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The health sector in Peru: barriers and opportunities for EU trade and investment and consequences for Peruvian society

SUPPORT TO EU MARKET ACCESS TEAM AND TRADE POLICY ANALYSIS IN PERU

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\ EXECUTIVE SUMMARY

This report examines the Peruvian health system, encompassing its structure; coverage; financial sources; physical, material, and human resources; stewardship functions, and health outcomes. The objective is to identify areas requiring improvement and explore how trade and foreign investment can contribute to bridging existing gaps. This aims to facilitate the Peruvian government's policy objective of enhancing the overall well-being of the country and supporting its sustainable growth.

The right to health, as enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights, forms part of a set of internationally agreed human rights standards. It asserts "the right of everyone to enjoy the highest attainable standard of physical and mental health." Achieving this right requires creating conditions to ensure medical attention in the event of sickness for the entire population.[1]

At the national level, the Political Constitution of Peru of 1993 incorporates robust provisions on health services in the Chapter of social and economic rights. It guarantees individual, family, and community health protection (Article 7). It establishes that health policy must be designed and executed in a pluralistic and decentralized manner to facilitate equitable access to health services for all (Article 9). Furthermore, it ensures free access to health services through public, private, or mixed entities, effectively monitored (Article 11).

These constitutional provisions later received further support from additional legal measures introducing universal health care. The Universal Health Insurance Law of 2009 (Law 29344) and its regulation (Supreme Decree No 008-2010-SA) granted all Peruvian citizens the right to access a basic package of health benefits equally and with quality care. This was particularly aimed at improving the quality of health care services for children and the impoverished, protecting them against the economic costs of diseases. However, as this report will demonstrate, much remains to be done to achieve effective quality universal health coverage in Peru.

An international reference linked to universal health security is found in one of the Sustainable Development Goals (SDGs), specifically SDG3, adopted in 2015 by the member states of the United Nations. It calls for ensuring a healthy life and promoting well-being for all at all ages, proposing Universal Health Coverage (UHC) in all countries by 2030 as a specific goal.[2] The National Multisectoral Health Policy to 2030 of Peru, "PERU, HEALTHY COUNTRY" (Supreme Decree No. 026-2020-SA), aligns with the agenda of the Sustainable Development Goals.[3]

After the entry into force of the Universal Health Insurance Law, coverage has increased significantly over time, but the overall quality of health services has not. Despite a notable increase in public resources assigned to the health sector, there has been some positive impact on public health indicators. For example, Peru has made significant progress in reducing maternal and child mortality, chronic child malnutrition, and transmissible diseases. Progress has also been made in primary health care and the provision of intercultural services. Additionally, some

[1] For more information, see: https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-ultural-rights

[2] United Nations (2015). Transforming our world: The 2030 Agenda for Sustainable Development. Available at: https://sustainable-development.un.org

[3] MINSA (2020). The National Multisectoral Health Policy for 2030 of Peru "PERU, A HEALTHY COUNTRY" https://cdn.www.gob.pe/uploads/document/file/1272348/Pol%C3%ADtica%20Nacional%20Multisectorial%20de%20Salud%_20al%202030.pdf

progress has been made with respect to general health conditions in Peru, as shown by other health indicators.[4]

However, as the Sustainable Development Goals Report (2023) indicates, important challenges persist for Peru in achieving SDG3 and guaranteeing universal health coverage. This includes addressing the changing epidemiological health profile of the population,[5] marked by an increased burden of non-transmissible diseases, mental health conditions, and an aging population associated with the prevalence of chronic-degenerative diseases.

A survey conducted among people in managerial positions in institutions providing health services in the public and private sectors revealed that the health system suffers from a shortage of human resources, lack of supplies and medicines, poor infrastructure, and a budget deficit.[6] A 2018 Report by the Office of the Comptroller General of the Republic stated that the health system in Peru is in a situation of extreme emergency,[7] with serious management deficiencies at all levels.[8] Illustratively, there have been 17 ministers of health from 2016 to July 2023, highlighting a high turnover in other positions in the ministry and the incorporation of personnel without the necessary qualifications. The transfer of health responsibilities to regional governments, lacking the necessary capacities, has further exacerbated the situation.

The COVID-19 pandemic exposed and intensified the existing weaknesses of the Peruvian health system in effectively protecting the most vulnerable.[9] This overwhelmed a health system already on the verge of collapse, exposing structural and management deficiencies, reinforcing negative public perception. A 2022 survey in Peru indicated that only 27% of respondents trusted the country's health system; over 80% believed that many people could not afford good health care, and only around 21% considered the quality of the Peruvian health system as good or very good.[10] The tragic death of a congressman in September, where no access to health services was available, heightened the urgency to guarantee the availability, accessibility, and quality of health services for all in Peru.

This report explores the aforementioned sanitary issues in depth, trying to identify possible trade and investment opportunities for EU companies. It is structured as follows: Section one provides a brief description of the Peruvian health system, characterized by the predominance of the public sector and a high degree of fragmentation. Section two analyses the extent of health insurance in the country, showing that its coverage expansion has not been accompanied by a parallel increase in health outcomes. Section three examines current health expenditures by both the public and private sectors. The analysis shows that the significant increase in expenditure in recent years s has not necessarily translated into a generalized improvement in health indicators. Section four describes the current health infrastructure in Peru and r, the necessary improvement of existing hospitals and the construction of new ones, which presents

[4] OECD (2017). Health Systems Magazine: Peru. Available at: https://read.oecd-ilibrary.org/social-issues-migration-health/oecd-reviews-of-health-systems-peru-2017_9789264282735-en#page60

[5] For more information, see: https://dashboards.sdgindex.org/profiles/peru

[6] Elizabeth Espinoza-Portilla Walter Gil-Quevedo Elvia Agurto-Távara (2021). Main problems in the management of health establishments in Peru. Cuban Public Health Magazine 46 (4) May 7, 2021 Oct-Dec 2020. Available at: https://scielosp.org/article/rcsp/2020.v46n4/e2146/ Interviews were conducted with 366 people in health care management positions.

[7] Office of the Comptroller General of the Republic CGR (2018). *Resultados del operativo "Por una salud de calidad"*. Executive Report Lima: Available at: http://lfweb.contraloria.gob.pe/BuscadorInformes/0/edoc/4811293/Resum_Ejec_634-2018-CG-SALUD-OCS.pdf

[8] COMEX PERU. Quality Report on Public Health Spending. Available at: https://www.comexperu.org.pe/upload/articles/reportes/informe-calidad-001.pdf

[9] Camila Gianella , Jasmine Gideon and María José Romero (2020). What does COVID-19 tell us about the Peruvian health system? Canadian Journal of Development Studies (*Revue Canadian d'études du Dévelopement*) 2021, vol. 42, nos. 1–2, 55–67. Available in: https://www.tandfonline.com/doi/full/10.1080/02255189.2020.1843009 . You can also consult Hart, Spencer (2021). "Lack of access to quality medical care in Peru." Ballard Report. www.ballardbrief.org

[10] For more information, see: https://www.statista.com/estadisticas/914612/opinion-general-sistema-de-atación-salud-peru/

interesting opportunities for European firms to participate in construction tenders and equipment supply.

Section five presents an examination of the situation of human resources in the Peruvian health system, existing an imbalance between administrative and health personnel in the public sector, with a significant scarcity of physicians and other health personnel. Section six analyses the Peruvian market for medicines and medical devices. In both cases, it is a growing market offering interesting business opportunities, predominantly supplied by imports. The market is highly competitive, with no significant import barriers to market entry, and multiple suppliers of medicines and medical devices. However, the delays in the issuance the sanitary certificate hinder the entry of new medicines, affecting the effective delivery of health services to the population. Finally, in Section 7 addresses intellectual property issues. For the pharmaceutical industry, with high research and development intensity, the protection of intellectual property rights, such as patents, trademarks registration, and counterfeited medical products.

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\ ABBREVIATIONS

AFIN	Association for the Development of Infrastructure
ANIN	National Infrastructure Authority
ANM	National Authority for Pharmaceutical Products, Medical Devices and Medical
ARCC	Authority for Reconstruction with Change
BIM	Building methodology Information Modelling
CCL	Lima Chamber of Commerce
CAN	Andean Community
CEABE	Central Supply of Essential Goods
CENARES	National Centre for the Supply of Strategic Health Resources
CLAS	Community Local Health Administration
CNS	National Health Council
CNCC	National Quality Control Centre
DIRESAs	Regional Health Directorates
DIGEMID	General Directorate of Medicines, Supplies and Drugs
DIN	Directorate of Inventions and New Technologies
DSD	Directorate of Distinctive Signs
ENAM	National Medicine Examination
ENAHO	National Household Survey
EPS	Health Service Provider Companies
ESSALUD	Social Health Insurance
EU	European Union
FOSFAP	Health Fund of the Peruvian Air Force
FOSPEME	Health Fund for Military Personnel of the Army
FTA	Peru-United States Free Trade Agreement
GDP	Gross Domestic Product
GMP	Certificate of Good Manufacturing Practices
GR	Regional Governments
IAFAS	Health Insurance Fund Administrative Institutions
IDB	Inter-American Development Bank
INEI	National Institute of Statistics and Informatics
INDECOPI	National Institute for the Defence of Competition and the Protection of Intellec-
INS	National Institute of Health
INN	International Non-proprietary Denomination
IPRESS	Health Services Providing Institutions
IPR	Intellectual Property Rights
MIB	Modified Institutional Budget
MFN	Most Favoured Nation Treatment
MINSA	Ministry of Health
MTPE	Ministry of Labour and Employment Promotion

PAHO	Pan American Health Organization
PIA	Initial Annual Budget
PMI	Multiannual Investment Program
PNISC	National Sustainable Infrastructure Plan for Competitiveness
PNP	National Police of Peru
PNUME	Single National Request for Essential Medicines
PRONIS	National Health Investment Program
REIPRESS	Health Service Providers Institutions
RIS	Integrated Health Network
RUC	Unique Registry
SDGs	Sustainable Development Goals
SDG3	Sustainable Development Goal N° 3
SCTR	Complementary Risk Work Insurance
SIS	Integrated Health System
SISOL	Metropolitan System of *La Solidaridad*
SOAT	Mandatory Traffic Accident Insurance
SPI	Specialized Chamber of Intellectual Property
SUNEDU	Superintendence of Higher Education
SUSALUD	National Health Superintendence
TM	Municipal Tax
UHC	Universal Health Coverage
UPSS	Health Services Production Units
VAT	Value Added Tax
WB	World Bank
WHO	World Health Organization

CHAPTER 1

THE PERUVIAN HEALTH SYSTEM

The World Health Organization (WHO) defines a health system as the collective framework of organizations, individuals, and actions whose primary objective is to promote, restore, or maintain health.[11] This encompasses endeavours to influence its determinants and direct activities to enhance it, with the ultimate goal of improving health outcomes for the general population equitably and without imposing financial burdens on individuals for care costs.

The health system in Peru, akin to global configurations, comprises both public and private healthcare providers structured under various schemes. These schemes independently incorporate financing and service delivery mechanisms, with total vertical integration in the public sector and partial vertical and horizontal integration in the private sector. However, the Peruvian health system is notably characterized by significant fragmentation9. This pertains to both the definition of obligations and the provision of services.[12] As per the Ministry of Health (MINSA), this fragmented situation "hinders access to services, encourages the provision of low-quality services, leads to the irrational and inefficient use of resources, and places undue emphasis on curative and hospital care, with inadequate performance in the promotion and prevention of diseases."[13]

1.1. GOVERNANCE OF THE HEALTH SYSTEM

The provision of health care in Peru is coordinated by the National Health Council (CNS), - an advisory body of the MINSA -, through the National Coordinated and Decentralized Health System (SNCDS),[14] whose objective is to achieve comprehensive health care and move towards universal health insurance coverage. In this framework, the MINSA, in its governing role, is responsible for establishing general norms and policies related to the promotion, implementation and strengthening of health care in the country.

As part of the decentralization process that began in Peru in 2002, the main responsibilities for the provision of health services were transferred to the Regional Governments (GR), including:[15]

- Formulate, approve, execute, evaluate, direct, control and manage the region's health systems.
- Establish policies in accordance with national policies and sectoral plans.
- Supervise and control public and private health services

[11] World Health Organization (2020). World health report 2000: Health systems: improving performance. Geneva, Switzerland: World Health Organization; 2000

[12] VIDENZA Consultants (2022). Current situation of the Peruvian health market. Commissioned by COMEX. Available at: https://www.comexperu.org.pe/upload/articles/publicaciones/situacion-actual-del-mercado-de-salud-peruano-informe.pdf

[13] MINSA (2023). Análisis de Situación de Salud del Perú 2021. p. 44. Available at: https://bvs.minsa.gob.pe/local/MINSA/6279.pdf

[14] According to its regulations, the National Coordinated and Decentralized Health System (Supreme Decree 004-2003-SA, is the interrelated set of organizations, institutions, agencies and national, regional and local resources of the health sector and other sectors, whose main objective is to develop activities aimed at promoting, protecting and recovering the health of the population. According to the Law of the National Coordinated and Decentralized Health System, Law No 27813, the system is made up of the National Health Council and the Regional and Provincial Councils of Health.

[15] Organic law of regional governments; Law 27687. November 16, 2002.

- Organize, implement and maintain health services for the prevention, protection, recovery and rehabilitation of health
- Organize the levels of care and administration of state health entities that provide services in the region, in coordination with local governments.

Decentralization of health functions also gave regional governments full responsibility for the construction of hospitals through their Regional Health Directorates (DIRESAs)., and the roles as health authorities and providers of health services in the territories under their jurisdiction.

All participating entities of the Peruvian health system - private, public or mixed -, whether they finance services or provide health services, are supervised by the National Health Superintendence (SUSALUD).[16] In the case of financiers, these are the Health Insurance Fund Administrative Institutions (IAFAS in Spanish);[17] and in the case of providers, they are the Health Services Providing Institutions (IPRESS in Spanish).[18] In the case of private IAFAS, they are also regulated and supervised by the Superintendence of Banking, Insurance and Private Pension System (SBS).

1.2. PUBLIC SECTOR

The public health sub-system includes 4 components:

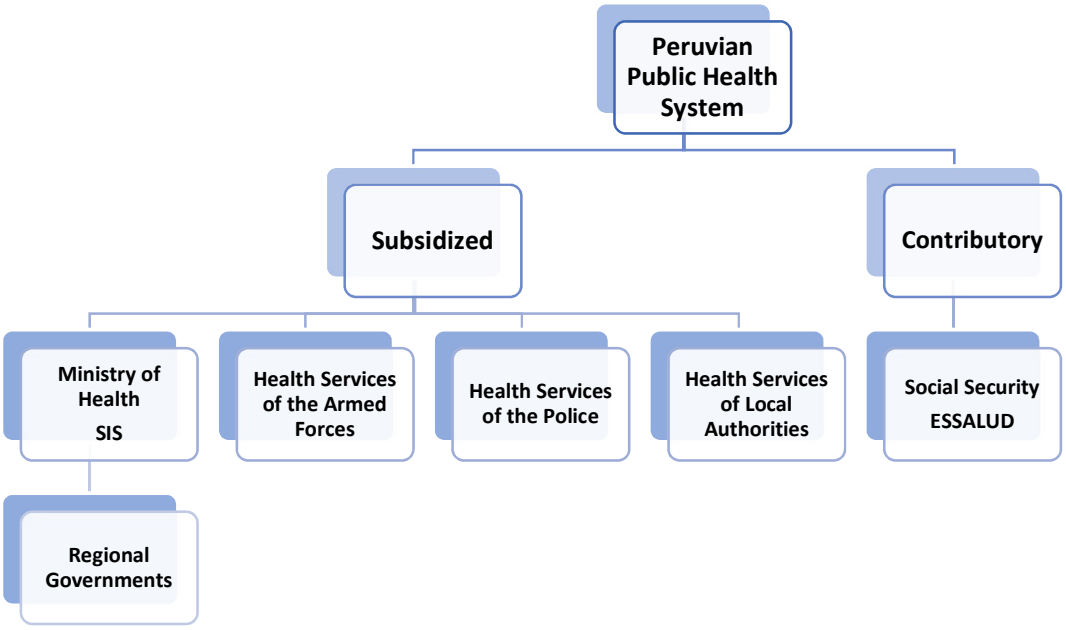
a) The MINSA and its decentralized bodies, assigned public organizations, and programs
b) The Armed Forces and the National Police of Peru (PNP);
c) ESSALUD, which is a public agency attached to the Ministry of Labour and Employment Promotion (MTPE) that manages a contributory social security scheme, financed by monthly contributions of workers;[19]
d) Local governments.

Figure 1 shows a summary of the Peruvian Public Health System.

Each one of these subsystems operates separately. Each has its own IAFA and health care services delivery through its own IPRESS. All available insurance schemes of the IAFAS, as well as the IPRESS that offer prepaid schemes in Peru, public or private, must cover a list of essential services included in the Essential Health Insurance Plan *(Plan Esencial de Aseguramiento en Salud,* PEAS), covering more than 140 different conditions.[20]

[16] SUSALUD also supervises the IPRESS Management Units (UGIPRESS), defined as those public, private or mixed entities or companies, created or to be created, other than IPRESS, responsible for the administration and management of the resources destined for proper functioning. of the last.
[17] According to article 6 of Legislative Decree 1158, IAFAS are public, private or mixed entities or companies, created or to be created, that receive, raise and/or manage funds for health care coverage or that offer risk coverage. of health, under any modality.
[18] Article 7 of Legislative Decree 1158 defines IPRESS as those public, private or mixed health establishments and medical support services, created or to be created, that provide health care for the purposes of prevention, promotion, diagnosis, treatment and/or rehabilitation; as well as those complementary or auxiliary medical care services, whose purpose is to contribute to the prevention, promotion, diagnosis, treatment and/or rehabilitation of health.
[19] Exceptionally, it can be financed by contributions from the Treasury, as was the case in the pandemic period.
[20] The current PEAS was updated by Supreme Decree 023-2021-SA as part of the national policy of Universal Health Insurance and Universal Health Coverage, to ensure that every person residing in the country has health insurance.

Figure 1
The Peruvian Public Health System



MINSA and sub-national governments

The MINSA manages the Comprehensive Health Insurance (SIS), which is a subsidized component, financed by the public sector budget, aimed to provide coverage to all Peruvians and foreigners residing in Peru who do not have other health insurance in force. It also provides out-of-pocket health care services.

The SIS is structured at three levels: national, regional and local. The national level is made up of the MINSA itself; the regional level is composed of the Regional Health Directorates (DIRESAs) of the regional governments, while at the local level the Health Directorates (DISA) are responsible for direct attention to SIS policyholders in the country's districts. It is composed of IPRESS operated by a Provincial or District local authority (e.g., the Metropolitan System of *La Solidaridad* (SISOL) with its *Solidarity Hospitals* of the municipality of Metropolitan Lima.

Historically, MINSA has been responsible for providing health care services to the poor and vulnerable population through its IPRESS throughout the country. In 2002 two important events occurred. The first, the beginning of the progressive transfer of health care powers from the MINSA to the regional governments, within the framework of the decentralization process. The second, the implementation of the SIS as a government-subsidized health insurance plan intended to provide coverage to uninsured citizens.[21]

The transfer of responsibilities to the regional governments was largely completed in 2020, while, in the case of the SIS, it first focused specifically on the most vulnerable sectors of the

[21] The Intangible Solidarity Health Fund (FISSAL) was created in 2011 as an IAFAS to complement the functions of the SIS in financing high-cost diseases, such as the most common cancers, chronic kidney failure (CKD) and rare and orphan diseases.

population, defined by the government as those living in poverty or extreme poverty, as well as uninsured children and pregnant women.

SIS coverage was progressively expanded and in 2019 the coverage gap was closed by establishing that all residents in Peru without health insurance would have access to SIS (Urgent Decree No 017-2019). Therefore, every person in Peru who do not have health insurance, regardless of their socioeconomic level, can receive free health care treatment in any IPRESS of the Ministry of Health or the Regional Governments.[22] It also provides a partial subsidy for low-income households of formal and informal workers, who can pay a contribution and can join the SIS through a monthly payment that depends on the size of the household.[23]

In 2018 it was published the Law Establishing the Formation and Operation of Comprehensive Health Networks RIS (Law 30885), to be applied to any IPRESS operated by the MINSA and Regional Governments, establishing that they must provide an equitable and comprehensive health care portfolio to a defined population, through the articulation, coordination and complementation of its health establishments. Furthermore, it also left open the possibility for other IPRESS from the public and private sector to participate in the RIS. These exchanges have been very limited, in part because of the lack of agreement on the costs of provision among the various health insurances.

When it comes to health care subsidized by local governments, whether at the provincial or district level, some of them run their own IPRESS. According to the Organic Law of Municipalities (Law 27972), it is the function of local governments to manage primary health care, as well as build and equip health facilities and public emergency services for the benefit of the residents of their localities. In 2021, 509 municipalities (27.1% of all municipalities in the country), reported that they manage some type of health facility. The municipalities manage a total of 1,099 health facilities of different types throughout the country. Standing out for their relevance are 16 hospitals, 144 health centres, 407 health posts, 76 medical offices, 50 dental offices and 292 pharmacies.[24]

Armed Forces and PNP

In the case of the Armed Forces (Army, Navy and Air Force of Peru members and their families) and PNP, both health systems are financed by their own public budgets. In the first one each branch has its own IAFA (Health Fund for Military Personnel of the Army, FOSPEME; Health Fund of the Peruvian Navy, and the Health Fund of the Peruvian Air Force*, FOSFAP*). Additionally, each branch operates its own IPRESS.[25] The case of the PNP works in a similar way, with the PNP Health Insurance Fund and its own health care providing entities.

[22] The SIS offers comprehensive coverage, covering more than 12,000 diagnoses, including various types of cancer, rare and orphan diseases. In addition, medications, tests, operations, emergency transfers and others.

[23] SIS coverage covers medicines, procedures, operations, supplies, burial and transfer vouchers, depending on the type of SIS; There are different SIS insurance plans: "Free SIS", aimed at people in poverty and extreme poverty, as well as pregnant mothers, children, firefighters, among others; "SIS for all", for people who do not have any other type of insurance; which belong to the subsidized financing regime. There is also the "independent SIS", which allows access to low-cost insurance; in addition to "SIS MYPE" and "*SIS Emprendedores-NRUS*"; which belong to the semi-contributory financing regime. It should be noted that 99.5% of the affiliates belong to the subsidized regime. In case of partial subsidization, monthly insurance contributions to be paid range between 15 to 40 US$ depending on household size.

[24] INEI (2022). Municipal Management Indicators. April. Available at: https://www.inei.gob.pe/media/MenuRecursivo/publicaciones_digitales/Est/Lib1849/libro.pdf

[25] Military Hospital, Navy Hospital and Air Force Hospital.

ESSALUD

As mentioned before, ESSALUD ia a non-subsidized contributory health insurance scheme, that provides mandatory coverage for all people formally employed in all sectors of the economy.[26] In terms of coverage, it is the second most important insurance scheme in the country, after the SIS, but the first in quality in the provision of public health services.

ESSALUD covers the insured worker and his beneficiaries (spouse, children under 18 years of age and older children unable to work). It is financed mainly by the contributions of workers and pensioners. The contribution is 9% of gross income in the case of active workers and 4% of the pension in the case of retirees. It has around 380 health centres and 90 hospitals IPRESS distributed throughout the country, , although half of the establishments are located in Lima.

The Law of Modernization of Social Security in Health (Law 26790 of 1997) created the Health Service Provider Companies (EPS), which are health services providers, either private or public IAFAS - excluding ESSALUD -, which can provide those services, whether with its own infra-structure or that of third parties. [27] Also, they can be authorized to offer additional health plans for workers covered by ESSALUD and optional plans for people who are not insured by it. In the case of ESSALUD members, they can freely choose a health plan that is financed through a contribution of 9% of the worker's remuneration, transferring 2.25% to the chosen EPS and the remaining 6.75% remaining as a contribution to ESSALUD. These EPS are also authorized to offer **Complementary Risk Work Insurance** (SCTR).

Health plans for those insured by an EPS must cover at least the single layer attention, work accidents and diseases not covered by the SCTR, as well as care for pre-existing ailments. Additionally, the EPS can offer coverage for contingencies corresponding to the complex layer. The EPS coverage is the same as that offered by ESSALUD to the worker and their dependents. Insurance under EPS has two kinds of coverage. **Mandatory coverage** is basically financed with credit resources, charged to ESSALUD contributions and are equivalent to 25% of these resources. Meanwhile, **complementary coverage** is financed with additional payments by the worker and/or employer. Workers affiliated with the EPS maintain their right to coverage for highly complex care, chronic diseases and financial subsidies paid by ESSALUD. As of the first quarter of 2023, there are five EPS operating in the country.

1.3. THE PRIVATE SECTOR

The private sector subsystem is made up of the IAFAS, and the private for-profit and non-profit IPRESS. This sector provides health benefits both to the population with the ability to pay through private health insurance or through out-of-pocket expenses, and to the vulnerable population, through the non-profit IPRESS.[28] There are also independent health services providers, formal and informal, operating in cities and also in rural areas. Traditional medicine is practiced in Peru.[29] Currently, there are different types of private IAFAS in operation in Peru: 12

[26] ESSALUD administers special mandatory health insurance for the agricultural sector that covers dependent and independent workers, natural or legal persons who carry out agricultural, livestock, poultry, agro-industrial or aquaculture activities (except in the forestry industry). Only 5% of the workers insured by ESSALUD are under this coverage.
[27] Article 13, Law 26790.
[28] The private non-profit sector is represented by a diverse set of non-profit civil associations. Most of them provide world-class services and often receive financial resources from external and internal donors, governments and households. Some are managed by church groups.
[29] Informal providers include traditional medicine providers: shamans, healers, bonesetters and midwives, among others.

private insurance companies authorized to offer health insurance, of which 6 are active in the market; 5 EPS; 22 health service providers, mostly private clinics and hospitals, offering prepaid services; 14 self-insurance and health funds, and 39 Associations of Funds Against Traffic Accidents (AFOCAT).[30]

There is a wide range of private IPRESS that offer health care services, from less to more complex, distributed throughout the national territory, but with a high concentration in Metropolitan Lima and other main cities. Private IPRESSs include specialized and non-specialized private clinics, medical centres and polyclinics, medical and dental offices, laboratories, diagnostic imaging services and the health establishments of some large companies.

The private health sub-system in Peru has experienced a process of concentration and vertical integration in some of its links.[31] Peru exhibits the highest concentration rate in the general insurance market compared to other South American countries.[32] Four private insurance companies that offer health insurance in the country concentrate 83% of the market (Rímac, Pacífico, La Positiva and Mapfre), which at the same time are part of the small group of eight companies authorized to market Mandatory Traffic Accident Insurance (SOAT) throughout the country, which covers health treatment in cases of road accidents. Furthermore, these four companies, together with SANITAS, are the owners of all the EPS, which have agreements, especially with clinics for the execution of their health and insurance plans. Additionally, these private insurance companies have also purchased or established clinics to provide health services covered by their insurance plans.[33] On the other hand, each private IAFA that offers prepaid health insurance controls a number of clinics through which these services are provided, for example, the Auna Group with 7 clinics, the San Pablo Group with 13 clinics, SANNA with 12 clinics, and Mapfre with 4 clinics, among others.

In terms of the number of health insurance affiliations to IAFA from the private sector, the general health insurance and EPS market are dominated by Rímac and Pacifico, while, in the case of prepaid services, the dominant player is Oncosalud, which offers specialized insurance for cancer treatment (see Table 1). It is important to note that prepaid providers compete with insurance companies in providing coverage, although benefits vary widely between different providers.

[30] Table 2.1. YOUR HEALTH. SUSALUD Statistical Bulletin First Quarter 2023.

[31] Public Eye (2021). The eight economic groups behind the health business in Peru. December. Available at: https://ojo-publico.com/3225/los-ocho-grupos-economicos-detras-del-negocio-la-salud

[32] Mc Kinsey & Company (2023). Global Insurance Report: Capturing the next wave of growth in Latin America, September. Chart 9. Available at:
https://www.mckinsey.com/~/media/mckinsey/industries/financial%20services/our%20insights/insurance/global%20insurance%20report%202023%20capturing%20growth%20in%20latin% 20america/global-insurance-report-2023-capturing-el-growth-in-latin-america-espanol.pdf

[33] For example, Seguros El Pacífico, which also owns EPS Pacífico, acquired the San Borja, San Felipe and El Golf clinics, and the Roe Clinical Laboratory (in alliance with the Chilean Banmédica) in the last decade and then created its own network of Sanna Health Centres, with 12 locations in Lima and provinces. In addition to these businesses, it controls complementary service companies: the American Dental Centre (COA), the Aliada Cancer Centre, the Doctor + outpatient services division, and the diagnostic centre requires clinical laboratory.

Table 1
Peru: Number of Affiliations of the Main Private IAFA Health Insurance 2023

Insurance company	For natural persons	For workers through EPS	Prepaid services
Rímac	617,634	435,246	
Pacífico	557,114	439,199	
Mapfre	72,414	53,168	
La Positiva	65,563	21,465	
Protecta	20,827		
Chubb Peru	16		
SANITAS		66,218	
Oncosalud -AUNA			993,031
San Pablo Clinic			60,519
Ricardo Palma Clinic			41,047

Source: SUSALUD. Statistical Bulletin II Quarter 2023. Table 2.5. Prepared by the authors.

In relation to legal barriers to market access, foreign IAFA or IPRESS established in Peru do not face limitations regarding the participation of foreign capital, being subject to the same regulations as those of national capital. For example, in the case of IAFAs, UnitedHealth Group's has invested in El Pacífico; there is also the Spanish Mapfre; the French BNP Paribas with the Cardif insurance; Hong Kong's Fosun International Limited's majority stake in insurance company La Positiva; Swiss investors in the insurer Chubb, through a holding company in Delaware, as well as Chilean participation in Protecta.

There is also a foreign presence in the IPRESS, such as that of the Spanish company QuirónSalud, which recently sold the shares it held in the Ricardo Palma clinic in Lima; UnitedHealth Group 's participation in SANNA clinics; the Colombian capital in the AUNA clinics, and foreign capital in the Delgado Clinic through the Enfoca investment fund. On the other hand, in recent years, new foreign-owned companies have entered the market, such as Bupa, BMI, Best Doctors and Allianz, more positioned in the high-income segment of the population.

CHAPTER 2 HEALTH INSURANCE COVERAGE

Health insurance coverage in Peru has expanded significantly in the last decade. In 2011, only 64.7% of the population had health insurance, while in 2023 38.9 million people are currently affiliated in a company insurance schemes offered by the existing IAFAS.[34] This figure is higher than the total population of the country, given that a person can be enrolled in several health insurance programs at the same time. In this context, those people residing in the national territory who have health insurance are identified as insured. The National Household Survey (ENAHO), carried out by the National Institute of Statistics and Informatics (INEI) indicates that, at the national level, as of the first quarter of 2023, 86.7% of the total population has at least one health insurance.[35]

It should be noted that coverage does not necessarily translate into access to health care services, particularly in remote areas where health infrastructure and human resources are lacking, with a major problem being guaranteeing timely access and quality of health services, the latter showing high variability between different suppliers and regions. An even more important challenge for the Peruvian health system is the extension of coverage to that 13.3% of the population, around 4.4 million people, without health insurance and without access to basic medical care.

Table 2 presents health security coverage in Peru by type of IAFA for years 2011 and 2023, which allow to examine the expansion of coverage during that period, as well as the importance of the different schemes in the provision of health care coverage. As is clear from the table, the public sector is the main provider of health insurance coverage in the country through the SIS and ESSALUD, where the greatest total expansion of coverage during the period is due above all to the progressive expansion of the SIS, which almost doubled its number of affiliations. As a result, 58.6% of people with some health insurances are only covered by the SIS, while 23.9% are only covered by ESSALUD. This means that 82.5% of insured people depend exclusively on the services provided by the public health system.[36]

Table 2
Peru: Regular Health Insurance Affiliations by Type of IAFA (2011-2023)

IAFA	2011	2023
SIS	12,760,504	24,800,288
ESSALUD	9,128,957	10,960,584*
EPS	1,365,959	984,735**
Armed Forces and police	1,329,118	675,566
Self-insurance and health funds	n.a.	85,809
Prepaid Health Coverage	648,474	1,217,148
Private insurance companies	640,000***	1,349,673

Source: SUSALUD Statistical Bulletin 2011 and 2023 II Quarter.
*Includes 358,971 SCRT. ** In addition, the EPSs have 3,322,134 affiliations for SCTR coverage.
***Estimated by the author based on data from the MINSA Analysis of the Health Situation in Peru, 2013.

[34] Registry of Affiliates of the AUS of SUSALUD (RAAUS).
[35] For more information, see: *Encuesta Nacional de Hogares - ENAHO 2023*.
[36] SUSALUD. Statistical Bulletin II Quarter 2023. Table 2.2.

The coverage of the mandatory health insurance of ESSALUD and the EPS depends largely on the generation of formal employment in the country. However, there has not been much dynamism in expanding coverage by these IAFAs. Most of the employment generation in the country has been in the informal sector, which currently accounts for around 76 percent of total employment.[37]

The private sector has increased coverage, both through people enrolled in the different programs offered by private insurers, and in the prepaid health insurance schemes offered by some private IPRESS. Self-insurance and health funds, which are special insurance plans contracted with private IAFAs and financed with contributions from workers in large private companies or public sector entities, have limited coverage. In general, only about 10% of the population has any type of health coverage with the private sector, whether through an IAFA or IPRESS, including those affiliated with ESSALUD and who have additional coverage with the EPS. Although Peru is the Latin American country with the lowest health insurance prices in dollar terms, the purchasing power of the majority of the population is too low to allow access to private health insurance.[38]

Considering that private IAFA and IPRESS coverage is significantly lower than in other Latin American countries, there is room to increase private health insurance participation in Peru as the middle class expands.[39] In Chile, for example, 22% of the population has some type of private health insurance,[40] while the global average for low- and middle-income countries is 28.6%.[41] An interesting feature of private health insurance coverage in Peru is the fact that people in high-income quintiles 3 and 4 in urban areas have the highest percentage of the population not covered by any health insurance (22 .8% and 23.6% respectively), which means that there is some capacity to acquire private health insurance coverage that is not exploited in the country.[42] People in these high-income quintiles cover their health care costs through out-of-pocket expenses.

[37]INEI (2022). Informal Production and Employment in Peru, Informal Economy Satellite Account 2007-2021, December. Available at: https://www.gob.pe/institucion/inei/informes-publicaciones/3799186-produccion-y-empleo-informal-en-el-peru-cuenta-satelite-de-la-economia-informal-2007 -2021

[38]CELAG (2022). Report on health insurance prices in Latin America. February. Available at: https://www.celag.org/informe-sobre-los-precios-de-los-seguros-de-salud-en-america-latina/

[39] IPE (2023) In Peru, the population belonging to the middle class had almost doubled: from 21% in 2004 to 40% at the end of 2019. However, with the pandemic, the low dynamism of the national economy and high inflation, the recovery of this socioeconomic group slowed down. Thus, at the end of 2022, the percentage was reduced to only 33% of Peruvian households. With the return of normality and the reactivation of the economy it is expected that the middle class will return to the pre-pandemic level. Available at: https://www.ipe.org.pe/portal/hablemos-sobre-la-recuperacion-de-la-clase-media/#:~:text=En%20el%20Per%C3%BA%2C%20la%20poblaci%C3%B3n,recuperaci%C3%B3n%20de%20este%20grupo%20socio-econ%C3%B3mico.

[40]Economic Context Observatory (2021) Report No 5. Diagnosis of Social Security in the Health Area. Available at: https://ocec.udp.cl/cms/wp-content/uploads/2021/11/Informe-OCEC-5-VF.pdf

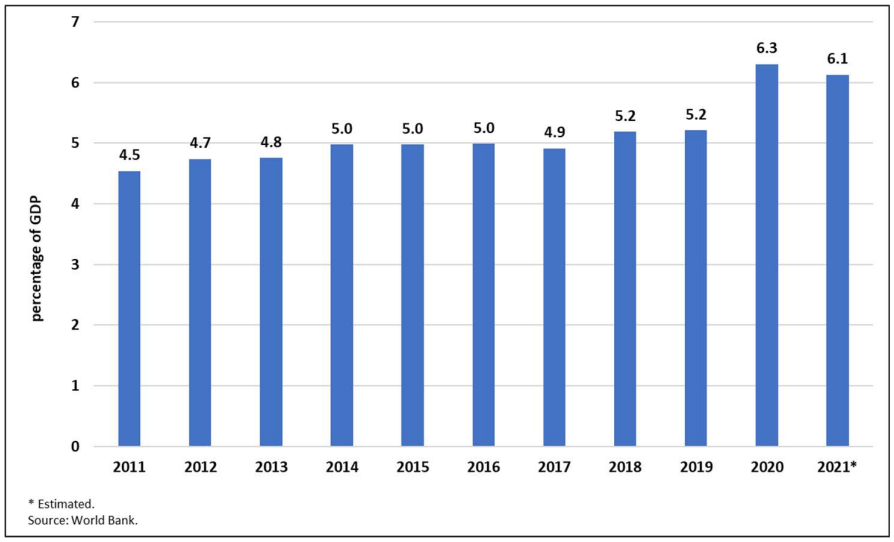
[41] https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00951

[42]ECLAC database. https://statistics.cepal.org/portal/inequalities/other-dimensions.html?lang=es&indicator=4754 In the lowest income quintiles 1 and 2, people without health insurance are 17.8 and 19.8 % respectively, and in quintile 5, the highest economic income, 19.6% of the population does not have any health insurance.

CHAPTER 3 CURRENT HEALTH SPENDING

Current total spending on health care has increased significantly in Peru over the last decade, both as a percentage of the Gross Domestic Product (GDP) and in absolute terms.[43] In 2021, said spending was 6.1% of GDP, 1.6 percentage points more than the 2011 GDP (see Chart 1). Meanwhile, in current dollars, in 2021 this was slightly more than double that of 2011, reaching US$ 12.3 billion (see Table 3). Health care expenditures are an important factor in determining health outcomes, although increasing them those expenditures alone cannot guarantee better health outcomes. The efficient and effective use of health resources is the key to improving these results in any country. Hence, the lack of a positive correlation between expenditures and health outcomes would indicate that such expenditures are defective in efficiency and effectiveness. This has been the case in Peru, where the significant increase in health spending, although it has contributed to improving some health outcomes – e.g. reduction of the infant mortality rate, expansion of vaccination, proportion of women receiving pre-natal care, reduction of mortality because transmissible deceases, among others - has not meant a substantive improvement in the general state of health in the country. There are still important gaps in many areas of health services delivery.

Chart 1
Peru: Total health spending 2011-2021
(% of GDP)



As shown in Table 3, although current expenditures in Peru, both public and private, have increased, the main effort has been made by the public sector. By 2021, current public spending

[43] Current health expenditure measures the final consumption of health goods and services, which includes personal health (cure, rehabilitation, long-term care, auxiliary medical services and equipment) and collective services (prevention and public health services, as well as administration of the health system), but excludes investment expenses.

almost doubles that of the private sector, with the latter's contribution to total current spending having constantly decreased, from 44.6% in 2011 to 35.2% in 2021. This reflects a policy of constant increase in the public sector health budget.

Table 3
Peru: Total current expenditure on health by sector 2011-2021
(Million US$)

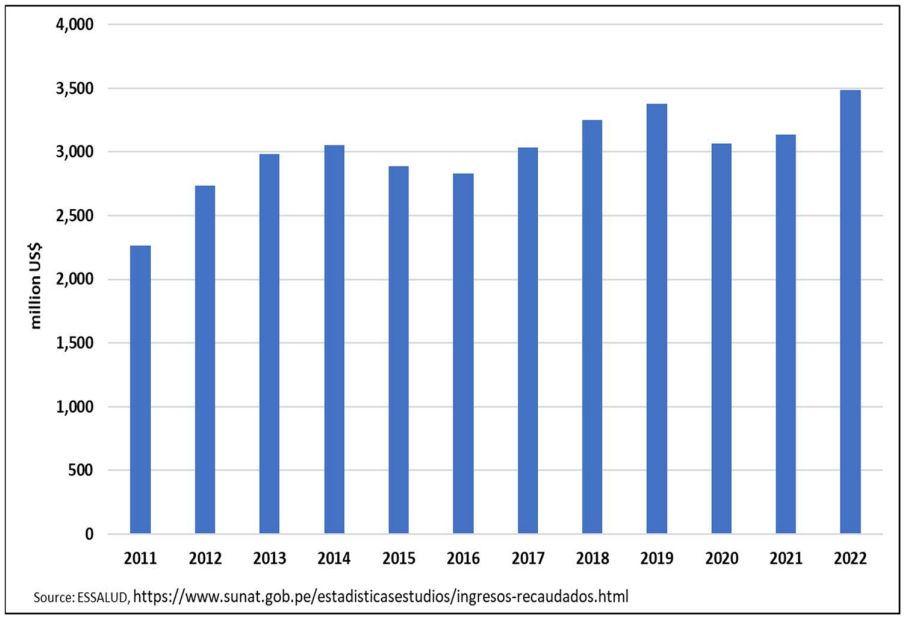
	Total expense	Público expense	Private expense	Private/Total
2011	5,706	3,159	2,547	44.6%
2012	6,690	3,802	2,887	43.2%
2013	7,461	4,340	3,121	41.8%
2014	8,172	4,902	3,270	40.0%
2015	7,991	4,764	3,226	40.4%
2016	8,456	5,074	3,382	40.0%
2017	9,391	5,601	3,790	40.4%
2018	10,002	6,020	3,983	39.8%
2019	10,608	6,309	4,299	40.5%
2020	11,670	7,301	4,369	37.4%
2021	12,350	7,998	4,352	35.2%

* Data in current soles have been converted to US$ using the average exchange rate for the year. Does not include ESSALUD expenditures. Private sector data corresponds to the sector's gross value of production. Does not include capital expenditures.
Source: INEI.

The data in Table 3 does not include ESSALUD health expenditures, therefore it underestimates the total expenditure in this area. Strictly speaking, ESSALUD is financed privately by employees and workers, through the deduction made in their salaries as a contribution to the ESSALUD budget, although it is administered by the social security system. Chart 2 presents the social security contributions received by ESSALUD for the period 2012-2022. According to the ESSALUD 2022 management report, the annual percentage share of salaries and remuneration expenses in ESSALUD's total expenses was 32.9%, followed by services provided by third parties (29.3%); medicines, and surgical supplies (15.2%). Capital expenses represented only 4.7% of the total. .[44]

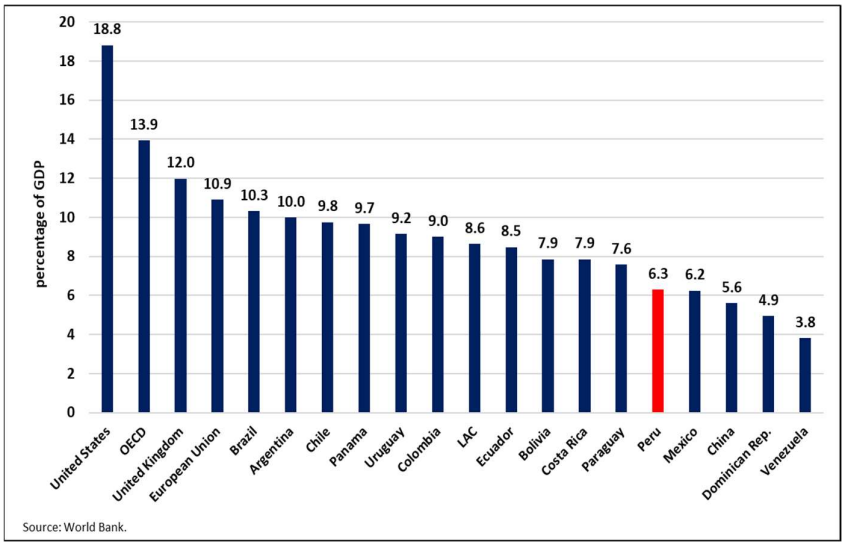
[44] I Essalud's Annual Business Management and Budget Evaluation Report 2022. Available at: http://www.essalud.gob.pe/downloads/oegrs/YDRAY-Estudio-de-Gestion-de-EsSalud.pdf

Chart 2
Peru: Contributions to ESSALUD 2911-2022
(Million US$)



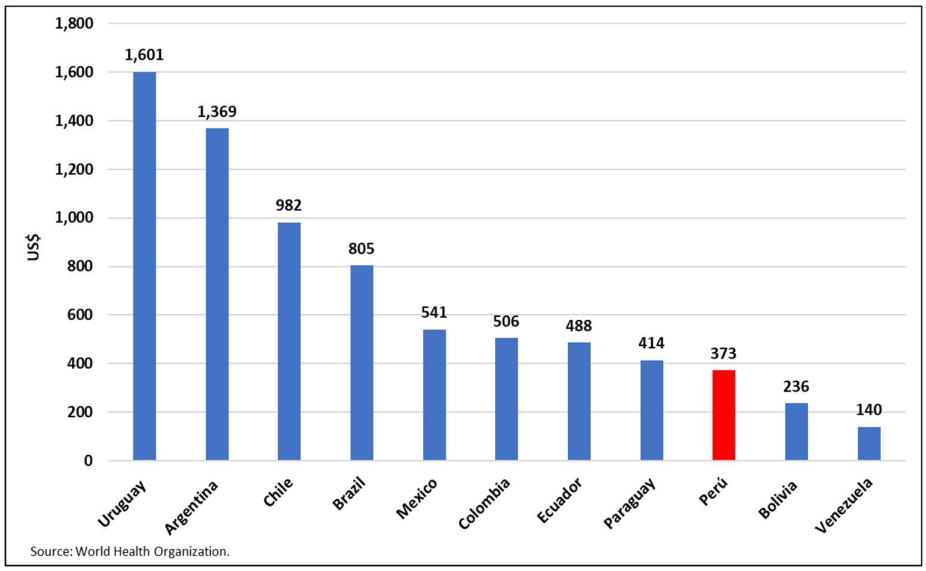
Although Peru has significantly increased current spending on health in the last decade, its level is still relatively low compared to other South American countries. Taking as a reference health spending as a proportion of GDP in 2020 (the year for which World Bank data are available) Peru's ratio of 6.3% is well below those of more developed countries such as the United States (18.8%); United Kingdom (12.0%) or the European Union average (10.9%), and also most countries in the Latin American region (e.g. Brazil 10.3%, Argentina 10.0%, Chile 9.8%, Colombia 9.0%, Ecuador 8.5% and Bolivia 7.9%). It is only close to Mexico's expenditure ratio of 6.2% (see Chart 3).

Chart 3
International comparison of total health spending 2020
(% of GDP)



Another way to see the relatively low levels of health spending in Peru is to look at per-capita health spending levels.. Peru, Bolivia and Venezuela are the countries with the lowest per capita current spending on health in South America., Even Paraguay, with a significantly lower level of per capita income, has higher per capita health expenditures (see Chart 4).

Chart 4
Average per-capita current spending on health 2018-2020
(in current US$)



To improve the general health status of the general population and achieve UHC, Peru will have to increase its health expenditures and, at the same time, improve efficiency in the use of committed resources. Demands on the health system will increase over time as a result of population growth and the consequences of the epidemiological transition. Although with a lower growth rate, the Peruvian population, given its current age structure, will continue to grow, and the emergence of a middle class represents a growing latent demand for quality health services.

In this regard, the current levels of public spending on health in Peru - only 3.6% of GDP in 2021 – are well below the 6% recommended by the Pan American Health Organization (PAHO). According to the World Bank, the financing gap in health is between 0.5% and 2.7% of GDP and with a goal of 6% of GDP for health spending, potential gains barely cover 9% of the gap and 47% of the universalization gap with the current quality level. The bank concludes that this leads to demands for increased budget allocation from the central government and the use of any additional fiscal space that exists.[45]

Given the growing demand of the population for better medical care in the country and the political commitment demonstrated by the authorities to address current problems, the health system in Peru would be expected to improve in the future, offering interesting market opportunities.

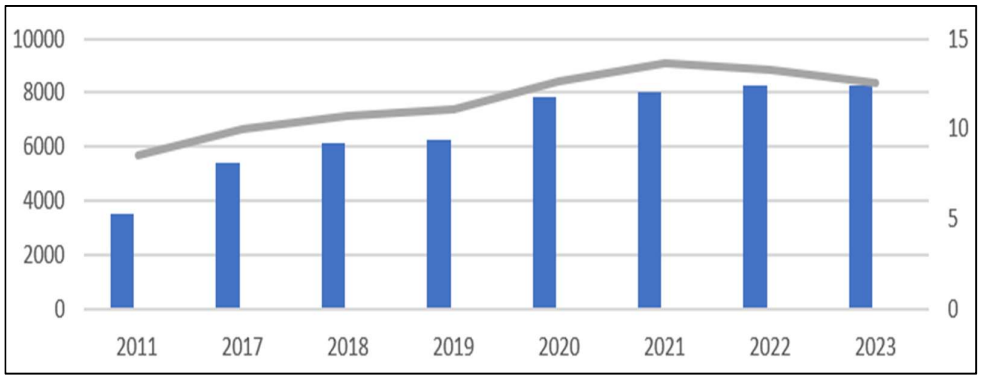
[45] World Bank (2021). Financing for Universal Coverage Health in Peru after covid-19. September, p. 30. Available in: https://www.bancomundial.org/es/country/peru/publication/financing-para-la-cobertura-universal-de-salud-en-el-per-despu-s-de-la-covid-19

3.1. CURRENT PUBLIC SPENDING ON HEALTH PUBLIC SECTOR

The total allocation of public funds to the health function as a percentage of the general government budget has increased from 8.5% in 2011 to 12.5% in 2023 in Peru. During 2021 and 2022 due to the expenses necessary to address the COVID-19 pandemic, this ratio was 13.6% and 13.3% respectively. Chart 5 allows us to compare the increase in the Modified Institutional Budget (MIB) of the General Government for the health function between 2011 and the period 2017-2023. The total budget in 2011 was US$ 3.53 billion, while in 2022 it was US$ 8.26 billion. When using the MIB, the changes made to the initial annual budget (*Presupuesto Inicial de Apertura, PIA*) are incorporated as it is a more precise indicator of the actual allocation of public resources.

Normally, not all of the allocated budget is spent. On average, for the period 2018-2021, of the total health MIB, only 88% was actually spent. Regional and local governments had the lowest utilization rate, indicating a lack of capacities to execute their health functions efficiently.[46]

Chart 5
Peru: Modified institutional budget for health
Total in current US dollars (left axis) and % of total general government budget (right axis)
Grey line is the % of total Public Budget right axis



Source: MEF Friendly Consultation. Prepared by the author. Data in current soles have been converted to US dollars using the average exchange rate for the year. The data for 2023 is until September. Available at:
https://apps5.mineco.gob.pe/transparencia/Navegador/default.aspx?y=2019&ap=ActProy

Current public health expenditures are carried out by central, regional and local governments. Regional governments, in line with the transfer of different responsibilities, have progressively increased their participation in total health spending. As the capacities of regional governments improve and the execution of health functions is consolidated, their share of total health spending could be expected to increase, at the expense of the central government. For their part, the contribution of local governments to total spending is marginal. On average for the 2021-2022 period, the MIB was distributed as follows: central government 47.9%, regional governments 47.7% and local governments 4.4%.[47]

Current public spending on health is allocated to the payment of the different components necessary for the provision of services, such as human resources, medicines and other supplies, plus various expenses. It has been estimated that in Peru 59.7% of total public health spending corresponds to the payment of human resources, including medical and non-medical personnel who perform health and non-health functions; 17.3% is allocated to the purchase of medications and other supplies (e.g. instruments, surgical and laboratory accessories, single-use

[46] MEF. Friendly Consultation.
[47] MEF. Friendly Consultation.

health items, as well as non-medical supplies used by the IPRESS); 15.4% for maintenance and improvement of buildings and equipment, and 7.6% for other miscellaneous administrative expenses.[48]

3.2. PRIVATE HEALTH SPENDING

Private health spending includes the purchase of private insurance and different forms of out-of-pocket spending. These are direct payments made by households to receive health services and purchase medications. These expenses include the "deductible" for those with private health insurance, which is the portion of the total cost not covered by insurance. Out-of-pocket expenses also reflect the direct payments made by SIS and ESSALUD members when they have to incur direct payments, because their IPRESS does not provide the medications or services, such as tests and other interventions, which the patient requires. This is particularly important in the case of Peru, since 62.9% of all out-of-pocket expenses are incurred by those covered by the SIS and ESSALUD. Furthermore, 7.5% of these expenses are incurred by those who have private health insurance (i.e., the deductible), and 24% by those who do not have health insurance.[49]

Out-of-pocket spending is a relevant indicator of the size of the market for medicines and health services purchased directly by the population, which in 2022 amounted to around US$ 4 billion. To the extent that the SIS and ESSALUD, through their IPRESS, can in the future provide all the medicines and services required by their insured, their importance in the health market will certainly increase, particularly as buyers of medicines, which is an area that represents an important part of total out-of-pocket expenses. According to the INEI, before the COVID-19 pandemic, health spending represented 8.4% of total household spending in Peru, being the fourth most important spending item after food, housing and transportation.[50]

The COVID-19 pandemic had a significant impact on household health spending. Measured in US$, out-of-pocket expenses have shown relative stability until 2019, then showing a sharp increase (see Chart 6). The drop observed in 2020 compared to 2019 in dollar terms is due to the depreciation of the Sol in 2020. In current soles there was a significant increase in out-of-pocket spending in 2020 compared to 2019.[51]

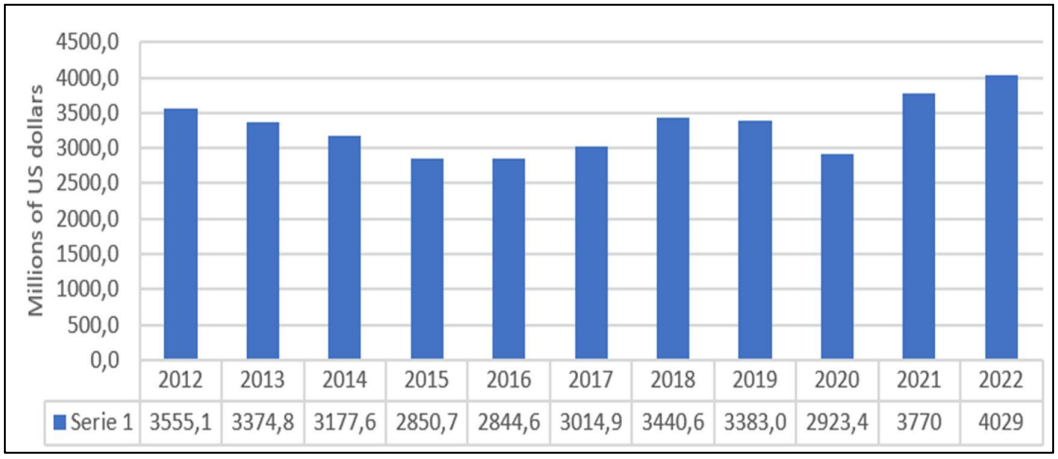
[48] Harold Erick Bravo Córdova (2019). Analysis of the evolution of the health sector and the perception of the public and private sectors. Thesis presented as part of the requirements to obtain the degree of Master in Health Services Management. Universidad ESAN. 1612028.

[49] Ministry of Health (MINSA-DIGEMID). (2021). Out-of-pocket spending on health and medications. Period 2012 - 2019 (1 ed.). Lime. Available at: https://www.digemid.minsa.gob.pe/webDigemid/estudios/2021/gasto-de-bolsillo-en-salud-y-medicamentos-2012-2019/

[50] INEI (2021). Peru: Poverty Profile by geographic domains, 2008-2018. Available at: https://www.inei.gob.pe/media/MenuRecursivo/publicaciones_digitales/Est/Lib1826/libro.pdf. It should be noted that out-of-pocket expenses presented in the National Household Survey (ENAHO) as a "private household spending on health." differ from the data provided by the INEI presented in Table 3. While the INEI data is the gross value of health sector production, the ENAHO database extrapolates the results from the monetary expenditure survey on household health of the sample covered by the survey to the total population.

[51] In current soles, the out-of-pocket spending of Peruvian households was 10,261 million soles in 2020, 14,629 million in 2021 and 15,394 million in 2022, respectively.

Chart 6
Peru: Out-of-pocket spending on health
(Million US$)

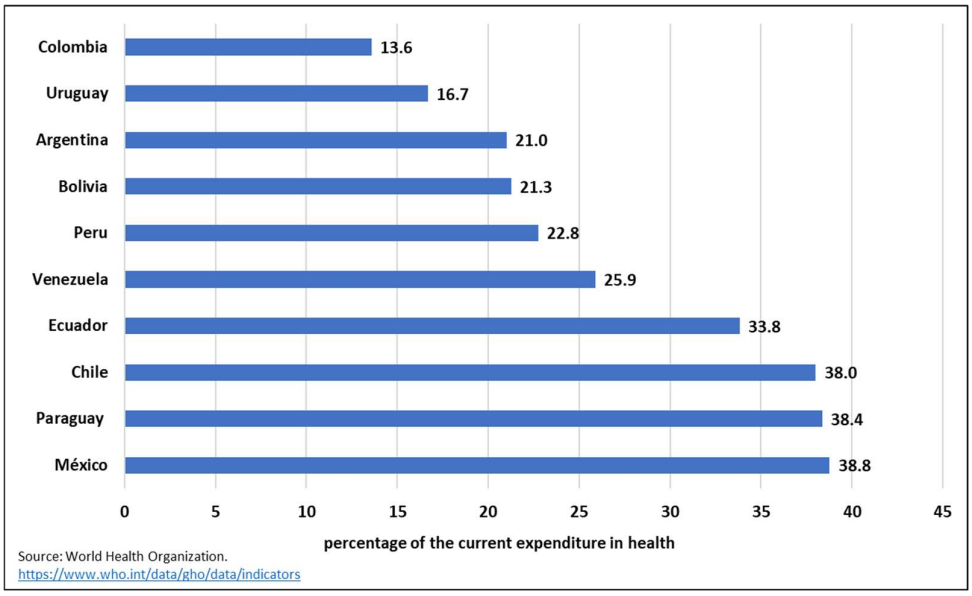


Source: Ministry of Health (MINSA-DIGEMID). (2021).[52]

Chart 7 presents out-of-pocket expenditures as a percentage of total current health expenditure for South American countries. As can be seen, there is a wide variation in the relative share of out-of-pocket spending in total current spending, being Perú around the average. Different factors explain the relative participation of this type of expenses and their detailed discussion is outside the scope of this report. However, the literature has identified that out-of-pocket payments for health services are related to a series of institutional factors that have to do with characteristics of the health service providers and those at the individual and household levels. Regarding the first, the variations are explained by the general coverage of the national health insurance system, both public and private, and the inefficiencies in the provision of health care by public health insurance systems. Regarding individual and household-level characteristics, commonly cited covariates explaining these expenditures include: socioeconomic status and size of the household, location of the household, age, gender, education, type of illness or condition and its severity, and the degree of self-medication by the population.

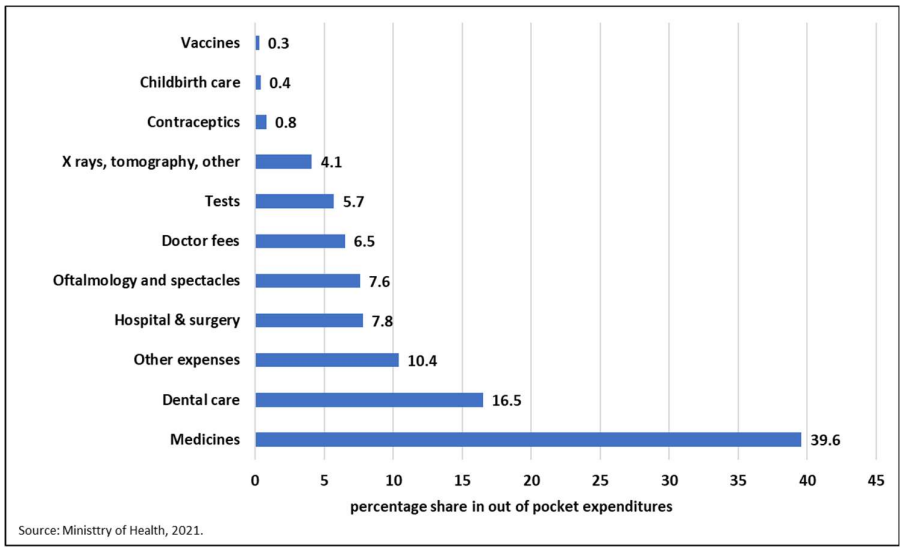
[52] Out-of-pocket spending on health and medicines Period 2012 – 2019. Chart 6 and ESSALUD (2023). Out-of-Pocket Expenses Made by the Population Insured by ESSALUD 2008-2022, September. Chart 3. Available at: https://repositorio.essalud.gob.pe/bitstream/handle/20.500.12959/4287/Gasto%20de%20Bolsillo%202008-2022.pdf?sequence=1&isAllowed=y

Chart 7
Out-of-pocket spending in Latin American countries 2020
(Percentage of current health expenditure)



The composition of out-of-pocket spending is an indicator of an important segment of the market for medicines and health services in a country, while showing the gaps in the health care coverage provided by different insurance schemes. Chart 8 presents the composition of the out-of-pocket spending of all Peruvian households on average during the three years prior to the COVID-19 pandemic, where it is clearly noted that the largest participation is held by medicines (39.6%), followed by for dental expenses (16.5%) and other types of health expenses.

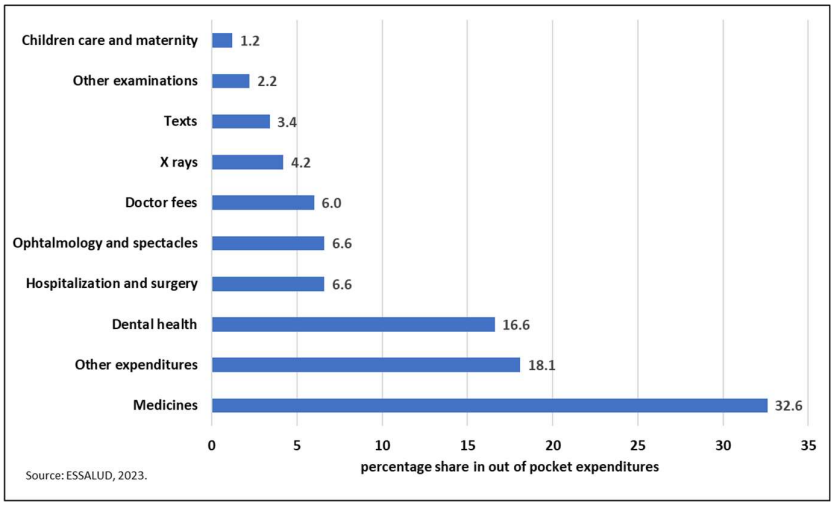
Chart 8
Peru: Average out-of-pocket spending on household health 2017-2019
(Participation percentages)



A similar exercise can be done in relation to the out-of-pocket expenses of those insured with ESSALUD, according to an average between the years 2018-2022. What can be seen is that

here there is also a domain of participation of expenses in medicines (32.6%), very distant from items that follow in order of participation, such as other health expenses (18.1%) and dental expenses (16.6%). The rest of the types of expenses have shares of only one digit (see Chart 9).[53]

Chart 9
Peru: Average out-of-pocket health expenditure of households insured by ESSALUD 2018-2019
(Participation percentages)



[53] ESSALUD (2023). Out-of-Pocket Expenditures by the ESSALUD Insured Population 2008-2022. Table 4. Op.cit .

CHAPTER 4 HEALTHCARE INFRASTRUCTURE

Infrastructure provides the necessary foundation for all health services and is a key pillar supporting the goal of promoting universal health coverage and improved standards of healthcare. It includes the physical facilities and all the support elements that make health care possible. This section briefly examines the state of health infrastructure in Peru, which is one of the most critical factors requiring urgent attention in the country to ensure universal health coverage and improve health care delivery.

The current health infrastructure in Peru is insufficient and inadequate. It has been estimated that investments of the order of US$ 7.5 billion would be needed to close the short-term infrastructure gap in the health sector, while to close the long-term gap – i.e. the amount of investment required to achieve the levels of access to basic infrastructure of developed countries -, US$ 15.4 billion would be necessary.[54]

The health infrastructure in the country, hospitals, clinics, laboratories, among other facilities, is insufficient to meet the growing demand and in general the existing public infrastructure faces serious deficiencies. The construction of new infrastructure has not kept pace with the significant increase in health insurance coverage, while the majority of public hospitals have been in existence for more than 40 years, having been built with less demanding technical standards than those they exist now. Additionally, the lack of maintenance over the years has contributed significantly to the physical deterioration of its facilities, as well as equipment. On the other hand, there is a high concentration in Lima and other large cities, while many regions of the country do not have the necessary hospitals or the minimum required health infrastructure.

4.1. HEALTH INFRASTRUCTURE IN PERU

The IPRESS in Peru are classified by categories according to their levels of complexity. These establishments are divided according to the functional characteristics they have. As established by Ministerial Resolution No. 546-2011 of the MINSA, the IPRESS are classified "based on levels of complexity and common functional characteristics, for which they have Health Services Production Units (UPSS), which together determine their resolution capacity, responding to similar socio-economic situations, health realities and designed to face equivalent demands."[55] All IPRESS must be categorized every three years and registered in the **Registry of Health Service Providers Institutions** *(*REIPRESS) with SUSALUD.[56] Table 4 presents the different categories of IPRESS.

[54] National Infrastructure and Competitiveness Plan. Available in: https://sinia.minam.gob.pe/sites/default/files/sinia/archivos/public/docs/ds238_2019ef.pdf Approved by Supreme Decree 238-2019-EF. Data in soles has been converted to US dollars at 3.8 soles per dollar.

[55] Available in: https://cdn.gacetajuridica.com.pe/laley/NORMA%20T%C3%89CNICA%20DE%20SALUD%20N%C2%BA021-MINSA-DGSP-V.03_LALEY.pdf

[56] The REIPRESS is available at: http://app12.susalud.gob.pe

Table 4
IPRESS Categories

Level of care	Categories
First level of care	Category I-1. Health post, or office with non-medical health professionals.
	Category I-2. Health post with doctor. In addition to medical offices (with or without specialist doctors).
	Category I-3. It corresponds to health centres, medical centres, specialized medical centres and polyclinics.
	Category I-4. They include health centres and medical centres with inpatient beds.
Second level of care	Category II-1. The set of hospitals and general care clinics.
	Category II-2. It corresponds to the most specialized hospitals and clinics.
	Category II-E. They group together hospitals and clinics dedicated to specialized care.
Third level of care	Category III-1. They group together hospitals and general care clinics with more health service production units.[57]
	Category III-E. They group together hospitals and general care clinics with the largest number of units producing health services and services in general.
	Category III-2. They correspond to specialized institutes.

In 2022 there were 24,729 IPRESS in Peru (see Table 5). Approximately 20% of the total IPRESS - 96% of them private - have not yet been categorized. This has raised concerns about informality in the provision of health services. Furthermore, according to the *Supervision Department of Health Providing Institutions,* there is a number of informal health establishments equal to the total registered in REIMPRESS.[58] These are mainly small medical centres, run by an independent doctor, with less than 10 workers, or individual medical practice offices not registered in the REIPRESS.

Likewise, there is a high territorial concentration of IPRESS, since Lima and Callao concentrate 40% of the total at all levels of care, with 22.6% located in five regions (Piura, Arequipa, Junín, La Libertad and Cajamarca). At the third level of care – i.e., with the capacity to offer complex health care -, there are only 55 IPRESS in the country, while only 515 second level for 33.4 million inhabitants. Furthermore, it is important to mention that almost 46% of the IPRESS (I-1) do not have a doctor.

[57] According to NTS Technical Standard No. 021-MINSA/DGSP-V. 03, a health services production unit is the basic functional unit of a health establishment constituted by the set of human and technological resources in health (infrastructure, equipment, medications, clinical procedures, among others) organized to develop homogeneous functions and produce certain services, in direct relation to its level of complexity.

[58] See *El Comercio* newspaper of 05/28/2023, p. 7.

Table 5
Peru: Number of Categorized IPRESS by Level – 2022

Level	Category	Public sector	ESSALUD	Private Sector	Total
One	I-1	4,396	2	4,322	8,720
	I-2	2,445	162	2,811	5,418
	I-3	1,502	122	2,290	3,914
	I-4	336	24	85	445
	Total	8,679	310	9,508	18,497
Two	II-1	99	39	90	228
	II-2	33	14	31	78
	II-E	18	6	185	209
	Total	150	59	306	515
Three	III-1	21	8	4	33
	III-2	11	2	1	14
	III-E	5	2	1	8
	Total	37	12	6	55
	Grand Total	**8,866**	**381**	**9,820**	**19,067**

Source: COMEX (2022) Current state of the Peruvian health market.

According to 2018 data on ownership and category of the IPRESS, , primary health care was covered mainly by regional governments and the private sector, while the MINSA, through the SIS, and ESSALUD played a marginal role, with the limited number of private IPRESS being notable at the highest level of complexity of health care provision (see Table 6). Note that, in category III, the public sector and ESSALUD have a relatively more relevant presence, along with the armed forces and the police.

It is worth mentioning here that Law 29124 of 2007 established the co-management and citizen participation of IPRESS of the first level of care of the MINSA and the Regional Governments, granting them responsibilities for the management of public resources for the administration of health services, based on a contract signed between the communal entity called **Community Local Health Administration** *(*CLAS), which are civil society organizations, and the regional health directorates. The services were financed with public funds, but their provision was the responsibility of CLAS. In 2018, these CLAS were 1,565, 20% of all first-level IPRESS. However, the results have not been very promising.[59]

[59] MINSA (2021). Analysis of the Health Situation of Peru. p. 38.

Table 6
Peru: IPRESS According to Ownership and Category 2018
(units)

	I-1	I-2	I-3	I-4	II-1	II-2	II-E	III.1	III-2	III-E	No category
MINSA	5	156	173	32	2	3	1	10	8	2	5
Regional Governments	4,363	1883	1,039	279	95	31	11	9	3	2	61
ESSALUD	2	108	98	13	41	16	2	8	2	1	82
Armed Forces and Police	58	127	53	17	2		3	4			11
Local Governments	2	12	48				1				56
Private sector	3,317	2,182	1,480	423	106	30	137	4	1	1	5599
NGOs & other	18	29	37		1		2				14

Source: MINSA (2019) *Análisis de Situación de Salud del Perú* 2019. Table 3.

To examine the changes in the stock of health infrastructure in the country, Table 7 shows the number of IPRESS by category for 2011 and the latest data for 2023. What can be seen is that said stock has increased to some extent. However, although the number of IPRESS increased by 75% during the period, the expansion of infrastructure has occurred mainly at the primary level, medical posts and medical centres. In levels II and III, only hospitals and clinics with greater specialization (II-2) show a certain increase, which includes both public and private IPRESS. However, this expansion over more than a decade is not at all impressive, particularly given population growth and the significant expansion of insurance coverage. These data require further analysis disaggregated by ownership and territorial location.

Table 7
Peru: Variation in the number of IPRESS by Category - 2011 - 2023
(Units)

Category	2011	2023	Difference
I-1	5,615	9,160	3,545
I-2	2.426	5,764	3,338
I-3	1,483	4,193	2,710
I-4	421	458	37
II-1	235	236	1
II-2	78	83	5
II-E	17	232	215
III-1	38	34	-4
III-2	14	14	0
III-E	4	10	6
No category	4,079	5,026	947
	14,410	25,210	10,800

Source: *SUSALUD Boletin Estadistico 2011 IV Trimestre and Boletin Estadistico II Trimestre 2023.*
Elaborated by the authors.

The evaluation made in 2022 by the MINSA, the health system's governing body, about the situation of the public sector health infrastructure, including ESSALUD, is that it is in a dire situation.[60] The existing gap occurs not only by comparing the current state of the infrastructure with what it should have, but also in terms of the difference between the available supply of infrastructure or access to services with the demand for health services in a given territory. That is to say, the gap is expressed in terms of insufficient quantity and quality of infrastructure to satisfy the population's growing demand for health services.

Some figures by establishment category can help illustrate these problems:

- In the case of first-level IPRESS, MINSA found that 94.5% of them have inadequate installed capacity at the national level, in terms of precarious facilities, as well as obsolete, inoperative or insufficient equipment. Likewise, the MINSA estimates that 1,791 new level 1 IPRESSs need to be established.
- In the case of IPRESS hospitals in categories II-1, II-2, II-E, III-1 and III-E, it was found that 91% have inadequate capacity[61] and that it is necessary to establish 156 new hospitals to serve the current demand, based on the number of new hospital beds needed.
- Of the 13 specialized hospitals in operation (III-2), 10 have inadequate capacity and provide limited services, as demand exceeds their capacity to provide those needed.
- Finally, of the 62 laboratories in the public health sector, only one was found to have adequate installed capacity.

This evaluation clearly indicates that, to achieve the objectives of providing quality health services to the population and achieving UHC, a significant investment in the health sector will be required in the immediate future. The following section briefly analyses investment in the health sector in Peru.

4.2. INVESTMENT IN THE HEALTH SECTOR

Background

The total investment in the health sector includes the construction and rehabilitation of new facilities, as well as the acquisition of equipment, by the public sector - including ESSALUD[62] - and the private sector. There is no easily accessible aggregated data on total investment in health in Peru, and only an approximation is presented in this section. Given the existing gaps, it is clear that the investment made over time has not been of sufficient quality and quantity to guarantee quality health care and offer universal health coverage.

For several years now, the Peruvian State, through the executive and legislative branches, has made regulatory modifications to facilitate the development of state infrastructure projects, not only through the traditional public works framework, but also through public-private partnerships, works for taxes and, more recently, using government-to-government agreements. There have also been regulatory changes in areas such as urban planning licensing, land release

[60] MINSA (2023). Diagnosis of infrastructure gaps or access to health sector services January. Available at: https://www.minsa.gob.pe/Recursos/OTRANS/08Proyectos/2022/Diagnostico-Infraestructura-Sector-Salud-2024-2026.pdf

[61] A hospital has inadequate installed capacity when the existing infrastructure, equipment and health services provided do not comply with the provisions of Technical Health Standard No. 110-MINSA/DGIEM-V.01 "Infrastructure and Equipment of Health Establishments of the Second Level of Care" or in the Technical Health Standard No. 119-MINSA/DGIEM-V.01 "Infrastructure and Equipment of Health Establishments of the Third Level of Care".

[62] ESSALUD is a decentralized public organization, with legal status under domestic public law, attached to the Labour and Social Promotion Sector (Law 27056).

and environmental and archaeological issues,[63] and the creation of the National Infrastructure Authority (ANIN).[64] All projects included in the Multiannual Investment Program (PMI) of the national, regional and local government levels have been placed under this authority - except those under the PPP scheme - that meet two conditions: a) they have not had physical execution and b) have an investment value equal to or greater than 200 million soles (around US$ 53 million). Additionally, any investment project that contributes to the development of economic and logistical corridors and prioritized services will also be incorporated.

At this stage it is not clear exactly how ANIN will operate and whether its establishment will cause a delay in bidding for projects in the pipeline. To the extent that the ANIN will be efficient and resolve current problems that affect investment in infrastructure, it could be an important contribution to the country's development efforts.

For the time being, within the Peruvian State, the most influential actors in the creation, operation and maintenance of infrastructure are the MINSA and ESSALUD. Within the MINSA, it is estimated that it will be necessary to establish 1,741 first-level IPRESS and 165 hospitals, as well as modernize almost all first-level IPRESS.[65] On the side of ESSALUD, it has determined that it is necessary to build 226 level 1 and 33 level 2 hospitals, but also modernize 241 level 1 and 73 level 2 hospitals.[66]

Ideally, as progress is made in closing gaps, interesting opportunities will open for participation by the private sector, foreign and national, in the construction of health infrastructure, provision of equipment and provision of health services, through different modalities of involvement. However, for the gap to be closed, it is essential to have a portfolio of projects whose execution will contribute to the improvement of health services and that may be of interest to the private sector.

Portfolio of public investment projects

In October 2022, the National Sustainable Infrastructure Plan for Competitiveness (PNISC) was published, prioritizing a portfolio of 72 projects for US$ 38.6 billion of investment.[67] Of them, 22 projects correspond to the health sector (19 to be carried out as public works and 3 as PPP), with an approximate investment amount of US$ 1,970 million (see Table 8). These projects refer to level II and III hospitals, in addition to two IPRESS of the first level of care (Lima and Ancash). Of the total of all these projects, 6 are in Metropolitan Lima and 16 in provinces of nine regions. Only one of the included projects is involved in an Integrated Health Network (RIS).

The projects include the improvement of existing facilities, as well as the construction of new ones, with the level of maturity of said projects being differentiated. To date, the Piura and Chimbote hospital projects, included in the PNISC, were awarded as PPP in June 2023 to the Spanish Group ITB Salud for 20 years.[68] However, there are delays in the progress of a good

[63] A recent example along these lines is the publication of Legislative Decree 1569 of May 2023), which establishes measures to facilitate the management and unblocking of projects included in the National Infrastructure, Sustainability and Competitiveness Plan.

[64] Law 31841 of July 2023, and its regulations. See https://busquedas.elperuano.pe/dispósito/NL/2198260-1

[65] For more information, see: https://www.minsa.gob.pe/Recursos/OTRANS/08Proyectos/2022/Diagnostico-Infraestructura-Sector-Salud-2024-2026.pdf

[66] ESSALUD Multiannual Investment Program 2024-2026 (2023). Executive Presidency Resolution No 226-PE-ESSALUD-2023, dated February 24, 2023. Available at: http://www.essalud.gob.pe/wp-content/uploads/RPE_226_ESSALUD_2023.pdf

[67] Supreme Decree 242-2022-EF National Sustainable Infrastructure Plan for Competitiveness 2022 – 2025. Available at: https://mef.gob.pe/contenidos/inv_privada/planes/DS_242-2022-EF.pdf
In the first version, published in 2019, the health sector was not considered.

[68] Both projects also include the acquisition and replacement of equipment, the maintenance of hospital infrastructure; as well as the provision of general services and support services in the grey coat modality (10 services including: laundry, food, security,

part of the PNISC projects. As examples, we can cite the cases of the hospital project in Huaraz, which has not begun construction for more than a decade;[69] that of the Papa Francisco hospital, whose technical file is still being prepared as of July 2023, or that of the Zacarias Correa hospital, whose works have been paralyzed since 2022.

Table 8
Prioritized Health Projects in the PNISC

Project	Approximate investment amount (million US$)	Modality
1. Creation of the specialized health services of the specialized hospital of the Piura healthcare network of ESSALUD, district of Veintiséis de Octubre, province of Piura, department of Piura.	Awarded US$ 161	PPP
2. Creation of the specialized health services of the specialized hospital of Chimbote in the Ancash healthcare network of ESSALUD, district of Nuevo Chimbote, province of Santa, department of Ancash.	Awarded US$ 162	PPP
3. Improvement and expansion of the II Huaraz hospital of the Ancash ESSALUD healthcare network in the district of Independencia, province of Huaraz, department of Ancash Preparatory acts for contracting the formulation of the Technical Dosstoier.	Under execution US$ 75	Public work
4. Improvement and expansion of the health services of the Florencia de Mora I hospital of the La Libertad-ESSALUD healthcare network, district of Florencia de Mora-province of Trujillo- department of La Libertad	Under execution US$ 62	Public work
5. Improvement and expansion of the health services of the Juliaca healthcare network in the district of Juliaca, province of San Román, Puno.	Under execution US$ 66	Public work
6. Improvement of the health services of the Chocope hospital of the La Libertad healthcare network-district of Chocope, province of Ascope, department of La Libertad in the process of reviewing the third deliverable of the technical file. No information, no information, no information.	Under execution US$ 77	Public work
7. Trecca Project. Awarded in 2010 as PPP with Auna and American Hospital Management. After 13 years, does not even pass the pre-investment phase.	Awarded US$ 51	PPP
8. Improvement of the health services of the II Pasco hospital of the Pasco healthcare network, in the district of Fundificación de Tinyahuarco, province of Pasco, department of Pasco	Under execution US$ 114	Public work

management and management of solid waste, cleaning, maintenance, acquisition and maintenance of equipment and intra-hospital logistics) and green. (3 services: haemodialysis, clinical laboratory and imaging). These projects do not consider the provision of medical services, since these will be continued by ESSALUD personnel.

[69] For more information, see: https://www.regionancash.gob.pe/noticias.php?id=1797

9. Improvement of the health services of the II Vitarte hospital of the Almenara-ESSALUD healthcare network, Vitarte district, province of Lima, department of Lima	Under execution US$ 105	Public work
10. Recovery of the health services of the María Reiche hospital of the Ica-ESSALUD healthcare network, Marcona district-Nasca province-Ica department	Under execution US$ 42	Public work
11. Improvement of the resolution and operational capacity of the Egoavil Pando Roman hospital in the district of Villa Rica, province of Oxapampa, Pasco region	Under execution US$ 38	Public work
12. Improvement of health services at the II Talara hospital of ESSALUD in the district of Pariñas, province of Talara, department of Piura.	Under execution US$ 77	Public work
13. Improvement of health services in the Huari health facility, district and province of Huari, department of Ancash.	Under execution US$ 51	Public work
14. Improvement of health services at the Huarmey Hospital, Huarmey District, Huarmey Province, Áncash Region.	Under execution US$ 42	Public work
15. Improvement of health services at the Zacarías Correa Valdivia regional hospital in Huancavelica; District of Ascensión, Province of Huancavelica and Department of Huancavelica.	Paralyzed US$ 78	Public work
16. Improvement and expansion of the health services of the Chincheros II-1 Hospital, Virgen de Cocharcas Health Network, District of Chincheros -Province of Chincheros -Department of Apurímac.	Under execution US$ 42	Public work
17. Creation of health services at the Papa Francisco de Manchay Hospital, Pachacámac district, province of Lima, department of Lima.	To be tender US$ 59	Public work
18. Improvement and expansion of health services at the Sergio Enrique Bernales National Hospital, in the town of Collique, Comas district, province of Lima, department of Lima.	To be tender US$ 265	Government to Government
19. Creation of health services at the Altiplano Hospital in the Puno-ESSALUD region, province of Puno.	Under execution US$ 92	Public work
20. Improvement and expansion of health services at the San Juan de Lurigancho hospital in the district of San Juan de Lurigancho, province of Lima.	Under execution US$ 142	Public work
21. Improvement and expansion of the first level health services of the Puente de Piedra health network.	Under execution US$ 15	Public work

Outside of the list of NPISC projects, there are other important health infrastructure projects, some **brownfield** and others **greenfield**, involving its construction or operation and maintenance. They belong to MINSA, ESSALUD and the Armed Forces and are eventually considered to be carried out as public works, PPPs or works for taxes (see Table 9).

Table 9
Other Health projects

Project	Approximate investment amount (million US$)	Modality
1. Hipólito Unanue National Hospital	US$ 250	PPP
2. New Military Hospital	US$ 116	PPP
3. Victor Ramos Guardia Hospital of Huaraz	US$ 270	Work for taxes
4. Villa El Salvador Emergency Hospital	US$ 110	AP
5. Comprehensive management of solid waste in health facilities of the Ministry of Health in Metropolitan Lima	US$ 24	APP
6. Leoncio Prado Hospital Support	US$ 33	n.d.
7. Cajamarca Hospital [Under construction]	US$ 100	PPP

Finally, the MINSA has other projects contained in the Multiannual Investment Plan 2024-2026, which includes 269 investment projects in infrastructure, access to services and purchase of medical equipment.[70] According to this plan, a budget allocation for investments of US$ 668 million is expected for 2024 and US$ 758 million for 2025 and 2026. Some of this investment is continuation of current projects. For its part, the ESSALUD Multiannual Investment Plan contains 50 projects in works and goods with an estimated cost budget of US$ 150 million by 2024, US$ 186 million by 2025 and US$ 268 million by 2026.[71]

Execution of investment in health infrastructure

a. Public investment

i. Public procurement

As of September 2023, MINSA is executing investment projects worth approximately US$ 500 million, with a progress of 23%.[72] On the same date, ESSALUD announced that it is investing

[70] MINSA Multiannual Investment Program 2024-2026. Available at: https://cdn.www.gob.pe/uploads/document/file/4185071/Programa%20Multianual.pdf?v=1677339213 The status of all MINSA projects can be evaluated at: https://obrasalud .pronis .gob.pe/ControlInicio.html

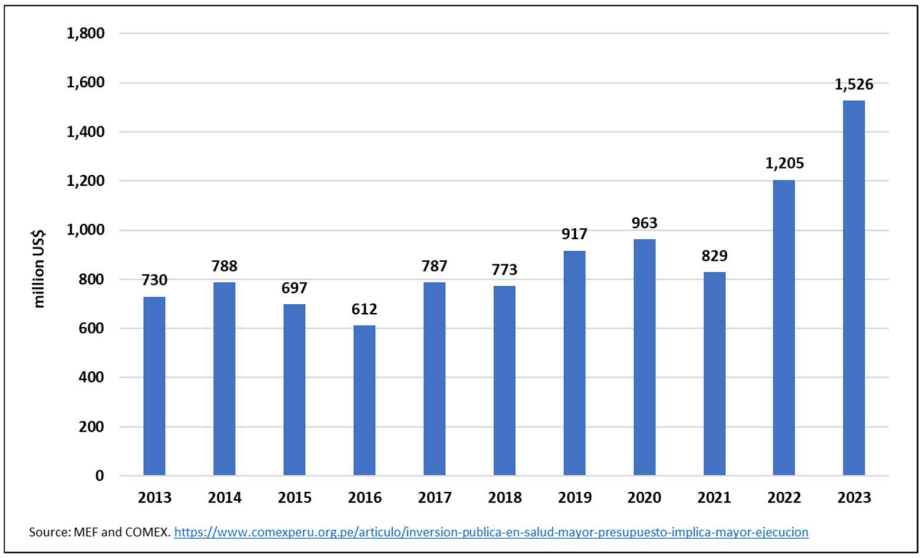
[71] Multiannual Investment Program (PMI) 2024-2026. Available at: http://www.essalud.gob.pe/wp-content/uploads/RPE_226_ESSALUD_2023.pdf

[72] General consolidated execution of the health sector as of September 2023. Available at: https://www.minsa.gob.pe/Recursos/OTRANS/08Proyectos/enejecucion/2023/ProyEjec09-2023.pdf

US$ 1.15 billion in the construction and improvement of ten hospitals in eight regions of the country.[73] . Chart 10 presents the MIB of investment in the public health sector, MINSA and regional governments, for the period 2013-2023.[74] As can be seen, after years in which the budget did not experience significant increases, after the COVID-19 pandemic there has been a significant increase in resources allocated to health investment by the public sector. In 2022, the budget distribution was 38.8% for the central government, 41.8% for regional governments and 19.5% for local governments.

Health investments under de MINSA umbrella is the responsibility of the National Health Investment Program (PRONIS), a body attached to the Vice Ministry of Health Benefits and Insurance of the Ministry of Health. This unit's functions include formulating, evaluating and executing health investment projects for all levels of complexity at the national level; provide technical assistance to regional and local governments in the pre-investment and investment phases of projects, and manage and supervise health investment project contracts under the modalities of Public Private Partnership, Works for Taxes and Government to Government. However, as will be seen later, its performance has not been the most efficient.

Chart 10
Peru: Public Sector: Modified Institutional Budget for Investment in Health 2013-2023
(million US$)



In relation to ESSALUD, it has not been possible to construct a time series of its investments made.[75] The available data show that the resources allocated to investment, both for works and for equipment of different types, represent a minor component of total expenditure. On average, it has been only 3.5% during the period 2019-2023.[76] In the 2023 budget, it is found that the resources allocated to infrastructure amounted to US$ 86 million and US$ 43 million to equipment. Of the total allocated to infrastructure, 70.5% was for the continuation of projects

[73] For more information, see: http://noticias.essalud.gob.pe/?inno-noticia=essalud-invierte-mas-de-s-4-mil-366-millones-en-10-proyectos-hospitalarios-a-nivel-nacional
[74] Includes central, regional and local governments, and MINSA entities and programs.
[75] ESSALUD is under the supervision of the National Fund for the Financing of State Business Activity (FONAFE), this latter an entity attached to the MEF, which regulates and directs the business activity of 35 state companies, being responsible for approving the annual budget of ESSALUD and making adjustments when necessary. scarcity of resources to sustain health coverage and benefits.
[76] For more information, see: https://www.fonafe.gob.pe/empresasdelacorporacion/essalud

already in execution.[77] It is worth mentioning that within these investment expenses are those that involve projects through PPPs, which will need additional financing.

ii. Alternative schemes to public procurement

In Peru there are some experiences of health infrastructure projects through **public-private partnership contracts** or PPP, which are the following:

- Kaelin hospital in Villa María de Triunfo and the Alberto Barton hospital in Callao, including design, construction, operation and maintenance, both operating under a white coat scheme. These were concessioned for 30 years in 2010 to the IBT Salud Group.
- The operation and maintenance of the National Institute of Child Health of San Borja (INSN-San Borja), under a grey coat and green coat scheme. This project was concessioned for 15 years to the consortium made up of the Spanish companies Iberia de Mantenimiento SA and DOSEKIM SL, in alliance with a local laboratory.
- Logistics management, storage and distribution of pharmaceutical products and medical devices of ESSALUD to the Brazilian Salog company.
- The hospitals of Piura and Chimbote will operate under the grey and green coat modality with Grupo IBT, for their design, construction, operation and maintenance. These were concessioned in 2023 for 20 years to Grupo IBT Salud.

Other infrastructure generation schemes are those linked to government-to-government agreements, financing from international organizations and works for taxes, such as the following cases:

- The Authority for Reconstruction with Change (ARCC)[78] signed a contract with the United Kingdom for the construction of four hospitals and two health centres worth approximately US$ 115 million.[79]
- The MINSA currently executes the Investment Program for the Creation of Integrated Health Networks (RIS), with 11 investment projects, for an amount greater than US$ 315 million, financed with loans from the Inter-American Development Bank (IDB), the World Bank (WB) and MINSA resources. These investments are being executed by PRONIS.[80] As of 2023, these projects are still in the initial programming phase.
- There are few cases under works for taxes, for example the Macusani hospital in Puno, awarded in 2013.

b. Private investment

Private investment in health over the last decade has shown significant progress, both through mergers and acquisitions and the establishment of new clinics. In 2022, the private sector had

[77] ESSALUD annual investment plan for fiscal year 2023. Resolution of the Executive Presidency No 339 -PE-ESSALUD-2023. Available at: https://www.gob.pe/institucion/essalud/normas-legales/4688505-339-2023-pe-essalud

[78] Entity created in 2017to address the damage to infrastructure caused by the El Niño Phenomenon of 2017.

[79] For more information, see: https://www.rcc.gob.pe/2020/arcc-firma-contratos-para-reconstruir-4-hospitales-2-centros-de-salud-y-15-instituciones-educativas-de-6-regiones- del-country/ May 5, 2021.

[80] For more information, see: https://www.gob.pe/institucion/pcris/noticias/647785-pcris-impulsa-la-implementacion-de-11-proyectos-de-inversion-destinados-a-fortalecer-el-primer-nivel-de- attention - health September 7, 2022.

16% of all hospital beds in the country, which is an indicator of its ability to offer more complex health care.[81] Currently, although there are some new projects, the pace of private investment has slowed, with most of the most recent investment being made in equipment, remodelling and expansions, rather than a significant increase in new private supply in the market. The predominant projects constitute mostly primary care centers, rather than clinics with a complex offer of health services.[82] This is due to lower demand, as a result of the deterioration of the population's purchasing power, the limited coverage of private health insurance, as well as a less favourable general investment climate. In Peru, only around 6% of the total population who require health services seek them in a private clinic or a private doctor, a situation that has not changed since 2011.[83]

Difficulties in closing gaps

As mentioned before, there are delays in progress in PNISC projects, but in general all public investment does not escape this problem. In the case of the projects under PRONIS, according to Allccarima, Lizano and Pereira (2022),[84] their contribution to closing the health infrastructure gap has been insufficient, citing poor management in compliance with schedules and in the execution phase of hospital infrastructure projects, due to reasons such as the following:

a. Inadequate development of **technical files**, associated with:
    i. The physical and financial programming of the projects is not planned correctly.
    ii. There is a high turnover of personnel in charge of preparing technical files.
    iii. Professionals have a large number of files assigned for their attention, and
    iv. There is no adequate coordination between specialties when preparing the technical file.
b. Inadequate attention in the **absolution of queries**, associated with the fact that
    i. Professionals have a large number of files assigned for their attention,
    ii. There is a high turnover of personnel in charge of absolving queries,
    iii. The construction supervision transfers queries to PRONIS that may be directly related to it, and
    iv. There is no adequate coordination between specialties when answering queries.

Faced with these problems, these authors propose to make management improvements in aspects such as better hiring of personnel; the approval of guidelines that include technical

[81] Graph 1. https://www.comexperu.org.pe/upload/articles/publicaciones/situacion-actual-del-mercado-de-salud-peruano-informe.pdf
[82] For more information, see: https://www.america-retail.com/peru/clinicas-en-2023-motivos-de-la-poca-inversion-en-el-peru/ The last major private investment in clinics in Peru was the Clínica Delgado in Lima, which required an investment of US$ 120 million. The existing new projects amount to about 7 million dollars.
[83] INEI. Living Conditions in Peru II Quarter 2023. Available at: https://m.inei.gob.pe/media/MenuRecursivo/boletines/boletin_condiciones_de_vida_2.pdf
[84] Gabriela Allccarima, Keyla Lizano and Sonia Pereira (2022). *Evaluation of the execution of projects of the National Health Investment Program – PRONIS (2017-2019)*. Research work presented to qualify for the Academic Degree of Master in Public Management. Pacific university. Available at: https://repositorio.up.edu.pe/handle/11354/3591?show=full

parameters for the evaluation of technical files and response to queries; the adoption of internal management measures to improve the attention to documentation related to the development of projects, and the implementation of the **Building methodology Information Modelling** (BIM) for the creation and management of a construction project.

The consequence of the aforementioned problems are deficiencies in budget execution, which cuts across the entire execution of the State's health infrastructure. According to MEF data, less than 70% of the total MIB is spent on investment. On average during the period 2018-2022, the central government executed 66.8% of the health sector investment budget, while regional governments and local governments 57.8% and 59.7% respectively.[85] Information as of October 2023 indicates that the central government has only executed 45.5% of the health investment budget, while the regional and local governments 36.4% and 31.4% respectively.[86]

An evaluation carried out by the Association for the Development of Infrastructure (AFIN) found that in 2022, of the 49 hospitals awarded between 2010 and 2019, only 15 were completed and operational, 5 were within the scheduled deadline for completion, 13 are facing long delays in their execution, and 16 are paralyzed or the contract has been terminated.[87] Furthermore, in general, infrastructure projects in Peru usually take 71% longer than the estimated execution time, and end up costing almost 30% more than the initial Budget.[88] The healthcare sector is not immune to these problems.

According to the Comptroller General of the Republic (CGR), as of September 2023, there were 67 paralyzed health projects at a cost of around US$ 900 million, of which 4 are 90% complete, and 6 are 80% complete.[89] Of that same total, 19 are the responsibility of the central government, 23 and 25 of the regional and local governments respectively. The implementation problems that this entity encounters are the following:

i. Non-compliance with technical and regulatory aspects considered in the technical files during the execution of the work.

ii. Approval of technical files with legal non-compliance or without support.

iii. Additional unsupported work services.

iv. Delays in the delivery of land, legal physical sanitation and release from interference.

v. Lack of financing, and

vi. Occurrence of disputes, controversies and arbitrations, among others.

For the CGR, among all these problems, the one that most influences the stoppage of works is the lack of financing (34.8%), followed by non-compliance with contracts (21.1%) and disputes, controversies and arbitrations (4 ,4%). In this regard, in July 2023 the government expressed its intention to unblock all paralyzed projects, which within the MINSA would imply the transfer

[85] MEF. Friendly consultation.
[86] Economic Transparency of the Ministry of Economy and Finance. Prepared by Management. Wednesday, October 4. p. 5.
[87] Cited by the Private Competitiveness Council. Available at: https://www.compite.pe/noticia/inversion-privada-en-salud-para-mas-y-mejores-servicios/
[88] Private Competitiveness Council. Competitiveness Report 2020. Available at: https://www.compite.pe/wp-content/uploads/2019/11/CPC_Peru_INC-2020_Libro-Web-Paginas.pdf
[89] Comptroller General of the Republic (2023). Report on Works in the National Territory Paralyzed as of September 2023 No 005-2023-CG/SESNC. June. Available at: https://cdn.www.gob.pe/uploads/document/file/5340671/4785130-informe-de-obras-paralizada-en-el-territorio-nacional-a-setiembre-2023.PDF?v =1698422854

of around US$ 920 million to activate paralyzed health projects throughout the country.[90] However, these funds have not been available in the 2023 health budget, with no transfers having been made until November 2023. To the extent that this happens, interesting possibilities will open up for the private sector to participate in the works and equipment of health facilities. However, this will depend on the amount of resources for investment that are allocated to the health function not only in 2024 general budget, but in the next years in order to converge towards the closing the health infrastructure gap.

[90] Presentation of the President to Congress, 28 July 2023.

CHAPTER 5

HUMAN RESOURCES IN THE HEALTH SECTOR

Ensuring effective health care, particularly under a universal security coverage scheme, requires a variety of indispensable resources, including qualified doctors, nurses and technical personnel, necessary to provide high-quality services and meet the needs of the patients. In 2021, including all public and private sector entities in Peru, there were just over 400,000 people employed in the health system, of which 46% were health professionals at different levels and specializations, and 54% were administrative and support staff. Of this total, 5% are employed in the private sector and 95% in the public sector,[91] constituting 6% of the country's total public employment.[92] Among the quality problems of health services, linked to the human resources used, are the following:

- Deficit of health professionals;
- Shortage of specialized doctors;
- Emigration abroad healthcare professionals;
- Unequal territorial distribution of health professionals;
- Low salaries for medical staff;
- Deficiencies in the institutional functioning of the public health sector, and
- Deficiencies in the quality of university medical training.

What follows is a brief description and analysis of these problems.

5.1. DEFICIT OF HEALTH PROFESSIONALS

The number of health professionals in the country has been growing constantly; however, there is a significant deficit at all levels of the health system in terms of availability, quality and good management of human resources, all of which contribute to the terrible state of the provision of health services in Peru.

Estimates of the gap vary. According to a 2019 MINSA report, 11,401 more specialist doctors were needed, and in the same year ESSALUD estimated that it needed 5,000 more doctors and 5,000 nurses. A more recent estimate from the Medical College of Peru indicates that the total gap in the health system is 18,000 doctors and 60,000 nurses.[93] The fact is that the availability of doctors and other health professionals in Peru is far below what is necessary to provide adequate coverage and quality health services to the population.

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[91] MINSA (2021) Information on Human Resources in the Peru Health Sector 2021. National Registry of Health Personnel. Human Resources Bibliography Series No 34. Available at: https://www.gob.pe/institucion/minsa/informes-publicaciones/3144627-informacion-de-recursos- humans-in-the-health-sector .

[92] INEI (2022). Statistical Compendium 2013-2021. Table 26.37.3

[93] For more information, see: https://www.infobae.com/peru/2023/10/02/cmp-informa-que-hay-12-a-14-medicos-por-100-mil-habitantes-el-sistema-de-salud-no-funciona/

Table 10 presents the number of health system professionals in Peru reported by the MINSA for the years 2013 and 2021 distributed by type of activity. However, these figures differ from those reported by entities such as the National Institute of Statistics and Informatics (INEI) and the Medical College of Peru,[94] which speaks to the need to improve data on the health system in Peru.

Table 10
Human resources in the Peruvian health sector: 2013-2021

	2013				2021			
	Number	shares %			Número	shares %		
		Public sector		Private sector		Public sector		Sector privado
		ESALUD	Rest of public sector			ESSALUD	Rest of public sector	
Doctors	34,911	29.0	61.2	9.8	55.477	27,6	67,8	4.6
Nurses	36.09	28,7	69,4	1.9	67.076	23.7	74	2.3
Midwifes	12,561	10.5	88.9	0.6	21,010	9.4	89.9	0.7
Dentists	5,021	15.4	73.1	11.5	7,217	13.2	81.3	5.5

Source: Statistical Compendium: Information on Human Resources in the Health Sector 2013-2021. MINSA

If a comparison is made of the availability of clinical doctors in countries in the South American region, the data clearly shows that the availability of health professionals in Peru is far below that of the majority of these countries. In the case of doctors, Peru has 16.6 per 10 thousand people, being second to last place in the sample of 11 countries. Something similar occurs in the cases of nurses- midwives and dentists (see Table 11).

Even though countries like Uruguay and Argentina top the list with 49.4 and 38.9 doctors per 10,000 people, these South American countries have a significantly low density of health professionals compared to most European countries. In Spain, for example, there are 45.7 doctors per 10,000 inhabitants; 41.3 in Italy and 42.2 in Germany. Similar distances are observed in other categories of health professionals.

Table 11
South America: Density of health professionals
(Number per 10,000 people)

	Doctors	Nurses and Midwifes	Dentists
Uruguay	49.4	72.0	14.5
Argentina	38.9	54.4	7.9
Paraguay	32.4	90.3	12.8
Chile	29.7	46.0	14.8
Mexico	24.4	29.6	1.5
Colombia	23.6	14.5	8.6
Ecuador	22.3	25.2	3.2
Brazil	21.4	55.1	6.7
Venezuela	16.6	20.1	1.3
Peru	16.5	22.0	2.4
Bolivia	10.1	15.3	1.8

Source: World Health Organization.

[94] However, there are differences between these figures and those provided by the INEI, which, for example, reports 90,094 doctors for 2020, while the Medical College of Peru reported 61,193 registered doctors in 2022, a figure closer to that reported by the MINSA.

5.2. SHORTAGE OF SPECIALIZED DOCTORS

To the problem of generalized shortage of professional human resources in the health system, we must add that there is a significant gap in terms of specialties and an unequal territorial distribution of human resources. In terms of specialists, for example, MINSA has only 42 specialized doctors per 100,000 inhabitants, and in some regions some specialties are completely absent.[95] To obtain the title of specialist in Peru, a doctor must complete between three and five additional years above the seven years of undergraduate university training, plus one year of the Marginal Urban Rural Health Service (Serums). However, wages and working conditions in the public sector, which is the largest employer, are not attractive enough to justify this additional effort. We must add to this that around 40% of health professionals who work in the public sector do so under different types of employment regimes, including different kinds of temporary contracts.

5.3. EMIGRATION ABROAD OF HEALTH PROFESSIONALS

An additional issue that contributes to the deficit of doctors - particularly specialized ones - and nurses in the country is emigration. In this regard, there is not much information available, but a 2016 study by the International Organization for Migration indicated that, between 1990 and 2015, 12,399 doctors and 18,352 nurses had left the country permanently to work abroad. This is 13% of all people who left during that period to reside abroad.[96] Anecdotal information indicates that there continues to be significant emigration of doctors and nurses seeking a better life abroad or wishing to specialise, but most of them do not return to the country. One of the main reasons for the emigration of doctors is better employment opportunities and the possibility of better working conditions, in terms of higher salaries and more flexible working hours. In addition, it should be taken into account that in Peru there is no medical career as in other countries and doctors want to specialise and constantly update their knowledge.[97]

5.4. TERRITORIAL DISTRIBUTION OF HEALTH PROFESSIONALS

Regarding territorial distribution, there is a high concentration of health professionals in Lima and other large cities, including the private sector. Lima and its port El Callao concentrate 57.5% of the total number of physicians, and four regions an additional 20.2%. Some regions do not have enough physicians to even provide primary health care. For example, the regions of Loreto, Puno and Cajamarca have only around 9 doctors per 10,000 inhabitants. In the case of nurses, Lima and Callao have 40.6% of the total, while four other regions have an additional 20.1%. In the case of midwives, Lima and Callao account for 36% of the total, and four additional regions account for another 22.8%.[98]

[95] Trade. Sunday August 6, 2023. EC Data.
[96] International Organization for Migration (2016). Statistics of international emigration of Peruvians and immigration of foreigners, 1990 – 2015. Available at:
https://peru.iom.int/sites/g/files/tmzbdl951/files/Documentos/211216EstEmigIntInm19902015.pdf .
[97]https://andina.pe/agencia/noticia-mil-medicos-emigran-cada-ano-busca-mejores-oportunidades-610849.aspx#:~:text=La%20raz%C3%B3n%2C%20agrega%2C%20es%20lograr,d%C3%B3lares%2C%20unos%20m%C3%A1s%20que%20otros.
[98] Calculated with data from INEI.

5.5. LOW REMUNERATION OF MEDICAL STAFF

In the public sector there is a marked asymmetry between health professionals and administrative staff, with a significantly high proportion between the second versus the first for all types and levels. The international reference suggests, for example, that there should be 5 administrative workers per physician, while in Peru in the public health sector there is one doctor for every two administrative workers.[99] Considering that the bulk of the budget of these entities is allocated to the payment of salaries, this situation does not allow health personnel to be adequately remunerated.

Currently, monthly salaries for doctors are in the range of US$ 1,200 to US$ 1,500, while for other health professionals between US$ 590 and US$ 740.[100] With all adjustments and bonuses, a doctor of the highest level and then, after many years of service, the best-case scenario can be a salary of US$ 2,280 per month. For comparison, we should mention that, according to the 2023 union agreement with employers, the salary and all extra bonuses for a top-level construction worker (i.e., operator) is currently US$ 850 per month.[101]

5.6. DEFICIENCIES IN THE INSTITUTIONAL FUNCTIONING OF THE PUBLIC HEALTH SECTOR

Another issue related to the low quality of the provision of health services is the need of improvement of training and updating of professional skills of health personnel, as well as the management of the public health sector. In relation to the latter, for years it is facing an institutional crisis, reflected in the instability at the higher levels of governance: 11 health ministers in 5 years and 8 Executive Presidents of ESSALUD in the last two years, which is usually associated with a high level of rotation of executive levels within these entities, many times with personnel not adequately specialized on which the post demands.

This institutional crisis has a very negative impact on the capacities of the public IPRESS to meet the health needs of the population. The sector has experienced, the weakening of some programs and the disappearance of some care units; excessive wait times for appointments and surgeries; shortage of medicines; corruption and delays in investment in infrastructure, among others. In this sense, private sector business associations have suggested changing the composition of the executive board of ESSALUD, giving control to those who finance it, companies and workers. To the extent that there are no significant improvements in the management of MINSA and ESSALUD, incorporating qualified personnel at all levels, it will be difficult to achieve the objectives of providing higher quality services and providing universal health coverage to a growing population.

[99] For more information, see: https://www.comexpru.org.pe/articulo/rumbo-al-bicentenario-recursos-humanos-de-salud

[100] For more information, see: https://www.gob.pe/institucion/minsa/noticias/33400-nueva-politica-remunerativa-reduce-brecha-salarial-del-sector-salud-en-todo-el-pais September 13, 2023. Others Professions include: Dental Surgeon, Pharmaceutical Chemist, Obstetrician, Nurse, Medical Technologist, Sanitary Engineer, Biologist, Psychologist, Nutritionist and Social Worker.

[101] For more information, see: https://www.ftccperu.com/images/TABLAS%20SALARIALES%20PDF/Table%20salarial%20%202023-2024.pdf

5.7. DEFICIENCIES IN THE QUALITY OF UNIVERSITY MEDICAL TRAINING

In 1996, the liberalization of higher education in Peru included incentives to create universities, in particular that there could be private for-profit universities. This produced an explosion in the creation of universities, whose number increased from 45 to 142 in 2014, the year in which a moratorium on the opening of new universities was established by law.

Even when many of the existing universities included medicine programs not guaranteeing a high standard of quality, approximately 3,500 doctors were joining the Peruvian Medical College each year - a necessary requirement to practice -. Contrary to what is required in many countries to practice medicine, where there is an additional filter to be authorized to practice medicine usually administered by the medical profession itself, the Medical Licensing Exam, in Peru the only requirement is the academic degree. In other words, medical practice is enabled only with the issuance of the university diploma, there being no incentive for subsequent medical upgrading or specialization for graduates.

In 2014, the new University Law and the creation of the Superintendence of Higher Education (SUNEDU) addressed these problems. Several universities were unable to become accredited under the new rules, with some being forced to close altogether or to close some of their faculties, including medicine. As of December 2022, of the 34 authorized universities offering programs in medicine, SUNEDU found that half needed to adjust improving their programs.[102] However, in July 2022 the university reform was reverted by a Law 31520 of Congress, weakening the power of SUNEDU to certify educational programs, with which there has been almost no incentive to improve the university training of physicians in Peru, with the consequent damage to the quality of health services.

As an illustration of the quality problems of medical training in Peru, a 2021 study showed that 42.8% of physicians who took the National Medicine Examination (ENAM), required to participate in the Serum, did not approve it. According to home university, 31.3% of graduates from public universities failed it, as well as 33.9% of graduates from private universities. Of the foreign graduates, 79% failed.[103]

In 2019, the Medical College of Peru tried to make ENAM approval mandatory for the practice of medicine. This initiative was appealed to the competition authority INDECOPI who, in Resolution 0555-2021/SEL-INDECOPI, established that "the requirement to prove having passed the ENAM with a minimum passing grade of eleven (11) for registration in the CMP Registration Registry constitutes a bureaucratic barrier requirement, since the CMP has exceeded its powers."[104] Consequently, doctors who could not pass the ENAM exam are practicing medicine in Peru.

In conclusion, much remains to be done to ensure that doctors in general are better able to treat the health of patients in Peru, providing quality medical care. This is an area in which foreign participation through agreements with Peruvian universities could make a useful contribution. Currently, there is a variety of modalities through which Peruvian and foreign higher-level educational institutions cooperate. These possibilities should be taken advantage of by

[102] SUNEDU (2022) https://www.gob.pe/institucion/sunedu/informes-publicaciones/2824150-iii-informe-bienal-sobre-la-realidad-universitaria-en-el-peru

[103] Gustavo Mendoza et.al. (2021), National Medicine Examination: Analysis of the last decade in theoretical evaluations in future doctors in Peru. Medical Act of Peru. The National Medical Examination (ENAM) is a written test of 200 multiple-choice questions, 30% of which are in general medicine, 15% in general surgery, 18% in pediatrics, 17% in gynecology and obstetrics, 10% in public health and management, and 10% in basic sciences.

[104] For more information, see: https://www.indecopi.gob.pe/documents/1902049/3897051/Resoluci%C3%B3n%20N%C2%B0%200555-2021-SEL-INDECOPI

universities and other European health care institutions with the capabilities to contribute to the improvement of the training of human resources in the health sector in Peru.

CHAPTER 6

THE MARKET FOR MEDICINES AND MEDICAL DEVICES

As is the case in almost all countries in the world, these two markets are highly regulated to ensure the health of the population. This section first presents the most notable characteristics of the pharmaceutical products and medical devices market in Peru, and then analyses the most important current regulations regarding market access and its operation.

The pharmaceutical market in Peru has potential for increasing in the near future, because despite the growth in current health spending, Peru has a modest per capita sales volume of medicines compared to other countries in the region. Similarly, in the medical devices market there are potential commercial opportunities, the realization of which requires scheduled public investments to improve existing hospitals and build new ones. However, there are some de facto institutional barriers to access, on the part of the State, that require specific public policy actions.

6.1. DRUG MARKET

The total pharmaceutical products market in Peru in 2021 represented a business close to US$ 4.3 billion, in which national and foreign laboratories operating in Peru participate, as well as imports from various countries. This includes not only medications but also other products supplied by laboratories, such as cosmetics, natural-based products, health products, infant formulas, among others. In the case of medicines, there is no chemical-pharmaceutical industry in Peru, so national production depends entirely on imports of **active pharmaceutical ingredients** (APIs), which are combined with excipients to prepare the medicine formulation, which is then converted into finished doses in different forms.

Market size

Table 12 presents the behaviour of the composition of the total supply of pharmaceutical products in the Peruvian market in the last decade, where national production is recorded at *ex-factory prices* and imports at CIF prices. The other components of the value chain were calculated by the INEI to obtain the total value of the offer.

The total market for pharmaceutical products has been increasing constantly, having had an accumulated growth since 2015 of 42.6%, and some important developments in this market can be derived from the data. Firstly, the growing dependence on imports, having raised its penetration rate (IPR) between 2011 and 2021 from 37.4% to 62.6%.[105]

[105] The IPR is estimated by determining the size of the local market, which is the national production plus imports minus exports, and then the total market imports.

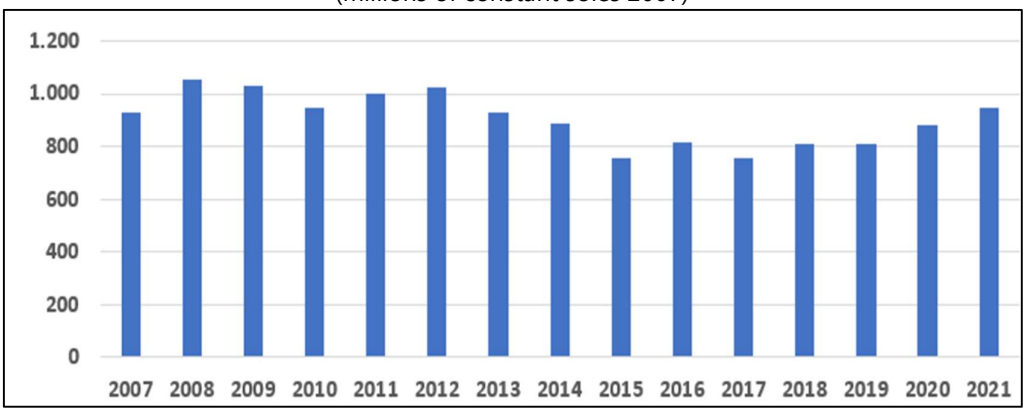
Table 12
The Peruvian pharmaceutical products market 2011-2021
(millions of soles and current US$)

	Domestic output		Imports		Tariff revenue		Commercial margin		VAT		Total supply	
	Soles	US$	Soles	US$	Soles	US$	Soles	US$	Soles	US$	Soles	US$
2011	3,038	1,105	1,747	635	54	20	2,686	977	957	348	8,491	3,088
2015	2,473	778	2,804	882	59	19	3,152	991	1,036	326	9,533	2,998
2016	2,718	807	2,849	845	60	18	3,516	1,043	1,081	321	10,234	3,037
2017	2,572	789	2,770	850	50	15	3,875	1,189	1,112	341	10,388	3,187
2018	2,751	839	3,225	983	51	16	4,108	1,252	1,226	384	11,370	3,466
2019	2,805	842	3,500	1,051	54	16	4,348	1,306	1,300	390	12,017	3,609
2020	3,043	867	4,090	1,165	14	4	4,757	1,355	1,449	413	13,364	3,807
2021	3,359	866	5,043	1,279	5	1	6,162	1,588	2,011	518	16,600	4,278

Source: INEI

These imports have been growing at a faster rate than national production, although this latter has shown a medium-term stagnation in real values(see Chart 10) and also exhibiting one of the lowest shares of national production from national laboratories in the total supply of medicines compared to other Latin American countries.[106] This has been the result of national laboratories leaving the market and the substitution of production by foreigners operating in Peru with imports from their central offices or subsidiaries in other countries. The increase in national production between 2020 and 2021 was exceptional, due to the demand generated by the COVID-19 pandemic.

Chart 10
Peru: Production of medicines and other pharmaceutical products
Gross domestic product
(millions of constant soles 2007)



Source: INEI.

[106] ECLAC (2021). Plan for self-sufficiency in health in Latin America and the Caribbean: lines of action and proposals. United Nations publication LC/TS.2021/115. Table 1.9. Available at: https://repositorio.cepal.org/server/api/core/bitstreams/5cb1c096-0162-4fd9-b620-d463cd14f9f8/content

Another notable aspect has been the growing participation of distributors and retailers in market value. In 2011, these agents appropriated 31.6% of that value, reaching 37.1% in 2021 (see in Table 12), a result of the transformation at the retail level, in which the degree of market concentration, and therefore power, of these market participants has increased. Finally, there has been a decrease over time in customs duties as a component of the supply value of pharmaceutical products. In 2021, customs duties collected on the value of imports of pharmaceutical products were 1%, as a result of the progressive tariff reductions of the free trade agreements signed by Peru and the temporary unilateral reductions in the pandemic years.

The laboratories established in the country sell medicines to the public sector, clinics and private pharmacies, and are not authorized to make retail sales. In the pharmacy market, prices are determined by the market,[107] while purchases of medicines by the public sector (e.g., MINSA and ESSALUD) are governed by general rules on public procurement.[108] In the case of the network of health centres linked to MINSA and sub-national governments, it is planned that purchases will be made by the National Centre for the Supply of Strategic Health Resources (CENARES) and, in the case of ESSALUD, through of the Central Supply of Essential Goods (CEABE). However, even with these specialized entities existing, the individual IPRESS carry out an important part of their own purchasing processes, often due to the fact that the contracting processes for purchasing medicines fall apart due to challenges to awards, defective market studies or corruption.

Purchases of medicines by the public sector linked to the MINSA are made on the basis of the *Single National* Request for Essential Medicines (PNUME),[109] determining the products that must be available in all public IPRESS, which is updated every two years.[110] PNUME has a total of 796 medicines contained in 32 therapy groups. Meanwhile, in ESSALUD, is the Institute for Health Technology Evaluation and Research (IETSI) that determines its request, which contains more medications than PNUME of the MINSA.[111]

Table 13 presents the sales of laboratory medicines in the Peruvian market for the period 2018-2022, including those from national production and imports, as reported by IMS Salud, [112] These sales can be considered at the ex-factory price, since it does not consider the other components of the market value. The table also includes the estimated market size for those years.

[107] In general, price controls are constitutionally prohibited.
[108] See the Public Procurement Fact Card. MAT Tean. EU Delegation.
[109] UNEP consists of a fraction of the World Health Organization's list of essential medicines.
[110] On July 5, 2023, Ministerial Resolution No. 633-2023/MINSA was published in the Official Gazette *El Peruano*, approving the Technical Document: Single National Application for Essential Medicines for the Health Sector.
[111] Both requests are insufficient because they are guided by a criterion of greater frequency of diseases at the national level, not taking into account the specialties of certain hospitals that are left short of supplies to care for diseases in which they have specialized. There are also Ministerial Resolutions that have established lists of essential medicines for certain diseases, such as cancer, malaria, tuberculosis and HIV-AIDS.
[112] IMS Health (2022). Peru: Pharmaceutical Market. Executive Summary. This was kindly provided by an AFAFARPE member laboratory.

Table 13
Peru: Medicines market size 2018-2022
(millions of soles and current US$)

	2018	2019	2020	2021	2022
Laboratory drug sales	1,133.7	1,106.8	1,165.4	1,196.4	1,190.8
Market size estimation	1,668.4	1,632.9	1,704.4	1,787.2	1,781.2

Source: IMS Health.

The estimation of the size of the medicines market was made based on the share of national production and imports in the total market value, according to the data presented in Table 12, where import duties have not been considered since they are reflected in the laboratory price. Taking into account that purchases of medicines by the public sector do not generate a commercial margin, since in most cases they are distributed free of charge to patients, our exercise would slightly overestimate the size of the total market. Considering that in 2022 the medicines market in Peru would have reached US$ 1,780 million, the medicines market would have represented 41.6% of the country's total pharmaceutical products market that year. ALAFARPE has a higher estimate of the medicines market, with US$ 1,970 million.[113]

As of June 2023, the composition of the Peruvian pharmaceutical market is as follows:

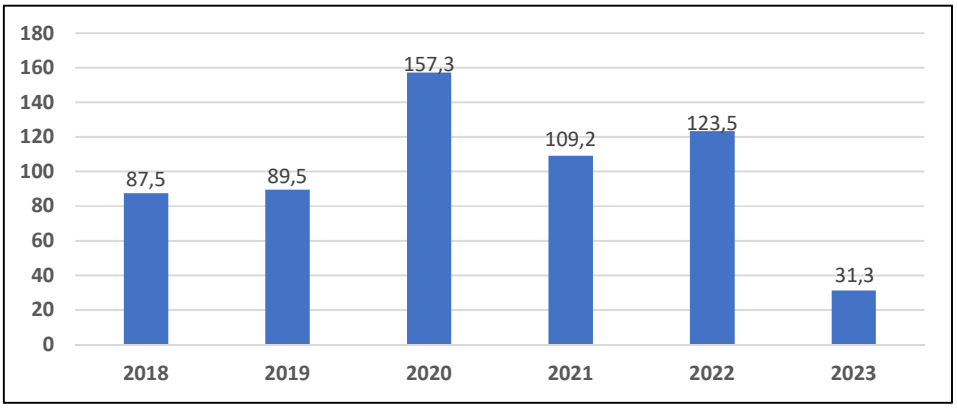
- There are 121 laboratories registered, authorized and certified in DIGEMID to market medicines. Of this total, 54 are registered as nationals and 67 are foreigners.[114] It is worth mentioning that not all laboratories sell medicines, as some are specialized in other types of pharmaceutical products, such as veterinary products or cosmetics.
- There are 4,915 wholesalers (drugstores), which import products or distribute products from laboratories operating in the country.
- There are 28,133 retail pharmacies, independent or part of a chain, and 868 pharmacies nested in private clinics. Although pharmacy chains represent only 14% of total establishments, they constitute 77.8% of total sales, which has raised concerns about competition in the market. Pharmacy sales amounted to US$ 1,416 million, US$ 1,472 million and US$ 1,312 million respectively in 2020, 2021 and 2022.[115] The difference between the sales of private pharmacies and the total market size estimated in Table 12 would indicate the magnitude of medication purchases by the public health system to provide its services.

Information on the proportion of pharmacy sales out of total sales of medicines indicates that around 80% were purchases directly by households out of pocket. It is worth mentioning that the bulk of out-of-pocket medication purchases are made by people covered by the SIS and ESSALUD, who are forced to buy medications since the IPRESS does not provide them as it should, due to shortages in the MINSA or in ESSALUD, or to restrictions on the content of their respective requests. In 2022, only 37% of the IPRESS of the MINSA and ESSALUD network at the national level had more than 80% availability of PNUME medicines.[116]

[113] Interview with Ángela Flores Executive Director of ALAFARPE. Management, November 16, 2023. p. 11.
[114] For more information, see: https://www.digemid.minsa.gob.pe/webDigemid/establecimientos/
[115] DIGEMID (2023). Bulletin of Pharmaceutical Establishments, Year 3, Edition 5. June. The data has been converted to US dollars using the average exchange rate for the year.
[116] COMEX (2022). Current situation of the Peruvian health market. Available in:
https://www.comexperu.org.pe/upload/articles/publicaciones/situacion-actual-del-mercado-de-salud-peruano-informe.pdf

The MINSA budget for medicines for the period 2018-June 2023 has been quite variable, falling to only US$ 31 million in 2023 (see Chart 11) This contrast to ESSALUD's budget with around US$ 330 million for medicine purchases in 2023.[117] In spite the fact that not all the budget is expended during the year, this data allows an approximation to the size of the government procurement market of medicines.

Chart 11
MINSA Budget for Medicines 2018-2023
(million US$)



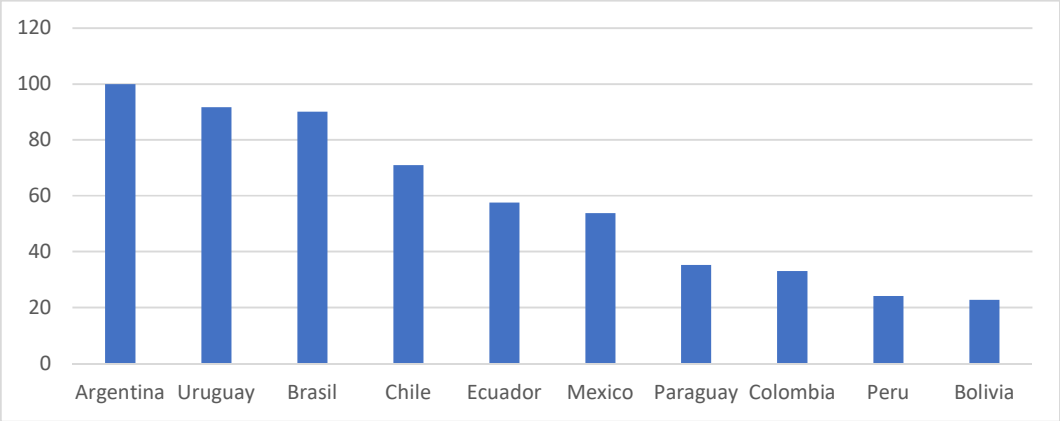
Source: Economic Transparency of the Ministry of Economy and Finance, accrued budget of the MINSA. Published by The Republic. Tuesday, June 20, 2023.p. 13.. The data has been converted to US dollars using the average exchange rate for the year.

The Peruvian medicines market could offer interesting potential in the future, since per capita spending on medicines is one of the lowest in South America, according an index of annual expenditure on medicines in selected countries in the region in comparative terms[118], where the. This means, for example, that in Argentina per capita spending on medicines is slightly higher than four times that of Peru.

[117] This information is from an ESSALUD press release available at http://noticias.essalud.gob.pe/?inno-noticia=essalud-destina-cerca-de-s-3000-millones-en-medicamentos-y-equipamiento -medico-para-el-2023 . Published on 04/04/2023. ESSALUD does not detail drug purchases in the budget. It is added under purchase of goods and supplies. The information available indicates that he dedicates around 10% of his budget to the purchase of medicines. Thus, in 2022 it would have been around $290 million. However, not all of the budget is used every year. ESSALUD budgets can be consulted at: http://www.essalud.gob.pe/transparencia/pdf/presupuesto/Ejecucion_presupuestal_de_ingresos_gastos_noviembre_2022.pdf

[118] The country with the highest per capita spending is 100.

Chart 12
Per capita spending on medicines: Latin American countries



Source: Institute of Studies and Training (2022) Medicalization of life: a profitable strategy of the pharmaceutical industry, Dec 3. Available at: https://iefctaa.org/medicalizacion-de-la-vida-una-estrategia-rentistica-de-la-industria-farmaceutica/

Pharmaceutical products are classified in Peru into four classes:

a. **Special numbered prescription**. They can only be dispensed in public or private pharmacies that meet the requirements established in the corresponding legal regulations;
b. **Sold with a doctor's prescription**. They can only be dispensed in pharmacies;
c. **Free sale**. They are dispensed exclusively in public and private sector pharmacies, and
d. **Low risk**. Those that can be sold in any commercial establishment.[119]

Table 14 presents data on sales by laboratories of prescription and non-prescription drugs, both in value and number of units, showing that prescription drugs represent almost 70% of the drugs sold by laboratories in terms of value and units.

Table 14
Peru: Laboratories Drug Sales by Class 2018-2022
(millions of soles and units)

	2018	2019	2020	2021	2022
Valor					
Total	1,133.7	1,106.8	1,165.4	1,196.4	1,190.8
Prescription drugs	829.6	805.0	811.6	830.7	814.8
Over the counter	304.2	301.8	353.8	365.7	376.0
Unidades					
Total	180.9	183.6	200.9	221.8	215.9
Prescription drugs	131.6	133.5	142.5	158.4	149.4
Over the counter	49.3	50.2	58.3	63.4	66.5

Source: IMS Health.

Another important classification of medicines is that which differentiates between those protected by patents and those whose formula is in the public domain: a) innovative products, protected by patent; b) generic products that can be sold under the International Non-proprietary Denomination (INN), and c) branded generic products.

[119] Regulations for the Registration, Control and Health Surveillance of Pharmaceutical Products, Medical Devices and Health Products, Supreme Decree 016-2011/SA.

Generics are those that are manufactured after the patent expiration of innovative products. However, according to Supreme Decree 024-2018-SA, which regulates the interchangeability of medicines for the purposes of the health registration of generic medicines, before producing and marketing them, the manufacturer must demonstrate therapeutic equivalence with the original reference medicine.[120] However, due to the lack of sufficient specialized laboratories, the relatively high cost of carrying out such studies, the resistance of laboratories that produce generics, and the reduced diligence of DIGEMID, very few products are traded as generics on the market..

However, as there is interest in promoting the sale of generic medications, Supreme Decree No. 026-2019-SA is in force, which orders, under penalty of sanction, that all pharmacies in the country, including those located within clinics, must have a list of 34 priority generic medications available for sale to the public and physicians are also instructed to inform their patients about generic alternatives. On the demand side, the share of generics has been growing in the Peruvian market; however, the Peruvian population is very suspicious about the quality of generic medications, and their acceptance is still low.[121]

As for laboratory unions, in Peru they are associated with three main ones: a) The *Association of National Pharmaceutical Industries* (ADIFAN), which brings together 8 national laboratories;[122] b) the *National Association of Pharmaceutical Laboratories* (ALAFARPE), composed mainly of foreign innovation laboratories, with 23 members, and c) the *Association of Latin American Pharmaceutical Laboratories* (ALAFAL), with 9 Latin American laboratories. According to IMS, in 2022, of the 121 laboratories operating in Peru, registered by DIGEMID and authorized to sell medicines, 70 represented 92.5% of total medicine sales; the 10 largest laboratories by sales account for 40.5% of the total, and 41 laboratories only 7.4%, each of the latter with low sales volume. Table 15 presents the sales of these laboratories for 2021 and 2022.

Although the market appears to be quite competitive, the degree of concentration in the market must be carefully evaluated, as there are independent submarkets, grouped according to the therapeutic characteristics of the drugs, in which the degree of concentration is generally high.

Table 15
Main laboratories in the Peruvian medicine market
(Sales in thousands of US$)

Laboratory	2021	2022	%	Laboratory	2021	2022	%	Laboratory	2021	2022	%
ABBOTT	104,412	**90,747**	7.62	**GRUNENTHA L**	19,493	**14,095**	1.18	**VIDASOL**	6,724	**6,624**	0.56
MEDIFARMA	81,902	**85,615**	7.19	**BONAPHARM**	10,971	**14,019**	1.18	**QUILAB**	5,956	**6,546**	0.55
MERCK CH	44,743	**43,940**	3.69	**ABBOTT CH**	11,617	**13,573**	1.14	**DEUTSCHE PHARMA**	6,599	**6,245**	0.52
TECHNOPHARMA	35,387	**41,220**	3.46	**PROCTER & GAMBLE**	11,722	**12,886**	1.08	**CIPA**	7,020	**6,151**	0.52

[120] Two medicines are considered bio-equivalent if they contain the same amount of the same active ingredient, in the same pharmaceutical form and have the same bioavailability: they do not present significant differences in the amount and rate of absorption of the same active ingredient, when administered in the same dose. and under similar experimental conditions.
[121] Guillermo G Mendoza- Chuctaya (2019). Perception of the population regarding generic medications versus branded medications in hospitals in Peru. Journal of Public Health 35 (10). Available in:
https://www.scielo.br/j/csp/a/7RqxcKJhYjTGKHfX8xSVykv/?lang=es#
[122] Membership in ADIFAN has been decreasing significantly. At its peak it had 25 members.

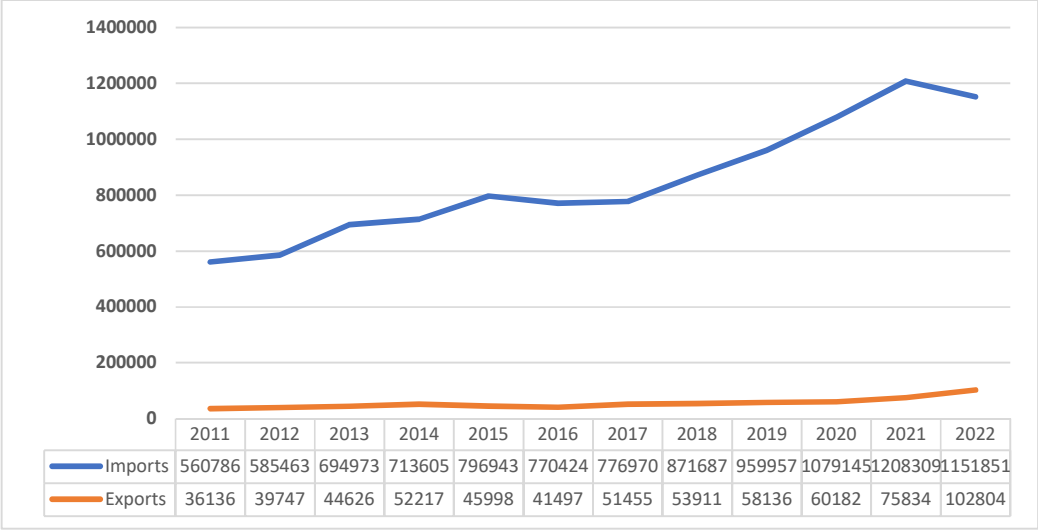
MEGALABS	40,323	**41,133**	3.45	**AC FARM**	11,795	**12,595**	1.06	**ABBOTT C&E**	6,567	**6,063**	0.51
RECKITT BENCK-ISER	38,693	**39,124**	3.29	**PH BAYER**	15,899	**12,535**	1.05	**ABBOTT DERMA**	5,174	**5,838**	0.49
ABBOTT P&G	40,420	**38,677**	3.25	**SIEGFRIED**	12,552	**12,324**	1.03	**PHARMACIST**	9,292	**5,778**	0.49
HERSIL	32,793	**34,942**	2.93	**FARMA-KONSUMA**	13,026	**12,035**	1.01	**SOL PHARMA**	6,788	**5,697**	0.48
GSK CONSUMER HEALTH	28,740	**33,995**	2.85	**FRAMES**	10,534	**11,756**	0.99	**SAVAL**	5,573	**5,667**	0.48
BAGO	31,724	**33,135**	2.78	**NOVARTIS**	12,098	**11,286**	0.95	**KEY FARM**	6,750	**5,318**	0.45
YOU GO	39,554	**31,728**	2.66	**ABBOTT NEURO**	10,624	**10,452**	0.88	**ORDESA**	4,236	**4,617**	0.39
IQ PHARMA	24,516	**27,820**	2.34	**MERCK SHARP DOHME**	9,983	**9,746**	0.82	**GARDEN HOUSE**	4,001	**4,197**	0.35
BAYER CH	24,593	**21,405**	1.80	**SOFIA**	10,655	**9,739**	0.82	**LIST**	4,027	**4,126**	0.35
GENOMMA	17,803	**19,970**	1.68	**ELIFARMA**	6,099	**9,733**	0.82	**BEIERSDORF**	2,419	**4,026**	0.34
EUROPHARM	19,780	**19,168**	1.61	**SANULAC**	9,174	**9,545**	0.80	**ITALFARMACO**	2,869	**3,505**	0.29
GLAX-OSMITHKLINE	14,871	**17,394**	1.46	**ABBOTT RC**	8,990	**8,256**	0.69	**ISDIN**	2,415	**3,498**	0.29
BE PROTECTED	16,163	**17,241**	1.45	**LANSIER**	8,812	**8,233**	0.69	**SHERPHARMA**	3,887	**3,448**	0.29
BOEHRINGER ING	14,902	**16,601**	1.39	**ORGAN**	9,152	**8,213**	0.69	**ALLERGAN**	3,076	**3,443**	0.29
ABBOTT WH	14,272	**16,542**	1.39	**PORTUGAL**	9,121	**8,022**	0.67	**VIFOR**	3,839	**3,369**	0.28
GENFAR	14,531	**16,162**	1.36	**CAFERMA**	5,938	**7,972**	0.67	**ALCON**	2,863	**3,292**	0.28
SANOFI PHAR-MACY	16,595	**16,051**	1.35	**LUKOLL**	10,190	**7,932**	0.67	**GALDERMA**	3,291	**3,222**	0.27
UNIMED	14,580	**15,728**	1.32	**PFIZER**	9,548	**7,649**	0.64	**REST**	90,492	**88,682**	7.44
SANOFI CHC	15,819	**15,061**	1.26	**ASTRAZENECA**	7,551	**7,346**	0.62				
MERCK BIO-PHARMA	15,131	**14,318**	1.20	**DCI-CA**	7,680	**7,056**	0.59				

Foreign trade in medicines

As mentioned above, the Peruvian market for medicines and other pharmaceutical products shows a growing dependence on imports, which have grown at an average annual rate of 6.7% since 2011. These products are contained in Chapter 30 of the Harmonized System (SA) on pharmaceutical products. Not all products in this chapter are strictly medicines, since it also includes some products used in the treatment of diseases (e.g. hydrophilic cotton, bandages,

gauze, reagents, sterile adhesives, etc., headings 3005 and 3006). However, all these products are also subject to strict regulatory controls. Chart 13 presents a longer-term view of Peruvian exports and imports of medicines.

Chart 13
Peru: Medicine trade
(Million US$)



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Imports	560786	585463	694973	713605	796943	770424	776970	871687	959957	1079145	1208309	1151851
Exports	36136	39747	44626	52217	45998	41497	51455	53911	58136	60182	75834	102804

Source: ITC Trade Map.

Table 16 shows that these imports are concentrated in heading 3002 (human blood, immunological products, vaccines, toxins, among others, 34% of total imports) and 3004 (miscellaneous medicines consisting of mixed or unmixed products, 58 .8%). Table 17 presents more disaggregated import data at the HS six-digit level, allowing for a better examination of the dynamics of Peruvian medicines imports.

Table 16
Peru: Imports of Medicines 2018-2022
(Million US$)

Tariff lines		2018	2019	2020	2012	2022
3001	Glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included.	6.0	4.9	4.0	5.9	4.5
3002	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immunological products, whether or not obtained by biotechnological processes; vaccines, toxins, cultures of microorganisms (except yeasts) and similar products.	273.8	317.8	355.3	445.5	391.5
3003	Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale.	5.2	5.3	7.8	8.2	5.2
3004	Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (whether or not in the form of transdermal delivery systems) or in forms or packings for retail sale.	530.5	574.0	669.3	689.0	677.4
3005	Wadding, gauze, bandages and similar articles (e.g. dressings, dressings, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.	12.3	17.4	13.7	19.7	25.6
3006	Pharmaceutical products specified in Note 4 to this Chapter.	43.8	40.6	29.1	40.2	47.7
Total		**871.7**	**960.0**	**1079.1**	**1208.3**	**1151.9**

Source. ITC trade map.

Table 17
Imports of medicines by main tariff items 2018-2022
(Thousand US$, 6 digits)

Código SA del producto	Descripción	2018	2019	2020	2021	2022
300490	Medicines consisting of mixed or unmixed products for therapeutic or prophylactic purposes, ...	384.6	411.8	469.1	495.9	500.9
300241	Vaccines for human medicine	0.0	0.0	0.0	0.0	201.5
300215	Immunological products, in measured dosage forms or in forms or packings for retail sale ...	82.7	78.1	134.1	124.4	90.9
300420	Antibiotic-containing medicaments, dosed "including those for transdermal administration" ...	49.7	54.2	72.3	65.7	54.5
300450	Medicines containing provitamins, vitamins, incl. natural concentrates and their derivatives	27.9	38.1	53.1	58.3	43.3
300242	Vaccines for veterinary medicine	0.0	0.0	0.0	0.0	38.1
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics, presented in ...	23.0	26.7	26.1	24.6	33.9
300212	Antisera and other blood fractions.	24.4	31.5	19.5	24.0	29.1
300290	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses.	24.8	23.5	50.1	35.7	23.6
300660	Chemical contraceptive preparations based on hormones, prostaglandins, thromboxanes, leukotrienes, ...	20.7	16.3	14.1	20.8	20.4
300590	Wadding, gauze, bandages and similar, e.g. dressings, plasters, poultices, impregnated ...	6.1	9.4	6.7	10.0	14.8
300432	Medicines containing corticosteroid hormones, their derivatives or structural analogues ...	12.8	11.4	14.0	13.1	14.3
300410	Medicines containing penicillin or derivatives thereof with penicillanic acid structure, ...	16.9	14.0	17.5	14.5	12.5
300431	Medicines containing insulin, but not antibiotics, dosed ...	9.0	10.9	10.7	8.7	11.9
300510	Adhesive dressings and other articles having an adhesive layer, impregnated or coated with ...	6.2	8.0	7.0	9.6	10.9
300640	Dental cements and other dental fillings; bone reconstruction cements	6.7	6.7	3.8	7.0	8.4
300630	Opacifying preparations for radiological examinations; diagnostic reagents for administration to patients	9.3	11.3	5.8	5.6	7.8
300249	Toxins, cultures of microorganisms and similar products, e.g. plasmodia (excl. yeasts and ...	0.0	0.0	0.0	0.0	7.4
300190	Glands and other organs for organotherapeutic uses, dried, whether or not powdered; heparin ...	5.8	4.9	4.0	5.8	4.4
300449	Drugs containing alkaloids or their derivatives, not containing hormones, steroids ...	3.6	4.2	3.1	3.7	3.1
300390	Medicaments consisting of two or more components mixed together for therapeutic or prophylactic purposes ...	3.2	2.4	6.4	5.0	3.0
300693	Blinded or double-blinded clinical trial placebos and kits for a recognized clinical trial, ...	0.0	0.0	0.0	0.0	2.9
300670	Gel preparations designed to be used in human or veterinary medicine as a lubricant for parts ...	2.2	1.8	1.4	1.3	2.8
300610	Sterile surgical catgut and similar sterile suture materials ...	1.8	1.6	1.1	1.7	2.7
300691	Identifiable devices for ostomy use	2.1	1.6	1.9	2.7	2.6
300442	Medicines containing pseudoephedrine "INN" or its salts, which do not contain hormones, steroids ...	1.6	2.2	2.9	3.8	2.6
300320	Drugs containing antibiotics, not in dosage form or in forms or packings for retail sale ...	1.3	1.5	1.0	2.7	1.3
300310	Medicaments containing penicillins or derivatives thereof with penicillanic acid structure, ...	0.5	1.1	0.4	0.4	0.8
300214	Immunological products, mixed, unmixed, not put up in measured doses or in forms or packings for retail sale ...	1.6	1.7	2.0	1.8	0.4
300213	Immunological products, unmixed, undosed or in forms or packings for retail sale ...	1.9	1.5	1.3	0.7	0.4
300441	Medicines containing ephedrine or its salts, not containing hormones, steroids used as hormones ...	1.3	0.5	0.3	0.5	0.2
300339	Medicines containing hormones or steroids used as hormones, not containing antibiotics, not containing ...	0.0	0.4	0.0	0.0	0.2
300650	First aid kits and first aid kits.	0.0	0.0	0.1	0.1	0.1
300460	Medicines containing any of the following antimalarial active ingredients: artemisinin "INN" ...	0.1	0.0	0.0	0.1	0.1
300259	Cell cultures, whether or not modified (excl. cell therapy products).	0.0	0.0	0.0	0.0	0.1
300120	Extracts of glands or other organs or their secretions, for organotherapeutic uses	0.2	0.0	0.0	0.1	0.1
300349	Medicaments containing alkaloids or their derivatives, not containing hormones, steroids ...	0.0	0.0	0.0	0.0	0.0
300211	Malaria diagnostic test kits	0.3	0.4	0.5	0.5	0.0
300219	Immunological products, nep.	6.4	5.2	8.6	8.6	0.0
300220	Vaccines for human medicine	96.2	138.2	106.4	211.6	0.0
300230	Vaccines for veterinary medicine	35.6	37.7	32.7	38.3	0.0
300342	Medicines containing pseudoephedrine "INN" or its salts ...	0.1	0.0	0.0	0.0	0.0
300620	Reagents for determining blood groups or blood factors.	1.1	1.2	0.9	1.1	0.0
Total		**871.7**	**960.0**	**1,079.1**	**1,208.3**	**1,151.8**

Source: SUNAT.

During the period 2018-2022, Peru imported medicines from 114 different countries, which would be an indicator that there are no significant barriers to entry into the Peruvian market. Taking those 2022 imports above US$ million in the year, it is observed that the 10 main exporters represented 70% of total imports in said year (see Table 18). However, the composition of the main exporters varies according to the type of medicine, which indicates a certain specialization of the country in certain products. For example, in heading 3003, **medicines consisting of products mixed together, prepared for therapeutic or prophylactic uses, not dosed or put up for retail sale**, the two main exporters are China and India, which represent 65 % of total Peruvian imports. In addition, there are differences in the type of product exported by countries, since some countries export mainly generics, such as China and India, while other countries, such as the US or Germany, have a greater participation in innovative products.

Table 18
Peru: Main medicine exporting countries - 2018-2022
(Million US$)

Countries	2018	2019	2020	2021	2022
United States	140.6	178.0	121.4	215.3	170.6
India	63.7	85.1	139.3	120.2	109.1
Germany	77.9	90.5	89.7	111.4	102.0
China	47.4	47.2	102.3	80.1	75.1
Mexico	49.4	58.0	69.0	80.6	71.1
Spain	21.3	22.1	21.5	28.2	60.2
Belgium	37.1	19.0	44.8	52.6	59.5
Colombia	55.7	54.2	57.1	57.1	59.3
Argentina	37.1	35.8	29.9	46.0	53.3
France	45.2	48.0	52.8	46.5	40.1
South Korea	28.2	41.7	51.3	52.4	38.2
Brazil	35.9	39.0	35.9	43.6	36.1
Switzerland	26.1	27.1	30.4	28.7	31.4
Italy	18.3	21.8	25.3	31.1	26.8
Ireland	24.3	20.7	25.8	21.0	24.0
Austria	13.6	19.2	19.1	17.4	21.3
Chile	23.9	20.6	14.9	19.5	20.9
Panama	5.9	7.8	11.2	13.5	15.0
The Netherlands	11.4	11.5	12.6	15.0	14.0
Paraguay	7.9	8.8	11.1	12.5	13.8
United Kingdom	12.4	13.2	15.6	14.3	13.6
Uruguay	10.8	16.7	16.0	15.0	13.0
Sweden	11.2	11.8	10.5	14.1	13.0
Denmark	10.1	9.6	8.7	8.7	12.7
Rest	56.3	52.6	62.9	63.7	57.9
World	871.7	960.0	1,079.1	1,208.3	1,151.9

Source. ITC trade map.

EU exports to Peru during the period 2018-2022 have grown by 37.4%, while those of the rest of the countries have grown by 29.6%. Despite the incursion of highly competitive countries such as China and India, the EU has been able to maintain its position in the market. Peruvian imports of medicinal products from member countries of the EU represent around a third of

total imports (see Table 19), which comes from almost all EU countries. However, more than US$ 10 million annually come from 10 of them, being Germany both Peru's main import source, with an average of 28.9% share between 2018 and 2022, and also the main one from the world in the same period (8.9%). On average, the top 5 country exporters represent over 73% of total imports of pharmaceutical products from the EU to Peru between 2018 and 2022.

Table 19
Peru: EU medicine exporting countries - 2018-2022
(Million US$)

Countries	2018	2019	2020	2021	2022
Germany	77.9	90.5	89.7	111.4	102.0
Spain	21.3	22.1	21.5	28.2	60.2
Belgium	37.1	19.0	44.8	52.6	59.5
France	45.2	48.0	52.8	46.5	40.1
Italy	18.3	21.8	25.3	31.1	26.8
Ireland	24.3	20.7	25.8	21.0	24.0
Austria	13.6	19.2	19.1	17.4	21.3
The Netherlands	11.4	11.5	12.6	15.0	14.0
Sweden	11.2	11.8	10.5	14.1	13.0
Denmark	10.1	9.6	8.7	8.7	12.7
Hungary	3.7	3.0	3.6	3.1	4.3
Portugal	3.4	3.0	4.4	6.0	4.2
Finland	1.5	0.7	0.5	1.1	1.9
Poland	1.1	1.0	0.6	1.6	0.8
Greece	0.5	0.5	0.3	0.6	0.7
Czech Republic	0.5	0.3	0.3	0.5	0.4
Romania	0.1	0.1	0.2	0.2	0.3
Croatia	0.0	0.1	0.1	0.3	0.3
Slovenia	0.2	0.1	0.2	0.2	0.2
Bulgaria	0.2	0.3	0.4	0.1	0.2
Cyprus	0.0	0.0	0.0	0.0	0.1
Malta	0.0	0.1	0.0	0.2	0.1
Lithuania	0.0	0.0	0.0	0.0	0.0
Luxembourg	0.0	0.0	0.4	0.0	0.0
Slovakia	0.0	0.0	0.0	0.0	0.0
Total EU	**281.6**	**283.3**	**321.8**	**359.9**	**386.8**
%of total imports	32.3%	29.5%	29.8%	29.8%	33.6%
World	**871.7**	**960.0**	**1,079.1**	**1,208.3**	**1,151.9**

Source. ITC trade map.

On the side of exports of medicines, Peru is not a larger one. However, during the last five years exports have almost doubled, showing growing dynamism in this area (see Table 20). Most exports correspond to medicines under tariff line 3004, which are the ones composed of mixed or unmixed products for therapeutic or prophylactic purposes, presented in measured doses or in forms or containers for retail sale. Peruvian exports are mainly destined for the regional market, representing the countries of the Andean Community and Chile 62.2% of all medicine exports in 2022, going the rest to other Latin American countries.

Table 20
Peru: Exports of medicines to the world: 2018-2022
(Thousand US$)

Code HS	Description	2018	2019	2020	2021	2022
3001	Glands and other organs for organotherapy, dried, whether or not powdered; extracts ...	0.1	0.1	0.0	0.0	0.1
3003	Medicaments consisting of two or more components mixed together for therapeutic or prophylactic purposes ...	0.4	0.2	0.2	0.1	0.2
3005	Wadding, gauze, bandages and similar, e.g. dressings, plasters, poultices, impregnated ...	0.8	0.7	0.8	1.1	1.8
3006	Pharmaceutical preparations and products of subheadings 3006.10.10 to 3006.93.00.	8.2	8.2	7.7	9.0	11.2
3002	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera ...	2.3	4.0	5.3	2.4	20.2
3004	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses....	42.1	45.0	46.2	63.3	69.3
	Total	**53.9**	**58.1**	**60.2**	**75.8**	**102.8**

Source: SUNAT.

6.2. MEDICAL DEVICES

National legislation establishes that the term *medical device* includes any instrument, apparatus, implement, machine, in vitro reagent or calibrator, computer application, material or other similar or related article, intended by the manufacturer for use on human beings, alone or in combination, for health treatment purposes.[123] Therefore, a wide variety of products qualify as medical devices. These products come from multiple economic activities, so it is not possible to estimate the total size of the market. However, it can be said that the national production of medical devices is quite limited, since Peru depends largely on imports.[124] This is mainly limited to medical furniture and a few other products such as safety masks and mechanical oxygen ventilators in the country, the latter encouraged by the COVID-19 pandemic.

To the extent that investment in the health sector increases, according to the plans for the construction and equipment of new and modernized hospitals, this market would become more dynamic. Regarding imports, during the period 2018-2022 this has shown a certain tendency to grow (see Table 21). On average over those 5 years, 74.6% of imports of medical devices have been linked to items 9018 of instruments and devices for medicine, surgery and dentistry (53.6%); 9021 of orthopaedic devices, surgical belts and trusses (10.2%), and 9022 of devices based on the use of X-rays or alpha, beta, gamma or other ionizing radiation (10.8%).

[123] Article 3 of Law 29459 – Law on Pharmaceutical Products, Medical Devices and Medical Devices.
[124] ICEX (2022). THE MEDICAL EQUIPMENT AND MATERIAL MARKET IN PERU. Available at: https://www.icex.es/content/dam/es/icex/oficinas/065/documentos/2022/12/estudios-mercado/Resumen%20Ejecutivo.%20El%20mercado%20del%20equipamiento%20y% 20material%20m%C3%A9dico%20en%20Per%C3%BA%202022.pdf

Table 21
Peru: Imports of medical devices: 2018-2022
(Million US$)

Code HS	Description	2018	2019	2020	2021	2022
9018	Instruments and appliances for medical, surgical, dental or veterinary purposes,...	219.2	231.7	264.8	282.1	307.2
9021	Orthopedic appliances, incl. crutches, surgical belts and trusses; splints and other fracture ...	51.1	51.4	35.9	48.3	62.9
9022	Apparatus based on the use of X-rays or alpha, beta, gamma or other ionizing radiations, ...	32.9	47.0	54.1	66.9	62.7
9030	Oscilloscopes, spectrum analyzers and other measuring or control instruments and apparatus ...	24.3	23.2	19.4	24.8	28.1
9004	Spectacles, goggles, spectacles, goggles and the like, corrective, protective or similar articles (excl. spectacles for ...	28.1	26.9	32.8	26.3	27.8
9003	Frames and mountings for spectacles, goggles or the like, and parts thereof ...	21.5	20.9	14.7	21.0	24.3
9019	Mechano-therapy apparatus; massage apparatus; psychological aptitude testing apparatus; ozone ...	10.2	13.0	61.9	96.9	19.2
9011	Optical microscopes, incl. photomicrographic, cinephotomicrographic or microprojection ...	8.6	8.2	9.9	6.5	7.4
9012	Electron microscopes, proton microscopes and diffraction apparatus.	2.4	0.5	1.8	0.3	1.5
9402	Medical, surgical, dental or veterinary furniture, e.g. operating tables, examination tables,	1.0	1.1	1.1	1.3	1.4
Total		**399.4**	**424.0**	**496.4**	**574.5**	**542.5**

Source: SUNAT.

Peru imports various medical devices from multiple sources; however, imports linked to the main import item (9018) are made from 77 countries. During the period 2018-2022, among the 10 main foreign suppliers of these products in Peru, on average in those years the main origins have been China (30.9%); United States (16.2%) and Germany (13.5%), accumulating just over 60% of imports (see Table 22). However, considering only EU countries, the main exporters to Peru have been Germany and Italy, with US$ 41.9 million and US$ 9.0 million, respectively. Other EU countries register low levels of exports to Peru; for example, France exported US$ 3.5 million in 2022; Poland US$ 2.2 million and Austria US$ 1.9 million. However, taking all EU countries together, they represented 22% of Peruvian imports of these products.

Table 22
Peru: Imports of heading 9018 by origin: 2018-2022
(Million US$)

Countries	2018	2019	2020	2021	2022
China	49.4	54.0	100.2	99.8	99.6
United States	40.6	43.5	39.9	43.4	44.3
Germany	37.3	34.3	30.0	32.6	41.9
Japan	16.6	17.8	15.6	15.8	18.8
South Korea	8.0	8.9	8.7	10.4	11.6
Italy	4.9	5.5	6.7	6.7	9.0
Mexico	4.5	5.0	6.6	5.7	7.0
Unired Kingdom	3.8	4.9	3.7	4.6	5.3
Costa Rica	4.7	5.6	3.3	6.0	5.0
Brazil	3.9	3.4	3.4	3.7	4.6
World	**219.2**	**231.7**	**264.8**	**282.1**	**307.2**

Source. ITC trade map.

As can be seen, the Peruvian medical device market is quite fragmented, with the participation of a significant number of importers, but also distributors. In the first case, there are 58 main importers of medical devices[125] and, in the case of distributors, the Health Guild of the Lima Chamber of Commerce (CCL) has 75 associates that sell medical devices, with a large number of other firms operating in this market. There are foreign companies with a presence in Peru, such as Nipro Medical, Covidien, Draeger, Roche, Braun, Novartis, Philip and Siemens, as well as with designated representatives in Peru.

In the case of the State, purchases of medical devices by MINSA, regional and local governments and ESSALUD must follow state purchasing regulations.

6.3. MARKET REGULATION

Pharmaceutical establishments and products are highly regulated in Peru. There are also established requirements for the importation of these products, labelling and advertising. Some of this regulation is common for drugs and medical devices. The applicable standard is the Law on Pharmaceutical Products, Medical Devices and Health Products (Law 29459)[126] and its regulatory standards (Supreme Decree 014-2011-SA[127] and Supreme Decree 016-2011-SA).[128]

Establishments[129]

Any establishment dedicated to the manufacturing, quality control, reconditioning, marketing, import, export, storage, distribution, pharmaceutical care, pharmaceutical preparations and sale of pharmaceutical products, medical devices or health products, among other activities, must have a health authorization to operate. The health authorization given by DIGEMID for laboratories is issued for 5 years and for other types of establishments for 3 years. After this period, the renewal of the authorization must be requested.

The requirements for health authorization vary depending on the type of establishment and the activities to which it is dedicated.[130] In addition to the very detailed information that in each case must be provided to DIGEMID,[131] including on the personnel that would be dedicated to the activities, an important requirement is the certification of good practices according to the type of operation. Laboratories must have a certificate of good manufacturing practices (GMP) and good laboratory practices. In other cases, for example, warehouses must have certification of good storage, pharmacies for pharmaceutical offices. There are also good practice requirements regarding distribution and transportation, and pharmacovigilance, among others.

[125] PROCÓRDOBA (2021). Health Sector Market Study. Available in: https://www.procordoba.org/images_db/noticias_archivos/Estudio%20mercado%20Per%C3%BA-%20Salud.pdf The list of main importers and website is found in this publication.
[126] For more information, see: https://cdn.www.gob.pe/uploads/document/file/2906846/Ley%2029459.pdf?v=1647256236
[127] For more information, see: https://cdn.www.gob.pe/uploads/document/file/272179/243288_14_-_DS_N_C2_B0_014-2011-SA.pdf20190110-18386-1g9v4p5.pdf?v=1547160907
[128] For more information, see: https://cdn.www.gob.pe/uploads/document/file/272181/243290_16_-_DS_N_C2_B0_016-2011-SA.pdf20190110-18386-a4eggt.pdf?v=1656602611
[129] All requirements for registration can be found at: http://serviciosweb.digemid.minsa.gob.pe/Consultas/Establishments The last modification of the regulations was promulgated by Supreme Decree No. 004-2021-SA, of January 2021.
[130] Refer to: Regulation of Pharmaceutical Establishments DS N° 014-2011-SA and DS 016-2017-SA.
[131] You can find all the requirements at: https://www.digemid.minsa.gob.pe/webDigemid/formatos-y-tramites-empresa/#1676554464120-584b7a71-97ab

Market access regulation

a. Medicines

In the field of medicines, there are 4 main problems linked to the operation of DIGEMID: a) delays in granting health registration; b) delays in granting good manufacturing practices (GMP) certification; c) generic products without bio-equivalence studies, and d) lag in the incorporation of innovative products in the country.

In this regard, a study carried out by INDECOPI in 2021 identified three problems associated with delays in meeting DIGEMID deadlines: (i) for the certification of good manufacturing practices (GMP) of foreign manufacturers that come from countries that do not have high health surveillance; (ii) a reduced supply of national laboratories authorized to carry out in vitro therapeutic equivalence studies that allow proving the interchangeability of pharmaceutical products; and, (iii) the evaluation in the procedure for granting the health registration.[132]

i. Delays in granting health registration

All products classified as pharmaceuticals, medical devices and health products, national or imported, must have a health registration for entry into the Peruvian market. The health registry is regulated by Supreme Decree No. 016-2011-SA of July 2011 and its amendments.[133]

The request for registration or re-registration in the health registry is made every 5 years and can only be made by those entities that have health authorization as a laboratory for pharmaceutical products, medical devices or health products or as drugstores. These requirements vary depending on whether the medication is classified in one of the following 3 categories:

Category 1: for pharmaceutical specialties whose active pharmaceutical ingredients (API) or associations are in the PNUME, the period for DIGEMID to grant health registration is no less than 45 days and no more than 60 calendar days.

Category 2: for pharmaceutical specialties whose IFA or associations are not in PNUME, but are registered in countries with high health surveillance, the period is no less than 45 days nor more than 90 calendar days. Currently, according to Peruvian regulation, the high surveillance countries are only 20: France, The Netherlands, United Kingdom, United States of America, Canada, Japan, Switzerland, Germany, Spain, Australia, Denmark, Italy, Norway, Belgium, Sweden, Republic of Korea, Portugal, Ireland, Hungary and Austria.

Category 3: for pharmaceutical specialties whose APIs are not considered in categories 1 or 2, the term is up to 12 months.

For example, in the case of Category 2 products, products from countries with high health standards, the following requirements must be satisfied before DIGEMID:[134]

- A request, in the form of an affidavit,
- Technical specifications of the product and product ingredients,
- Technical specifications of packaging materials,
- Validation of analytical techniques of the finished product,
- Flow diagram and validation of the manufacturing process, identifying critical control points,
- Stability studies,

[132] INDECOPI (2021). Market Report; Improvements to the health registration procedure for medicines. Available at: https://cdn.www.gob.pe/uploads/document/file/2153417/Reporte%20Registro%20Sanitario.pdf?v=1630812660
[133] Supreme Decrees 001-2012-SA, 016-2013-SA, 029-2015-SA and 016.2017-SA.
[134] Article 40. Supreme Decree No. 016-2011-SA, as modified by SD No. 016-2017-SA.

- Therapeutic equivalence studies to demonstrate interchangeability,
- Delete data sheet and insert,
- Packaging labelling project in Spanish,
- Pharmaceutical product certificate, or free marketing certificate issued by the authority of the country of origin,
- Certificate of Good Manufacturing Practices issued by DIGESA. Certificates issued by countries with high health standards are accepted,
- Risk management plan if the product contains an active pharmaceutical ingredient that has not been previously registered in the country.

However, the union that brings together the European chambers in Peru, EURO Camaras, and ALAFARPE have expressed serious concerns about the significant delays in the registration of medicines by DIGEMID. According to the regulations, if the active pharmaceutical ingredient is included in the list of "Single National Request for Essential Medicines" (PNUME) the period for granting the sanitary registration must not exceed 90 days, and the same period if the product comes from a country of high health surveillance. In the case of biological products, the registry should be granted at the most in 120 days. However, a sanitary registry is taking up to two years if not more.

This situation contrasts with that existing before the Law of pharmaceutical products, medical devices and medical devices (Law 29459) of 2009. In 1992, the registration of medicines in Peru was made more flexible, establishing a period of 30 days for the health authority to respond to a request for health registration submitted by a pharmaceutical company. If after those 30 days no response was obtained, positive administrative silence was applied, granting registration. Subsequently, the General Health Law of 1997 reduced this period to 7 days. However, with current regulations, it can take up to 18 years for a new drug to be marketed in the country.

ii. Delays in granting good manufacturing practices certification

GMP certification by DIGEMID is one of the requirements to access the health registry. In the case of laboratories in countries with high health surveillance, or in countries where mutual recognition has been agreed, DIGEMID will accept GMP certificates. The maximum period of the BMP certification procedure according to regulations is 90 calendar days; however, with respect to applications from foreign manufacturers, there is a failure to comply with the evaluation deadlines, accepting or denying GMP certificates.

As will be discussed below, temporary measures have been adopted to allow imports of products pending BMP registration. However, this situation has meant that products from national laboratories and imported products have been exposed to a different regulatory requirement, to the extent that national laboratories must comply with obtaining the BMP certificate issued by DIGEMID.

iii. Generic products without bio-equivalence studies

Considering that one of the requirements for obtaining a health registration is the presentation of therapeutic equivalence studies, which must be carried out in an authorized laboratory, there is an additional problem that increases evaluation times. In Peru, the Bioavailability and Bioequivalence Laboratory of the National Quality Control Centre (CNCC) of the National Institute of Health (INS) is the only laboratory with the capacity to carry out in vivo bioequivalence studies (for drugs with high health risk.) and in vitro bioavailability tests to demonstrate that a

generic and a brand-name drug, with the same active ingredient, are equally safe and effective.[135]

iv. Lag in the incorporation of innovative products in the country

Some international indicators place Peru among those with the least efficient performance in providing access to innovative products in its market. Taking into account 460 new drugs launched from 2012 to the end of 2021 in the Americas:[136]

- Only 15% of these medications entered Peru; magnitude only above Ecuador (12%), Uruguay (9%), Dominican Republic (7%) and Venezuela (1%). In countries like Chile or Colombia, 25% and 23% accessed, respectively.
- Regarding the percentage of new medicines launched within the year following the first global launch by country in the Americas, the percentage in Peru was zero, while in Chile it was 4%, in Argentina and Colombia 2%, and in Ecuador 1%.
- Regarding the average number of months from the first global launch of a product to the local launch by Country in the Americas, the delay in Peru was 37 months, longer, for example, than Chile (31), and Colombia and Argentina (both with 33).

Hence, the coverage of innovative molecules in the Peruvian health registry is only 55%.

All of these problems clearly illustrate that DIGEMID is not well prepared in terms of human and physical resources to adequately address the 4 problems described. Although progress has been made, this MINSA unit has not yet been classified by the Pan American Health Organization (PAHO) as a Level IV entity; that is, as an internationally recognized Reference Authority for Medicines and Biological Products.[137]

b. Medical devices

Medical devices are classified according to the risks they carry, which can be: low risk, moderate risk, high risk and critical risk. Health registration requirements vary depending on the level of risk, although not all medical devices require a health certificate. DIGEMID publishes a list of 1,473 products that do not require a health certificate, which is updated periodically.[138]

To obtain health registration in the case of a moderate risk product, for example, the following documents must be presented:

- Application in the form of an affidavit;
- Copy of the free marketing certificate issued by the competent authority of the country of origin or export, for imported products.
- Certificate of Good Manufacturing Practices (GMP) from the national or foreign manufacturer issued by the National Authority for Pharmaceutical Products, Medical Devices

[135] If in vivo and in vitro equivalence studies are carried out outside the country, DIGEMID accepts those approved in centres certified or authorized by the EMA (European Medicines Agency), the FDA (Food and Drug Administration) of the United States, Health Canada of Canada, the Spanish Agency for Medicines and Health Products (AEMPS) is recognized. the UK Medicines and Healthcare products Regulatory Agency (MHRA), the Swedish Medicines and Products Agency (MPA), the Swiss Medicines and Healthcare products Agency Therapeutics (Swissmedic), the National Health Surveillance Agency (ANVISA) of Brazil and the WHO (First Final Complementary Provision of Supreme Decree No. 024-2018-SA).

[136] PhRMA (2023). Global Access to New Medicines Report.

[137] For more information, see: https://www3.paho.org/hq/index.php?option=com_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=0&lang=es#gsc.tab=0

[138] For more information, see: https://www.digemid.minsa.gob.pe/webDigemid/registro-sanitario/productos-no-rs/ April 2023 .

and Medical Devices (ANM) or document that certifies compliance with specific international Quality Standards for the type of medical device, for example CE Certificate of the European Community, current ISO 13485 Standard, FDA or others according to the risk level issued by the Competent Authority or Entity of the country of origin.
- Technical report on the medical device.
- Technical studies and analytical checks. The following documents issued by the manufacturer: a) Summary of design verification and validation documents. b) Declaration of conformity with international reference standards, and c) Certificate of analysis of the finished medical product, if any.
- Labelling project for immediate containers and mid-packs as appropriate.
- Risk management report, according to the specific current ISO standard.
- Instructions for use manual or insert, if applicable, translated into Spanish.

In the case of medical devices there is also a significant delay in the registration process. Depending on the level of risk, registration should take a maximum of 30, 60 or 90 days according to regulations. In practice, registration of a medical device takes between 6 and 12 months.[139]

Import Regulation

To import medicines and medical devices to Peru, all general documentation applicable to all products must be presented.[140] The Most Favoured Nation (MFN) customs tariff applicable to medicines and for some medical devices such as orthopaedic products, glasses, among others, is 6%. For most medical devices the customs tariff is zero. On the other hand, imports must pay the Value Added Tax (VAT) of 16% and the Municipal Tax (MT) of 2%. These taxes are applied to the value of imports plus customs duties, if any. However, medicines for the treatment of cancer, diabetics, HIV and some others are free of customs duty and free of VAT and MT. To date, medicines and medical devices have met their respective tariff reduction deadlines in all Peruvian trade agreements, so that all imports of these products from the EU are tariff-free.

According to Peruvian regulations, pharmaceutical products and medical devices must be imported, marketed and distributed under the same conditions and characteristics in which they were authorized (e.g., in relation to labels, technical specifications, certificates of analysis, instruction manuals or leaflets, among others).

There are some specific requirements for the importation of medicines, such as that only laboratories and *drugstores* with current authorization registration can import medicines. In addition to all normal import documentation, to import medicines, the following must be presented to customs:

- Product health registration
- Importer authorization record.
- Batch test certificate.
- GMP Certificate
- For products containing narcotic or psychotropic drugs, official import certificate and DIGEMID Resolution authorizing the import.

[139] Carla Camargo Yabeta (2021). Improvement proposal to reduce delay times during obtaining health registration in the registration, re-registration and changes process: medical devices. Professional proficiency work to qualify for the Professional Title of Pharmaceutical Chemist. Available at: https://repositorio.upch.edu.pe/bitstream/handle/20.500.12866/8988/Propuesta_CamargoYabeta_Carla.pdf?sequence=1&isAllowed=y

[140] Consult MAT Infocard Import in Peru.

- For biological products derived from human plasma, or of animal origin, a certificate indicating their safety.

The GMP certificate that must be issued by the National Medicines Authority (ANM) of the DIGEMID, constitutes a strict requirement for foreign laboratories. Currently there are 268 foreign laboratories certified with GMP by the DIGEMID. For DIGEMID and customs to allow imports, , the requirements have been made more flexible since 2019 (Supreme Decree No. 007-2019-SA), establishing that foreign laboratories that have requested a GMP certificate, registered in the "Single List of laboratories abroad pending GMP certification by the ANM", as well as those who export from countries with high health surveillance, can present certificates issued by their national authorities. In this regard, an issue that EuroCámaras has raised is that only 15 EU member countries – out of a total of 27 members – are recognized as countries with high health surveillance, benefiting from this treatment. As was mentioned before, Peru only recognizes 20 countries under that status.

Currently, before DIGEMID there are 334 laboratories from around the world on the list pending certification by the ANM.[141] By Supreme Decree 012-2023-SA of May 2023, this treatment has been extended only to foreign laboratories until May 2028. After that date, if the deadline is not extended again, those laboratories not certified in GMP by the ANM would not be able to export to Peru. According to the ADIFAN union, this puts national laboratories at a disadvantage, which must be certified by the ANM before being able to put their products on the market.

Labelling

The labelling of medicines is regulated by the General Health Law and by technical standards. According to DIGEMID, the labelling of medication containers must contain the following information:[142]

- Name of the product and name of the active ingredient.
- Concentration of the active ingredient per dose close to the name of the drug.
- Dosage form.
- Form of administration.
- Net content per container.
- Product formula.
- Condition of sale, if it is under medical prescription.
- Name and country of the manufacturing laboratory.
- All products must be labelled "Keep away from children."
- Where applicable, the legends 'Paediatric Use' must also be included; "Sale of prescription drugs"; "No prescription, as well as other necessary legends.
- Health registration number.
- Lot number and expiration date.
- Imported products must include the name, address and Unique Registry (RUC) of the importer, and the name of the responsible Pharmaceutical Chemist.
- Storage conditions.
- Information if the product needs preparation.

[141] For more information, see: https://www.digemid.minsa.gob.pe/Archivos/Sunat/2023/OFICIO_493-2023.pdf

[142] For more information, see: legiscomex.com/BancoMedios/Documentos%20PDF/estudio-mercado-sector-farmaceutico-peru-empaquetado-etiquetado.pdf

Advertising

In 2020, the MINSA approved the technical health standard that is mandatory not only for pharmaceutical companies but for all market participants. In particular, it established the ethical criteria for the promotion and advertising of pharmaceutical products, medical and health devices.[143] This technical standard also contains specific criteria for the promotion and advertising of prescription and non-prescription pharmaceutical products, herbal medicines, dietary products and natural therapeutic resources, such as that the promotion and advertising of the products must not contain exaggerations or inaccuracies regarding therapeutic, nutritional, cosmetic, diagnostic, preventive or any other type of properties that are not in accordance with your health record.

Some more specific aspects of the technical standard include:

- The announcement must include the health registration number and any mandatory health notification.
- Online advertising of prescription drugs is prohibited.
- It is prohibited to claim that a product is completely harmless or safe.
- Comparison of products in the absence of verifiable scientific evidence is prohibited.
- Prohibition of promoting or advertising aimed at children.
- The promotion and advertising of the Products must not suggest that lack of use may affect health.

[143] The Technical Health Standard No. 162-MINSA/2020/DIGEMID was approved by Ministerial Resolution 162-MINSA/2020/DIGEMID on July 9, 2020.

CHAPTER 7

INTELLECTUAL PROPERTY RIGHTS

The pharmaceutical industry relies heavily on industrial property rights (IPR), particularly patents for inventions. The development of new products involves significant investments in research and development (R&D) and the exploitation of exclusive rights conferred by a patent for 20 years allows these investments to be recovered. Intellectual property protection plays an important role in providing incentives for the development and commercialization of new medicines. Consequently, adequate protection of these rights is a central issue of concern for the industry. Furthermore, brands play an important role in the pharmaceutical market. In the case of Peru, around 50% of all patent applications are for pharmaceutical products and around 10% of all trademark files processed before the competent authority, the National Institute for the Defence of Free Competition and Protection of Intellectual Property (INDECOPI), which include new registrations and renewals of trademarks, commercial slogans and trade names, are about medicines.[144]

In Peru, the Common Industrial Property Regime of the Andean Community (CAN) is implemented to protect industrial property rights. This regime is governed by CAN Decision No. 486 of 2000, plus Decisions No. 632 and No. 689 of 2008.[145] In addition, in 2008 Peru published Legislative Decree 1075 on Complementary Provisions to CAN Decision No. 486 to comply with the commitments assumed under the Peru-United States Free Trade Agreement (FTA).[146]

The current described regime is compatible with the WTO TRIPS Agreement and incorporates all its obligations. Likewise, these obligations have been reiterated in all trade agreements to which Peru is a party, which include a Chapter on Intellectual Property Rights (IPR), as is the case of Title VII of the Agreement with the European Union. In the TRIPS Agreement there are no exceptions to Most Favoured Nation Treatment (MFN), so all the commitments adopted in this matter by Peru in its different trade agreements are extended to all its trading partners. On the other hand, Peru is a contracting party to several international agreements on intellectual property rights.[147]

The main commitments on intellectual property included in the FTAs signed by the countries of the region with the United States are the following:

a. Extension of the term of pharmaceutical patents to compensate for the "unjustified reduction" in the term of patents as a result of delays by the national competent authority in the marketing approval process of the patented medicine;
b. At least five years of exclusivity on the *trial data* used to support the marketing application for a medicine; and
c. Linking mechanisms, relating to subjecting the granting of a marketing authorization for a generic medicine to the patent status of the original medicine.

[144] INDECOPI. Institutional Statistics Yearbook
[145] Decision No. 345 of 1993 was promulgated to ensure the protection of plant breeders' rights.
[146] Modified by Legislative Decrees 1309, published on December 30, 2016, and No. 1397, published on September 7, 2018.
[147] Peru is a Contracting Party to the Paris Convention for the Protection of Industrial Property since April 11, 1995. It is also a Contracting Party to the Patent Cooperation Treaty (PCT) since June 6, 2009. In addition, it is a Party to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and recently acceded to the Strasbourg Agreement Concerning the International Patent Classification, which divides the technology into eight sections with approximately 80,000 subdivisions. Classification is indispensable for the retrieval of patent documents in the search for "prior art."

INDECOPI is responsible for registration applications for different types of intellectual property and for implementing the legal provisions that protect IPR in Peru, including handling administrative enforcement cases. INDECOPI, through its different directorates, coordinates the implementation and supervises compliance with national and international commitments regarding intellectual property.[148] The **Directorate of Inventions and New Technologies** (DIN), which administers patents, and the **Directorate of Distinctive Signs** (DSD), which administers trademarks, are the first administrative bodies for the resolution of disputes. The Specialized Chamber of Intellectual Property (SPI) of INDECOPI resolves second instance cases before the Commissions on Distinctive Signs, Inventions and New Technologies and Copyright. Once the administrative process is complete, any dispute can be taken to the court system.

In what follows, there is a brief review of 4 issues related to the protection of intellectual property in Peru related to pharmaceutical products: patents, trademarks, parallel imports and counterfeit products.

Patents

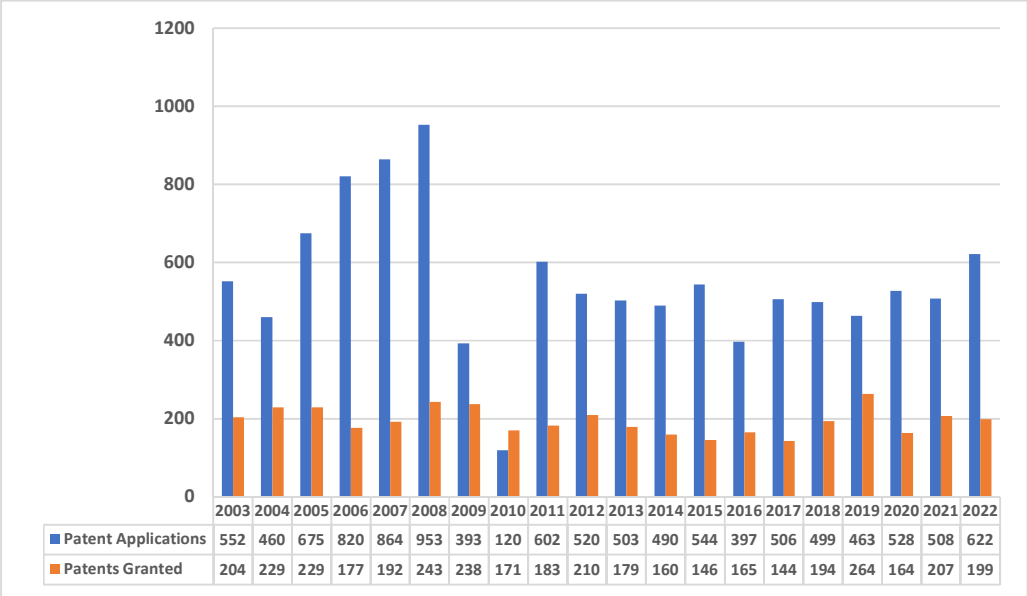
In Peru the approval of a patent takes some time, therefore, the patents granted each year correspond to applications submitted some time before. Taking into account Chart 14, which shows the number of pharmaceutical patent applications and the number of patents granted during the period 2003-2022, if we take only the last five years of the series, during that period a total of 2,620 pharmaceutical patent applications were presented and 1,028 were granted.

The data also shows that in the next five years 1,031 patents will expire and the invention will fall into the public domain. This will pave the way for greater competition in these products in the pharmaceutical market. The vast majority, if not all, of patent applications for pharmaceutical products are filed by foreigners.[149] National producers of pharmaceutical products invest little in R&D. Patent applications are filed by major multinational laboratories in the US, Europe and Asia.

[148] In the case of industrial property rights, the *Directorate of Inventions and New Technologies* (DIN) is responsible for receiving and resolving applications for patents for inventions, utility models, industrial designs, protection certificates, collective knowledge of the people. indigenous, new plant certificates. variety breeders and other new technologies. It is the first administrative instance for conflict resolution. The *Directorate of Distinctive Signs* (DSD) registers trademarks, trade names and commercial slogans, designations of origin, geographical indications and guaranteed traditional specialties. It is the first administrative instance to resolve registration opposition procedures, as well as for the cancellation and annulment of registrations and the vindication of rights. As a second administrative instance, it receives and resolves appeals voluntarily.

[149] INDECOPI does not provide data on patent applications for pharmaceutical products disaggregated by nationals and foreigners. However, on an annual average, 96% of all patent applications in all fields are filed by foreign companies or individuals.

Chart 14
Pharmaceutical Patent Applications and patents granted in Peru 2003-2022



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Patent Applications	552	460	675	820	864	953	393	120	602	520	503	490	544	397	506	499	463	528	508	622
Patents Granted	204	229	229	177	192	243	238	171	183	210	179	160	146	165	144	194	264	164	207	199

Source: INDECOPI. Yearbook of Institutional Statistics. Various themes.

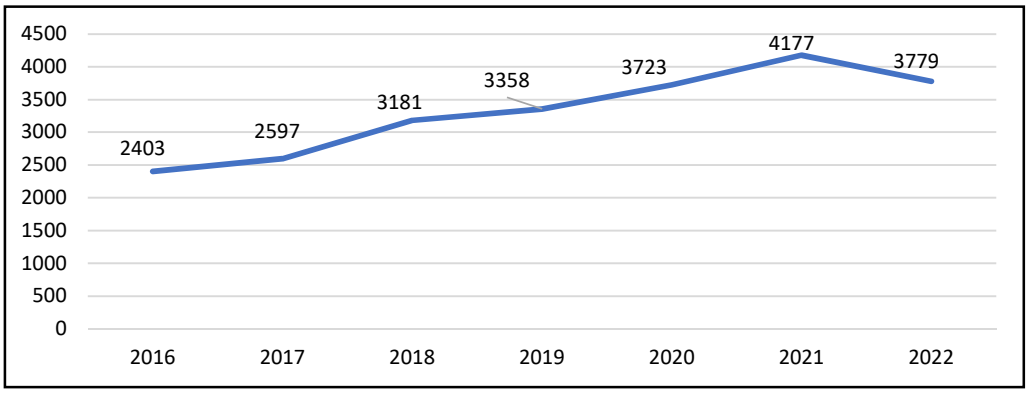
As is clear, there is a long period of time from when a patent application is opened until the process is completed. According to INDECOPI data, on average the processing of a patent application in Peru takes 45 months.[150] In the absence of protection during the processing of the application, this delay would reduce the period of exclusive exploitation of the patent. However, in Peru an extension of the Patent Term may be granted in case of an unreasonable delay in the granting procedure, or to compensate for the delay in obtaining marketing approval in the case of pharmaceutical products. This was included in Peruvian legislation to adapt to the commitments adopted in the trade agreement with the United States.[151]

Trademarks

Chart 15 presents the number of trademark files opened in INDECOPI related to pharmaceutical products. These numbers include new registrations, renewals, commercial slogans and commercial names. According to the International Classification of Products and Services, the Nice Classification (NCL) applied for the registration of trademarks, Class 05 medications are those with the highest number of registrations in Peru.[152]

[150] INDECOPI. Yearbook of Institutional Statistics. Various issues.
[151] For more information, see: https://inspire.wipo.int/system/files/pe.pdf This is a commitment adopted by Peru in article 16.9 of the trade agreement with the United States.
[152] Class 5 mainly includes pharmaceuticals and other preparations for medical or veterinary use. Includes: pharmaceutical products, medical and veterinary preparations; sanitary products for medical use; foods and dietary substances for medical or veterinary use, baby food; dietary supplements for humans and animals; plasters, dressing materials; tooth filling material, dental wax; disinfectants; preparations to destroy vermin; fungicides, herbicides.
https://www.wipo.int/classifications/nice/en/

Chart 15
Trademark Applications Submitted to INDECOPI on pharmaceutical products



Source: INDECOPI

Parallel imports and dual use patent

In another area, some concern has been expressed by foreign laboratories about the fact that Peru allows parallel imports, that is, the possibility of importing into Peru a pharmaceutical product patented and legitimately marketed in another country, by a person other than the owner of the patent in Peru and without its permission. However, this is permitted by the TRIPS Agreement. Another issue that has been raised by foreign laboratories is the fact that the Andean Intellectual Property Regime does not allow the patentability of a second use of a patented product, which is allowed in many developed countries.

Counterfeit products

Another problem that impacts the pharmaceutical market in Peru is product counterfeiting. According to the World Health Organization (WHO), Peru ranks high among countries in terms of the incidence of counterfeit pharmaceutical products.[153] A counterfeit medicine is a product that is deliberately and fraudulently mislabelled as to its identity or origin. The European Medicines Agency defines a **falsified medicine** as any medicine that contains a misrepresentation of its identifying characteristics (including packaging); labelling; the name or ingredients (including excipients) and their quantity; its manufacturer; the country of manufacture; the country of origin; the authorized marketing owner, and its history, including records and documents related to the use of distribution channels. Counterfeiting can be carried out with generic or branded medicines,[154] with correct or incorrect ingredients, with or without active ingredients, with insufficient active ingredients or through adulterated packaging.

According to a study carried out for the period 2015-2019 of tests carried out by the National Quality Control Centre of the National Institute of Health-Peru (CNCC), counterfeit products represented a significant proportion of the total products tested. Pharmaceutical products account for the largest proportion of counterfeit products. Of the total of 9,537 complaints issued, 835 (8.8%) were counterfeit products, of which 671 (80.4%) were pharmaceutical products; 157 (18.8%) health products and 7 (0.8%) medical devices. In the case of pharmaceutical

[153] WHO (2018). Global surveillance and monitoring system for substandard quality and falsified medical products [Internet]. Geneva. Available in:
https://www.who.int/medicines/regulation/ssffc/publications/GSMS_report_SP.pdf
[154] Herranz A, Negro E, SEFH-CGCOF Working Group (2018). European Directive on Counterfeit Medicines: lights and shadows for Hospital Pharmacy 2018 Available in: https://revistafarmaciahospitalaria.sefh.es/gdcr/index.php/fh/article/view/10997

products, the largest number corresponds to medicines.[155] ALAFARPE estimates a higher proportion of counterfeit products, stating that 25% of the medicines sold in the Peruvian market are counterfeit.[156] It is estimated that the illegal medicine market in Peru, which includes the informal business of adulterated medicines, moves around US$ 200 million a year.[157]

Finally, according to the US government, "the Government of Peru has increased its law enforcement activity over the past five years and generally offers strong regulatory protections of intellectual property rights (IPR)."[158] However, Peru has remained on the US Trade Representative's Section 301 "Watch List" due to long-standing implementation issues, particularly with respect to establishing statutory damages for infringement of trademark rights, authorship and counterfeiting of trademarks, as well as the notification, elimination and safe harbour system for Internet Service Providers. However, on the patent side, no problems have been raised.[159]

[155] Roberto Torres Olivera, Fredy Mostacero Rodríguez (2020). Counterfeit products in Peru in the period 2015 – 2019: A criminal activity that threatens people's health. Available at: https://boletin.ins.gob.pe/los-productos-falsificados-en-el-peru-en-el-periodo-2015-2019/ See also: Videnza Consultores (2019). Illegal medications in Peru: Diagnosis of the situation and policy recommendations. Final report. Commissioned by the Asoc National Association of Pharmacy Chains (Anacab), February. Available at: https://www.comexperu.org.pe/upload/articles/publicaciones/estudios/Medicamentos_Ilegales_Final.pdf

[156] For more information, see: https://alafarpe.org.pe/medicinas-falsificados-como-identificadorlas-para-que-no-poner-en-riesgo-la-salud/

[157] Cited in Videnza Consultores (2019). Op.cit.

[158] United States Department of State. Investment Climate Statement 2022. Available at: https://www.state.gov/reports/2022-investment-climate-statements/peru__trashed/

[159] Office of the United States Trade Representative. 2023 Special 301 Report: Available at: https://ustr.gov/sites/default/files/2023-04/2023%20Special%20301%20Report.pdf

CHAPTER 8 CONCLUDING REMARKS

The provision of health services is one of the core services in which the state has a predominant responsibility towards its population. In the case of Peru, despite the efforts undertaken by different administrations, which are reflected in the progressive increase of the public resources allocated to the provision of health services, as well as the significant expansion of mandatory health coverage, still it has not been possible to guarantee quality access to health services to the majority of the population. It is safe to assert that the Peruvian health system is currently in crisis, and ill prepared to confront the challenges of the epidemiological transition that progressively is taking place in the country. It is imperative to adopt the necessary measures to revert the situation in order to provide quality UHC for all, as required by the Sustainable Development Goals.

In Peru, the public health system is fragmented and plagued with administrative inefficiencies, which makes it almost impossible to provide the quality services required by the population. A restructuring of the public health system is a necessary condition for making any progress in this area. That would require strong political decision on the part of different stakeholders, and the commitment of various administrations with the implementation of a coherent state health policy through time. Furthermore, it will require an active involvement of the private sector in the process of improving health services delivery in the country. The necessary efforts to restructure the health system in Peru could offer interesting business opportunities.

In terms of health insurance coverage, Peru exhibits a very low level of private health insurance in comparison with other Latin American countries. There is a potential interesting market that could be exploited in the higher income segments of the population, either though the establishment of firms in the country, or through the export of health insurance services. As a matter of fact, many Peruvians are looking abroad to buy medical insurance that could offer better coverage than the one they find in the Peruvian market.

There is a significant health infrastructure gap in the country. One of the reasons of the collapse of health care provision in the country has been the expansion of health insurance coverage without the parallel expansion and improvement of the health infrastructure. As discussed in this report, closing the gap will offer interesting investment opportunities for the national and foreign private sector. The state is increasingly relying on the participation of the private sector in the expansion and upgrading of the health infrastructure through different modalities. These include not only the concession of hospitals through grey, green and white coat modalities, but also in general the Peruvian state is incrementally using the PPP arrangements, work for taxes, and other modalities to advance public infrastructure investment. The private sector can take the initiative in proposing investments under these different modalities, as is contemplated in the regulation. One main constraint will be the public budget one, since the vast majority of the necessary infrastructure will have to be subsidized.

On the other hand, the participation in the private health market by investing in clinics could offer profitable investment opportunities. There is also a gap in private health infrastructure in the country, in particular outside Lima. The first level of attention that should cover 80% of the interventions is particularly underserved by the private sector in the interior of the country. As

mentioned in the report, there are no significant barriers to establishment in the country and foreign investment received national treatment.

Another area to examine by foreign entities is the formation of human resources for the heath sector. There is a significant gap in Peru in terms of medical professionals in the different disciplines and all levels, and serious issues with the quality of the medical education. In Peru already different modalities of collaboration between national and foreign education entities is taking place and growing every year.[160] Opportunities in this area should be explored, and to the extent that they crystallize would make a very important contribution to the health sector in Peru.

Finally, as this report shows, the Peruvian market for both medicines and medical devices is predominantly an import market, which offers interesting opportunities for foreign suppliers. It is a very competitive market with multiple players from all over the world. However, it is a very slow market for the entry of new medicines. As long as the current problems with health registration are solved, it will allow the entry of new patented medicines offering business opportunities, which at the same time will contribute significantly to the improvement of health care delivery in the country. The generic medicines market in Peru is a growing market, as it is being promoted through public policies, and the Peruvian consumer is increasingly accepting this type of medicines. In this context, there are also interesting opportunities for both branded generics and those marketed under the international name of the active substance.

[160] Refer to Infocard: Post Graduate Studies in Peru. MAT Team. November 2023.