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POLICY BRIEF

DO AS EVERYONE ELSE:

Policies and strategies for the growth of Africa's pharmaceutical sector: lessons from South Korea, Algeria and South Africa

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EXECUTIVE SUMMARY

The development of a robust pharmaceutical manufacturing sector in Africa is critical for public health, pandemic response, and economic growth.

The role of trade and supportive industrial policy in developing and sustaining a medical manufacturing sector has proven crucial. Experiences from South Korea, Algeria, and South Africa demonstrate that a balanced approach of trade and industrial policy measures combining protectionist policies and supportive measures is essential for a successful and sustainable domestic medical manufacturing base. While incentives, tax rebates, and lifting import duties on raw materials are important, making imported finished products more expensive through tariffs and non-tariff barriers has played a significant role in fostering competitive domestic industries.

Key conclusions:

- A phased and sequenced approach that includes protective industrial policy tools, alongside supportive measures, is necessary for developing African pharmaceutical manufacturing.
- Pricing of locally manufactured products should be addressed through a long-term strategy, balancing manufacturer price guarantees with targeted tariffs or trade barriers on imported goods.
- Continental coordination, particularly through AfCFTA and Africa CDC collaboration, is crucial for implementing effective trade policies and facilitating intra-African pharmaceutical trade.
- African policymakers should consider using the same trade tools being employed globally in other strategic sectors to strengthen their domestic pharmaceutical industries.
- A comprehensive strategy that includes both “push” factors (cost-lowering incentives) and “pull” factors (market guarantees and protectionist measures) is essential for creating a robust and competitive African pharmaceutical sector.

INTRODUCTION

A robust pharmaceutical manufacturing sector is vital for public health and pandemic response, especially for Africa. The Covid-19 pandemic revealed that without control over production, African countries have little say in accessing pharmaceutical products.[1] Reliance on global redistribution efforts based on equity and solidarity proved unsustainable.[2]

Hence, key motivations to regionalise pharmaceutical manufacturing include securing reliable supply during global demand spikes and reducing dependence on imports from countries that may prioritise domestic populations.

Consequently, African manufacturing of medicines and vaccines has become a political priority, linked to health security[3] and pandemic preparedness. Simultaneously, industrial policies and trade barriers are intensifying globally across sectors such as automotive and semiconductor manufacturing,[4] adding to a tendency of undermining the order of global trade frameworks. In many instances, this forms part of explicit strategic political interests related to both geopolitics and to issues of supply security.

However, low- and middle-income countries – particularly in Africa – face challenges in implementing similar trade policies, despite pharmaceutical manufacturing being identified as a clear strategic priority. Global procurement institutions such as Gavi, GFATM and UNICEF, while reducing product prices through economies of scale, may inadvertently hinder the growth of African medical manufacturing through their procurement from international manufacturers. Concurrently, donors remain keen on maintaining "healthy markets", protecting earlier and existing investments in non-African manufacturing. In doing so, they are not considering that, in some instances, buying cheaper products to be delivered as development assistance to Africa amounts to medical dumping, and impedes African manufacturing and trade.

The Covid-19 pandemic challenged reliance on outsourced medical manufacturing and globally stretched supply chains.[5] Subsequently, developed countries are investing in their own medical manufacturing and adapting intellectual property frameworks.[6] The latter is partially characterised by a double standard resonating with the global Covid-19 pandemic response.

The current global recognition of the need to build and strengthen domestic pharmaceutical manufacturing and the increasing practice of reciprocal trade conflict,[7] is instructive for the potential and likely necessary tools, that Africa may need to institute to strengthen its continental manufacturing capacities.

Medical manufacturing is complex, requiring a balance of incentives and disincentives, as well as coordination across policy areas including health procurement, industrial policy, trade policies and research.

This brief examines experiences from South Korea, Algeria and South Africa in developing their pharmaceutical industries, focusing on conducive policies, including the potential of trade barriers and tariffs. It aims to provide insights for African policymakers to foster growth in their pharmaceutical sectors, and to elaborate how unorthodox tools such as trade barriers and tariffs can prove useful to furthering their interests.

THE SIGNIFICANCE OF THE PHARMACEUTICAL SECTOR

A strong domestic pharmaceutical industry contributes to improved healthcare outcomes by ensuring a reliable supply of essential medicines at affordable prices, often through manufacturing of generic products.[8] Moreover, the sector has the potential to drive economic growth through job creation, technology transfer and reduced reliance on imports.

Developing local medical manufacturing capabilities is particularly important for African countries, as they face unique challenges such as high disease burdens not commensurate with global pharmaceutical market dynamics, limited access to medicines and vulnerability to supply chain disruptions.

Lastly, and more poignantly, a change in relation to the dynamics of access to relevant medical products has emerged, highlighting the fact that, in crucial instances, who manufactures certain products matters at least as much as the historical and prevailing assumption that lower prices and greater volumes facilitate access. In other words, access to medicines is in equal measure determined on where certain products are made, as much as, or more, than the price of certain products.

Aside from well-established challenges of access to finance, reliance on donor and international procurers, lack of regulatory harmonisation and market fragmentation, there are other specific challenges that require continental coordination. Some of them are being addressed through the African Medicines Regulatory Harmonisation (AMRH) Initiative and the Africa Continental Free Trade Agreement (AfCFTA) through the Protocol on Trade in Goods in the Technical Barriers to Trade (TBT annex 6), which speaks to harmonisation of standards, technical regulations and conformity assessment procedures.[9]

In general, the pharmaceutical manufacturing sector is characterised by a centralised knowledge basis (the know-how of manufacturing processes of highly complex products), and slow development of this knowledge basis. Thus, in a sector where experience and expertise are as important as technology, it is considered commensurately difficult for new industry actors to "catch up" with existing industry players.[10]

In identifying necessary tools to support the regional manufacturing sector, African

policymakers are required to consider more traditional aspects of push and pull factors of industrial policies.[11] Pull factors relate to incentives for investments, including certain property rights or commitments of support, such as procurement and market guarantees. Push factors relate to promoting innovation through lowering associated costs, for example through tax breaks, grants or other financial support. Other pull factors are support for R&D or government-funded primary research available to innovators more broadly.[12] Already, specific pull factors are being developed. In June 2024, the Nigerian president announced a series of measures, such as specific volume guarantees to national manufacturers, and zero-tariff and tax on imports of specialised machinery equipment and raw materials. Moreover, the Africa Centres for Disease Control and Prevention's (Africa CDC) African Pooled Procurement Mechanism (APPM) was developed as a recognition of the need for continental-level supportive measures.

African policymakers should equally consider strong continental collaboration and coordination regarding tools that have been used and applied in the medical manufacturing sector historically, and that are currently being applied in other strategic sectors across the world. African policymakers should understand and accept, that trade-related tools, including deterrents and restrictions, at a continental level, are necessary to secure the sought-after African health security through the growth of the African pharmaceutical manufacturing sector.

CASE STUDIES OF SUCCESSFUL PHARMACEUTICAL SECTOR DEVELOPMENT

South Korea

Following the Second World War, South Korea implemented a mixed series of protectionist policies to support its nascent pharmaceutical industry. The trajectory of the supporting policy and sector went from import bans of products not made locally and other strong protectionist measures, from the 1970s onward.

As the sector developed capacities and grew, this led to a gradual opening of the market and import bans being lifted in the 1980s, allowing for international competition. In turn, this necessitated direct support and investment in R&D, to maintain a competitive industry. Initially, these supportive policies focused on needs within the domestic market, graduating into a more cluster-based approach targeting support for specific product categories. Notably, it was only in the 1990s that the South Korean pharmaceutical manufacturing sector reached a stage where it was considered as a source of employment and wealth creation.[13]

One particular and key aspect of South Korea's industrial policy was the implementation of high tariffs and import quotas on foreign pharmaceutical products. This aspect was designed to limit competition from established international players and create a protected market for domestic manufacturers. By shielding local companies from foreign competition, the government aimed to provide them with the necessary space and time to develop their capabilities and gain a foothold in the domestic market.[14]

In addition to specific trade barriers, the South Korean government provided direct financial support to the pharmaceutical sector through subsidies and investment incentives. These incentives intended to encourage domestic companies to invest in R&D and expand their production capabilities. The government also established dedicated funds and programmes to support the development of new drugs and technologies, further boosting the sector's growth.[15]

Another important aspect of South Korea's industrial policy was the promotion of technology transfer and collaboration with foreign pharmaceutical companies. The government actively encouraged partnerships between local firms and international players, facilitating the transfer of knowledge and expertise. These collaborations helped

South Korean companies acquire advanced technologies and manufacturing processes, accelerating their development and enabling them to compete in the global market.[16]

The South Korean government recognised the importance of human capital development in building a strong pharmaceutical sector. The country invested heavily in education and training programmes to cultivate a skilled workforce, with a focus on science, technology, engineering and mathematics (STEM) fields. The government established specialised universities and research institutes dedicated to pharmaceutical R&D, ensuring a steady supply of qualified professionals to drive innovation in the sector.[17]

Furthermore, and more recently, South Korea's industrial policy included targeted support for the development of specific pharmaceutical segments, such as biosimilars. The government implemented policies to promote the production and uptake of these products, recognising their potential to improve access to affordable medicines and reduce healthcare costs, while also seeking out a role for South Korean manufacturers in developing and expanding product category.[18] This targeted approach helped domestic companies build expertise in these areas and capture a significant share of the market.

The success of South Korea's industrial policy in developing its pharmaceutical sector is evident in the emergence of strong domestic players such as Samsung Bioepis and Hanmi Pharm. These companies have not only become major players in the domestic market but have also expanded their presence in international markets, competing with established global pharmaceutical giants.

However, South Korea's protectionist policies also had some unintended consequences. The limited exposure to foreign competition and the focus on domestic market protection led, in some instances, to higher product prices for consumers and more narrow innovation compared to countries with more open markets. As the sector matured, the government gradually relaxed some of these protectionist measures to encourage greater competition[19] and also came under pressure from external actors to enforce intellectual property (IP) rights, eventually affecting the industry. Stricter IP rights enforcement led to a larger proportion of the uncompetitive Korean market being dominated by international companies, reducing the relative value of the Korean pharmaceutical sector compared to international actors in the Korean market.[20]

Nonetheless, the sequencing of strong and supportive industrial policies, including tariffs and non-tariff barriers, proved instrumental in particular stages of the development of South Korea's pharmaceutical manufacturing sector.

Algeria

Algeria's pharmaceutical industry has a rich history that dates back to the country's independence in 1962. The Algerian government has played a significant role in shaping the sector's development through various policies and initiatives, aimed at promoting domestic production and reducing dependence on imports.

A significant part of this has been a deliberate and strong focus on import substitution policies, pricing regulations and premiums for locally manufactured products. The latter in some cases up to 27%.[21]

In recent years, Algeria has made significant strides in revitalising its pharmaceutical industry. The government established the Ministry of Pharmaceutical Industry (MOPI) in 2021 and the National Agency for Pharmaceutical Products (ANPP) in 2008 to modernise the sector, streamline regulations and encourage foreign investment.[22] Today, The Algerian industry covers between 60-70% of the country's need for generic medicines.[23]

The Algerian example follows a pattern of sequenced industry protection, followed by gradual opening of the sector to international companies, and a partnership-focused industry approach, which in broad strokes has similarities with South Korea. In the 1970s, Algeria embarked on a series of nationalisation policies that brought key industries, including pharmaceuticals, under state control to regulate the sector and promote local production.[24] During this period, Algeria focused on building its manufacturing capabilities and developing a strong foundation for its pharmaceutical industry.

This was followed by gradually increased private investment, informed by a national development plan for the sector that included incentives for private companies to invest in the industry and encouraged partnerships with foreign firms to transfer technology and expertise.

A significant milestone in Algeria's pharmaceutical industry came in the 1990s with the establishment of the Saidal Group, a state-owned pharmaceutical company. Saidal played a crucial role in the development of the sector by producing essential medicines and collaborating with international partners to acquire new technologies. The company's success demonstrated the potential for domestic production and paved the way for further

investment in the sector. In 2022, Saidal established the region's first bio-equivalence centre.[25]

Algeria's pharmaceutical sector has however, faced challenges over the years. Import restrictions and local content requirements, have led to supply chain disruptions and hindered the competitiveness of local manufacturers on the global market.[26] This in turn led to a renewed focus on strengthening the regulatory framework and improving production standards. The government introduced the National Agency for Pharmaceutical Products (ANPP) in 2008 to oversee the quality, safety and efficacy of medicines.[27] This institutional reform helped to enhance the credibility of locally produced medicines and attract foreign investment. Both the improvement of domestic regulatory capacity and ability to attract international investments resulted in the Algerian market to be worth an estimated minimum of $4-billion and growing at double-digit rates,[28] making it the second largest in Africa, by volume and value, after South Africa.[29]

Despite the attractive market, international manufacturers and their governments have in the past described the Algerian market as difficult within which to establish a presence,[30] which the Algerian government has sought to address through simplified registration processes. The pharmaceutical industry along with select others, remain categorised as a strategic industry, where majority Algerian ownership is required.[31] However, as part of targeting export markets, Africa in particular, pharmaceutical export companies can now be 100% foreign-owned.[32]

The establishment of the Ministry of Pharmaceutical Industry (MOPI) in 2021 and the ongoing efforts to streamline regulations and attract foreign investment demonstrate the government's commitment to further developing the sector.[33] Such specific and strategic support has helped to develop a manufacturing sector that today caters for almost 70% coverage of domestic market needs, as well as reducing the pharmaceutical import bill by 40%, partially through targeting specific products and categories reliant on imports.[34]

Algeria's experience in developing its pharmaceutical industry highlights the importance of strong and well-sequenced government support. It is not always without difficulties and complexities, as stock ruptures indicate, yet it highlights the relevance of strong import substitutions policies and gradual opening of international competition, guided by long-term planning and collaboration.

South Africa

Since 1994, South Africa has developed various industrial policies to support the growth and development of its pharmaceutical sector and improve access to essential medicines. While some policies have had a positive impact, others have faced limitations and challenges in their implementation, resulting in limited beneficial impact on the industry.

South Africa, like Algeria, represents one of the most advanced medical manufacturing sectors in Africa, and the South African pharmaceutical market remains the largest in Africa[35]. The South African government is also one of the largest procurers of antiretroviral medicines globally[36].

In 2007, the Department of Trade and Industry (dti) introduced the Accelerated and Shared Growth Initiative for South Africa (AsgiSA), and the Industrial Policy Action Plan (IPAP).[37] Both industrial policies intended to support the pharmaceutical manufacturing sector. The IPAP, a whole-of-government initiative that covers several industries,[38] identified the pharmaceutical sector as a priority industry and outlined strategies to promote local manufacturing by increasing investment and enhancing competitiveness. The plan included measures such as preferential procurement of locally produced medicines, support for research and development, and the establishment of a Pharmaceutical Industry Development Strategy.[39]

The Preferential Procurement Policy Framework Act (PPPFA) of 2000, and subsequently a revised Act taking effect in 2023, has equally sought to support the local pharmaceutical industry. The PPPFA allows for the preferential procurement of goods and services from historically disadvantaged individuals and local suppliers. In the context of the pharmaceutical sector, this policy has encouraged the procurement of locally manufactured medicines by government entities, providing a market for domestic producers. However, for non-pharmaceutical products, the highly decentralised structure of public procurement of health products has not always favoured locally manufactured goods.[40]

Another key policy initiative has been the South African Health Products Regulatory Authority (SAHPRA), established in 2018 to replace the Medicines Control Council (MCC). SAHPRA aims to streamline the regulatory process for medicines registration and approval, seeking to reduce delays and backlogs that have historically hindered the entry of new products into the market.[41] By

improving the efficiency of the regulatory system, SAHPRA seeks to create a more conducive environment for pharmaceutical innovation and investment. Through its route to becoming the first Maturity Level 4 regulator in Africa, it is likely to further impact and support the South African manufacturing sector.

The South African government has moreover implemented policies to support the production and use of generic medicines, which play a crucial role in improving access to affordable treatments. The Medicines and Related Substances Control Amendment Act of 1997 introduced measures to promote generic substitution and parallel importation, aiming to lower drug prices and increase competition in the market.[42] However, the impact of these policies has been limited by concerns about the quality and safety of generic medicines, and resistance from healthcare providers and consumers.[43]

To directly support the pharmaceutical industry, the South African government implemented various incentives and funding mechanisms. The Technology and Human Resources for Industry Programme (THRIP) provides grants for research and development projects that involve collaboration between industry and academia,[44] including for pharmaceuticals. The Strategic Industrial Projects (SIP) scheme offers tax incentives for investments in the pharmaceutical sector, and the Critical Infrastructure Programme (CIP) supports the development of infrastructure needed for pharmaceutical manufacturing.[45]

South Africa's pharmaceutical trade deficits have grown over the years, and international manufacturers have decreased their manufacturing capacities in the country. South Africa's policy measures have led to some successes in specific product areas. The government's targeted support for the local production of paracetamol active pharmaceutical ingredient (API), through import restrictions on finished paracetamol products, has helped to sustain domestic manufacturing capabilities in this area. Currently, South Africa is home to one of only two to three African API manufacturers. This example highlights the potential for strategic industrial policies to support specific segments of the pharmaceutical value chain.[46]

Despite the various efforts, the South African pharmaceutical industry continues to face challenges. The impact of industrial

policies has been limited by factors such as inadequate implementation, lack of coordination among government agencies and resource constraints. This has been exacerbated by strong competition from imported medicines.[47] For example, the country's intellectual property and licensing framework is criticised for hampering access to medicines due to the lack of a compulsory licence.

South African manufacturers have struggled in the context of global value chains and competition with cheaper imports, including APIs. The exposure to and reliance on global value chains and competition have, on one hand, allowed for better access to products through imports. On the other hand, as witnessed both during the Covid-19 pandemic and recently in relation to specific products such as insulin pens,[48] have highlighted the vulnerability of such reliance, leading to a risk of product shortages.

South Africa represents an example where policies in and of themselves, including preferential procurement, have proven insufficient. The balance between industry protection and global market integration has to some extent weakened the domestic pharmaceutical manufacturing industry. South Africa exemplifies a context where the absence of a more sequenced approach of stronger protective industrial policy, including tariffs and non-tariff barriers, has undermined the sector. This is highlighted in the growing trade deficit in pharmaceutical products, with imports continuing to grow.[49]

LESSONS FOR AFRICAN POLICYMAKERS

The case studies of South Korea, Algeria and South Africa offer valuable insights for African policymakers seeking to develop their pharmaceutical sectors:

Balanced approach to non-tariff barriers and tariffs

Protectionist policies, such as tariffs and other barriers, alone are not sufficient for growing the African pharmaceutical sector. There is also a need for support measures to establish an enabling environment for manufacturing, including through comprehensive sectoral strategies, public investments, preferential procurement, and market guarantees from governments and international donors. However, protectionist policies have played a significant role in fostering and developing a competitive pharmaceutical industry in several countries. In addition to supporting the manufacturing ecosystem, African policymakers should therefore consider a gradual and sequenced approach that includes protective industrial policy tools.

Policymakers must carefully balance the benefits and recognise the risk of such measures with potential drawbacks, such as higher drug prices for consumers and risk of slower innovation. Yet, the documented and necessary role that tariffs and non-tariff barriers have played, warrants that such tools should be constructively considered. A phased approach that gradually exposes domestic companies to international competition can help strike this balance. Measures such as the new order on pharmaceutical trade announced recently in Nigeria – relinquishing tariffs and VAT on certain input materials crucial to build and support the local manufacturing sector[50] – are important to support local manufacturers in accessing the needed materials for production at a more affordable price. However, in the absence of additional measures to actively protect the sector, such as tariffs and protective trade barriers on imported medicines and final products, such supportive polices and incentives are unlikely to have the desired effect.

Overall, political will is key enabler in supporting a strong pharmaceutical industry. Such political will need to have a balanced approach between push factors and protectionist policies that primarily encourage and facilitate manufacturing through cost lowering, and pull factors for an enabling environment, including reliable guarantees.

Pricing of locally manufactured products

The elephant in the room is the price that African-made products will arrive at. Pricing should be addressed through a phased and long-term approach that is based on engagement with the domestic industry to ensure corresponding price guarantees from the manufacturers. "Made in Africa" should not be a blank cheque to supply a domestic or African market without clear targets for lower and competitive pricing.

On the other hand, and within a corresponding timeframe, this should be balanced out by targeted and specific tariffs or trade barriers that protect the domestic industry by making imported goods more expensive: a phased and time-bound *quid pro quo* strategy that integrates push and pull factors.

Positive support measures, such as in Nigeria, or preferential procurement frameworks, are most likely to work if accompanied sufficiently by protectionist trade measures that make imported and competing products more expensive. South Africa's vaccine procurement in 2023 demonstrates the risks of an approach where price is a deciding factor. Significantly lower prices for imported vaccines were insufficiently addressed and left the South African government with limited choice in terms of procurement. Hence, pricing of locally manufactured products should be considered over the long term.

Comprehensive strategy for sector development and regional coordination

Currently, tariffs and trade barriers are instituted unilaterally and selectively on sectors that more powerful nations consider of strategic relevance. For Africa to do the same won't be easy, and it will require exceptional continental coordination. However, as countries globally are looking to near-shore and rekindle support for specific manufacturing sectors, including pharmaceutical and vaccine manufacturing, Africa could in many instances be following global trends.

Secondly, protecting and growing a pharmaceutical manufacturing sector in Africa may further entice investment and partnerships with international manufacturers, who are otherwise reluctant. Trade policies will prove no panacea, as other policy initiatives are necessary as well. As witnessed in both Kenya and Nigeria in 2023,[51] monetary and fiscal policy play equally important roles in maintaining international manufacturing.[52]

As the AfCFTA is implemented, the role that intra-African trade can play in support of African medical manufacturing is crucial. It is necessary, that efforts of the AfCFTA

and in practical terms, its secretariat, are integrated into other continental policy frameworks and initiatives. This includes the AfCFTA supporting the APPM and regulatory harmonisation initiatives by practically facilitating and supporting inter-African pharmaceutical trade. The AfCFTA can moreover support the medical manufacturing sector broadly through advocating and engaging its Member States on the need for a phased and comprehensive approach on push and pull factors, including potential tariffs and trade barriers.

Continental guidance and leadership are necessary to enable African countries to make difficult policy decisions on matters that may not be easy or popular, such as tariffs and barriers protecting the continent as a whole. This is a role well suited for AfCFTA, as it represents Africa at global stages and interacts with multilateral and international actors. Strong collaboration and cooperation between the AfCFTA secretariat and Africa CDC is a key step in addressing trade barriers for locally manufactured medical products. A potential framework for collaboration between the agencies offers the opportunity to harness complementary functions of the agencies and to promote an ecosystem-wide approach for policy development for African-made value chains in pharmaceutical manufacturing.

Facilitating trade across African countries and manufacturers, should be made a priority. In this regard, strengthening the Pan-African Payment and Settlement System (PAPSS) as a tool to facilitate trade and exchange. The PAPSS, in its current state, however, struggles under slow adaptation from central banks, limited actual trade to facilitate and accelerate its rapid adoption, as well as requiring training and education of relevant staff in the banks that have adopted PAPSS. As with other continental initiatives, this highlights the risk of discrepancy between official political declarations and the commitment to implementing concrete policy measures.

CONCLUSION

The experiences of South Korea, Algeria and South Africa demonstrate that strategic use of trade barriers and tariffs can play a vital role in the development of a strong domestic pharmaceutical sector. However, African policymakers must adopt a balanced and comprehensive approach that considers the unique challenges and opportunities faced by their countries

By investing in infrastructure, research and development, and human capital, fostering an enabling environment for domestic companies and promoting regional cooperation, African countries can build resilient and competitive pharmaceutical industries that contribute to improved healthcare outcomes and economic growth.

This may only serve to address one side of the coin, however. For the African medical manufacturing sector to become competitive in products and prices, countries must equally consider strong internal and continental coordination, including tools that actively disincentivise relying on cheaper and imported products at a national, regional and international level, also addressing pooled procurement mechanisms of international health organisations. Equal opportunity does not necessarily lead to equal outcome – and if African medical manufacturing is to play a bigger role in continental health security, countries and continental institutions should not shy away from using the same trade tools that are being used at a global level in other, equally strategic sectors.

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