



POLICY BRIEF

STRATEGIES FOR ENHANCING AFFORDABILITY THROUGH PROCUREMENT & RELATED POLICY INCENTIVES FOR THE PHARMACEUTICAL SECTOR



Strategies for Enhancing Affordability through Procurement & Related Policy Incentives for the Sector

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1. EXECUTIVE SUMMARY

This policy brief arises from a study commissioned by the Scinnovent Centre and undertaken by ACTS under the auspices of the Science Granting Councils Initiative (SGCI). The study focused on building competitive and socially inclusive local pharmaceutical industries in West Africa and addressed five issues: affordability, human resources, research and development, intellectual property and technology transfer. This policy brief presents findings on the impact of public health procurement policies as a tool for promoting growth and performance of local pharmaceutical industries and enhancing affordability. Overall, it shows that whereas West African countries have put in place several policy incentives, the impact to local industries and social inclusion has been on the minimum. The policy brief explains why and makes recommendations on what else can be done to enhance affordability of locally manufactured medicines.

2. INTRODUCTION

Many African countries, through their development plans, have prioritized access to affordable healthcare services. However, the realization of these aspirations has been constrained due to the high costs of imported medicines, which not only increase the health burden but also have negative implications on access and affordability of medicines. Affordability is important since up to 90 % of the populations buy medicines through out-of-pocket payments. As a result, many African countries have started initiatives to promote local pharmaceutical manufacturing, to address the issue of high costs of imported medicines and to tap on additional benefits that local pharmaceutical industries can bring, such as creation of employment opportunities, technology and skills transfer and enhancing intra-Africa trade. This has led to the establishment of about

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172 local pharmaceutical firms in the ECOWAS region. Nigeria is leading with 120 firms, followed by Ghana with 37 firms; while Senegal and Cote d'Ivoire have five firms each. Benin, Burkina Faso, Cape Verde and Guinea Conakry have one firm each.

Despite the above high number of local firms, currently local production covers less than 30% of the demand for medicine in the region. Ironically, most of these firms operate at less than 40 % capacity. This is a paradox, illustrating a challenge that whereas there is at least 70% unmet local market for medicines in the region, the existing local firms cannot access it. To get answers for this contradiction and other related issues, a study was commissioned to review the sector and propose interventions. The study focused on issues of affordability; human resources; research and development; intellectual property; and technology transfer and covered nine ECOWAS countries - Ghana, Nigeria, Senegal, Côte d'Ivoire, Togo, Benin, Mali, Guinea Conakry and Cape Verde. These countries were selected based on the existence of at least one local pharmaceutical manufacturing firm. The study, explored the use of public health procurement, as a tool for promoting the growth and performance of local pharmaceutical production. It was premised on the procurement policy that provides preferential treatment to local pharmaceutical industries would spur more local production of essential medicines, reduce cost of medicine and therefore enhance access and affordability and social inclusion. The study (a) documented the existence of procurement policy incentives that promote local pharmaceutical industries; (b) their impacts on production and consumption patterns; growth and capabilities of the local pharmaceutical manufacturing; and ability of the local manufacturing to serve the poor; (c) documented experiences, best practices and success stories from those countries that have implemented such policies; and (d) make appropriate policy recommendations and interventions.

3. METHODOLOGY AND RESULTS

The required information was obtained through desk study, interviews, and stakeholder's consultations, in five ECOWAS countries (Nigeria, Ghana, Cote d'Ivoire, Senegal, and Togo) by national consultants. In addition, a scoping desk study was undertaken on Mali, Guinea Conakry, Cape Verde and Benin. In addition to national/in-country studies, comparative country studies were also used to document the differences and similarities in approaches between Anglophone and Francophone countries. Benchmarking studies were also undertaken targeting India, China, Brazil, Morocco and Ethiopia, to identify some best practices. The national consultants prepared national reports, which were moderated during a three-day experience sharing amongst the five consultants in Abidjan, Cote d'Ivoire. The main findings of this study are outline below:

There exists procurement policy Incentives:

The study established that most of the West African countries have in place procurement policy incentives to support local pharmaceutical industries. These are: preferential treatment of local companies; ring-fencing certain products for local manufacturing companies; and prohibiting importation of medicines that are being produced locally.

- a. *Preferential treatment* – All the countries studied have policy incentives that provide between 5-15 % preferential treatments of local industries for public procurement of

medicines. In Ghana, for example, the Public Procurement Act (Act 914)⁸ (as Amended in 2016) provides a margin of preference of 15% to locally produced medicines under the National and International Competitive Tendering processes. In Nigeria, the Public Procurement Act of 2007 has a provision for a domestic preference policy which gives an extra margin of 7.5% for goods and 15% for services on prices is allowed for domestic suppliers when bidding with their foreign counterparts under an international competitive bid and has been used to support local pharmaceutical industries. In Senegal, there is the National Preference Programme, under which, local industries are allowed a margin of 5-15% during international tenders. From the first review of the trade policies and practices of WAEMU held in October 2017, it is reported that national preference policy is applicable to all Members of the West African Economic and Monetary Union, WAEMU (Benin, Burkina Faso, Côte d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal, and Togo).

- b. *Ringfencing of certain products:* All the countries have recently applied the policy of ringfencing certain products for local companies. For example, Ghana, in August 2017, through a Gazette Notice No 74 (LI 2255⁹), ring-fenced forty-nine (49) products to restrict them to only local manufacturing with the hope that this policy intervention will bring down the prices of those products. Similarly, Senegal, in collaboration with the industries developed in 2017 a national tender program, in which, a list of 60 products have been ringfenced for the local industries. Again, this policy is applicable to all WAEMU countries.
- c. *Prohibiting importation of certain products:* Finally, WAEMU countries are using national preference agreement, which prohibit importation of medicines with the same active ingredient, pharmaceutical formula and dosage as those manufactured locally, to support the local pharmaceutical industries. It is said that this policy is also applicable to other WAEMU countries. This is with reference to the trade policy review of October 2017. It is further noted that WAEMU, trade in local products is, in principle, free of duty and import taxes. Tariff preferences for processed products require two prior approvals (of the product and the manufacturer) in addition to the certificate of origin in order to guarantee the origin of the product and the nationality of the manufacturer.

In Nigeria, pharmaceutical products are on the import prohibition list. This is intended to give further encouragement and desirable protection to local manufacturers of pharmaceutical products. However those who, despite the prohibition, import such products under special permission, pay the required duties.

- d. Apart from the above incentives, all the countries have put in place National Health Insurance Schemes, which can be an important tool for enhancing access and affordability. For example, the Ghana National Health Insurance Schemes, NHIS¹⁰ is a major player in the Pharmaceutical sector and a determinant on the promotion of LPP since more than 50% of pharmaceuticals to consumers are financed by it. As a result, following the introduction of a policy which exempts Active Pharmaceutical Ingredients from VAT payments for manufacturers, NHIS is in discussion with the stakeholders to reduce their published prices by 30%. From the Francophone side, government of

⁸ PPA (Act 914) as Amended 2016

⁹ <https://ghalii.org/gh/gazette/GHGaz/2017/2017/74/01-august-2017>

¹⁰ <http://www.nhis.gov.gh/files/ACT852.pdf>

Senegal has set up the Universal Health Coverage (CMU) program to enable medical coverage of populations, in particular, the rural population and the informal sector through community health. (Source: Ministerial circular MSAS Sept 2019).

In Nigeria, the intervention of Public Bureau for Public Procurement has facilitated bulk purchase of medicines and other products, lowering the cost of medicines for NHIS only in Nigeria. The Federal Government is expected to procure drugs for the Federal University Teaching Hospitals and Federal Medical Centres; who are at the tertiary levels whereas the state and local governments cater for the healthcare in their subunits respectively. This fragmentation of drug procurement also affects the affordability, quality and quantity of drugs dispensed at each level of healthcare in Nigeria.

The Impact of the preferential procurement policies on local pharmaceutical industries is minimal:

This is attributed to low level of competitiveness; low production capacities and taxes on finished pharmaceutical products. There are also country specific factors.

- a. Low Competitiveness: Local manufacturers in the nine countries are not able to take advantage of the procurement preferential policies because of lack of competitiveness of the locally produced products compared to imported drugs. This is attributed to the following three reasons. First, the cost of energy and water is significantly higher in ECOWAS than in India and China, the main sources of imported medicines. Secondly, all pharmaceutical industries in the region import over 80 % of their inputs, mainly from the two competitor countries (India and China). Almost all machinery and equipment, laboratory equipment and reagents, and raw production materials, including active pharmaceutical ingredient (APIs), aluminum foil for blister packaging, other labelling materials, and excipients are imported. Thirdly, due to long duration for imports of inputs, local industries are forced to hold large inventories to ensure steady production. This has a significant consequence on working capital given the high cost of finance in African countries.
- b. Production Capacity: Local industries have not adequately benefitted from the national tender programme of ring-fencing products, since they did not have in their portfolio all the 60 requested products which is a generalized principle in the region.
- c. VAT on finished products: Since 1969, World Health Assembly VAT was charged on the finished pharmaceutical products, which increased the prices of the drugs produced locally. However, this has since been reviewed in the ECOWAS countries. For example, in 2018, the Government of Ghana launched the third edition of the National Medicines Policy (NMP)¹¹, which recommended, amongst others, VAT exemptions on Finished Pharmaceutical Products (FPP) and Active Pharmaceutical Ingredients (APIs). Similarly, WAEMU countries have also zero-rated imported medicines, granting them exemption from customs duties and VAT on imports
- d. Country specific policies: In Ghana, the margin of preference of 15% is limited only to national level and excludes regional and facility levels which constitute almost 50 % of the total public medicine procurement. Therefore, local manufacturers lose out at the

¹¹ <http://www.moh.gov.gh/moh-launches-revised-national-medicines-policy/>

regional and facility procurement levels where the margin of preference is not considered since they are often not very competitive where the margin of preference is not applied. This means that outside the preferential cluster they will be locked out and they can only access these benefits if a regional specific policy is established.

Building local pharmaceutical industries require better incentives and strong protectionist policies.

For example India, China and Brazil demonstrate this:

- a. High customs duties on imported products: For example, India applies customs duties on formulas or rules or statements up to 56% on import tariffs. Brazil applies 15% on formulas and China has recently imposed import tariffs of up to 37% on products imported from India.
- b. Purchasing preferences: Brazil manufacturers enjoys preferential prices of 25%, whereas Russia has introduced measures to ensure that 70% of the products purchased by the state are manufactured locally and this has led many Indian companies to consider building manufacturing plants in Russia.
- c. Prohibition of importation of certain medicines: Moroccan production currently covers nearly 60% of the country's needs. This has been achieved mainly through a policy of prohibition of importation of medicines that could be manufactured in Morocco. This made multinationals that were established in Morocco to move to the production stage.¹²
- d. Export support: In India, producers of drug formulations receive substantial government support to promote exports. These include low utility rates and working capital loans.
- e. Mobilization finances: In Ethiopia, if a local pharmaceutical industry wins a tender, the government provides 30 % for mobilization and a letter which can be used to get credit facility.

Donor subsidies have negative impacts on local industries

First, to participate in donor funded procurement requires that the product must be WHO prequalified. Out of the 172+ manufacturing companies, only 6 have products that are prequalified. This means that the rest cannot access this market. Secondly, where the donor subsidies supply a product which is manufactured locally, this distorts the market. For example, in 2010, the Government of Ghana implemented the Affordable Medicine Facility-malaria¹³ policy to improve the access of Antimalarials at affordable prices. This was an innovative global financing mechanism for the provision of quality assured Artemisinin-based combination therapy (ACTs) in eight countries in sub-Saharan Africa. At that time, a local pharmaceutical company, Amponsah Efah Pharmaceutical (AEP) had embarked upon upgrades of equipment and

¹² *The drug in Africa: how to better respond to the issues of accessibility and quality? April 3, 2018 French Development Agency*

¹³ Insights into the Affordable Medicines Facility-malaria in Ghana: the role of caregivers and licensed chemical sellers in four regions. Available at <https://malariajournal.biomedcentral.com/articles>

machinery to transition from Chloroquine production to ACTs. The policy made AEP products uncompetitive and created huge cash flow challenges for the company.

Local industries are losing out on donor funded programmes due to lack of World Health Organization Certification

Out of the 172+ manufacturing firms, only 6 have products that are prequalified. To improve on the situation several ECOWAS countries have embarked on WHO Certification Roadmaps, which are supported by WHO and UNIDO. For example, Ghana, since 2015, is pursuing the Ghana Good Manufacturing Practice (GMP) Certification Roadmap 2015-2020. Ghana benefits greatly from Department of Public Safety, for the procurement of medicines for malaria, TB, HIV/AIDS, and reproductive health. However, local companies have not participated in the procurement processes for these medicines their products are not WHO GMP Prequalified. Thus, the donor supported segment of the Ghana pharmaceutical market has never benefited the local pharmaceutical companies. It was expected that if the roadmap program had gone as planned most of the companies are expected to be WHO GMP compliant within five years by 2020. However, the companies have been very slow to follow the WHO GMP Roadmap and hence their own CAPAs to bridge the gaps identified because they complain of unavailability of a long term or development financing needed for the upgrades. In addition, there is also the ECOWAS Pharmaceutical GMP Roadmap Initiative which was launched in 2017 in Accra Ghana. The objective of the initiative is to establish a strong pharmaceutical manufacturing industry in the ECOWAS region by bringing pharmaceutical manufacturers up to WHO GMP and other international standards in a step-by-step individualized improvement program to meet the goals of access to quality safe and affordable medicines.

4. CONCLUSIONS AND RECOMMENDATIONS

The following conclusions and recommendations are made from the five main findings of the study:

- a. All the nine countries reviewed have in place procurement policy incentives to support local pharmaceutical industries and enhance access to and affordability of medicines through lowering of the costs. These are (a) 5-15 % preferential treatment of local industries for procurements of medicines; (b) ringfencing of certain products for local industries; and (c) prohibiting the importation of medicines with the same active ingredient, pharmaceutical formula and dosage as those manufactured locally. These interventions by ECOWAS countries are laudable and demonstrate West African governments' commitment towards promoting local pharmaceutical industries. Even though major challenges in funding which is still inadequate to enhance on the technical, infrastructural and production capacities of the local firms and also lack of effective and efficient implementation and enforcement strategies of the available policies, regulations and other interventions in order to enhance on the competitiveness and inclusion of the pharmaceutical firms in the region.
- b. Despite the above-mentioned commendable efforts by ECOWAS countries, the desired outcomes of these interventions have not been realized. This is mainly due to weak competitiveness of the local products and the limited capacity of the local industries. To improve on competitiveness in ECOWAS countries, there is need to intervene at three levels. First is to promote local production of some of the imported inputs. Particular

attention should be given to the active pharmaceutical ingredient, which is the most expensive component and 95 % is being imported. Promoting mutual collaboration between the local firms, universities and research institutions and foreign firms would boost both technical, infrastructural and production capacities of the local firms. This can be realized just as earlier mentioned through various tax incentives such as duty free import, zero rated VAT, Investment incentives etcetra. Second, is to revisit the cost of local inputs, particularly provide energy and water and third is to review the VAT policy and regulations imposed on finished pharmaceutical products both at the national and regional level. On considering both the technical, infrastructural and even production capacities of the firms it is recommended that local pharmaceutical firms should consider forming a consortium to submit joint bids. The pharmaceutical manufacturer Associations should divide the products portfolio so that each manufacturer has its own list for submission. Secondly, as a consortium, they can also consider partnering with Indian industries by virtue of their local presence and existing collaborations to receive bulk products and make secondary packing.

- c. The following three interesting interventions by various ECOWAS countries are worth replicating in other African countries. These are (a) VAT exemptions on Active Pharmaceutical Ingredients (APIs) introduced by Ghana in 2018; (b) National Health Insurance Schemes working together with local pharmaceutical industries on pricing as well as influencing policies (example of Ghana and Nigeria); and (c) tax incentives for investment in local pharmaceutical industries and the application of local content policy in Senegal.
- d. The following three lessons learned elsewhere are worth considering by ECOWAS countries and other African countries: (a) need for deliberate efforts to protect local pharmaceutical industries through heavy import taxes has done by Brazil, India and China; (b) using policy on ringfencing of products (purchase preferences) to forced exporting companies to establish local manufacturing as was the case in Russia and Morocco and (c) provision of mobilization fund and letter of support for accessing credit (as is the case in Ethiopia) when local companies get government contracts.
- e. Although donor subsidies negatively impact on local pharmaceutical industries, donor support on provision of medicines is key factor in enhancing access to healthcare and affordability and can therefore not be wished away. However, care should be taken to ensure that affected companies are supported.
- f. WHO Certification is the most single intervention that can unlock huge potential for the local pharmaceutical industries. Apart from providing access to donor funded drug market, it is believed that certification will have several other benefits. These include providing confidence in potential financiers and investors that can partner with local industries. Therefore, deliberate efforts by the governments and industries should be invested in the WHO certification roadmaps initiated by several ECOWAS countries.