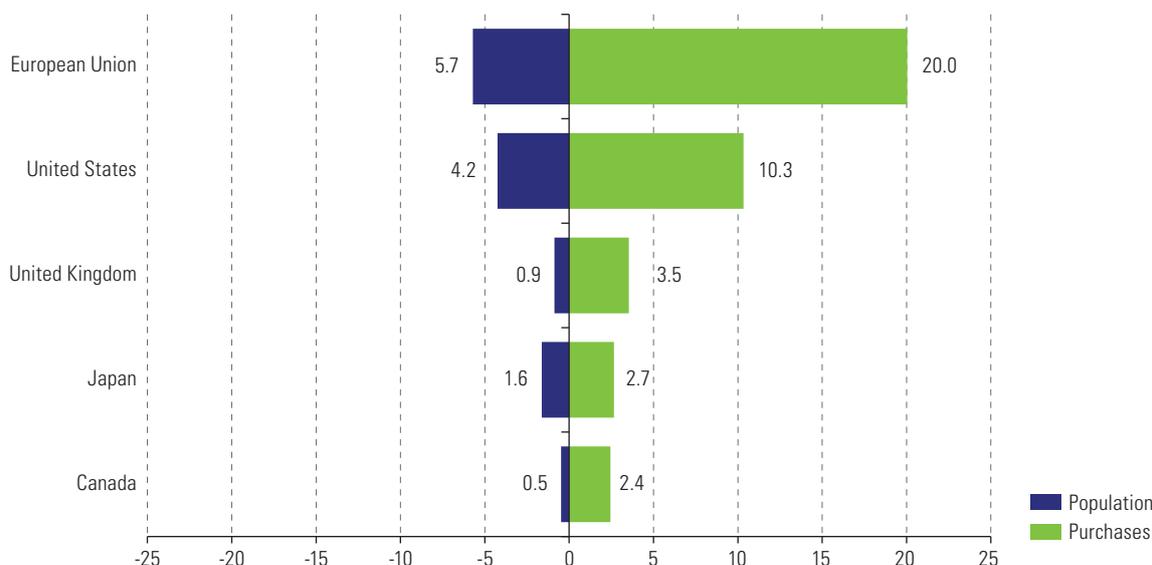
Although several effective COVID-19 vaccines are already available and it is estimated that current aggregate production capacity could meet global vaccination requirements, vaccine access and distribution among countries has not matched their needs. The problem is no longer one of having an effective vaccine, but of ensuring, accelerating and scaling up their production and distribution globally.

In the context of the pandemic, aside from bilateral donations, a country can obtain vaccines in three ways: direct agreements between its government and manufacturers, aggregate purchases between countries, and participation in the COVID-19 Vaccine Global Access (COVAX) Facility. A strategy common in many countries, especially those that are more developed, has been to establish advance purchase commitments for vaccines, even when they are in the research phase, thus securing privileged access when they become available.

As of 31 August 2021, the total number of doses committed under individual agreements, block deals and the COVAX Facility was 15.6 billion. Although this is enough doses to vaccinate the entire global population, the distribution is very uneven, with a high concentration in the more developed countries. A group of developed countries, home to just 12.9% of the world's population, accounted for 39% of those purchase commitments (see figure I.1).

Figure I.1

Grouping and selected countries: population and COVID-19 vaccines committed under bilateral contracts
(Percentage of global totals)



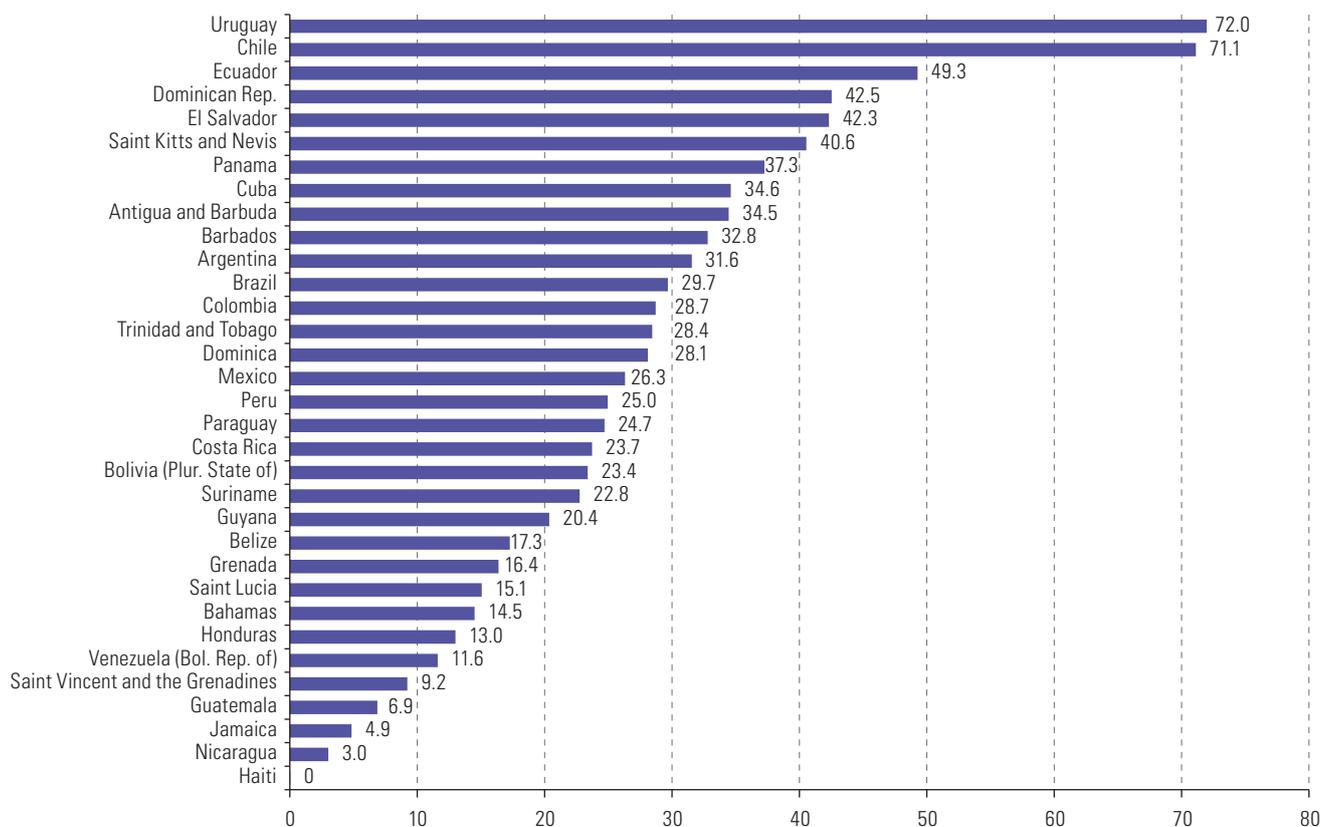
Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of Duke Global Health Innovation Center, "Launch and Scale Speedometer", 2020 [online] <https://launchandscalefaster.org/COVID-19> [date of reference: 31 August 2021] and United Nations, World Population Prospects [online] <https://population.un.org/wpp/>.

There is also a temporary supply constraint problem. The combination of these two factors has led the vaccination process in various countries to advance at different speeds. As of 31 August 2021, 54% of the population of the United States and Canada and 58% of the population of the European Union had been fully vaccinated. By contrast, that proportion was 24.8% in Latin America and the Caribbean. The situation

within the region is also uneven. Whereas in South America, 26.8% of the population had been fully vaccinated, in Central America the proportion was a mere 12.8%, and in the Caribbean, excluding Haiti, 14.6% (see figure I.2).

Figure I.2

Latin America and the Caribbean: population fully vaccinated against COVID-19, as of 31 August 2021 or latest available date



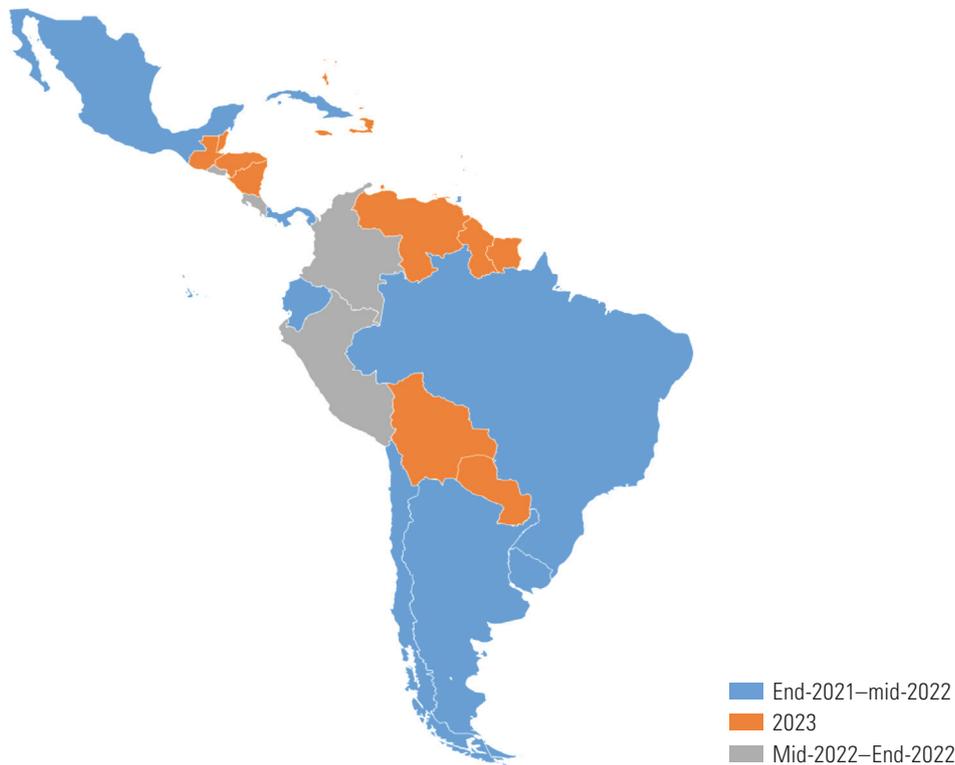
Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of Our World in Data [online] www.ourworldindata.org.

Note: Record for countries reporting the breakdown of administration of first and second doses.

Despite the great progress made in some countries, it is estimated that, if current conditions of access to vaccines continue, the region as a whole will not be able to vaccinate 70% of the population by the end of 2021. In other words, the region is facing a supply problem, with countries falling into three groups depending on the pace at which the vaccination process can proceed. A first group of 10 countries could fully vaccinate 70% of their population between the end of 2021 and mid-2022. A second group of 9 countries will reach this point at the end of 2022, while a third group of 14 countries will not do so until 2023 (see map 1). This projection represents a more optimistic scenario than was estimated in April 2021: the number of countries that could vaccinate 70% of their population between the end of 2021 and mid-2022 has doubled, and the number that will not reach this goal until 2023 has fallen from 22 to 14.

Map I.1

Latin America and the Caribbean: vaccination scenarios and year in which 70% of the population could be fully vaccinated



Source: Economic Commission for Latin America and the Caribbean (ECLAC).

Note: The boundaries and names shown on this map do not imply official endorsement or acceptance by the United Nations.

2. Local vaccine development and production

Although there were vaccine development projects at the preclinical stage in some countries at the end of August 2021, only Cuba, Brazil and Mexico had projects in clinical trials (see annex 3.1 for details).

The facilities with the most advanced research were the Finlay Institute of Vaccines (IFV) and the Centre for Genetic Engineering and Biotechnology (CIGB), both in Cuba. Three of the five vaccines under development, Abdala and Soberana 02 and Soberana Plus, were in phase III clinical trials and approved for emergency use. As of 1 September 2021, more than 14.1 million doses had been administered. Although the country's strength lies in its expertise in research and production of vaccines and biotech drugs, it is not without its difficulties, including limited access to external resources and to other countries to widen its clinical trials. Nevertheless, progress has been made: the Abdala vaccine has entered the approval process in Mexico, and on 31 August received a ruling in favour from the New Molecules Committee of the Federal Commission for Protection Against Health Risks (COFEPRIS), which is the first step in the process of approval for emergency use. IFV has also reached an agreement with the Pasteur Institute of Iran to conduct clinical trials of Soberana 02, under the name Pasteur, in that country.

In addition, a vaccine is being developed in Brazil (Butantan Institute) and Mexico (Avimex) in collaboration with the Icahn School of Medicine at Mount Sinai and the University of Texas. Mexico's Patria vaccine is in a phase I clinical trial and Brazil's ButanVac is in a combined phase I/II trial.

With regard to local production of vaccines, agreements with international laboratories have been established in several countries.

- AstraZeneca signed a technology transfer agreement with the Carlos Slim Foundation to enable the Argentine biotechnology firm mAbxience to produce the active pharmaceutical ingredient for the vaccine and the Mexican laboratory Liomont to complete the process of stabilization, production, and packaging for subsequent distribution in Latin America. As of 6 August 2021, 22 million doses had been produced based on an estimated production capacity of 150–250 million doses per year.
- In Argentina, Laboratorios Richmond produces the first and second component of the Sputnik V vaccine with an estimated capacity of 40 million doses in 2021 and 200 million in 2022, with imports of the active pharmaceutical ingredient in the first stage.
- In Brazil, the Oswaldo Cruz Foundation (Fiocruz) has a local production agreement with AstraZeneca, initially with the active pharmaceutical ingredient imported. As of 30 August 2021, 87.9 million doses had been produced. For its part, the Butantan Institute began production of the CoronaVac vaccine under a technology transfer agreement with Sinovac and had delivered 92 million doses as of 30 August 2021. In August, Pfizer-BioNtech reached an agreement with Eurofarma Laboratorios to carry out vaccine fill and finish processes starting in 2022, with an annual capacity of 100 million doses. In addition, pending approval for emergency use, União Química is expected to produce the Sputnik V vaccine in the country, with a capacity of 8 million doses per month.
- In Chile, an agreement was announced in August 2021 for the installation of a Sinovac production plant (fill and finish), which is expected to start operating in 2022.
- In Mexico, Drugmex packages CanSinoBIO's Convidecia vaccine and had produced 4.5 million doses as of 6 August 2021.
- In Colombia, a memorandum of understanding has been signed with Sinovac for production, technology transfer and vaccine development projects, starting with fill and finish processes in the second quarter of 2022.
- In August, in the framework of an initiative of the World Health Organization, the Pan American Health Organization (PAHO) issued a call for expressions of interest in developing manufacturing capabilities for mRNA vaccines in Latin America and the Caribbean. The initiative seeks to ensure that the region will have the installed capacity for all stages of vaccine production.¹

C. Structure and performance of the pharmaceutical industry: stylized facts

The main characteristics of the pharmaceutical industry in the region are summarized in the following points.

1. The pharmaceutical industry is highly innovative

Since its inception, the pharmaceutical industry has been an example of a “science-based” industry as shown in figure I.3. As such, innovation is largely driven by joint advances in basic and applied sciences, as well as complementary advances in research technologies by public institutions and firms (Mazzucato and Dosi, 2006).

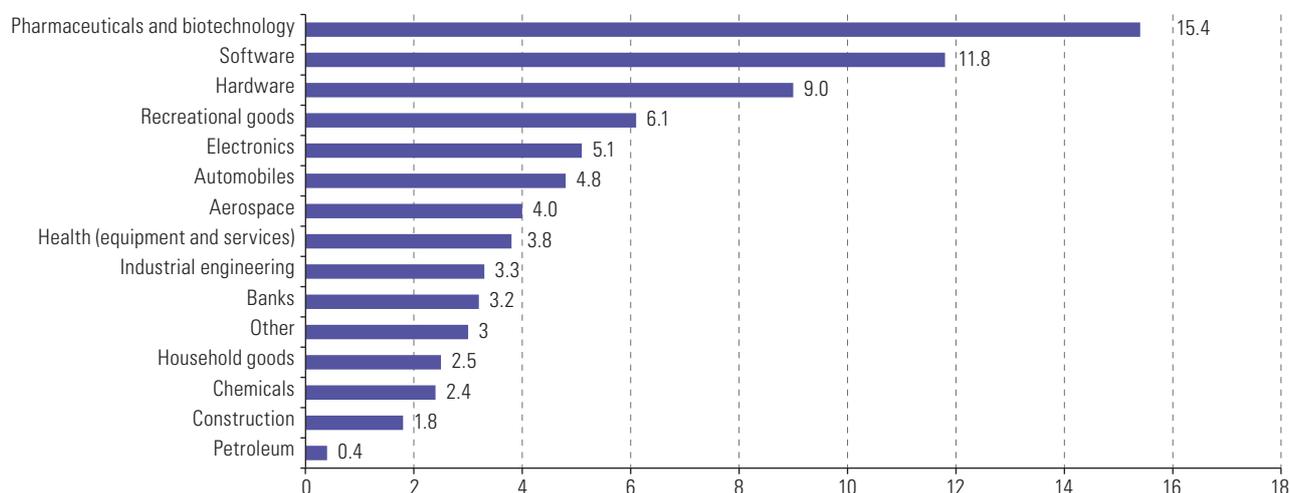
Great differences in terms of strategic orientation and capacity for business innovation has been a feature of the industry's evolution. Competition in the most advanced segment of the industry has always centred on the introduction of new products subject to incremental advances over time and on imitation and competition from generic medicines whose patents have expired (Malerba and Orsenigo, 2015).

¹ See [online] <https://www.paho.org/en/news/25-8-2021-call-expression-interest-contribute-value-chain-and-supply-reagents-sustainable>.

Figure I.3

Spending on research and development relative to global sales, by sector, 2019

(Percentages)



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of data from Statista, August 2021.

2. The structure of the pharmaceutical industry is that of an oligopoly and research and technological development activities are concentrated in large transnational companies

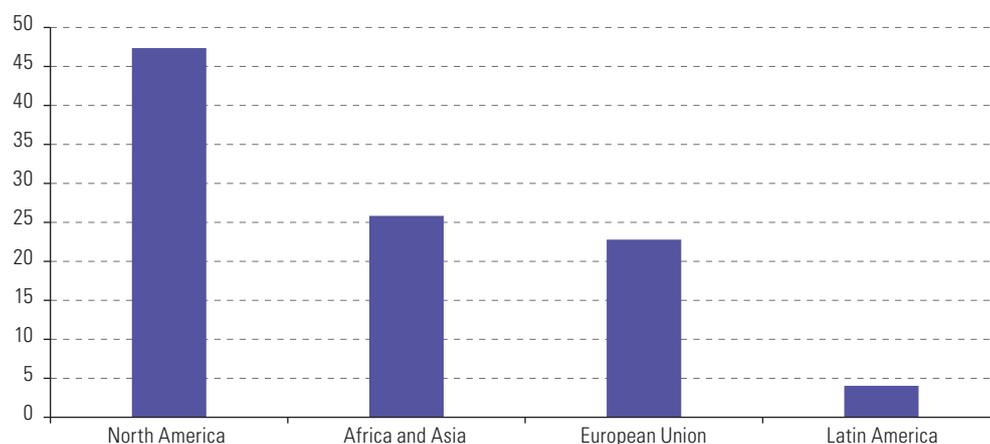
The pharmaceutical industry is organized as a differentiated oligopoly involving four types of agents: (i) large transnational pharmaceutical companies (big pharma), (ii) large specialized biotechnology companies, (iii) companies producing generic medicines with strong growth in China and India, and (iv) companies producing biosimilar medicines whose activities are based on imitative development following the expiry of patents on a wide range of drugs (ECLAC, 2020).

The largest pharmaceutical companies are headquartered in the United States, Switzerland, the United Kingdom, Germany and France. In turn, the largest market in terms of revenue is North America (United States and Canada). Almost half of global sales are concentrated in the United States, while Latin America's share is just 4% (see figure I.4).

Figure I.4

Region or grouping: share in revenues of global pharmaceutical market, 2019

(Percentages)



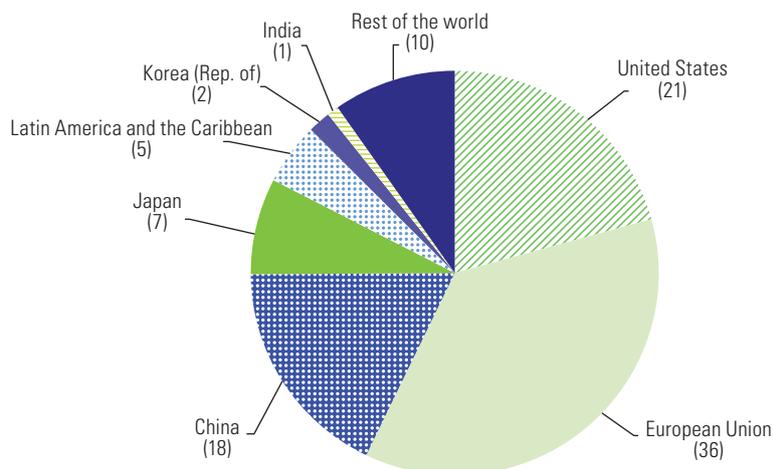
Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of data from Statista, August 2021.

Note: North America includes the United States and Canada.

In terms of value added generated in the pharmaceutical industry, Latin America's contribution is practically the same as that of sales revenue. While the European Union and North America account for more than half of the value added created in the industry, Latin America contributes only 5% (see figure I.5).

Figure I.5

Value added by region, 2014
(Percentages)

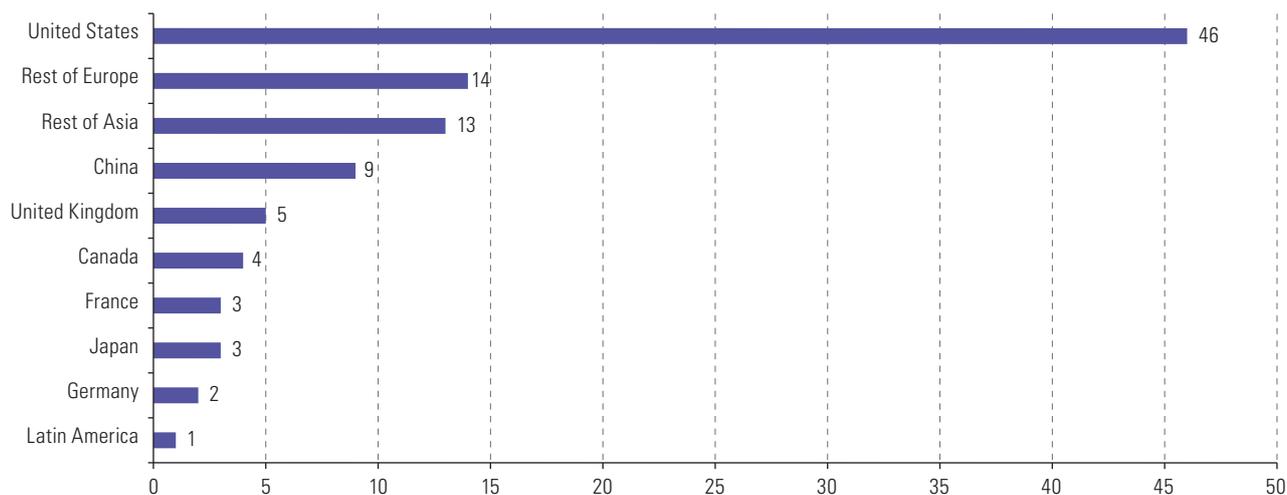


Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of the global input-output table for Latin America [online] <https://www.cepal.org/en/events/global-input-output-tables-tools-analysis-integration-latin-america-world>; and M. P. Timmer and others, "An illustrated user guide to the World Input-Output Database: the case of global automotive production", *Review of International Economics*, vol. 23, 2015.

The oligopolistic core of the pharmaceutical industry also accounts for much of the research and development (R&D) and new patents. This results from the pattern of path dependence, i.e. the historical process of building technological and organizational capabilities in the industry. Figure I.6 shows the percentage distribution of the number of R&D firms among countries or regional groupings, while table I.1 records the number of patents per million population in pharmaceutical research registered with the United States Patent and Trademark Office. Once again, Latin America plays a minor role in new drug discoveries.

Figure I.6.

Selected countries and groupings: number of research and development firms in the pharmaceutical industry as a share of the world total, 2020
(Percentages)



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of data from Statista, August 2021.

Table I.1

Patents granted to the pharmaceutical industry in the United States, 2011–2015

(Per million population)

	2011	2012	2013	2014	2015
United States	12.98	16.25	19.14	21.01	21.9
European Union	4.75	5.77	6.53	7.43	7.60
China	0.04	0.08	0.14	0.14	0.16
India	0.07	0.09	0.12	0.12	0.15
Latin America	0.07	0.10	0.13	0.14	0.13
Japan	4.72	5.38	5.99	6.30	6.46

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of data from the United States Patent and Trademark Office (USPTO).

Note: Patents granted by the pharmaceutical industry in classes 514 (Drug, Bio-affecting and Body Treating Compositions) and 424 (Drug, Bio-affecting and Body Treating Compositions).

3. Ongoing trends in the pharmaceutical industry envisage a patent “cliff”, the rise of digital health and the growth of biotech drugs

Among other trends, the so-called patent “cliff” is expected to continue into the future, with patents on 9 of the top 20 best-selling drugs in the United States set to expire between 2020 and 2030. In particular, in 2023, the patent on the drug Humira, which has been the number-one selling drug in the last decade, will expire.

In addition, explosive growth is projected in the biotech drug market, which is notable for its high technological complexity and high regulatory barriers. The share of biotech medicines in total global prescription and OTC sales increased from 18% in 2010 to 29% in 2019, and is estimated to reach 32% in 2024 (EvaluatePharma, 2019). In the biotech drug market, biosimilars account for an average of 10–15% of sales. Also projected is a rapid rise in revenues associated with e-health: from about US\$ 20 billion in 2018 to US\$ 84 billion in 2025 (estimates predict annual growth in these revenues of 11% between 2021 and 2025) (Statista, 2021).

4. On average, the pharmaceutical industry is more productive, more innovative, has a higher proportion of skilled workers and a more balanced gender composition, pays higher wages, and is less export-oriented than the manufacturing industry

The pharmaceutical industry is a sector with high labour productivity, whose capacity for innovation is reflected in a higher proportion of skilled workers and the payment of higher wages than in manufacturing overall (see table I.2). In turn, in terms of gender composition, employment is almost equally divided between the sexes. Regarding export orientation, a large part of the production is destined for the domestic market compared to the industry total. Finally, although the pharmaceutical industry is innovative and a heavyweight in terms of R&D spending in the region, innovation intensity—measured as R&D over sales—lags far behind the values seen in the European Union or the United States.

Table I.2

Latin America, United States and European Union: stylized facts on the pharmaceutical sector, 2019
(Thousands of dollars and percentages)

	Labour productivity per worker, per year (thousands of dollars)				Annual wages per worker (thousands of dollars)		
	Brazil	Colombia	Mexico		Brazil	Colombia	Mexico
Manufacturing industry	32	41	43	Manufacturing industry	10	9	9
Pharmaceutical sector	75	53	78	Pharmaceutical sector	22	14	16
	Foreign sales (percentages of total)				R&D spending relative to sales (percentages)		
	Brazil	Colombia	Mexico		Argentina	United States	European Union
Manufacturing industry	33	13	40				
Pharmaceutical sector	7	12	13	Pharmaceutical sector	2.6	22	18.5
	Women employees (percentages of total employment)				Unskilled workers (percentages of total employment)		
	Chile	Colombia	Mexico		Brazil	Colombia	
Manufacturing industry	27	35	37	Manufacturing industry	74	58.3	
Pharmaceutical sector	50	54	54	Pharmaceutical sector	49	41.2	

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of industry and innovation surveys.

5. The pharmaceutical industry directly contributes 3.1% of manufacturing gross domestic product (GDP) and 0.4% of total GDP in Latin America

The direct contribution of the pharmaceutical industry varies considerably among the region's countries (see table I.3). Thus, while in Brazil it accounts for 4.3% of total manufacturing GDP, in Nicaragua that proportion is only 0.6%.

Table I.3

Latin America, United States and European Union: direct economic contribution of the pharmaceutical industry to GDP, 2014
(Millions of dollars and percentages)

Country	Value added of the pharmaceutical industry	Percentage of manufacturing GDP	Percentage of total GDP
Argentina	2 756	3.3	0.5
Bolivia (Plurinational State of)	32	1.0	0.1
Brazil	10 800	4.3	0.4
Chile	943	3.2	0.4
Colombia	1 434	3.1	0.4
Ecuador	220	1.6	0.2
Paraguay	174	2.3	0.4
Peru	389	1.4	0.2
Uruguay	244	3.8	0.4
Venezuela (Bolivarian Republic of)	292	--	0.1
South America	17 286	3.7	0.4

Table I.3 (concluded)

Country	Value added of the pharmaceutical industry	Percentage of manufacturing GDP	Percentage of total GDP
Costa Rica	150	2.4	0.3
El Salvador	92	2.5	0.4
Honduras	31	0.8	0.1
Guatemala	127	1.6	0.2
Nicaragua	10	0.6	0.1
Panama	92	2.8	0.2
Dominican Republic	352	3.6	0.5
Central America	854	2.3	0.3
Mexico	3 457	1.7	0.3
Cuba	1 090	9.0	1.4
Latin America	22 687	3.1	0.4
United States	94 871	1.6	0.5
European Union	169 610	2.4	0.7

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of the global input-output table for Latin America [online] <https://www.cepal.org/en/events/global-input-output-tables-tools-analysis-integration-latin-america-world>; and M. P. Timmer and others, "An illustrated user guide to the World Input-Output Database: the case of global automotive production", *Review of International Economics*, vol. 23, 2015.

6. The pharmaceutical industry accounts for 1.5% of jobs in the manufacturing sector and 0.2% of total employment

The direct share of the pharmaceutical industry in employment in the Latin American manufacturing sector varies between 1% and 2.8% and is equivalent to just over 300,000 jobs in the region. That figure is similar to that recorded in the United States and half that of European Union (see table I.4).

Table I.4

Latin America, United States and European Union: direct share in employment of the pharmaceutical industry (Number of jobs and percentages)

Country	Employment	Percentage of employment in the manufacturing sector	Percentage of total employment
Argentina (2017)	41 784	1.8	0.2
Brazil (2019)	108 039	1.0	0.1
Chile (2019)	14 634	1.7	0.2
Colombia (2019)	42 486	1.5	0.2
Uruguay (2018)	4 502	2.8	0.3
Costa Rica (2017)	4 227	2.0	0.2
Mexico (2018)	88 699	1.0	0.2
United States (2019)	306 000	1.8	0.2
European Union (2016)	642 000	1.8	0.2

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of the global input-output table for Latin America [online] <https://www.cepal.org/en/events/global-input-output-tables-tools-analysis-integration-latin-america-world>.

7. The pharmaceutical industry contributes 1.2% of the region's GDP (direct, indirect and induced effects)

The indirect, direct and induced impact of the region's pharmaceutical industry is around 1.2% of GDP, which is lower than the corresponding figures for the United States (1.6%) and the European Union (1.4%).²

As shown in table 5, multiplier I (direct and indirect effects) has a value of 1.59 in Latin America, with no major differences between countries. However, multiplier II (direct, indirect and induced effects) has a much larger total impact in South America than in Central America and Mexico. Moreover, multiplier II for Argentina and Brazil is higher than that of the United States (the total weight of the pharmaceutical industry in the two countries' GDP is 2.3% and 2.5%, respectively).

Table I.5

Latin America, United States and European Union: contribution of the pharmaceutical industry to GDP, 2014
(Multiplier value and as a percentage of GDP)

	Indirect and direct impact		Indirect, direct and induced impact	
	Multiplier I	Percentage of total GDP	Multiplier II	Percentage of total GDP
Argentina	1.58	0.8	4.95	2.3
Bolivia (Plurinational State of)	1.42	0.1	3.64	0.3
Brazil	1.70	0.8	5.81	2.5
Chile	1.69	0.6	3.35	0.9
Colombia	1.60	0.6	3.58	1.6
Ecuador	1.39	0.3	2.80	0.4
Paraguay	1.38	0.6	2.69	0.8
Peru	1.68	0.3	4.01	0.6
Uruguay	1.37	0.6	3.90	1.4
Venezuela (Bolivarian Republic of)	1.66	0.1	2.84	0.6
South America	1.66	0.7	4.37	1.6
Costa Rica	1.47	0.4	3.67	0.9
El Salvador	1.46	0.6	4.87	1.7
Honduras	1.66	0.2	5.19	0.7
Guatemala	1.43	0.3	4.46	0.8
Nicaragua	1.21	0.1	1.88	0.1
Panama	1.25	0.2	3.25	0.4
Dominican Republic	1.24	0.7	2.27	0.7
Central America	1.35	0.4	3.21	0.7
Mexico	1.49	0.4	2.87	0.5
Latin America	1.59	0.6	3.88	1.2
United States	1.87	0.9	4.00	1.6
European Union	1.49	0.9	3.09	1.4

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of the global input-output table for Latin America [online] <https://www.cepal.org/en/events/global-input-output-tables-tools-analysis-integration-latin-america-world>; and M. P. Timmer and others, "An illustrated user guide to the World Input-Output Database: the case of global automotive production", *Review of International Economics*, vol. 23, 2015.

² To quantify the contribution of the pharmaceutical industry to regional GDP, two multipliers were calculated on the basis of the input-output matrix: (i) the direct and indirect effect of intermediate purchases based on the value added generated in activities other than pharmaceutical activity that is produced by the purchase of goods and services necessary for the production of pharmaceutical goods (multiplier I); (ii) the direct, indirect and induced effect of purchases made by workers, given by the value added generated in activities other than pharmaceutical activity that is produced by the purchase of goods and services by workers in the pharmaceutical industry from the wage component of the value added of the pharmaceutical industry (multiplier II).

8. The differences in the total contribution of the pharmaceutical industry to GDP between one country and another is due to imports and the distribution of production between intermediate consumption and final demand

The multiplier I differences are due to the fact that, the higher the imports for pharmaceutical production, the lower the multiplier. In turn, the higher the propensity of households to import and/or save, the lower multiplier II will be. For example, in Mexico, multiplier I has a value of 1.49, while multiplier II is 2.87 (some of the lowest values in the region) because that country's pharmaceutical industry imports 36% of the inputs for its output (see table I.6).

Table I.6

Imports, final demand, intermediate consumption and value added of the pharmaceutical industry, 2014
(Percentages of output)

	Imports relative to output	Final demand relative to output	Intermediate consumption relative to output	Value added relative to output
South America	14	60	40	43
Central America	31	74	26	42
Mexico	36	64	36	28
United States	10	45	55	44

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of the global input-output table for Latin America [online] <https://www.cepal.org/en/events/global-input-output-tables-tools-analysis-integration-latin-america-world>; and M. P. Timmer and others, "An illustrated user guide to the World Input-Output Database: the case of global automotive production", *Review of International Economics*, vol. 23, 2015.

9. The pharmaceutical industry's share of employment is around 0.8% (direct, indirect and induced effects)

The calculation of multiplier II for employment requires labour data matrices with the same sectoral disaggregation as the input-output matrix. As shown in table I.7 for the countries for which this information is available, multiplier II for employment in the pharmaceutical industry indicates that its contribution to total employment has risen from 0.2% to 1% in Argentina and from 0.2% to 0.6% in Mexico.

Table I.7

Employment multiplier for the pharmaceutical industry

Country	Multiplier II	Percentage of total employment
Argentina (2014)	4.53	1.0
Chile (2016)	4.62	0.9
Costa Rica (2017)	3.33	0.7
Mexico (2013)	3.47	0.6
United States (2014)	5.21	1.0
European Union (2016)	3.93	0.9

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of the global input-output table for Latin America [online] <https://www.cepal.org/en/events/global-input-output-tables-tools-analysis-integration-latin-america-world>.

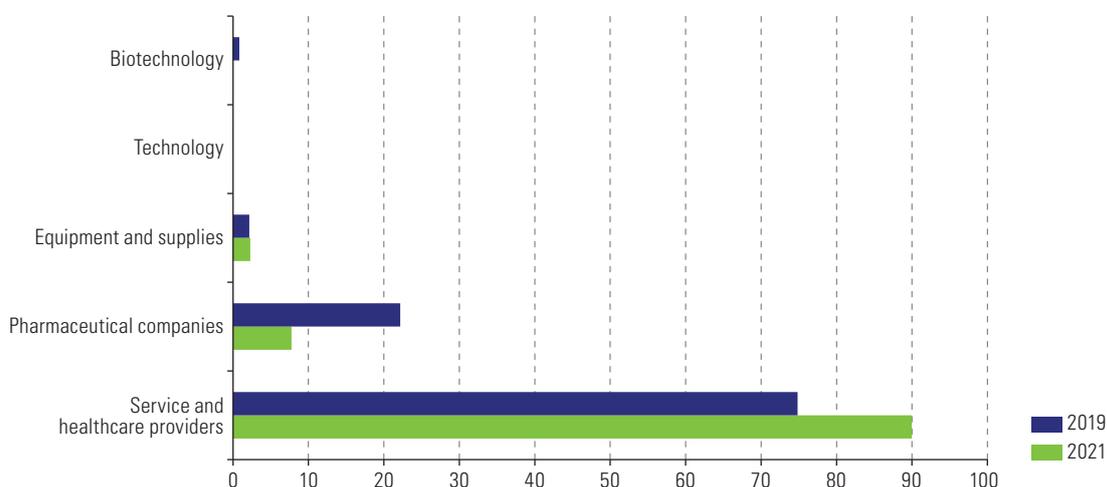
10. The stock market value of health economy companies in 2021 shows a rise in private health care and a relative decline for health technology and biotech firms

The market value of the 25 largest Latin American healthcare industry companies grew 139% between 2019 and 2021. In contrast, the growth in the stock market value of the industry's largest companies worldwide over the same period was 57%. Despite that strong growth, the stock market value of health firms in the region represents less than 1% of the total for the health manufacturing industry globally.

Most of the healthcare companies among the 5,000 largest in Latin America and the Caribbean are private firms and services (clinics, residential services, diagnostic facilities). As of 30 March 2021, pharmaceutical companies represented just 8% of the market value of the total health economy in the region (see figure 1.7). Moreover, there were no digital or biotech companies in that universe. By contrast, on that same date, pharmaceutical companies accounted for 51% of the market value of healthcare companies globally and there were 17 digital health companies among the top 5,000 largest enterprises in the world, representing 3% of market capitalization.

Figure 1.7

Latin America and the Caribbean: sectoral structure of the health economy, 2019 and 2021
(Percentages of total market value)



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of figures from Bloomberg.

Note: The "technology" category corresponds to "Companies providing information technology services primarily to health-care providers. Includes companies providing application, systems and/or data processing software, internet-based tools, and IT consulting services to doctors or hospitals".

D. International trade in pharmaceuticals

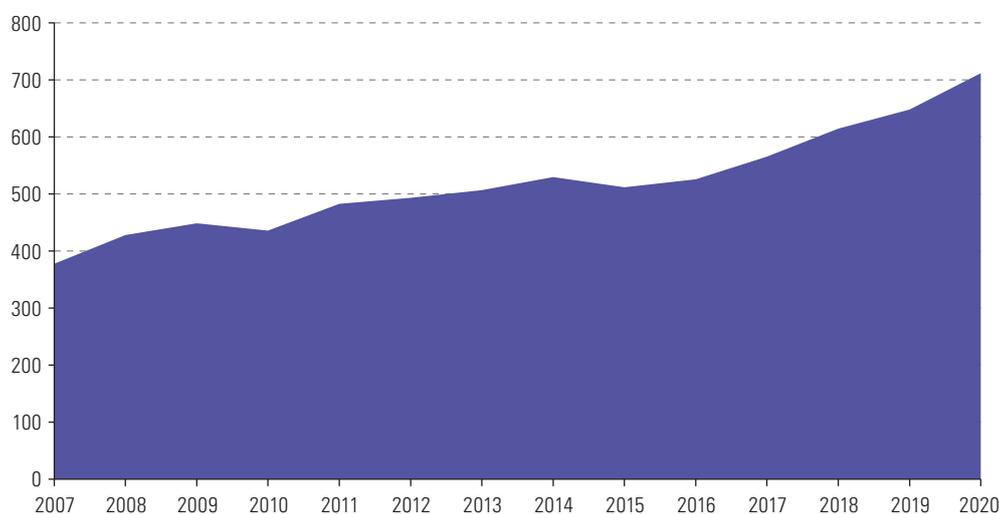
1. Increasing reliance on imports

Global exports of pharmaceutical products (medicines and active ingredients) totalled around US\$ 712 billion in 2020,³ equivalent to 4% of that year's global merchandise trade. Of this amount, medicines accounted for 87%, and active ingredients the remaining 13%. While the value of global merchandise exports shrank by 7.5% in 2020 as a result of the COVID-19 pandemic, pharmaceutical exports grew by 10% (see figure 1.8).

³ Based on data available for 94 countries, including all major world exporters and importers.

Figure I.8

Global exports of pharmaceutical products, 2007–2020

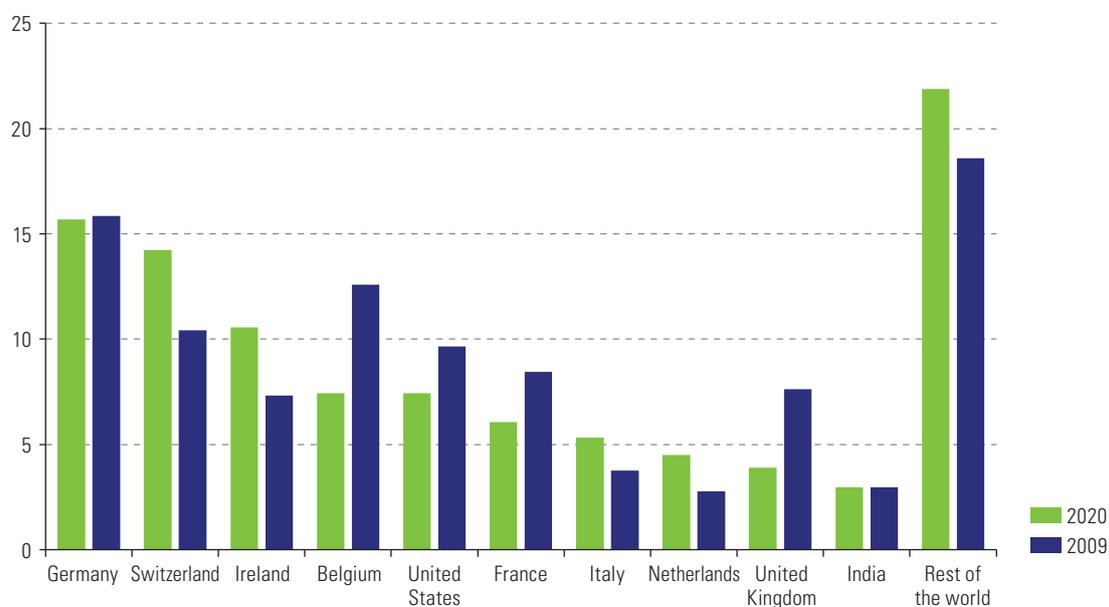
(Billions of dollars)

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

The list of the world's 10 leading exporters of medicines is dominated by developed countries, eight of them European. There have been no major changes in this group over the last decade, except for the entry of India in tenth place. The combined share of the 10 leading exporters has remained stable around 80% (see figure I.9).

Figure I.9

Ten leading global medicine exporters, 2009 and 2020

(Percentages of global exports)

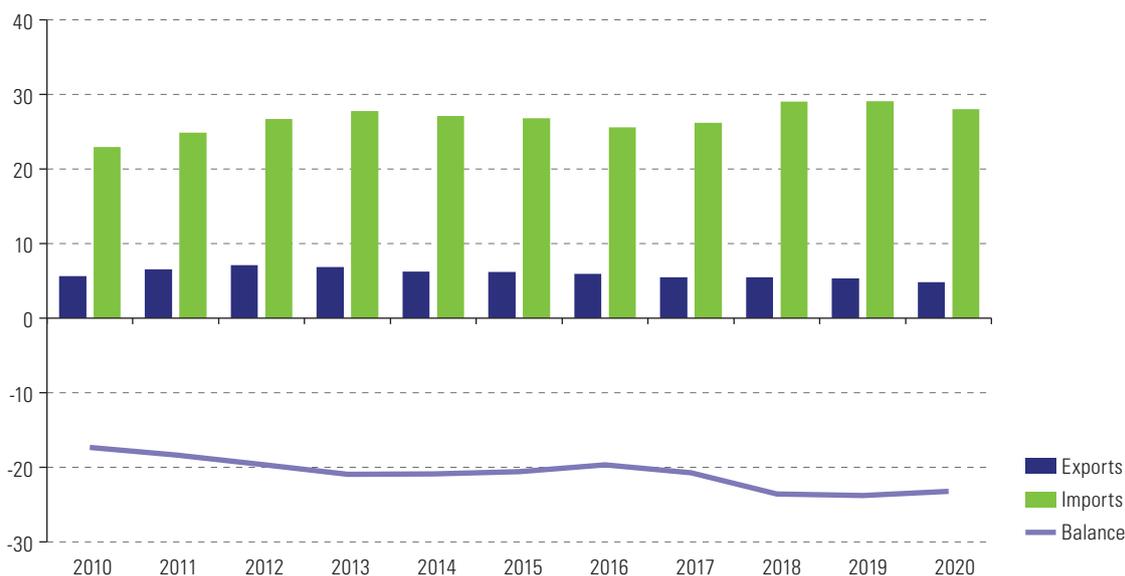
Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

The region's share of global pharmaceutical exports was 0.7% in 2020 —much less than its 5.4% share of global exports of all goods in that year. The region's pharmaceutical exports have been trending down since the start of the last decade, their value having shrunk by 32% from a peak of US\$ 7.1 billion in 2012 to about US\$ 4.9 billion in 2020.⁴ The region runs a persistent deficit in pharmaceuticals trade, with its imports in 2020 six times that of exports (see figure I.10).

Figure I.10

Latin America and the Caribbean: trade in pharmaceutical products, 2010–2020

(Millions of dollars)



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

Note: Does not include Panama because it is not possible to separately identify re-exports from the Colón Free Zone. The figures for 2020 include mirror data for Chile, Costa Rica, Dominican Republic, Ecuador, Honduras, Jamaica, Nicaragua, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia and Saint Vincent and the Grenadines.

The region's trade pattern reflects the chief characteristics of its pharmaceutical industry and market. Demand for innovative drugs (including biopharmaceuticals) is satisfied mainly by imports sourced from transnational companies outside the region. Generic drugs, in contrast, are mostly produced by firms operating locally, albeit with an increasing use of imported active ingredients. In recent decades there has been a trend in the region to abandon the production of active ingredients. Thus, its heavy reliance on the extra-regional supply of medicines with valid patents and active ingredients explains the region's persistent trade deficit.

2. Significance of intra-regional trade

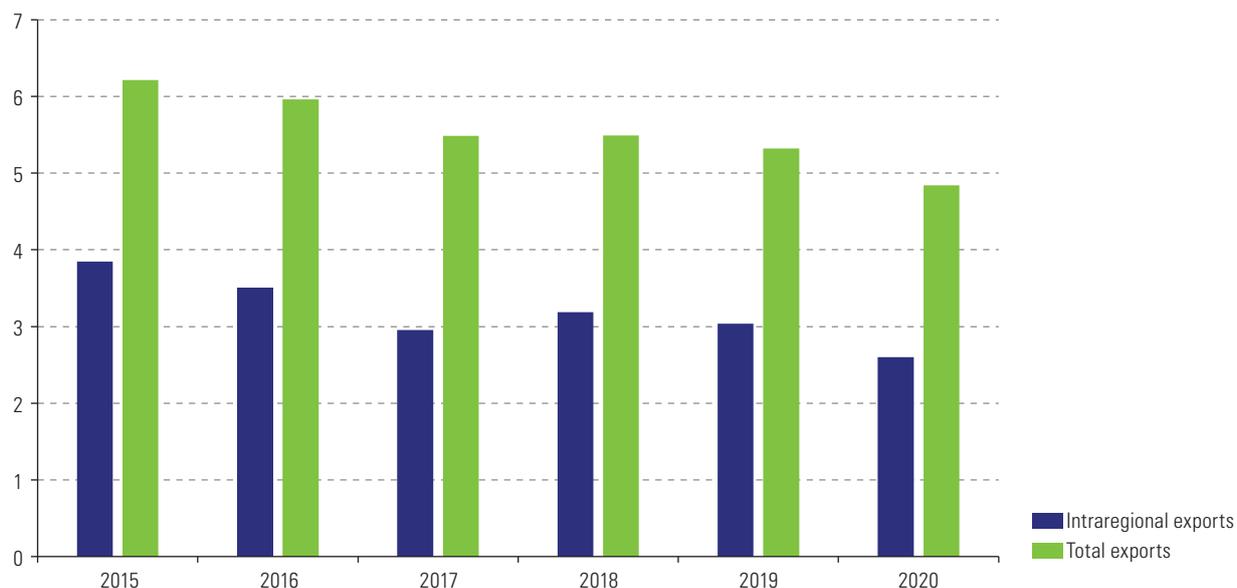
In 2020, intraregional trade in pharmaceutical products —measured by exports— amounted to approximately US\$ 2.6 billion (see figure I.11). Between 2015 and 2020, this indicator fell by a cumulative 32%, compared to a 22% drop in the region's total pharmaceutical exports in that period. Consequently, the regional market share in total pharmaceutical exports shrank from 62% in 2015 to 54% in 2020. The main reason for this is that Mexico and the Dominican Republic have increasingly been sending their pharmaceutical exports to the United States market. The intraregional share of the region's total pharmaceutical imports is much less than

⁴ The regional trade figures given in this section do not include Panama because it is not possible to separately identify pharmaceutical re-exports from the Colón Free Zone. The figures for 2020 include mirror data for Chile, Costa Rica, the Dominican Republic, Ecuador, Honduras, Jamaica, Nicaragua, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia and Saint Vincent and the Grenadines.

in the case of exports (14% on average between 2015 and 2020) and has experienced a less pronounced contraction (see figure I.12). The region's chief suppliers of pharmaceuticals are Europe and the United States, with shares of 49% and 16%, respectively, in 2020.

Figure I.11

Latin America and the Caribbean: exports of pharmaceutical products, total and intraregional, 2015–2020
(Billions of dollars)



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

Note: Does not include Panama because it is not possible to separately identify re-exports from the Colón Free Zone. The figures for 2020 include mirror data for Chile, Costa Rica, the Dominican Republic, Ecuador, Honduras, Jamaica, Nicaragua, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, and Saint Vincent and the Grenadines.

Figure I.12

Latin America and the Caribbean: intraregional share in total pharmaceuticals trade, 2015–2020
(Percentages)



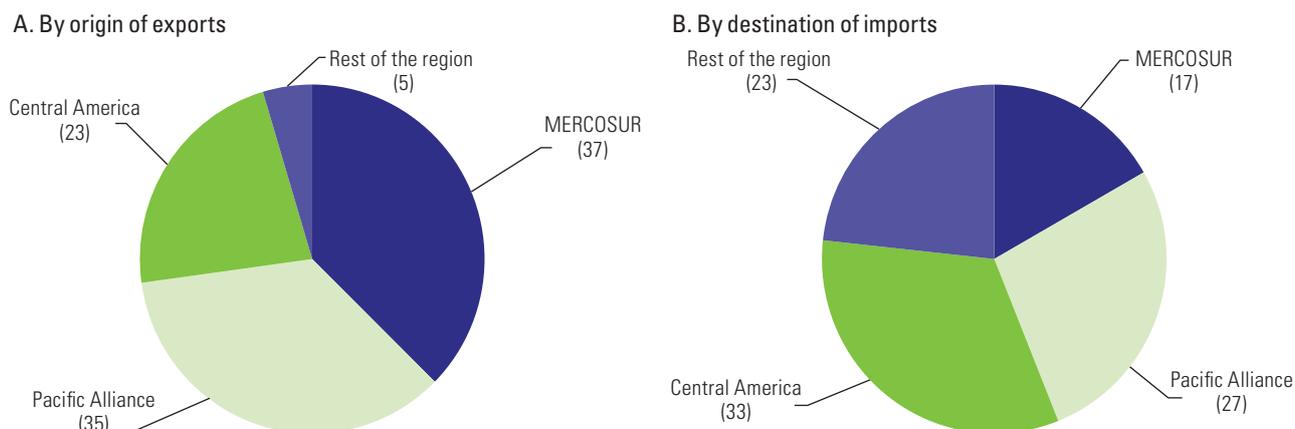
Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

Note: Does not include Panama because it is not possible to separately identify re-exports from the Colón Free Zone. The figures for 2020 include mirror data for Chile, Costa Rica, the Dominican Republic, Ecuador, Honduras, Jamaica, Nicaragua, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, and Saint Vincent and the Grenadines.

The Pacific Alliance and MERCOSUR between them generate 72% of intraregional exports of pharmaceutical products (see figure I.13A), as they include the region's largest pharmaceutical exporters (Brazil, Mexico and Argentina, in descending order). In the case of intraregional imports, Central America is the largest buyer, absorbing one third of the total. Other countries outside of these three groupings (the Dominican Republic, Ecuador and the Plurinational State of Bolivia, along with various Caribbean countries) account for 23% of intraregional purchases (see figure I.13B).

Figure I.13

Subregional groupings: distribution of intraregional trade in pharmaceuticals, 2019
(Percentages)



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

Note: Does not include Panama because it is not possible to separately identify re-exports from the Colón Free Zone.

Despite its loss of momentum in recent years, the intraregional market remains the leading destination for nine of the ten leading exporters of pharmaceutical products to the region. The exception is the Dominican Republic, which sends its exports mainly to the United States. Excluding Brazil, Mexico and the United States, the regional market absorbs between 73% and 97% of all pharmaceutical exports of the other seven countries in the 10 leading exporters to the region (see table I.8). Although the region's share of Mexico's pharmaceutical exports has diminished in recent years, it remains the most important market with a 53% share in 2019. This is much more than the region's share in total Mexican exports, which is about 7%.

Table I.8

Latin America and the Caribbean: 10 leading intraregional exporters of pharmaceutical products, 2019
(Millions of dollars and percentages)

Rank	Country	Exports to Latin America and the Caribbean (millions of dollars)	Share of the country in total intraregional pharmaceutical exports (percentages)	Share of the region in the country's total pharmaceutical exports (percentages)
1	Mexico	625	19	53
2	Brazil	580	18	41
3	Argentina	485	15	75
4	Colombia	308	10	88
5	Costa Rica	296	9	91
6	Guatemala	243	8	97
7	El Salvador	158	5	94
8	Chile	154	5	87
9	Uruguay	101	3	73
10	Dominican Republic	90	3	17
	Subtotal:	3 040	94	60

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

Note: Does not include Panama because it is not possible to separately identify re-exports from the Colón Free Zone.

The situation of intraregional imports differs from that of exports in several respects (see table I.9).

- Intraregional imports are less concentrated (the 10 leading importers accounted for 75% in 2019, compared to 94% in the case of the 10 leading exporters). This is to be expected, since export capacities in the pharmaceutical industry are much more concentrated than the demand for their products.
- The countries that top the ranking of the leading importers are different: the first four positions are occupied by Central American and Andean countries, with relatively small economies in first and second place (Guatemala and Ecuador, respectively).
- The intraregional share of total pharmaceutical imports varies considerably between the largest and smallest economies. The three largest, which are also the three largest importers of pharmaceutical products in the region (Brazil, Mexico and Argentina, in that order), only source between 2% and 6% of their purchases within the region; and Argentina is not even among the 10 leading intra-regional importers (it ranks 14th, after Nicaragua, Paraguay and El Salvador) (see table I.9).

Table I.9

Latin America and the Caribbean: 10 leading importers of pharmaceutical products, 2019

Rank	Country	Imports to Latin America and the Caribbean (US\$ million)	Share of the country in total intraregional pharmaceutical imports (percentages)	Share of the region in the country's total pharmaceutical imports (percentages)
1	Guatemala	459	12	60
2	Ecuador	444	12	42
3	Colombia	306	8	10
4	Peru	266	7	25
5	Chile	251	7	14
6	Brazil	243	6	2
7	Mexico	236	6	5
8	Honduras	233	6	46
9	Dominican Republic	233	6	30
10	Costa Rica	220	6	26
	Subtotal:	2 891	75	12

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of United Nations, UN Comtrade Database.

Note: Does not include Panama because it is not possible to separately identify re-exports from the Colón Free Zone.

In short, the smaller economies with less pharmaceutical production capacity depend the most on supplies from the rest of the region.⁵ This can be explained by the fact that they satisfy much of their demand for generic drugs by importing them from countries such as Argentina, Brazil and Mexico. In contrast, these three countries largely self-supply generic medicines, and they purchase innovative drugs mainly from developed countries.

3. Local production of medicines in the framework of free trade agreements

The numerous free trade agreements that Latin American and Caribbean countries have signed with developed countries can exert multiple influences on the cost, variety, efficacy and safety of pharmaceutical products in each country, and also on the countries' potential to foster domestic production. Analyses of this have focused almost exclusively on the impact of intellectual property provisions, the scope of which exceeds that of the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization (WTO) (the TRIPS Agreement). This is most clearly the case in FTAs signed with the United States, whose pharmaceutical industry systematically seeks to achieve WTO-plus ("TRIPS-plus") levels of protection in trading partners. Moreover, Gleeson and others (2019) indicate other important provisions contained in four of the most recent and exhaustive FTAs.⁶ These provisions and their possible effects on national pharmaceutical policies are summarized in table I.10.⁷

⁵ Belize 47%, Ecuador 42%, El Salvador 38%, Guatemala 60%, Honduras 46%, Nicaragua 52%, Paraguay 56% and the Plurinational State of Bolivia 49%.

⁶ The Trans-Pacific Partnership (TPP) Agreement, along with its successor the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), the United States-Mexico-Canada Agreement (USMCA) and the EU-Canada Comprehensive Economic and Trade Agreement (CETA).

⁷ Details of the main agreements reached between the Pacific Alliance and MERCOSUR on medicines and medical equipment are provided in annex 6.2.

Table I.10

Provisions included in modern trade agreements with possible effects on national pharmaceutical policies

Type of provision	Possible effects	Possible effects on pharmaceutical policies
Stronger intellectual property protection than provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-plus)	Long exclusivity periods for patented drugs, along with other market entry barriers applied to generic medicines and biosimilars, can reduce competition and force governments and consumers to pay monopoly prices for lengthy periods.	Affordable access to medicines may be reduced.
Investor-State dispute settlement mechanisms	Investment disputes can cause pharmaceutical policy decisions to be reversed or even give rise to “regulatory chill” situations. This can result in long periods of exclusivity, relaxation of regulatory standards or inability to support local producers.	Affordable access to medicines may be reduced. Local production, rational use of medicines and health standards could be compromised.
Government procurement rules	Governments / hospitals may pay lower prices as a result of open tenders. The viability of the domestic pharmaceutical industry may be compromised unless preferences can be granted to local suppliers.	Medicines could become more affordable. Local production could be compromised.
Regulatory requirements for assessing the safety, efficacy and quality of drugs	National standards can be influenced by pressures from pharmaceutical industry trade partners (for example pressure to speed up regulatory approval processes could lead to increased safety risks). Cooperation on pharmaceutical inspection issues can improve drug quality and consumer safety.	The safety, efficacy and quality of medicines could decrease or increase.
Procedural requirements with respect to national pharmaceutical pricing and reimbursement programmes	Pharmaceutical policy-making may be subject to pressure from business partners with large pharmaceutical industries, including the possibility of pharmaceutical companies challenging the decisions of health authorities.	Affordable access to medicines and their rational use could be either enhanced or compromised.
Rules on State-owned pharmaceutical companies and designated monopolies	The viability of domestic industry in developing countries may be affected if State-owned enterprises have to operate as commercial entities, cannot receive financial support or preferential treatment, or cannot give preference to local suppliers. Pressure to reform State-owned enterprises can lead to increased competition and lower prices.	Local production and health safety could be either enhanced or compromised.

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of D. Gleeson and others, “Analyzing the impact of trade and investment agreements on pharmaceutical policy: provisions, pathways and potential impacts”, *Globalization and Health*, vol. 15, No. 78, 2019.

The impact of FTA provisions on a country’s capacity to promote the local production of medicines can be either positive or negative, depending crucially on the structure of its pharmaceutical industry (in particular, the share of innovative drugs relative to generics). The following provides a conceptual assessment of the three types of provisions considered most relevant.

(a) Intellectual property⁸

The pharmaceutical industry in Latin America and the Caribbean consists mostly of producers of generic drugs. Accordingly, “TRIPS-plus” provisions that extend the period of exclusivity enjoyed by patented drugs beyond the 20 years stipulated in the TRIPS Agreement harm local industries that manufacture generic versions, by delaying the market entry of their products. The main provisions of this type included in the FTAs signed by the countries of the region with the United States are the following:

- (i) Changes in the duration of pharmaceutical patents to compensate for the “unjustified curtailment” in the effective patent term, as a result of the marketing approval process of the patented drug;
- (ii) At least five years’ exclusivity over the test data used to support the marketing application for a drug; and
- (iii) Linkage mechanisms (making the granting of a marketing authorization for a generic drug subject to the patent status of the original drug).

⁸ This analysis is based only on the FTAs signed with the United States, since they contain the most detailed provisions on intellectual property and are the most ambitious (in other words the furthest removed from the TRIPS standard).

These three types of provisions are included (and with very similar language) in all FTAs signed by the countries of the region with the United States (Chile, the Dominican Republic-Central America Free Trade Agreement (CAFTA-DR), Colombia, Panama, Peru, the United States-Mexico-Canada Agreement (USMCA). As the most recent agreement, USMCA establishes a higher standard of protection than previous FTAs; and, in addition to the aforementioned provisions, it includes the following:

- (i) Patent term adjustment is added to compensate the patent holder for any “unreasonable delays” in the granting of the patent itself (article 20.46).
- (ii) The period of test data exclusivity is extended to at least 10 years for biological drugs (article 20.49). This additional protection applies expressly to vaccines.
- (iii) An additional requirement to grant patents for new uses of already known products, as well as new methods or procedures of use of a known product (in this case, a new medical use of an already known substance, known as a second-use patent).

These additional provisions contained in USMCA were also found in the text of the Trans-Pacific Partnership (TPP). Nonetheless, following the withdrawal of the United States, it was decided to suspend their application in its successor agreement, the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

(b) Investor-state dispute settlement

Nearly all FTAs and investment promotion and protection agreements signed by countries in the region with developed partners contain investor-State dispute settlement (ISDS) mechanisms. These allow a foreign investor to sue the host State before an ad hoc international tribunal (generally within the framework of the International Centre for Settlement of Investment Disputes (ICSID)), if it considers that some of the guarantees contained in the respective agreement have not been respected.

The guarantees to foreign investors included in FTAs (national treatment, fair and equitable treatment, non-imposition of performance requirements, prohibition of indirect expropriation, among others) are generally cross-cutting and, therefore, do not refer to any industry in particular. However, they can affect the pharmaceutical industry in several ways. Firstly, the agreements grant protection to the intellectual property of the foreign investor (patents, trademarks, trade secrets, and so forth), so any measure adopted by the host State that could be interpreted as impinging on these rights could be challenged before an international court. Secondly, provisions such as the prohibition on performance requirements could, for example, prevent the host State from requiring a foreign pharmaceutical company to purchase locally produced inputs or to share its specialized know-how with local partners or suppliers.

The mere possibility of a measure being challenged before an international court may lead the host State to decide to reverse it, or to even refrain from implementing it (a phenomenon known as regulatory chill). For example, in the pharmaceutical sector, in 2016 Colombia desisted from granting a compulsory license for the drug imatinib (brand name Glivec/Gleevec), used in cancer treatments, after the patent-holding laboratory (Novartis) filed notice of an international lawsuit (Gleeson and others 2019). In the same year, Ukraine de-registered a generic hepatitis-C drug after the Gilead Sciences laboratory (patent holder of the original drug, Sovaldi) indicated that it would pursue international arbitration (Gleeson and others, 2019).

Growing international pressure against the use of investor-State dispute settlement mechanisms to challenge public health measures has led to the most recent agreements (including CPTPP) restricting, but not eliminating, this possibility. A different approach, which gives greater guarantees to the host State, is exemplified by the Peru-Australia Free Trade Agreement, which expressly excludes measures to promote or protect public health from the scope of investor-State mechanisms.

(c) Public procurement

The scope of commitments to open public procurement made by the countries of the region in their agreements with developed partners vary considerably. They are applicable only as follows:

- (i) above specified monetary thresholds (which vary according to the agreement, and also depend on whether goods, services or public works are involved);
- (ii) for the goods, services and public works that each country expressly designates; and
- (iii) to the entities (central, regional, local government, public enterprises or others) that each country expressly designates.⁹
- (iv) According to the recognition, in several of the FTAs that the region's countries have signed with developed partners (including the agreements with the European Union, CPTPP and USMCA) of the right of the parties to grant preferential treatment in public procurement to small and medium-sized enterprises (SMEs).

As a whole, points (i) to (iv) give countries a significant margin of flexibility in the management of their pharmaceutical procurement. Moreover, competition in public procurement between nationally-owned and international laboratories is diminished by the fact that the former specialize in generics and the latter in innovative/patented drugs. Nonetheless, additional information specific to each case is required to estimate the impact of FTAs on the capacity of countries to promote local pharmaceutical production.

E. Firm size, ownership and specialization

Despite the fact that Latin America and the Caribbean generated just 3.5% of global pharmaceutical sales in 2020 (at ex-factory prices) (EFPIA, 2021), the major global transnationals in biopharmaceutical industry, based on research and development (R&D), have a strong presence in the region.

Most of these firms originate from Europe or the United States and have a long history. They are represented in the region through chambers and associations, at both the national and regional levels. Of the 20 transnationals most represented in the region's trade associations, half were founded before the First World War, and only three in the twenty-first century (see annex 3.2). In fact, the most recent (2012) is a spin-off from the Abbott laboratory, which dates back to 1888. Although these are generally large firms, the largest being Johnson & Johnson with 132,200 employees and revenues of US\$ 82.6 billion, several firms specializing in specific market niches have smaller revenues than the average of this group.

The Latin American Pharmaceutical Industry Federation (FIFARMA) encompasses 11 national associations in Latin America and the Caribbean and 15 global firms.¹⁰ The latter also have individual representation in other national chambers and associations, alongside firms from the region and other foreign transnationals.

National firms are also strongly represented in associations and chambers. Membership of the Latin American Association of Pharmaceutical Industries (ALIFAR), founded in 1980, includes more than 400 nationally-owned pharmaceutical companies from Latin American and Caribbean countries. The countries with chambers belonging to this association are Argentina, the Bolivarian Republic of Venezuela, Brazil, Colombia, Dominican Republic, Ecuador, El Salvador, Guatemala, Paraguay, Peru, the Plurinational State of Bolivia and Uruguay.

⁹ For example, Argentina and Brazil did not make commitments to openness at the subfederal level (that is, Argentine provinces and Brazilian states) in the EU-MERCOSUR agreement.

¹⁰ Trade associations from Argentina, Bolivarian Republic of Venezuela, Brazil, Central America, Chile, Colombia, Dominican Republic, Ecuador, Mexico, Peru, Uruguay and Venezuela.

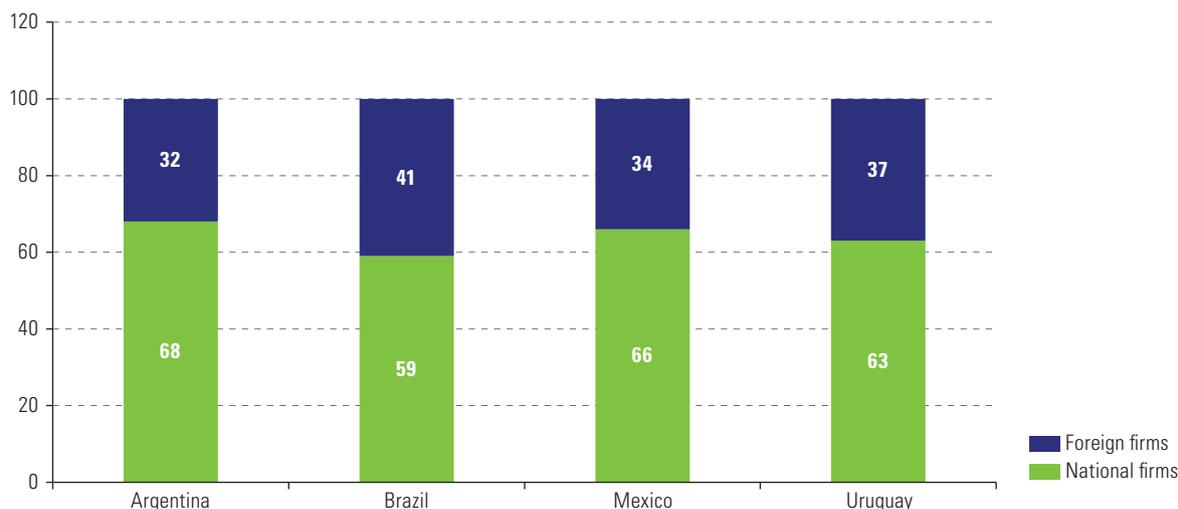
Within national chambers there are different partnerships of industry players. In Brazil, for example, Grupo Farma, which was founded in 2011 to represent domestically research, development and innovation firms, consists of 12 enterprises which account for 30% of the volume of drugs manufactured in the country. With a longer historical tradition, the Industrial Chamber of Argentine Pharmaceutical Laboratories (CILFA) was founded in 1964 and encompasses 36 relatively large laboratories, one of them public. The situation in Colombia is similar, where the Association of Pharmaceutical Industries (ASINFAR), created in 1974, has the most important nationally owned firms among its affiliates. In Mexico, in contrast, the National Chamber of the Pharmaceutical Industry (CANIFARMA), founded in 1946, has a mixed profile, with 186 members, including domestic firms and global transnationals (see annex 4.2 for a list of the main chambers and associations in the region's countries).

This high rate of participation in trade associations demonstrates the importance of collective advocacy activities to defend the sector's interests. This makes sense considering the great complexity of this industry's regulatory framework, which includes ethical issues pertaining to research on human health and medical care, along with intellectual property issues and their derivations in trade agreements and market regulation, issues related to rights of access to health care and the public policies implemented by the states to guarantee them (Bianchi, 2021), and the impact and feedback of this regulatory framework on the structure, conduct and performance of the firms involved.

In some cases, the large transnationals compete in the region with nationally-owned laboratories, some of which have internationalized within the region, but generally produce for the domestic market. In countries that have local production capacity, foreign transnationals generally account for 40% of the value of sales in the domestic market while national firms generate 60% (see figure I.14).

Figure I.14

Latin America (4 countries): share of the pharmaceutical industry in domestic market sales, by firm ownership, latest available year
(Percentages)



Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of data from Industrial Chamber of Argentine Pharmaceutical Laboratories CILFA) for Argentina; Research-based Pharmaceutical Manufacturers Association (Interfarma), *Guía 2020 Interfarma*, April 2020 [online] https://www.interfarma.org.br/app/uploads/2020/12/2020_VD_JAN.pdf for Brazil; and data from IQVIA for Mexico (year-on-year as from April 2021) and Indufarma for Uruguay.

Market share varies by type of product. While transnational firms have a larger share in the sales of patented medicines, while national laboratories are more important in the generics market. In Brazil, for example, foreign transnationals accounted for 77% of retail sales of patented medicines (innovative or original) in 2019 (compared to an average of 41%), but just 24% of generics and 20% of biosimilars (Interfarma, 2020).

This pattern is also seen in other countries. In Mexico, 85% medicines produced by foreign transnationals are under patent, while around 95% of production by Mexican national companies consists of generic drugs (*El Financiero*, 2018). In Argentina, the national firms and groups with the highest turnover produce drugs that use imported active ingredients for which the patents have expired, although there are also some high-quality niches (ECLAC, 2020). In Uruguay, foreign transnationals (numbering approximately 15) operating in the market sell imported patented products, and about 20 nationally owned laboratories sell mainly generic or similar products (Bianchi, 2021). In Colombia also, transnationals supply the market with imported products, while national production imports the active molecules and carries out the formulation and mixing production processes (DNP, 2004).

Laboratories of national origin have a major share in the countries that have the greatest pharmaceutical production capacity. In Argentina and Brazil, for example, national laboratories have a major presence in the 20 firms with the highest sales turnover. In Argentina, 12 of the 20 largest laboratories by sales are of national origin and account for 72% of the total sales of that group. In Brazil, 10 of the largest 20 laboratories by turnover are Brazilian and generate 58% of total sales. The situation in Mexico is similar, although with a higher proportion of foreign laboratories among the 10 largest (see annex 3.2).

In Colombia, only one of the 10 laboratories with the highest sales in 2019, Tecnoquímicas (founded in 1934), is national. Lafrancol (founded in 1911) was initially acquired by the Chilean Corporación Farmacéutica Recalcine and then taken over by Abbott. The 10 largest laboratories accounted for approximately 40% of the market in 2019 (see annex 3.2). In Uruguay, sales in the sector are also highly concentrated, with 10 firms generating more than half of all sales, and 20 firms account for three quarters (Bianchi, 2021).

In Argentina, the largest laboratories produce brand drugs; they have some R&D activities, and some have gained access to international markets. Large domestically-owned conglomerates have become transnationals, with manufacturing and commercial subsidiaries in Latin American countries—for example in Uruguay, the United States, Europe and some Asian countries (Grupo Insud, Roemmers, Bagó, Laboratorios Richmond) (ECLAC, 2020).

In Costa Rica, there are 27 drug manufacturing laboratories, of which nine are foreign and 18 are Costa Rican-owned. Three of these are State-owned: two by the Costa Rican Social Security Fund (CCSS) and the Clodomiro Picado Institute, attached to the Faculty of Microbiology of the University of Costa Rica, which specializes in venom antiserum.

Similar to the case of large global transnationals, the largest laboratories with the greatest share in the region's markets are firms with a long track record. Of the main laboratories in Argentina and Brazil, for example, nine were founded in 1940 or earlier, nine have their origins between 1957 and 1997, and just four were founded in the twenty-first century (between 2000 and 2006).

Lastly, the growth and consolidation of firms through mergers and acquisitions is a widespread global phenomenon. In Uruguay, for example, there were various mergers and acquisitions of domestically owned firms between 2009 and 2018, resulting in increased participation by regional business groups, such as Roemmers of Argentina, Medifarma of Peru and Eurofarma of Brazil, among others (Bianchi, 2021). These processes demonstrate the importance of regional markets for the operations of certain business groups and may signal that regional integration would strengthen the industry (Bianchi, 2021).

F. Fragmentation, segmentation and insufficiency of resources in the health sector

Health policies and programmes stem from the prioritization of health targets and objectives and the definition of road maps for implementing them. As such, they are important for designing a regional strategic health plan proposal that includes universal access to vaccination. Health systems and, above all, the first level of care and the primary health-care strategy, are pillars of the policy given their links with the population and response to their health problems—in particular, the need to contain the current COVID-19 pandemic.

The development of a virtuous circle between the production or availability, distribution and use or consumption of vaccines and essential drugs is closely related to the health system and primary health care, in terms of financing, structuring of the system and organization of service delivery, including vaccination. It also relates to the provision of infrastructure, human resources and technology, including drugs and vaccines. The health sector is a major player in the economy, developing production functions and processes, ways of setting priorities, and policies on coverage and access that guide economic decisions, such as resource allocation.

Health systems are complex entities with structures connected to the various sectors of economic activity, government administration and the population. In Latin America and the Caribbean, health systems suffer from problems such as chronic public underfunding and the consequent heavy reliance on out-of-pocket spending. They are also fragmented into several watertight subsystems and segmentation of the population with different levels of access to health services, and scant development of primary health-care strategies. Overcoming these problems requires an integrated and comprehensive vision of the health of individuals and communities, with organized and hierarchical actions ranging from health promotion to rehabilitation. These would include implementing curative procedures, with an emphasis on prevention, and addressing the determinants of health through local intersectoral work and social participation. The strategy also assumes curative capabilities in the first level of care, which acts as the organizational hub of all health-care services. The problems that exist within health systems compound access barriers and result in low response capacity and low levels of efficacy and quality of health coverage—a problem that has been accentuated by the COVID-19 pandemic (ECLAC/PAHO, 2020; ECLAC, 2020; PAHO 2017).

Funding problems and the low fiscal priority assigned to health in the region result in health expenditure that averages around 6.8% of GDP, with only 3.8% of GDP corresponding to public expenditure, and significant differences between countries (see figure I.15A). The rest is private spending, mainly out-of-pocket household spending, although private insurance is also important, particularly in Chile, Colombia and the Dominican Republic (see figure I.15B). Thus, just over half (57%) of total expenditure on health comes from public sources. This is much less than in regions that have more developed health systems, such as the OECD countries where 76% of expenditure is publicly financed (Organization for Economic Cooperation and Development–OECD, 2019). Very few of the region's countries have health systems that are more than 40% fiscally funded; and private health expenditure accounts for more than 40% of the total in many cases.

The only countries in which public spending on health exceeds 6% of GDP—a figure that corresponds to the regional recommendation under the Pan American Health Organization (PAHO) Strategy for Universal Access to Health and Universal Health Coverage, agreed on by the countries in 2014 (PAHO, 2014)—are Cuba and Uruguay. In recent years, Costa Rica and Argentina have fluctuated above and below that level. Nonetheless, the health sector is important in the economy and accounts for about 7% of GDP, or close to 10% in some countries, such as Brazil.

Segmentation problems generally occur in situations where there is a combination of: a non-contributory public system serving more vulnerable population groups; a social security health sector that covers groups of formalized workers and their families, who are usually a minority of the population; and private insurance or provision for higher-income sectors that express willingness to pay. This segmentation has implications for distribution and type of financing (see figure I.16B), which result in different per capita expenditures, health services of differing quality, and different health outcome indicators between population groups. All of this occurs in a context of lack of solidarity; and the efficiency gains associated with the operation of wide-ranging, universal and single funds are forgone.

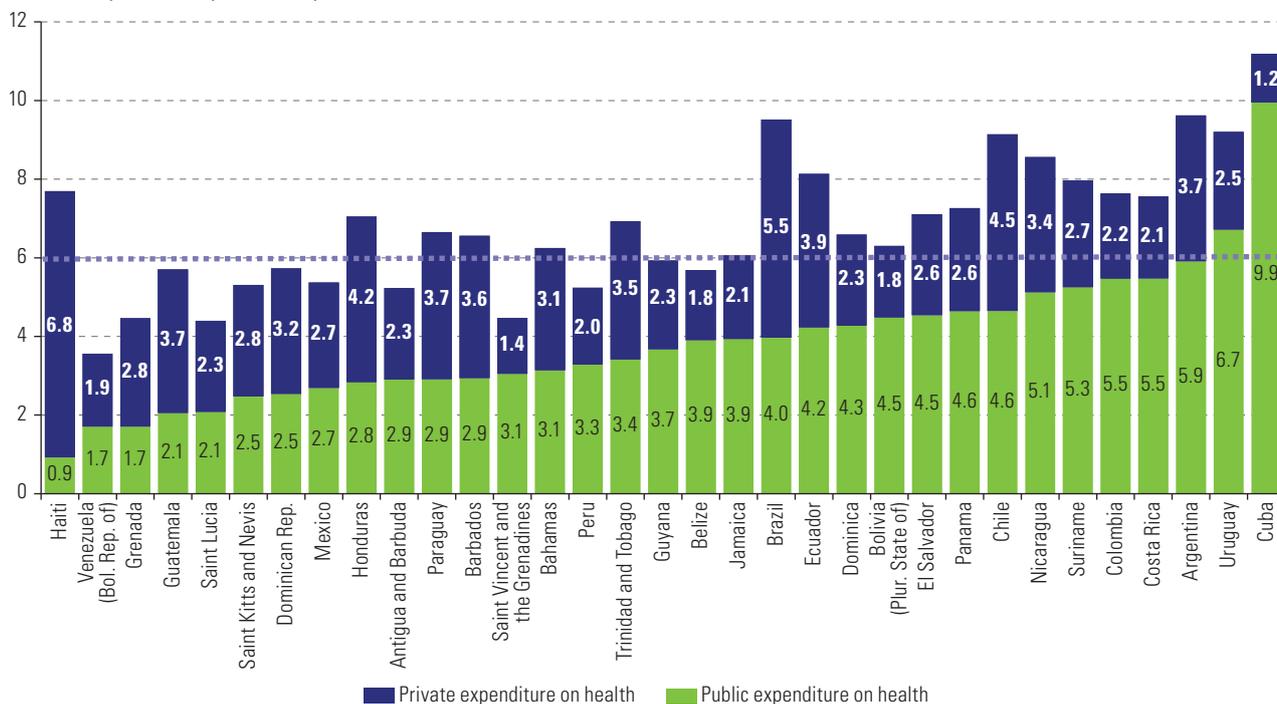
In some countries that have a universal health system, the coverage of the different systems can overlap. For example, in Brazil, although 100% of the population is entitled to access the Unified Health System (SUS), 25% also have private supplementary plans (Massuda and others, 2018). In Uruguay, the 2008 reform universalized coverage while maintaining the contributory system, so that about 80% of the population belongs to that system. This pools all of its resources in the National Health Fund (FONASA) and then distributes them to the various health-care providers (*mutuales*) through a risk-adjusted per capita system. In Argentina, between 35% and 40% of the population is affiliated to social security systems, which partly overlap with the private sector; and the remainder have access to the provincial public systems. In Chile, about 18% of the population is affiliated to the system of private health insurers (Isapres) and 75% to the National Health Fund (FONASA).

Figure I.15

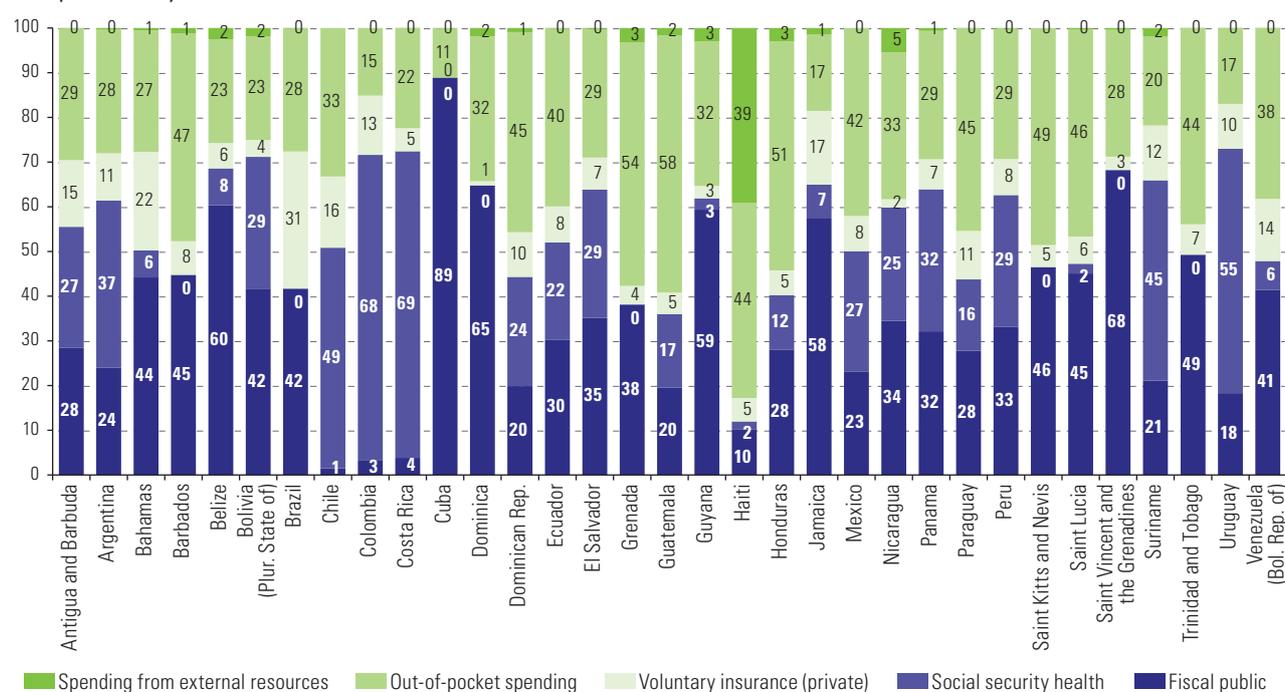
Latin America and the Caribbean: health expenditure relative to GDP and its composition, 2018

(Percentages)

A. Total expenditure, public and private



B. Expenditure by income sources

Source: World Health Organization (WHO), Global Health Expenditure Database (GHED) [online] <https://apps.who.int/nha/database>.

Note: Both figures, I.15A and I.15B, refer to the 33 countries for which information is available in the Global Health Expenditure Database (GHED) of the World Health Organization.

The ways in which resources are collected for management by health-care financiers (in particular, whether they are channelled into one or more funds) are directly related to health system structures (Mathauer and others, 2020). Countries that perform better in terms of health system functions and health outcome indicators (such as maternal and infant mortality and life expectancy, among others) show less segmentation. Countries such as Cuba, Uruguay and Costa Rica are notable not only for being close to, or having surpassed the target of 6% of GDP, but also for low levels of out-of-pocket spending. This results in more advanced health systems, practically unified and universal, with large funds for the administration of financial resources and a networked organization of services that promote the primary care strategy. Those three countries approximate to systems of national health services or national health insurance arrangements (Cuadrado and others, 2019). Lastly, there is the case of Argentina which, despite exceeding the 6% of GDP level of public expenditure on health in some years, displays a high degree of segmentation, in which robust social health insurance systems coexist with provincial systems organized as subnational health services (Sabignoso and others, 2020).

The allocation of resources for health actions, interventions and benefits, including essential drugs and vaccines, is associated with capacities in the primary care system and the organization of services. At this level, systems are fragmented and lack a development strategy; they also suffer from functional overlaps which, as noted above, together with problems of financing and timely access to health care resulting from different barriers, lead to inefficiency and inequity. The way resources are allocated in fragmented systems is based on historical budgets, generally unrelated to effective costs and with little development of strategic purchasing systems for benefits and drugs (Cid Pedraza, 2020). This results in low capacity for coordination and continuity of the care process, with a focus on specialized curative care and a precarious first level of low priority and curative capacity that receives a small share of public funds (Cid Pedraza and others, 2020). The expanded programmes on immunization (EPI) of each country, which are largely based on the first level of care or primary care, have rolled out the vaccination process successfully in some countries, but with significant limitations in others.

The key resources for the supply of services, such as infrastructure, personnel and technology, are limited by their scarcity and unregulated development. As a result, the region's countries fall short of the standards and levels of more advanced regions. The region's average of 20 physicians per 10,000 inhabitants is far below the average of 35 per 10,000 inhabitants in OECD countries and the parameters recommended by the World Health Organization (WHO).¹¹ The same applies to nursing staff. The number of hospital beds available is also much lower than the average for OECD countries, with rates of 2.0 per 1,000 inhabitants in Latin America and the Caribbean compared to 4.8 in the OECD countries (ECLAC-PAHO, 2020; ECLAC, 2020). Health technologies, including medicines, medical supplies and vaccines, are procured through methods defined nationally. In general, although countries have central purchasing centres for centralized strategic procurement, there are also possibilities for deconcentrated purchasing within countries and health systems. In addition, there are international mechanisms for joint regional or subregional procurement that seek to improve purchasing conditions and supply chain management.

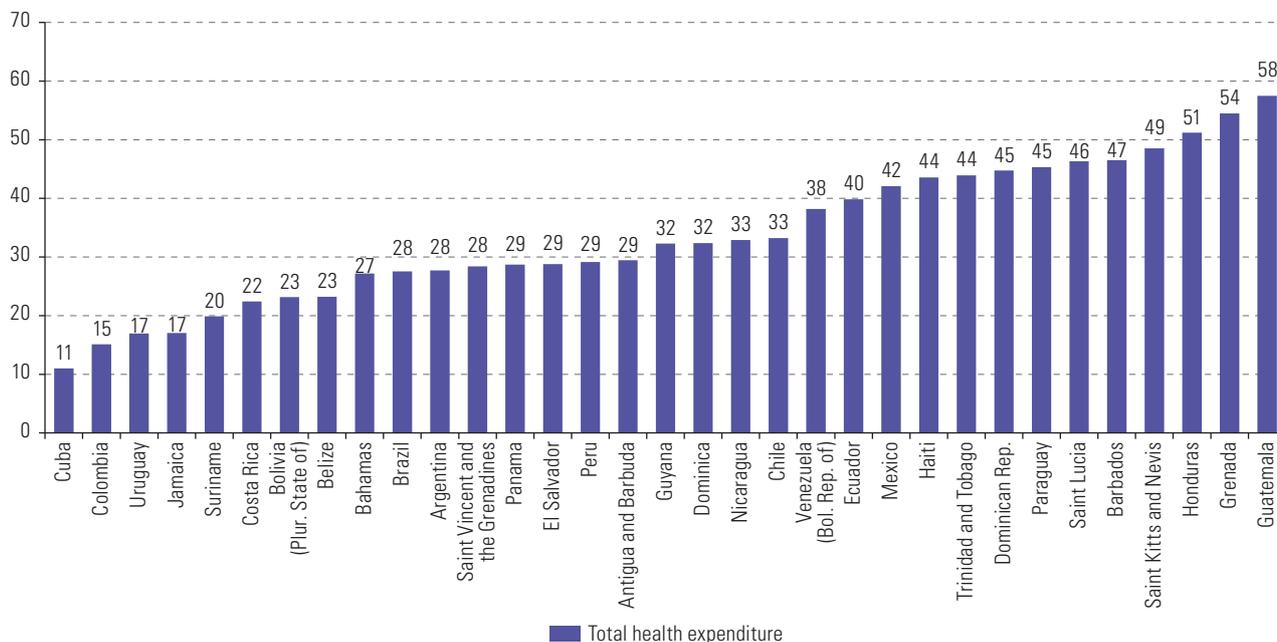
One of the chief barriers to access to health services on the demand side is the lack of financial protection, which can plunge families into poverty or deepen the poverty in which they already live, and even spell financial disaster for families that are not necessarily poor, should a catastrophic event occur. In the long run, this constrains the levels of health that populations can achieve. The relative or total lack of coverage with financial protection forces households to tackle their health problems through out-of-pocket spending, which accounts for the vast majority of private spending. Partly as a consequence of insufficient public funding, out-of-pocket spending on health is very high, accounting for 33.6% of total health expenditure in the region. Only a few countries report out-of-pocket spending on health below 20%: Colombia and Jamaica, in addition to those already mentioned, in which public expenditure on health is above the threshold of 6% of GDP (see figure I.16A). In some countries, these expenditures can push more than 2% of the population into poverty; and in Haiti the figure is more than double that (see figure I.16B).

¹¹ The World Health Organization (WHO) recommends a minimum of 30 physicians per 10,000 inhabitants and at least 23 physicians, nurses and midwives to provide reasonable maternal and child health care.

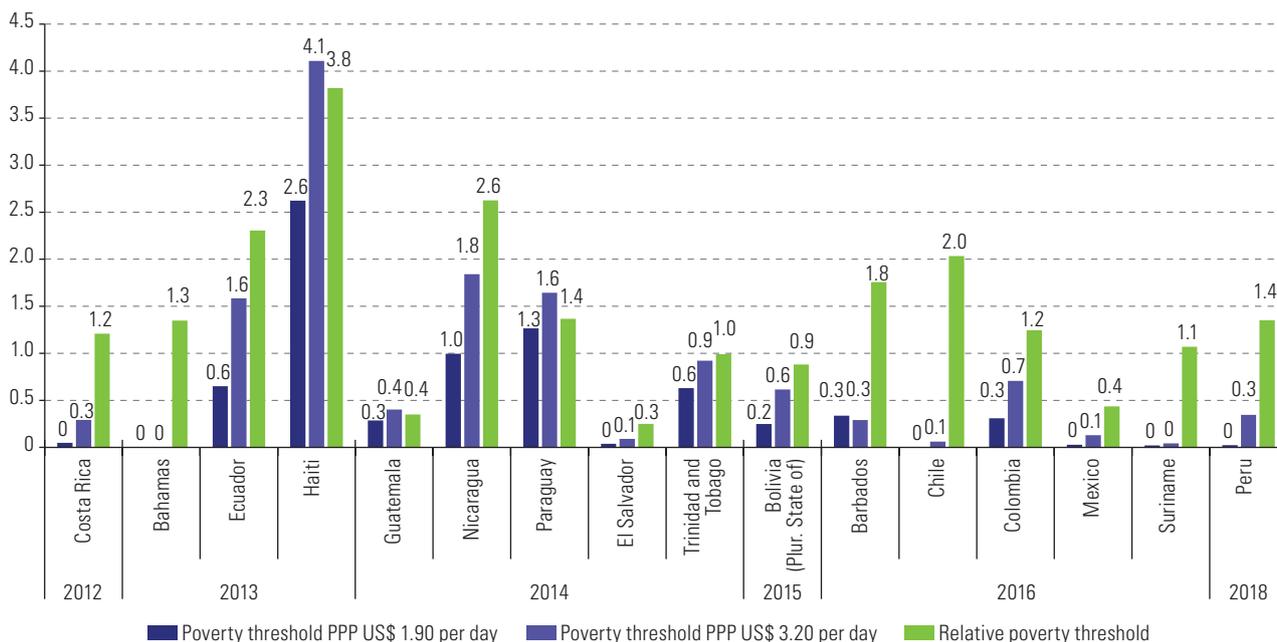
Figure I.16

Latin America and the Caribbean: out-of-pocket spending on health relative to total health expenditure and incidence of poverty caused by effect of household out-of-pocket health expenditure (Percentages)

A. Out-of-pocket spending on health relative to total health expenditure, 2018



B. Poverty caused by effect of household out-of-pocket health expenses, latest year available



Source: World Health Organization (WHO), Global Health Expenditure Database (GHED) [online] <https://apps.who.int/nha/database> and C. Cid Pedraza and others, "Objetivos de Desarrollo Sostenible: impacto de la falta de protección financiera en salud en países de América latina y el Caribe", Revista Panamericana de Salud Pública, vol. 45, 2021, unpublished.

Note: Figure I.16A refers to the 33 countries for which data are available in the Global Health Expenditure Database (GHED), and figure I.16 B refers to the 16 countries for which there are financial protection indicators for 2012. Out-of-pocket spending on health is impoverishing when it reduces total household consumption expenditure below a defined poverty line. The World Health Organization (WHO) and the World Bank use the three poverty lines shown in figure I.16 B.: living on US\$ 1.90 and US\$ 3.20 per capita per day (purchasing power parity of 2011) and a relative line equivalent to 60% of median total household per capita expenditure/consumption. (WHO/World Bank, 2019).

Expenditure on medicines can be part of public expenditure on health when it is an institutional expense, or it can be a private institutional expense. Otherwise it can come directly from households, in which case it is an out-of-pocket expense. Vaccines are financed publicly in nearly all countries. Most private out-of-pocket spending is to purchase medicines. In Brazil, Colombia, Ecuador, Mexico and the Plurinational State of Bolivia, medicines account for more than 50% of total out-of-pocket spending, followed by payments for outpatient services. In Chile, the Dominican Republic, and Peru, medicines are also the main out-of-pocket expense, albeit not more than half, followed by payments for hospitalization services in the Dominican Republic and payments for outpatient services in Chile (Cid Pedraza and others, 2021).

G. Policy formulation and implementation: the big picture

The region has a long track record in formulating and implementing industrial policies for the pharmaceutical industry and national or subnational health plans, even in its smaller economies. A number of lessons that can be drawn from these experiences are presented below as stylized facts closely linked to the data presented in this chapter.¹²

1. The importance of the time dimension

The time dimension for achieving short-term objectives (access to, and rollout of vaccines) is very different from that of long-term objectives (investments driven by industrial policies). As with all processes of institution and capacity building, industrial policies for the pharmaceutical industry require long implementation and maturation periods, which exceed the duration of government mandates. There are numerous examples:

- (i) The main current business and institutional developments are of long standing: Fiocruz, Brazil (1900), Butantan Institute, Brazil (1901), Liomont, Mexico (1938), Clodomiro Picado Institute, Costa Rica (1970), mAbxience (2010), of the Argentine-owned Chemo group (1977), IFV, Cuba (1991), Iclos, Uruguay (formerly Clausen) (1990s), BioCubaFarma (2012). As noted above, most of these were created during or even before the State-led industrialization strategy.
- (ii) Following the creation of the regional Joint Procurement Mechanism of the Council of Ministers of Health of Central America and the Dominican Republic (COMISCA), it took a long and sustained effort to define a regional medicines policy, which was adopted in 2007, followed by a first regional procurement exercise in 2009 and, in 2013, a system of prequalification of suppliers and products and, in 2016, a system for regional price negotiation and comprehensive automated management.

2. The key role of science and technology policies and boards

- (i) In Costa Rica, the National Science and Technology Plan (PNCTI) 2015–2021 seeks to develop an integrated health information system to evaluate the efficacy of health, clinical and preventive measures; and set up an innovation-oriented national biomedical research programme. Among other priorities, the National Bioeconomy Strategy 2020–2030 includes the promotion of a favourable business climate for the development of new biotechnological and nanotechnological products, applications and platforms, and the strengthening of biotechnological entrepreneurship.
- (ii) In Mexico, the National Council of Science and Technology (CONACYT) and Laboratorios de Biológicos y Reactivos de México, S.A. de C.V. (Birmex) signed a framework collaboration agreement in April 2021 to implement strategies to strengthen scientific research and the national production of biopharmaceuticals, vaccines, serums and reagents. The aim is to guarantee their supply and consolidate

¹² Lessons from the policy experiences that are most relevant to the lines of action proposed in this document are discussed in detail in the description of the lines of action in chapter II.

the country's self-sufficiency in this area. In July 2021, CONACYT and the National Chamber of the Pharmaceutical Industry (CANIFARMA) signed a framework collaboration agreement establishing the bases and mechanisms for joint actions to promote, develop and strengthen scientific research, technological development and innovation in the health sector.

- (iii) In Argentina, there are 89 health-related institutes affiliated to the National Scientific and Technical Research Council (CONICET), which encompasses 3,259 researchers in biological and health sciences. Among them, 24 institutes are specialized in health-related biotechnology research. The incorporation of good laboratory practices (GLP) is recent. These involve preclinical activities in the following areas: toxicity studies, mutagenicity, toxicokinetics, pharmacokinetics and preclinical safety assessment of pharmaceutical biotechnology products. There are currently eight private and public centres with this certification.

3. The advantages of a strategic approach to intellectual property

- (i) Argentina's accession to the TRIPS Agreement shows that states have several degrees of freedom in the face of international regulatory changes by not adhering to or not including intellectual property issues in the negotiation agenda of bilateral agreements. Thus, Argentina has restricted the tendency of multinational companies to apply patenting strategies that prevent incremental innovations.
- (ii) Analogously, in Brazil, the sole paragraph of article 40 of the Intellectual Property Law (No. 9279) of 1996, which extended the effective duration of patents in certain cases beyond the provision of the TRIPS Agreement (20 years from the date of application), was eliminated in May 2021.

4. The important role of the regulatory agencies

Owing to the existence of regulations on both supply conditions (quality and prices of medicines) and on demand (public sector procurement), relations between regulators, buyers and producers are at the heart of policies, particularly the crucial public procurement policy.

5. The need for competition policies

Given the oligopolistic or monopolistic structure of the markets in question, competition policies are needed. For example, in Colombia, the CONPES Social 155 report of 2012 states that the growth of national pharmaceutical expenditure in the previous decade was largely due to excess supplier-induced demand, high prices and unduly high margins. Enhanced competition would be necessary for adequate fulfilment of the pharmaceutical policy, by reducing the asymmetries of power between market agents, with benefits for the consumer and the health system. In certain circumstances, competition policy may be contradictory to industrial policy.

6. The overlap of sectoral regimes

In general, the sectoral regimes originate in three uncoordinated ministries (health, science and technology, and production) and frequently in the national development bank (for example the Programme to Support Development of the Pharmaceutical Product Chain (PROFARMA), launched in 2004 by Brazil's National Economic and Social Development Bank (BNDES). In several cases, there are also other actors —such as PAHO in drug imports in Brazil, or the states or provinces in federal or highly decentralized countries.

With regard to coordination problems, Mexico's General Health Council (CSG), which is studying the implementation of a National Pharmaceutical Policy (PNF) for April 2022, makes the following diagnostic assessment:

- (i) Fragmentation in terms of responsibilities for implementation and monitoring of actions related to the different links in the pharmaceutical chain.
- (ii) Absence of a harmonized legal framework that encompasses all regulatory instruments related to medicines and that is linked to health policies.
- (iii) Lack of a clear plan for the process of formulating a national pharmaceutical policy and participation in it by the different stakeholders.

7. The lack of coordination among national strategies

These institutional organizational problems lead to a lack of coordination in national strategies with disjointed promotion regimes and regulatory frameworks. Nonetheless, there are a number of exceptions from which lessons can be drawn:

- (i) In Cuba, the experience of BioCubaFarma demonstrates the potential benefits of coordinating actions and business policies. This State-owned business conglomerate was founded in 2012 with the aim of producing medicines, equipment and high-tech services. It encompasses 38 companies, including IFV, a centre of international prestige and recognition.
- (ii) In Brazil, the coordinated stimuli provided to domestic firms by the Industrial, Technological and Foreign Trade Policy (2003), the Productive Development Policy (2008) and the Greater Brazil Plan (*Plano Brasil Maior*) (2011–2014) boosted the transformation of the industrial structure. As noted above, the industry went from being dominated by multinational firms to having seven national laboratories (two of them public) among the country's 20 largest firms in the sector. In addition, technological development gathered pace, enabling these laboratories to develop vaccines to combat the COVID-19 pandemic.

8. The interdependence with health plans

Policies targeting the pharmaceutical industry are closely related to health plans, which absorb a large share of national budgets. These plans are more important and have more resources than science and technology or production support plans.

- (i) Mexico's Health Sector Programme 2020–2024 (PSS) —the pillars of which include universal access to health services and free medicines for the entire population, the Integrated Primary Health Care (APS-I) model, and the reorganization and regulation of health care— seeks to strengthen the national pharmaceutical industry and promote research.
- (ii) In the Productive Development Policy and the Greater Brazil Plan, mentioned above, a key instrument for scoping and scaling was government purchasing power which, in this sector, was concentrated in the Unified Health System (SUS).

9. The incentives

The incentives used are those generally applied in industrial policy: tax exemptions, supplier development, financial support for SMEs or for new firms in national territory, and financial support for R&D activities. It is also possible to use public procurement with the potential for market reservation for national firms (Uruguay) or price preference margins for SMEs or innovative firms (Argentina). Most incentives are targeted towards national firms. Transnationals are generally considered in the policy for attracting foreign direct investment.

10. Resources and institutional development

In terms of resources involved and institutional development, the region's experience contrasts with the measures adopted to boost vaccine development in the United States. These include the following: (i) participation of the Department of Defense (DoD) and creation of the Biomedical Advanced Research and Development Authority (BARDA) which finances R&D, manufacturing capacity increases and advance purchase contracts; (ii) supply contracts based on the Defense Production Act; (iii) the rapid action of vaccine manufacturers, which started large-scale manufacturing during clinical trials and combined the clinical trial stages, sometimes even carrying them out simultaneously; (iv) the signing of contracts by the federal government for the production of complementary supplies: syringes, plastic containers, needles, and (v) the amounts involved (as of July 30, 2021, DoD and the Department of Health and Human Services (DHHS) had committed US\$ 27 billion to develop, produce and distribute COVID-19 vaccines).

11. Planning and prioritization in the health sector vary

These two aspects vary between the countries of the region. Some planning processes have medium- and long-term horizons and prioritize health benefit packages or plans, as well as programmes or plans to strengthen levels of care or target specific population groups. There are also health technology assessment processes that operate in conjunction with benefit packages, generally targeted on groups with high costs or risks.

- (i) Countries with comprehensive public health systems generally have wide-ranging national health plans. Examples include Antigua and Barbuda (National Strategic Plan for Health 2016–2020), Brazil (National Health Plan 2020–2023), Colombia, Cuba, Costa Rica (National Health Plan 2010–2021), Chile (Health Objectives for the Decade 2011–2020), Mexico (Sectoral Health Programme 2020–2024), Panama (National Health Policy 2016–2025).
- (ii) Some countries prioritize a set of services, as is the case in the health systems of Chile (Plan for Universal Access to Explicit Guarantees–AUGE), Uruguay (Integrated Health-care Plan–PIAS), Peru (Essential Health Insurance Plan–PEAS), Argentina (Obligatory Medical Programme–PMO), Colombia (Health Benefits Plan–PBS) and Mexico (Universal Catalogue of Health Services CAUSES) (Gedion and others, 2016).
- (iii) Other countries, including Barbados, Guatemala, Honduras and Haiti, adopt programmes that prioritize specific services (generally related to mother and child health problems or chronic diseases in specific population groups, such as childhood cancer or HIV/AIDS).

12. Interaction with other plans

In terms of interaction with plans that extend beyond the sector, in some countries sectoral policies are linked systematically to the respective national development plans, as is the case in El Salvador, Guatemala, Mexico and Nicaragua. Others do not produce plans extending beyond the annual budget.

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Components of the plan for self-sufficiency in health matters

A. Considerations, scope, objectives and structure

1. Strategic considerations

Based on the diagnostic assessment of the health-care industry presented in chapter I of this document, the following factors can be identified as specific to this sector, and to the pharmaceutical industry in particular; and they define some of the key pillars of the plan for self-sufficiency in health matters.

The first factor to be considered is that the industry is intensive in scientific research and experimental development. Firstly, progress in medical sciences, chemical sciences, and more recently biotechnology and genomics, have led to the emergence of new treatments, medicines and medical devices. Secondly, the requirements of mass production and ever more stringent product health and safety requirements have required firms to constantly develop new production processes.

The second factor relates to the key role played by intellectual property rights, given the importance of scientific and technological research in this industry, and the need to ensure that the corresponding investments are profitable.

These two factors alone make it possible to distinguish two segments of the industry that are subject to different modes of competition: (i) products that are protected by valid patents, generally marketed through brands with pricing strategies that exploit the temporary monopoly power afforded by the patent; and (ii) “generic” products (of chemical origin) or “biosimilars” (of biological origin), which are sold in more competitive markets since the respective intellectual property rights have expired. However, this does not inhibit the original holders of the patent rights, and other competitors, from trying to differentiate their product based on their brand.

Access to current patent information, if liberalized or made more flexible, could contribute to the development of technological capacities in the countries of the region; but this is not the only barrier to be overcome, especially when there are no previously existing capabilities associated with the relevant technologies (knowledge, human resources, infrastructure, and others), such as in the production of COVID-19 vaccines based on messenger RNA (mRNA).¹

¹ It remains to be seen how the recently announced project for Pfizer-BionTech to produce its vaccine in Brazil will develop. For the time being, this is a “fill and finish” project; in other words, the active component of the vaccine would not be produced in Brazil but imported.

A third factor is that the medical product industry is one of the most heavily regulated in the world, as the health and, possibly, the lives of the individuals who consume its products are at stake. This industry operates under stringent safety, quality and efficacy regulations. Health regulation cuts across all of the processes that form the vaccine and medicine supply chain, spanning from the manufacturer, through the distributor to the point of sale or use. Regulation thus has a direct impact on the economic activity and the innovation and investment processes of pharmaceutical firms, research centres and other industry actors.

These three constituent elements of the industry, and the environment in which the institutions and firms operate (which is highly intensive in research, development and innovation, patenting and intellectual property rights, and regulation) are interrelated. Although the proposed plan specifies lines of action in these three areas, they need to be viewed in an integrated way and not considered as mutually independent.

Health-sector manufacturing industries are also generally associated with high economies of scale. Attractive markets need to be generated, in terms of both volume and stability. Given the size of most Latin American and Caribbean countries, regional cooperation to integrate markets, thereby increasing the possibilities for producers to achieve high economies of scale, together with the promotion of joint innovation efforts and the transfer of best policy practices, are three crucial elements for promoting the sophistication and growth of health-sector industries in the region.

2. Scope of the plan

Features that define the scope of the proposed plan include the following:

The plan considers both supply and demand dimensions. The demand side has elements linked to both private demand (domestic or external) and public sector demand. Given its role in the promotion of new activities, the project takes account of the institutional demand of the health system. Along with industrial policies to promote the regional production of medicines and vaccines, it is essential to have primary health systems in which the institutional framework provides the elements needed for efficient and successful distribution, administration, management and communication.

The project strategy involves increasing complementarity in production by developing value chains with the broadest possible regional scope. The main mobilizing mechanism will be investment by public and private enterprises, funded by national or foreign capital. This requires a coordinated effort to foster new businesses and the expansion and diversification of existing enterprises—in other words, industrial and technological policies. It is essential to strengthen regulatory models and the relations between regulatory entities to eliminate unnecessary trade barriers between countries.

The project defines both short- and medium/long-term initiatives. The ultimate objective of self-sufficiency in health matters for the region requires considerable investment in medium- and long-term resources, especially to build capacity in sectors or areas that are very weak or sometimes non-existent, such as mRNA vaccines. The region also has immediate or very short-term urgencies to address, such as international access to vaccines against COVID-19 to inoculate its population. The proposed plan considers lines of action in both categories.

The plan for self-sufficiency in health matters proposes regional initiatives with lines of action to be implemented at the regional or subregional level. Although a plan of this type requires capacity building within each country and recognizes the importance of national policies, its focus is not on proposals of national scope but on regional cooperation and integration.

3. Objectives and lines of action

From a medium- and long-term perspective, the ultimate goal of the plan for self-sufficiency in health matters for the countries of the Community of Latin American and Caribbean States (CELAC), is the development, expansion and competitive strengthening of research, development and production capacities for vaccines and medicines regionwide. To this end, three specific objectives are defined:

- (i) Provide a stable, large-scale market that gives clear signals and certainty for firms to invest in.
- (ii) Encourage and facilitate research and development in innovative projects.
- (iii) Support local production and integration into regional production chains.

Moreover, in view of the urgency of the COVID-19 pandemic, the fragile status of international access to vaccines and the slow progress of the inoculation processes in most countries, an additional aim is to speed up vaccination rollout, for which the following specific objectives have been defined:

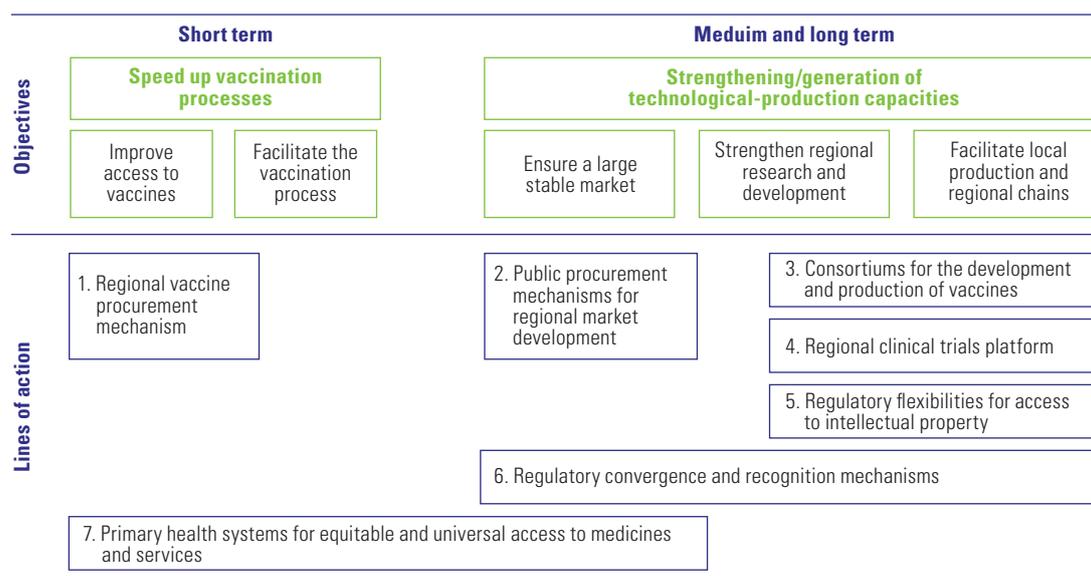
- (i) Improve international access to vaccines.
- (ii) Facilitate domestic inoculation processes.

In view of the above, seven lines of action were defined, prioritized and structured, as shown in diagram II.1.

- (i) Strengthen mechanisms for pooled international procurement of vaccines and essential medicines
- (ii) Use public procurement mechanisms for medicines to develop regional markets
- (iii) Create consortiums for vaccine development and production
- (iv) Implement a regional clinical trials platform
- (v) Take advantage of regulatory flexibilities to gain access to intellectual property
- (vi) Strengthen regulatory convergence and recognition mechanisms
- (vii) Strengthen primary health systems for equitable distribution of vaccines and universal access to them

Diagram II.1

Plan for self-sufficiency in health matters



Source: Economic Commission for Latin America and the Caribbean (ECLAC).

The lines of action are supported by an exercise to identify the key actors and assess regional capacities in research, development and production in the pharmaceutical industry. The progress associated with this supporting exercise is described in this document in the annexes under the heading “Inventory of capabilities”.

In section B, each line of action is presented in a project-fiche format, which contains the name of the line of action, its description and the objectives pursued, the corresponding rationale or diagnostic assessment, the key actors involved in its execution, the main actions that need to be implemented to achieve the objectives and the next steps to be taken.

B. Lines of action

Line 1.

Strengthen mechanisms for pooled international procurement of vaccines and essential medicines

Description and objective

The main objective of this line of action is to improve the negotiating position of CELAC countries vis-à-vis international laboratories and other mechanisms that supply vaccines and essential medicines to combat COVID-19. The aim is to gain access to a larger number of such products as soon as possible, by strengthening pooled international procurement mechanisms.

While this line of action seeks to solve an urgent problem in the very short term, it could also generate benefits when dealing with other health emergencies in the future.

Diagnostic assessment or rationale^a

Access to vaccines is highly unequal between the countries of Latin America and the Caribbean; and, more than a year and a half into the pandemic, the region remains in a complex situation. Although, in August 2021, all countries had started their vaccination rollouts, all but a few had made slow progress, and only about 24,8% of the region's population had been fully vaccinated.

This slow start reflects the difficulties faced by suppliers in meeting the agreed-upon requirements, the problems faced by many countries when negotiating with the firms, and the weak functioning of the COVAX mechanism for global access to vaccines against COVID-19, which did not deliver the vaccines to the region's countries as rapidly as required.

As mentioned in the first part of chapter I, a country can procure vaccines through various channels: through direct agreements between its government and the manufacturers; through aggregate purchases between countries; and through participation in the COVAX Mechanism, as well as through donations between countries. The ability of countries to access vaccines has been affected by economic factors (availability of funds to procure vaccines), government efficiency (some countries have performed much better than others, even when per capita income is controlled for), and political power (to influence delivery decisions by the firms).

Negotiation processes have been heterogeneous. As of mid-April 2021, at least 17 countries in Latin America had reached agreements with various laboratories through advance vaccine purchase commitments; and 14 of them would also obtain vaccines through the COVAX Mechanism. In addition, four countries are potential recipients of vaccines funded by the COVAX AMC Mechanism. Only Cuba has excluded itself from these mechanisms and opted to develop its own vaccine. In the Caribbean, however, no country has direct agreements with laboratories, although eight of them have made commitments through the COVAX Mechanism, and a further six are beneficiaries of COVAX AMC. In this context, the region has diversified its options among vaccines from the United States, Europe, Russia, China and India.

Although the region has improved its relative position on advance vaccine procurement, there is still egregious inequality of access, in terms of both the purchase of vaccines and the distribution of doses. Moreover, the heavy reliance on the COVAX Mechanism by some of the region's countries leaves them potentially vulnerable in the event of distribution delays.

The region has vast experience with joint initiatives to procure vaccines or medicines. Since the Revolving Fund for Access to Vaccines has operated under the Pan-American Health Organization (PAHO), with the aim of improving access to quality vaccines and related products at affordable prices, through joint purchasing. This is a solidarity-based cooperation mechanism for the purchase of vaccines, syringes and supplies (vaccines and immunoglobulins, syringes, cold chain equipment), in which 42 countries and territories participate. It also has a catalogue of vaccination-related products. In the Americas, the Revolving Fund operates one of the procurement channels for the COVAX Mechanism, through which PAHO Member States are recognized as a unified bloc. Also within the PAHO framework, the Strategic Fund has been operating since 1999. This is a regional technical cooperation mechanism for the pooled procurement of essential drugs and strategic public health supplies, the catalogue of which includes medicines, medical devices, and vector control equipment and supplies.

In addition to these efforts, some countries are pursuing specific initiatives through subregional integration and other international mechanisms for the purchase of medicines (see line of action 2).

^a Prepared on the basis of ECLAC (2021).

Participating institutions and actors

Country representatives

International organizations

- Pan-American Health Organization (PAHO): Revolving Fund, Strategic Fund
- COVAX Mechanism
- GAVI Alliance

Subregional integration organizations:

- Central American Integration System (SICA), Council of Ministers of Health of Central America (COMISCA)
- MERCOSUR
- Pacific Alliance
- Caribbean Community (CARICOM)
- Association of Caribbean States (ACS)
- Pharmaceutical Procurement Service of the Organization of Eastern Caribbean States (OECS)

Actions

This line of action seeks to strengthen mechanisms for the pooled international procurement of vaccines and essential medicines, by setting up permanent coordination among CELAC countries. In particular, it aims to:

- Strengthen the functioning of the COVAX Mechanism, both in each individual country and through regional representation in the PAHO Revolving Fund.
- Support the operation of the PAHO funds as a complement to COVAX, to encourage joint purchases of COVID-19 vaccines in the short term.
- Consider the possibility of pooled procurement based on subregional procurement platforms.

- Include possible financing sources to meet immediate vaccine procurement requirements, such as international or regional financial institutions (World Bank, Inter-American Development Bank (IDB), and others), donor countries and immunization partners (GAVI, Global Fund).
- Promote the exchange of information on experiences and best practices in pooled procurement mechanisms among subregional integration systems; and support these processes with technical capacity-building activities in the respective countries.

Next steps

- Convene a regional dialogue with the ministries responsible for these areas, such as Ministries of Health, Ministries of Finance and Ministries of Social Development, to discuss and advance with the creation of a mechanism for the permanent coordination of pooled procurement to meet the needs of COVID-19 vaccination plans.

Line 2.

Use public procurement mechanisms for medicines to develop regional markets

Description and objective

Public procurement mechanisms for medical products have increasingly been promoting pooled or centralized procurement, so as to improve purchasing conditions and supply chain management. Experiences range from national initiatives (municipalities, states/provinces, territorial health directorates, ministries or health institutions in the same country) to international ones (regional or global).

Pooled procurement should afford access to better prices as result of improved bargaining terms, owing to greater volume, and thus meet the needs of the health system. It is also possible to use government purchasing power as an industrial policy tool.

The central objective of this line of action is to improve, level up and coordinate national public procurement systems in a way that fosters demand for a large and stable regional market for medicines. The project aims to take advantage of public purchasing power as an industrial policy instrument which could also be used to:

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

Diagnostic assessment or rationale

Sufficient and secure regional demand can stimulate investment in production projects. The harnessing of demand necessarily involves the health system, particularly its main pillar: primary health care. This institutional level must provide the elements needed for efficient and successful distribution, administration, management and communication.

In addition, for demand to be expressed adequately, national and regional procurement mechanisms need to be established, such as consolidated or pooled and centralized joint procurement, both in individual countries and regionwide.^a This link between demand, prioritization for inclusion, and procurement mechanisms strengthened and sustained by the health system, can generate a virtuous circle between the production or availability, distribution, and use or consumption of vaccines and essential medicines.

Most Latin American countries have public procurement laws; and the corresponding regulations have formed the basis for the implementation and standardization of medicine procurement processes. The most commonly used methods involve competitive bidding. Many countries have a national formulary or list of basic medicines, which is a health policy instrument (sometimes part of a national medicines policy), since it identifies medicines that are considered essential.

Latin American countries have examples of recognized good practices in terms of central procurement centres for health products. These include Chile's National Supply Centre of the National Health Services System (CENABAST), the wide-ranging and consolidated purchases made by Brazil's strategic medicines programme associated with the Unified Health System (SUS), and the centralized procurements made by the Mexican Social Security Institute (IMSS), or the Costa Rican Social Security Fund (CCSS) in Costa Rica. In order to cover exceptional costs, some countries set up "high-cost, high-risk" coverage systems to provide medicines, such as the National Resources Fund in Uruguay, or the Intangible Solidarity Fund in Peru, associated with the Comprehensive Health Insurance (SIS), which is a public insurance system.

At the subregional level, there are several bodies that could be strengthened. In the Central American Integration System (SICA), COMISCA is the political body that seeks to identify and prioritize subregional health problems. COMISCA promoted the regional health initiative "Joint Negotiation of Prices and Purchase of Medicines" to procure medicines in an integrated way and at lower cost.

The COMISCA Joint Negotiation includes a process for prequalifying firms and their products, which are subsequently included in the price negotiation sessions, either through reverse auctions or through direct negotiations between the pre-qualified firms. This mechanism has made it possible to acquire drugs for the treatment of major diseases such as cancer, diabetes, hemophilia, cardiovascular diseases, hepatitis, respiratory distress syndrome in newborns, HIV, and also for kidney transplants.

Other regional integration bodies also have cooperation mechanisms on health matters. For example, Sub-Working Group No. 11 "Health" of MERCOSUR set up a Negotiation Group on the Prices of High-Cost Medicines. Nonetheless, institutionalized mechanisms for joint procurement, such as implemented by COMISCA, have not been promoted. In addition, in 1986, the OECS Pharmaceutical Procurement Service (PPS) was created with the aim of raising funds for the purchase of medicines for the Eastern Caribbean Member States. According to its 2016 report, the fund had about US\$ 25 million in its coffers.

Recognition should also be given to the procurement mechanisms of international organizations, such as the Revolving Fund (see line of action 1) or the Strategic Fund, both pertaining to PAHO.

In this context, priority should be given to procurement strategies that make it possible to meet essential objectives by stabilizing a minimum base of suppliers which, operating in the region, can guarantee fulfilment of the required quality standards, security and timeliness of supply, and adequate prices. To this end, it is advisable to deepen the mutual recognition initiatives that regulatory entities have been implementing in recent years (see line of action 6).

^a The centralized procurement of medicines is a procedure in which the demand for medicines from several public health institutions is consolidated for a defined period, and the procurement process is made public.

Participating institutions and actors

- Ministries of Health
- Ministries of Economy or Industry
- Subregional integration mechanisms
- PAHO

Actions

The main action involves generating a mechanism for permanent coordination among CELAC countries to:

- Level up procurement processes for medicines and technologies among CELAC countries, to support the regional procurement effort and creation of the regional market for medicines and technologies.
- Support the operation of pooled or centralized procurement mechanisms in the various forms they may adopt in individual countries, and the development of purchasing centres that have an influence on the domestic market and, at the same time, serve as important interlocutors for consolidated international purchasing.
- Exchange information on experiences and best practices in pooled procurement mechanisms, such as those associated with the operation of procurement centres, for example, CENASBAST in Chile, and mechanisms to cover high risks and costs, such as the National Resources Fund (FNR) in Uruguay.
- Promote the convergence of prioritized lists, formularies, sets of essential or basic medicines covered in health systems, including prioritization criteria.
- Support these processes with technical capacity-building activities for the countries in the relevant areas of the project; for example, in aspects such as enabling laws and standards, technology platforms, prioritization and planning of procurement and regulation.
- Establish a database of firms in the regional health industry that are certified in their manufacturing practices under standards and examination procedures agreed upon by the countries' health-sector entities, to facilitate qualification in procurement award processes by health product procurement agencies.
- Explore the possibility of forging international agreements between the countries of the region, which prioritize supply by domestic firms in emergency scenarios, such as the current pandemic.
- Strengthen regional positioning in aggregate purchasing mechanisms, such as the PAHO Strategic Fund, to incorporate criteria other than price, including local supplier development and technology transfer.

By consolidating actions of this type it will be possible to create a framework of incentives for regional firms to strengthen their quality systems, explore the possibility of expanding their scales of production by reducing costs, and give their marketing strategies a regional focus. This will enable progress in the formation of a regional production base which, on a structural basis, satisfies the quality, reliability and cost requirements of national and regional health systems.

Next steps

- Convene a regional dialogue with the ministries responsible for these areas, such as Ministries of Health and the Ministries of Industry or Economy, with a view to setting up a permanent coordinating body.

Line 3.**Create consortiums for the development and production of vaccines****Description and objective**

Strengthen manufacturing capacities in the region through regional consortiums, to make it possible to improve regional and international cooperation between vaccine developers and manufacturers, governments, multilateral organizations, financial institutions and civil society in facilitating the mobilization and deployment of economic and human resources for vaccine production. This line of action promotes:

- Regional partnership between national research institutions;
- National, regional and international collaboration between public and private institutions;
- Coordination between government agencies, such as Ministries of Health, Economy, Industry, Science and Technology, Foreign Affairs, Planning and others.

The creation of consortiums and the promotion of investment in science and technology would enable the region's manufacturing and human capital capacities to be strengthened, which will facilitate investment in R&D projects, and link public and private sector investment to lasting commitments to catalyse regional cooperation and integration.

In particular, the creation of a regional consortium would aim to: (i) diversify or consolidate existing technology platforms for vaccine production; (ii) coordinate regional technology transfer processes; (iii) support partners' efforts in vaccine discovery, production and distribution; and (iv) increase regional participation in R&D in countries both in and outside the region.

Diagnostic assessment or rationale

While some of the region's countries have the capacity to manufacture essential vaccines, there are policy actions that could make the region more health resilient. Vaccine production poses specific challenges, including process development and maintenance, lead time, production facilities, equipment, life-cycle management and product portfolio management (Plotkin and others, 2017). The planning of investment in vaccine production in Latin America and the Caribbean must take the following into account:

- Vaccine development is a lengthy, risky and expensive endeavour.
- Obstacles stemming from limited scientific, technological and manufacturing capabilities in some countries could undermine the quality and consistency required by biological processes in the manufacture of vaccine batches.

- Robust and stable manufacturing processes are needed, with constant supplies of components to ensure the long life cycle of a vaccine on the market. The choice of production technologies will have consequences for the success of vaccine production, since these technologies have a major impact on production cost, in terms of process stability and maintenance, life cycle and delivery time.
- National regulatory authorities (NRAs) need to be strengthened, since weak institutions create difficulties for product development and the plan for implementing establishments and maintaining facilities. Accordingly, their institutional capacities should be evaluated on aspects such as the supervision of pharmaceutical products and biopharmaceuticals.

Given the difficulties and needs of investment, one of the most efficient models involves the creation of consortiums between countries in the region that are sustainable, facilitate co-financing between government entities and private sector entities, and achieve high levels of impact, as measured in terms of the adoption, transfer and commercialization of their results.

The region needs to have:

- Biosafety laboratories of level III and IV to handle highly pathogenic viruses
- Biotheriums for preclinical testing
- Clinical trial units (CTUs)

Initiatives have high costs and long research project timelines. Including the proof of concept, the production of a batch for clinical trials, and phase I to III trials, a project can take between 7 and 10 years, depending on its scope and nature, and cost between US\$ 4 million and US\$ 6 million.

Funding for a regional consortium will require grants, innovation loans and public-private partnerships with national and international actors. These consortiums will strengthen links among the region's scientific community, which will relate to the scientific advances produced in the public and private sectors, while enhancing links within the research communities and between them and the business world.

In August 2021, PAHO announced the establishment of a collaborative platform to boost regional production of COVID-19 vaccines. This initiative is aimed at fostering manufacturing in the region, and includes elements relating to investment —public and private— technology transfer and regulatory capacity-building. This could be an important point of reference in discussing action line 3 in technical and operational terms.

Participating institutions and actors:

- National ministries and entities (Ministries of Health, Industry, Science and Technology, Economy, Foreign Affairs, Planning, among others)
- PAHO collaborative platform to boost regional production of COVID-19 vaccines
- COVID-19 scientific advisory boards
- National universities^a
- Clinical trial consortiums located in universities, research centres and private sector institutions and firms
- Coalition for Epidemic Preparedness Innovations (CEPI)
- Network of embassies and trade offices aimed at strengthening national efforts and promoting contacts between vaccine developers and research institutions of excellence, both nationally and worldwide
- Vaccine manufacturers in the region's countries (local and multinational firms) (see annexes 3.1 and 3.2)

^a 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. Examples in Chile are: the Pontifical Catholic University, University of Chile, University of Los Andes, Universidad Austral, Universidad San Sebastian, University of Antofagasta, University of Valparaíso, and Universidad del Desarrollo.

Actions

1. By actors^a

Governmental

- Assess their willingness to support national, regional or global investors with tax incentives, the provision of infrastructure and monetary support.
- Facilitate the necessary capacity-building among national regulatory agencies through training, or support collaboration with competent authorities in other countries and with the World Health Organization (WHO).
- Analyse the political will and economic support that exist to develop regional consortiums to facilitate pharmaceuticals manufacture.

National regulatory authorities (NRAs)

- As capacities vary from country to country, most NRAs need to build capacity in terms of vaccine quality control laboratories and technical expertise to perform batch release.
- Assess whether NRAs are willing to collaborate with WHO and relevant NRAs in other countries during an interim period to satisfy the regulatory need for oversight of vaccine manufacture and batch release.
- Promote regulatory collaboration mechanisms to facilitate the global supply of vaccines in Latin America and the Caribbean.

Vaccine manufacturers in the countries of the region

- Ascertain the critical issues for establishing vaccine production capacity. Most manufacturers face problems in accessing specialized knowledge, sources of raw materials, equipment and markets; and they are also affected by national import policies and regulatory shortcomings, such as lengthy timelines for dossier review and approval. Other critical issues are the construction of facilities, financial support and acquisition of technology.
- Analyse public-private partnership mechanisms to assess financial support for plant construction, production start-up and commitment to use the vaccine produced.

Experts from multinational companies

- Analyse research and development (R&D) costs and plant investment costs, to be taken into account in potential vaccine prices.
- Ascertain the motivations and the necessary incentives for firms to operate.

Global associations such as CEPI

- Promote high-level meetings to make financial support and the expansion of projects and lines of support in Latin America and the Caribbean feasible.

2. By implementation timelines

Short- and medium-term actions

- Promote agreements for access to sequencing data and pathogen samples. The aim is to encourage countries to promote and sign cooperative agreements for open access to genomic sequencing data and physical samples of pathogens to track emerging variants (with WHO at the global level and PAHO at the regional level).
- Form a committee of scientific, health and technology experts to evaluate technology platforms at the international level.
- Create vaccine production consortiums with technology transfer mechanisms.
- Implement reverse technology transfer mechanisms.

- Short term (6 months): Transfer “fill and finish” technology for selected vaccines, with a view to taking advantage of available capacity (with good manufacturing practices, good quality practices, and biosafety).
- Short/medium term (12 months): Coordinate technology transfer to two or three regional nodes for the manufacture of active ingredients to supply the regional market, prioritizing existing bioprocessing facilities that have good manufacturing practices, good quality practices, and biosafety (Argentina, Brazil and Cuba).
- Finance development processes in countries that are in the clinical phase on technological platforms that are compatible with production capacities, both for vaccines against COVID-19 and to combat other indigenous diseases such as Chagas.
- Structuring of training programmes (master’s and doctorate level) in vaccinology between institutions in different countries.
- Integration between training programmes and organizations with local production capacity.

Medium- and long-term actions

- Promote the creation of a regional R&D fund, to be financed by CELAC member countries, international cooperation, international organizations and philanthropic foundations. Financing to be based on both core and emergency funds.
 - Finance medium-term projects (18 to 36 months) of reverse technology transfer to public drug laboratories starting with fill and finish processes. In the long term, finance new regional nodes of production of the active substance on new technological platforms to be developed in the region.
 - Finance medium- and long-term local joint development of vaccines in consortiums with R&D organizations in the region and the rest of the world, compatible with the production capacities and platforms that have been developed.

^a The organization of this section used Makenga and others (2019) as a reference.

Next steps:

In conjunction with the focal points defined by CELAC member countries and institutions interested in this regional effort, hold a series of meetings to develop a more in-depth understanding of how to activate investment for production in Latin America and the Caribbean and create regional consortiums.

The information survey should target the following:

- National innovation, science and technology ecosystems
- National officials from governmental institutions (Ministries of Health, Industry, Science and Technology, Economy, Foreign Affairs, Planning, among others)
- NRA officials from vaccine manufacturing countries
- Members of vaccine manufacturers from developing countries
- Global vaccine manufacturers / multinational firms
- Global vaccine stakeholders

Consultation is recommended on issues related to investment costs, the benefit of self-reliant vaccine production, experience with potential challenges faced during the establishment of their facilities, government incentives and the development of regulatory capacities.

- In collaboration with experts in the field, create and evaluate a consortium partnership model for designing an action plan to build manufacturing capacity in Latin America and the Caribbean. This would include developing high-level planning scenarios for the installation of manufacturing capacity, assessing feasibility, identifying needs for the development of regulatory capacity in the region, and describing the impact that increased manufacturing and regulatory capacity would have on the introduction of new vaccines in the region and their sustainability.
- Analyse opportunities for collaboration and convergence between the plan for self-sufficiency in health matters and the PAHO collaborative platform to boost regional production of COVID-19 vaccines.

Line 4.

Implement a regional clinical trials platform

Description and objective

Clinical trials are an essential but complex step in the process of developing a vaccine, drug or treatment. Determining the safety and efficacy of new treatments by measuring their effects on human health is a prerequisite for approval and eventual marketing. However, despite the region's extensive experience in conducting clinical trials, it has been unable to take advantage of this capacity, with a few exceptions, as a tool for negotiating preferential access to markets and technology.

The objective of this line of action is to create a Latin American and Caribbean COVID-19 vaccine clinical trials network, to generate efficiencies, scale and consistency in vaccine evaluation, thereby nurturing the region's scientific prowess. A clinical trials platform will improve coordination among regional research groups working on COVID-19 vaccines and treatments; and it will enable the region to participate as a co-developer of new products by drawing on its clinical research strengths. By leveraging the region's existing infrastructure and experience, the network will serve as a starting point for developing platforms that span all stages of clinical research and other diseases affecting the region.

Diagnostic assessment or rationale

Biomedical clinical trials are conducted in four phases. Studies in phase I generally test new drugs or vaccines for the first time, among a small group of people to evaluate a safe dose range and identify side-effects. Those of phase II test treatments that have been found safe in phase I, but require a larger group of human subjects to monitor for any adverse effects. Phase III studies are conducted in larger populations and in different regions and countries; they are often the step prior to the approval of a new treatment by the regulatory authority. Phase IV studies are conducted after the drug has been applied in the population, to assess long-term effects.

The region has participated actively in all four phases of clinical trials related to COVID-19, and also in observational studies. As of 27 August 2021, the region had taken part in 614 clinical trials and 230 observational studies related to COVID-19, representing 7.6% of the global total.^a The fact that studies have been conducted by a wide range of actors, including multinational pharmaceutical companies, university research areas, hospitals and regional vaccine producers, indicates the breadth of expertise

existing in the region. However, trials for the treatment and prevention of COVID-19 have generally been small-scale and fragmented (Carracedo and others, 2020). Moreover, participation in the trials has not secured preferential access to vaccines.

The establishment of a clinical trials platform for Latin America and the Caribbean, starting with phase III clinical trials of vaccines against COVID-19, would improve the region's clinical research capacity and position it as a potential co-developer in the vaccine and treatment development process. Clinical trial networks optimize the use of scarce research resources by avoiding duplication of effort and leveraging the research expertise existing in the network. Drawing on the findings of many studies makes it possible to reach rapid conclusions as to the best candidate vaccines, generating valuable data.

Increased mutual recognition of regulatory approval decisions within the region would help to underpin the creation of a regional clinical trials platform. Mutual recognition of clinical trials in the regional reference authorities for medicines, designated by PAHO and WHO (Argentina, Brazil, Chile, Colombia, Cuba and Mexico) would be an important first step in this direction.

^a Data from the International Clinical Trials Registry Platform (ICTRP) of the World Health Organization. See [online] at <https://www.who.int/clinical-trials-registry-platform>.

Participating institutions and actors

The establishment of a clinical trials network requires close collaboration between the academic sector, private industry and government. Technical support from WHO and PAHO will be essential.

Academic sector and clinical research centres

- Research centres implementing clinical trials (see annex 4.1)
- Universities and research foundations
- Research hospitals

Industry

- Pharmaceutical industry chambers and associations (see annex 4.2)
- Chambers of contract research organizations

Government

- Ministries of Health
- Clinical Trial Registration and Regulatory Authorities

Actions

- Set up a regional network to develop the phases of clinical studies for COVID-19 vaccines and treatments. The core components of the network structure will be clinical research sites, an operations centre, a scientific advisory committee and a supervision structure.
 - Research and clinical trial sites that are already conducting trials of COVID-19 vaccines and treatments will form the nucleus of a regional network of medical and research institutions, in which vaccine trials are conducted under the supervision of lead researchers.
 - The network will be coordinated by a secretariat embedded in a regional centre of excellence, to supervise and support the network. Its functions could include evaluation, training and strategic, operational and business planning, as well as coordination and administration of the network's research activities.

- A scientific committee comprising leading researchers will oversee the network’s research agenda.
- A data safety and monitoring board will evaluate the overall progress of the clinical trials, with a special focus on safety and efficacy data.
- Coordination and governance mechanisms for the clinical trials network will be developed in consultation with network members.
- Seek out areas of policy convergence in collaboration with the regulatory entities to support the activities of the regional clinical trials network.

The successful functioning of a regional network of phase III clinical trials of vaccines and treatments could lead to expansion into all phases of the COVID-19 vaccine clinical trial process and, possibly, into other regional clinical trial networks for other diseases.

Next steps

- Convene a meeting of key stakeholders and institutions that would be interested in joining the clinical trials network. The meeting will seek to identify participants in each of the network nodes and discuss possible network governance structures.
- Identify potential sources of seed funding for grants to finance the creation of the network.
- Establish a strategic plan for the creation and sustainability of the network.
- Convene a meeting of level IV regulatory agencies to discuss the regulatory convergence of clinical trials.

Line 5.

Take advantage of regulatory flexibilities to gain access to intellectual property

Description and objective

Improving the procurement and production of vaccines, drugs and medical equipment by making use of the regulatory flexibilities that exist in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), could encourage greater access to these goods in the region. So also could promoting the ongoing negotiations at the World Trade Organization (WTO) for a waiver of intellectual property right (IPR) protections in respect of the technologies needed to prevent, contain or treat COVID-19.

This line of action promotes capacity building to update the relevant legislation and take advantage of TRIPS flexibilities to improve access to vaccines, medicines and medical equipment, and to make them more affordable. Activities in this line of action will support capacity building and the sharing of knowledge and experiences to address the COVID-19 pandemic and future health emergencies. It will also create mechanisms through which the region’s countries can develop common positions in the ongoing discussions at WTO for a waiver of intellectual property rights during the pandemic.

Diagnostic assessment or rationale

Signed when WTO was created in 1995, the TRIPS Agreement aimed to create a global intellectual property rights (IPR) regime, based on the harmonization of legal standards in developed countries. Under the TRIPS IPR regime, WTO member States must grant product patents and exclusive marketing rights to producers for defined periods of time (usually 20 years). In a highly concentrated and R&D-intensive market, such as that of pharmaceuticals, patent protection has allowed companies to set high prices in order to recover R&D costs. However, this system has put many drugs beyond the reach of developing countries. Moreover, debates over the interpretation of certain articles of the agreement, for example in relation to the exclusivity of clinical trial data, have sometimes erected additional barriers to accessing medicines.

To ensure access for developing countries, the TRIPS Agreement offers governments some degree of flexibility in the management of patents on critical goods such as pharmaceuticals (see table II.1).

Table II.1

Flexibilities in the Agreement on trade-related aspects of intellectual property rights (TRIPS Agreement)

Measure	Article	Definition
Compulsory licensing and non-commercial public use	Art. 31	Governments are allowed to authorize a party other than the holder of a patent on an invention to use that invention without the consent of the patent holder, on the condition that efforts have been made to obtain the authorization from the right holder, or in cases of national emergency.
Parallel imports	Art. 6	The import and resale of a product from another country (where the same product is legitimately for sale at a lower price) without the consent of the patent holder.
Exceptions to rights conferred	Art. 30	WTO Members may provide limited exceptions to exclusive rights conferred by a patent (for example, the regulatory (Bolar) exemption ^a and research exemptions).

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of Burlamaqui and Cimoli, 2014. "Industrial Policy and IPR: A Knowledge Governance Approach", *Intellectual Property Rights*, Oxford University Press, 2014.

^a These exemptions are often referred to as "Bolar" exemptions in reference to a law that was enacted in the United States after a court ruling in the case of Roche Products, Inc. vs. Bolar Pharmaceutical Co., Inc. (1984). This mechanism allows the conduct of trials to establish the bioequivalence of generic medicines before the expiry of the patent

The Declaration on the TRIPS Agreement and Public Health, approved at Doha in 2001, and the amendment to the TRIPS Agreement that entered into force in 2017, confirmed the right of countries to use compulsory licensing and other flexibilities to safeguard health, and their freedom to determine the grounds for compulsory licensing.

Compulsory licenses are the most widely used TRIPS flexibility, with 100 compulsory licenses or public licences for non-commercial use having been issued between 2001 and 2016 (Hoen and others, 2018). Compulsory licenses allow a patent to be used without the patent holder's authorization. Specifically, the issuance of a compulsory licence for a pharmaceutical treatment allows a government to manufacture locally, or import, generic versions of the treatment without the patent holder's consent. The licences may be granted for a number of reasons, including to remedy anti-competitive practices or because the patent is not being used; when the patented drug is inaccessible due to high cost or unavailability; when the patent holder refuses to license the patent to other qualified producers, including domestic producers; when there is a risk of shortages; and when public health is at stake.

The laws of Latin American and Caribbean countries provide different rationales for compulsory licensing (see annex 5.1). Some countries have benefited from the use of these provisions and have obtained significant cost reductions and increased access to medicines. In the context of the COVID-19 pandemic, Brazil, Chile, Colombia and Ecuador have amended their laws to facilitate compulsory or government licensing to combat the pandemic.

However, the use of TRIPS flexibilities faces problems. Since the specific application and granting of compulsory licenses or government-use licenses are subject to the provisions of the applicable national law, enabling legislation and institutional mechanisms need to be in place. Moreover, as discussed in chapter I, “TRIPS-plus” provisions in free trade agreements have imposed additional restrictions on countries’ access to intellectual property and, at times, have induced “regulatory chill”. Recent developments in the pharmaceutical industry, and the specific characteristics of certain vaccines against COVID-19, could make the use of compulsory licensing in the context of the pandemic extremely difficult.

Firstly, some vaccines against COVID-19 are protected by multiple forms of intellectual property rights, including patents, copyrights, industrial design, undisclosed data, and trade secret protections. These “patent thickets” have made compulsory licensing difficult, since each protection would require a separate license.

Secondly, the global supply chains used in vaccine production make it difficult to implement TRIPS flexibilities that rely on product-specific and country-specific compulsory licensing. Entities wishing to produce vaccines through compulsory licensing must apply for licenses for each IP-protected input and in its country of manufacture and export.

Thirdly, some of the countries that attempted to use TRIPS flexibilities were threatened with sanctions by drug producers and by the countries in which they are based.

For these reasons, some analysts argue that the only way to access the intellectual property needed to produce the vaccines needed to end the pandemic is through a broader waiver of TRIPS protections. A proposal brought by India and South Africa for a temporary waiver of certain TRIPS obligations in response to COVID-19 is currently being discussed in the WTO TRIPS Council.

The proposal, initially tabled in October 2020 and revised in May 2021, would cover obligations in four sections of the TRIPS Agreement: on copyright and related rights, industrial designs, patents and the protection of undisclosed information. The waiver would last for at least three years, whereupon the circumstances justifying the waiver would be reviewed.

Although rates of vaccination against COVID-19 in Latin America and the Caribbean have lagged behind those of developed countries, the region has failed to reach a unified position. Only the Bolivarian Republic of Venezuela and the Plurinational State of Bolivia co-sponsored the revised May 2021 proposal; and while Argentina, Brazil and Mexico have expressed support for a temporary patent waiver, most other Latin American countries have chosen to maintain an ambivalent stance. A unified consensus-based position for the region would send a strong signal of the importance of this measure for Latin America and the Caribbean.

Participating institutions and actors

This line of action seeks to build on existing initiatives to expand access to intellectual property to enable increased production and procurement of medicines, vaccines and medical equipment in CELAC member countries. In particular, WHO, the World Intellectual Property Organization (WIPO) and WTO are cooperating on issues related to public health, intellectual property and trade, including the organization of a series of workshops for policymakers to build capacity to address the pandemic.

This line of action seeks to increase the capacity of CELAC member countries to implement relevant legislation and mechanisms, through workshops and dialogues that convene key actors from international organizations, national governments and regional integration mechanisms.

International organizations

- WIPO
- WTO
- WHO/PAHO

National governments of CELAC member countries

- National intellectual property institutes
- Ministries of Health
- Foreign trade ministries
- Antitrust authorities
- Departments responsible for compulsory licensing

Regional integration mechanisms

- Andean Community
- Pacific Alliance
- MERCOSUR
- SICA
- CARICOM

Actions

The line of action will consist of the following activities:

- Training workshops and exchanges of experience aimed at strengthening the capacity of CELAC member governments to access intellectual property for medicines, vaccines and medical equipment. These workshops will address issues such as intellectual property legislation and institutions, licensing alternatives, the implementation of TRIPS Agreement flexibilities, the treatment of intellectual property in free trade agreements and technology transfer. A key element of these workshops will be peer learning and mutual understanding of the different intellectual property regimes existing in the region.
- In addition, a regional dialogue will be held on the proposal for a waiver of intellectual property rights currently being negotiated in WTO, to discuss the positions of CELAC member countries with the aim of promoting regional convergence.
- These activities are expected to generate additional demand for specific technical assistance to address the needs of the various CELAC member countries.

Next steps

- Hold an initial round of consultations with CELAC member countries to determine the intellectual property issues in which they require support.
- In coordination with WHO, PAHO, WTO and WIPO, launch the series of training workshops for CELAC member countries. A first workshop will compare variants of intellectual property regimes in the region and highlight country experiences in using flexibilities to facilitate experience sharing and peer learning.
- Convene a regional dialogue with foreign trade ministries on the negotiations in WTO for a waiver of intellectual property rights.

Line 6.**Strengthen regulatory convergence and recognition mechanisms****Description and objective**

Medical product regulators play a central role and are key players in health systems. Their actions affect not only the health system itself, but also the economy and the development of the health industry, since their decisions have a cross-cutting effects on the drug supply chain. Insofar as national regulatory capacities are strengthened, and regulations are harmonized and convergent between the countries of the region, people's health will be protected, and production and trade in this industry will be boosted.

The objective of this line of action is to foster regulatory convergence and recognition of health registrations among regulatory entities, in order to improve, create or complement national capacities and thus facilitate local production, commercial exchange and regional production self-sufficiency. Regulatory agencies are thus key players in both competition policy and industrial policy.

The specific aim is to optimize the authorization or registration of medicines, in order to have a network of countries in which, ideally, a medicine is registered in one and, through an expeditious procedure, that registration is recognized in the other countries of the network.

Diagnostic assessment or rationale

The production and marketing of medicines, and also that of other medical products, is one of the most heavily regulated activities in the world, since the health and potentially the lives of the people who consume these products are at stake. The absence of regulatory standards, or their inadequacy, can put the safety of the population at risk.

National regulatory authorities oversee the safety, quality and efficacy of medical products and therefore constitute a central actor in health systems. They have the following main functions:^a

- Registration (licensing) of products
- Inspection and licensing of manufacturers
- Inspection and licensing of distributors
- Post-marketing surveillance
- Regulation of any claims made to promote the products commercially
- Authorization of clinical trials

The actions of these entities directly affect economic activity, the development of the health care industry, and firms' investment, research and development, and marketing decisions.

Regulations define market entry barriers for medical products and, ultimately, decide whether or not a product can be put on the market. The processes of approving a product also influence its speed of entry on the market. Moreover, the degree of regulatory harmonization and convergence between countries, or the mutual recognition of regulatory decisions, can have a direct influence on international trade and the possibility of establishing regional production and distribution chains for medicines and vaccines.

Health regulation capacities vary across the region; and PAHO has developed a tool, based on WHO recommendations, to assess the capacities of national regulatory systems. Application of this tool makes it possible to classify national regulatory agencies (NRAs) into four categories, the highest being Level IV,

which is defined as a “National regulatory authority that is competent and efficient in performance of the health regulation functions recommended by PAHO/WHO in order to guarantee the safety, efficacy, and quality of medicines.” These are also referred to as regional reference authorities (NRAR) for medicines.^a

PAHO has evaluated 27 regulatory systems (25 from Latin America and the Caribbean, plus those of the United States and Canada), and found that eight (including those of the United States and Canada) meet the requirements to be designated as regional reference authorities (PAHO, 2020). The six NRAs of regional reference in Latin America and the Caribbean are:^a

- (i) Argentina: National Drugs, Food and Medical Technology Administration (ANMAT)
- (ii) Brazil: National Health Surveillance Agency, Ministry of Health (ANVISA)
- (iii) Chile: Public Health Institute (ISP)
- (iv) Colombia: National Drug and Food Surveillance Institute (INVIMA)
- (v) Cuba: Centre for State Control of Medicine Quality, Ministry of Public Health (CECMED)
- (vi) Mexico: Federal Commission for Protection against Health Risks (COFEPRIS)

Based on the analysis of the regulatory capacities of the 35 member states, PAHO concludes that four groups of countries can be distinguished (PAHO, 2014):

- (i) Eight countries with national regulatory authorities of regional reference
- (ii) Thirteen countries that have the necessary legal bases and organizational structures to have a comprehensive regulatory system
- (iii) Seven countries that have some of the legal bases and organizational structures necessary to have a regulatory system
- (iv) Seven of the countries do not currently have the legal basis and organizational structures for a regulatory system

There is a positive correlation between the size of countries and their regulatory capacity.

The foregoing sets the stage for a scenario that requires not only regulatory harmonization and convergence between countries, but also strengthening of the domestic capacities of each country.

PAHO has suggested strategies to support smaller countries and countries with weakened capacities, including:

- Regionalization: the process whereby countries that are geographically or culturally close to each other “combine their resources, harmonize disparate rules and processes, and/or rely on and share common information and policies to establish a collective system that is stronger and more efficient than what would be feasible individually.” It adds that “the concept is becoming increasingly common around the world, particularly in economic communities, and regionalization exists in Europe, Africa, the Middle East, and Asia.”
- Use and recognition of decisions of other regulatory authorities: the use of information or assessments made by an institution in another country. PAHO notes that “Recognition may be unilateral, bilateral, or multilateral, and may be the subject of a policy or legal agreement. Numerous authorities in the region practice some form of reliance, and a common application of reliance is in the marketing authorization function, where for example, a regulatory system may use the results of another’s assessment report to help make a decision about approval of a particular product.”

^a See “About the Quality and Regulation of Medicines and Health Technologies Projects” [online] at https://www3.paho.org/hq/index.php?option=com_content&view=article&id=2384:acerca-calidad-regulacion-medicamentos-tecnologias-sanitarias&Itemid=1179&lang=en.
See “System for Evaluation of the National Regulatory Authorities for Medicines” [online] at https://www3.paho.org/hq/index.php?option=com_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=1179&lang=en.
See PAHO (2021b) for a detailed assessment of these six entities.

Participating institutions and actors

Three types of actors are central: the established regulatory agencies, or agencies that could perform this role in each country; subregional integration agencies; and international support agencies, in particular PAHO. (The list of regulatory agencies evaluated by PAHO is presented in annex 6.1.) In particular, the participation of the six regional reference regulatory agencies is crucial:

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

The collaboration networks and subregional mechanisms to be considered are as follows:

- The Pan-American Network for Drug Regulatory Harmonization (PANDR) of PAHO
- COMISCA of SICA
- The Caribbean Public Health Agency (CARPHA) of CARICOM
- Working Subgroup No. 11, on Health Of MERCOSUR
- The Technical Subgroup on Regulatory Cooperation in Pharmaceutical Matters of the Pacific Alliance

Actions

- Strengthen existing mechanisms and forums for discussion of the harmonization, convergence and recognition of drug regulations: in order to have a network of countries with harmonized regulations in which, ideally, a drug is registered in one country, and that registration is recognized in the other countries of the network through an expeditious procedure.

The following are considered, in particular:

- Generate a virtual repository of clinical data: in which all companies should enter information on their registration applications and dossiers; and regulatory entities could retrieve the information necessary for the registration processes.
- Establish an observatory of good regulatory practices. This information would be very useful, not only for the respective regulatory authorities, but also for the industry itself.
- Create a regulatory convergence card to determine equivalence in terms of general requirements for the sanitary authorizations of medicines and vaccines; it will also make it possible to identify the regulatory gaps that exist between national level IV regulatory authorities. This could be the basis for moving towards regional sanitary authorizations, specifically to address local or global health emergencies.
- Create a package of tools that makes it possible to strengthen both level-IV NRAs and those that are still at a lower level. This package can be implemented on the basis of the following pillars: (i) strengthening of the institutional capacities of the regulatory authorities with a robust quality management system; (ii) the implementation of communication and innovation strategies that allow better interaction between their functions and with the industrial sector; (iii) creation or strengthening of laboratories to enable much more expeditious decision-making and risk prevention; and (iv) strengthening of pharmacovigilance and post-marketing programmes with a national and regional vision.

- Establish a programme of visits and exchanges between the different regulatory authorities in the region, to enable them to gain a better understanding of regional problems from the standpoint of the different sectors on which regulatory decisions have effects.

Although the central focus of this work should be the PAHO Pan American Network for Drug Regulatory Harmonization (PANDRH) and, in the first instance the six national regulatory authorities of regional reference, the task should be extended and deepened at the subregional level in institutions such as SICA, CARICOM, Mercosur and the Pacific Alliance.

The joint actions that this network should undertake include the inspection of laboratories, both in and outside the countries forming part of it, of the laboratories that supply medicines to Latin America and the Caribbean, through coordinated visits aimed at ensuring the quality of these suppliers.

Next steps

- Establish guidelines and specify responsibilities for collaboration between ECLAC, PAHO and CELAC.
- Convene technical-political dialogues: (i) among the national regulatory authorities of regional reference; and (ii) in the different subregional organizations, to inform them about the CELAC initiative, validate the proposal and coordinate the technical work.

Line 7.

Strengthen primary health systems for equitable distribution of vaccines and universal access to them

Description and objective

Strengthen primary health care systems in a comprehensive manner, focusing on (i) the strengthening of national vaccination plans and the logistics to implement them; (ii) vaccine management and distribution; (iii) follow-up and monitoring of both vaccination plans and safety and effectiveness; (iv) strengthening of registries and information systems, to manage mobility and traceability of people and the evaluation and improvement of communication and information programmes for citizens, and other health programmes and sectors that have links with immunization at the local level.

Diagnostic assessment or rationale

Health policies and programmes are vitally important for a regional strategic health plan proposal that includes universal access to vaccination. The health systems and, in particular, the first level of care (primary health care) is a main pillar of the policy, given its link with the population and the response to the health problems presented—in particular, the need for containment of the COVID-19 pandemic. In this context, the first level of care, which ought to be responsible for the implementation of public health measures, such as testing, traceability, isolation and others, is complemented by the rollout of national mass vaccination plans.

Most countries are striving to develop their health systems to achieve universal access and coverage, by strengthening their primary health care strategy, by expanding and consolidating the first level of health care with increased capacity to solve problems that affect the health situation of individuals and communities, on a sustainable basis. The primary level also acts as a catalyst for the rest of the health network, assuming a large part of its coordination. This strategy includes the creation of multidisciplinary teams that perform the tasks of promotion, prevention, protection, diagnosis, treatment, rehabilitation, damage reduction, palliative care and health surveillance.

In this context, planning and prioritization processes in the various countries need to be reviewed, as do the shortcomings of the health systems and primary care, and how these conditions have been expressed in the vaccination plans. This will make it possible to generate ideas for strengthening proposals that could be supported under the project.

Using public health criteria, the health authorities in the region's countries have prioritized vaccination for health-care workers, persons over 55 years of age and persons with certain comorbidities. In addition, nearly all countries prioritized teaching and non-teaching staff in educational institutions. However, given the criteria used in several cases, access has not incorporated equity criteria; and this has generated inequalities and relative disadvantages for certain vulnerable groups.

Most countries in the region report vaccination uptake rates of over 65%, which is higher than the rates achieved in North America and Europe. People's doubts centre on the speed with which the process of developing vaccines was carried out, and the rigour required in the approval processes; assurance of their efficacy and safety; uncertainty about possible adverse effects; and the lack of reliable data and the proliferation of fake news (UNESCO, 2021).

In developing their national strategies for the COVID-19 vaccine roll-out, countries should include activities to strengthen immunization programmes and plans, health services and health systems, with cross-programme collaboration. In addition, for countries to be able to implement COVID-19 vaccination in a timely and appropriate manner, multisectoral collaboration is needed, involving high-level technical experts from relevant ministries and departments, as well as key in-country partners (PAHO, 2021a).

The operational activities to be coordinated within primary care in the vaccination roll-out process are important and include territorial planning (micro-plans), strengthening of human resource management, vaccine training, establishment of new points of contact for vaccination considering target groups, adopting traceability systems and technologies to ensure the integrity and efficiency of supply chains, in order to improve and expand comprehensive disease surveillance, and systems for monitoring and notifying adverse events associated with the vaccination. It also includes integrated advocacy and communication activities to promote the demand for vaccination as part of an overall increase in demand and uptake of all essential primary health care services. At the same time, it must ensure the vaccination of vulnerable groups, and the coordination of immunization programmes with other health programmes (older adults, women and migrants, among others) and those of other sectors at the local level (education and other social sectors).

Financing COVID-19 vaccination is a priority government responsibility and requires close coordination between the Treasury Department or Ministry of Finance, the Ministry of Health, and other line ministries.

While vaccines may be available, in-country distribution may be insufficient owing to lack of funds to cover operational costs or organizational failures in primary health care programmes and services. Plans should take into account these problems and ways to overcome them. It is also necessary to make sure that funding for COVID-19 vaccination is linked to three steps: robust costing of a realistic plan, promotion and active participation by the health sector in budget preparation; and the subsequent monitoring and evaluation of expenditures.

COVID-19 vaccination should be integrated into routine national health planning and budgeting processes, national immunization and sector plans and regular health-sector activities. Financing COVID-19 vaccination is not only a matter of identifying resource gaps and overcoming them; another critical issue is how budgets flow through the different levels of government and through the health system, to be spent on different first-level providers (PAHO, 2021a).

Greater flexibility does not necessarily mean less accountability and less monitoring of results. In fact, greater budget flexibility is generally associated with greater transparency and accountability, since budget holders are also accountable for the results (PAHO, 2021a).

Participating institutions and actors

- Ministries of Health
- Treasury Departments of Ministries of Finance
- Local or subnational authorities
- Directorates of health service networks
- First level of care or primary health care

Actions

- Support the development of comprehensive primary health care to ensure equitable access to services and vaccines by individuals and communities.
- Strengthen mechanisms for participation in pooled procurement at the first level of health care, ensuring adequate distribution and availability of vaccines and essential medicines.
- Improve planning, operation and management processes for the implementation of immunization and associated programmes in primary health care systems.
- Promote mechanisms for the exchange of information on experiences and best practices in the development of primary health care and the rollout of vaccination plans, both nationally and internationally.
- Prioritize funding for primary health care, considering that of the regional target of at least 6% of GDP for public expenditure on health, as agreed by the countries of the region in the framework of PAHO (PAHO, 2014), at least 30%, should be allocated to the first level of care.
- Address the deficit and inefficient distribution of human resources in health, both in terms of hospital specialists and at the first level of care, where their shortage has been a major problem during the COVID-19 pandemic.
- Strengthen the technical capacities of the key actors in the first level of care, the primary health care strategy and all levels that participate in their development.

Next steps

- Hold national and regional meetings with the agencies involved in the improvement of health systems, particularly the first level of care, and with a focus on the distribution of vaccines and medicines, in order to agree on a joint work plan.

- Promote an agreement on best practices and criteria for the availability, management, and distribution of vaccines and medicines at the primary care level, to support care models that strengthen primary health care.
- Establish common mechanisms among the countries to overcome the chronic weaknesses of the first level of health care, particularly the deficit in human resources and their inefficient distribution.
- Organize meetings to establish the financing requirements for improvements or transformations and levelling-up between countries, the health system and primary health care, to make sustainable plans for universal access to primary health care, medicines and technologies.
- Develop capacity-building activities in the area of universal access to medicines and technologies, in both general and specific aspects related to management for availability.
- Investigate ways to finance pilot projects to improve management in priority areas of primary health care, and to improve health system performance generally, in order to achieve universal access to medicines and technologies.

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Inventory of capabilities

Line of action 3

3.1 Vaccine development in Latin America and the Caribbean, including vaccines against COVID-19¹

1. Ongoing research

Country: Cuba

Summary: Cuba has developed five vaccines, of which three have been approved for emergency use and are being administered widely (Abdala, Soberana 02 and Soberana Plus) and two that are still in clinical trials (Mambisa and Soberana 01).

Cuba: vaccines researched

Laboratory	Vaccine	Specifications	Dosage	Efficacy	Phase
Centre for Genetic Engineering and Biotechnology	Abdala	Coronavirus protein Receptor-binding domain (RBD)	3 doses	92.28%	Emergency approval in Cuba In process of approval in Mexico ^a
Centre for Genetic Engineering and Biotechnology	Mambisa	Coronavirus protein + hepatitis B protein	Nasal spray	...	Phase I
Finlay Institute of Vaccines	Soberana 01	Coronavirus protein + bacterial proteins and aluminium hydroxide	Phase II
Finlay Institute of Vaccines	Soberana 02	Coronavirus protein + tetanus vaccine + aluminium hydroxide	2 doses	62%	Emergency approval in Cuba Emergency approval in Iran under the name Pasteur
Finlay Institute of Vaccines	Soberana Plus	Coronavirus protein receptor-binding domain (RBD)	1 dose	Combined with Soberana 02: 92%	Emergency approval in Cuba

^a The New Molecules Committee of the Federal Commission for Protection against Health Risks (COFEPRIS) ruled to approve the Abdala vaccine for emergency use, indicating its therapeutic use for active immunization against COVID-19. The next step is for the pharmaceutical company to submit dossiers for expert review by the Health Authorization Commission (CAS).

Laboratories:

- Centre for Genetic Engineering and Biotechnology
 - Established in 1986.
 - Research has focused on the fight against infectious diseases such as Dengue and HIV.
 - The vaccine department works on R&D for vaccines against hepatitis B, hepatitis C, dengue fever, and meningococcal meningitis, as well as the development of new adjuvants and immunopotentiators.

¹ In this section, the symbol of three dots [...] refers to data not available or not reported.

- The Institute has over 1,500 employees, 4 locations and more than 25 products, including the Heberpenta®-L vaccine (diphtheria, tetanus, whooping cough, hepatitis B and haemophilus influenzae type b (Hib)); Heberbiovac HB® (hepatitis B) vaccine; and Quimi-Hib® (Haemophilus influenzae type b (Hib) vaccine designed for children aged 2 months to 5 years).
- Finlay Institute of Vaccines
 - Established in 1991.
 - Forms part of the Cuban Fund for Science and Innovation (FONCI) of the Ministry of Science, Technology and Environment of Cuba.
 - It has developed vaccines against meningococcal disease caused by serogroups B and C; meningococcal disease caused by serogroups A and C; leptospirosis disease; tetanus; typhoid fever; and others.

Country: Mexico

Summary: According to CELAC reports, Mexico has six vaccine projects in various stages of development. The most advanced is the Patria vaccine, currently in phase I and developed with the Icahn School of Medicine at Mount Sinai and based on the Newcastle disease virus (NDV). The vaccine is also being researched, under other names, in Brazil and Thailand.

Mexico: vaccines researched

Laboratory	Vaccine	Specifications	Dosage	Efficacy	Phase
Avi-Mex CONACYT UNAM IMSS INER	Patria	NDV is a pathogen that infects birds and does not cause symptoms in humans. The virus was modified to carry the gene for a modified version of the coronavirus protein called HexaPro. The modified virus was grown in chicken eggs and combined with adjuvants	Phase I
Instituto Gould-Stephano	Livion.vac	Nucleic acids	Preclinical
National Autonomous University of Mexico and Alpha Pharma Laboratories	UNAM/AP-rP9	Recombinant technique, which consists of producing the vaccine in bacterial cultures, so it does not contain adenovirus	Preclinical
Cinvestav	NG19M	Recombinant protein	2 doses	...	Preclinical

Laboratories:

- Avi-Mex
 - Established in 1952.
 - Devoted mainly to the research, development, manufacture, import, export and marketing of biological, pharmaceutical, disinfectant and mycotoxin detoxifiers for animal health.
 - Avi-Mex produces over 2 billion doses of vaccines per year and has a presence in more than 25 countries.
 - It produces vaccines for poultry and swine, as well as medicines for poultry, swine, cattle and aquatic animals.
 - Patria vaccine research is conducted with support from National Council on Science and Technology (CONACYT) and in collaboration with the Mexican Institute of Social Security (IMSS), the National Autonomous University of Mexico (UNAM) and the National Institute of Respiratory Diseases (INER).²
- Gould-Stephano Institute
 - An institute recently established by a group of Mexican biotechnologists.
 - Created with the aim of researching and developing a vaccine against COVID-19.
 - Working in laboratories of the Bioprocesses Development and Research Unit of the National Polytechnic Institute.

² See [online] <https://avimex.com.mx/noticias-y-eventos/38>.

- Centre for Research and Advanced Studies (Cinvestav)
 - The Centre for Research and Advanced Studies of the National Polytechnic Institute was created in 1961 by presidential decree and is devoted to the development of science, technology and graduate education.
 - It has 28 lines of research, including cellular biology, molecular biomedicine, biochemistry and biotechnology.
- Alpharma Laboratories
 - A Mexican laboratory of nearly 50 years of experience in generics, pharmacovigilance and over-the-counter medicines.
 - It has several research centres: CedProf (a research and development centre for differentiated products); Cidat (a centre for pharmacovigilance, research and early detection of clinical alterations); and CIM (a drug information centre).

Country: Brazil

Summary: In Brazil, the Butantan Institute is developing the ButanVac vaccine in conjunction with the Icahn School of Medicine at Mount Sinai, based on the Newcastle disease virus (NDV). It is currently in phase I. The vaccine is also being researched, under other names, in Mexico and Thailand.

Approval to conduct clinical trials has been requested for three other vaccines: one from the Faculty of Medicine of Ribeirão Preto - University of São Paulo, with the company Farmacore and PDS Biotechnology (both of the United States); one from the Federal University of Rio de Janeiro; and one from the Federal University of Minas Gerais.

Brazil: vaccines researched

Laboratory	Vaccine	Specifications	Dosage	Efficacy	Phase
Butantan Institute	ButanVac	NDV is a pathogen that infects birds and does not cause symptoms in humans. The virus was modified to carry the gene for a modified version of the coronavirus protein called HexaPro. The modified virus was grown in chicken eggs and combined with adjuvants	Phase I
Federal University of Rio de Janeiro	S-UFRJvac	Recombinant SARS-CoV-2 spike protein	Preclinical approval has been requested to conduct clinical trials
Faculty of Medicine of the University of São Paulo (FM-USP)	Versamune CoV-2FC	Coronavirus protein combined with epitope-specific T cells (viral antigens) Nasal spray	Preclinical approval has been requested to conduct clinical trials
CT-Vacinas of the Federal University of Minas Gerais	SpiN-TEC	Genetic modification of E. coli bacteria with parts of coronavirus to produce S and N proteins	2 doses	...	Preclinical approval has been requested to conduct clinical trials
State University of Ceará	...	Attenuated avian infectious bronchitis virus	Preclinical

Laboratories

- Butantan Institute
 - Founded in 1901 as a result of the bubonic plague of 1900.
 - A public institution reporting to the State Secretariat of Health of the State of São Paulo.
 - It is the main producer of immunobiological products in Brazil, manufacturing a large percentage of the country's hyperimmune serums and the national production of vaccine antigens, which are used in the vaccines administered under the National Immunization Programme of the Ministry of Health.
 - It has over 2,000 employees, 300 of whom work on the production of the CoronaVac vaccine.

- CT-Vacinas (Federal University of Minas Gerais)
 - A biotechnology research centre.
 - Partnership established between the Federal University of Minas Gerais (UFMG), the René Rachou Institute of the Oswaldo Cruz Foundation (Fiocruz-Minas) and the Belo Horizonte Technological Park (BH-TEC).
 - It has a team of 40 researchers and laboratories working on immunochemistry, recombinant proteins and molecular biology, among other areas and equipment.

Country: Argentina

Summary: Argentina has several vaccine projects in preclinical phases, the most advanced being the ARVAC Cecilia Grierson vaccine, developed by the National University of San Martín and the Cassará Laboratory; the Argenvac221 vaccine of the National University of La Plata; the vaccine developed by the Universidad del Litoral and the laboratories Cellargen Biotech SRL and Biotecnofe SA; and the vaccine developed by the Leloir Institute with the biotechnology company Vaxinz. The four projects mentioned are supported by the National Scientific and Technical Research Council (CONICET).

Argentina: vaccines researched

Laboratory	Vaccine	Specifications	Dosage	Efficacy	Phase
National University of San Martín Cassará Laboratory CONICET	ARVAC Cecilia Grierson	Receptor-binding domain (RBD) of SARS-CoV-2 spike protein expressed as a recombinant in mammalian cells based on stable producer clones + adjuvant	Preclinical
National University of La Plata CONICET	Argenvac221	Nanoparticles with SARS-CoV-2 protein fragments	Preclinical
Universidad del Litoral Cellargen Biotech SRL Biotecnofe SA	...	Recombinant proteins	Preclinical
Leloir Institute Vaxinz CONICET	...	Hybrid adenoviral vectors	1 dose	...	Preclinical

Laboratories

- Cassará Laboratory
 - Established in 1948.
 - The company has over 1,000 employees, 13% of whom are devoted to R&D.
 - It has developed a variety of medicines, with a focus on nasal application drugs.
 - In addition to the coronavirus vaccine, it is currently researching vaccines for cutaneous melanoma and human rabies, as well as drugs for other diseases.
- Cellargen Biotech
 - A biotechnology company incubated by the Universidad Nacional del Litoral, with a platform for the production of recombinant proteins and new generation vaccines using cell culture bioreactors.
- Leloir Institute
 - Established in 1947.
 - It was founded and directed by Bernardo Houssay and Luis Federico Leloir, recipients of the Nobel Prize for Medicine and for Chemistry, respectively.
 - It is an Argentine research centre devoted to biochemistry, pharmacy and cellular and molecular biology.
 - It has 24 research groups and over 170 researchers.

Country: Chile

Summary: Chile has one vaccine development project led by the Catholic University of Chile. It is expected to begin clinical trials in late 2021.

Chile: vaccines researched

Laboratory	Vaccine	Specifications	Dosage	Efficacy	Phase
Catholic University of Chile and the Millennium Institute of Immunology and Immunotherapy	...	Based on SARS-CoV-2 proteins or protein fragments extracted from the genetic material of the virus. One of the four strategies being tested is equivalent to that used to develop the vaccine against the respiratory syncytial virus.	Preclinical

Country: Peru

Summary: The vaccine development project in Peru, led by the veterinary laboratory Farvet, was stopped after failing to gain approval at the preclinical stages.

Peru: vaccines researched

Laboratory	Vaccine	Specifications	Dosage	Efficacy	Phase
Farvet	...	RBD protein (baculovirus production) + FAR-Squalene adjuvant	Cancelled at preclinical stage

2. Production capabilities

(a) Current production

Country: Argentina/Mexico

Vaccine: AZD1222 or Vaxzevria - Oxford/AstraZeneca

Summary: An agreement was reached between the Carlos Slim Foundation and the companies mAbxience and Liomont to produce AZD1222 vaccine. The Argentine company mAbxience produces the active component of the vaccine, while the Mexican laboratory Liomont completes the stabilization, manufacturing and packaging process. As of September 2021, over 20 million doses of the vaccine have been produced.

Laboratory/companies/institute

- mAbxience
 - Established in 2010.
 - Produces biopharmaceutical products in Argentina since 2012.
 - It has R&D and production plants in Argentina and Spain.
 - Its plant in Garín (Argentina) produces the active ingredient of the vaccine, while the plants in Munro (Argentina) and León (Spain) will continue with their traditional production of biosimilars.
- Liomont
 - Established in 1938.
 - It has four production plants, two in Cuajimalpa, one in Mexico City, and one in Ocoyoacac (State of Mexico).
 - It produces recombinant vaccines for papillomavirus and influenza.
- COVID-19 vaccine production capacity: between 150 million and 250 million doses per year.

Country: Brazil

Vaccine: AZD1222 or Vaxzevria - Oxford/AstraZeneca

Summary: The Oswaldo Cruz Foundation (Fiocruz) imports and packages the vaccine, producing over 90 million doses to date and an estimated 200 million doses during 2021.

Laboratory/companies/institute

- Fiocruz
 - Public foundation under the Ministry of Health of Brazil.
 - Founded in 1900 in Rio de Janeiro as Instituto Soroterápico Federal, with the objective of producing serums and vaccines against the bubonic plague.
 - It focuses on research, development and production of medicines for tropical diseases.
 - Its main research concerns yellow fever and smallpox, and it produces vaccines against both diseases.
 - Production capacity: 200 million doses per year of COVID-19 vaccine.

Country: Argentina

Vaccine: Sputnik V - Gamaleya

Summary: The Richmond laboratory has reached an agreement to produce the Sputnik V vaccine, having received certification in early August 2021.

Laboratory/companies/institute

- Richmond
 - Established in 1935
 - Manufactures and exports oncological, cardiovascular and HIV/AIDS medicines.
 - It has a portfolio of more than 80 products, including antiviral, oncological and oncohematological, cardiometabolic and neuropsychiatric products.
- Production capacity: 3 million doses per month of Sputnik V vaccine.

Country: Brazil

Vaccine: Coronavac - Sinovac

Summary: The Butantan Institute is packaging the vaccine after receiving the active pharmaceutical ingredient from China, and has produced 94.8 million doses to date.

Country: Mexico

Vaccine: Convidecia - Cansino

Summary: The vaccine is being packaged in Mexico by the Drugmex pharmaceuticals company in Queretaro. Over 6 million doses had been packaged by August 2021. Drugmex manufactures sterile injectable products for human consumption in lyophilized form and solutions in ampoules. Its overall estimated capacity is 7 million lyophilized vials and 6 million injectable solutions per year.

Vaccine: Sputnik V - Gamaleya

Summary: Birmex will begin packaging Sputnik V vaccine with a capacity of 4 million doses per month. They are currently awaiting approval.

(b) Future production

Country: Brazil

- Pfizer/BioNtech: An agreement was reached with Eurofarma Laboratorios to carry out the vaccine fill and finish process from 2022, with a capacity of 100 million doses per year.³

The technology transfer to start production will come from the United States.

Eurofarma is a Brazilian-based multinational pharmaceutical company founded in 1972. It has 10 production plants and is present in 20 countries in Latin America.

- Sputnik V: União Química has the capacity to produce 8 million doses per month and is awaiting approval of the vaccine in the country. It has requested approval from ANVISA and expects to produce the vaccine in its Brasília and Guarulhos plants.

Country: Chile

- Sinovac: Agreement for the installation of a Sinovac production plant to start operations in 2022. The plant will carry out the fill and finish process of the CoronaVac COVID-19 vaccine and other vaccines such as for hepatitis and influenza. The plant is expected to have a capacity of 60 million doses per year.

Country: Colombia

- Sinovac: A memorandum of understanding has been signed with Sinovac to develop production, technology transfer and vaccine development projects, starting with fill and finish operations from the second quarter of 2022.

(c) General vaccine production capabilities (not only against COVID-19)⁴

Country: Argentina

- Malbrán Institute
 - DPT (diphtheria, pertussis, tetanus)
 - Bacillus Calmette–Guérin (BCG)
- Julio Maiztegui National Institute of Human Viral Disease
 - Argentine hemorrhagic fever (AHF)

Country: Brazil

- Fiocruz
 - DPT (diphtheria, pertussis, tetanus)
 - Yellow fever
 - Haemophilus influenzae type B (Hib)
 - Meningitis A and C
 - 10-valent pneumococcal
 - Oral poliomyelitis vaccine (OPV)
 - Inactivated poliomyelitis vaccine (IPV)
 - Human rotavirus
 - Triple virus vaccine
 - Tetravalent anti-viral

³ See [online] <https://eurofarma.com.br/releases/pfizer-e-biontech-anunciam-colaboracao-com-a-eurofarma-para-producao-da-vacina-contra-a-covid-19-para-a-america-latina>.

⁴ According to data from the United Nations Educational, Scientific and Cultural Organization (UNESCO), *COVID-19 y vacunación en América Latina y el Caribe: desafíos, necesidades y oportunidades*, Montevideo, 2021.

- Butantan Institute
 - Trivalent influenza
 - Hepatitis A
 - Hepatitis B
 - Human papillomavirus (HPV)
 - Rabies
 - DTP, DT, dT
 - DTPa (diphtheria, tetanus and pertussis)

Country: Colombia

- National Institute of Health
 - Bacillus Calmette–Guérin (BCG)
 - Yellow fever

Country: Cuba

- Centre for Genetic Engineering and Biotechnology (CIGB)
 - Hepatitis B
 - Haemophilus Influenzae type b
 - DPT-HB (diphtheria, pertussis, tetanus, hepatitis B)
 - Pentavalent (DPT-HB-Hib)
- Finlay Institute of Vaccines
 - Meningococcus B and C
 - Trivalent leptospirosis Vi
 - DT (diphtheria, tetanus)
 - DPT (diphtheria, pertussis, tetanus)
 - Tetanus
 - Typhoid fever

Country: Mexico

- BIRMEX
 - Polyvalent anti-scorpion venom serum
 - Polyvalent anti-snake venom serum
 - Bivalent oral poliomyelitis vaccine
 - TD (tetanus, diphtheria)

Country: Venezuela (Bolivarian Republic of)

- Rafael Rangel National Institute of Hygiene
 - DPT (diphtheria, pertussis, tetanus)
 - Rabies

3.2 Latin America and the Caribbean: main pharmaceutical companies

20 transnationals with largest presence in business chambers in the region

Company	Origin	Year established	Employees (2020)	Revenue, 2020 (millions of dollars)	Percentage of business chambers analysed in which company participates
Bayer	Germany	1863	99 538	47 219	100
Novartis	Switzerland	1996	105 800	48 660	100
Pfizer	United States	1849	88 300	41 900	100
Roche	Switzerland	1896	101 500	62 050	100
Sanofi	France	2004	100 400	41 080	100
GSK Glaxo Smith Kline	United Kingdom	1715	99 400	43 770	90
Janssen-Johnson & Johnson	United States	1953	132 200	82 600	90
Merck KGaA	Germany	1668	58 096	20 122	90
AstraZeneca	Sweden-United Kingdom	1913	70 600	26 620	80
Boehringer Ingelheim	Germany	1885	22 290	22 454	80
MSD	United States	1891	73 500	47 994	80
Novo Nordisk	Denmark	1989	20 240	19 533	80
Takeda	Japan	1781	47 100	30 002	80
Eli Lilly	United States	1876	35 000	24 540	70
AbbVie	United States	2012	47 000	45 804	70
Bristol-Myers Squibb	United States	1989	30 250	42 518	70
Amgen	United States	1980	24 300	25 424	50
Astellas	Japan	2005	15 460	11 715	50
Biogen	United States-Switzerland	1978	9 100	13 445	50
Grünenthal	Germany	1946	4 700	1 589	50

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of data from the Latin American Federation of the Pharmaceutical Industry (FIFARMA); Association of Pharmaceutical Research and Development Laboratories (AFIDRO) of Colombia; National Association of Pharmaceutical Laboratories (ALAFARPE) of Peru; Mexican Association of Pharmaceutical Research Industries (AMIIF), Argentine Chamber of Medicinal Specialties (CAEME); Chilean Chamber of Pharmaceutical Innovation (CIF); Central American and Caribbean Federation of Pharmaceutical Laboratories (FEDEFARMA); Pharmaceutical Research and Innovation Industry (IFI) of Ecuador; Association of Pharmaceutical Research Industry (INTERFARMA) of Brazil, and Association of Pharmaceutical Representatives, Agents and Producers (ARAPF) of the Dominican Republic; Statista; Fiercepharma and Fortune.

Argentina, Brazil and Mexico: turnover of the largest laboratories

(Millions of dollars)

Argentina (2020)	Origin	Turnover (millions of dollars)	Share (percentages)
Roemmers	National	423	8
Elea Phoenix	National	374	7
Gador	Nacional	297	5
Casasco	National	296	5
Montpellier	National	250	4
Bagó	National	248	4
Baliarda	National	246	4
Raffo	National	232	4
Sanofi Aventis	Foreign	182	3
Bayer	Foreign	175	3
GSK	Foreign	162	3
Novo-Nordisk	Foreign	148	3
Pfizer	Foreign	126	2
Bernabo	National	108	2
Boehringer Ingelheim	Foreign	102	2
Investi	National	101	2
Andrómaco	National	99	2
Teva	National	99	2
Genomma	Foreign	91	2
Novartis Pharma	Foreign	87	2
Total for 20 laboratories		3 846	69
Rest of the industry		1 711	31
Total (wholesale prices)		5 557	

Brazil (2019)	Origin	Turnover (millions of dollars)	Share (percentages)
Aché	National	1 052	8
EMS	National	911	7
Eurofarma	National	830	6
Sanofi	Foreign	756	6
Takeda	Foreign	458	3
Neo Química	National	449	3
Novartis	Foreign	426	3
Mantecorp Farmasa	National	404	3
Medley	Foreign	404	3
Libbs	National	391	3
Biolab Sanus Farmacêutica	National	388	3
Cimed	National	363	3
Bayer Pharma	Foreign	338	2
Boehringer Ingelheim	Foreign	318	2
Pfizer	Foreign	309	2
GSK Farma	Foreign	294	2
AstraZeneca	Foreign	278	2
Novo Nordisk	Foreign	269	2
FQM GRUPO	National	267	2
Hypera	National	267	2
Total for 20 laboratories		9 173	67
Rest of the industry		4 480	33
Total		13 653	

Mexico (2020)	Origin	Turnover (millions of dollars)	Share (percentages)
Sanofi México	Foreign	734	12
Genoma Lab Internacional	Foreign	712	11
Liomont	National	600	9
Pfizer México	Foreign	528	8
Boehringer Ingelheim México	Foreign	474	8
Roche México	Foreign	420	7
Probiomed	National	317	5
Farmacéuticos Maypo	National	308	5
Novartis México	Foreign	297	5
Bausch Health México	Foreign	249	4
Sanfer	National
Laboratorios Armstrong	National
Laboratorios Hormona	National
RIMSA	National
Landsteiner Scientific	National
DEFSA	National
Total for 10 largest laboratories		4 638	73
Rest of the industry		1 681	27
Total		6 319	

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of data from the Cámara Industrial de Laboratorios Farmacéuticos Argentinos (CILFA) for Argentina; Research-based Pharmaceutical Manufacturers Association (Interfarma), *Guía 2020 Interfarma*, April 2020 [online] https://www.interfarma.org.br/app/uploads/2020/12/2020_VD_JAN.pdf para el Brasil; Statista *Pharmaceutical Industry in Mexico, 2021*; *The Pharma 1000: Top Global Pharmaceutical Company Report, September 2020* [online] www.torreya.com and J. C. Ferreyra, *Evolución de la industria farmacéutica mexicana al primer trimestre de 2020 INEFAM-LATAM*, June 2020, for Mexico.

Colombia: sales share of the 10 largest laboratories, 2019 (Percentages)

Pfizer	5.9	Foreign
Sanofi Aventis	5.5	Foreign
Novartis	5.4	Foreign
Roche	5.0	Foreign
Bayer	3.9	Foreign
Lafranco-Abbott	3.6	Foreign
Glaxosmithkline	3.3	Foreign
Tecnoquímicas (TQ)	2.9	Foreign
Janssen	2.8	Foreign
Merck Sharp Dome	2.5	Foreign
Others	59.2	

Source: Colombian Superintendence of Industry and Commerce, *Estudios de mercado: sector farmacéutico en Colombia*, Bogotá [online] <https://www.sic.gov.co/sites/default/files/documentos/032021/ES-Sector-Farmacéutico-en-Colombia.pdf>, 2020.

Line of action 4

4.1 Latin America and the Caribbean: primary sponsors of clinical trials of COVID-19 vaccines and treatments, up to 27 August 2021

Country	Clinical trial sponsor	Phase I	Phase II	Phase III	Phase IV
Argentina	Administración Nacional de Laboratorios e Institutos de Salud Dr. Carlos G. Malbrán		X	X	
	Asociación Argentina de Medicina Hiperbárica e Investigación		X		
	Centro de Educación Médica e Investigaciones Clínicas Norberto Quirno (CEMIC)			X	
	Clínica San Camilo				X
	Clínica Zabala		X		
	Estudios Clínicos Latinoamérica			X	
	Fundación Huésped		X		X
	Hospital de Infecciosas Francisco Javier Muñiz		X		
	Hospital Italiano de Buenos Aires			X	
	Instituto de Cardiología de Corrientes		X	X	
	Instituto de Medicina y Biología Experimental de Cuyo, UNCUYO				X
	Inmunova S.A.		X	X	
	Laboratorio Elea Phoenix S.A.		X	X	X
	Laboratorios Roemmers S.A.I.C.F.		X	X	
	Ministerio de Salud de la Argentina	X	X	X	
Ministerio de Salud de la Ciudad Autónoma de Buenos Aires		X			
Bolivia (Plurinational State of)	Universidad Mayor de San Simón		X		
Brazil	Applied Biology, Inc.			X	
	Apsen Farmacêutica S.A.			X	
	Associação Fundo de Incentivo à Pesquisa		X		
	Azidus Brasil	X	X	X	
	Beneficência Portuguesa de São Paulo			X	
	Brazilian Clinical Research Institute				X
	Cardresearch			X	
	Centro de Estudios e Investigación en Emergencias Médicas y Terapia Intensiva			X	
	Centro Universitario Augusto Motta		X		
	Facultad de Medicina de Ribeirão Preto		X		
	Facultad de Medicina de São José do Rio Preto		X		

Country	Clinical trial sponsor	Phase I	Phase II	Phase III	Phase IV
Brazil	Fundación de Medicina Tropical Doctor Heitor Vieira Dourado		X		X
	Hospital Alemán Oswaldo Cruz				X
	Hospital de Clínicas de la Facultad de Medicina de la Universidad de São Paulo	X	X	X	X
	Hospital de Clínicas de la Universidad Federal de Minas Gerais		X		
	Hospital de Clínicas de Porto Alegre	X		X	
	Hospital del Corazón	X	X	X	
	Hospital Eduardo de Menezes		X		
	Hospital Israelita Albert Einstein			X	
	Hospital Santo Antônio		X		
	Hospital São Domingos		X		
	Hospital Sirio-Libanés			X	
	Hospital Universitario Antônio Pedro				X
	Instituto Butantan	X	X	X	X
	Instituto Corpometria		X	X	
	Instituto del Cáncer del Estado de São Paulo		X		
	Instituto D'Or de Investigación y Educación	X	X	X	X
	Instituto Federal de Paraná			X	
	Instituto René Rachou (Fiocruz Minas)			X	
	Latin American Cooperative Oncology Group		X		
	Ministerio de Ciencia, Tecnología e Innovaciones			X	
	Ministerio de Salud		X		
	Science Valley Research Institute			X	
	Sociedad Brasileña de Ozonioterapia Médica			X	
	Universidad Anhembi Morumbi	X			
	Universidad de Pernambuco			X	
	Universidad de São Paulo	X	X	X	
	Universidad del Valle de Sapucaí			X	
	Universidad Estadual de Campinas				X
	Universidad Federal de Ceará			X	
	Universidad Estadual Paulista			X	
Universidad Federal de Goiás			X		
Universidad Federal de Pernambuco			X		
Universidad Federal de Río de Janeiro			X		
Universidad Federal de Roraima			X		
Universidad Federal de São Carlos			X		
Chile	Fundación Arturo López Pérez		X	X	
	MELISA Institute Genomics & Proteomics Research SpA		X	X	
	Pontificia Universidad Católica de Chile	X	X	X	
	Universidad de Chile			X	
	Universidad del Desarrollo		X		
Universidad Nacional Andrés Bello	X	X			
Colombia	Ayudas Diagnósticas Sura S.A.S		X	X	
	Centro de Estudios en Infectología Pediátrica		X	X	
	Fundación Banco Nacional de Sangre Hemolife		X		
	Fundación Cardiovascular de Colombia		X		
	Fundación Clínica Valle del Lili		X		
	Fundación Santa Fe de Bogotá		X	X	
	Fundación Universitaria de Ciencias de la Salud			X	
	Hospital San Vicente Fundación			X	
	Hospital Universitario San Ignacio		X	X	
	Lifefactors Zona Franca, SAS		X	X	
	Pontificia Universidad Javeriana			X	
	Universidad de Antioquia			X	
	Universidad CES			X	
	Universidad del Rosario			X	X
Universidad Nacional de Colombia	X	X	X		

Country	Clinical trial sponsor	Phase I	Phase II	Phase III	Phase IV	
Costa Rica	Caja Costarricense de Seguro Social		X	X		
Cuba	Centro de Inmunología Molecular (CIM)	X	X			
	Centro de Ingeniería Genética y Biotecnología de Cuba (CIGB)	X	X	X		
	Centro Nacional de Investigaciones Científicas				X	
	Empresa Laboratorios AICA	X				
	Instituto Finlay de Vacunas	X	X	X		
Jamaica	The University of The West Indies		X	X		
Mexico	Centenario Hospital Miguel Hidalgo			X		
	Centro de Hematología y Medicina Interna de Puebla		X			
	Centro Médico ABC			X		
	Centro Médico Nacional 20 de Noviembre	X				
	Clinedem		X	X		
	Coordinación de Investigación en Salud, Instituto Mexicano del Seguro Social		X	X		
	Grupo Cooperativo de Hemopatías Malignas	X	X			
	Grupo Mexicano para el Estudio de la Medicina Intensiva		X			
	Hospital Central Militar		X			
	Hospital General de México Dr. Eduardo Liceaga		X			
	Hospital Materno Perinatal Mónica Pretelini Sáenz				X	
	Hospital Regional de Alta Especialidad del Bajío			X		
	Hospital Regional de Alta Especialidad de Zumpango		X			
	Hospital Regional Lic. Adolfo López Mateos	X				
	Hospital San José TecSalud	X	X			
	Hospital Universitario Dr. José E. González		X	X		
	Instituto de Investigaciones Biomédicas, UNAM		X			
	Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado	X	X			
	Instituto Estatal de Cancerología, Secretaría de Salud Colima	X	X			
	Instituto Nacional de Cancerología de México	X	X			
	Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán	X	X	X		
	Instituto Nacional de Enfermedades Respiratorias			X		
	Instituto Nacional de Neurología y Neurocirugía Manuel Velasco Suárez		X	X		
	Instituto Politécnico Nacional		X			
	Investigación Biomédica para el Desarrollo de Fármacos S.A. de C.V.		X			
	Laboratorio Avimex	X				
	Laboratorios Silanes S.A. de C.V.		X			
	Universidad Autónoma de Coahuila	X	X			
	Paraguay	Universidad Nacional de Asunción		X	X	
	Peru	Marina de Guerra del Perú (MGP)		X		
Oncosalud S.A.C.			X			
Seguro Social de Salud (ESSALUD)			X			
Universidad Católica De Santa María			X			
Universidad Peruana Cayetano Heredia			X	X		

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of World Health Organization (WHO), International Clinical Trials Registry Platform (ICTRP) [online] <https://www.who.int/clinical-trials-registry-platform>.

4.2 Main chambers and associations in the region

1. Latin America

Latin American Association of Pharmaceutical Industries (ALIFAR)

Year founded: 1980

Members: 12 national chambers

An umbrella organization for more than 400 domestic companies in the pharmaceutical industry from 12 countries in Latin America and the Caribbean. The countries with chambers belonging to this association are Argentina, Bolivarian Republic of Venezuela, Brazil, Colombia, Dominican Republic, Ecuador, El Salvador, Guatemala, Paraguay, Peru, Plurinational State of Bolivia and Uruguay.

Its priorities are cooperation and reciprocal knowledge among business owners in the region's countries, support for and strengthening of domestic companies in member countries, and promotion and defense of their common interests at the international level.

Latin American Federation of the Pharmaceutical Industry (FIFARMA)

Year founded: 1962

Members: 16 global transnational companies and 11 local associations

Affiliation: International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

Represents companies in the biopharmaceutical research and development (R&D) industry in Latin America and the Caribbean as well as the health care community in supporting and promoting health policies that prolong, preserve and improve the lives of patients. The local associations represented are from Argentina, Brazil, Chile, Colombia, Dominican Republic, Ecuador, Mexico, Peru, Uruguay and Venezuela (Bolivarian Republic of) and Central America.

It fosters dialogue within the industry and works in collaboration with intergovernmental bodies, non-governmental organizations, health authorities and civil society organizations to contribute to society by advocating sustainable health systems with high regulatory standards and ethical principles and by offering patients the possibility to live longer and better lives.

2. Central America and the Caribbean

Central American and Caribbean Federation of Pharmaceutical Laboratories (FEDEFARMA)

Members: 19 affiliated entities

Affiliation: FIFARMA and IFPMA

The Central American and Caribbean Federation of Pharmaceutical Laboratories (FEDEFARMA) represents the innovative pharmaceutical sector that researches, develops and markets medicines and therapies that prevent, treat and cure diseases.

It seeks to be a pacesetter and strategic actor in the Central American and Caribbean region through pharmaceutical innovation and the development and implementation of proposals to widen access to innovative, high-quality medicines that help to improve people's health and quality of life.

3. National chambers

Argentina

Cámara Industrial de Laboratorios Farmacéuticos Argentinos (CILFA)

Year founded: 1964

Members: 36 laboratories

Affiliation: ALIFAR, Argentine Industrial Association (UIA)

It works for the development of national industry, the creation of quality jobs, access to medicines, and scientific and technological development.

It is an umbrella organization for relatively large laboratories, mostly private and one public.

Cámara Argentina de Especialidades Medicinales (CAEME)

Year founded: 1925

Members: 41 companies

Affiliation: FIFARMA and IFPMA

It represents foreign-owned laboratories or pharmaceutical and biopharmaceutical companies.

Acting on behalf and at the service of innovation companies, it seeks to promote new models of sustainable access, foster a culture of ethics and transparency, raise the standards of quality, safety and efficacy, and preserve the principles of integrity for the benefit of the general health of society.

Cámara Empresaria de Laboratorios Farmacéuticos (COOPERALA)

Year founded: 1959 (as Cooperativa de Laboratorios Argentinos de Especialidades Medicinales para el Abastecimiento y Distribución Limitada); it became Cámara Empresaria de Laboratorios Farmacéuticos in 1998.

Members: 82 laboratories

Preserving its cooperative roots, it represents mainly Argentine-owned pharmaceutical laboratories that specialize in medicinal fields, many of them small and medium-sized companies.

Cámara Argentina de Productores de Medicamentos Genéricos y de Uso Hospitalario (CAPGEN)

Year founded: 1999 - 15 member laboratories

It represents Argentine laboratories specializing in the production of generics. Its objective is to form a national pharmaceutical industry of generic drugs to meet demand from the State and patients, thereby facilitating access to medicines at prices in line with the economic reality of Argentina.

Cámara Argentina de Medicamentos de Venta Libre (CAPEMVeL)

Members: 14 laboratories

Affiliation: World Self-Medication Industry (WSMI)

It comprises national and international laboratories that produce over-the-counter medicines.

Cámara Argentina de Biotecnología (CAB)

Members: 32 companies

Founded with the aim of advancing a policy of public-private partnership and fostering the development of a robust biotechnology sector in Argentina. Its members are companies from a wide range of industries, including pharmaceuticals, biotechnology, food, animal and plant health, diagnostics, agriculture and livestock, forestry and biofuels. It has a holistic vision, ranging from R&D and production, to marketing and export of high value-added biotechnology products.

ANLAP (Agencia Nacional de Laboratorios Públicos)

Year founded: 2014

Members: in Argentina there are more than 30 State-owned laboratories.

Created by Law 27113 (regulated by Decree 795/2015) as a decentralized national entity under the Ministry of Health. The objective of ANLAP is to link and promote the activities of the Argentine State-owned drug-producing laboratories in a planned way under centralized State control.

Brazil

Associação Brasileira das Indústrias de Química Fina (ABIFINA)

Year founded: 1986

Members: 26 companies

The association works for the development of the sector's industrial capacity in Brazil and is committed to transparency, ethics and national economic advancement. ABIFINA seeks to promote competitiveness in the sector on two fronts: public-policy input and technological training for companies.

Grupo FarmaBrasil

Year founded: 2011

Members: 12 national companies

Affiliation: ALIFAR

Founded as the lead institutional representative of the Brazilian pharmaceutical industry for research, development and innovation, today Grupo FarmaBrasil acts for 12 nationally owned Brazilian companies, including some of the largest in the market.

Associação Brasileira das Indústrias de Medicamentos Genéricos (PróGenéricos)

Year founded: 2001

Members: 15 companies

PróGenéricos members account for approximately 90% of sales in the generic segment in the country. The association engages with various sectors of society, as well as public and private institutions. The association represents its members, contributing substantively to public discussions on issues of importance to the health sector and to the development of the pharmaceutical industry in the country.

Associação Brasileira de Medicina Farmacêutica (SBMF)

Year founded: 1972

Members: 17 companies

A non-profit civil society organization, it is active nationwide and has its headquarters in the capital of the state of São Paulo. Its main objective is to encourage debate on technical aspects related to pharmaceutical medicine, offering advice, assistance and leadership for the continuous advancement of its members in research on medicines, vaccines, medical equipment, and diagnostic and health products in general; scientific support for marketing such products; scientific support to the medical profession and the public for the correct use of such products; registration and related activities; moral principles; technical and scientific development; safe use of medicines and related medical, pharmacological and other aspects in the field of pharmaceutical medicine.

Associação da Indústria Farmacêutica de Pesquisa (INTERFARMA)

Year founded: 1990

Members: 22 companies

Affiliation: FIFARMA and IFPMA

It is a non-profit sectoral entity that represents domestic and foreign companies and researchers involved in health innovation in Brazil.

INTERFARMA's members include Brazilian and international research laboratories and startups. Individual Brazilian researchers, institutions, foundations, universities, and institutes can also belong to the entity.

Sindicato da Indústria de Produtos Farmacêuticos (SINDUSFARMA)

Year founded: 1933

Members: 19 companies

Sindicato de la Industria de Productos Farmacéuticos was established for the purpose of study, coordination and legal protection of the economic interests of the industry, importers and exporters of pharmaceutical products, related products and functional foods.

Associação Brasileira da Indústria de Insumos Farmacêuticos (ABIQUIFI)

Year founded: 1983

Members: 47 companies

Its main objective is to stimulate the production of pharmaceutical ingredients in Brazil, with a view to supplying the Brazilian industry and the international market.

With the support of its members, government agencies and other institutions representing the sector, ABIQUIFI has been implementing a series of measures to increase the competitiveness and visibility of the country's industry.

Chile

Cámara de la Innovación Farmacéutica de Chile (CIF) (formerly Cámara de la Industria Farmacéutica de Chile)

Year founded: 1953

Members: 23 entities

Affiliation: FIFARMA and IFPMA

It was established in 1953 with the purpose of promoting good practices and fostering the industry in Chile. It currently represents 23 global innovative pharmaceutical companies with a presence in Chile.

Colombia

Cámara de la Industria Farmacéutica de la Asociación Nacional de Empresarios de Colombia (ANDI)

Year founded: 1993

Members: 63 entities

It is the sector's main actor and representative in Colombia. It acts as an umbrella for domestic and multinational laboratories producing medicines and dietary supplements, whose sales account for 80% of total medicine sales in the country.

Asociación de Industrias Farmacéuticas en Colombia (ASINFAR)

Year founded: 1974

Affiliation: ALIFAR

Its members include the most important domestically and foreign-owned companies with drug production plants in Colombia and the region. Most of its members are Colombian-owned.

Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo (AFIDRO)

Year founded: 1956

Members: 28 entities

Affiliation: FIFARMA and IFPMA

It represents global pharmaceutical research and development companies established in Colombia that develop innovative therapeutic solutions of the highest quality to benefit health and wellness.

Costa Rica

Cámara de Industrias de Costa Rica (CICR)

A business organization that promotes the sustainable development of the productive sector. Its mission is to promote the sustainable development of the industrial sector and to support the competitiveness of its member companies.

Dominican Republic

Asociación de representantes, agentes y productores farmacéuticos (ARAPF)

Year founded: 1948

Members: 65 entities

Affiliation: FIFARMA and IFPMA

It brings together and represents companies in the sector, which include both global laboratories and local companies. Since its founding, ARAPF has called on the pharmaceutical sector to combat illegal medicines, joining forces with the Dominican authorities in order to supply high-quality products to ensure the welfare of the Dominican public. In the context of the pharmaceutical trade, ARAPF promotes free enterprise, competition, respect for patent law and the practice of the highest morality, as well as cooperating in health programs designed by national authorities.

Ecuador

Industria Farmacéutica de Investigación (IFI)

Members: 12 entities

Affiliation: FIFARMA and IFPMA

An organization that represents most of the innovation, biotechnology and vaccine laboratories from Europe, the United States and Japan in Ecuador. Its mission is to be the pacesetter for the pharmaceutical industry, contribute to the health and welfare of the Ecuadorian population and facilitate access to innovative and quality medicines based on high standards of research and ethics.

El Salvador

Cámara de Comercio e Industria de El Salvador

Year founded: 1915

Members: More than 2,000

It is the most representative private-sector business association in the country and brings together companies of every size from all sectors. Its mission is to steadfastly promote and defend free enterprise, fostering national unity and business development with social responsibility, while spearheading measures and facilitating services that promote competitiveness and innovation in its members, as well as protecting their rights.

Guatemala

Gremial de Fabricantes de Productos Farmacéuticos attached to Cámara de Industria de Guatemala

Year founded: 1948

It comprises national laboratories that promote the manufacture and marketing of pharmaceutical products that adhere to strict internationally recognized standards, in order to offer high-quality medicines to the entire population at affordable prices. It serves the domestic market and exports to Central America, the Caribbean, southern Mexico and other world regions. Its members' products are designed to meet the demand from the health care sector for preventing, alleviating and curing disease in patients.

Mexico

Cámara Nacional de Industria Farmacéutica (CANIFARMA)

Year founded: 1946

Members: 186 entities

It acts as the Mexican pharmaceutical industry's institutional representative before authorities. Its members come from three specialities: medicines for human use, medicines for veterinary use and medical devices.

Its mission is to be the facilitator, contributor and promoter of development in the pharmaceutical industry as a key component of the health of Mexicans and a driver of the national economy.

Consejo de Ética y Transparencia de la Industria Farmacéutica (CETIFARMA)

Year founded: 2005

Members: 106 entities, in addition to 4 that adhere to its codes of ethics.

Affiliation: FIFARMA

Companies belonging to Cámara Nacional de la Industria Farmacéutica, Asociación Mexicana de Industrias de Investigación Farmacéutica (AMIIF) and Asociación Nacional de Fabricantes de Medicamentos A.C. (ANAFAM), which signed documents of accession the CETIFARMA codes of ethics.

Asociación Mexicana de Industrias de Investigación Farmacéutica, A.C. (AMIIF)

Members: 60 companies

Affiliation: FIFARMA and IFPMA

AMIIF represents leading pharmaceutical research and biotechnology companies with a national and global presence. Its members are committed to the development of and search for new therapies that provide alternative treatments for the diseases of today and tomorrow with the sole objective of increasingly improving quality of life for patients who need it.

Asociación Mexicana de Laboratorios Farmacéuticos, A.C. (AMELAF)

Year founded: 2003

Members: 43 companies (all Mexican) with 68 plants in the country

It seeks to influence public policies for the benefit of Mexico and the pharmaceutical industry. It promotes a national pharmaceutical industry of excellence and reliability, comprising Mexican laboratories that manufacture high-quality, safe, effective generic drugs that are accessible to the Mexican public.

Asociación Mexicana de Genéricos (AMEGI)

An organization whose objective is to manufacture generic drugs of international quality and make them available to Mexicans. It is a member of the International Generic Pharmaceutical Alliance (IGPA), a body that works to promote international pharmaceutical harmonization and regulatory decisions that best benefit the public, as well as to strengthen the generic drug industry worldwide.

Asociación Nacional de Fabricantes de Medicamentos (ANAFAM)

Year founded: 1945

Members: 24 entities

It represents pharmaceutical companies that are majority Mexican-owned, as well as some international companies established in the country, which play an active and recognized part in the supply of medicines to the public sector and the private market.

Its goal is for Mexico to reduce its foreign dependence in the area of health, in terms both of active ingredients and innovation and technology. Its objective is for the active ingredients necessary to produce all medicines in Mexico be domestically manufactured.

Asociación Nacional de Distribuidores y Laboratorios de Medicamentos Genéricos (DILAMEG)

Members: 32 entities

Association established to encourage, develop and promote the consumption of safe, effective, quality generic and brand-name generic medicines of national origin, bringing accessibility and health to all Mexican families.

Asociación de Fabricantes de Medicamentos de Libre Acceso (AFAMELA)

Year founded: 1985

AFAMELA represents the main national and global companies with a presence in the country. It promotes responsible self-medication in Mexico as a safe, effective and accessible way to foster self-care in the area of health and, thus, contribute to public welfare and health.

Panama

Cámara de Comercio Industrias y Agricultura de Panamá

Year founded: 1915

Members: More than 1,600

An entity that represents the private sector in Panama, providing its members with various services that contribute to the full development of their commercial, industrial, agricultural and professional activities.

Peru

Asociación Nacional de Laboratorios Farmacéuticos (ALAFARPE)

Year founded: 1953

Members: 22 entities

Affiliation: FIFARMA and IFPMA

It represents foreign and national laboratories, and its mission is to be an institution that promotes timely access to innovative, quality, safe and effective medicines to improve the quality of life and life expectancy of patients in the country.

Uruguay

Asociación de Laboratorios Nacionales (ALN)

Year founded: 1942

Members: 22 entities

Affiliation: ALIFAR, Cámara de Industrias del Uruguay (CIU)

An entity that represents both domestically and regionally owned pharmaceutical companies, its main objectives are to promote the development of the Uruguayan industry within a framework of free competition and to favour public access to high-quality medicines at reasonable prices.

Cámara de Especialidades Farmacéuticas y Afines (CEFA)

Year founded: 1954

Members: 13 entities

Affiliation: FIFARMA

It is an umbrella organization for international laboratories established in Uruguay. It works to generate a space for dialogue and participation where issues that laboratories engaged in pharmaceutical scientific research and development have in common can be resolved.

Venezuela (Bolivarian Republic of)

Cámara Venezolana del Medicamento (CAVEME)

Affiliation: FIFARMA

Cámara de la Industria Farmacéutica (CIFAR)

It promotes and represents pharmaceutical laboratories and affiliated companies before public and private institutions.

Cámara Nacional de Medicamentos Genéricos (CANAMEGA)

Year founded: 2000

CANAMEGA was established as a non-profit civil association in response to the need to bring together the main laboratories manufacturing essential generic medicines.

Line of action 5

5.1 Provisions on flexibilities with regard to intellectual property rights in Latin America and the Caribbean

Latin America and the Caribbean (20 countries) and the Andean Community: compulsory licensing provisions

Country/grouping	Provisions of law	Compulsory licensing for unmet patent working requirements	Compulsory licensing for dependent patent	Compulsory licensing to correct patent abuse	Compulsory licensing for public interest	Separate provision on government use
Antigua and Barbuda	Sections 34–35 of the Patent Act No. 22 of 2018	Yes	Yes	Yes	Yes	Yes
Argentina	Articles 42–50 of the Patents Act No. 24.481 of 1996 as amended by Decree No. 27/2018 of January 10, 2018	Yes	Yes	Yes	Yes	Not explicitly provided
Barbados	Articles 49 and 50 of the Patents Act (Cap. 314) (as amended by Act No. 2 of 2006)	Yes	Yes	Yes	Yes	Yes
Belize	Articles 38 and 39 of the Patents Act, Chapter 253, of 21 June 2000	Yes	Yes	Not explicitly provided	Not explicitly provided	Not explicitly provided
Brazil	Articles 68–74 of Industrial Property Law No. 9.279 of 14 May 1996 as last amended by Law No. 10.196 of 14 February 2001	Yes	Yes	Yes	Yes	Not explicitly provided
Chile	Articles 51–51 bis D of Industrial Property Law No. 19.039 of 24 January 1991 as last amended in 2012	Not explicitly provided	Yes	Yes	Yes	Not explicitly provided
Costa Rica	Articles 18–20 of the Law No.6867 of 25 April 1983 as amended up to Law No. 8686 of 21 November 2008	Yes	Yes	Yes	Yes	Not explicitly provided
Cuba	Articles 53–57 of Decree-Law No. 290 of 20 November 2011	Yes	Yes	Yes	Yes	Yes
Dominica	Sections 35, 38 and 39 of the Patent Act No. 8 of 7 October 1999	Yes	Not explicitly provided	Yes	Yes	Yes
Dominican Republic	Articles 39–48 of Law No. 20-00 on Industrial Property of 18 April 2000	Yes	Yes	Yes	Yes	Yes
El Salvador	Articles 133 and 134 of Intellectual Property Legislative Decree No. 604 of 15 July 1993 as last amended by the Intellectual Property Legislative Decree No. 611 of 15 February 2017	Not explicitly provided	Not explicitly provided	Not explicitly provided	Yes	Not explicitly provided
Grenada	Sections 14 and 14 A of the Industrial Property Bill of 2002	Not explicitly provided	Yes	Not explicitly provided	Yes	Yes
Guatemala	Articles 134–138 of Industrial Property Law No. 57 of 18 September 2000 and sections 78-79 of Government Decision No. 89-2002, Regulations under the Industrial Property Law	Not explicitly provided	Yes	Yes	Yes	Yes
Honduras	Articles 65–71 of Industrial Property Law, Decree Law No. 12-99-E of 30 December 1999	Yes	Yes	Not explicitly provided	Yes	Not explicitly provided
Mexico	Articles 146–153 of the Federal Law on the Protection of Industrial Property of 1 July 2020	Yes	Not explicitly provided	Not explicitly provided	Yes	Not explicitly provided

Country/grouping	Provisions of law	Compulsory licensing for unmet patent working requirements	Compulsory licensing for dependent patent	Compulsory licensing to correct patent abuse	Compulsory licensing for public interest	Separate provision on government use
Nicaragua	Sections 51–56 of Industrial Property Law No. 354 of 19 September 2000	Not explicitly provided	Yes	Yes	Yes	Not explicitly provided
Paraguay	Articles 42–50 of Patents Law No. 1630 of 29 November 2000 and 27–31 of Decree No. 14.201 regulating Law No. 1630/00 on Patents of Inventions	Yes	Yes	Yes	Yes	Not explicitly provided
Saint Lucia	Sections 51–61 of the Patents Act No. 16 of 27 August 2001	Yes	Yes	Yes	Yes	Yes
Trinidad and Tobago	Sections 46–48 of Patents Act No. 21 of 1996 (as amended by Act No. 18 of 2000)	Yes	Not explicitly provided	Yes	Not explicitly provided	Yes
Uruguay	Articles 50–80 of Law No. 17.164 of 13 January 2000 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs (as amended up to Law No. 19.924 of 18 December 2020)	Yes	Yes	Yes	Yes	Not explicitly provided
Andean Community	Articles 61–69 of Decision No. 486 of 14 September 2000 of the Commission of the Andean Community - Common Industrial Property Regime (Cartagena Agreement)	Yes	Yes	Yes	Yes	Not explicitly provided

Latin America and the Caribbean (18 countries) and the Andean Community: patent exhaustion provisions

Country/grouping	Provision of Law	Exhaustion	
		National	International
Antigua and Barbuda	Section 32 (4) a) of Patent Act No. 22 of 2018		X
Argentina	Article 36 c) of Patents and Utility Models Law No. 24.481 of 1996 as amended by Decree No. 27/2018 of 10 January 2018		X
Barbados	Article 6 b) of the Patent Act, 2001 (Cap. 314) (as amended by Act No. 2 of 2006)	X	
Belize	Article 33 (4) a) of the Patents Act, Chapter 253, of 21 June 2000	X	
Brazil	Article 43 IV of Industrial Property Law No. 9.279 of 14 May 1996 as last amended by Law No. 10.196 of 14 February 2001	X	
Costa Rica	Article 16 (2) d) of Patents Law (Consolidation), No. 6867 of 25 April 1983, as amended up to Law No. 8686 of 21 November 2008		X
Dominica	Article 33 (4) (a) of Patent Act No. 8 of 7 October 1999	X	
Dominican Republic	Article 30 d) of Law on Industrial Property No. 20-00 of 18 April 2000		X
El Salvador	Article 116 d) of Legislative Decree No. 604 of 15/07/1993 on the Promotion and Protection of Intellectual Property Rights as last amended by Legislative Decree No. 611 of 15 February 2017	X	
Grenada	Section 12 (4) (a) (i) of the Industrial Property Act of 2002	X	
Guatemala	Article 131 of Industrial Property Law, Decree No. 57 of 18 September 2000		X
Honduras	Article 18 of Industrial Property Law, Decree Law No. 12-99-E of 30 December 1999		X
Mexico	Article 57 III of the Federal Law on the Protection of Industrial Property of 1 July 2020	X	
Nicaragua	Article 47 of Industrial Property Law No. 354 of 19 September 2000		X
Panama	Article 19 no. 3 of Industrial Property Law No. 35 of 10 May 1996	X	
Paraguay	Article 34 c) of Patents Law No. 1630 of 29 November 2000		X
Trinidad and Tobago	Section 43 of Patents Act No. 21 of 1996 (as last amended by Act No. 18 of 2000)	X	
Uruguay	Article 40 of Industrial Property Law No. 17.164 of 2 September 1999 (as amended up to Law No. 19.924 of 18 December 2020)		X
Andean Community	Article 54 of the Cartagena Agreement, Decision No. 486 of 14 September 2000 of the Commission of the Andean Community		X

Latin America and the Caribbean (20 countries) and the Andean Community: exemption for research and regulatory review (Bolar exemption)

Country/grouping	Research exemption	Bolar exemption
Antigua and Barbuda	Section 32 (4) c) of Patent Bill No. 22 of 2018	
Argentina	Article 36 (a) of Law No. 24.481 on Patents and Utility Models of 1996 as amended by Decree No. 27/2018 of 10 January 2018	
Barbados	Article 6 (1) a) of the Patents Act, 2001 (ch. 314) (as amended by Act No. 2 of 2006)	
Belize	Article 33 (4) c) of the Patents Act (Ch. 253) of 2000	
Brazil	Article 43 II of Industrial Property Law No. 9.279 of 14 May 1996 as last amended by Law No. 10.196 of 14 February 2001	Article 43 VII of Industrial Property Law No. 9.279 of 14 May 1996 as last amended by Law No. 10.196 of 14 February 2001
Costa Rica	Article 16 (2) b) and c) of Patents Law No. 6867 of 25 April 1983 as last amended up to Law No. 8686 of 21 November 2008	Article 16 (2) e) of Patents Law No. 6867 of 25 April 1983 as last amended up to Law No. 8686 of 21 November 2008
Cuba	Article 47(a) of the Decree Law No. 290 of 20 November 2011	
Dominica	Article 33 (4) c) of Patents Act No. 8 of 7 October 1999	
Dominican Republic	Article 30 b) and c) of the Law on Industrial Property No. 20-00 of 18 April 2000	Article 30 g) of the Law on Industrial Property No. 20-00 of 18 April 2000
El Salvador	Article 116 b) and c) of the Legislative Decree No. 604 of 15 July 1993 as last amended by Legislative Decree No. 611 of 15 February 2017	
Grenada	Section 12 (4) (a) of the Industrial Property Bill of 2002	
Guatemala	Article 130 b) and c) of the Industrial Property Law, Decree No. 57-2000	
Honduras	Article 18 of the Law on Industrial Property Law, Decree Law No. 12-99-E of 30 December 1999	
Mexico	Article 57 (1) of the Federal Law on the Protection of Industrial Property of 1 July 2020	
Nicaragua	Article 46 a) and b) of the Law on Patents, Utility Models and Industrial Design No. 354 of 19 September 2000	
Panama	Article 19 No. 1 and 2 of the Law on Industrial Property No. 35 of 10 May 1996	
Paraguay	Article 34 a) and b) of the Law on patents for invention No. 1630 of 29 November 2000	
Saint Lucia	Section 62 (2) a) of Patents Act No. 16 of 27/08/2001	
Trinidad and Tobago	Section 42 b) of Patent Act No. 21 of 1996 (as amended by Act No. 18 of 2000)	
Uruguay	Article 39 of Industrial Property Law No. 17.164 of 2 September 1999 (as amended up to Law No. 19.924 of 18 December 2020)	Article 39 of Industrial Property Law No. 17.164 of 2 September 1999 (as amended up to Law No. 19.924 of 18 December 2020)
Andean Community	Article 53 (b) of Decision No. 486 of 14 September 2000 of the Commission of the Andean Community	

Source: Economic Commission for Latin America and the Caribbean (ECLAC), on the basis of World Intellectual Property Organization (WIPO), Database on Flexibilities in the Intellectual Property System [online database] <https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html> and WIPO Lex [online database] <https://www.wipo.int/wipolex/en/index.html>.

Line of action 6

6.1. National regulatory systems pre-evaluated or evaluated in the Americas region, 2018

Country	Institution	Year of last reporting period
Argentina	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT)	2017
Bahamas	Bahamas National Drug Agency (BNDA)	2017
Barbados	Barbados Drug Service (BDS)	2015
Bolivia (Plur. State of)	Unidad de Medicamentos y Tecnologías de la Salud (UNIMED)	2009
Brazil	Agencia Nacional de Vigilancia Sanitaria (ANVISA), Ministry of Health	2017
Canada	Health Canada (HC)	2015
Chile	Instituto de Salud Pública (ISP)	2016
Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	2017
Costa Rica	Dirección General de Salud/Universidad/Caja Costarricense del Seguro Social	2011
Cuba	Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED)	2017
Dominican Republic	Dirección General de Drogas y Farmacia	2011
Ecuador	Instituto Nacional de Higiene y Medicina Tropical "Leopoldo Izquieta Pérez", Ministry of Health	2017
El Salvador	Dirección Nacional de Medicamentos	2017
Guatemala	Departamento de Regulación y Control de Productos Farmacéuticos y Afines	2010
Guyana	Food and Drug Department (FDD)	2013
Haiti	Direction de la Pharmacie, du Médicament et de la Médecine Traditionnelle (DNM/MT)	2017
Honduras	Secretaría de Salud/Dirección General de Regulación Sanitaria	2011
Jamaica	Standards and Regulation Division (SRD)	2013
Mexico	Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)	2017
Panama	Dirección de Drogas y Farmacia	2011
Paraguay	Dirección Nacional de Vigilancia Sanitaria	2016
Peru	Dirección General de Medicamentos, Insumos y Drogas (DIGEMID)	2013
Suriname	National Regulatory Authority	2013
Trinidad and Tobago	National Regulatory Authority	2011
United States of America	Food and Drug Administration (FDA)	2016
Venezuela (Bolivarian Rep. of)	Instituto Nacional de Higiene Rafael Rangel (IHRR)	2013

Source: Pan American Health Organization (PAHO), "System for Evaluation of the National Regulatory Authorities for Medicines" [online] https://www3.paho.org/hq/index.php?option=com_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=1179&lang=en.

6.2 Agreements reached in the Pacific Alliance and the Southern Common Market (MERCOSUR) on the regulation and trade of medicines and medical devices

1. Pacific Alliance

(a) Health cooperation agreement

In June 2013, the health authorities of the four member countries of the Pacific Alliance signed an inter-institutional agreement to lay the foundations for cooperation to facilitate the processes of sanitary registration and certification of good manufacturing practices (GMP) for chemically synthesized medicines in the member countries of the Pacific Alliance.⁵ To that end, the participants adopted several commitments, in particular the following:

⁵ The text of the agreement is available at <https://alianzapacifico.net/descarga-documentos-acuerdos-interinstitucionales/> ("Acuerdo de cooperación sanitaria") (Spanish only).

- To include in the sanitary registration and GMP certification processes the information and evaluations that served as the basis for granting sanitary registration or GMP certification by any of the participants.
- To notify the other participants of the cancellation or revocation of a sanitary registration, as well as any adverse reactions, alerts and any other problems related to the quality, safety or efficacy of medicines, and other circumstances concerning establishments with GMP certificates for medicines.
- To incorporate into each participant's processes the necessary mechanisms to comply with the commitments made in order to expedite the granting of sanitary registrations for medicines in accordance with the domestic standards of each country, which does not necessarily imply reducing statutory time frames or waiving requirements.

The agreement is only applicable to those health authorities that are certified by PAHO as a Level IV National Regulatory Authority (NRA). To date, that is the case of the Institute of Public Health (Instituto de Salud Pública–ISP) of Chile, the National Institute for the Monitoring of Medicines and Food National (INVIMA) of Colombia and the Federal Commission for Protection against Health Risks (COFEPRIS) of Mexico.

(b) Elimination of technical barriers to trade in medical devices

In December 2020, by which time the COVID-19 pandemic was in progress, Pacific Alliance countries approved a new annex on removing technical barriers to trade in medical devices, which will become part of the Alliance's Trade Protocol. The Annex (not yet in force) will apply to the preparation, adoption and implementation of technical regulations, conformity assessment procedures and sanitary registrations that may affect trade in medical devices between the Parties.⁶ The main commitments undertaken are as follows:

- The Parties will collaborate through the initiatives of international organizations in order to harmonize their respective regulations and regulatory activities relating to medical devices.
- The Parties agree that, should they consider an amendment to their respective national definitions of medical devices, they will take into account the international reference standards for such amendments.
- When developing the regulatory framework for medical devices, the Parties will consider their available resources and technical capacity to minimize the application of requirements that could:
 - (a) Inhibit the effectiveness of the procedure to ensure the quality, safety and performance of medical devices; or
 - (b) lead to delays in the sanitary registration of medical devices for sale on the market.
- The Parties agree that, for the issuance of the sanitary registration of medical devices, they will accept the certificate attesting to good manufacturing practices issued by the country of origin or the current ISO 13485 certificate.
- For the granting of the sanitary registration for imported medical devices, the Parties shall accept the validity established in the certificate of free sale.
- The Parties will recognize low-risk medical device health registrations issued by any of the Parties, to which end they will establish a mechanism for recognition through a working group, including the issuance procedure and periods.

⁶ The Parties agree to adopt the definition of medical devices established by the International Medical Device Regulators Forum (IMDRF), as amended and updated.

2. MERCOSUR

MERCOSUR members have adopted more than 60 resolutions related to the pharmaceutical sector since its inception in 1991, evincing an intense agenda of regulatory harmonization. Those efforts began in 1992 with resolution 04/1992 on “Good Manufacturing Practices and Quality Inspection of Medicines” (Prácticas adecuadas para la fabricación e inspección de la calidad de los medicamentos).⁷ Also noteworthy are resolutions 41/2014 on “Minimum content of the certificate of compliance with good manufacturing practices in the pharmaceutical area” (Contenido mínimo del certificado de cumplimiento de buenas prácticas de fabricación en el área farmacéutica) and 14/2015, “MERCOSUR Pharmacopoeia: Vaccines for human use” (Farmacopea MERCOSUR: Vacunas de uso humano). The two most recent resolutions on the pharmaceutical sector, which were adopted in the context of the COVID-19 pandemic, are 30/2020 “Good Practice Requirements for the Organization and Operation of Clinical Analysis Laboratories” (Requisitos de Buenas Prácticas para la Organización y Funcionamiento de Laboratorios de Análisis Clínicos) and 02/2021 “Minimum Criteria for the Application of Risk Analysis in the Classification of Good Manufacturing Practice Deficiencies in Medicines” (Criterios mínimos para la aplicación de análisis de riesgo en la clasificación de deficiencias en buenas prácticas de fabricación de medicamentos).

⁷ All resolutions are available at <https://www.mercosur.int/documentos-y-normativa/normativa/>.



The *Plan for self-sufficiency in health matters in Latin America and the Caribbean: lines of action and proposals* is a strategic document setting out lines of action to strengthen capacities to produce and distribute vaccines and medicines in the region. It was prepared by the Economic Commission for Latin America and the Caribbean (ECLAC) at the request of the Government of Mexico, in its capacity as Pro Tempore Chair of the Community of Latin American and Caribbean States (CELAC).

The pandemic has highlighted the need for strong health systems and capacities. This document proposes seven lines of action that include short-, medium- and long-term initiatives to strengthen mechanisms for pooled international procurement of vaccines and essential medicines; use public procurement mechanisms for medicines to develop regional markets; create consortiums for the development and production of vaccines; implement a regional clinical trials platform; take advantage of regulatory flexibilities to gain access to intellectual property; strengthen regulatory convergence and recognition mechanisms; and strengthen primary health systems for equitable distribution of vaccines and universal access to them.

These lines of action and proposals for a plan for self-sufficiency in health matters in Latin America and the Caribbean are a call to action and set a clear and specific agenda, while advocating and requiring greater regional integration, cooperation and solidarity.