

El Salvador: Pharma Industry SECTOR FICHE

1. Sector overview

1.1. Health system

The Salvadorean Administration, which entered into office in 2019, has aimed to modernize and transform El Salvador's Integrated National Health System. The government priorities are to resolve the shortage of medicines, improve the lack of hospital maintenance and infrastructure, and increase the accessibility of health services. According to the approved 2023 El Salvador National Budget, the health budget totals \$1,165 million USD.¹

Public health sector services are provided by the Ministry of Public Health and Social Assistance (MINSAL), the Salvadoran Social Security Institute (ISSS), the Salvadoran Integral Rehabilitation Institute (ISRI), Salvadoran Institute of Teachers Welfare (ISBM), the Institute of Social Prevision of the Army (IPSFA), and the Solidarity Fund for Health (FOSALUD).

The Ministry of Health has a total of 31 hospitals, and 372 health units; and the ISSS has 11 hospitals, and 71 health units and community units. There is only one military hospital.

The private health sector is made up of hospitals, clinics, and non-profit organizations. There are approximately 30 hospitals, and over 116 private clinics concentrated in the country's three main cities: San Salvador, Santa Ana, and San Miguel.

The public sector is the primary purchaser of medical equipment and supplies through the Ministry of Health and the ISSS. Public institutions differ from private entities as they only buy new equipment.

The government is implementing the Digital Agenda 2020-2030, which lays out the design, creation, and implementation of an Electronic Health Record. The 2021-2024 Health Road Map² published by MINSAL aims to implement a digital health system in El Salvador.

¹ <https://www.transparencia.gob.sv/institutions/minsal/documents/presupuesto-actual>

² https://mcpelsalvador.org.sv/wp-content/uploads/2021/06/9.-Agenda-Digital-en-Salud-2021-2024-Hoja-de-Ruta_ElSalvador_v6.pdf

The ISS offers health insurance and health services to Salvadorans who have a formal job. Contributions to the ISSS are based on the employee's salary - the employee pays 3%, and the employer 7.5%. However, most of the population works in the informal economy with no access to the ISSS system, and therefore depend on the public hospitals for health services.

The 2020 Multipurpose Household Survey Report (EHPM)³ organized by the General Directorate of Statistics and Census (DYGESTIC) in El Salvador, reported that 24.8% of the total population had some type of medical insurance, broken down as follows: 91.6% ISSS, 5.9 % ISBM, 2.1% IPSFA, and 0.4% private or other.

1.2. Pharmaceutical industry

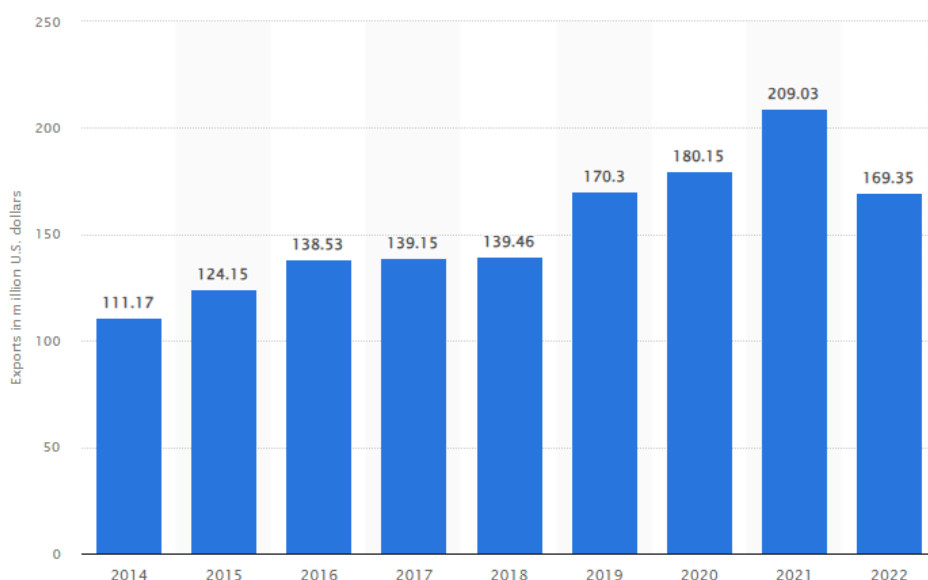
The pharmaceutical industry is strategic for Salvadorans' access to medicines and is also one of the country's most competitive sectors. The pharmaceutical sector is quite dynamic at the regional level, and access to new devices and drugs will depend on the ambition of the administration in setting drug prices.

El Salvador is making steady, if slow progress in establishing itself as a viable market for pharmaceuticals, as evidenced by the construction of a mega-structure production plant at Santa Tecla.

However, despite improvements in the regulatory environment since the Medicine Law of El Salvador was approved in 2012, only a few international companies -mostly Latin Americans- have established in the country as result of underdeveloped infrastructure and manufacturing.

In 2022 the Association of Chemical-Pharmaceutical Industrialists of El Salvador (INQUIFAR) reported that the sector closed 2021 with record growths of the last 10 years in terms of exports, jobs, and sales. Direct employment in the sector at the end of 2021 was 6,394, with an increase of 224 compared to 2020.

Value of pharmaceutical exports from El Salvador (in million U.S. dollars)



³ <https://onec.bcr.gob.sv/encuesta-de-hogares-de-propositos-multiples-ehpm/>

INQUIFAR also reported that around 40% of national production is destined for exports to international markets. Exports were US\$209.03 million, while imports amounted to US\$622 million. Exports declined to US\$169.35 million in 2022.

Citing data from the Central Reserve Bank (BCR), INQUIFAR noted that the pharmaceutical sector recorded exports to 34 countries, but 85% were destined for Central American markets. Indeed, El Salvador ranks 10th among Central America's main suppliers with exports totaling \$175.9 million in 2021. 89% of the industry's exports correspond to medicines for human consumption, and 11% for veterinary use.

Central government purchases totaled US\$272.5 million in 2021, a growth of 11% versus 2020. Only 29 % of the drugs purchased by the MINSAL are produced locally and 71 % are imported products. Public procurement announcements are centralized at COMPRASAL⁴. Procurement announcements carried out by MINSAL are also accessible in also in the Transparency Portal (Portal de Transparencia).⁵

There are several ongoing initiatives funded by the InterAmerican Development Bank (IDB)⁶ aimed to strengthen the health system in El Salvador:

- Support for the Strengthening of the Health System in El Salvador (US\$ 150.000, in implementation): it aims to (i) continue supporting the preparation of the technical bases for the bidding process for the Rosales Hospital Phase 2 and define the total cost of the interventions for its implementation; (ii) provide technical assistance to lay the foundations for the instruments to improve hospital management with emphasis on the start-up of the Hospital Zona Norte and Hospital Rosales, and (iii) support the definition of a model for the maintenance of hospital equipment and improvements in the efficiency of support services.
- Integrated Health Program III (US\$ 235 million, in preparation): its objective is to improve the populations health by strengthening hospital and digital health care service delivery, and to improve the operational efficiency of the public system (in preparation).

The construction of the Hospital Rosales kicked off in June 2023. The IDB originally approved a loan of US\$ 170 million for this project. The bid for the design and construction announced in 2021 was cancelled by MINSAL 2022. The Ministry of Health appointed the recently created organization, Municipal Works Directorate (DOM), as a co-implementer of the project, and announced that the project would be funded with the State's budget. The total investment is approximately \$80 million, of which \$19 million will be allocated for the purchase of medical equipment.

2. Regulatory framework

The National Medicine Directorate (DNM) is responsible for the importation and commercialization of medical devices, medical equipment, pharmaceuticals, nutritional supplements, natural, dental, and hygiene products under the Medicine Law that entered into force in April 2012. These products need to be registered at the DNM⁷ before entering the

⁴ <https://www.comprasal.gob.sv/login>

⁵ <https://www.transparencia.gob.sv/institutions/minsal/contracts/190201>

⁶ <https://www.iadb.org/en/countries/el-salvador/projects-glance> It is important to note that some of the IDB's loans have not been disbursed due to lack of budget transparency.

⁷ <https://expedientes.medicamentos.gob.sv/productos/buscarProducto>

Salvadorean market. The DNM is undertaking a series of actions to reduce the product registration time.

New and used medical equipment can be imported into El Salvador but cannot be older than 10 years from the date of manufacture. In the case of medical devices, some products are excluded from the registration process. In addition, ionizing radiation devices or equipment require an import permit from the Radiation Protection Directorate at the MINSAL.

Central America Customs Union (CACU) member countries, among them El Salvador, have harmonized Sanitary Registration and Sanitary Inscription procedures (Central American Technical Regulation-RTCA in Spanish)⁸. Through this procedure, products registered in one CACU country do not need to be registered again in another. Products manufactured in the EU are not eligible for this registration exemption. However, the product's Country of Origin is considered CACU if processed in a CACU member country, even if the raw material originates from a non-CACU country.

The RTCAs⁹ establish unified standards and requirements for commercial pharmaceuticals, cosmetics, healthcare products and others within the Central America region. The RTCAs require a Certificate of Free Sale (Certificado de Libre Venta, CLV) for imports of regulated products. Registrants shall present the original, signed, and notarized certificate of free sale issued by the competent authority in the country of origin.

Central American Mechanism for the Joint Evaluation of Drug Dossiers

It is worth noting that the Pan American Health Organization (PAHO) has a system for evaluating National Regulatory Authorities for Drug Products, which is based on the recommendations of the World Health Organization (WHO) for strengthening regulatory bodies. Four levels of regulatory development (from 1 to 4) are defined, and authorities considered as Regional Reference Authorities by PAHO are those classified as Level 4. Currently, none of the National Regulatory Authorities in Central America are considered competent and efficient to carry out the health regulatory functions recommended by PAHO / WHO to ensure the efficacy, safety, and quality of drug products, that is, Level 4.

In June 2021, the PAHO presented the Central American Mechanism for the Joint Evaluation of Drug Dossiers, which seeks to ensure the quality, safety and effectiveness of medicines and health technologies in the region.

The mechanism was launched by the National Regulatory Authorities (NRAs) of Costa Rica, El Salvador, Guatemala, and Honduras, with the support of the Pan American Health Organization (PAHO), in October 2019.

Respecting the regulations, processes and administrative procedures of each participating country, the mechanism ensures a single technical review that will reduce registration times in the subregion, completing the process in less than three months.

Likewise, the mechanism will allow the global pharmaceutical sector to access the Central American pharmaceutical market, optimizing processing time and avoiding that the same dossier, with the same regulatory framework, is given different results in the evaluations. At the meeting, it was announced that at this stage chemical synthesis drugs will be admitted. However, the objective is to broaden the complexity of the products that can be reviewed in this mechanism.

⁸ https://members.wto.org/crnattachments/2018/TBT/SLV/18_4422_00_s.pdf

⁹ https://members.wto.org/crnattachments/2018/TBT/PAN/18_4358_00_s.pdf



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