HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

The healthcare system in Argentina is composed of three main sectors: public, private and social security. Each sector has specific roles and responsibilities in providing healthcare services.

Within the public sector, we have the National/Federal Government, plus the provincial and municipal governments.

The National Ministry of Health (MoH) is the primary authority responsible for regulating and supervising the healthcare system at the national level. The MoH sets health policies, standards and regulations related to healthcare. It also coordinates national health programmes and partially funds the public healthcare system.

Provinces and municipalities are responsible for implementing and managing healthcare services within their jurisdictions. This includes the administration of public hospitals and healthcare centres, as well as the execution of local health programmes. Resources for these services come from both the national government, and provincial and municipal budgets.

The public sector is financed through national, provincial and municipal resources. Public hospitals and healthcare centres provide coverage to individuals who do not have access to other types of health coverage.

Under the scope of the MoH, the National Superintendence of Health Services (Superintendencia de Servicios de Salud de la Nación or SSS) has monitoring, control and enforcement capacities over healthcare insurance providers of the National Health Insurance System, and has authority over the national healthcare insurers' providers and the National Institute of Social Security for Retired Persons and Pensioners (Instituto Nacional de Servicios Sociales para Jubilados y Pensionados or INSSJP, also known as Programa de Atención Médica Integral or PAMI). At the local level, the SSS does not have regulatory authority over local healthcare insurance providers.

In the social security sector are public healthcare insurance providers called '*Obras Sociales*' (OOSS), which include national and provincial social security entities, as well as PAMI. These entities are funded by mandatory contributions from workers and employers, and in some cases, by provincial resources.

The beneficiaries of social security entities are employees whose contributions fund services, as well as retirees and pensioners. Healthcare insurance providers are healthcare professionals and healthcare institutions directly and/or indirectly hired by social security companies for this purpose.

In the private sector, we have pre-paid medicine companies that offer healthcare plans to individuals and families who can afford these services. This is purely private and therefore provides coverage to people who can afford the services of these companies. It is funded by the health insurance plans that these companies sell to their members, based on the health plans chosen. Private healthcare providers are healthcare professionals and healthcare institutions directly and/or indirectly hired by the pre-paid medicine companies for this purpose.

Pre-paid medicine companies are mainly regulated by Law No 26,682 and OOSS are regulated by Law No 23,660. Both public and private healthcare insurance providers are supervised by the SSS.

The SSS ensures that public and private healthcare insurance providers comply with the minimum and mandatory coverage standards established in the Mandatory Medical Program (Programa Médico Obligatorio or PMO) regulated by MoH Regulation No 201/2002.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

The legal framework governing healthcare financing and reimbursement in Argentina is multifaceted, involving several laws and regulations at both the national and provincial levels. Key components include:

National laws
Primary laws include the National Health Insurance Law (Law No 23,.661) and Social Security Law (Law No 23,.660), which establish the structure and functioning of social security entities (OOSS) and their financing mechanisms. Additionally, the Law on Prepaid Medicine Companies (Law No 26,682) regulates private healthcare insurance providers.

Product/service specific acts
There are also specific laws addressing particular health conditions and treatments, such as those related to disability, HIV treatment, fertility and cystic fibrosis. These laws mandate coverage for related treatments and drugs by healthcare insurance providers. High-cost medicines, particularly those used to treat rare or low-incidence diseases, are also subject to specific regulations, often involving special coverage provisions or reimbursement due to their high financial impact.

Provincial and municipal regulations
Provinces and municipalities have their own regulations and laws that complement national legislation, particularly in the administration and financing of public healthcare services.

The legal framework for healthcare financing and reimbursement in Argentina is complex

and involves a combination of national laws, provincial regulations and private agreements. National laws provide the overarching structure, while specific acts address particular health conditions and treatments. Private agreements between industry players further regulate the conduct of each party involved. Negotiations between these parties, often facilitated by their respective associations, are crucial for determining the terms of service provision and reimbursement, ensuring that the healthcare system operates efficiently and effectively.

Although there are some industry codes within the pharmaceutical and healthcare industries in Argentina, they do not refer to pricing and reimbursement. Some companies within the industry, especially multinational companies, have pricing policies that they follow for setting their products' prices in Argentina, and for commercial rebates and discounts within the chain of commercialisation.

As mentioned, agreements play a significant role in healthcare pricing and reimbursement systems. For instance, agreements between pharmaceutical laboratories and social security entities, as well as private health coverage companies, establish the terms for discounts on medication and reimbursement processes. These agreements are often facilitated by industry chambers, and are crucial for ensuring the availability and affordability of medication. These agreements allow patients to access medication with discounts at participating pharmacies. Discounts vary by product and are later reimbursed by social security entities.

Negotiations between healthcare providers (eg, hospitals, clinics and pharmacies) and payors (including social security entities, private healthcare insurance reimbursed and government bodies) are essential for determining the terms of service provision, pricing and reimbursement. These negotiations often result in formal agreements that outline the scope of services covered, reimbursement rates and payment schedules.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

The MoH is the primary authority responsible for the overall regulation and supervision of the healthcare system in Argentina. Within its scope and under various legal frameworks of administrative law, different state agencies operate with specific specialisations depending on the subject matter, in addition to local regulations at the province and municipal levels.

Regarding the financing and reimbursement of healthcare services and medication, the primary agency involved is the SSS. The SSS is a decentralised agency under the MoH. It is responsible for overseeing and regulating public and private healthcare insurance providers. The SSS ensures compliance with the PMO and other health regulations, in addition to reimbursement for high-cost treatments, supervises the financial and operational aspects of health coverage entities, and handles complaints and disputes related to healthcare services. In connection with the financing and reimbursement of healthcare services and medication, we can highlight that the SSS administers funds from the Fondo Solidario de Redistribución (Solidarity Redistribution Fund), which is used to equalise resources among public healthcare insurance providers, and ensure equitable access to healthcare services and medication.

In addition, the SSS created the Unique Reimbursement System (Sistema Único de Reintegro or SUR), to provide reimbursement for low-incidence, high-cost medical treatments,

according to SSS Regulation No 1,200/2012. The SUR was later replaced by the Unique Reimbursement System for Disease Management (Sistema Único de Reintegro por Gestión de Enfermedades or SURGE) through SSS Regulation No 731/2023, with similar functions.

The National Commission for Health Technology Evaluation (Comisión Nacional de Evaluación de Tecnologías Sanitarias y Excelencia Clínica or CONETEC) is the primary body responsible for evaluating health technologies in Argentina. It operates under the MoH and plays a crucial role in advising on the incorporation, use and funding of health technologies within the national healthcare system.

CONETEC evaluates the efficacy, safety, cost-effectiveness and impact of medical technologies, including drugs, medical devices and procedures, to ensure they meet national healthcare standards.

In addition, CONETEC provides evidence-based recommendations to policy-makers, helping them determine which technologies should be included in the public healthcare system or covered by public/private healthcare insurance providers. The technical definitions submitted for consultation with CONETEC are binding on the MoH and its decentralised and deconcentrated agencies.

Another relevant organism related to pricing and reimbursement is the INSSJP, a specialised body that provides healthcare services to retirees and pensioners. It is funded by contributions from workers and employers, and is supervised by the SSS.

Regarding Pharmaceutical Industry Chambers, as mentioned, several industry chambers represent pharmaceutical laboratories and play a crucial role in negotiating agreements with social security entities and private healthcare insurance providers. These include:

- Argentine Chamber of Medical Specialties (Cámara Argentina de Especialidades Medicinales or CAEMe);
- Industrial Chamber of Argentine Pharmaceutical Laboratories (Cámara Industrial de Laboratorios Farmacéuticos Argentinos or CILFA); and
- Business Chamber of Argentine Pharmaceutical Laboratories (Cámara Empresaria de Laboratorios Farmacéuticos or COOPERALA).

These chambers facilitate agreements on medication pricing and reimbursement processes, ensuring the availability and affordability of medication.

Associations representing pharmacies and wholesalers are also significant players in the healthcare system. They include:

- Argentine Pharmaceutical Confederation (Confederación Farmacéutica Argentina or COFA);
- Argentine Federation of Pharmacy Chambers (Federación Argentina de Cámaras de Farmacias or FACAF);
- Association of Mutual and Union Pharmacies of the Republic of Argentina (Asociación de Farmacias Mutuales y Sindicales de la República Argentina or AFMSRA); and

- Association of Distributors of Medical Specialties (Asociación de Distribuidores de Especialidades Medicinales or ADEM).

These associations advocate for the interests of their members, and help establish standardised terms and conditions for service provision and reimbursement.

It is worth mentioning the National Commission for the Defense of Competition (Comisión Nacional de Defensa de la Competencia or CNDC), which is the antitrust authority responsible for ensuring fair competition within the healthcare market. It oversees mergers, acquisitions and other business practices to prevent monopolistic behaviour and ensure a competitive market environment.

Finally, the judicial system in Argentina can be involved in resolving disputes related to healthcare financing and reimbursement. Courts handle cases involving non-compliance with health regulations, disputes between healthcare providers and payors, and issues related to patient rights and access to healthcare services. Decisions made by the courts can have significant implications for the interpretation and enforcement of healthcare laws and regulations. Considering the complexity of such claims, the Technical Assistance Committee for Judicial Proceedings (Comité de Asistencia Técnica para Procesos Judiciales or CATPROS) was created, which is an advisory and permanent agency tasked with providing technical assistance to federal and local courts on judicial proceedings in which a party requests treating rare diseases or special pathologies using innovative drugs or procedures, or medical technologies, within the scope of Law No 26,689.

4. Has there been a change to healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

The Covid-19 pandemic led to some changes in Argentina's healthcare financing and reimbursement mechanisms, primarily to address the increased demand for healthcare services and ensure equitable access during the crisis. Key changes include:

Emergency health funding
The government allocated additional resources to the healthcare sector, including direct funding for public hospitals and the creation of emergency programmes to support public and private healthcare insurance providers. The Fondo Solidario de Redistribución (Solidarity Redistribution Fund) played a crucial role in channelling financial support to ensure the sustainability of the system.

Expanded coverage and reimbursement
The pandemic prompted changes in reimbursement policies to include Covid-19 testing, treatment and vaccination. OOSS and pre-paid medicine companies were required to cover these services as part of their mandatory health coverage.

Increased use of telemedicine
To reduce the burden on physical healthcare facilities, the use of telemedicine services expanded significantly. This required adjustments in reimbursement models to include remote consultations as a covered service.

Centralised procurement of medicines and supplies

The government centralised the acquisition of vaccines, medication and medical supplies related to Covid-19 to ensure cost-effectiveness and equitable distribution. These expenses were largely funded through state resources and international loans.

Financial strain on public and private healthcare insurance providers
The increased demand for healthcare services, combined with the economic downturn, created financial challenges for public and private healthcare insurance providers. This led to temporary financial assistance programmes from the government and adjustments in premium payment deadlines for private insurance.

Overall, the Covid-19 pandemic highlighted the need for a more resilient and integrated healthcare financing system in Argentina, accelerating reforms and adjustments to meet immediate challenges while also revealing structural weaknesses.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

As mentioned above, patients in Argentina have access to the healthcare system through three primary subsystems: public healthcare, private healthcare insurance provider (via pre-paid medicine companies) and social security healthcare via OOSS.

Public healthcare is open to all individuals, including residents and non-residents, regardless of age, nationality or immigration status. These services are free of charge in public hospitals.

Private healthcare insurance provider membership is typically voluntary and requires the payment of monthly premiums. Membership is available to residents and often to non-residents who meet certain contractual conditions.

Public healthcare insurance provider access is generally tied to formal employment, as contributions are deducted directly from employees' salaries. Workers are automatically enrolled in the OOSS corresponding to their industry, but they may have the option to switch after a certain period. Dependents may also be covered.

Private and social security sectors may have different plans and coverage levels based on age. However, social security entities and pre-paid medicine entities are at least obliged to cover what is called the PMO, which includes several drugs, studies and treatments. Additionally, each entity is allowed to provide further coverage in addition to the minimum prescribed programme. There are also several other laws (eg, including disability, HIV treatment, fertility and cystic fibrosis) that mandate that treatments and drugs related to them be covered by these entities.

The treatment of residents abroad is usually not covered by public healthcare unless under specific bilateral agreements. Private insurance may offer international coverage. Non-residents can access emergency care in public hospitals free of charge. Private providers may require proof of payment or insurance.

Medical service providers/suppliers of medical goods can participate in the healthcare system through contracts with public/private healthcare insurance providers and public healthcare

programmes/entities.

Providers (doctors, hospitals, clinics and suppliers of medical goods) must be registered and authorised to operate by national or provincial health authorities. Compliance with quality, operational and legal standards is mandatory.

OOSS must sign agreements with these entities to receive funding or reimbursement.

Private healthcare insurance providers must negotiate terms, and comply with the quality and operational standards established by these entities.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

As we explained above, the financing of healthcare insurance providers depends on the type of entity providing the coverage.

In Argentina, the health insurance system is divided into mandatory and optional components:

Mandatory insurance
This includes OOSS and the INSSJP. These entities are financed through mandatory contributions from workers and employers. The contributions are a percentage of the employee's salary, which is collected by the Collection and Customs Control Agency (Agencia de Recaudación y Control Aduanero or ARCA, formerly known as the Federal Administration of Public Revenues (Administracion Federal de Ingresos Públicaos or AFIP)) and then distributed to the respective social security entities. Employees contribute three per cent of their gross salary and employers contribute an additional six per cent (amounts may vary based on sector-specific agreements).

Optional insurance
This includes private health insurance provided by pre-paid medicine companies. These companies are financed through the premiums paid by their members. Membership is voluntary, and individuals can choose to join these plans based on their healthcare needs and financial capacity.

The government plays a significant role in regulating premiums for both mandatory and optional health insurance.

Social security sector
The premiums (contributions) for social security entities are determined by law and are a fixed percentage of the employee's salary. The government ensures that these contributions are sufficient to cover the services mandated by the PMO and other specific healthcare laws. Some OOSS may charge additional fees for specific services or enhanced coverage, but these must comply with regulatory guidelines.

Private sector
The premiums for pre-paid medicine companies used to be subject to government regulation

to ensure fairness and prevent excessive charges. This was amended by Decree No 70/2023, which deleted the SSS's surveillance and control of the prices fixed by the pre-paid medicine companies for their plans.

In Argentina, it is possible for members of pre-paid medicine companies to request a judge to review the value of premiums if they deem the increases excessive or unjustified. The courts assess whether the increases comply with the regulatory framework, and whether they are justified based on the financial and actuarial data provided by health insurance providers. The judicial system ensures that the rights of consumers are protected and that health insurance providers do not impose unreasonable financial burdens on their members. This oversight helps to maintain a balance between the financial sustainability of health insurance providers and the affordability of healthcare for the population.

After Decree No 70/2023 lifted the SSS's price controls on pre-paid health coverage plans, several companies significantly increased the prices of their plans. The government claimed that some of the largest companies colluded to implement these price increases and filed complaints against them with the CNDC.

As a result, in April 2024, the Ministry of Economy's Secretariat of Industry and Commerce, in collaboration with the CNDC, issued a precautionary measure requiring companies in the sector to roll back their health plan prices to the levels in effect in December 2023.

7. How is the coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?

In Argentina, health insurance carriers, including both public and private healthcare insurance providers, have some degree of freedom to define the coverage they offer. However, such freedom is not absolute and is subject to significant regulatory oversight to ensure that minimum standards are met.

PMO

All healthcare insurance providers are required to provide coverage for a set of essential medical services defined by the PMO. This programme includes a comprehensive list of medical services, treatments and medication that must be covered. The PMO ensures that all beneficiaries receive a baseline level of healthcare services, regardless of the specific insurance provider.

Additional coverage

Beyond the PMO, insurance providers can offer additional services and coverage options. These can include more comprehensive plans that cover services not included in the PMO, such as advanced medical treatments, higher-end hospital accommodation and additional wellness programmes. However, these additional services are often subject to higher premiums.

As mentioned in our response to Question #1, the SSS is the primary regulatory body overseeing health insurance providers. It ensures compliance with the PMO and other healthcare regulations. The MoH also plays a role in defining and updating the PMO to reflect current medical standards and practices.

Various laws and regulations, such as the laws on specific health conditions (eg, disability, HIV treatment, fertility and cystic fibrosis), mandate that treatments and drugs related to these conditions be covered by health insurance providers. These laws ensure that coverage is comprehensive and inclusive of critical health needs.

The coverage of telemedicine services has become increasingly relevant, especially in the context of the Covid-19 pandemic. The Argentine Government has taken steps to regulate telemedicine to ensure that it is covered by health insurance providers. Telemedicine services are generally included in the PMO and insurance carriers are required to cover these services similarly to in-person medical appointments.

There is an effort to ensure that telemedicine appointments are treated equivalently to in-person medical appointments in terms of coverage. This means that patients should not face additional barriers or reduced coverage when opting for telemedicine services.

Orphan drugs, which are used to treat rare diseases, are often expensive and may not be included in the standard PMO. However, specific regulations and resolutions may mandate their coverage. The government may also provide additional funding or support to ensure that patients have access to this critical medication.

The coverage of off-label drug use (using a drug for an indication not approved by regulatory authorities) is more complex. Health insurance carriers may cover off-label use if it is supported by strong medical evidence and recommended by a qualified healthcare provider. However, this is typically evaluated on a case-by-case basis and additional approvals may be required.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

Public hospitals in Argentina are primarily financed through national, provincial and municipal budgets. The funding is allocated to cover both inpatient (stationary) and outpatient (ambulatory) services. This ensures that individuals who do not have any other form of health coverage can access necessary medical care.

Public hospitals often operate on fixed budgets provided by the government (federal, provincial and municipal, as the case may be), which can limit their ability to expand services or invest in new technologies.

Private hospitals and clinics are financed through payments from members of pre-paid medicine companies. These companies charge premiums for their members, which are used to cover the cost of the medical services provided.

Private hospitals typically operate on a fee-for-service model, where patients or their insurance providers pay for each specific service rendered. This model can lead to a higher cost for patients, but allows for more flexibility and access to advanced medical treatments.

Social security entities are financed through mandatory contributions from workers and employers. These contributions are a percentage of the employee's salary and are used to fund both inpatient and outpatient services provided by hospitals associated with or contracted by the social security system.

Social security entities have agreements with hospitals to reimburse them for services provided to their beneficiaries, often on a fee-for-service basis or through pre-negotiated rates. These agreements ensure that hospitals receive payment for the care they deliver.

Some hospitals may use bundled-payment models where a fixed price is set for a specific treatment category or medical indication. This model aims to simplify billing and control costs by providing a single payment for all services related to a particular treatment episode.

Bundle payments can encourage hospitals to provide efficient and cost-effective care, as they receive a fixed amount regardless of the number of services provided.

The fee-for-service model is prevalent. Hospitals charge for each individual service provided, such as consultations, diagnostic tests, surgery and hospital stays. This is the dominant model for reimbursing hospitals in Argentina. Hospitals bill public/private healthcare insurance providers, or other payers based on the specific services provided, with itemised pricing for procedures, tests and treatments.

The fee-for-service model can lead to higher healthcare costs and may incentivise the overutilisation of services, as providers are paid based on the volume of care delivered rather than the quality or outcomes.

Critics of the fee-for-service model argue that it can lead to inefficiencies and higher healthcare spending. Alternative models, such as value-based care and capitation, are being explored to enhance economic efficiency and improve patient outcomes.

The value-based care model focuses on paying providers based on the quality and outcomes of care rather than the quantity. It aims to encourage hospitals to deliver high-quality, cost-effective care.

Under capitation, providers receive a fixed amount per patient for a specified period, regardless of the number of services provided. This model encourages providers to focus on preventive care and manage resources efficiently.

9. How are the prices of such services determined? How is economic efficiency controlled?

The public, social security and private sectors overlap in terms of membership, with some affiliates of the public sector or social security insuring themselves with private insurers as well due to a shortage of certain services or the deficient quality of others.

While stationary (inpatient) and ambulatory (outpatient) services provided by private hospitals are not regulated, the following schemes apply when such services are provided by public hospitals.

First, the public sector includes national and provincial ministries, public hospitals (which also may provide services to people who are covered by public or private healthcare insurance providers) and primary healthcare entities (which provide assistance to the uninsured population).

Services provided by public hospitals to the uninsured population are financed through taxes, whereas the prices of services provided to those covered by public or private healthcare insurance providers are left to agreements between the public hospital and the corresponding health insurance agent. In this sense, Decree No 172/2024 sets forth that health insurance agents included in Law Nos 23,660 and 23,661 may enter into agreements with public subsystem effectors to implement the payment of benefits either through the corresponding jurisdictional authority or on an individual basis. These agreements may establish the type of practices covered and their codification, prices, billing rules and payment, and dispute resolution methods, among other provisions.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

The private sector mainly includes all private healthcare insurance providers that offer health services (including private insurance agencies: pre-paid medicine companies). This sector is financed mainly through voluntary contributions to private insurance providers, who generally search for larger and more efficient coverage. However, since the issuance of Decree Nos 70/2023 and 170/2024, they can also be financed through payroll contributions from employees and employers (insurance schemes), as employees can now choose freely between public or private healthcare insurance.

On 25 October 2024, SSS Regulation No 3,934/2024 entered into force, which sets forth that to offer healthcare plans, health insurance agents must submit the following information to the SSS: (1) a list of providers for each plan, stating the healthcare professionals, medical centres and all those authorised to provide services within the framework of the plan; and (2) clearly specify whether the plan is open or closed, expressing access and coverage conditions, and the particular characteristics that regulate the healthcare of beneficiaries.

According to the regulation, within the framework of closed health plans, the coverage of medical practices and medicines will be granted exclusively based on prescriptions issued by physicians who are part of the corresponding health insurance agent's list of providers. This aims to reduce costs in the healthcare system and avoid the prescription of medicines by physicians that don't have access to the patient's clinical record. Therefore, patients who wish to choose external professionals will have to opt for open plans or pay for medicines without any discount.

11. How are the prices of such services determined? How is economic efficiency controlled?

Argentina lacks a comprehensive regulatory framework that ensures that the pricing of services provided by physicians, therapists and laboratories aligns with economic efficiency. Prices in the private sector are not regulated, as there is no centralised body that monitors the

costs of services. Therefore, economic efficiency is not thoroughly controlled.

Regarding private healthcare insurance providers, prior to the issuance of Decree No 70/2023 the SSS set forth minimum mandatory fees to be charged by public and private providers to ensure their efficient performance; however, this was repealed by the decree. Furthermore, in February 2024, Decree No 171/2024 was issued, which sets forth that private healthcare insurance providers may freely establish increases during the term of the contract, with the sole requirement of informing users no less than 30 calendar days prior to the payment due date.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

The PMO defines the minimum benefits that social security and private healthcare insurance providers must cover, which is determined by the National Government. While it sets this baseline, case law has clarified that the PMO does not represent a ceiling, but a minimum threshold, allowing healthcare providers to offer broader coverage.

Orphan drugs are eligible for reimbursement by public and private insurance if they are included in the PMO. If an orphan drug is not covered, patients may resort to judicial claims to secure treatment, as their right to health would not be ensured. Decree No 794/2015 ensures treatment coverage for patients with rare diseases, but the PMO does not specify the extent of coverage for treatments beyond its specific scope.

In addition to the PMO, SURGE provides reimbursement to healthcare insurance providers for the coverage of low-incidence, high-cost medical treatments.

In addition, Law No 26,689 guarantees healthcare coverage for patients with rare diseases, but decisions on which treatments and medicines are covered are made by entities such as CONETEC and CATPROS.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

Although the PMO sets forth the minimum treatment coverage and medicines, the regulatory framework governing the pricing of medicines remains limited. The National Administration of Drugs, Foods, and Medical Technology (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica or ANMAT) has not issued specific regulations to standardise prices for products under its control. Nevertheless, ANMAT Regulation No 5,039/2014 introduced the National Vademecum of Medicines (Vademecum Nacional de Medicamentos or VNM), an online platform intended to provide a comprehensive list of medicines available in Argentina, including their pricing information based on data submitted by marketing authorisation (MA) holders. While this regulation has not been abrogated, in practice, the VNM no longer lists the prices of medicines, despite the original intent to do so. As a result, these prices, which were meant to serve as reference points, are currently unavailable on the platform.

The lack of a comprehensive regulatory framework applicable to the pricing of pharmaceuticals and medical devices has led to ad hoc interventions by the MoH. For

instance, during the Covid-19 pandemic, the MoH imposed maximum prices for certain drugs critical to treating high-risk patients. Additionally, the MoH has occasionally set specific prices for high-cost orphan drugs to ensure accessibility. Since 2022, the MoH has also been issuing monthly reference price lists for selected medicines, aimed at establishing the minimum coverage healthcare insurance providers must offer. Despite these efforts, pricing regulation remains fragmented and reactive.

The regulatory landscape for orphan drugs presents further challenges. Decree No 794/2015, which implements Law No 26,689 on Rare Diseases, ensures PMO coverage for treatments addressing such conditions. However, the law does not define the extent of coverage for therapies or medicines outside the PMO's scope. Although the law envisions special coverage for orphan drugs, the provision has not been effectively implemented. No specific pricing regulation for orphan drugs exists, leaving healthcare providers to navigate these complexities on a case-by-case basis.

A case of regulatory intervention in orphan drug pricing occurred in 2020, when the MoH removed Nusinersen, a critical treatment for spinal muscular atrophy (SMA), from the PMO. This decision followed a health technology assessment report by CONETEC, which concluded that the drug's high cost threatened the healthcare system's economic sustainability. The controversy prompted the SSS to reinstate Nusinersen into the SUR system, now replaced by SURGE, allowing financial assistance for treatments with significant economic implications. To further address accessibility concerns, the Secretariat of Domestic Trade set forth a maximum price per vial for Nusinersen.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

In Argentina, healthcare litigation, particularly regarding high-cost treatments and orphan drugs, has become increasingly significant. Since the enactment of Law No 26,689 on Rare Diseases, the legal landscape for orphan drugs has been more structured. This has led to numerous lawsuits filed by patients against public and private healthcare insurance providers, demanding coverage for these high-cost treatments.

Considering the complexity and recurrent nature of said claims, CATPROS was created as an advisory and permanent agency tasked with providing technical assistance to federal and local courts on judicial proceedings in which a party requests treating rare diseases or special pathologies using innovative drugs or procedures, or medical technologies, within the scope of Law No 26,689. The creation of the agency was motivated by the circumstance that such drugs or technologies are often approved 'under special conditions' at early stages of their development, hence the need to continue to assess their effectiveness, safety and quality. The assistance of CATPROS is optional for the intervening courts and its reports are non-binding.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please

outline any unresolved issues, proposed changes or trends for healthcare financing and reimbursement, and briefly indicate how these may foreseeably affect the medical sector in the near future.

The ongoing deregulation of the social security and pre-paid medicine systems are likely to remain a central topic of debate and reform throughout 2025. Furthermore, another key issue that is expected to garner significant attention in the near future is the reduction of medicine prices in Argentina. As the government has recently communicated that provinces do not require authorisation from ANMAT or the MoH to import medicinal products destined to be used exclusively in provincial territory, it is expected that medicines will be imported from other countries at a lower price. For instance, the province of Mendoza recently purchased medicinal products directly from India, which represented an estimated saving of 45–50 per cent compared to the usual price.