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Ogada, Tom; Erhun, Wilson; Nortey, Louis; Toure, Aida S.; Gbolo, Jules-Olivier; Yerima, Mouhoudine; and Obunga, Patrick;

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ESTABLISHING COMPETITIVE AND SOCIALLY INCLUSIVE LOCAL PHARMACEUTICAL INDUSTRIES IN WEST AFRICA

Enhancing Affordability Through Procurement

Tom Ogada¹, Wilson Erhun², Louis Nortey³, Aida S. Toure⁴, Jules-Olivier Gbolo⁵, Mouhoudine Yerima⁶, and Patrick Obunga⁷

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 human resource situation for the pharmaceutical sector in West Africa. The policy brief explains the current situation and what can be done in terms of training, linking with diaspora, collaboration and partnership with Asian countries and building synergy within ECOWAS to address the human resource requirements for the sector in West Africa.

INTRODUCTION

Many African countries, through their development plans, have prioritised access to affordable healthcare services. However, the realisation 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 population buys 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 into 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 172 local pharmaceutical firms

in the ECOWAS region. Nigeria is leading with 120 firms, followed by Ghana with 37 firms, while Senegal and Côte 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

¹Prof Tom Ogada is the Executive Director of the African Centre for Technology Studies. He holds a MSc in Mechanical Engineering and PhD in Chemical Engineering. His expertise is in the area of industrialization and intellectual property.

²Prof Wilson Erhun (Nigeria) is a Professor of Pharmacy Administration and the current Dean of the Faculty of Pharmacy, Obafemi Awolowo University, Nigeria. He is also a Fellow of the Nigerian Academy of Pharmacy. He holds BSc, MSC and PhD in Pharmacy.

³Mr. Louis Nortey (Ghana) is currently the Chief Pharmaceutical Policy Analyst at PHEBS Consult, Ghana. He has also served as National Pharmaceutical Expert for over 8 years with UNIDO. He holds BSc in Pharmacy and MBA. He is a Fellow of Ghana College of Pharmacists.

⁴Dr Aida Sall Toure (Senegal) is currently Pharma GMP Consultant for local companies in ECOWAS. Previously she

worked with Pfizer West Africa as Site Leader. She holds MSc in Pharmacy and MSc in Development of Pharmaceutical and Nutritional Products.

⁵Dr Jules-Olivier Gbolo (Cote d'Ivoire) works as Regional Manager of CIV (Pharmaceutical Wholesaler Company in Cote d'Ivoire). He holds a BSc in Pharmacy and MSc in Health Systems Engineering.

⁶Dr Mouhoudine Yerima (Togo) is currently Pharmacology Assistant Professor at Health Science Faculty, University of Lome and also Pharmacovigilance Country Head at the Ministry of Health, Togo. He holds BSc in Pharmacy, MSC in Pharmacology and PhD in Pharmacology.

⁷Patrick Abunga is a Research Assistant at the African Centre for Technology Studies under Prof Ogada. He holds a BSc in Agriculture and he is currently pursuing MSc in project management.

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 fact that a procurement policy that provides preferential treatment to local pharmaceutical industries would spur more local production of essential medicines, reduce the cost of medicine and therefore enhance access, affordability and social inclusion.

The study achieved the following:

- Documented the existence of procurement policy incentives that promote local pharmaceutical industries.
- Looked at the impact on production and consumption patterns; growth and capabilities of the local pharmaceutical manufacturing; and ability of the local manufacturing to serve the poor.
- Documented experiences, best practices and success stories from those countries that have implemented such policies.
- Made appropriate policy recommendations and interventions.

METHODOLOGY AND RESULTS

The required information was obtained through desk study, interviews, and stakeholders' consultations, in five ECOWAS countries (Nigeria, Ghana, Cote d'Ivoire, Senegal, and Togo) by national consultants. In addition, a scoping desk study was undertaken in 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 that were moderated during a three-day experience sharing amongst the five consultants in Abidjan, Côte d'Ivoire. The main findings of this study are:

1. Procurement policy incentives are in place

The study established that, most 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.

- **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 (2007) has a provision for a domestic preference policy that gives an extra margin of 7.5% for goods and 15% for services on prices 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).

- **Ring-fencing of certain products:** All the countries have recently applied the policy of ring-fencing certain products for local companies.

For example, Ghana, in August 2017, through a Gazette Notice No 74 (LI 2255)⁹, ring-fenced 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 programme, in which, a list of 60 products have been ring-fenced for the local industries. Again, this policy is applicable to all WAEMU countries.

- **Prohibiting importation of certain products:** Finally, West African Economic and Monetary Union (WAEMU) countries, are using national preference agreements, 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

⁸PPA (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>

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 to guarantee the origin of the product and the nationality of the manufacturer.

- 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 that exempts VAT payments on some selected finished pharmaceutical products (FPP) for manufacturers, NHIS is in discussion with the stakeholders to reduce their published prices by 30%.

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

2. 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.

- **Low Competitiveness:** Local manufacturers in the nine countries are not able to take advantage of the procurement preferential policies due to lack of competitiveness of the locally produced products compared to imported drugs.

This is attributed to 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.

Second: 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 ingredients (APIs), aluminum foil for blister packaging, other labelling materials, and excipients are imported.

Third: due to the long duration of 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.

- **Production Capacity:** Local industries have not adequately benefitted from the national tender programme of ring-fencing products, since they do not have in their portfolio all the 60 requested products which is a generalised principle in the region.
- **VAT on finished products:** Since 1969, World Health Assembly VAT has been 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.

- **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 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 region specific policy is established.

3. Building local pharmaceutical industry requires better incentives and strong protectionist policies

For example, India, China and Brazil demonstrate this:

- **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.
- **Purchasing preferences:** Brazil manufacturers enjoys preferential prices of 25%, whereas Russia has introduced measures to

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

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.

- **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 move to the production stage.¹²
- **Export support:** In India, producers of drug formulations receive substantial government support to promote exports. These include low utility rates and working capital loans.
- **Mobilisation finances:** In Ethiopia, if a local pharmaceutical industry wins a tender, the government provides 30% for mobilisation and a letter that can be used to get credit facility.

4. 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 more than 172 manufacturing companies, only six have products that are prequalified. This means that the rest cannot access this market. Second, where the donor subsidies supply a product that 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 anti-malarials 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 machinery to transition from chloroquine production to ACTs. The policy made AEP products uncompetitive and created huge cash flow challenges for the company.

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

Out of more than 172 manufacturing firms, only six 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 greatly relies on the 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 since 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 programme had progressed as planned most of the companies were expected to be WHO GMP compliant within five years by 2020.

However, the companies have been slow to follow the WHO GMP Roadmap and hence their own Corrective and Preventive Actions (CAPAs) to bridge the gaps identified. 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 that 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 individualised improvement program to meet the goals of access to quality, safe and affordable medicines.

CONCLUSIONS AND RECOMMENDATIONS

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

1. 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) ring-fencing 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. However, there are still major challenges such as inadequate funding to upgrade the technical, infrastructural and production capacities of the local firms; lack of effective and efficient implementation and enforcement

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

¹³Insights 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>.

strategies of the available policies, regulations. They will also need to put in place other interventions that enhance the competitiveness and inclusion of the pharmaceutical firms in the region.

2. Despite the above-mentioned commendable efforts by ECOWAS countries, the desired outcomes of these interventions have not been realised. 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 of which 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 realised through various tax incentives such as, duty free import, zero-rated VAT, Investment incentives et cetera. Second, is to revisit the cost of local inputs, particularly 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 capacity of the firms it is recommended that local pharmaceutical firms should consider forming a consortium to submit joint bids.

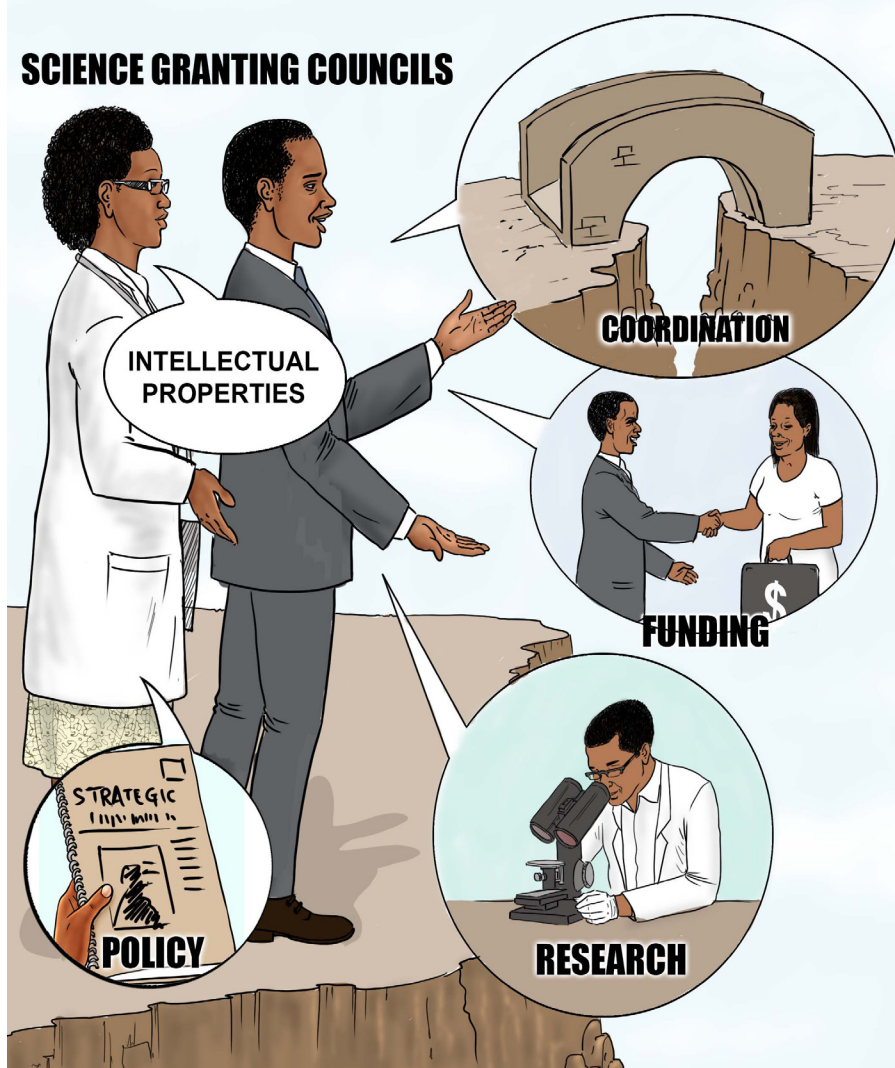
The pharmaceutical manufacturer associations should divide the products portfolio so that each manufacturer has its own list for submission. As a consortium, they can also consider partnering with Indian industries by virtue of their local presence and existing collaborations to receive bulk products and make secondary packaging.

3. There are three interesting interventions by various ECOWAS countries that are worth replicating in other African countries.
(a) VAT exemptions on some selected FPP 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
(c) Tax incentives for investment in local pharmaceutical industries and the application of local content policy in Senegal.
4. Three lessons learned from elsewhere are worth considering by ECOWAS countries and other African countries:
(a) The need for deliberate efforts to protect local pharmaceutical industries through heavy import taxes as done by Brazil, India and China;
(b) Using policy on ring-fencing of products (purchase preferences) to force exporting companies to establish local manufacturing as was the case in Russia and Morocco; and
(c) Provision of mobilisation fund and letter of support for accessing credit (as is the case in Ethiopia) when local companies get government contracts.
5. Although donor subsidies negatively impact on local pharmaceutical industries, donor

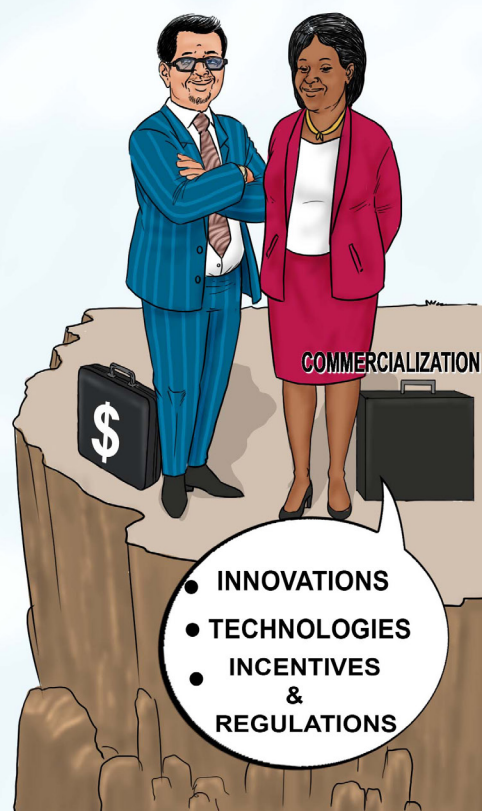
support on provision of medicines is a key factor in enhancing access to healthcare and affordability and can therefore not be wished away. However, care should be taken to ensure that affected companies are supported.

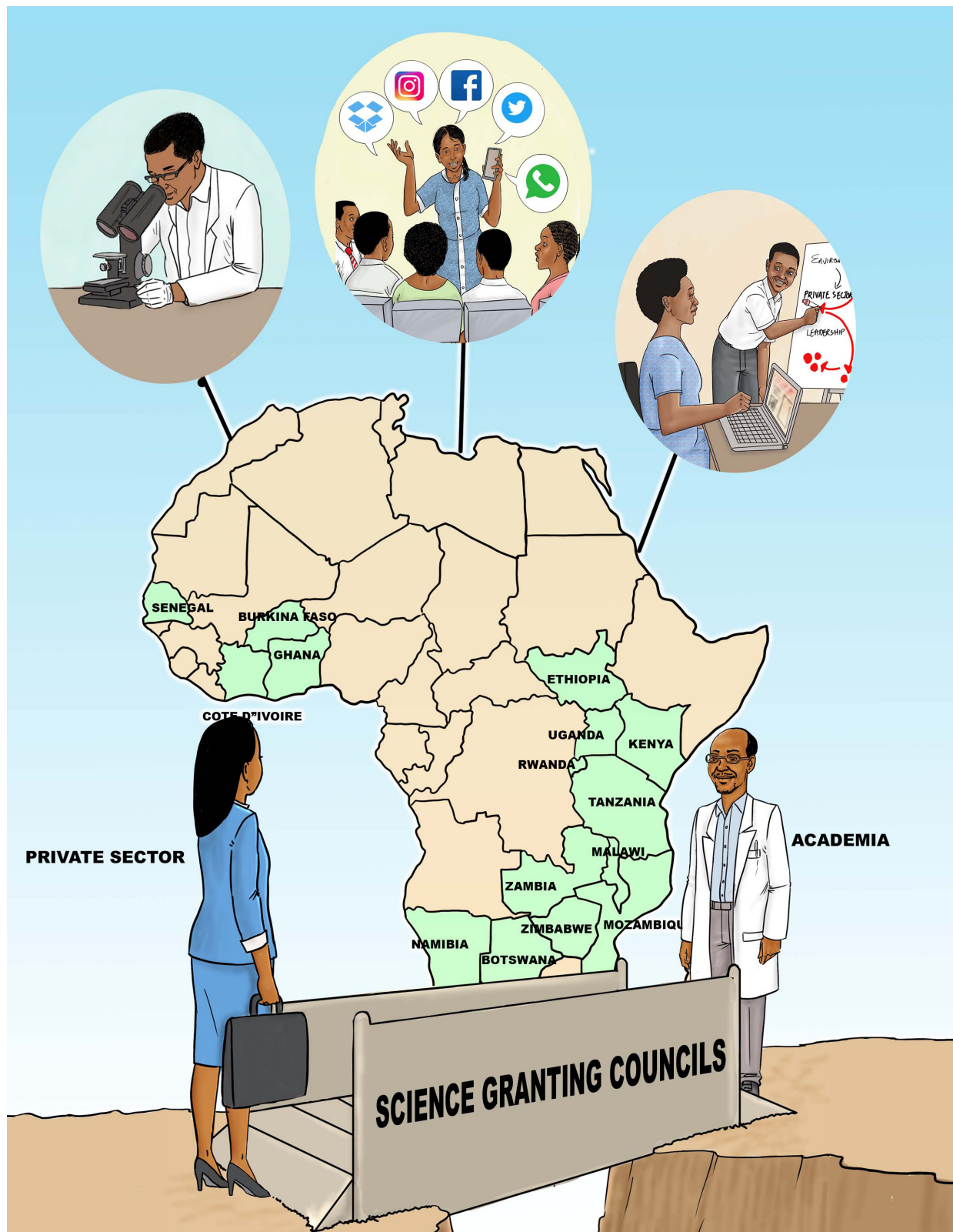
6. WHO Certification is the single most critical intervention that can unlock huge potential for the local pharmaceutical industries. Apart from providing access to donor funded drug market, it is believed that certification will have several other benefits. These includes providing confidence in potential 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.

SCIENCE GRANTING COUNCILS



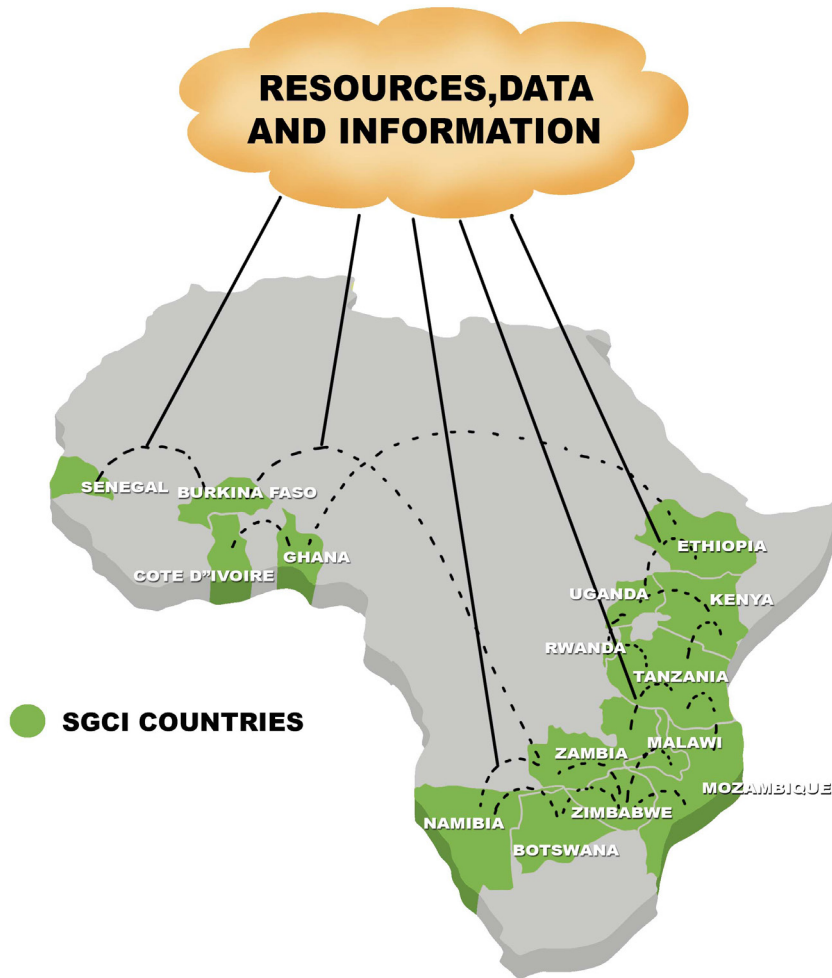
PRIVATE SECTOR







Tanzania



The Scinnovent Centre
 Second Floor, Karen Plains Arcade
 P.O. Box 52486 - 00100, GPO, Nairobi, Kenya
 Website: www.scinnovent.org; Tel: +254 020 2173433