

Health sector in Central America

SECTOR FICHE

1. Policy and regulatory framework

The Council of Ministers of Health of Central America and the Dominican Republic (COMISCA), part of the Central American Integration System (SICA), focuses on establishing the healthcare regional policies, through instruments like the Policy Healthcare Plan for the 2021-2025 period¹.

In 2013 the Central American Biotechnology and Biosafety Initiative (ICABB) was officially established at the headquarters of Inter-American Institute for Cooperation on Agriculture (IICA). ICABB's objectives include concurring and strengthening the actions of countries related to biotechnology and biosecurity, supporting the modernization and harmonization of their legal frameworks, promoting scientific research and improving the perception of these issues among the population.

Central America Customs Union (CACU) member countries have harmonized Sanitary Registration and Sanitary Inscription procedures (Central American Technical Regulation-RTCA in Spanish)². 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 RTCAs³ establish unified standards and requirements for commercial pharmaceuticals, cosmetics, healthcare products and others within the Central America region. Compliance with these technical regulations assures that products may be imported without major complications. 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.

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.⁴ Four levels of

¹ https://www.sica.int/documentos/plan-de-salud-de-centroamerica-y-republica-dominicana-2021-2025_1_128463.html

² https://members.wto.org/crnattachments/2018/TBT/SLV/18_4422_00_s.pdf

³ https://members.wto.org/crnattachments/2018/TBT/PAN/18_4358_00_s.pdf

⁴ https://www.paho.org/hq/index.php?option=com_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=1179&lang=en

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 **Costa Rica**, pharmaceuticals, drugs, cosmetics, medical devices and some chemical products, such as solvents, agricultural inputs and precursor chemicals used to produce narcotic drugs, must have import permits (valid for five years) and be registered with the Ministry of Health⁵. In addition, the Costa Rican Institute of Social Security (CCSS) Procurement Department requires bar code identification on all purchases of medicines and medical supplies upon entry into the Costa Rican market.

Surgical and dental instruments and machines can be sold only to licensed importers and health professionals. Also, regulations require that imported biomedical equipment and materials be registered with the Ministry of Health⁶. Under local sanitary registry regulations all dietary supplements and natural medicinal products should be registered with the Ministry of Health before being sold in Costa Rica⁷.

To register a medical device to sell in Costa Rica, approval from the Ministry of Health-from Costa Rica must be first obtained. It is also necessary to appoint a representative within the country and properly classify the device in accordance with the classification system of four levels of the Ministry of Health to enter the market of Costa Rica.

In **El Salvador**, medical devices, pharmaceuticals, and dental products are regulated under the 2012 Medicine Law. These products need to be registered at the National Medicine Directorate (DNM)⁸. In the case of medical devices, some products are excluded from the registration process.⁹ In addition, ionizing radiation devices or equipment require an import permit from the Radiation Protection Directorate at the Ministry of Health.

New and used medical equipment can be imported into El Salvador and needs to be registered at the DNM; however, used or refurbished equipment cannot be older than 10 years from the date of manufacture. In addition, exporters should be advised that a Good Manufacturer Certificate (GMC) is required when exporting new, used or refurbished equipment to El Salvador.

The **Guatemala** Division of Registration and Control of Medicines and Foods of the Ministry of Health issues import permits for medical devices, pharmaceutical products, and cosmetics. In addition, some products require an inscription (registration) at the registration office of the Ministry of Health¹⁰. These registrations need to be renewed every five years.

Surgical devices that require a registration are those classified as cutting the skin or a membrane, or which touch blood, such as syringes or finger pricks. Devices such as anesthetics and asthmatic inhalers, high-pressure measuring apparatus, laser-guided apparatus and others do not require a registration. These would be classified under medical equipment and supplies and undergo normal customs clearance procedures.

⁵<https://www.ministeriodesalud.go.cr/index.php/tramites/empresas/34-tramites/registros-2/160-registro-de-medicamentos>

⁶<https://www.ministeriodesalud.go.cr/index.php/tramites/empresas/28-tramites/registros/159-registro-de-equipo-material-biomedico-emb>

⁷<https://www.ministeriodesalud.go.cr/index.php/tramites/empresas/28-tramites/registros/156-registro-de-alimentos>

⁸<https://www.medicamentos.gob.sv/index.php/es/servicios-m/en-linea/expediente-electronico>

⁹ For a current list of excluded products please visit: <http://www.medicamentos.gob.sv/index.php/es/normativa-m/normativa-por-unidad-de-registro-de-insumos-medicos>

¹⁰ <https://medicamentos.mspas.gob.gt/index.php/servicios/autorizacion-de-productos-farmaceuticos-y-afines/registros-sanitarios> and <https://medicamentos.mspas.gob.gt/index.php/servicios/importacion-de-productos-farmaceuticos>

In Honduras the Ministry of Health (MOH) governs the sector, coordinates all health-related activities, sets health priorities, and charts the course of development efforts in the public and private subsectors. Product registration is required for all pharmaceuticals and is handled through the Sanitary Regulation Agency (ARSA), who issues the sanitary registration number (SRN) and is also in charge of inspection of medicines, natural products, cosmetics, medical devices and hygiene products approved to be sold at the retail and wholesale level¹¹. Requirements for obtaining sanitary licenses for medical devices vary in accordance with product classification and risk categories¹².

The Nicaragua Ministry of Health, Pharmaceutical Office, issues import permits for medicines, cosmetics and hygiene products. Importers must present documentation demonstrating safety and effectiveness and pay fees to obtain a sanitary registration, as well as fees for laboratory analysis¹³. The Ministry of Health also requires that pharmaceutical products be packaged and labeled in Spanish for retail distribution and that their dosages be clearly indicated. For companies interested in participating in government tenders, sample products must be submitted with the required labels in Spanish.

In Panama, it is mandatory to obtain previous authorization to import, develop, test and market a drug product by the manufacturer, distributor and importer (License). To market a product, a sanitary registration and a pharmaceutical or non-pharmaceutical License must first be obtained¹⁴. For testing, all trials must be approved by the Bioethical National Committee. Phyto-pharmaceuticals must be registered before being imported or marketed in the country.¹⁵

Importation, exportation, marketing and use of a medical device on a public or private level can be authorized once the applicant demonstrates with documental evidence that the medical device complies with all the security, efficiency and quality defined by international regulations. Also, the manufacturer and distributor need the authorization (License) to import and market medical devices.

Central American Mechanism for the Joint Evaluation of Drug Dossiers

In June 2021, the Pan American Health Organization (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.

¹¹ <https://www.arsa.gob.hn/requisitos-productos-farmaceuticos/>

¹² <https://www.arsa.gob.hn/requisitos-dispositivos-medicos/>

¹³ <https://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/>

¹⁴ <https://www.minsa.gob.pa/contenido/departamento-de-registros-sanitarios>

¹⁵ <https://www.panamadigital.gob.pa/InformacionTramite/registro-sanitario-a-medicamentos-fitofarmacos>

2. Market assessment

2.1.1. Market overview

The Pan American Health Organization (PAHO) recommends that states in Latin America and the Caribbean invest at least 6% of GDP in health, with 30% of that amount devoted to primary care. Costa Rica is the only Central American country that is close to comply with this recommendation.

Latin American pharmaceutical market is estimated grow with a compound annual growth rate (CAGR) of 7% through 2023, to reach a total value of US\$76 billion. Between 2012 and 2017, private investment in Latin America's pharmaceutical industry almost doubled from US\$ 68 billion to US\$ 110 billion¹⁶. This influx of private capital is also driving the development of new medical devices, treatments, and medications that revolutionize healthcare in Latin America.

In recent years, the healthcare industry in Central America has also shown significant progress, gaining recognition among pharma and OTC (over the counter drugs) companies as a promising region. The region's development supports the medium-term growth of the middle class and the enhanced accessibility of healthcare services. This situation is promoting the expansion of the healthcare, pharma, and OTC industries in Central America. In fact, the healthcare sector was valued at US \$17.8 billion in 2015 and the Pharma and OTC industry reached US \$4 billion and grew at 5.6%.¹⁷ Within the region, two countries stand out for their potential to generate business opportunities for EU companies: Panama and Costa Rica. Guatemala has also developed a relatively strong pharma manufacturing base, followed by El Salvador.

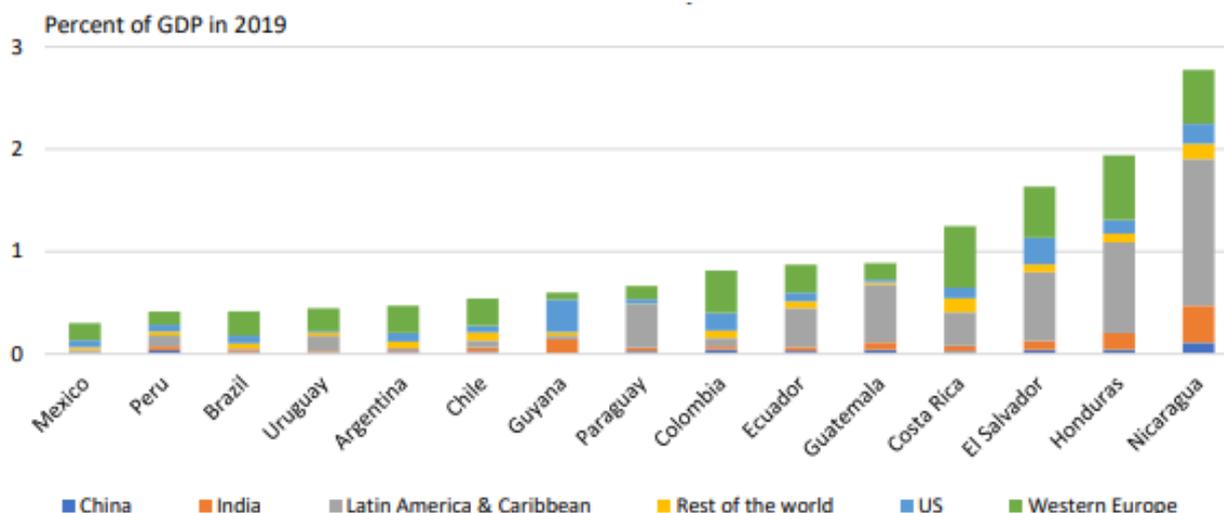
The region also offers relevant opportunities for biotech development. The most significant challenge for biotech development is the upfront risk of investing in a product that has not been tested on the market. Many devices and medications must be subjected to clinical trials and tests before they can debut on the market so a biotech startup cannot grow without capital like a bootstrapped fintech company or marketplace. These startups see a competitive advantage in Latin America: access to top scientists and hospitals with modern technology, for a fraction of the cost of a lab in the more developed countries.

Import shares by type of product vary with the importer's level of development. In upper-middle-income countries, such as Brazil, Argentina, and Colombia, biologics represent more than 25% of total pharmaceutical imports. The share falls below 5% in lower-income countries, where synthetic drugs account for the bulk of purchases abroad.

¹⁶ Biotech is Booming in Latin America: Here's Why", Nearshore Americas, 2019

¹⁷ "Discovering Untapped Business Opportunities for OTC and Pharma in Central America", Chamaleon Pharma Consulting, 2019

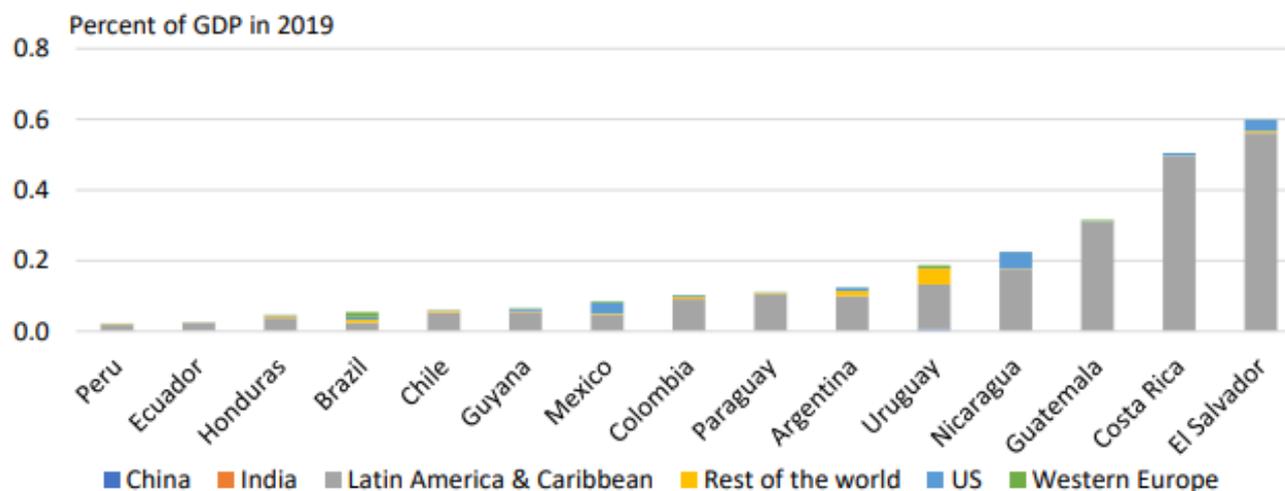
Pharmaceutical imports at the country level by origin¹⁸



At present, pharmaceutical exports from Latin America originate mainly in two distinct geographical areas: Mexico plus Central American countries on the one hand and South America on the other. Each of these two areas accounts for roughly the same export value.

Exporting Central American countries include Costa Rica, Guatemala, and El Salvador. Pharmaceutical exports account for a bigger share of GDP in Central American countries and Uruguay. The destination markets are different as well. Mexico and Central American countries lean toward the US market. In contrast, South America has more diversified destinations, primarily Western Europe, followed by the US, China, and India.

Pharmaceutical exports at the country level by destination



2.1.2. Trends and opportunities

Costa Rica has a very strong Medical Devices ecosystem, with more than 88 companies, including OEM's (Original Equipment Manufacturers), manufacturing contractors and suppliers, according to data from the country's investment promotion agency CINDE.

As a result, the Life Sciences industry has become the sector with the greatest impact on manufacturing and has become the number one exporter in Costa Rica since 2018. The country

¹⁸ Pharmaceuticals in Latin America and the Caribbean: Players, access, and innovation across diverse models, World Bank, 2022

has become the largest exporter of medical goods to the United States after Mexico. Such growth has translated into a strong economic and social impact, resulting in exports of US\$3.8 billion in 2020 and more than 38.000 direct jobs.

The Life Sciences industry in Costa Rica is the source of items such as medical-aesthetics devices, dental products, orthopedic and optical devices, and products used in endoscopy, among others. The presence of this wide variety of production is another reason Costa Rica is globally recognized as a top-tier player in the medical device industry.

The MedTech industry in Costa Rica is heading towards new areas that require greater customization, and which demand closer proximity to the target markets, faster and cheaper logistical solutions, the convergence of hardware and software applications, and human resources with a greater knowledge of the industry, a stronger relationship with science, and even professional profiles not yet in existence.

In addition to large companies such as Baxter, Abbott Labs, Boston Scientific, and others, the Life Sciences sector in Costa Rica has a volume of production that creates a lucrative space for companies that are suppliers of items such as raw materials and subcomponents, as well as of engineering services. Small and mid-sized companies can establish themselves in Costa Rica to become partners with the larger corporations in the country's Life Sciences sector in innovation and the creation of sophisticated, high value-added products.

It is also worth mentioning the National Center for Biotech Innovations (CENIBiot), a laboratory of the National Center of High Technology (CeNAT-CONARE) that works in the biotechnological scaling, with the purpose of promoting the development of biotechnology in the region. The CENIBiot Laboratory promotes accessibility to installed capacity in three sectors fundamental: academia, government and industry, supporting initiatives that strengthen the entrepreneurship, technology transfer and university-business relationship. It also works in the approach and linking of the different biotechnology managers at the regional level.

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. Supporting this are the Ministry of Health's efforts to solicit outside assistance to bolster health care provision in all quarters of the country. Despite improvements in the regulatory environment since the Medicine Law of El Salvador was approved in 2012, only a few international companies -mostly Latin American- have established in the country as result of underdeveloped infrastructure and manufacturing.

Guatemala is one of the largest pharma markets in the region of Central America. Guatemala is also one of the leading manufacturers in the region, and the largest supplier of pharmaceuticals to the Central American market. Investments in new medical equipment within the private healthcare sector are expected to continue, as new clinics and existing hospitals buy periodically to meet their equipment needs and continue to invest strongly in new technology, such as diagnostic and treatment equipment. Despite the economic difficulties faced by each country in the region, demand in this sector has not diminished, as 60% of service users have private medical insurance.

The healthcare industry's medical devices and equipment sector in **Honduras** is highly dependent on imports. However, despite the existing opportunities there is significant margin for improvement in its healthcare system and regulatory frameworks are still being consolidated. Public investment in the health sector is highly dependent on bilateral and multilateral donors.

In recent years **Nicaragua** has begun significant investments to improve and modernize the country's health care sector with the support of multilateral donors. As result of several new and renovated hospitals, specialized centers, a growing focus on oncology care, and additional

investments by the public sector and multilateral donors, there are multiple large-contract opportunities for international suppliers. Specialized and diagnostic equipment, pharmaceutical products, and hospital equipment all have growth potential in the country.

Panama's economy's strength in the last decade has been witnessed by the public funding for healthcare services and medicines, which is currently worth over US \$3 billion. Panama remains the largest importer of pharmaceutical drugs and medicines in Central America. Local demand is high, and the government is increasing access to healthcare for the majority of the population under a universal healthcare policy. Eighty percent of the population lives in urban areas contributing to ease of access, GDP has been growing steadily over the past years and the economy is one of the strongest and most stable in the region.

As the sector develops further, Panama aims to become a pharmaceutical hub for the region. Considering Panama's ideal geographic location between North and South America, maritime connectivity along the Panama Canal and Tocumen International Airport, which is the largest airport in the region, these factors make it a business-friendly place along with tax and fiscal incentives.

3. Entry barriers

From a general perspective, it is evident that physical distance, limited exposure and awareness, cultural differences and language may act as barriers for many new EU entrants to the Central American markets. Also, economies of scale may be difficult to achieve in several sectors due to limited market size, as well as logistics costs, and as a result these may also act as trade disincentives.

While there are no significant restrictions on the importation or marketing of medical equipment and pharmaceuticals, EU exporters often raise concerns with overly burdensome bureaucratic obstacles, and less-than-transparent processes applied by each individual country. This also limits intraregional trade, which fragments the markets, increases the registration costs and therefore reduces the attractiveness of the region for EU companies and, particularly, SMEs.

The best market entry strategy is to find a reliable and qualified local distributor or representative that is knowledgeable on the requirements and can expedite the processes before the relevant authorities.

Considering that the public sector is a key purchaser in the medical sector across the region, in some cases there may exist some additional challenges derived also from the not-very-clear procurement processes and the specifics of some contracts.

From another perspective, many well-established local distributors are used to being offered favorable credit terms by US exporters (very often 30 to 60 days open account credit terms). While this is not per se an entry barrier, working under these same terms may prove challenging to EU exporters, who normally require cash in advance or irrevocable letter of credit. US exporters also benefit from lower freight costs -even for small purchases, and shorter delivery times.

On another note, import of contraband and counterfeit pharmaceuticals -reportedly from India and China primarily, may also degrade the market and hinder introduction of products in the formal distribution channels, as there is a growing availability of substandard, falsified and unregistered medicines.

4. Competitive environment

The SWOT analysis presented below uses the following scopes:

- Strengths: positive, favorable features of the current development of the sector, and that make it attractive to EU businesses (e.g., favorable regulations or incentives, etc.)
- Weaknesses: constrains or negative features of the current development of the sector, that as result make it less attractive to EU businesses (e.g., small market size, costs of logistics of exports from the EU, etc.)
- Opportunities: external factors to the sector itself, or currently absent in the corresponding market, that may increase the attractiveness of the sector for EU businesses (e.g., growth drivers)
- Threats: external or potential, negative factors that may reduce the attractiveness of the sector for EU businesses or hinder their competitiveness (e.g., increasing competition).

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| STRENGTHS | WEAKNESSES | OPPORTUNITIES | THREATS |
| <p>Growing demand, both from the public sector and private health systems.</p> <p>Post-covid strengthening of healthcare networks.</p> | <p>Limited market size and fragmentation.</p> <p>Challenges to achieve economies of scale.</p> <p>Slow increase of purchasing power.</p> <p>Limited demand for high-tech, innovative devices.</p> <p>Bureaucratic obstacles, and less-than-transparent registration and authorization processes (also between Central American countries).</p> <p>Governments are financially constrained/ cost containment.</p> <p>Logistics costs from EU.</p> | <p>Limited local production (except medical devices in Costa Rica and relevant, though small, pharmaceuticals production in Guatemala and Panama).</p> <p>Clinical trials and tests: Guatemala, Costa Rica and Panama are among the 10 Latin America countries where a highest number of registered clinical studies is carried out</p> <p>In Costa Rica, development of a life sciences mega hub, including R&D and manufacturing opportunities.</p> <p>In Guatemala, opportunities for manufacturing OTC and generic drugs and distribution across LATAM.</p> <p>Biodiversity for Health biotechnology (HBT).</p> <p>Latin America is the fastest aging region in the world.</p> | <p>Limited number of double taxation avoidance agreements with EU countries to avoid impact of withholding tax may hinder potential for new entrants.</p> <p>Ongoing cooperation of Costa Rica with Israel and US.</p> |



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