



MARKET RESEARCH



PHARMACEUTICAL SECTOR 2026



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PART I

POLITICAL AND ECONOMIC SITUATION OF VENEZUELA



PART I

POLITICAL AND ECONOMIC SITUATION OF VENEZUELA

Geographic and Demographic Overview of Venezuela

Venezuela is located in the northernmost part of South America, bordering the Caribbean Sea to the north, the Cooperative Republic of Guyana and the Atlantic Ocean to the east, the Federative Republic of Brazil to the south, and the Republic of Colombia to the west. Its total area of 916,445 km² makes it the sixth largest country in Latin America ¹. The territory is administratively organized into 23 states, a Capital District, and Federal Dependencies, and is geographically articulated into five major natural regions: the Llanos region, the Andean region, the Coastal region, the Guayana region, and the Amazonian region.

In demographic terms, the National Survey of Living Conditions (Encuesta Nacional de Condiciones de Vida) produced by the Institute of Economic and Social Research of the Andrés Bello Catholic University (IIES-UCAB) estimates Venezuela's population at 29.37 million inhabitants for 2024², a figure that reflects the cumulative impact of sustained migratory outflows since 2015. The average population density is 30.8 inhabitants per km², although the distribution is markedly uneven: more than 75% of the population is concentrated in the northern coastal strip and in the country's central axis.

This extensive coastal strip, spanning more than 2,813 kilometers along the Caribbean Sea and 700 kilometers along the Atlantic Ocean, not only concentrates the majority of the population, but also grants the country a privileged geostrategic position as a gateway to Latin America. Its maritime location functions as a natural and direct channel linking the region to global markets in North America, Central America, the Caribbean, Europe, and Asia, while also facilitating access to the Panama Canal route.

Areas of Highest Population Concentration

The most populous states are Zulia (with its capital Maracaibo, the country's second most populated city), Miranda, Carabobo, Lara, and the Capital District (Caracas), which together concentrate approximately 55% of the national population³. The Caracas–Valencia–Maracay axis represents the country's highest-density industrial and services corridor. Venezuelan agricultural production also has a significant presence in this central strip, particularly regarding horticulture in the valleys of the coastal mountain range⁴.

This demographic and industrial concentration in the north-central and western regions of the country greatly facilitates commercial penetration, given the strategic proximity to the main maritime

¹https://www.exteriores.gob.es/documents/fichaspais/venezuela_ficha%20pais.pdf

²https://cdn.prod.website-files.com/5d14c6a5c4ad42a4e794dof7/6803aeed2dfc5c19a4ac96cd_ENCovi%202024_presentacio%CC%81n_integrada.pdf

³<https://www.proyectoencovi.com/encovi-2024>

⁴<https://www.fao.org/venezuela/venezuela/venezuela-en-una-mirada/es/>



terminals. With the majority of consumers concentrated within very short distances of key infrastructure such as Puerto Cabello, La Guaira, and the port of Maracaibo, a logistical advantage is created that expedites distribution and direct supply of the domestic market. These terminals thereby function as direct gateways to the most populated areas, reducing transit times. In this context, port economics function as the main artery of the nation's commercial and fiscal activity. Although in recent decades this model gave rise to a deep dependence on consumer goods imports, port infrastructure remains the irreplaceable engine for Venezuelan exports.

Areas of Lowest Population Concentration

The states with the lowest population density are located in the south and southeast of the country. The states of Amazonas, Delta Amacuro, and Bolívar have the lowest relative density, despite together covering more than 35% of the national territory⁵. This low density is explained by tropical rainforest coverage, a scarcity of road infrastructure, and the remoteness from consumption centers, although these regions hold the country's largest natural resource reserves, particularly those near the Orinoco Mining Arc (AMO).

Primary Mining Areas

Venezuelan mining activity is fundamentally concentrated in the Orinoco Mining Arc (AMO), which covers an area of more than 113,598 km² in Bolívar state, equivalent to 12.4% of the national territory, where reserves of gold, diamonds, coltan, copper, iron, and bauxite are found, with the potential participation of 150 companies from 35 countries⁶.

Venezuela holds the world's largest proven oil reserves, with approximately 303 billion barrels according to data from the Organization of the Petroleum Exporting Countries (OPEC), a figure confirmed by multiple international organizations including the U.S. Energy Information Administration (EIA) and the BP Statistical Review⁷. The majority of these reserves are located in the Orinoco Oil Belt, situated across the states of Anzoátegui, Monagas, Guárico, and Apure, followed by reserves in the country's northwest in the states of Falcón and Zulia⁸.

Primary Agricultural Areas

Venezuelan agricultural production is concentrated in the west-central and plains regions. Its geographic location gives the country strong potential for tropical agriculture, enabling high yields in permanent crops such as coffee, cocoa, oil palm, and fruit trees, or semi-permanent crops such as sugarcane, plantain, and cassava⁹. Portuguesa state is the country's main agricultural hub: with

⁵ <https://www.proyectoencovi.com/encovi-2024>

⁶ https://www.sinembargo.mx/4746786/datos-tiene-petroleo-gas-oro-tierras-raras-venezuela-es-el-gran-pastel-para-eu/?_cf_chl_tk=NpjU6B6qRVeeIWxVKx6JqdmW8.tVq3mNM_7i3IsLyVg-1781282300-1.0.1.1-ij62Lt12LNRFLcleePItUmuoJ8EmdWyY.iCRwKl.gU

⁷ <https://www.elimparcial.com/mundo/2025/12/01/venezuela-posee-303000-millones-de-barriles-de-petroleo-la-mayor-reserva-probada-del-mundo-confirmada-por-organismos-internacionales/>

⁸ <https://www.analitica.com/economia/pdvs-reservas-probadas-de-petroleo-de-venezuela-superan-los-300-800-millones-de-barriles/>

⁹ <https://www.fao.org/venezuela/venezuela/venezuela-en-una-mirada/es/>



approximately 800,000 hectares suitable for farming, it generates more than 50% of national maize production, 65% of rice, and 52% of sugarcane¹⁰.

The states of Barinas, Guárico, Cojedes, and Apure complete the plains axis of cereal and livestock production. In the Andean region, the states of Mérida, Táchira, and Trujillo concentrate production of vegetables, potatoes, and coffee, with family-based operations adapted to hillside topography. Zulia state, in its Sur del Lago de Maracaibo sub-region, is the country's leading producer of plantain and oil palm. The states of Aragua, Carabobo, and Yaracuy form the central agro-industrial axis, with production of sugarcane, maize, and vegetables¹¹.

Political-Economic Perspectives and Institutional Reforms

Currently, the country is in a political situation of instability and forced environmental changes—especially in the political and economic spheres. De facto power operates under the figure of Delcy Rodríguez as acting president following her swearing-in on January 5, acting parallel to the influence of the United States in the process. According to the announcement by the United States Secretary of State, Marco Rubio, the evolution of events for Venezuela is projected in three operational phases: stabilization, economic recovery, and transition¹².

In this process, there coexists internal tensions between the interim government—whose stabilization depends on the support of the armed forces and U.S. approval—and opposition forces backed by the international community, which demand greater clarity regarding the process termed "transition." Despite the resilience of the Venezuelan economy, where the adoption of digital payments, de facto dollarization, and the adoption of crypto assets by people have guaranteed momentary stability, the inflation projection estimated by the International Monetary Fund (IMF) remains high for 2026, posing a hyperinflation scenario of 628.8%¹³. This, of course, with variables subject to unpredictability—and with the possibility of changes favoring market dynamics that were not considered by the study.

Therefore, in accordance with on-site events, diagnoses made by national or multilateral organizations are conditioned by the decisions that are made daily within public branches of government. Namely, the positive socioeconomic reforms are already materializing, such as the partial reform of the Ley de Hidrocarburos (January 2026)¹⁴—which, fundamentally, allows for greater private participation—the approval of the Industrial Property and Socioeconomic Rights Laws, and the contemplation of future laws regarding administrative dynamization or electrical modernization¹⁵. This acts as a catalyst for the economy, and the effectiveness of the reforms and proposals—beyond their legislative approval—can modify the initial perspectives on the evolution of the Venezuelan economy for the coming years.

¹⁰ <https://fedegro.org/wp-content/uploads/2025/03/Resultados-2024-WEB.pdf>

¹¹ Ibid.

¹² <https://www.bbc.com/mundo/articles/cwywpdoxnzo>

¹³ <https://www.bloomberglinea.com/latinoamerica/venezuela/fmi-proyecta-inflacion-de-682-en-venezuela-en-2026-ademas-de-contraccion-en-su-economia/>

¹⁴ <https://www.bbc.com/mundo/articles/cg7y4kznypgo>

¹⁵ <https://www.asambleanacional.gob.ve/noticias/parlamento-aprueba-plan-basico-legislativo-2026-2027>



Preliminarily, the expectations and reception of the domestic and foreign markets have been positive. For example, the exchange rate gap decreased to 34.94%¹⁶ in early 2026, which is a significant improvement compared to the 90% recorded in December 2025¹⁷; this reduction acts as a natural stabilizer, as it slows down the implicit devaluation of purchasing power and grants greater predictability in price structure to producers and consumers, which is vital for projecting the demand for goods. Also, a 30%¹⁸ revaluation of the country's government bonds and those of PDVSA (the national company that monopolizes the hydrocarbon sector) was perceived, indicating that external anticipation of possible economic and institutional changes manifests favorably for the productive environment.

Within this framework, given the instability in the Middle East resulting from the conflict between Iran and the United States, Venezuela positions itself as a relevant actor in the international arena. This is because, in the short term, the increase in oil prices stimulates the demand for B2B services, corporate technology, and logistics, and improves general macroeconomic conditions, benefiting all sectors of the economy due to the interconnection between the economy and oil. However, in the long term—the one considered due to the unpredictability of the conflict's extension keeping prices high—Venezuela, as an energy provider for the United States and Europe, positions the country as an attractive hub for investments, which will possibly impact the country's productive environment, which boasts enormous potential.

Because Installed Capacity Utilization (ICU) is around 52%¹⁹, Venezuela's strategic relevance in the hydrocarbon sector can materialize into growth across various high-growth sectors, such as those previously mentioned, by taking advantage of this idle capacity. Despite the optimism, basic infrastructure—such as the electrical grid—and monetary and fiscal policies—legal reserve requirements and tax levels—need favorable reforms for the productive sector in order to achieve the aforementioned production possibilities.

Economic Growth and GDP Dynamics

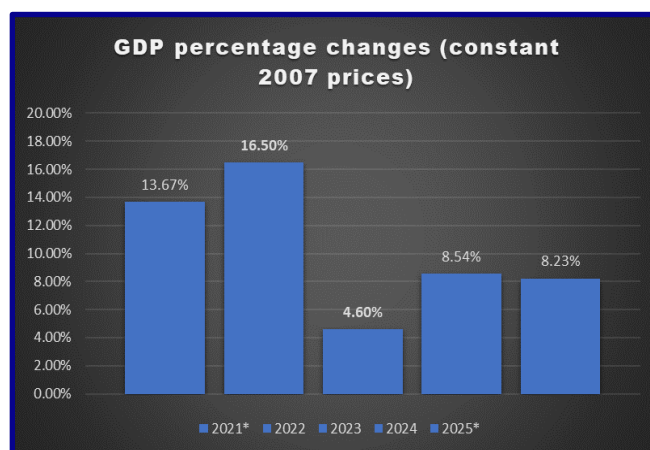
According to data provided by Banco Central de Venezuela (BCV) from the second quarter of 2021 to the third quarter of 2025, the Venezuelan economy has shown pronounced variations in its economic growth, with high growth rates (16.50%) in 2021, while shows difficulties for its consolidation, with a sharp drop in 2023 and a gradual recovery in the subsequent years.

¹⁶ <https://www.bcv.org.ve/estadisticas/tipo-cambio-de-referencia-smc> <https://monitordolarve.com/precio-del-dolar-en-venezuela-hoy-tasa-bcv-y-monitor-27-de-febrero-de-2026/>

¹⁷ <https://bitacoraeconomica.com/economistas-brecha-cambiaria-muertesubasta-bcv/>

¹⁸ <https://www.bloomberglinea.com/mercados/bonos-de-venezuela-y-pdvsa-suben-mas-de-30-en-la-semana-pero-hay-desafios-por-delante/>

¹⁹ <https://finanzasdigital.com/conindustria-capacidad-instalada-2025/>



Source: Own elaboration, based on data from Banco Central de Venezuela and the International Monetary Fund²⁰.

Now, in the following table, a comparison is made between Banco Central de Venezuela (BCV) and international multilateral organizations, comparing the percentage growth of the country's Gross Domestic Product (GDP). The most significant contrast is demonstrated in the data provided by the International Monetary Fund (IMF), which has projected notably lower percentages in 2024 and 2025 compared to those presented by the other organizations.

Percentage GDP growth			
Entity	2023	2024	2025*
BCV	4.6	8.54	8.23
ECLAC ²¹	3.2	8.5	6.5
UNDP ²²	4.7	8.5	5.8
IMF ²³	4	5.3	0.5

*2025 figures updated as of the end of the third quarter.

The growth currently observed in Venezuela, as a primarily oil-based economy, is attributed to the reactivation of the industry following its most critical years, spanning from 2014 to 2020: In

²⁰ Banco Central de Venezuela (2025). *Producto Interno Bruto*. Estadísticas. <https://www.bcv.org.ve/estadisticas/producto-interno-bruto>. Banco Central de Venezuela. (2025, 16 de octubre). *La economía venezolana avanza: El PIB aumentó 8,71% en el tercer trimestre de 2025*. Nota de Prensa. <https://www.bcv.org.ve/notas-de-prensa/la-economia-venezolana-avanza-el-pib-aumento-871-en-el-tercer-trimestre-de-2025>

Banco Central de Venezuela. (2025, 01 de mayo). *La economía venezolana continúa avanzando: El PIB creció 9,32% en el primer trimestre de 2025*. Nota de Prensa. <https://www.bcv.org.ve/notas-de-prensa/la-economia-venezolana-continua-avanzando-el-pib-crecio-932-en-el-primer-trimestre>

Banco Central de Venezuela. (2025, 22 de Julio). *La economía venezolana creció 6,65% en el segundo trimestre de 2025*. Nota de Prensa. <https://www.bcv.org.ve/notas-de-prensa/la-economia-venezolana-crecio-665-en-el-segundo-trimestre-de-2025>

International Monetary Fund. (s.f.). *Real GDP growth, Annual Percent Change*. Datamapper. https://www.imf.org/external/datamapper/NGDP_RPCH@WEO/VEN?zoom=VEN&highlight=VEN

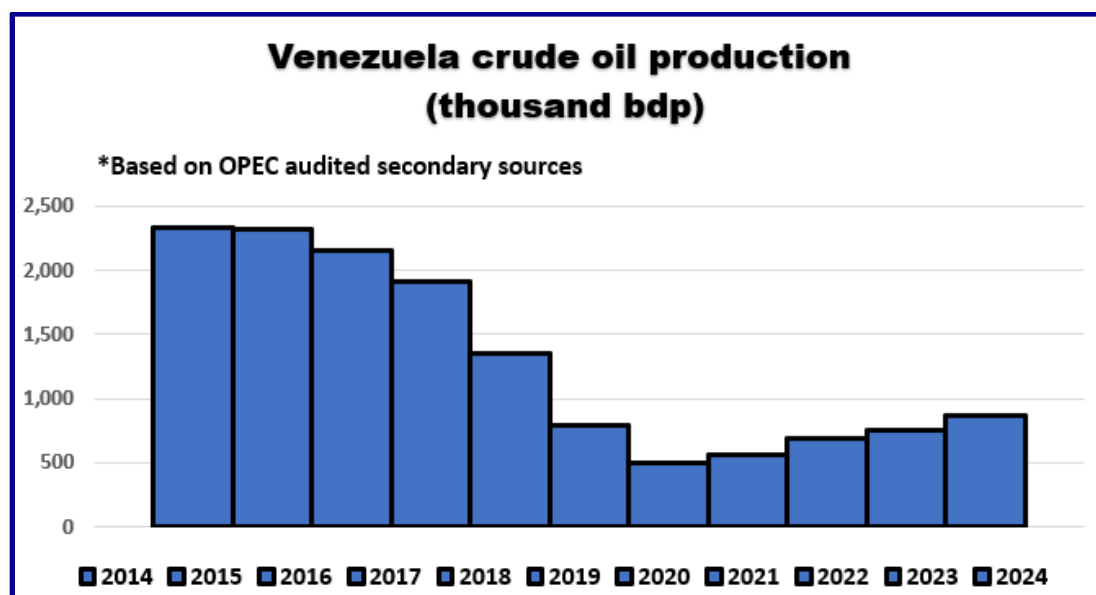
²¹ p129. <https://www.cepal.org/es/publicaciones/84460-balance-preliminar-economias-america-latina-caribe-2025>; https://www.cepal.org/sites/default/files/pr/files/tabla_prensa_pib_estudioeconomico2023-esp.pdf <https://www.mppef.gob.ve/venezuela-cierra-2023-con-un-crecimiento-economico-sostenido/>

²² <https://www.undp.org/es/venezuela/publicaciones/desempeno-macroeconomico-de-venezuela-tercer-trimestre-2025>

²³ <https://www.undp.org/es/venezuela/publicaciones/desempeno-macroeconomico-de-venezuela-tercer-trimestre-2025>



contrast, for 2024, according to the Macroeconomic Performance Bulletin of Venezuela²⁴, oil activity generated at least 90% of foreign exchange, consolidating itself as the country's main source of income. Consequently, the rest of the non-oil productive sectors, which represent 89% of the economy and are considered a non-tradable sector, operate under an adverse efficiency and competitiveness environment. The correlation between these indicators and oil production is evident when considering the influence of oil production on macroeconomic indicators and, therefore, on all productive sectors of the country. Currently, oil production averaged 1,064 thousand barrels per day between January and December 2025, marking the country's best result since 2019 (UNDP, 2025)²⁵.



Source: Own elaboration based on OPEC annual reports (2014-2024)²⁶.

Likewise, the UNDP estimates that GDP growth in the third quarter of 2025 will reach 8.7%, driven primarily by the oil sector, which grew by +16.1%, and the non-oil sector, which recorded a +6.1% increase. According to BCV figures, although the recovery in non-oil activities such as construction (+16.40%), transport and storage (+9.35%), manufacturing (+8.98%), commerce, along with vehicle repair (+8.19%) and mining (+7.08%) have contributed positively to annual growth, significant challenges remain for their actual influence on the GDP.

Inflation and Purchasing Power

In particular, it is observed that these sectors operate in a context of high inflation, accelerated exchange rate depreciation, and a continuous loss of household purchasing power²⁷. These conditions

²⁴ https://www.undp.org/sites/g/files/zskgke326/files/2025-04/boletin_pnud_4to_trimestre_digital.pdf

²⁵ https://www.undp.org/sites/g/files/zskgke326/files/2025-12/reporte_macroecomico_nov25_digital.pdf

²⁶ <https://www.opec.org/assets/assetdb/annual-report-2021.pdf> 2021 - 34,

<https://www.opec.org/assets/assetdb/annual-report-2022.pdf> 2022 - 33,

<https://www.opec.org/assets/assetdb/annual-report-2023.pdf> 2023 - 23,

<https://www.opec.org/assets/assetdb/annual-report-2024.pdf> 2024 - 23,

<https://www.opec.org/assets/assetdb/annual-report-2020.pdf> 2020 - 36,

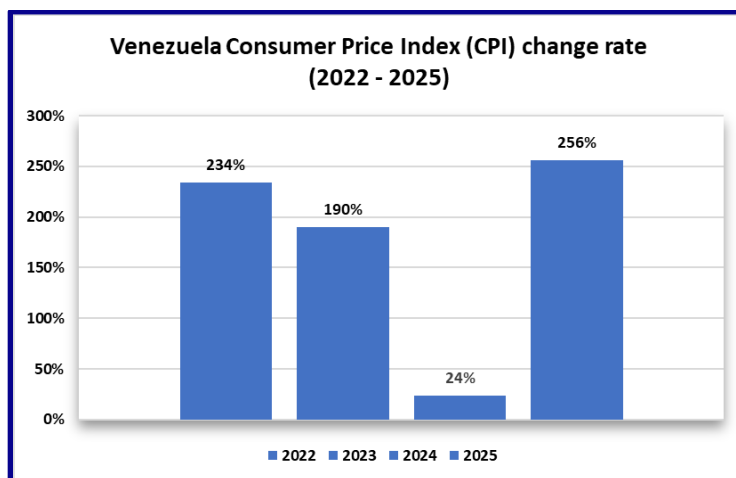
<https://www.opec.org/assets/assetdb/annual-report-2019.pdf> 2019 - 36,

<https://www.opec.org/assets/assetdb/annual-report-2018.pdf> 2018 - 36-37.

²⁷ <https://www.bcv.org.ve/notas-de-prensa/la-economia-venezolana-avanza-el-pib-aumento-871-en-el-tercer-trimestre-de-2025> and

https://www.undp.org/sites/g/files/zskgke326/files/2025-12/reporte_macroecomico_nov25_digital.pdf

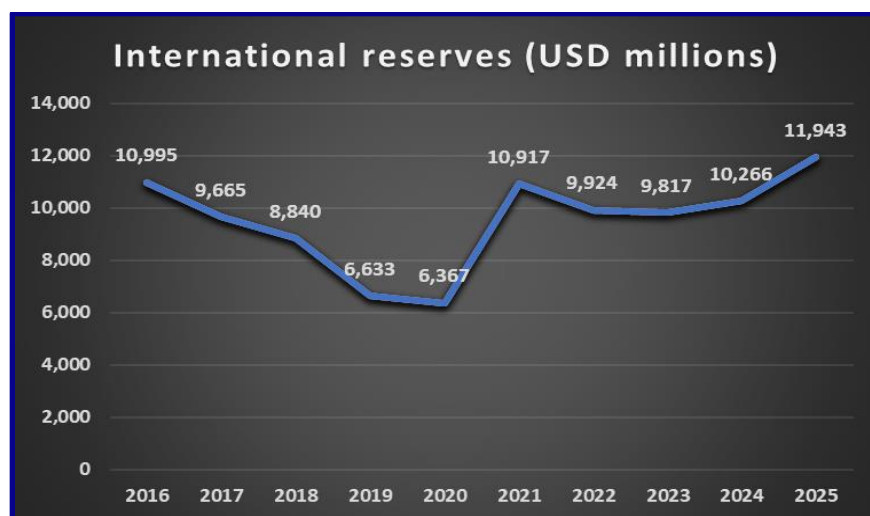
limit the ability of the non-oil productive sector to contribute effectively given the progressively declining demand, fiscal or operational costly requirements, and limited access to credit. In that vein, inflation has remained around 250% for 2025. Reality that, given the expectations of economic reforms, the progressive increase in oil production, and the facilitation of its export under the new political conditions, projects to the economy a scenario of moderate inflation.



Source: Own elaboration, data from ECLAC and UNDP.

International Reserves and External Debt

On the other hand, regarding international reserves, a gradual recovery is observed compared to the year 2020, Venezuela's lowest point in 45 years. The pressure created on the external balance has progressively diminished; however, the delayed pace of recovery denotes risks to macroeconomic sustainability in the face of rising external debt and a foreign exchange market constantly intervened by the State for exchange rate stabilization.

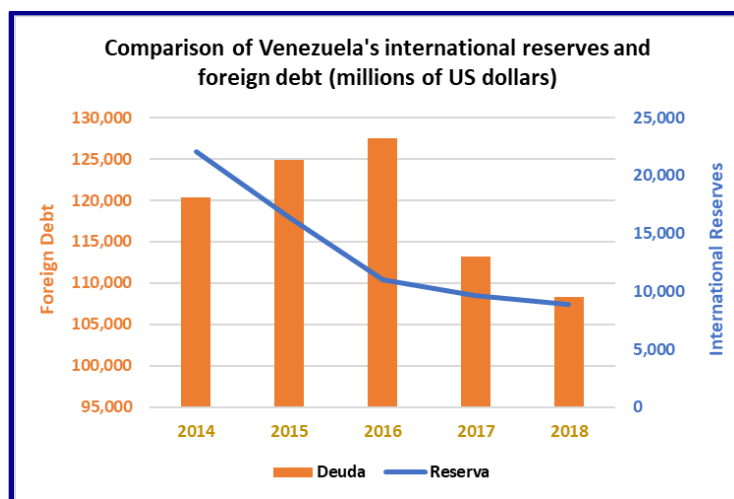


Source: Own elaboration, data from Banco Central de Venezuela²⁸.

²⁸ <https://www.bcv.org.ve/estadisticas/reservas-internacionales>



Regard to the external debt—according to available data—, it has shown an upward trend, which contrasts negatively with the increase in the country's international reserves. It is estimated that, in recent years, the imbalance between debt and international reserves has damaged Venezuela's international investment position globally.



Source: Own elaboration, data from Banco Central de Venezuela²⁹.

International Reserves Trade Balance and Bilateral Relations

Venezuela's trade dynamics in recent years have resulted in a trade balance that depends on the volatility of hydrocarbon sector revenues and, consequently, on the international licenses permitted to Venezuela in this area. In 2024, the increase in oil production and the rise in external sales, especially from Chevron and Repsol, elevated the value of both total exports and total imports³⁰. In parallel, this increase, coupled with the inflow of remittances, has contributed to generating a positive balance in the current account.

Regarding income distribution, 53% originated in Asia, 22% in the United States, and the remainder was managed by independent operators³¹. On its part, Ecoanalítica points out that for 2024, oil-related GDP grew by 11.8%, while non-oil GDP increased by 3.8%.

Meanwhile, for 2025, non-oil exports have recently grown, positioning themselves between 66% and 87% compared to 2024, highlighting items such as rum, marine resources (shrimp, crabs), and other raw materials (such as coffee, fruits, wood chips, and cement)³². Overall, the sectors that saw a production increase that year were: oil, agriculture, food industry, pharmaceuticals, paper, auto parts, plastics and rubber, technology, and commerce³³.

In perspective, according to the Observatory of Economic Complexity³⁴, Venezuela exported approximately 3.69 billion dollars and imported 20.6 billion dollars in 2025 from India, resulting in a

²⁹<https://www.bcv.org.ve/estadisticas/reservas-internacionales> and <https://www.bcv.org.ve/estadisticas/deuda-externa>

³⁰ <https://acading.org.ve/wp-content/uploads/2025/03/Balance-de-la-economia-venezolana-2024-y-perspectivas-2025.-Alejandro-Gutierrez.pdf>

³¹ <https://www.elnacional.com/2026/01/balance-del-comercio-exterior-venezolano-2025-y-perspectivas-2026/>

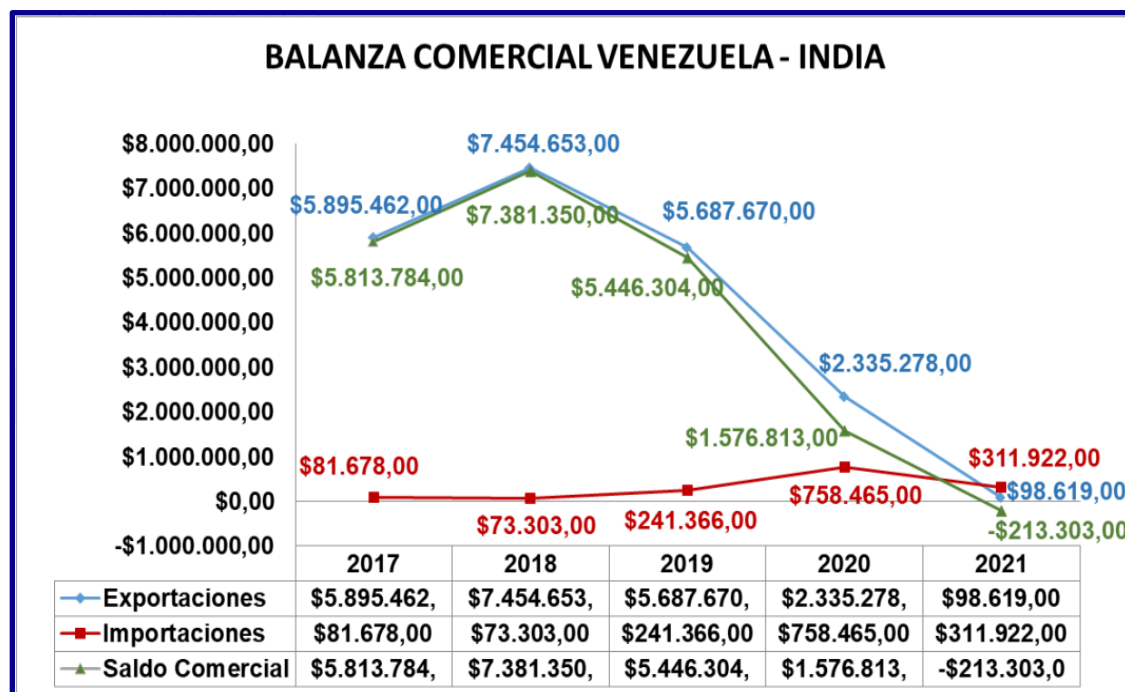
³² <https://www.elnacional.com/2026/01/balance-del-comercio-exterior-venezolano-2025-y-perspectivas-2026/>

³³ <https://www.elnacional.com/2026/01/balance-del-comercio-exterior-venezolano-2025-y-perspectivas-2026/>

³⁴ <https://oec.world/es/profile/bilateral-country/ven/partner/ind>



negative balance of 17 billion dollars for Venezuela. The main exports from Venezuela to India, by November 2025, were aluminum products, lead, and their derivatives; while the majority of imports were medicines, ceramics and related products, paper and its derivatives. The Banco de Comercio Exterior (BANCOEX) developed the following chart tracking the trade balance between both countries.



Source: Banco de Comercio Exterior (2023)³⁵.

³⁵ <http://www.bancoex.gob.ve/wp-content/uploads/2024/02/Perfil-Pais-INDIA-2023.pdf>



PART II

EXCHANGE MARKET AND PAYMENT MANAGEMENT



PART II

EXCHANGE MARKET AND PAYMENT MANAGEMENT

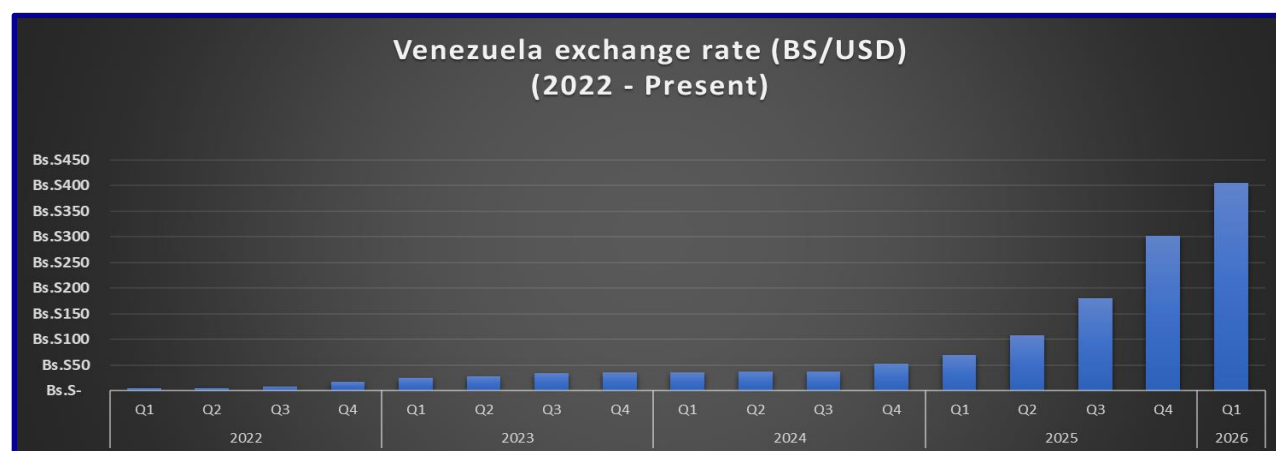
Characteristics of the exchange market in Venezuela

Historically, the Venezuelan exchange market has reflected the evolution of the country's balance of payments and a close connection with oil revenues³⁶. In this sense, the State has attempted to maintain a fixed exchange rate which, combined with an expansionary monetary policy, has generated capital flight and parallel markets.

The main characteristic of the exchange market has been an overvaluation of the "digital bolivar"³⁷ as it has transitioned through multiple exchange control systems (RECADI, OTAC, CADIVI, SITME, SICAD, CENCOEX), a characteristic that, coupled with the fall in oil revenues and the monetization of the fiscal deficit by the BCV, generated the hyperinflationary cycle that reached its peak in 2018. In the last five-year period (2021-2026), following the repeal of the Illicit Exchange Law (2018) and the entry into force of Exchange Agreement No. 1³⁸, the State allowed—in practice—the free convertibility of the currency and the circulation of the dollar; which generated a temporary price stabilization due to spontaneous transactional dollarization, breathing life into commerce and allowing the industry to set prices and trade in foreign currency.

Dynamics of the exchange rate gap and supply deficit

By 2023, the BCV adopted a progressive injection of cash dollars into the foreign exchange market to meet the demand for foreign currency and, as these stipulate the price of goods and services, contain inflation. In parallel, the Large Financial Transactions Tax (IGTF, for its Spanish acronym) was implemented for payments in foreign currency, in order to maintain the traceability of the bolivar and prevent total dollarization. However, starting in 2024³⁹, the real market demand for foreign currency exceeded the BCV's monetary injections.



Source: Own elaboration, data from Banco Central de Venezuela.

³⁶ https://frrodriguez.web.wesleyan.edu/docs/Books/Venezuela_Anatomy_of_a_Collapse.pdf

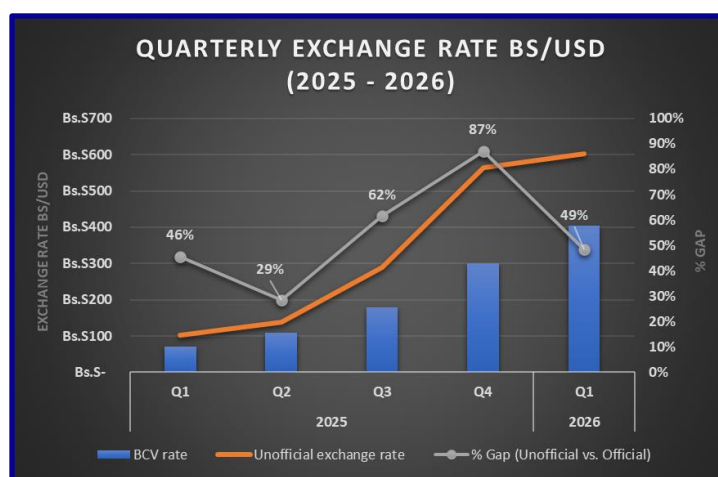
³⁷ Which, for the purposes of this report, we will refer to hereafter as "bolivar".

³⁸ https://petroleosdeamerica.com/VENEZUELA/ARCHIVOS/Gaceta_Oficial_07_09_18_num_Extra_6405.pdf

³⁹ <https://observatoriodefinanzas.com/>, dollarization index.



Hence, after a gradual devaluation, when the unsatisfied demand for foreign currency exceeded its supply in 2025⁴⁰, the demand shifted to the unofficial market, which widened the exchange rate gap. The exchange rate gap—which, in other words, is the reflection of the foreign exchange supply deficit at the official rate—accelerates the currency devaluation by the Central Bank, in order to close the arbitrage window and optimize the State's fiscal cash flow, which allows reducing the necessary injection of foreign currency—mostly coming from international reserves—into the exchange market. This dynamic makes it possible to regularize the supply and demand of the foreign exchange market, restoring the price signals necessary for the proper functioning of the economy.



Source: Own elaboration, data from Banco Central de Venezuela and monitordolarve.com⁴¹.

Faced with this reality, the impact is negative on a domestic industry whose production is affected by imports (for the acquisition of raw materials and intermediate goods), as a result of the historical overvaluation of the bolivar and specialization in the hydrocarbon sector, which has increased production costs and makes goods less competitive. The exchange rate gap forces domestic producers who bill at the official rate to decapitalize. While their replacement costs—inputs, spare parts and raw materials, and risk coverage—are implicitly priced at the parallel dollar given the shortage of foreign currency in the official exchange market, their profits are accounted for in bolivars. This situation, according to the economic sector and inflation, worsens in accordance with the business production cycle. The initial real value of the bolivar compared to the real value of the bolivar collected at the end of the cycle is lower than what is necessary to cover replacement costs.

Therefore, the merchant is faced with limited options. If they adjust their prices in bolivars to cover the replacement cost, the nominal price at the official rate skyrockets, exposing them to national regulations or forcing them out of the market. In addition, economic agents, aware of the exchange disparity, are encouraged to make purchases in bolivars as a form of market arbitrage, limiting the access to foreign currency by businesses. Coupled with this, when taxes are paid in bolivars on accounting profits that do not reflect economic reality, accounting books generate nominal profits that

⁴⁰ <https://www.bcv.org.ve/estadisticas/balance-general-al-31012026>, <https://www.ucab.edu.ve/investigacion/centros-e-institutos-de-investigacion/iies/informes-de-coyuntura/>

⁴¹

https://monitordolarve.com/?fbclid=PAVERFWAQP9z9leHRuA2FlbQIxMABZcnRjBmFwcF9pZA8xMjQwMjQ1NzQyODcoMTQAAad3feHLCsM8GwzY4frZP6gnd9kmbFkTDKJVH-J8pfGf7g4GBrBLOYE-f3CU7Q_aem_j1gX3PRnbjBPuZ9FLJUxnw



force the entrepreneur to pay proportionally high taxes (with respect to their real profit), which contributes to the decapitalization of businesses.

Thus, its impact is reflected both in economic terms (decapitalization) and in operational or transactional costs. Companies have to manage a bi-monetary ecosystem, that is, bolivars in national accounts, cash dollars, and dollars in foreign accounts or digital wallets, each with a different value and liquidity in order to reduce the costs generated by the exchange rate differential; along with the administrative cost of reconciling this reality.

Challenges for international capital and repatriation of dividends

However, for international capital, the exchange rate gap raises the country's risk premium regarding the repatriation of dividends. Finding a limited supply of foreign currency, or competing against a large demand for it in the domestic market, earning profits in bolivars limits its convertibility into foreign currency for repatriation due to market illiquidity. Also, companies are exposed to legal compliance risks and the operational difficulties of valuing their assets. Using the official rate would artificially overvalue assets, while using parallel valuation contravenes the accounting regulations of the country of origin⁴², thus complicating the financial statements of transnational companies.

In accordance with the above, the complicated situation of the exchange rate market, characterized by the exchange difference and the lack of capital (due to operational decapitalization), forces economic actors to diversify traditional banking options in search of new forms of settlement. The difficulty of accessing foreign currency in the official market, coupled with the need to safeguard the value of productive operations, drives companies towards more flexible payment management. In this context, the financial structure of businesses ceases to be just an accounting aspect and becomes a strategy, using tools that allow them to overcome both the lack of local liquidity and the isolation from the international banking system.

Understanding the scenario of uncertainty in recent years, carrying out international transactions has become an exercise in financial complexity. This is mainly due to Venezuela's disconnection from the "global network" regarding the payment system with respect to the economic order, backed by the Western Hemisphere and adopted by the rest of the world, where Venezuela is isolated from the SWIFT system, embodying in its image the phenomenon of over-compliance for foreign investors. In this regard, there is a real impact of the restrictions on the BCV and public banking, which turns private banking into the only (and narrow) bridge to the SWIFT system. Nevertheless, despite the existence of this link, international banks fear indirect sanctions from contact with Venezuelan banks, resulting in even transactions to non-sanctioned companies being rejected, subject to meticulous review, or to internal consideration due to the degree of risk exposure.

It is in this context where there are increases in banking transaction costs, and waiting times affect not only the exchange itself, but also subject organizations to presenting rigorous reports and documents justifying the origin and destination of each movement to ensure transaction transparency. This forces banking entities to work in bureaucratic structures parallel to the global banking network, while having to adhere to its rules and considerations.

⁴² https://petroleosdeamerica.com/VENEZUELA/ARCHIVOS/Gaceta_Oficial_07_09_18_num_Extr_6405.pdf



However, the private sector has developed mechanisms to ensure operability despite the barriers. In this regard, one of the considered solutions refers to payment triangulation where, through "payment service providers (PSPs)" and accounts in jurisdictions such as Panama, the U.S. or Europe, cash flow has been mobilized outside Venezuelan jurisdiction⁴³. Domestically, the country has moved towards digitalization, achieving 98% digital transactions through tools such as: mobile payment (P2P/C2P), bank transfers (VES), biopago, and foreign currency custody accounts that act as an operational value refuge. Some of these allow companies to manage dollars within the national system, although their mobility abroad is restricted, enabling a certain normalization in economic flow and value safeguarding.



Source: Raylí Luján in Bloomberg Línea (2023), based on information from Ecoanalítica⁴⁴.

In Venezuela, the integration of crypto assets and stablecoins such as USDT or USDC has been demonstrated as a tool for economic survival in the face of distortions in the local financial system. This practice allows small and medium-sized companies to expedite their international B2B payments, achieving an immediacy given the constant need for market revaluation. It is a model that strictly responds to an operational need within an environment with limited access to global banking, a situation that we hope will become less of an issue as we move forward with our phased implementation following the current circumstances.

This ecosystem operates under the supervision of SUNACRIP, which defines these assets as intangible personal property, but their use entails significant tax challenges that limit their appeal as a simple savings alternative. Operations are subject to a robust tax burden that includes additional VAT rates, ranging between 5% and 25%, in addition to the application of the Large Financial Transactions Tax (IGTF), which considerably raises the costs of each movement. Consequently, the Venezuelan

⁴³ <https://publications.iadb.org/publications/spanish/document/Fintech-en-América-Latina-y-el-Caribe-un-ecosistema-consolidado-con-potencial-para-aportar-a-la-inclusión-financiera-regional.pdf>

⁴⁴ <https://www.bloomberglinea.com/2023/06/09/en-venezuela-circulan-us4825-millones-en-efectivo-mientras-aumentan-transacciones-en-divisas/>



model does not present itself as a deregulated route, but as a complex accounting management structure. Companies are forced to balance their cash flows between bolivars, foreign currency, and crypto assets, facing an environment where transactional agility is counterbalanced by strict and costly state tax control. This reality reflects that adoption in the country is a technical response to systemic problems and not a frictionless preference.

Future expectations: towards a return to the financial system

In that perspective, the resolution of these obstacles does not depend solely on technical tools, but on the recovery of trust in institutions, as well as the flexibilization of international sanctions, whose status is on hold following the ongoing economic rearrangement. At present, although a possible reintegration of Banco Central de Venezuela (BCV) into the global system is being discussed, the changing reality and the existing dependence on foreign exchange flow must be taken into account. Meanwhile, as the formal supply of foreign currency stabilizes and cost dispersion is reduced, companies will continue to operate under a traditional hybrid system, influenced by international digital wallets and digital asset exchange, configuring a payment management system with logistical challenges, adaptable solutions, and a uniqueness in replicability worldwide.

As events that contribute to macroeconomic stability occur, such as the decrease in the exchange rate gap—which has decreased by up to 60% in two months—, oil revenues increase due to the world's geopolitical reality, and the gradual insertion of Venezuela into the international financial system without restrictions takes place; the productive apparatus will be boosted. Furthermore, since the population's adoption of different payment methods has taken place, companies will face a favorable scenario to diversify their collection channels and prioritize those methods that optimize their profitability.



PART III

GENERAL CHARACTERISTICS OF THE PHARMACEUTICAL SECTOR IN VENEZUELA



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The new hybrid model: recovery and investment incentives

The Venezuelan pharmaceutical market is undergoing a sustained recovery following the critical point reached in 2018. Following a period of structural transformation that included the departure of transnational companies and the absorption of their market share by national laboratories and branded generics, a hybrid operational model was established. This model consists of a domestic production that covers 90% of market units and a strategic opening to international alliances—especially with India—which guarantees the supply of high-complexity molecules. These include molecules associated with biological or technological medicines featuring large, three-dimensionally intricate chemical structures found in insulins, hormonal therapies, oncological treatments, and modern vaccines, among others.

In this context, the pharmaceutical market grew by 17.11% in 2025 compared to the previous year. Despite the coverage provided by the hybrid model, industrial operability is estimated to be at 63% of its installed capacity. This presents viable investment opportunities in idle local production plants—currently at 40%—which are available for reactivation in a growing market poised for increased purchasing power, thereby offering avenues for technology transfer. All the aforementioned aligns with data provided by the Chamber of the Pharmaceutical Industry (CIFAR). Specifically, CIFAR reports that the first half of 2025 closed with a 23.4% growth in sales volume, while mid-2025 showed a 39% year-over-year recovery for the sector. These favorable trends have continued into early 2026, with the chamber projecting a 20% growth by year-end.

Currently, the sector operates under a legal framework designed to stimulate its revitalization. The entry of machinery and equipment, benefiting from the "Single Window" (Taquilla Única) system to expedite registrations and utilize tax credits, is coupled with modernization incentives stemming from import tax exemptions aimed at facilitating the influx of goods and technology. Naturally, a sector as critical to society as pharmaceuticals receives state support (such as Decrees 5.196 and 5.197, or the relaunch of bilateral relations in January 2026 emphasizing this industry), which complements and drives the market's reactivation and gradual growth observed in recent years.

Structural gaps and the challenge of technological autonomy

However, despite this growth and positive projections, a structural deficit persists in local manufacturing, primarily due to raw material shortages. Over 60%⁴⁵ of the active pharmaceutical ingredients (APIs) used in the country's 11 main plants are imported (for instance, the APIs used by Grupo Leti in Miranda, Laboratorios Elmor in Carabobo, or Laboratorios Calox in Caracas). Relying on imported raw materials is considered a "costly supply" chain, heavily dependent on the stability of trade flows. Therefore, mitigating this dependency will require installing additional chemical synthesis plants, demanding direct investment in heavy manufacturing equipment and chemical processing machinery. Furthermore, the regulatory framework permits the utilization of Special Economic Zones not only as strategic districts to develop these plants but also as spaces for repackaging and semi-manufacturing.

⁴⁵ <https://www.bancaynegocios.com/cifar-hasta-el-60-porciento-de-la-materia-prima-para-fabricacion-de-medicinas-en-el-pais-es-importada/>



This has become a viable alternative for conditioning processing facilities for foreign capital and enterprises.

In this regard, the Venezuelan pharmaceutical sector also presents a critical technological deficit in the production of biologicals, hormones, insulins, and monoclonal antibodies. This is compounded by a quantitative deficit of at least 40%⁴⁶ regarding the stable supply of treatments for hypertension, diabetes, and mental health. Due to the country's delayed modernization without external cooperation, specialized technology transfer for these biotechnological products is necessary to achieve logistical management consistent with an expanding market. Nevertheless, owing to structural deficiencies in the national electrical grid, laboratory technology and refrigeration-dependent medications require electrical backup from generators to guarantee operational continuity.

Dynamics of rational consumption and modernization of commercialization

Transversally, similar to other industries, the pharmaceutical sector is affected by exchange rate volatility and cumulative costs (driven by economic, political, or social instability). Consequently, the procurement and maintenance of technological equipment must account for the average price per medication unit, which has currently stabilized around \$3.94. This not only reflects the subsistence market behavior typical of the Venezuelan buyer but also dictates the configuration and optimization of corporate production cycles to sustain fast-moving inventories.

Therefore, understanding the Venezuelan consumer's profile and behavior is crucial for adaptation and consolidation within this sector. After years of economic adjustments, the Venezuelan buyer has developed highly rational purchasing habits—focusing on price and showing high adaptability to different payment methods due to exchange rate volatility (which directly impacts pricing and, ultimately, consumer choices). The consumer market is primarily composed (85%) of the C/D income segment on the purchasing power scale. This implies the vast majority of the market bases purchasing decisions fundamentally on the price per dose, showing a high willingness to try new brands provided a pharmacist guarantees their efficacy and they remain the cheapest available option. Conversely, the 15% comprising the A/B income segment relies almost exclusively on intermittent state imports, particularly for oncology and retroviral drugs.

Recently, a "fractioning" habit at the point of sale has intensified due to liquidity constraints. This manifests in consumers rarely purchasing 30-tablet boxes or multi-dose medications in advance; instead, they buy the exact doses required for immediate timeframes, thereby boosting the demand for smaller presentations. At the manufacturing level, this trend demands production lines and machinery technologically adapted to facilitate fractioned sales while simultaneously enabling production scalability and massification.

Additionally, the Venezuelan buyer requires visual validation to ensure product safety. This characteristic forces companies to implement secondary packaging technology featuring high-quality materials and authentication systems, such as security holograms or anti-tampering designs. These enhancements complement the consumer shift toward generic brands, which are generally 40% to 60% cheaper than traditional transnational brands.

⁴⁶ <https://www.infobae.com/venezuela/2024/04/25/alerta-por-la-escasez-de-medicamentos-clave-en-venezuela-el-desabastecimiento-alcanzo-el-369/>



Faced with this reality, resilient local laboratories—such as LETI, Calox, or Meyer—have maintained market dominance by capturing the branded generics segment and gradually earning consumer trust, establishing themselves as the primary market competitors. Despite their operational capacity, these actors focus on producing basic treatments (like acetaminophen and simple antibiotics) and lack the financial muscle or technological innovation necessary to develop more advanced molecules. This limitation highlights a severe underinvestment in laboratory technology, equipment, and R&D environments.

This operational gap among local laboratories has been filled by "Commercial Representation Houses" (according to CIFAR, over 7 were recently registered), which act as a logistical bridge for importing finished products; primarily from China, Turkey, and Iran. However, products from these representation houses often lack the legitimacy associated with "international certified quality." While highly attractive in terms of pricing for the Venezuelan consumer, they falter in public perception regarding reliability.

Consequently, the private logistics environment is modernizing, increasingly relying on automated storage centers to achieve the efficiency required to operate in a market with short production cycles. This modernization aligns with a growing interest in applying Artificial Intelligence to industrial processes and pharmaceutical manufacturing, alongside the digitalization of corporate commercial management. Paradigmatically, mobile and delivery apps already account for 15% of total urban retail sales volume—a surge that has compelled laboratories and retailers to ensure their products are listed and prominently featured on digital platforms. Nevertheless, the sustained growth of this channel will remain conditioned by the stability of basic infrastructure (electricity and internet).



PART IV

LEGAL STRUCTURE



PART IV LEGAL STRUCTURE

By 2026, the legal framework and health permitting ecosystem of the Bolivarian Republic of Venezuela have undergone progressive structural changes aimed at balancing national health sovereignty with the adoption of imports tailored to market dynamics. Fundamentally, the regulatory framework for the health and pharmaceutical sector is grounded in the Constitution, the 1998 Organic Health Law⁴⁷, and the 2000 Medication Law—which regulates manufacturing, importing, and marketing—designating the State as the guarantor of public health⁴⁸. Furthermore, the "Constitutional Law of Productive Foreign Investment"⁴⁹ grants foreign investors the same rights and duties as domestic ones, offering additional benefits if registered with the International Center for Productive Investment (CIIP). Similarly, the "Anti-Blockade Law for National Development"⁵⁰ allows the Executive branch to bypass certain regulations to facilitate strategic projects and protect capital confidentiality against international pressures or sanctions.

It is also important to note that system operations currently fall under the Ministry of Popular Power for Health (MPPPS), which defines national pharmaceutical policy, issues permits, and oversees technical execution. Meanwhile, the "Rafael Rangel" National Institute of Hygiene (INHRR), acting as an executing arm of the MPPPS, is responsible for managing sanitary registrations, authorizing clinical trials, coordinating national pharmacovigilance (CENAVIF), evaluating technical quality, and managing exceptional agile import mechanisms like "service medicines"—a legal framework functioning as an express permit for drug entry. Alternatively, the Autonomous Service of Sanitary Comptroller (SACS) oversees surveillance, issues operating permits for pharmaceutical establishments, strictly controls licenses for raw materials and controlled substances, and conducts Good Manufacturing Practice (GMP) inspections. Additionally, the Pharmaceutical Products Review Board (JRPF) acts as the advisory body issuing final rulings for product sales and regulating promotional and advertising materials. Moving forward, these institutions must align with the recent "Plan for Health and Life 2026"⁵¹, which establishes pharmaceutical sovereignty as a national security objective, boosting the "pharmaceutical engine" to reduce dependence on foreign—especially Western—markets and fostering local production through state laboratories and private sector alliances⁵².

Investment Protocol Route before the CIIP

When opting for infrastructure investment—specifically regarding alliances aimed at substituting API imports—it is imperative to follow a strict protocol with the International Center for Productive Investment (CIIP):

⁴⁷ <https://www.asambleanacional.gob.ve/storage/documentos/leyes/ley-organi-20220316141637.pdf>

⁴⁸ Article 83: "Health is a fundamental social right and an obligation of the State, which shall guarantee it as part of the right to life. The State shall promote and develop policies aimed at improving the quality of life, collective well-being, and access to services. All persons have the right to health protection, as well as the duty to actively participate in its promotion and defense, and to comply with the health and sanitation measures established by law, in accordance with the international treaties and conventions signed and ratified by the Republic."

⁴⁹ <https://www.asambleanacional.gob.ve/leyes/sancionadas/ley-constitucional-de-inversion-extranjera-productiva>

⁵⁰ <http://www.vuce.gob.ve/wp-content/uploads/2023/05/Ley-Antibloqueo-Y-CENTRO-INTERNACIONAL-DE-INVERSION-PRODUCTIVA.pdf>

⁵¹ <https://inhrr.gob.ve/?p=10164>

⁵² <https://mincyt.gob.ve/gobierno-bolivariano-lanza-plan-por-la-salud-y-la-vida-2026-para-fortalecer-atencion-integral/>



- **Foreign Investor Registration:** Involves the formal presentation of the investment plan and documentation proving the origin of funds, strictly complying with current anti-money laundering regulations.
- **Execution of the Investment Contract:** A legal instrument establishing and formalizing supply commitments alongside fiscal and tax benefits.
- **Investment Registration (RI):** A foundational document providing the legal certainty required for profit or dividend repatriation and capital re-exportation.
- **Juridical Stability Agreement:** A contract executed with the State guaranteeing the immutability of tax and customs regulations applicable to the investment for a set period of five (5) to ten (10) years. The legal entry of international generic products into the Venezuelan market requires navigating a dual registration system: the standard pathway and the expedited emergency pathway.

A. Standard Pathway

Initially, every pharmaceutical product requires a "sanitary registration" issued by the INHRR prior to its import or local manufacture. Notably for 2026, the "Good Evaluation Practices Manual"⁵³—a document defining standards and procedures to ensure quality and reliability in evaluation processes—has tightened anti-fraud requirements:

- A Certificate of Pharmaceutical Product (WHO model) issued by the health authority of the country of origin (e.g., India) is required.
- Good Manufacturing Practice (GMP) Certificates from the finished product manufacturer, the API manufacturer, and the packager must be legalized or apostilled.
- All documentation in English or Hindi must be translated into Spanish by a public interpreter authorized by the Ministry of Popular Power for Internal Relations, Justice, and Peace. If the document is translated by a public interpreter from the country of origin, a list confirming their authorization for that language must be provided, along with a justification explaining why the translation was not performed in Venezuela.

B. Expedited Emergency Pathway

The legal figure of "service medicines" serves as an immediate market insertion method. Through Circular CIR-PE-2026-0002⁵⁴, the INHRR permits the expedited importation of known pharmaceutical specialties experiencing supply shortages in the country until December 31, 2026. This only requires a sanitary justification of the need, a WHO certificate, the complete formula, packaging artwork, and a Spanish prospect leaflet. Exceptions include medicines containing new molecules not previously registered in Venezuela, as well as biological products, psychotropics, or narcotics.

⁵³ https://inhrr.gob.ve/wp-content/uploads/2024/09/M-RCMD-002-MANUAL-DE-BUENAS-PRACTICAS-DE-EVALUACION-PARA-LA-RENOVACION-DE-REGISTRO-SANITARIO_compressed.pdf

⁵⁴ <https://inhrr.gob.ve/wp-content/uploads/2026/02/Circular%20PE-2026-002%2025%20de%20febrero%20de%202026%20Rev%20JRPF.pdf>



Furthermore, during 2026, the INHRR reinforced this mechanism through additional regulatory circulars. Circular CIR-PE-2026-004 digitalized the issuance of the "service medicine" status, incorporating electronic signatures, QR validation codes, and electronic notifications to the sponsoring pharmacist, thereby reducing administrative processing times and improving documentary traceability⁵⁵. In parallel, Circular CIR-PE-2026-005 clarified the applicable requirements for bioequivalence studies, mandating the endorsement of the health authority from the country of origin, certification of the clinical research center, and documentation duly legalized or verifiable through official portals⁵⁶. These measures reflect a regulatory trend oriented toward administrative simplification and the strengthening of technical sanitary evaluation standards.

C. Exceptional Medicines

This section pertains primarily to operations involving raw materials, psychotropics, or narcotics. The SACS administers an international control permit via the "Quota License 2025/2026"⁵⁷. This requires: formalizing the request detailing establishment/company data and the sponsoring pharmacist, import justifications, and standardized traceability balances.

Regulatory Framework and SIVERC 2.0 Platform

The regulatory baseline for operations relies on the 2000 Medication Law, which establishes rules for manufacturing, importing, and commercializing these products, mandating the appointment of a "sponsoring or regent pharmacist," who must be a properly accredited Venezuelan professional.

By 2026, the system underwent a substantial upgrade focused on a Fast-Track process via the implementation of the SIVERC 2.0 digital platform. This system is designed to mitigate shortages by allowing Indian laboratories to quickly obtain commercialization permits for essential medicines. Through the Single Service Window (VUS), the sponsoring pharmacist handles the digital submission of dossiers. The system is designed to issue real-time "tickets" (red alerts) for inconsistencies. If no issues arise upon process completion, the system automatically generates the digital sanitary registration certificate.

Essential documentary requirements for SIVERC 2.0

- **Legal Scope:** Duly apostilled Power of Attorney, Good Manufacturing Practice (GMP) Certificates, and the Certificate of Pharmaceutical Product (CPP) complying with the World Health Organization (WHO) model, which in this case must be issued by India's CDSCO.
- **Technical-Scientific Scope:** Detailed qualitative/quantitative formula, analytical methodology, and relevant Stability Studies for Climatic Zone IV (tropical climate, a mandatory requirement for the Bolivarian Republic of Venezuela). For high-risk generics, the submission of bioequivalence tests is required.
- **Packaging:** Labeling and prospect leaflets must be strictly written in Spanish, alongside the delivery of physical commercial batch samples to the "Rafael Rangel" National Institute of Hygiene (INHRR).

⁵⁵ https://inhrr.gob.ve/wp-content/uploads/2026/03/CIR_PE_2026_004%20CIRCULAR.pdf

⁵⁶ <https://inhrr.gob.ve/wp-content/uploads/2026/03/CIR-PE-2026-005.pdf>

⁵⁷ http://www.sacs.gob.ve/site/wp-content/uploads/2024/11/Circular_licencia_cupo_2025.pdf



Fiscal Framework and Special Economic Regimes

The fiscal outlook for 2026 features concrete measures to ease tax and customs burdens alongside specific exemptions. In an effort to guarantee public health and foster local pharmaceutical production, the National Executive Power, via Decree No. 5.196, established an annual exemption covering 1,445 specific tariff codes, including the majority of essential medicines and APIs. This is complemented by Decree No. 5.197, which grants a 90% reduction on the Import Tax and a 90% reduction applicable to goods listed in its Appendix I, covering both the public and private sectors⁵⁸.

The Organic Law of Special Economic Zones (LOZEE) offers a preferential investment environment, particularly in areas with high logistical and productive potential. Companies establishing production activities within these Special Economic Zones can benefit from a significant reduction in their corporate income tax (ISLR) rate. This tax benefit can be extended for up to ten (10) years, contingent upon compliance with approved investment and employment plans. Furthermore, current legislation actively promotes technology transfer and development. Additional and specific ISLR deductions are available for profit reinvestment, provided such reinvestment targets the acquisition and implementation of local technology or fosters import substitution and national supply chain integration.

For investments aimed at leveraging Venezuela's geopolitical position—serving as a platform towards the Caribbean and other regions—indirect tax refund mechanisms have been activated. Goods manufactured within Venezuelan territory intended for export, particularly to the Caribbean, qualify for Drawback utilization. This mechanism allows for the total or partial refund of internal taxes (like VAT paid across the production chain) and customs duties levied on inputs and raw materials used to manufacture the exported goods.

Despite this incentive framework, investors must account for the Large Financial Transactions Tax (IGTF), as it directly impacts cash flow and financial cost structures. Financial operations and transactions executed in foreign currency are subject to this tax. The applicable rate for 2026 remains at 3% of the total transaction amount. This tax must be rigorously integrated into financial planning, especially concerning imported input purchases, dividend repatriation, or any significant payments made outside the national currency system.

The projected regulatory and economic dynamics for 2026 will initially be evaluated based on the legal transformations implemented since 2025,

- Referred to the "Organic Law for the Protection of Socioeconomic Rights", it addresses the approximately 30% profit margin limits previously stipulated by the 2015 "Fair Prices Law." This introduces a state-agreed pricing model negotiated with economic agents to determine final prices, guaranteeing profitability for both parties while ensuring necessary national supply.
- Extraordinary Official Gazette No. 6.952 published three decrees altering logistical and fiscal planning for 2026. Specifically, "Decree No. 5.198"⁵⁹, which establishes the ninth tariff reform, mandates that import exemptions and permits for chemical and pharmaceutical products

⁵⁸ <https://lega.law/lega-informa/exoneraciones-aduanas-2026/>

<https://www.tradex.com.ve/wp-content/uploads/Tradex-Reforma-Arancel-de-Aduanas-Decreto-de-Exoneracion-GO.-6.952.pdf>

⁵⁹ <https://inseroca.com/cambios-clave-en-impuestos-exoneraciones-y-aranceles/>



require obligatory processing through the Presidential Commission's digital portal: the Foreign Trade Committee (COMEX). It should be noted that a failure in this procedure can halt imports at customs and generate cost overruns. The centralization through COMEX has established Legal Regime 9 (RL9) as the bottleneck for tax exemption access: while the fiscal benefit exists by law, access to it is contingent upon validation through the COMEX digital platform⁶⁰. RL9 thus becomes the essential prerequisite for customs clearance. Without the COMEX certificate, the cargo is held at customs and automatically loses the 90% exemption.

Clearly, the 2026 regulatory dynamic revolves around Decree Nos. 5.196 and 5.197. While these establish beneficial fiscal exemptions for the Venezuelan pharmaceutical sector during the year, they may present long-term unpredictability risks; nonetheless, the decrees respond to structural needs that are not expected to be resolved in the short term. Expansion would therefore be viable within a scenario where fiscal benefits align with the country's established public health objectives. The practical implications for leveraging both decrees are analyzed in the sector's situational analysis.

Intellectual property and risk management

Venezuela's 2026 legal framework saw reinforcements in intellectual property, specifically concerning patents⁶¹. In October 2025, the Autonomous Intellectual Property Service (SAPI) reactivated pharmaceutical patent concessions, as per Bulletin No. 646⁶². Currently, Venezuela applies WTO TRIPS standards via SAPI, granting 20 years of protection to pharmaceutical patents. Relatedly, under the National Strategic Intellectual Property Program (PENPI), Venezuela reached record registration numbers in 2025, with 23,714 out of 26,943 intellectual property rights corresponding to industrial property⁶³.

Mandatory compliance actions

- **OFAC Audits:** Implementing compliance clauses and third-party audits throughout the supply chain is required.
- **SAPI Preventive Registration:** Since Venezuela does not automatically recognize patents registered exclusively in India, pursuing local preventive registration is imperative.
- **International Arbitration:** To mitigate risks stemming from regulatory shifts, all investment contracts must incorporate international arbitration clauses or, alternatively, submit to neutral jurisdictions.

Another vital consideration involves the "Good Pharmacovigilance Practice Guidelines"⁶⁴, which place legal liability on the sanitary registration holder. Therefore, it is mandatory to designate a Venezuela-based representative capable of reporting adverse reactions, responding to these reports

⁶⁰ <https://inseroca.com/cambios-clave-en-impuestos-exoneraciones-y-aranceles/>,
<https://lega.law/lega-informa/exoneraciones-aduanas-2026/>,
<https://www.tradex.com.ve/wp-content/uploads/Tradex-Reforma-Arancel-de-Aduanas-Decreto-de-Exoneracion-GO.-6.952.pdf>

⁶¹ <https://www.clarkemodet.com/articulos/venezuela-reactiva-la-concesion-de-patentes-nacionales-en-farma-y-quimica/>

⁶² <https://sapi.gob.ve/download/aviso-oficial-drpi-11-2025-lapsos-de-vigencia-646/>

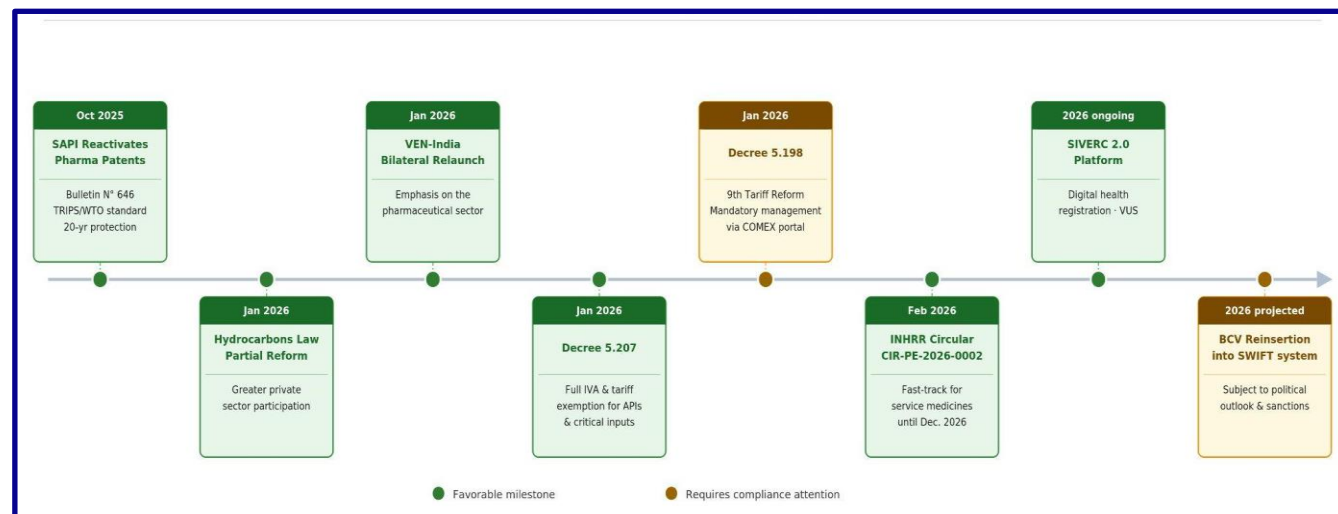
⁶³ <https://sapi.gob.ve/record-historico-en-2025-venezuela-alcanza-cifras-sin-precedentes-en-materia-de-propiedad-intelectual/>

⁶⁴ https://inhrr.gob.ve/wp-content/uploads/2025/09/X-RCCE-002_REV1%20GU%C3%8DA%20DE%20FV%20PARA%20LA%20INDUSTRIA.pdf? t=1758033716



before agencies like the National Pharmacovigilance Center (CENAVIF)—attached to the INHRR—and issuing Periodic Safety Update Reports (PSURs).

Reform of the Venezuelan Legal Framework: Key Milestones for the Indian Investor



Source: Author's elaboration based on cross-referenced data from specialized industry sources.

Currently Active Processes

From May 12 to June 30, 2026, the Instituto Nacional de Higiene Rafael Rangel (INHRR) has an active public consultation on the Regulation for Biosimilar Products. This consultation is being conducted to identify possible changes to the regulatory framework in force since 2008, which was not designed for the current technological diversity in biologics and biosimilars. Given that biosimilars — insulins, monoclonal antibodies, and fill & finish products — constitute the segment of highest strategic value for the Indian pharmaceutical industry in Venezuela, monitoring through the INHRR's official portal and the SIVERC 2.0 system is recommended to determine the specific implications for those producers and importers affected by a change in the legal regime⁶⁵.

⁶⁵ https://inhrr.gob.ve/?page_id=4163



PART V

SITUATIONAL ANALYSIS OF THE SECTOR



PART V

SITUATIONAL ANALYSIS OF THE SECTOR

The Venezuelan pharmaceutical industry is in a phase of adaptation and strengthening, boasting a projected 20% growth for 2026, alongside technological and regulatory gaps, and market-opening signals favoring foreign investment. This creates specific opportunities for the Indian pharmaceutical industry. Unmet demand for high-complexity molecules and the inactivity of 40% of local plants position Venezuela as a potential hub for technology transfer, provided logistical and political risks are mitigated.

Structurally, fortifying health infrastructure faces constraints due to the exodus of qualified local professionals. This brain drain has eroded the public health system's response capacity, rendering it highly dependent on international cooperation from entities like the UNDP—which acts as a fundamental stabilizer for the logistical supply chain and the management of high-complexity, hard-to-access drugs. Given the volatility and uncertainty within the public network, consumers have redirected their demand toward the private channel, cementing pharmacies as the primary access point.

This shift in consumer behavior is particularly critical given the national epidemiological profile, marked by a strong prevalence of chronic pathologies requiring continuous medication: musculoskeletal conditions (31.7%), diabetes (18.06%), and cardiovascular diseases (15.6%). In this recurring expenditure scenario, the commercial viability of Indian generics—backed by clinical efficacy guarantees—and fractioned blister sales (a scalable model for Indian manufacturers) are reaffirmed as indispensable mechanisms for aligning supply with consumer purchasing power.

Typical pathologies of the venezuelan consumer

The epidemiological profile of the Venezuelan consumer is heavily defined by non-communicable chronic diseases (NCDs), which account for over 65% of mortality causes and have been exacerbated by an aging population and nutritional deterioration⁶⁶. These typical pathologies can be grouped as follows:

1. Cardiovascular and Metabolic Diseases (Primary Market)

- **Hypertension and Ischemic Heart Disease:** Hypertension is the most common chronic condition in the country. Nearly 70% of seniors in Venezuela suffer from hypertension or diabetes, requiring lifelong medication⁶⁷. Additionally, the country faces an ischemic heart disease epidemic, which remains a leading cause of death.
- **Diabetes and Obesity:** The prevalence of both has risen significantly due to survival diets based on ultra-processed foods high in sugar and sodium. Over 53% of the population over 15 suffers from overweight or obesity⁶⁸.

⁶⁶ <https://hia.paho.org/es/perfiles-de-pais/venezuela>

⁶⁷ <https://conviteac.org/wp-content/uploads/2025/03/CONDICIONES-DE-VIDA-Y-SALUD-DE-LAS-PERSONAS-MAYORES-EN-VENEZUELA-1.pdf>

⁶⁸ <https://hia.paho.org/es/perfiles-de-pais/venezuela>



2. Gastrointestinal and Vascular Disorders

- Everyday conditions like gastritis, constipation, and irritable bowel syndrome are highly frequent among Venezuelan consumers, largely stemming from stress and dietary shifts⁶⁹.
- Venous insufficiency (varicose veins) is also among the most frequent morbidities in the adult population.

3. Respiratory, Oncological, and Renal Diseases

- **Asthma and respiratory conditions:** These are common and represent a constant need; for instance, hospitals report frequent and critical inhaler shortages⁷⁰.
- **Cancer and chronic kidney conditions:** These also form part of the primary NCDs affecting the country⁷¹. The most recurrent cancers with the highest mortality rates (per 100,000 inhabitants) are prostate (25.5) in men and breast (16.8) in women, followed by lung and colon/rectum cancers in both sexes⁷².

4. Ophthalmological Ailments

- Due to an aging population (also a product of youth migration), there are high rates of presbyopia, cataracts, and astigmatism⁷³.

5. Infectious Diseases

- Though to a lesser extent than chronic diseases, there are significant spikes and incidences of dengue, acute diarrhea, tuberculosis, and HIV⁷⁴.

Technological Aspect

There is a gap in basic infrastructure (unstable electricity or limited internet), yet a high interest in Artificial Intelligence for industrial processes exists. Consequently, favorable opportunities for India include using AI in the supply chain to mitigate disruptions and technology transfer for biosimilars (insulins, monoclonal antibodies), as well as biological fill & finish processes. Thus, the aforementioned 40% of inactive plants could be reactivated with Indian technology, turning Venezuela into a regional low-cost generic hub.

Demand and Structural Deficit Analysis

Projected growth contrasts with notable operational supply gaps. Currently, the sector faces a 40% deficit in chronic pathology therapies—such as hypertension, diabetes, and mental health—and a 20% shortage in specialty lines encompassing hormonal and biotechnological treatments. Concurrently,

⁶⁹ <https://conviteac.org/wp-content/uploads/2025/03/CONDICIONES-DE-VIDA-Y-SALUD-DE-LAS-PERSONAS-MAYORES-EN-VENEZUELA-1.pdf>

⁷⁰ Ibid.

⁷¹ <https://institutoeducardio.net/enfermedades-no-transmisibles-en-venezuela-2025/>

⁷² <https://hia.paho.org/es/perfiles-de-pais/venezuela>

⁷³ <https://conviteac.org/wp-content/uploads/2025/03/CONDICIONES-DE-VIDA-Y-SALUD-DE-LAS-PERSONAS-MAYORES-EN-VENEZUELA-1.pdf>

⁷⁴ Ibid.

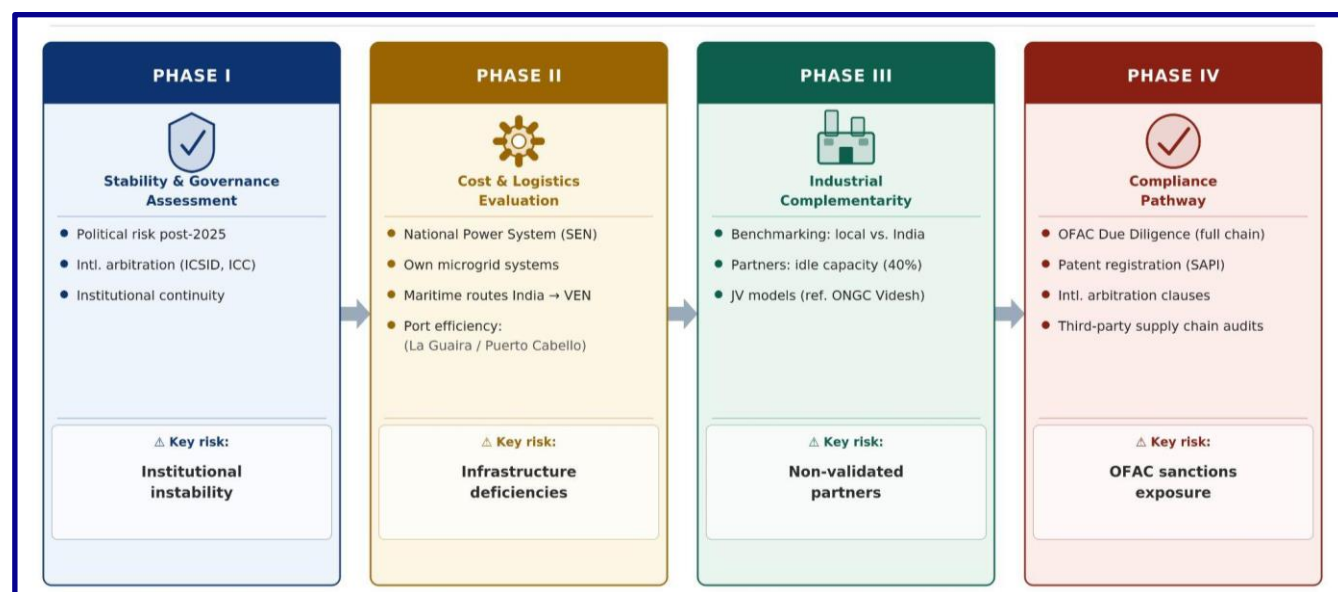


the high-cost drug segment, vital for oncology and retroviral patients, remains highly vulnerable commercially as it strictly depends on intermittent import flows.

In light of this, the following opportunities arise for Indian capital:

- Substituting luxury imports with premium generics.
- Establishing repackaging and semi-manufacturing hubs in special economic zones.
- Alliances for biosimilars and technology transfer.
- Joint ventures in APIs to reduce import dependency.
- Developing logistical hubs for re-exportation to the Caribbean/ALBA, capitalizing on idle plants.

Market Entry Route for Indian Capital in Venezuela: 4 Critical Phases



Source: Author's elaboration based on cross-referenced data from specialized industry sources.

Competitor Analysis

By 2026, the Venezuelan pharmaceutical market exhibits a fragmented structure where national capital laboratories exert clear dominance, driving between 72% and 88% of sector growth and guaranteeing 74% of total supply. Traditional actors like LETI, Calox—with an operational capacity of 3.5 million monthly units—Meyer, Farma, Vargas, and Behrens lead this block. Their commercial strategy leverages deep-seated historical consumer trust and a competitive offering anchored in accessible pricing, averaging US\$3.94 per unit. However, their portfolios concentrate on essential medicines, facing severe limitations in R&D and biotechnological lines—a weakness exacerbated by a 95% structural dependency on API imports.

Parallely, the import ecosystem outlines clear segmentation. On one hand, bolstered by geopolitical agreements, new representation houses have emerged (with over seven recent CIFAR



additions) introducing products from China, Turkey, and Iran. While these options aggressively compete for cost leadership, they face the challenge of low perceived quality due to the absence of top-tier regulatory certifications (FDA or EMA). On the other hand, imports from the United States and Europe—led by firms like Novartis (US\$229.7 million) and Grupo Farma (US\$68.3 million)—have consolidated into a premium market niche. Despite this fragmentation, the market's appeal remains strong: the entry of approximately 12 additional transnational corporations (backed by German, U.S., Swiss, and Spanish capital) is projected, operating under the representation model.

Thus, the Indo-Venezuelan strategic relationship can be leveraged to break entry barriers in a sector lacking consolidated transnational competition, positioning the Indian industry as the primary supplier for the complex medicine deficit. Simultaneously, thanks to India's industrial capabilities, it competes to displace national producers through cost efficiency.

Main Commercializing Companies in Venezuela

1. **Grupo Leti:** Grupo Leti comprises Laboratorios Leti—focused on traditional pharmaceutical solutions—Genven (Genéricos Venezolanos)—producing generics for the domestic market—and Biocontrolled, S.A., dedicated to R&D, housed in a 75,000-square-meter industrial complex in Guarenas⁷⁵. Founded in 1950, it is considered one of the sector's most active companies. In 2025, Grupo Leti confirmed receipt of its first raw material imports for the 2026 cycle, registering an annual volume increase of 34.56%⁷⁶. Additionally, the business group periodically publishes the *Faro Farmacéutico* bulletin, thus dominating the sector's main source of market intelligence.
2. **Laboratorio Behrens:** Operating since 1904, Laboratorio Behrens holds one of the most extensive historical track records in Venezuela. Its production encompasses solid tablets and pills, syrups, suspensions, and injectables in vials and ampoules, maintaining an active network of commercial representatives in key cities including Caracas, Maracaibo, and Puerto La Cruz⁷⁷.
3. **Laboratorios Vargas:** Headquartered in Caracas, Laboratorios Vargas is a Venezuelan pharmaceutical manufacturer established in 1955. It is positioned as a benchmark domestic producer within the established brands segment⁷⁸.
4. **Laboratorios Farma:** Laboratorios Farma S.A. defines itself as a leading company in the Venezuelan pharmaceutical industry, demonstrating progressive and sustained market growth, supporting healthcare professionals via continuous medical education, and actively promoting pharmacovigilance⁷⁹.

Public Companies

The Conglomerate of Public Medicine Producing Companies, attached to the Ministry of Popular Power for Health (MPPS), coordinates Espromed BIO, C.A.; Productos Farmacéuticos para el Vivir

⁷⁵ <https://grupoleti.com/>

⁷⁶ <https://www.tendenciainternacional.com/2026/02/12/produccion-nacional-garantiza-el-74-del-suministro-farmacautico-en-venezuela-con-los-precios-mas-bajos-de-la-region/>

⁷⁷ <https://labbehrens.com/>

⁷⁸ <https://www.laboratoriosvargas.com/>

⁷⁹ <https://laboratoriosfarma.com/>



Viviendo (Profarmacos), C.A.; Laboratorios Miranda, C.A. (Lambrica); and Quimbiotec, C.A., with the goal of coordinating joint drug and health supply production and commercialization activities⁸⁰.

Wholesale Channel: Drugstores (Droguerías):

- **Grupo Cobeca:** The Health Division of Grupo Cobeca consists of four drugstores—Cobeca Occidente, Cobeca Oriente, Cobeca Centro, and C.A. Mafarta—operating as distribution centers serving the entire national territory with pharmaceutical products, maintaining a portfolio of allies including national and international laboratories. Originating in 1908, Grupo Cobeca also operates the Farmacia SAAS network—the first chain to introduce self-service in Venezuela in 1986—and Botiquería, boasting over 100 point-of-sale franchises nationwide⁸¹.
- **Droguería Nena (DRONENA):** With over 39 years of experience distributing medicines and miscellaneous products in the Venezuelan market, Droguería Nena is headquartered in Barquisimeto, Lara State, with a capital branch in Guarenas, Miranda State, from which it manages central and eastern distribution. In 2025, it expanded its footprint by acquiring the Farmahorro chain, thereby absorbing a retail channel component⁸².

Retail Channel: Pharmacy Chains

- **Farmatodo:** Farmatodo commands 13.7% of the Venezuelan pharmaceutical market, ranking as the top chain by sales⁸³. By late 2025, it operated 204 stores nationwide, with additional presence in Colombia and Argentina⁸⁴. Owned by the Zubillaga family, the chain launched an ambitious "stores of the future" project in 2024, incorporating educational spaces, wellness centers, and tech innovations like self-checkout kiosks.
- **Locatel:** Originally established as a medical equipment rental and sales store, Locatel integrated pharmacy services in 1994, introducing an affiliation system that sets it apart⁸⁵. In 1997, it materialized its "health supermarket" model, gathering pharmacy, optics, clinical laboratory, and nutrition services under one roof⁸⁶.

Return of International Representation Houses

Finally, according to the CIFAR president, companies like P&G, Novo Nordisk, and GlaxoSmithKline are already operating in Venezuela via representation houses. It is anticipated that this activity will generate employment opportunities and boost tax revenues for the Venezuelan State. This phenomenon, projected as a key 2025 trend, provides a direct window of opportunity for Indian laboratories interested in entering the market through this legal structure⁸⁷.

⁸⁰ <https://www.espromedbio.gob.ve/inicio/empresas-productoras/>

⁸¹ <https://www.grupocobeca.com/>

⁸² <https://www.dronena.com/Home/>

⁸³ <https://ultimasnoticias.com.ve/general/datos-un-70-tiene-como-habito-comprar-en-farmatodo/>

⁸⁴ <https://www.farmatodo.com>

⁸⁵ <https://ultimasnoticias.com.ve/negocios/de-la-botica-de-velasquez-a-red-vital-como-cambio-la-forma-de-comprar-medicinas-en-venezuela/>

⁸⁶ <https://www.locatel.com.ve/>

⁸⁷ <https://cronica.uno/la-industria-farmaceutica-crecera-en-2025-gracias-al-regreso-de-las-casas-de-representacion/>



Visual Diagram: Key Players - Venezuelan Pharmaceutical Industry



Source: Author's elaboration based on cross-referenced data from specialized industry sources.

Consumer Insights

As outlined in the sector characteristics, given that the Venezuelan consumer is highly driven by cost-effectiveness, the Indian industry can structurally integrate into the distribution network under a hybrid scheme. Using representation houses to import products as pivots, Indian medicines can flow through key wholesalers like Droguería Nena and Cobeca, eventually reaching retailers led by Farmatodo, which holds 75% of the urban presence. Sustaining this chain requires impeccable just-in-time logistics, strict cold-chain controls, and robust support from the burgeoning delivery sector. To ensure inventory turnover, brands combine push tactics via digital medical visits with pull strategies leveraging social media to educate and solidify consumer confidence.

The Venezuelan pharmaceutical market is dictated by a highly rational consumer segmented by purchasing power. While 15% (A/B segments) opt for branded generics in recognized chains, the remaining 85% (C/D segments) seek to maximize their budgets. This opens doors for Indian laboratories, whose products are well-received if they guarantee efficacy, leveraging pre-existing trust in Indian vaccines and complex treatments. Similarly, the need to optimize spending has cemented fractioned blister purchasing as a standard consumption habit.

Pharmaceutical Distribution Chain

Venezuela's distribution system is hybrid, heavily emphasizing traceability (product tracking).



- **Strategic Importation:** Foreign capital primarily enters via Commercial Representation Houses. In 2026, these manage complex molecules such as biotechnological and oncological drugs.
- **Storage and Collection Centers:** Post-January 2026 restructuring, new state nodes exist for the public sector alongside automated centers for the private sector.
- **The Last Mile (Retail): Divided into two main channels.**
 - **A. Wholesale Channel (Drugstores):** Logistical allies purchasing from Representation Houses and distributing to pharmacies. Key actors: Droguería Nena, Cobeca, and Farvenca. Coverage: Reaching inland cities in under 24 hours. Strategy: Negotiating 10-15% margins and fast payments.
 - **B. Retail Channel (Pharmacies):**
 - **Pharmacy Chains:** Like Farmatodo, Locatel, and Red Vital; handling 75% of private urban sales. They demand robust inventory and promotions.
 - **Independent Pharmacies:** Crucial for neighborhoods and towns; dependent on drugstore credit lines.
 - **Community/Public Pharmacies:** State-managed; ideal for subsidized Indian generics via public tenders.

Payment Mechanisms in the Pharmaceutical Sector: Corporate Triangulation and Representations

By 2026, recommended entry structures for Indian investors in the Venezuelan pharmaceutical industry feature strategies that optimize the supply chain and facilitate market access by incorporating triangulation mechanisms and establishing representations. These approaches leverage logistical hubs and efficient legal figures to mitigate operational challenges.

- **Joint Venture:** A strategic partnership with a local or state laboratory allows for the exploitation of the partner's idle capacity, estimated at 40%, facilitating access to government tenders (such as IVSS or Ministry of Health) and significantly expediting customs procedures. However, performing comprehensive due diligence is vital to mitigate the critical risk of partnering with an OFAC-sanctioned entity. This structure can integrate with triangulation strategies, such as turning Venezuela into a regional re-export hub for the Caribbean and ALBA nations, maximizing local plant utilization.
- **Representation House:** This is the most efficient legal alternative if local manufacturing is not desired, particularly for foreign Indian capital. This local legal entity represents a foreign laboratory, holding sanitary registration ownership, conferring total control over the brand and marketing strategy. Its primary appeal lies in avoiding the high operational costs (CAPEX) of building and maintaining an proprietary plant. Under the 2026 projected scenario, these houses manage the entry of new, high-demand complex molecules like biotech and oncology drugs. Implementation requires submitting incorporation documents and possessing a warehouse (proprietary or subcontracted) strictly complying with Good Storage Practices (BPA). Due to national power grid deficiencies, hybrid electrical generation systems (e.g., solar panels and



diesel generators) must be installed to protect inventory, particularly the cold chain. Over 7 houses were recently registered with the sector's chamber, acting as bridges for importing finished products.

- **Branch Office (*Sucursal de Sociedad Extranjera*):** This represents the parent company operating directly in Venezuela. It is ideal for preserving total operational control within the investment legislation framework; nevertheless, it exposes the Indian parent company to potential local legal actions.

Additionally, to optimize operations, logistical triangulation strategies are recommended: utilizing intermediate Caribbean hubs to reduce transit times to under 15 days; implementing dual-sourcing to homologate local or Caribbean suppliers for inputs like packaging, reducing reliance on Indian shipments; and performing secondary packaging (repackaging) in Special Economic Zones like La Guaira or Puerto Cabello, minimizing tariffs and complying with "Made in Venezuela" regulations for state purchasing eligibility. These tactics accelerate inventory response times and bolster resilience in a challenging environment.

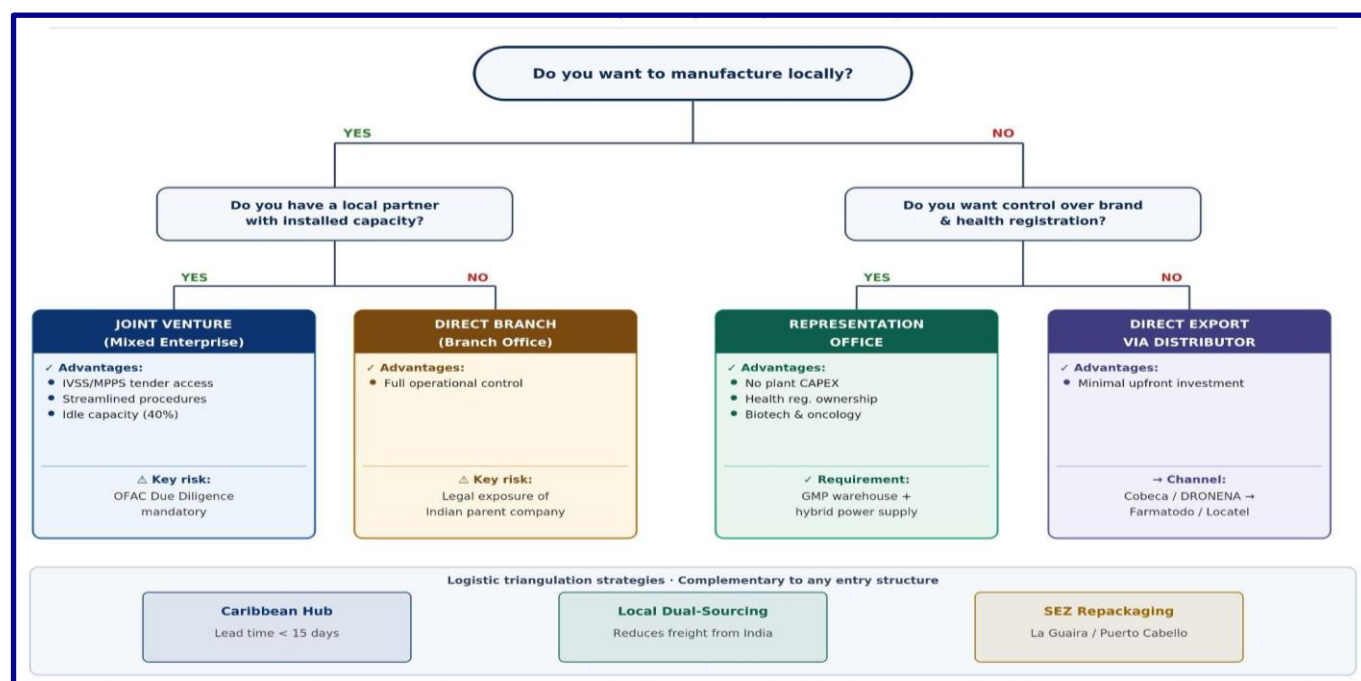
For Indian companies seeking to position Venezuela not only as a destination market but as a regional re-export platform toward the Caribbean and the countries of the Bolivarian Alliance for the Peoples of Our America (ALBA), the exporter must first obtain from the INHRR a Certificate of Pharmaceutical Product (CPP) in accordance with the WHO model—a document frequently required by foreign regulatory authorities⁸⁸. This document certifies that the medicine is legally authorized for commercialization in Venezuela and constitutes the baseline requirement demanded by most Caribbean sanitary authorities. Second, depending on the nature of the product—particularly in the case of substances subject to special sanitary controls—authorizations issued by the SACS in coordination with the relevant competent health authorities may be required. Third, the operation must be processed before the Foreign Trade Committee (COMEX) under Legal Regime 3 (RL3), established by Decree No. 5.198 (Extraordinary Official Gazette No. 6.952, 2025) as the prior control mechanism for exports of chemical and pharmaceutical products—the functional equivalent of Legal Regime 9 (RL9) applicable to imports⁸⁹. Failure to complete this step prevents customs clearance. Finally, the corresponding commercial, sanitary, and customs documentation must be submitted before the competent customs authority to authorize the export and dispatch of the goods to the destination market.

⁸⁸ <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/certification-scheme>
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/inspections/trs1033_annex9_guidelines-on-implementation-of-cpp.pdf?sfvrsn=c40c033b_1&download=true

⁸⁹ <https://www.pwc.com/ve/es/assets/documentos/stl/NAL-COMEX-RL-3-Decreto-5198-20250119.pdf>



How Should Indian Capital Enter the Venezuelan Pharmaceutical Market?



Source: Author's elaboration based on cross-referenced data from specialized industry sources.

Summary Table on Corporate Triangulation and Representations

Structure /Strategy	Description	Advantages	Requirements/Risks	Integration with Triangulation
Joint Venture	Strategic partnership with a local or state laboratory, leveraging idle capacity (40%).	Access to government tenders (IVSS, Ministry of Health); expedited customs procedures.	Comprehensive due diligence to avoid OFAC sanction risks.	Convert Venezuela into a regional re-export hub for the Caribbean and ALBA; use local plants to optimize the supply chain.

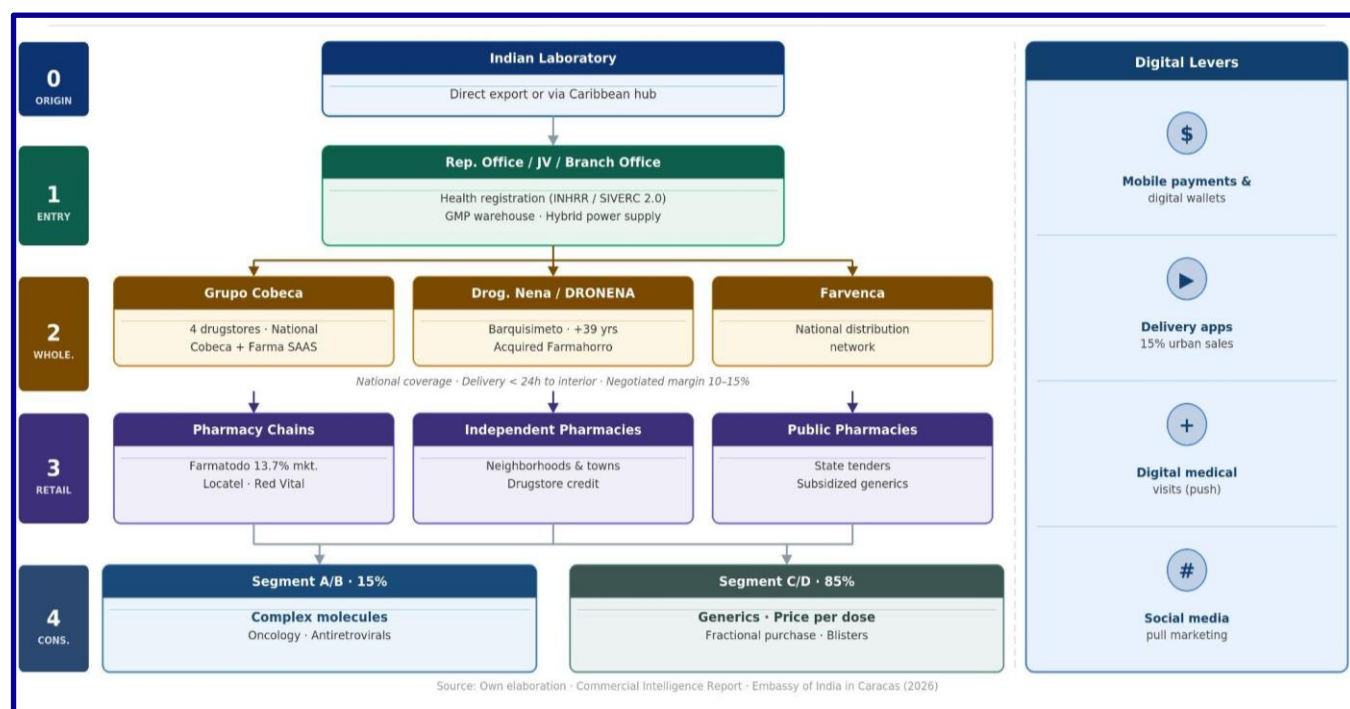


Representation House	Local legal entity representing a foreign lab; sanitary registration holder. Over 7 recently registered.	Total brand/marketing control; avoids proprietary plant costs; manages entry of complex molecules (biotech, oncology).	Submit incorporation documents; BPA warehouse; hybrid electrical generation (solar panels, generators) for power resilience and cold chain.	Acts as a bridge for importing finished products; compatible with local/Caribbean dual-sourcing and SEZ repackaging.
Branch Office	Direct representation of the parent company in Venezuela.	Preserves total operational control under investment legislation.	Indian parent company exposure to local legal actions.	Facilitates direct operations with Caribbean hubs to cut transit times (< 15 days) and SEZ repackaging (La Guaira, Puerto Cabello) for "Made in Venezuela" rules.
General Triangulation Strategies	Use intermediate Caribbean hubs; dual-sourcing of inputs; SEZ repackaging.	Cuts transit times (from 30-45 days to < 15); minimizes tariffs; speeds up inventory/response.	Complying with local regulations; dependency on allied suppliers.	Optimizes supply chain: fractions sea freight; homologates local packaging; re-exports from Venezuela; facilitates public tender participation.

Source: Author's elaboration based on cross-referenced data from specialized industry sources.



Venezuelan Pharma Distribution Chain 2026: India's Entry Point



Source: Author's elaboration based on cross-referenced data from specialized industry sources.

Legal (Emergency Reforms)

The 2026 Venezuelan regulatory framework is favorable for foreign investments, with Industrial Property and Socioeconomic Rights laws guaranteeing greater security for capital, protecting patents, and securing rights within an economic opening context. Decrees 5.196 and 5.197 offer import tax and VAT exemptions for basic goods like pharmaceutical raw materials, albeit with strict Foreign Trade Committee (COMEX) controls to ensure compliance.

Operationally, the regulatory body—the "Rafael Rangel" National Institute of Hygiene (INHRR)—modernized protocols by introducing a fast-track mechanism for essential medicine sanitary registrations. This route cuts time-to-market and accelerates the approval of new generic molecules and biotechnological lines. Simultaneously, rolling out a Single Window (Taquilla Única) has optimized processing, drastically reducing bureaucratic friction. From a risk mitigation standpoint, legal architecture is bolstered by the Anti-Blockade Law, enabling flexible partnership schemes designed to protect foreign capital against international sanction regimes, creating a highly receptive and secure environment for Indian capital.

This juncture unfolds high-value opportunities for India. The current environment favors partnerships between local and Indian companies to manufacture medicine raw materials (APIs) and biosimilar treatments. This enables technology sharing and exploits India's vast expertise in low-cost research and production. Aligning with the "Made in Venezuela" push, these corporations can establish operations in strategic Special Economic Zones (SEZs) like La Guaira and Puerto Cabello. By leveraging the tariff incentives in these jurisdictions, it becomes feasible to reactivate idle installed capacity, transforming it into local premium generic manufacturing hubs. This tactical move would not only



alleviate the country's chronic import dependency but also cement India as the definitive strategic partner in the sector's industrial revival.

Aspect	Benefits	Issues
Economy	Projected 20% growth for 2026; opportunities for Indian investments in generics and biosimilars; potential as a low-cost regional hub; reactivation of idle plants (40%).	Regulatory gaps; 95% dependency on API imports; logistical and political risks; supply chain volatility.
Technology	Interest in AI for industrial processes and supply chain; tech transfer opportunities for biosimilars, insulins, and antibodies; plant reactivation via Indian technology.	Basic infrastructure gaps (unstable electricity, limited internet); past contraction (75% collapse in 2018); R&D and biotech line limitations.
Demand	Expansion to 400 million units by 2026; unmet demand in complex molecules (oncology, diabetes, vaccines); viability of Indian generics and fractioned sales; import substitution alliances.	40% deficit in chronic therapies (hypertension, diabetes, mental health); 20% shortage in specialties; reliance on intermittent imports for high-cost drugs.
Competition	Dominance of national labs with accessible prices (US\$3.94/unit); entry of new transnational corporations; opportunities for joint ventures and repackaging hubs.	Fragmented market; low quality perception for imports from China, Turkey, and Iran; local R&D limits; structural API import dependency.
Consumer	Segmentation by purchasing power (85% seeks low costs); migration to private channels due to public volatility; prevalence of chronic conditions requiring recurring expenses.	Rational consumer with low brand loyalty and preference for established (nominal) ones; hybrid distribution network focused on delivery and social media.



Legal	Favorable framework for foreign investment; tax/VAT exemptions; fast-track sanitary registration; Anti-Blockade Law protects foreign capital; Special Economic Zone incentives.	Strict COMEX controls; need to mitigate international sanction risks; past bureaucratic friction (now improved via Single Window).
Structural	Sector strengthening via recovery (17.11% in 2025); 90% local volume supply; international cooperation (UNDP); consolidation of commercial pharmacies.	Exodus of qualified professionals (brain drain); public system reliance on external cooperation; sanitary infrastructure constraints.

Source: Own elaboration, based on cross-referenced data from specialized sources in the area.

Opportunity: Pharmaceutical Service Outsourcing

India holds a significant business opportunity within the Venezuelan pharmaceutical sector through service outsourcing, specifically targeting generic medicines. This strategy would leverage the underutilized installed capacity of the Venezuelan industry (operating at 63% of its potential) by activating instruments available for its immediate reactivation. Considering the National Executive's "Health and Life Plan 2026"—which seeks private sector alliances to address the population's health needs—outsourcing aligns with state supply priorities by facilitating the provision of quality generic medicines to a high-demand market. Furthermore, this initiative capitalizes on the Venezuelan political momentum toward diversifying international suppliers amidst the current institutional rearrangement.

One of the optimal vehicles to tackle this outsourcing would be the "Representation House" legal figure, recognized as the most efficient option under governance analysis. This legal entity acts as the foreign laboratory's representative in the country. While it does not conduct local manufacturing, it holds ownership of sanitary registrations. This ensures complete control over the brand and commercial strategy while circumventing significant operational expenditures (CAPEX) tied to building a production plant from scratch. Under this framework, India would manage manufacturing and export, whereas receiving and selling the product in Venezuela would fall to the partner or subsidiary. This only requires a warehouse, whether proprietary or subcontracted, that rigorously adheres to Good Storage Practices (BPA).

From a regulatory standpoint, outsourcing in Venezuela benefits from a modernized permitting ecosystem. Digital systems like SIVERC 2.0 function as a Fast-Track pathway, enabling digital dossier submissions and expedited commercialization permit procurement, cutting through paper bureaucracy. Also, to rapidly introduce generics to the market, utilizing "service medicines" is recommended. Until December 31, 2026, this permits the agile importation of known pharmaceutical specialties facing supply shortages in Venezuela, requiring a simplified dossier that includes the WHO-model Certificate of Pharmaceutical Product.

Evaluating the cost and logistics matrix, the outsourcing model enjoys competitive fiscal incentives. Under Decree 5.196 and 5.917, VAT and customs fee exemptions apply to critical medical



supply imports. Accordingly, a proposed hybrid strategy involves outsourcing API production in India while conducting secondary packaging via a Joint Venture, tapping into the available installed capacity for the immediate activation of Venezuelan laboratories. These operations would be situated in Special Economic Zones like La Guaira, allowing for Corporate Income Tax reductions for up to 10 years.

As previously stipulated, the Venezuelan market exhibits a sustained recovery, showing 17.11% growth in 2025 and projecting 20% for 2026, generating expectations of its entry into a productive consolidation phase. However, it must be emphasized that while projections are optimal, no outsourcing strategy is viable without a strict compliance roadmap. Although the Constitutional Law of Productive Foreign Investment grants foreign investors equal rights to nationals, partnering with local logistics operators and distributors is necessary and demands due diligence to ensure no supply chain actor is subject to OFAC sanctions. Additionally, to protect innovative formulas produced in India, undertaking preventive patent registration with the Autonomous Intellectual Property Service (SAPI) is mandatory. This is because Venezuela follows TRIPS standards but does not automatically recognize foreign-registered patents.

Opportunity: Bilateral Memorandum of Understanding

On March 17, 2026, Health Minister Nuramy Gutiérrez and Ambassador Ashokbabu Puliyadikumaran signed a Memorandum of Understanding between Venezuela's Ministry of Health and the Pharmacopeia Commission and the Ministry of Health and Family Welfare of the Republic of India. This agreement reflects the excellent bilateral relationship between the Republic of India and the Bolivarian Republic of Venezuela, with Venezuela's recognition of India's potential contributions to the national pharmaceutical sector.

The agreement, valid for 5 years with the possibility of renewal, establishes a reduction of the bureaucratic procedures that previously caused delays in the arrival of essential medicines and is regarded as an instrument that could facilitate direct investment in Venezuelan territory. Notably, India's Pharmacopeia Commission—whose responsibility is to establish the official quality and purity standards for medicines—is a signatory party, guaranteeing that agreements derived from the Memorandum will incorporate internationally recognized Indian national quality standards for imported medicines.

Venezuela's political will, is going to strengthen the pharmaceutical sector with India as a strategic reference extends beyond a diplomatic gesture. Through Indian Know-how, productive capacity, and a patent regime favorable to South-South cooperation, the Venezuelan State may seek to establish multilevel, long-term supply and exchange channels, as reflected in the renewal clause of this agreement⁹⁰.

⁹⁰ <https://mpps.gob.ve/venezuela-y-la-india-suscriben-memorando-de-entendimiento-para-fortalecer-cooperacion-binacional-en-medicamentos/>



PART VI

FINAL CONSIDERATIONS



PART VI

FINAL CONSIDERATIONS

The Venezuelan pharmaceutical sector represents a strategic opportunity for the Indian industry, where post-crisis recovery intertwines with persistent gaps demanding external innovation. Beyond the sector's expansion figures, the market is undergoing a structural transition: it operates under a limited self-sufficiency scheme that imperatively demands the injection of foreign expertise in complex areas, such as biotechnology and API synthesis. In this regard, the evolving situation presents a perfect opportunity to mitigate vulnerabilities in the domestic supply chain by leveraging the favorable regulatory frameworks still in effect.

Consequently, it is essential to consider capital injection into specialized machinery and equipment to address the structural deficit in local manufacturing. India, as a global leader in the production of low-cost generics and APIs, possesses a clear competitive advantage in the export and implementation of chemical processing machinery and heavy manufacturing. This would facilitate the installation of additional chemical synthesis plants in special economic zones. As previously mentioned, the "Plan for Health and Life 2026," combined with the political-economic context unfolding in Venezuela, appears to create fertile ground for the injection of Foreign Direct Investment (FDI) and cooperation through private sector alliances. Additionally, prioritizing direct investment in the implementation of laboratories and production lines for complex molecules—such as biologicals, insulins, and oncological treatments—is recommended, given the critical technological deficit and supply shortages in therapies for hypertension, diabetes, and mental health. By investing in these assets, Indian companies can optimize production cycles adapted to Venezuelan consumer behavior, ensuring efficiency in a volatile environment. Ultimately, this convergence of interests would allow India to consolidate its position as the "pharmacy of the world," utilizing Venezuela not merely as a destination market, but as a potential manufacturing and distribution platform for the rest of the region.

Likewise, the recent institutional strengthening of the bilateral relationship through the March memorandum provides an additional axis of predictability for investors. Beyond the diplomatic relaunch observed in early 2026, the conclusion of new sectoral cooperation instruments during 2026 represents a qualitative advancement in the India–Venezuela relationship, particularly in areas related to technology transfer, protection of industrial knowledge, intellectual property, and pharmaceutical development. This framework creates more favorable conditions for long-term projects based both on the commercialization of finished products and on the progressive localization of technological and productive capacities.

Thus, the suggestion remains that Indian companies should not limit themselves to exporting their products, but rather partner with local firms to produce and operate jointly. By absorbing and reactivating Venezuela's base industrial capacity, Indian enterprises can establish local manufacturing operations (fill & finish), ensuring profound control over the supply chain. Although inherent challenges exist due to infrastructure instabilities, the industry's proven resilience and adaptability allow for the structuring of efficient initial investment schemes to mitigate these risks. In fact, this operational complexity works in India's favor: it becomes an entry barrier for less adaptable Western competitors, clearing the way for Asian leadership.



Commercially, there is a strategic alignment between India's strengths and the needs of the local consumer. The profound economic rationality and high price sensitivity of the demand create the ideal scenario to capture the market with the Indian portfolio of high-quality generics. To maximize momentum and volume, the Indian industry merely needs to agilely adapt its entry strategy, prioritizing blister fractioning to dominate mass consumption, coupled with demonstrating product safety and reliability to Venezuelan consumers—for instance, through advertising. Simultaneously, the aggressive shortage of high-cost chronic therapies creates direct avenues for Indian laboratories to secure profitability margins superior to regional averages.

Added to this is a particularly favorable tax environment for the pharmaceutical sector. The exemptions and fiscal benefits currently in force for imported medicines, raw materials, and strategic inputs significantly reduce entry and operational costs for new projects. In practice, these incentives not only benefit the pharmaceutical market broadly, but also enhance the competitiveness of medicines, technologies, and investments of Indian origin entering the country under the regulatory schemes currently in effect.

Finally, the current process of regulatory flexibilization and tax incentives opens a tactical window for India. Today, the Indian corporate and diplomatic ecosystem has the capacity to directly influence local regulatory standardization, promoting legal frameworks that harmonize with their own protocols, shield their intellectual property, and guarantee the fluid repatriation of capital. In light of this, it is recommended that the Embassy of India assume a commercial vanguard role, spearheading high-level corporate engagements to structure pilot programs. This strategic move would not only secure the return on investment but also consolidate India as the indispensable hegemonic power for the healthcare sector in Venezuela.