

AFRICA'S PUBLIC
HEALTH SUPPLY CHAIN
INSTITUTION

THE PHARMACEUTICAL INDUSTRY IN SENEGAL



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ABBREVIATIONS

AfCFTA: The African Continental Free Trade Agreement

ANSD: National Agency for Statistics and Demography

CIP: Competitive Industrial Performance Index

DU: Delivery Unit (Project Management Unit for

Local Pharmaceutical Industry Relaunch)

ECOWAS: Economic Community of West African States

IPD: Pasteur Institute of Dakar

PRIPH: Local Pharmaceutical Industry Relaunch Project in Senegal

PSE: Emerging Senegal Plan

SCM: Substandard and Counterfeit Medicine

SCMPs: Substandard and Counterfeit Medical Products

UNCTAD: United Nations Conference on Trade and Development

UNIDO: United Nations Industrial Development Organization's

WAEMU: West African Economic and Monetary Union

WHO: World Health Organization

BACKGROUND

Africa in general, and Senegal in particular, are heavily dependent on the rest of the world for their pharmaceutical supplies. Africa is home to 17.2% of the world's population in 2020, but only accounts for 3% of global pharmaceutical production (375 manufacturers in 37 African countries, compared to 5,000 in India and 10,500 pharmaceutical companies in China, for example) (CENUA, 2019).

Access to essential medicines is a right recognized as universal by the international community. However, there is a huge gap between this right and the reality of the global pharmaceutical market. Indeed, the Covid-19 pandemic, with its containment measures, posed serious pharmaceutical supply problems for the entire African continent. By 2020, the main exporters of pharmaceutical products to Africa (the EU, India, Switzerland, China and the USA) had imposed export bans and/or factory closures, resulting in higher prices and, due to the drop in air traffic, higher transport costs.

This context of crisis has given rise to a new awareness requiring African countries to implement strategies to ensure the resilience of the pharmaceutical sector. The aim is to cover pharmaceutical needs by securing supplies and developing local production. In addition, since 25% of the world's patients from all pathologies are African, the development of pharmaceutical production has become a major issue of sovereignty.

In Senegal, as in most Sub-Saharan African countries, local production covers no more than 11% of pharmaceutical needs. In order to correct this heavy dependence on external sources, a plan to revive the pharmaceutical industry has been drawn up for 2021, in line with Senegal's industrialization strategy (2021-2035).

The aim of this article is to analyze the pharmaceutical industry in Senegal and propose recommendations for its sustainable development.

I. PRODUCTION CAPACITY IN SENEGAL

In Senegal, the number of production units was down between 2017 and 2019, due to the departure of 2 international players due in particular to problems with the profitability of their local operations and a change of strategy. Since 2020, this number has risen to 9, 6 of which are effectively operational (Table 1).

Table 1: Growth in the number of production units in Senegal between 2017 and 2021

Years	2017	2018	2019	2020	2021
Number	6	6	6	9	9

Source: ANSD, 2023

In 2021, local pharmaceutical production is estimated at 11.2% of the domestic market. It is divided between 6 manufacturers, as shown in table 2 below.

Table 2: Production units in Senegal in 2023

Name	Status	Year of creation	Pharmaceutical forms
IPD	Foundation	1896	Vaccines
VALDAFRIQUE	SA**	1942	Forms for external use
WEST AFRICA PHARMA	SA	2004	Dry forms & Liquid forms
TERANGA PHARMA	SAA	2019	Dry forms & Liquid forms
MEDIS	SA	1973	Dry, liquid and injectable forms
PARENTERUS	SA	2016	Solid solutions

^{*}IPD: Pasteur Institute of Dakar ** SA: limited company

1. Pasteur Institute of Dakar

The Pasteur Institute of Dakar was founded in 1896 and is now a private, non-profit foundation under Senegalese law. A pioneer in vaccine production in Africa, it offers a real comparative advantage. In addition, the advent of the COVID-19 pandemic revealed the relevance of a structure such as the IPD, which has consolidated its position as a regional health hub in Africa by offering its expertise in vaccine production, training, research and epidemic surveillance.

In Senegal, the IPD Manufacturing In Africa for Disease Immunization & Building Autonomy (MADIBA) initiative has been launched to set up a modular vaccine manufacturing plant capable of producing up to 30 million doses a year at full capacity in the Diamniadio area (Dakar region). Ultimately, the IPD will produce up to 300 million doses of vaccine a year against COVID-19 and other endemic epidemics (measles, rubella, etc.). Strong support has been provided by the Senegalese government and various partners from Africa, Europe and the USA to achieve this ambition.

2. Medis

Winthrop Pharma Sénégal, the international Sanofi Group's leading plant in West Africa, has been operating in Dakar since 1973 under the name SIPOA. Since its creation, the plant has been acquired in turn by Rhône-Poulenc, Aventis, Sanofi and, most recently, Médis-Tunisie. Today, it is one of the largest pharmaceutical production sites in West Africa. Medis has benefited from the financial support of the Senegalese government, which has invested FCFA 3 billion of the FCFA 5.5 billion initially pledged.

3. Valdafrique

Created in 1942 by the inventor of the Valda lozenge, pharmacist Henri Canonne, Valdafrique has become a major player in the West African hygiene and health products market.

The company manufactures a number of medicines and parapharmaceuticals, as well as household insecticides and bactericides.

It is now well positioned in the pharmaceutical production value chain, and aims to capitalize on its experience and expertise.

4. West Africa Pharma

West Africa Pharma is the Senegalese subsidiary of Moroccan pharmaceutical group SOTHEMA. Founded in 2004, its first industrial batch, COTRIXAZOL, an intestinal anti-infective, was launched in 2011. The medicines produced by West Africa Pharma are mostly generics. They are intended for the treatment of fevers, malaria and other diseases that are prevalent in the region.

5. Parenterus

Parenterus is a pharmaceutical industrial unit that was inaugurated on January 15, 2019. Born of a public-private partnership with players such as the Deposit and Consignment Office (DCO), DUOPHARM and leading businessmen and individuals, Parenterus is located in the commune of Diender (Thiès region). The plant produces massive solutions commonly known as "perfusions".

This project is one of the priorities of Senegal's health policy, aimed at democratizing the health system and guaranteeing every citizen access to quality health and social services at the lowest possible cost.

6. Teranga Pharma

Teranga pharma is a pharmaceutical industry owned by 670 Senegalese citizens, 95% of whom are dispensing pharmacists. Its ambition is to manufacture Teranga brand and generic medicines, as Senegalese pharmaceutical policy recommends the use of generic products. Its vision is very simple: to ensure Senegal's pharmaceutical sovereignty by 2030.

This clearly defined vision is based on three strategic axes. The first strategic axis is the production of Teranga brand medicines; the second is the launch of a logistics platform; and the third is the production of medicines for multinationals, i.e. subcontracting. The industry is working on generic pharmaceutical products, printing well-known brands such as flu and fever syrups.

II. DEVELOPMENT OF LOCAL PRODUCTION

After a period of steady growth, the local pharmaceutical industry began to decline sharply in 2013. Between 2013 and 2019, production fell from US\$84 million to US\$41 million, a decrease of 51%. In the most recent period, 2017-2021, the decline in production (19%) continues, but at a slower pace.

Local industry's share of the domestic market remains low and continues to deteriorate, despite the fact that a development strategy has been drawn up for 2021 in Senegal's industrialization policy and strategy document 2021-2035. This unfavorable trend can be explained by the steady rise in imports, coupled with declining production that is becoming less and less competitive. Between 2005 and 2021, in a period of 16 years, current-value imports grew at an average annual rate of 8.07%.

Factors hindering the development of pharmaceutical production include:

- Limited market size, limiting economies of scale and hence profitability prospects for pharmaceutical players,
- National regulations governing Marketing Authorization (MA) involve long and complex procedures (up to 2 years on average), making it difficult for different laboratories to access the market. This period was shortened with the creation of the Senegalese Pharmaceutical Regulatory Agency, which is committed to respecting the timeframe recommended by regulation N°04/2020/CM/UEMOA,
- Tax and customs regime largely favors medicine imports: finished pharmaceutical products entering the country are exempt from all taxes, unlike pharmaceutical inputs,
- The illicit pharmaceutical market and substandard and counterfeit medicines (SCM). A UNODC report in 2022 estimates that around 40% of SCMs are present in official distribution chains in the Sahel,
- The high cost of energy in Senegal can account for up to 20% of medicine cost structure, severely limiting the competitiveness of local players,
- Access to raw materials: over 90% of inputs for local pharmaceutical manufacturing are imported,
- A shortage of skilled workers, particularly in certain professions specific to the pharmaceutical industry (bio-production, operational professions, etc.),
- The high cost of pharmaceutical manufacturing equipment and technologies: most pharmaceutical manufacturing equipment is imported,
- Low investment in pharmaceutical R&D,
- The low contribution of research and development to local pharmaceutical innovation and the poor use of Pharmacopoeia resources,
- Pharmaceutical distribution in French-speaking Africa is dominated by two international players with their supply centers in Rouen, resulting in an almost systematic transit of most imports through France,
- The absence of a community marketing authorization for medicinal products for human use, unlike those for veterinary use,
- The population's low purchasing power, the high cost of hospital care and the lack of medical coverage for the vast majority of the population are structural factors that curb demand for pharmaceutical products and encourage recourse to traditional medicine and the illicit market.

III. IMPACT OF TAX AND COMMERCIAL POLICIES

In order to make medicines accessible to the population, the Government sets the prices of medicines in the public and private sectors through price regulation mechanisms such as approval, structuring of medicines prices or purchasing by tender. With this in mind, medicines are exempt from all import duties and taxes, justifying their classification in Category Zero (Social Goods) of the Common External Tariff (CET), which applies to all imports into the WAEMU and ECOWAS zones.

However, since the late 90s, there have been increasingly frequent conflicts between the tariff positions of products registered as medicines by the Ministry of Health on the one hand, and classified as nutritional supplements by Customs on the other. Between 2020 and 2021, in the context of COVID-19, this situation has been exacerbated, with growing disagreement between the players involved due to the significant increase in demand for vitamin and mineral complexes, and the multiplication of references classified in this category.

The Senegalese Pharmaceutical Regulatory Agency and the Senegalese Customs Service must reach a definitive agreement on the status of all the products concerned, in line with national pharmaceutical policy and the customs nomenclature, in order to give them an indisputable status that will put an end to recurring disputes.

IV. ANALYSIS OF THE PHARMACEUTICAL INDUSTRY'S COMPETITIVENESS

The United Nations Industrial Development Organization's (UNIDO) Competitive Industrial Performance Index (CIP) for the year 2023 ranks Senegal at the bottom end, to one hundred and two position (102nd).

The Doing Business and Global Competitiveness Index indicators show that there has been a deterioration in the structural competitiveness of the Senegalese economy since 2010. This trend is not conducive to the recovery and development of the pharmaceutical industry.

1. Benchmarking the pharmaceutical market

The pharmaceutical industry remains a very important and fast-growing sector for many economies around the world. According to IMS Health, global sales in pharmaceuticals are expected to reach between \$1,400 and \$1,430 billion by 2020. While the sector is dominated by developed countries such as the United States, the European Union and Japan, in recent years we have seen a growing improvement in emerging markets since the sudden arrival of the COVID-19 pandemic.

With its small pharmaceutical market size, Senegal presented ~229 Mn EUR (~ 250 million dollars) in 2019. This market is 80% dominated by the private sector and 20% by the public sector. Senegal imports around 90% of its medicines. This external dependence has been strongly felt by the pharmaceutical sector since the outbreak of the COVID-19 pandemic.

2. Pharmaceutical imports

Pharmaceutical product imports into Ghana, Tunisia and Morocco have followed a general upward trend over the last 20 years, between 2003 and 2022. This trend is more pronounced for Morocco, where between 2003 and 2022, the sum of imports rose from 194,826 thousand us dollars to 825,704 thousand us dollars, i.e., a fourfold increase.

In Senegal, pharmaceutical imports rose significantly from 97,981 thousand us dollars in 2004 to 313,129 thousand us dollars in 2022. Despite this trend, Senegal remains behind Ghana, which also saw an increase in pharmaceutical imports, from 42,382 thousand us dollars in 2003 to 348,773 thousand us dollars in 2022. In 2022, Senegal was the only country to have maintained an increase in pharmaceutical imports among the four countries studied. In general, the average of imports over the last five years reveals that Morocco imports the most, followed by Tunisia, Ghana and finally Senegal.

3. Pharmaceutical exports

In the pharmaceutical sector, Senegal and Ghana export very small amounts compared to Tunisia and Morocco. In the case of Senegal, pharmaceutical exports rose from 2,976 to 3,187 thousand us dollars between 2003 and 2020. In 2021, Senegal recorded a very low level of pharmaceutical exports compared to other years (922 thousand us dollars).

Ghana, which remains ahead of Senegal, has improved its pharmaceutical exports over the last 20 years, rising from 1,441 thousand dollars in 2003 to 1,962 thousand dollars in 2022. Only Senegal has recorded very low levels of pharmaceutical exports over the last two years. Overall, Tunisia is the biggest exporter, followed by Morocco, Ghana and Senegal.

V. NATIONAL DEVELOPMENT STRATEGY FOR THE PHARMACEUTICAL INDUSTRY

The Monitoring Operational Bureau (BOS) of the Emerging Senegal Plan (PSE) has organized a pre-Lab Pharma in 2020 and a Lab Pharma in September-October 2021, co-financed by Enabel (Belgian Development Agency), to develop the roadmap for the recovery of the pharmaceutical industry in Senegal to achieve local production targets (20% in 2025; 30% in 2030 and 50% in 2035) and minimize the risks of shortages or stock-outs.

One of Lab Pharma's key recommendations was to set up a Relaunching the Local Pharmaceutical Industry Project (PRIPH) management unit called the Delivery Unit (DU) within the Cabinet of the Ministry of Health and Social Action.

Table 03 below summarizes the intervention framework for Senegal's pharmaceutical sovereignty by 2035, as part of Senegal's industrialization strategy 2021 - 2035.

Table 3: Intervention framework for pharmaceutical sovereignty by 2035

PSE Guideline	Rebalance the balance of trade, which has been eroded by pharmaceutical imports.	
Strategic objective	Increase local coverage of national demand for pharmaceutical products to reduce dependence on imports	
Axis	Area 3: Development of the pharmaceutical industry and pharmacopoeia	
Programs	Lines of action	
3.1 Creating a framework conducive to the development of the pharmaceutical and pharmacopoeia industry value chain	Implement sector reforms for the pharmaceutical industry and pharmacopoeia	
3.2. Development of dedicated infrastructures for the pharmaceutical industry and pharmacopoeia	Set up integrated, connected platforms for the pharmaceutical industry and pharmacopoeia	
3.3. Developing human capital to support the pharmaceutical industry and pharmacopoeia	Guarantee the availability of skilled personnel to meet the needs of the pharmaceutical industry and pharmacopoeia	
3.4. Support for private initiatives in the pharmaceutical industry and pharmacopoeia	Strengthen existing pharmaceutical units. Support the installation of new pharmaceutical manufacturing and packaging units	

Source: Senegal's Industrialization Strategy 2021 - 2035

1. Establishing a framework conducive to the development of the pharmaceutical and pharmacopoeia industry value chain

The priority is to implement sector reforms for the pharmaceutical industry and pharmacopoeia.

Sectoral reforms were envisaged to create a framework conducive to the development of the pharmaceutical industry. These involve (i) revising the legal framework to attract new investors to the industry and (ii) supporting the restructuring of existing industries. To this end, the planned reforms include:

- Updating the 1954 texts governing pharmacy. A new law n°2023-06 of June 13, 2023, was promulgated.
- The creation of a national pharmaceutical regulatory authority. The ARP was created by decree 2022-824 of April 07, 2022.
- The simplification and acceleration of marketing authorization procedures (shorter lead times).
- Strengthening the fight against counterfeit medicines.

2. Human capital development in support of the pharmaceutical industry and pharmacopoeia

Investment in training and knowledge exchange is a priority, in line with the development of the Pharma Campus of the Pharmapolis project. The Faculty of Medicine and Pharmacy will also be a major asset in the development of skills. In the short term, the focus will be on the packaging and formulation segments, as well as the development of related industrial trades, to create local expertise focused on industrial pharmaceuticals and making it available for market exploitation. Training will also include in-company internships.

In support of this expertise, collaboration mechanisms are envisaged between local industries and multinationals to promote the exchange of knowledge and ongoing training of players. The Ministry of Industry will work with the Ministries of Health, Higher Education and Vocational Training to ensure that training needs are regularly updated.

3.Supporting private initiatives in the pharmaceutical industry and pharmacopoeia

Senegal is committed to providing targeted support for the development of the pharmaceutical industry and pharmacopoeia. The aim is to set up integrated and connected platforms for the pharmaceutical industry and pharmacopoeia. More specifically, this involves:



Strengthening existing pharmaceutical units

The reinforcement focuses on already established companies, to ensure that Senegal has a high-performance pharmaceutical industry. Support for these existing companies will be based on needs identified through an indepth diagnosis of each company, taking into account their development potential. Units operating in the pharmacopoeia sub-sector are also targeted.



Supporting the installation of new pharmaceutical manufacturing and packaging units

Senegal will also seek to develop investment opportunities all along the value chain, focusing initially on the installation of packaging and manufacturing units for priority molecules.

Positioning in these two segments is more strategic for Senegal in the short term, since they generate more revenue and require less investment. Each of these segments has a volume of between 40 and 65 billion FCFA on the national market, and 195 and 327 billion FCFA on the WAEMU market.



Promoting pharmacopoeia

Pharmacopoeia also represents a promising niche for local, regional and international markets. At the national and regional levels, in-depth studies are needed to gain a better understanding of current and potential consumption of medicinal plant-based products, and to analyze the possibilities for import substitution and the development of new products.

Through the regulation and promotion of the pharmacopoeia, Senegal aims to guarantee greater financial and geographical accessibility of medicines to populations, in line with international and regional guidelines. ECOWAS has set up a Traditional Medicine Program within the West African Health Organization (WAHO), and in 2012 drew up the document entitled the ECOWAS Pharmacopoeia of Medicinal Plants.

VI. RECOMMENDATIONS FOR PROMOTING THE LOCAL PHARMACEUTICAL INDUSTRY

1. Taking into account the African Union Strategy and the African Continental Free Trade Agreement (AfCFTA)

Small, fragmented markets and weak regulatory frameworks are among the main challenges facing Africa. For this reason, public institutions and private companies need to join forces, particularly when it comes to the wider harmonization and simplification of regulatory procedures for the licensing and marketing of medicines.

At present, African countries cannot compete with the European, Asian and American giants, who operate in larger markets and therefore benefit from economies of scale. With the AFTA and the creation of an African common market of 1.4 billion consumers by 2023 and 2.2 billion consumers by 2050, Africa can look forward to welcoming the world's pharmaceutical manufacturers.

To address this market fragmentation, the African Medicines Agency (AMA), a specialized institution of the African Union (AU), has been legally mandated by member states to improve their capacity to regulate medical products. The Agency will fulfill this mandate by coordinating and strengthening continental initiatives to harmonize the regulation of medical products, providing guidance, complementing, and reinforcing the efforts of the Regional Economic Communities (RECs) and Member States, and contributing to the expansion of access to medical products on the continent.

2. Lessons to be learned from international experience

Six (6) key success factors can be drawn from the international experience of emerging countries that have successfully taken up the challenge of developing their local pharmaceutical industry:

- Strengthening political will at the highest level of government, by reinforcing multi-sectoral cooperation and defining a holistic strategy,
- Promoting local production by regulating imports, accessing public procurement contracts, and encouraging foreign manufacturers to set up shop locally,
- Establishing a favorable business environment for foreign investors, notably by improving the tax framework,
- Eliminating customs duties and taxes on imported inputs so that finished pharmaceutical products enter Senegal without paying customs duties and are not taxed,
- Improving local skills in clinical and industrial pharmacy, bio-manufacturing and pharmaceutical regulation by setting up dedicated training courses,
- Improved governance: reviewing marketing authorization procedures and greater transparency within the national regulator (NM3 Country).

3. Economies of scale and firm specialization

Economies of scale refer to the reduction in the unit manufacturing cost of a product (or service) as production increases. Economies of scale can be promoted by pooled procurement mechanisms at the level of central medical stores and by access to the regional market. Furthermore, players in the Senegalese pharmaceutical industry complain that the relatively high cost of electricity partly explains their lack of competitiveness.

Indeed, a relatively low kilowatt-hour price is a competitive advantage, as are low prices for labor or other factors of production, but in the final analysis, what determines competition is the unit cost of production. And the latter is negatively correlated with economies of scale, which in turn increase with market size or demand growth.

Germany, for example, has the world's highest cost per kilowatt per hour, yet is the world's 3rd largest producer of pharmaceuticals, while Senegal, with a price (\$0.173) 5 times lower than Germany's (\$0.910), has negligible pharmaceutical production. The competitiveness of the German pharmaceutical industry is essentially based on the size of its domestic/foreign markets and its capacity for innovation.

4.Human capital development

One of the most fundamental aspects of the long-term sustainability of the pharmaceutical industry is the development of the human resources needed to fulfill the various functions within the pharmaceutical production system.

The system requires a strengthening of human capital within the regulatory functions, the operational technical aspects of manufacturing, and the business and management aspects of manufacturing.

5. Combating the illicit pharmaceutical market and substandard and counterfeit medicines

As part of a national action plan, preventive and repressive measures are urgently needed to eradicate this scourge and avoid its harmful health, social and economic consequences. Prevention, Detection, and Intervention are the trilogy of recognized solutions against substandard and counterfeit medicines, as recommended by the World Health Organization (WHO).

6. Integrated national strategy to boost the local pharmaceutical industry

The strategy for making the PRIPH project operational must be rapidly drawn up and shared, to stimulate a coherent, relevant industrial movement that guarantees the sustainability, competitiveness, equity and financial and geographical accessibility of healthcare products and technologies.

All this will inevitably have to take place within a pharmaceutical ecosystem that is strongly and scientifically regulated, in order to protect public health. Therein lies the challenge for Senegal and other African countries, particularly French-speaking ones, none of which has yet reached WHO level 3 maturity.

To ensure effective management of the local pharmaceutical industry's development strategy, the Delivery Unit will need to place greater emphasis on the concerted regulation of pharmaceutical production and encourage the specialization of local pharmaceutical firms, considering sub-regional and regional strategies.

CONCLUSION

Senegal has a weak pharmaceutical industrial base, but a long tradition of vaccine production gives it a comparative advantage in this field. Pharmaceutical production in Senegal has been declining steadily since 2013, stabilizing at 11.2% of the domestic market, a low share compared with Maghreb countries with domestic market shares of over 60%.

The objective of achieving local production covering 20% of national needs in medicines by 2025 seems objectively out of reach at the current pace of certain reforms.

However, there is room for hope if all the reforms envisaged are effectively implemented within the framework of a clear and realistic roadmap. In particular, the Senegalese government should, without delay, put in place the necessary physical infrastructure, promote human capital and create a business environment conducive to the development of the pharmaceutical industry.

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- 5. In this way, Senegal will not only ensure that its local industry contributes to local availability of medicines and other health products, but also makes a strong contribution to availability of and access to these medicines at regional level.



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