

ESTABLISHING COMPETITIVE AND SOCIALLY INCLUSIVE LOCAL PHARMACEUTICAL INDUSTRIES IN WEST AFRICA

Role of Research, Innovation, and Development

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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

The Economic Community of West African States (ECOWAS), which was established by the Lagos Treaty of 1975, brings together 15 countries: five Anglophones, eight Francophones and two Lusophones. The need to promote local pharmaceutical industries in the region is motivated by a number of factors such as high disease burden, high cost of imported medicines, growing regional market for medicines, expected increase in access to anti-retroviral drugs and pressure from non-governmental organisations.

Currently, there are over 172 local pharmaceutical industries, based in nine out of 15 West African countries. These initiatives have been aimed to promote local pharmaceutical industries, not only to address the issue of high costs of imported medicines but also to tap into additional benefits that local pharmaceutical industries can bring, such as creation of employment opportunities and enhancing intra-Africa trade. However, there are several bottlenecks

experienced by the sector, along its value chain (access to inputs, manufacturing, and marketing). These include:

(a) Access to raw material- over 90% of the inputs for local pharmaceutical manufacturing is imported i.e. active pharmaceutical ingredients (APIs), packaging materials, as well as other inputs that are not manufactured in the region.

(b) Shortage of skilled labour- the human resources challenge is not only on the number of pharmacists and other professionals, but also on their limited or non-existent industrial pharmaceutical knowledge and skills.

(c) Expensive pharmaceutical manufacturing equipment and technologies i.e. the bulk of the pharmaceutical manufacturing equipment are imported, and therefore expensive.

(d) Low investment in pharmaceutical R&D in the region.

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(e) Medicines regulations in the ECOWAS region, member states have in place basic legal framework for the regulation and control of the manufacture, distribution and utilisation of medicines for human use.

A review of the systems (Anglophone and Francophone) showed that medicine regulation is still problematic, due to weak infrastructure, weak enforcement power, and inadequate human resource capacity, amongst others.

The medicines regulatory sector is also faced with the problem of poor motivation and low retention of staff; high levels of counterfeit and illicit medicines; and lack of harmonisation of medicines regulation.

There are also differences in the requirements for medicines registration in member countries.

(f) Accessing market- the local manufacturers have problems with procurement of pharmaceutical products by public agencies as it is usually based on the quoted price, with a tendency to select the lowest bidder. This normally favours international pharmaceutical agencies over local industries due to the low production costs of the former, and also all donor and development partner-funded procurement of essential medicines requires that suppliers should have WHO's product prequalification.

Research and development (R&D) play a critical role in the development of a vibrant, sustainable and socially inclusive local manufacturing pharmaceutical industry and can enhance affordability of essential drugs, productivity, increase employment opportunities as well reduce dependency on foreign support.

Therefore, this policy brief explores the impact of R&D on local

pharmaceutical manufacturing industry. It documents the following:

- The status of R&D in the pharmaceutical sector, particularly in developing pharmaceutical materials to support local industries.
- The level of involvement of pharmaceutical industries on research, innovation and development, and the challenges they face.
- Existing activities around drug development targeting treatment of malaria and HIV-AIDS based on indigenous knowledge and biodiversity.
- Local production of active pharmaceutical ingredients (APIs) and what needs to be done to jumpstart local production.

APPROACH

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) undertaken by five national consultants, who were contracted in each of these countries. 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 on some of the issues.

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, Cote d'Ivoire. The main findings of this study are outlined below:

RESULTS

1. There are limited Research, Innovation and Development activities to support pharmaceutical industries in the ECOWAS countries.

ECOWAS countries' universities and research organisations have various R&D oriented departments/faculties within which drug research and development are entrenched in the following areas- Pharmacognosy, Pharmacology, Pharmaceutics, Pharmaceutical Technology, Herbal Medicine, Industrial Pharmacy and Pharmaceutical Chemistry.

These departments and units conduct research in different aspects of drug research including development and elucidation of active compounds from indigenous knowledge and biodiversity. For example:

- Nigeria: In 2019, there were 21 universities in Nigeria with faculties of Pharmacy. In addition, there are four research institutes that stand out with mandate in R&D activities relating to identification, analysis of drugs and development of raw materials from local resources to the pharmaceutical industry. These are: The National Institute for Pharmaceutical Research and Development (NIPRD), The Nigerian Institute of Medical Research (NIMR) in Lagos, The Raw Materials Research and Development Council (RMRDC), and the Nigerian Natural Medicine Development Agency (NNMDA). The parent ministries, mandates and thematic areas of activities of these pharmaceutical research institutions are documented (UNIDO, 2011).
- Ghana: In Ghana, science and technology policy development issues come under the Council for Scientific and Industrial Research (CSIR)⁸. Science and

⁸<http://www.csir.org.gh>

Technology Policy Research Institute (STEPRI) and Industrial Research Institute (IRI) who are directly involved impact on LPP. In addition, universities with faculties of pharmacy, such as Kwame Nkrumah University of Science and Technology (KNUST) and the University of Ghana (UG) also conduct R&D related to the pharmaceutical sector.

- Senegal: In Senegal, research and development around pharmacy takes place at the Pharmacy University and institutes as Institute of Research and Development whereas the Institut Pasteur Foundation in Dakar is known as one of the four producers of yellow fever vaccines in the world and the only institution in Africa prequalified by WHO for the manufacturing of yellow fever vaccine.
- Mali: The Malaria Research Centre viewed by many as a model for research centre in developing countries, as its research is planned, directed, and executed by African scientists. It also has a robust training programme for new generation Malian scientists critical to the success and sustainability of the programme.
- Côte d'Ivoire: Similarly in Cote d'Ivoire, there are several universities that undertake R&D in medicine. These include Université Félix Houphouët-Boigny; Université d'Abobo-Adjamé and École de Médecine. However, only Felix Houphouey Boigny Universite offers training in pharmacy and has postgraduate programmes where meaningful R&D activities in pharmaceutical areas take place.

In the health sector, Simpkin et al. (2019) identified the three major players involved in funding research in many African countries as the public (government), private sector, and international institutions. Currently the level of investment of R&D by all the West African countries is

below the 1% of the GDP required. According to UNESCO science report of 2015, Mali was leading (0.66% in 2010), followed by Senegal (0.54% in 2010), Ghana (0.38% in 2010), Togo (0.22% in 2012), and Gambia (0.13% in 2011). Consequently, many African countries rely heavily on research grants and/or aids from foreign and international organisations. Therefore, R&D activities for diseases that disproportionately affect African countries and address Africa's unmet health needs are poorly funded (Gedye, 2013).

2. Involvement of local industries in research and development

In West Africa, unlike in many developed countries with well-developed pharmaceutical industries, local pharmaceutical industries invest very little in R&D. Most of the local companies are either subsidiaries of foreign companies or operating under licensing agreement. In both cases, the R&D needs of these local industries are met elsewhere.

The bulk of the rest of the local industries do not have adequate resources to support their own R&D needs, and these needs could be met through collaboration with local universities. However, this is currently difficult due to weak university-industry linkages in these countries.

In addition, investment in pharmaceutical R&D in many African countries by the private sector is hampered by unstable political environments, weak or absent intellectual property laws, poor governance, weak regulatory structures and corruption (West and Schneider, 2017).

3. There are many activities on Drug Development based on indigenous knowledge and biodiversity

The bulk of research activities taking place in West African universities and research organisation revolve around drug development based

on indigenous knowledge and biodiversity. These are moves in the right direction and should be supported and encouraged. Below are some examples targeting malaria, HIV/AIDS, sickle cell anaemia and yellow fever:

- Ghana: Malaria and HIV/AIDS Drug Development based on indigenous knowledge. There are several herbal preparations with cryptolepine-based extracts in special liquid dosage forms as antimalarias on the Ghanaian market. Nibima preparations, as antimalarias are also products from the Centre for Research into Plant Medicine[1] at Mampong, Akwapim in the Eastern Region.
- Côte d'Ivoire: According to the National Programme for the Promotion of Traditional Medicine (PNPMT), Kroa Ehoulé, 1,421 species of medicinal plants used in traditional medicine and allowing the management of patients have been identified to date by Ivorian researchers.

According to PNPMT, in Côte d'Ivoire, five million patients are monitored and treated each year by traditional healers. "Traditional medicine does not compete with conventional medicine. On the contrary, it offers care and collaborates with modern medicine".

In addition, medicinal plants are generally used to treat malaria, opportunistic infections contracted by people living with HIV/AIDS, diabetes, hypertension and sickle cell disease. PNPMT has developed and implemented an information and management software for traditional health practitioners (TPs) to address population health issues. The software has made it possible to identify more than 8,500 traditional health practitioners in 12 administrative regions of Côte d'Ivoire.

The West African Health Organisation (WAHO) has adopted the TPs as a model for identifying traditional healers in the sub-region. As a result, traditional medicine has been integrated into the Ivorian public health system and works alongside conventional doctors to take care of patients.

The first pavilion was opened recently at the University Hospital Centre in Treichville. In addition, researchers from the University of Bioscience and the Pharmacodynamics and Biochemistry Laboratory have identified and highlighted the antimalarial properties of plants found in central Côte d'Ivoire (Toumodi) and used by the people of the Centre for malaria treatment. *Artemisia afra* (of African origin) has been investigated and is currently being used as herbal tea to treat malaria.

To date, *Artemisia* is grown in experimental fields, particularly in Grand-Bassam, not far from Abidjan, but also in the botanical garden of the University of Korhogo.

- Nigeria: In conjunction with the Government, the National Institute for Pharmaceutical Research and Development (NIPRD), initiated and completed the research and development of a new phytomedicine (Niprisan/Nicosan) for the management of sickle cell anaemia.

The product has been granted orphan drug status by the United States Food and Drug Administration (USFDA) and the European Medicine Evaluation Agency (EMA).

The fact that Niprisan/Nicosan is the only therapy which will be accessible to over 10 million sickle cell anaemia patients in sub-Saharan Africa will give a boost to the local pharmaceutical industry

and NIPRD is now developing other phytomedicines for the management of prevailing priority diseases.

- Senegal: In addition to research performed at the University, there is also research carried out by UMR VITROME (Mixed Research Units: IRD / Aix-Marseille University) on malaria.

This work focuses on three main areas: the discovery and molecular identification of emerging pathogens, the study of insect vectors and therapeutic research. (Source Mission UMR VITROME). Institut Pasteur Foundation in Dakar is one of the four producers of yellow fever vaccine in the world and the only one in Africa pre-qualified by WHO for the manufacturing of yellow fever vaccine.

This project should therefore sustainably strengthen the fight against this disease. Scientists from the Institut Pasteur, the CNRS and Sanofi Pasteur have recently developed a novel alternative method to animal testing that can be used to verify the safety of vaccines such as the yellow fever vaccine.

In addition, Senegal has a rich experience in medicinal plants and has some traditional medicine centres and Community Centre for Appropriate Technologies for Health (CCTAS). Senegal has established by ministerial decree a National Commission for Senegalese Traditional Pharmacopoeia and the National Formulary.

This commission aims to develop the Senegalese pharmacopoeia and the national form. Regulatory texts relating to the registration of improved traditional medicines (MTAs) have been also developed. The updating of these documents and their adoption will allow the development of MTAs. Today,

traditional healers need scientific supervision to guarantee the safety of MTAs. For this purpose, centres of clinical experimentation of medicinal plants have been created in the health centre but they are not functional due to lack of operating budgets. (Source PNP 2014).

- Mali: Malaria Research Centre currently conducts research around vaccines, diagnostics, immunology and genetics, and prevention.

Mali Traditional Medicines established in 1973 is the official institute connected to the National Institute of Research in Public Health and the main activities it is engaged in are; registration of traditional practitioners, medicinal plants, research and development of Improved Traditional Medicines.

4. Local production of Active Pharmaceutical Ingredients (APIs) and other inputs for pharmaceutical industries

Production of active pharmaceutical ingredients

Local production of active pharmaceutical ingredients (APIs) is key to the growth and development of the pharmaceutical industry in ECOWAS. This is because the region imports 95% of their requirements as inputs for local production. API production is capital intensive and the technology involved is also relatively expensive and sophisticated. Internationally, API production is shifting to China and India. Relatively few companies have been involved in the production of APIs in West Africa.

Ghana-based Lagray Chemical Company Limited was the first vertically integrated generic pharmaceutical manufacturer in West Africa. They were involved in the development, manufacture, and marketing of APIs. Lagray produced the API erythromycin, which was used as an intermediary for the

production of Azithromycin. Lagray fully utilised the API they produced as an intermediary and none was offered for sales to other companies. From all indications, the volumes of the API produced were not that high and the company folded due to low revenue generation and mobilisation. The company's products were mostly second and third line products for treatment and the necessary prescription traction could not be generated in the Ghana Health System.

The local production of APIs has been hampered by factors like weak or absent intellectual property laws, poor governance structures, weak regulatory structures, lack of transparency (corruption), inadequate funding, lack of incentives to support R&D, lack of collaboration between academia and industries, and instability of government policies.

Local production of other inputs for the pharmaceutical sector

The Nigerian National Institute for Pharmaceutical Research and Development (NIPRD) has carried out research and development into pharmaceutical grade starch as it would be most advantageous to local drug manufacturers if starch could be processed locally to produce pharmaceutical grade starch; pre-gelatinised starch used as pharmaceutical binder; and dextrose monohydrate marketed as glucose powder (nutraceuticals), which is a major ingredient in intravenous infusions.

CONCLUSION AND RECOMMENDATIONS

With reference to the above findings of the study, the following conclusions and recommendations are worthwhile considering:

- Currently the impact of research institutions on local pharmaceutical production is minimal due to inadequate funding and the low demand for R&D by local industries. There is need to increase funding,

particularly those related to alternative local sources of inputs for the pharmaceutical sector.

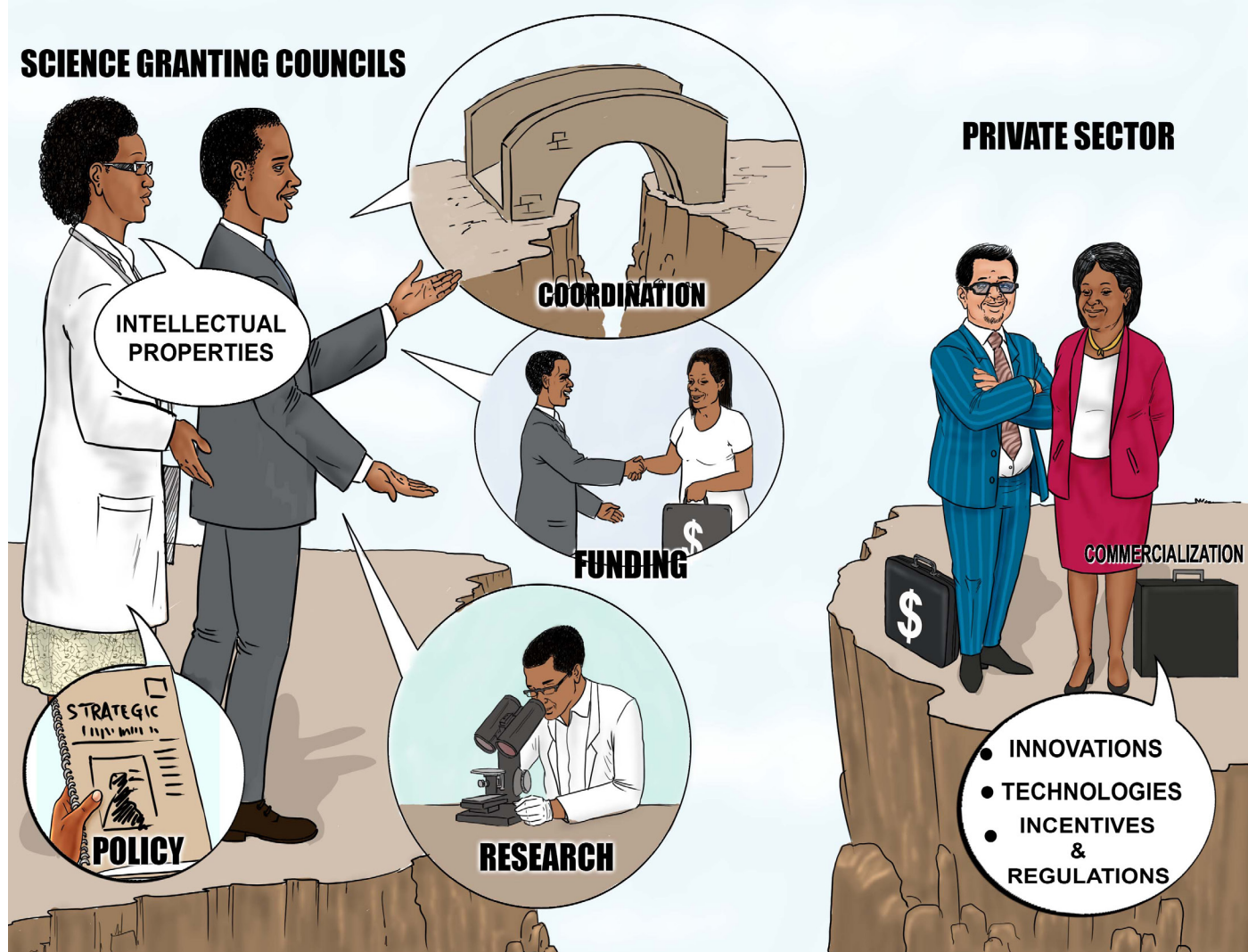
- Plenty of effort has been made towards drug development based on the local indigenous knowledge and biodiversity especially in Cote d'Ivoire and Senegal to curb malaria and HIV/AIDS challenges. These efforts should be strengthened and supported.
- There should be a national database and an integrated regional database for the traditional healers in the region, and policies formulated on integrating them in the national and regional R&D system.
- The current practice of integrating the local/ traditional medicines with the conventional ones in hospitals for treatment of patients in some countries is commendable and should be adopted by other countries in the region and beyond. Policy makers can influence this through establishment of the right legislative and regulatory frameworks.
- The involvement of local pharmaceutical industries in research is minimal and collaboration between local pharmaceutical industries and universities and research organisations in the region for R&D is negligible. There is also need to provide local pharmaceutical industries with incentives (tax) on R&D works and capital investment in research and development projects in the region. Funding of joint research undertaken by universities and industries in the sector should also be encouraged.
- The level of involvement of research organisations in the pharmaceutical sector conducting research, innovation and development is growing but it still lacks the capacity and right capability for effective and efficient identification, analysis of drugs and development of raw

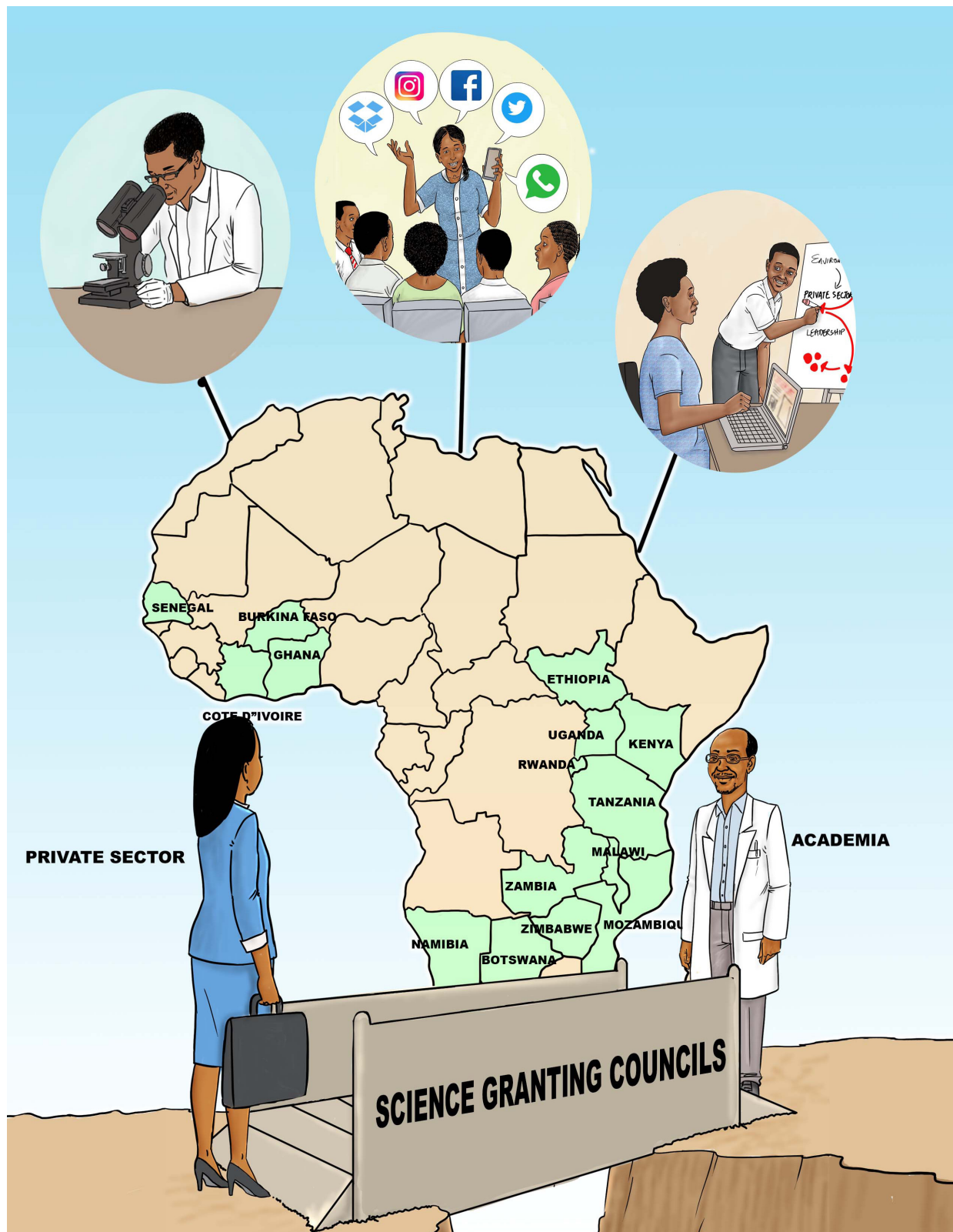
materials for the local industries.

The high cost of equipment, high level of professional skills and expertise required are also contributing factors. Hence we recommend tax exemptions or tax incentives on importation of these equipment and raw materials for the industry.

- Production/manufacturing of active pharmaceutical ingredients in the region is hampered by low volumes, high cost of production and low revenue generation and mobilisation. To make the production of APIs more feasible, there should be tax exemption on APIs raw material imports, and tax incentives for investment in local pharmaceutical industries. It is also considered that local industries and R&D organisations have a better chance of producing API based on local products.

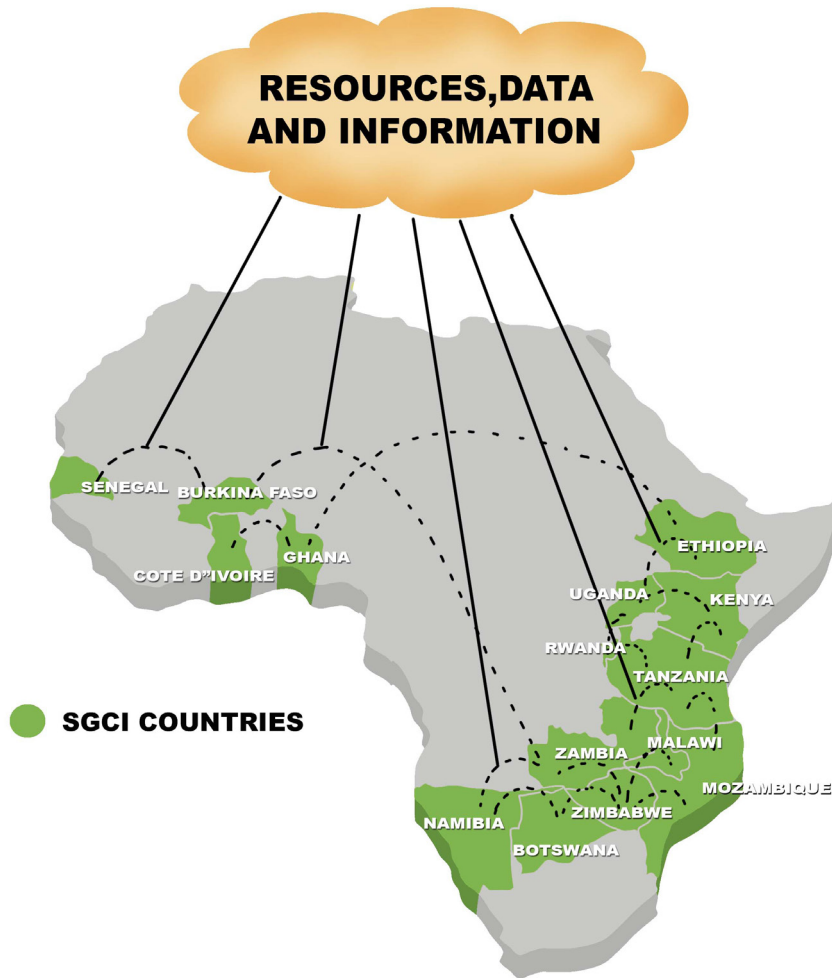
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