

# Public Production of Medicines: Contribution to Health Autonomy in Colombia

Producción pública de medicamentos: contribución a la autonomía sanitaria en Colombia

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## Antioquia: Cradle and Future of Public Medicine Production in Colombia

The pharmaceutical tradition in Antioquia, Colombia, dates to 1915, when the first School of Pharmacy was established in Medellín. Since then, the region has been a pioneer in training human talent and consolidating scientific capacities in the pharmaceutical field. In the 1950s, the Social Security Institute (*Instituto de Seguros Sociales, ISS*) became the main health entity in Colombia (1). Although it underwent transition with Law 100 of 1993, it remained active until its liquidation in 2007, marking several decades of influence in the public access model to health services.

In the 1990s, the then Faculty of Pharmaceutical Chemistry at the University of Antioquia (*Universidad de Antioquia, UdeA*) promoted the creation of the Essential Medicines Production Plant, located at the University Campus in Medellín. This infrastructure emerged while the ISS was still operating, allowing a temporary coexistence and the transmission of its vision of social and academic service. Since then, the plant has consolidated itself as a key player in the production of basic medicines, as well as a platform for applied research and a practical training space for students and professionals. Today, attached to the Faculty of Pharmaceutical and Food Sciences, it has the capacity to produce more than 38 million units of non-sterile medicines per year and is certified in Good Manufacturing Practices by the National Institute for Food and Drug Surveillance (*Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA*) (2).

Nevertheless, although strategic, this infrastructure is insufficient in the face of growing national needs. Therefore, the new headquarters projected in El Carmen de Viboral (Antioquia, Colombia), with secured resources of more than 423 billion pesos and execution over seven years, represents a qualitative leap towards greater production capacities. The inter-administrative agreement, signed in December 2025 between UdeA, the Ministry of Health and Social Protection (*Ministerio de Salud y Protección Social, MinSalud*), and the National Institute of Health (*Instituto Nacional de Salud, INS*), guarantees the construction, equipment, and commissioning of this larger-capacity plant, aimed at contributing to Colombia's pharmaceutical autonomy (3,4).

### JOURNAL VITAE

School of Pharmaceutical and  
Food Sciences  
ISSN 0121-4004 | ISSNe 2145-2660  
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**How to cite:** Salamanca, C. H., & Amariles, P. (2026). Public Production of Medicines: Contribution to Health Autonomy in Colombia. *Vitae*, 33(1). <https://doi.org/10.17533/udea.vitae.v33n1a364050>



## National Policy Framework: Law 2386/2024 and Strategic Alignment

The construction of the new public pharmaceutical plant in Antioquia is framed within a broader national policy context. Law 2386 of 2024 established the foundations of Colombia's National Policy on Scientific Research, Technological Development, Innovation, and Pharmaceutical Industry Production for Health Autonomy, recognizing the pharmaceutical sector as strategic and promoting incentives for national production, international cooperation, and the training of specialized human talent (5). This law defines concrete routes to strengthen the scientific and technological capacities of the national pharmaceutical industry, ensuring the availability and access to essential medicines and technologies for the health system and the population.

In harmony with this legislation, Resolution 1452 of 2024, issued by the Ministry of Science, Technology and Innovation (*Ministerio de Ciencia, Tecnología e Innovación, MinCiencias*), adopted the Policies of Research and Innovation Oriented by Missions (*Políticas de Investigación e Innovación Orientadas por Misiones, PIIOM*), among which the mission of Health Sovereignty and Social Well-being stands out. Its purpose is to guarantee the availability of health technologies of public interest, while strengthening national scientific, technological, and industrial capacities (6).

Equally significant is the National Council of Economic and Social Policy (*Consejo Nacional de Política Económica y Social, CONPES*) Document 4129 of December 2023, which defined the National Policy of Reindustrialization. This document explicitly prioritized the pharmaceutical sector as a pillar of health autonomy and industrial strengthening in Colombia (7). More recently, CONPES Document 4170, approved in October 2025, declared of strategic importance the investment project Strengthening National Production of Pharmaceutical Products to Guarantee National Health Sovereignty, fiscally endorsed by the Superior Council of Fiscal Policy (*Consejo Superior de Política Fiscal, CONFIS*) (8).

Taken together, these instruments demonstrate that the new plant is not merely a regional project but a national strategy that articulates academia, the State, and industry. It embodies the path toward pharmaceutical autonomy envisioned by Law 2386/2024 and the CONPES documents, while reaffirming Antioquia's symbolic role as both the cradle of pharmaceutical education in Colombia and the epicenter of its future sovereignty in medicines.

## Pharmaceutical Sovereignty: The Right to Produce for Health

The notion of pharmaceutical sovereignty has gained increasing relevance in recent years, particularly after the COVID-19 pandemic, which exposed the fragility of health systems dependent on imports and concentrated production in a few countries. During the global health crisis, Colombia faced delays in the arrival of vaccines, shortages of basic supplies, and disruptions in international supply chains. These events revealed that the capacity to produce locally is not a luxury but a strategic necessity.

Pharmaceutical sovereignty is understood as the ability of a State to guarantee timely and equitable access to essential medicines and health technologies through local production, investment in science and technology, and adequate market regulation. In this sense, it becomes a practical extension of the right to health, recognized as fundamental in Colombia's Statutory Law 1751 of 2015 (9).

Scholarly analyses have emphasized that sovereignty requires a transformation in the role of the State. Calderón and colleagues argue that the State must move from being a mere market regulator to becoming an active economic agent, capable of driving innovation and national production (10). Similarly, Amariles and collaborators highlight that health autonomy depends on a solid pharmaceutical industrial policy, one that integrates academia, industry, and government to strengthen local scientific and technological capacities (11).

Ultimately, pharmaceutical sovereignty is not only about ensuring internal access but also about positioning Colombia as a regional actor capable of cooperating and competing in the international pharmaceutical market. It is a strategic dimension of health autonomy that links national well-being with global competitiveness.

## International Lessons: Reference Models

International experience demonstrates that public production of medicines can transform a country's position in the global pharmaceutical landscape. India, often referred to as the "pharmacy of the world," advanced through policies such as compulsory licensing and a strong commitment to generic drug production. These measures enabled the country to become one of the leading global suppliers of medicines and vaccines, and today India is preparing to scale up the pharmaceutical value chain, with projections of reaching 450 billion USD by 2047 through innovation in biotechnology, self-sufficiency in active pharmaceutical ingredients, and international expansion (12).

Brazil offers another significant example through the Institute of Drug Technology (*Instituto de Tecnologia em Fármacos, Farmanguinhos*) of the Oswaldo Cruz Foundation (*Fundação Oswaldo Cruz, Fiocruz*). This public complex has developed technologies for antiretrovirals and essential medicines, consolidating itself as a key actor in universal access policies and price regulation within the Unified Health System (*Sistema Único de Saúde, SUS*) (13).

Argentina has also institutionalized public pharmaceutical production through the National Agency of Public Laboratories (*Agencia Nacional de Laboratorios Públicos, ANLAP*), created by Law 27.113. ANLAP coordinates and strengthens a network of public laboratories dedicated to producing medicines, vaccines, and medical supplies. Among its most notable initiatives is the multipurpose plant project and the production of high-complexity medicines, such as biologicals derived from human plasma. The Hemoderivatives Laboratory of the National University of Córdoba stands as an emblematic example, consolidating Argentina's capacity to manufacture essential biological products and positioning the country as a regional reference in equitable access to health technologies (14).

Vietnam, a developing country with emerging economic potential comparable to Colombia, has recently approved its National Strategy for the Development of the Pharmaceutical Industry through 2030, with a vision to 2045. This ambitious plan establishes that 80% of medicines consumed in the country must be produced locally and that 70% of the market value should come from national production. The strategy also seeks to integrate Vietnam into global value chains and consolidate its role as a regional hub for technology transfer within the Association of Southeast Asian Nations (ASEAN). This approach not only guarantees internal access but also positions Vietnam as a relevant actor in the international pharmaceutical market, offering an inspiring model for Colombia as it seeks to strengthen its sovereignty through long-term policies (15).

## Challenges and Projections Toward Pharmaceutical Sovereignty

The construction of the new public pharmaceutical plant in Antioquia represents a historic milestone for Colombia. Yet, achieving pharmaceutical sovereignty requires more than infrastructure; it demands the articulation of policies, institutions, and social actors around a long-term national project.

Financial sustainability and maintain political support are the most pressing challenges. The initial investment is significant, the true test will be ensuring permanent resources for operation, research, and technological updating. International experience shows that public production initiatives often falter when they rely exclusively on state budgets without reinvestment mechanisms or efficient management models. Colombia must therefore design hybrid schemes that combine public financing with strategic alliances, avoiding dependence on political cycles and guaranteeing continuity over time.

Equally critical is the formation of highly specialized human talent. Pharmaceutical production requires professionals with competencies in chemistry, biotechnology, regulatory affairs, and industrial management. The University of Antioquia (*Universidad de Antioquia, UdeA*) and other institutions will need to expand their training programs and develop postgraduate curricula focused on pharmaceutical innovation, ensuring a steady flow of researchers and technicians capable of sustaining plant operations and driving new development lines.

Innovation and technology transfer constitute another decisive challenge. Colombia cannot limit itself to producing generics; it must advance toward biotechnology, vaccines, and advanced therapies. This implies strengthening international negotiation capacities to access frontier technologies, promoting applied

research in universities and research centers, and stimulating the creation of pharmaceutical startups that complement public production.

Regulation and governance are equally essential. The country requires a legal framework that balances intellectual property protection with universal access. During the pandemic, several nations resorted to compulsory licenses to guarantee access to medicines and vaccines. Colombia must be prepared to apply such mechanisms when public interest demands it, ensuring that patents do not become barriers to health.

Environmental sustainability also emerges as a priority. Pharmaceutical production generates chemical and biological waste that must be managed responsibly. The new plant in Antioquia must incorporate clean technologies, circular economy processes, and international sustainability standards, ensuring that sovereignty is not achieved at the expense of environmental degradation.

Finally, Colombia faces the challenge of regional integration. Latin American cooperation in public medicine production would reduce costs, share technologies, and strengthen collective health autonomy. Joint initiatives with countries such as Brazil and Argentina could generate synergies in research and production, positioning the region as a competitive bloc in the global market.

In the medium term, projections suggest that the new plant could supply a significant portion of national demand and contribute to the regional export of essential medicines. In the long term, Colombia could position itself as a leader in pharmaceutical innovation in Latin America, integrating biotechnology, vaccine production, and advanced therapies. Achieving this horizon requires a sustained State policy that transcends governments and consolidates itself as a national project of health and development.

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