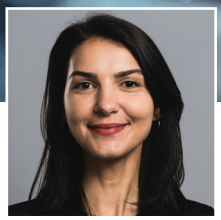
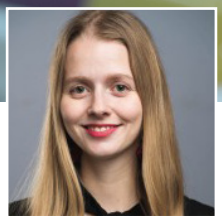
PRECISIONadvisors

What you need to know about key stakeholders and P&MA dynamics in Latin America for 2023 and beyond

Salvador Alvarez Rio, Dilyana Dimitrova & Dominika Meszarosova | PRECISIONadvisors


Salvador Alvarez Rio


Dilyana Dimitrova


Dominika Meszarosova

This paper provides an overview of key figures, stakeholders, and market access trends in the 5 largest Latin American markets, with a focus on key opportunities and challenges for manufacturers looking to launch innovative treatments in this region.

PRECISIONadvisors' LATAM expertise

PRECISIONadvisors is a specialist global pricing and market access consultancy. In 2022 alone, our team worked on projects with 25 different markets in scope, including key LATAM countries. We have a specialist team dedicated to developing our LATAM presence lead by Salvador Alvarez Rio. Salvador is a Senior Engagement Manager and his experience spans across many access, commercial, and distribution roles both in the pharmaceutical industry and as a consultant in Latin America, including 8 years at Novartis in Mexico.

Additionally, PRECISIONadvisors has a robust native Spanish-speaking team formed of several team members spanning from Analyst to Director, allowing us to conduct primary and secondary research in the local language in Latin America. We also collaborate with alliance partners in Brazil and the rest of the region who help us further build our local expertise.

Following on our success with our US and EU payer expert panels, we are developing a Latin American panel with profiles such as Senior Manager in the General Health Council in Mexico and Advisor to UNO, regional HTA organisations, and Head University HTA in Chile.

Introduction

Latin America is a rapidly growing pharmaceutical market, valued at an estimated USD $43 billion*. Sales from 2021 to 2025 are expected to have a compound annual growth rate of 9.7%, higher than all other world regions. Over 90% of this market is concentrated in 5 countries: Brazil, Mexico, Argentina, Colombia, and Chile, and more than 75% of the health spending takes place in Brazil, Mexico, and Argentina. Each of these markets have completely different healthcare models and pricing and reimbursement archetypes.

One thing the whole region has in common is a constantly evolving political situation with ongoing processes striving to improve access to medicines. From a regulatory perspective, progress has been seen with the Brazilian, Mexican, Argentinian, Colombian, and Chilean regulatory agencies achieving WHO/PAHO Level 4 certification. Additionally, creating more formal and improved HTA processes looking to evaluate high-cost therapies more efficiently and objectively is helping to improve access across markets. For example, from a pricing and innovative contracting perspective, managed-entry-agreements (MEA) are increasingly considered in Brazil, Mexico, and Argentina as a way to include high-cost drugs and orphan products in national formularies.

With the highest estimated regional growth rate for pharmaceuticals in the world for the coming years, it is important to understand who the key stakeholders are, as well as the characteristics of the major markets, alongside country-specific and regional dynamics.

Table 1: Latin America data overview

COUNTRY	POPULATION (2021)	GDP (2021)	GDP DESTINED TO HEALTH, % (2019)	PHARMA MARKET SIZE (2020)*
Latin America & Caribbean	**658,089,208**	**$5.49 trillion**	**7.96**	**$42.9 billion**
Brazil	213,993,441	$1.61 trillion	9.59	$20.8 billion
Mexico	130,262,220	$1.29 trillion	5.43	$7.4 billion
Argentina	45,808,747	$491.49 billion	9.51	$4.8 billion
Colombia	51,265,841	$314.32 billion	7.71	$4.8 billion
Chile	19,212,362	$317.06 billion	9.33	$1.6 billion

**Ex-factory prices, excluding tenders.*

Brazil

Brazil is the largest pharmaceutical market in Latin America with an estimated population of approximately 214 million. In 2019, 9.59% of the GDP was spent on healthcare with 20.5% of this being on pharmaceuticals and medical devices.

Brazil has a public health system predominantly represented by the Unified Health System (Sistema Único de Saúde, SUS) that covers every person legally living in the country. SUS is decentralised with funding by the Ministry of Health (MoH), states, and municipalities. Healthcare administration is handled regionally, leading to a lot of disparity in quality and access to care. Additionally, one-third of Brazilians have private health insurance regulated by the National Regulatory Agency for Private Health Insurance (ANS), which amounts to about 58% of the total healthcare expenditure.

The Brazilian Health Regulatory Agency (ANVISA) is responsible for the marketing authorisation of medicines based on their efficacy, safety, and quality. Once approved, a medicine is subject to price negotiations with Medicine Regulation Chamber (CMED) for maximum price approval (price cap). For drugs considered to be innovative, maximum wholesaler price is set using international reference pricing (IRP), while all other drugs are priced in line with the existing alternatives. Public reimbursement is contingent on the inclusion in the national list of medicines (RENAME), which is published by the MoH and takes into consideration the assessment by the national HTA body, National Committee for Technology Incorporation (CONITEC). The HTA process focuses on 3 key aspects: 1) effectiveness and safety vs existing drugs; 2) cost effectiveness, cost utility, or cost-benefit studies if therapeutic benefit is claimed and if there are additional costs compared to existing products; and 3) budget impact.

Despite having a national health system and a well-established HTA process, Brazil has one of the largest private health insurance markets in the world. Although the formation of CONITEC was associated with improvements in terms of time to access and transparency of the HTA process, most innovative and high-cost treatments tend to only be available through the private sector due to public budget constraints, further contributing toward disparities in access to care. Nevertheless, opportunities for manufacturers may arise as pharma-friendly policies are expected with the recent election of Luis Inácio Lula da Silva as president. Some of his goals are to increase healthcare spending and to strengthen the ANVISA workforce, which could lead to faster medicines approval.

Table 2: Key market access stakeholders in Brazil

RESPONSIBILITY	STAKEHOLDER		ROLE
Policy	MoH/MS	Ministério da Saúde –Ministry of Health	Responsible for national health policy
Regulatory	ANVISA	Agência Nacional de Vigilância Sanitária–Sanitary Vigilance National Agency	National regulatory agency
HTA	CONITEC	Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde–National HTA Comission	Responsible for advising the Brazilian Ministry of Health in the inclusion of health technologies into the SUS and development of clinical guidelines
Pricing	CMED	Câmara de Regulação do Mercado de Medicamentos–Medicine Regulation Chamber	The inter-ministerial body responsible for the economic regulation of the pharmaceutical market in Brazil. It also establishes limits for drug prices and sets and monitors the application of the mandatory minimum discount for public purchases
Payers/ Providers/ Others	SUS	Sistema Único de Saúde–Single Health System	Provides universal health coverage to the population. It is financed from the national, state, and municipal budgets and is conformed by public and private clinics (through agreements with the government)
	Privado	Seguro Privado–Private Insurance	Multiple hospital chains and national and international private health insurance companies operate in Brazil

Mexico

Mexico is the second-largest pharmaceutical market in the region. It has the lowest percentage of GDP spent on healthcare of the 5 main markets by a substantial margin. Mexico has a mixed and complex health system comprised of a public sector with multiple stakeholders and institutions alongside a robust private sector. IMSS, ISSSTE and INSABI are the three main payers in the public sector where INSABI is financed by government funds only, while IMSS and ISSSTE are also funded through companies and workers' contributions. The private sector is funded through out-of-pocket payments and private insurance.

Regulatory processes have historically been slow and disorganised. The Mexican Regulatory Agency (COFEPRIS) is currently implementing new changes aimed at simplifying and accelerating regulatory approvals. Market access has no well-established process and National Centre for Health Technology Excellence (CENETEC), Mexico's HTA agency, lacks relevance in this process. In recent years with the current administration, relations with the local industry have been complicated. Medicine supply shortages have been common, with general purchases conducted through United Nations Office for Project Services (UNOPS) and, with direct purchases being the norm instead of previously more formal national tendering processes.

Willingness to pay for advanced therapies is growing but understanding the hurdles and how to reach the relevant stakeholders remains complicated. Despite the challenges, the market size and future growth opportunities make Mexico a very interesting market to participate in.

Table 3: Key market access stakeholders in Mexico

RESPONSIBILITY	STAKEHOLDER		DESCRIPTION
Policy	SSA	Secretaría de Salud–Ministry of Health	Responsible for health policy and includes all mayor national speciality research institutes (e.g., neurology, cardiology and cancer institutes)
	CSG	Consejo de Salubridad General–National Health Council	Health authority reporting to the president and responsible for the Compendio Nacional de Insumos para la Salud, which is the national reimbursable medicine formulary
Regulatory	COFEPRIS	Comisión Federal para la Protección de Riesgos Sanitarios–National Medicine Agency	National regulatory agency
HTA	CENETEC	Centro Nacional de Excelencia Tecnológica en Salud–National Health-Technology Excellence Centre	Evaluates the safety, efficacy/effectiveness, and efficiency of the health technologies proposed for incorporation into the National Compendium of Medicines. However, it currently has little relevance in the market access process
Pricing	CCNPMIS	Comisión Coordinadora para la Negociación de Precios de Medicamentos e Insumos para la Salud–Price Negotiation Comission	The objective is to negotiate the price of medicines contained in the basic formulary for basic-level medical care and in the Compendio Nacional de Insumos para la Salud
Payers/ Providers/ Others	INSABI	Instituto de Salud para el Bienestar–National Health and Well-being Institute	Responsible for providing healthcare services to all people not affiliated to any other public social security institutions
	IMSS	Instituto Mexicano del Seguro Social–Mexican Social Security Institute	Responsible of providing healthcare services to salary workers from the private sector
	ISSSTE	Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado–Social Security Institute for Government Workers	Provides healthcare services to government workers
	SEDENA	Secretaría de la Defensa Nacional–Army Ministry	Provides healthcare services to Army personnel and their families
	MARINA	Secretaría de Marina–Navy Ministry	Provides healthcare services to Navy personnel and their families
	PEMEX	Petróleos Mexicanos–Mexican Petroleum Company	Provides healthcare services to its employees and their families
	Private	Seguro Privado–Private Insurance	Multiple hospital chains and national and international private health insurance companies operate in Mexico

Argentina

Argentina is a large upper-middle-income market with one of the highest percentages of GDP spent on healthcare in this region. The majority of Argentinians are covered through social security (~63%), while ~36% receive care through the public sector, and ~16% have private insurance, with ~10% of the population having multiple coverage (ie, either public and private, or provincial and national social security).

Drugs can be marketed in Argentina once approved by ANMAT, but reimbursement depends on their inclusion in formularies. Both public and private insurers have their own formularies, and coverage is very heterogeneous and largely driven by the drug's price. In theory, drug prices in Argentina are not regulated by law and can be set freely by the manufacturer. However, pricing is heavily influenced by contracting and government price rollback orders. Maximum price setting is expected to become more common since the establishment of an HTA body (CONETEC) in 2018, especially when it comes to innovative and high-cost medicines. Additionally, high-cost drugs for diseases with low incidence or those that require long-term treatment are subject to additional financial support through Sistema Unico de Reintegro (SUR), which redistributes funds on a national level to ensure equal access for all patients.

One of the most important challenges in Argentina is hyperinflation, which heavily impacts the pricing dynamics and affordability in the healthcare and pharmaceutical sectors. Moreover, the size of the country, decentralisation and fragmentation of the public health sector, and socio-economic factors lead to large differences in wealth, access to care, and quality of care between and within provinces. Nevertheless, the increasing importance of HTA, relatively high spend on healthcare, and emerging mechanisms for redistribution of funds for high-cost medicines offer great opportunities to increase access to innovative treatments in an equitable manner.

Table 4: Key market access stakeholders in Argentina

RESPONSIBILITY	STAKEHOLDER		DESCRIPTION
Policy	MINSA	Ministerio de Salud–Ministry of Health	Responsible for national health policy
	SSSalud	Superintendencia de Servicios de Salud–Superintendence of Health Services	Health authority reporting to the president and responsible for the Compendio Nacional de Insumos para la Salud, which is the national reimbursable medicine formulary
Regulatory	ANMAT	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica–Argentina Medicine Agency	National regulatory agency
HTA	CONETEC	Comisión Nacional de Evaluación de Tecnologías de Salud-National Commission for Health Technology Assessment	Evaluates the safety, efficacy/effectiveness, and efficiency of the health technologies proposed for incorporation into the National Compendium of Medicines. However, it currently has little relevance in the market access process
Payers/ Providers/ Others	OS	Obras Sociales–Insurance Plans	Union-backed, private health insurance entities (national or provincial) for workers that is co-financed by employers and employees
	PAMI	Programa de Atención Médica Integral– Integral Medical Atention Program	Obra social for pensioneers and retired workers, elderly without pension (aged >70 years) and veterans from the Malvinas/Falkland War
	Prepago	Aseguradoras Privadas–Private Insurance Companies	National and international private health insurance companies

Colombia

Colombia is the third-largest pharmaceutical market in Latin America. The country provides near-universal health coverage with 97% of the population receiving care under the public health service (SGSSS). Healthcare coverage operates under 2 schemes:

1) **Contributory**: For employees and/or persons who are able to pay for coverage, financed through contributions from the persons and their employers

2) **Subsidised**: For persons who are not able to pay and/or vulnerable populations, financed via cross-contributions from the contributory sector and national/regional taxes

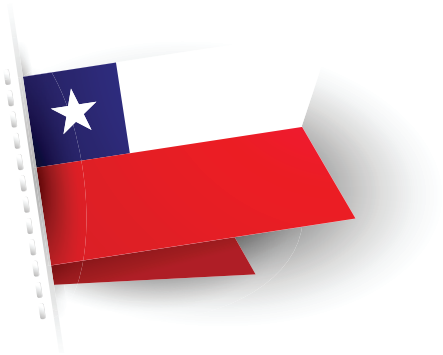
In contrast with many other countries in the region, all drugs in Colombia are subject to an HTA by the National Commission for Health Technology Assessment (IETS), which is performed simultaneously with the regulatory assessment and considers the drug's safety, efficacy, efficiency, usefulness, and economic impact. The non-binding IETS recommendation informs the pricing decision by the National Commission for Pricing of Medicines and Medical Devices (CNPMDM), with 2 possible outcomes in terms of price setting depending on the drug's inclusion in the national compulsory health plan (POS). Products that the MoH includes in the POS are subject to a maximum wholesaler selling price. Non-POS therapies approved by the regulatory agency (INVIMA) are subject to free pricing, though since 2019 a price cap based on IRP has been established for non-POS products to limit pharmaceutical expenditure. Healthcare is provided via nearly 70 different public health insurers, which are obliged to provide all medical services/treatments within the POS. Premium innovative drugs are usually excluded from the POS, but the Ministry of Health provides public health insurance plans (EPS) with a set annual budget to finance non-POS therapies.

Healthcare reforms in Colombia over the past 2 decades have been associated with rapid reduction in out-of-pocket expenditure and improvement in access to care. There is also a strong incentive to provide broad and equitable access to medicines and medical technologies to promote health across the country. Unified regulatory and HTA process creates opportunities for manufacturers to simplify and speed up access to patients by removing the obstacle of multiple payers and the need for numerous pricing and reimbursement negotiations. However, challenges remain for products not included in the POS, for which reimbursement is scarce and depends on decisions made by the individual public health insurers.

Table 5: Key market access stakeholders in Colombia

RESPONSIBILITY	STAKEHOLDER		ROLE
Policy	MINSALUD	Ministerio de Salud y Protección Social–Ministry of Health and Social Protection	Responsible for national health policy
Regulatory	INVIMA	Instituto Nacional de Vigilancia de Medicamentos y Alimentos– Colombia Medicine Agency	National regulatory agency
HTA	IETS	Instituto de Evaluación Tecnológica en Salud– National Commission for Health Technology Assessment	A decentralised, private-public HTA entity that has brought credibility to the health technologies evaluation since its inception in 2011; it is also responsible for developing treatment guidelines, horizon scanning and early scientific dialogues
Pricing	CNPMDM	Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos– National Commission for Pricing of Medicines and Medical Devices	Entity responsible for the establishment and control of prices for pharmaceuticals
Payers/ Providers/ Others	SGSSS	Sistema General de Seguridad Social en Salud de Colombia–National Health System	Regulates essential primary care public health for the general population. There are 2 coverage systems: the contributory regimen for those with enough income, and the subsidiary regimen for those with limited resources
	EPSs	Entidades Promotoras de Salud– Health-Public Health Insurance	Responsible for the affiliation, the collection of contributions, and providing healthcare through the Plan Unico de Proteccion Integral (POS) from the Ministry of Health and Social Protection
	IPSs	Instituciones Prestadoras de Salud– Health Provision Institutions	Hospitals, clinics, and laboratories, among others, in charge of providing healthcare services
	ADRES	Administradora de los Recursos del Sistema General de Seguridad Social en Salud–Health System Fund Management Entity	Its objective is to guarantee the adequate flow of resources of the General System of Social Security in Health (SGSSS) and implement the controls

Chile



Chile is the fifth-largest pharmaceutical market in Latin America. It has a mixed system divided into public and private healthcare. The public sector covers close to 80% of the population through the National Health Fund (FONASA) and social security funds for the police (DIPRECA), and the military (CAPEDENA). The private sector is represented by sick funds (ISAPRES) and non-profit insurance companies (Mutuales) and covers the majority of the additional 20% of Chile's population. There is unequal access to advanced and high-cost treatments in Chile, and a very high out-of-pocket expenditure.

Since recent public unrest in 2019, the health system is being challenged and new health system financing and structuring schemes are being proposed. A new proposed constitution, which included changes to the health system, was recently rejected by the public. Nevertheless, recent laws and public pressure are expected to continue shaping access to treatments aimed at achieving universal coverage and reduction of out-of-pocket expenses. One of the proposed changes is the formation of an autonomous HTA body, as the HTA process is currently housed in, and fully dependent on, the Ministry of Health (Departamento de ETESA y Salud Basada en Evidencia).

Table 6: Key market access stakeholders in Chile

RESPONSIBILITY	STAKEHOLDER		ROLE
Policy	MINSAL	Ministerio de Salud–Health Ministry	Responsible for national health policy
Regulatory	ANAMED	Agencia Nacional de Medicamentos–National Medicine Agency	National regulatory agency
Payers/ Providers/ Others	FONASA	Fondo Nacional de Salud–National Health Fund	Fund responsible for collecting, managing, and distributing the government budget for health
	DIPRECA	Dirección de Previsión de Carabineros de Chile– Police Social Security	Institution responsible for the social security and health of all police bodies and their families
	CAPEDENA	Caja de Previsión de la Defensa Nacional–Military Social Security	Decentralised institution responsible for the social security and health of all military personal and their families
	ISAPREs	Instituciones de Salud Previsional–Sick Funds	Private insurance entities responsible for providing financing and treatment to registered clients
	Mutuales	Mutuales-Not-for-profit Insurance Companies	Hospitals, clinics, and laboratories, among others, in charge of providing healthcare services

Considerations and conclusions

Launching novel medicines in Latin America is an opportunity for pharmaceutical companies to reach a large number of patients in need of new therapies. The growing presence of HTAs and a shift toward universal coverage across key markets is aiming to secure equitable access to medicines, but political instability and an often fragmented, multi-stakeholder healthcare system represents a challenge in navigating the market access pathways for manufacturers. Therefore, partnering with experts on the region is an essential ingredient for a successful launch.

For further information, contact our market access strategy experts:

Salvador Alvarez Rio
Senior Engagement Manager
PRECISIONadvisors
Salvador.AlvarezRio@precisionvh.com
Madrid, Spain

Dilyana Dimitrova
Consultant
PRECISIONadvisors
Dilyana.Dimitrova@precisionvh.com
London, UK

Dominika Meszarosova
Engagement Manager
PRECISIONadvisors
Dominika.Meszarosova@precisionvh.com
London, UK

References:

1. PharmaBoardroom. InFigures: Latin America. February 2022. Accessed February 2, 2022. **https://pharmaboardroom.com/country-reports/infigures-latin-america-2022/**
2. IQVIA. Market Prognosis 2022: The Outlook for the Latin American Pharmaceutical Market Following the Impact of the COVID-19 Pandemic.
3. Vargas V, Rama M, Singh R. Pharmaceuticals in Latin America and the Caribbean: Players, access, and innovation across diverse models. World Bank, Washington DC. Accessed February 4, 2022. **https://openknowledge.worldbank.org/handle/10986/36871**
4. Tikkanen R, Osborn R, Mossialos E, Djordjevic A, Wharton GA. International health care system profiles: Brazil. June 5, 2020. The Commonwealth Fund. Accessed February 2, 2023. **https://www.commonwealthfund.org/international-health-policy-center/countries/brazil**
5. Datamonitor Healthcare. Market access trends in the US, Europe, and emerging markets. March 2019. Accessed February 2, 2023. **https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2019/files/whitepapers/global-market-access-whitepaper_.pdf**
6. The World Bank. Countries and economies. Accessed February 2, 2023. **https://data.worldbank.org/country**
7. Oficina de Presupuesto del Congreso. Characteristics of the Argentine health care system. 2021. Accessed February 2, 2023. **https://www.opc.gob.ar/en/public-policies-evaluation/characteristics-of-the-argentine-health-care-system/**
8. Catalano HN, Hamilton G, Izcovich A, et al. Agencia de evaluación de tecnologías sanitarias en Argentina. Fundación Sanatorio Güemes. 2018. Accessed February 2, 2023. **https://www.sadamweb.com.ar/news/2018_12Diciembre/eBook-AgenciaEvaluacionTecnologiasSanitarias.pdf**
9. **https://www.neuroeconomix.com/es/todo-lo-que-usted-debe-saber-del-sistema-de-salud-en-chile/**

To learn more about PRECISIONadvisors, visit **www.precisionadvisors.com**.

PRECISIONadvisors
a precision value & health team