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Pricing and Healthcare Access in Latin America Quick Guide

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The Healthcare and Life Sciences industry in Latin America is highly regulated. This one-pager provides brief insight into the basis for price controls as well as the authorities, categories and regulations governing those controls. It also provides initial information on access to public health systems and regulations regarding the drugs available through those systems. Finally, it sheds light on what you should consider when it comes to the regulation of private healthcare plans including mandatory minimum coverage.

Latin America Healthcare & Life Sciences Steering Committee

ARGENTINA

Vanina Caniza

Global Chair, Healthcare and Life Sciences Industry Group

Partner, Argentina
vanina.caniza
@bakermckenzie.com

BRAZIL

Henrique Frizzo*

Partner,
Trench Rossi Watanabe, Brazil
henrique.frizzo
@trenchrossi.com

CHILE

Valentina Venturelli

Partner, Chile
valentina.venturelli
@bakermckenzie.com

COLOMBIA

Juan Pablo Concha

Partner, Colombia
juan.concha
@bakermckenzie.com

MEXICO

Christian López-Silva

Partner, Mexico
christian.lopez-silva
@bakermckenzie.com

PERU

Álvaro Gutiérrez

Partner, Peru
alvaro.gutierrez
@bakermckenzie.com

VENEZUELA

Adriana Gonçalves Apitz

Sr. Assoc., Venezuela
adriana.goncalves
@bakermckenzie.com

**Trench Rossi Watanabe and Baker McKenzie have executed a strategic cooperation agreement for consulting on foreign law*

Pricing

Consider conditions such as authority, basis, definition(s) and adjustments when it comes to market authorization and economic regulation.

- Marketing Authorization holders can set the price for pharmaceuticals but must inform the National Administration of Drugs, Foods and Medical Devices' (ANMAT's) registry of the price.
  - The limits to the right to set prices are found in the following laws and regulations: Civil and Commercial Code, Antitrust Law, Commercial Loyalty Decree, Consumer Protection Law, Supply Law, and the Patent Law.
  - Authorities recently regulated the prices of a specific orphan drug and froze prices of specific pharmaceuticals, preventing price increases due to inflation based on the Supply Law, cited above.

Access to Public Health Systems

Be aware of issues regarding identifying systems, selecting drugs by system. Who's responsible for reviews and updates?

- The Ministry of Health ("MOH") manages administrative issues related to the public health service. It is part of the centralized Public Administration. Provincial ministries work in conjunction with the MOH.
- ANMAT is dependent on the MOH and grants import and manufacturing licenses, controls adherence to Good Manufacturing Procedures (GMP) and grants marketing authorizations.
- The National Comprehensive Drug Policy Department (Secretaría de Políticas Integrales sobre Drogas de la Nación Argentina (SEDRONAR) controls operations with certain chemical substances capable of being used in the illicit manufacture of narcotic drugs and psychotropic substances. SEDRONAR depends on the Office of the President.
- The Superintendence of Health Services (SSS) has monitoring, control, and enforcement capacities over healthcare insurers of the National Health Insurance System.

Access to Private Health Plans

What should you consider when it comes to the regulation of private plans as well as mandatory and/or minimum coverage?

- Once a product obtains a marketing authorization from ANMAT, it does not require any further approval to be sold in the private market.
- Health insurance providers are subject to strict regulations and oversight, including minimum mandatory coverage. The scope of this coverage is mostly regulated by the administrative authorities, but in certain cases courts may also require specific treatments or products to be included in the minimum coverage.

Key Contact

Vanina Caniza
Partner, Argentina
vanina.caniza@bakermckenzie.com

Pricing

Consider conditions such as authority, basis, definition(s) and adjustments when it comes to market authorization and economic regulation.

- The Drugs Market Regulation Chamber (CMED) sets limits for drug prices, adopts rules that stimulate competition in the sector and applies penalties when its rules are violated. Additionally, it sets the allowed readjustment index to be applied over the Ex-factory prices annually.
- Prices are set based on different categories:

Innovative drugs are subject to an international price comparison based on a basket of 12 countries.

Non-innovative medicines are subject to both the international price comparison and a comparison with the prices of available therapies.

Generics must be at least 65% of the price of the reference drug.

- The price is defined for producers and importers inclusive of tax, defined as "ex-factory".
- On top of those, other maximum prices are defined, such as the maximum consumer price and maximum government price (which is generally 20% less than the ex-factory price).

Top Tip

- In the dossier to be su bmitted to CMED for requesting the pricing approval, it is important to develop a strategic rational with arguments based on scientific evidence, reinforcing clinical and technical aspects of the product, as well as operational elements that impact on prices. The developed strategy must be key to convincing CMED evaluators regarding the drug category and its pricing.

Access to Public Health Systems

Be aware of issues regarding identifying systems, selecting drugs by system. Who's responsible for reviews and updates?

- Drugs available at the Unified Health System (SUS), the Brazilian public health system, are selected and standardized in the National Essential Medicines List (EML).
- The review and update process is conducted by the Ministry of Health with the assistance of the National Commission for the Incorporation of Technologies (CONITEC), which evaluates the drugs and treatments based on available scientific evidence (efficacy, safety, cost-effectiveness), and then recommends them for incorporation into the SUS.

Top Tip

- It is important to evidence to CONITEC why the therapy must be made available in SUS and how it is different and/or more advanced than other therapies already available.
- Sometimes, due to budgetary constraints, it is not possible to make the new therapy available to the entire population. If this may be the case, proposing a partial incorporation is a possibility. Suggestions of risk sharing agreements should be carefully considered.

Access to Private Health Plans

What should you consider when it comes to the regulation of private plans as well as mandatory and/or minimum coverage?

- Private health plans are regulated by the National Supplementary Health Agency (ANS), which publishes a basic Reference List for mandatory minimum coverage of health plans.
- Treatments present on the ANS list must be covered by health plans.
- ANS now has the duty to incorporate the technologies that have been positively evaluated and recommended by CONITEC.

Top Tip

- Be aware of the cut-off date for automatic incorporation into the ANS list of treatments recommended by CONITEC. ANS understands that the automatic incorporation is only valid to technologies recommended and published by CONITEC after March 2022.

Key Contacts

Henrique Frizzo*
Partner, Trench Rossi Watanabe, Brazil
henrique.frizzo@trenchrossi.com

Carla Moraes*
Senior Associate, Trench Rossi Watanabe, Brazil
carla.moraes@trenchrossi.com

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Pricing

Consider conditions such as authority, basis, definition(s) and adjustments when it comes to market authorization and economic regulation.

- There are no price controls for pharmaceutical products in Chile to date; however, these controls may be included in the proposed Pharmacy Law II which is still being discussed in Congress.
- The formula to set prices has not yet been determined.

Access to Public Health Systems

Be aware of issues regarding identifying systems, selecting drugs by system. Who's responsible for reviews and updates?

- The Ministry of Health is responsible for elaborating, updating and following up on the National Formulary.
- The Ministry of Health works with a Technical-Scientific Commission, which advises on these matters.

Access to Private Health Plans

What should you consider when it comes to the regulation of private plans as well as mandatory and/or minimum coverage?

- Access to private health plans is not regulated in Chile; there is no minimum coverage.

Key Contact

Valentina Venturelli
Partner, Chile
valentina.venturelli@bakermckenzie.com

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Consider conditions such as authority, basis, definition(s) and adjustments when it comes to market authorization and economic regulation.

The National Drugs and Medical Devices Pricing Commission (CNPMDM) is responsible for price controls

- Currently prices are set based on two different categories:

  Supervised freedom regime covers the majority of medicines. Applies for those medicines that are not under direct control regime.

  Direct control medicines are specific medicines established by CNPMDM annually.

- The prices of medicines sold in outlets such as drugstores are not expressly regulated by the CNPMDM; however, the players must consider a fair margin between the wholesale purchase price and the sale price to consumers.
- The Health Technology Assessment Institute (IETS) evaluates the price of new medicines, that is those that are not covered by the pharmacological norms, have new indications or have a new form of administration.
- The Superintendence of Commerce and Industry imposes penalties for violations of pricing provisions.

Key Contact

Juan Pablo Concha
Partner, Colombia
juan.concha@bakermckenzie.com

Access to Public Health Systems

Be aware of issues regarding identifying systems, selecting drugs by system. Who's responsible for reviews and updates?

- Public health system is divided into two regimes:

  The Subsidized regime which covers the majority of people who do not have an employment or service contract.

  The Contributory regime which covers people who have an employment or service contract.

- The Ministry of Health reviews, determines and updates the medicines, services and technologies that can be prescribed through the public health system as well as those that have specific prescription requirements. It also determines what is to be excluded from the public health system.

Access to Private Health Plans

What should you consider when it comes to the regulation of private plans as well as mandatory and/or minimum coverage?

- Private health plans are regulated by two different entities:

  The Superintendent of National Health regulates Prepaid Medical Services Plans and Complementary Health Plans - PAC.

  The Financial Superintendence regulates health insurance.

Top Tip

- Be aware of the cut-off date for automatic incorporation into the ANS list of treatments recommended by CONITEC. ANS understands that the automatic incorporation is only valid to technologies recommended and published by CONITEC after March 2022.

Take Note of these Exceptional Circumstances

It is possible to commercialize medicines and medical devices that have not obtained the sanitary registration in specific and extraordinary situations.

The Colombian government has submitted a bill to the Congress in order to reform the public health system which may have an impact on the comments above.

Pricing

Consider conditions such as authority, basis, definition(s) and adjustments when it comes to market authorization and economic regulation.

- Pricing in the private market depends on patent protection:

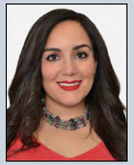
  If patented, the product is subject to an international price referencing system, which can be updated.

  If not patented, the price is determined by supply and demand.

- Pricing in the public market no longer depends on patent protection. In both cases (patented or not) the price will be determined through the public acquisition process, which includes: (i) a prior market research and (ii) the bases of a tender (not patented) or the draft contractual bases for direct awards (patented).
- Additionally, recent legal amendments introduced a requirement to the procedure to request the addition of products to the National Formulary, where a maximum price has to be provided and will be used in subsequent public acquisitions.

Key Contacts

Christian López-Silva
Partner, Mexico
christian.lopez-silva@bakermckenzie.com



Carla Calderón
Senior Associate, Mexico
carla.calderon@bakermckenzie.com

Access to Public Health Systems

Be aware of issues regarding identifying systems, selecting drugs by system. Who's responsible for reviews and updates?

- The General Health Council, an autonomous regulator, is in charge of managing the National Formulary.
- The methodology used to assess product applications includes several Pharmocol-Economics tools. Both public institutions and private companies can submit applications to add, modify or remove products.
- In addition, there are Institutional Formularies, managed by each of the main Payors, which include the National Institute of Social Security (MSS) and the Institute for Social Security Service for Public Servants (ISSTE).
- Additionally, recent legal amendments to the procedure to request the addition of products to the National Formulary, now require to generate a Sponsor Letter from one of the public institutions, which has been litigated for becoming an entry barrier.
- In principle, public institutions can only acquire products that: (i) have a marketing authorization from the Federal Committee for Protection from Sanitary Risks (COFEPRIS), (ii) are listed in the National Formulary and (iii) are listed in the respective Institutional Formulary.
- Completing the whole public access pathway can take 4-5 years.

Top Tip

- Companies need to consider either: (i) litigating the Sponsoring Letter, at the first refusal to add products to the National Formulary, to be exempted from that new requirement, or (ii) embrace the change and introduce new compliance rules for the interaction they will now have to implement with the payors or administrative units of the public health institutions.

Access to Private Health Plans

What should you consider when it comes to the regulation of private plans as well as mandatory and/or minimum coverage?

Access to private health plans is not regulated in Mexico and there is no minimum coverage.

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Consider conditions such as authority, basis, definition(s) and adjustments when it comes to market authorization and economic regulation.

- There are no pharmaceutical price regulations in Peru.

Access to Public Health Systems

Be aware of issues regarding identifying systems, selecting drugs by system. Who's responsible for reviews and updates?

- The public sector is divided into the subsidized or indirect contributory regime and the direct contributory regime. The direct contributory regime corresponds to social security.
- The social security health system has two subsystems: social security with traditional provisions (EsSalud) and social security with private provisions (EPS).
- Drugs are standardized in the Single National Petition for Essential Medicines (PNUME). The Ministry of Health is responsible for reviewing and updating the PNUME.

Access to Private Health Plans

What should you consider when it comes to the regulation of private plans as well as mandatory and/or minimum coverage?

- In the private sector, a distinction is made between the private for-profit sector and the private non-profit sector.
- The private for-profit sector includes the EPS, private insurers, specialized and non-specialized private clinics, medical centers and polyclinics and medical and dental offices/laboratories.
- The non-profit private sector is classically represented by a varied set of non-profit civil associations, which include non-governmental organizations (NGOs), the Peruvian Red Cross, the Volunteer Fire Companies, among others.
- The Essential Health Insurance Plan - PEAS is the minimum benefit plan that a person will receive when signing up for public, private or mixed health insurance. It specifies the basic medical procedures a person needs to receive to maintain or recover from health.

Key Contact

Álvaro Gutiérrez
Partner, Peru
alvaro.gutierrez@bakermckenzie.com

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Consider conditions such as authority, basis, definition(s) and adjustments when it comes to market authorization and economic regulation.

- The Fair Price Law allows a maximum profit margin of 30% with respect to the prices of goods and services in general, including those in the healthcare sector.
- The Ministry of Health and the National Superintendence for the Defence of Socio Economic Rights (SUNDDE) are responsible for applying the law.
- Although the Fair Price Law is still in force, authorities have not enforced its provisions or the last three years.

Access to Public Health Systems

Be aware of issues regarding identifying systems, selecting drugs by system. Who's responsible for reviews and updates?

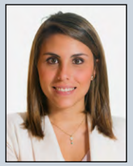
- The National Public Health System is organized and supervised by the Ministry of Health.
- The responsible party for acquiring drugs is the Ministry of Health through the National Institute of Social Security (IVSS) and this process must be carried out through public procurement procedures.

Access to Private Health Plans

What should you consider when it comes to the regulation of private plans as well as mandatory and/or minimum coverage?

- Insurance policies, including health plans, are regulated by the Insurance Activities Law.
- The Insurance Activities Law does not provide or mandatory minimum coverage.

Key Contact



Adriana Gonçalves Apitz
Senior Associate, Venezuela
adriana.goncalves@bakermckenzie.com

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