



PRIORITIZING & GROWING PHARMACEUTICAL & HEALTH MANUFACTURING IN AFRICA

A 5-PART SERIALISED ARTICLES BY





PARTS 1 - 5

PART 1

BACKGROUND & INTRODUCTION

I. INTRODUCTION

The sheer proportion of the disease burden on Africa and the level of pharmaceutical production makes the prioritizing and growing of these industries a must. During the last decade promoting sustainable access to quality and affordable medicines and integrating local production as part of the overall health systems has been of significant concern to African leaders. They have stopped asking whether their countries should encourage local pharmaceutical manufacturing and are now looking at how best to grow local manufacturing as it is clear that the benefits of growing local manufacturing far outweigh the challenges and investments required.



The reasons are not far-fetched.

In 2015, world leaders committed to 17 sustainable development goals (SDGs) to help end extreme poverty, fight inequality and injustice, and fix climate change. One of the targets of the third goal of SDGs is to achieve universal health coverage, including financial risk protection; access to quality essential health care services; and access to safe, effective, quality, and affordable essential medicines and vaccines for everyone.

Medicines or pharmaceuticals play an important role in the health care sector. They are needed for prognosis, diagnosis, prevention, treatment of diseases, and even maintenance of health status. In addition, the quality of pharmaceuticals is at the core of the World Health Organization (WHO) constitution as health care systems are compromised by the availability of substandard drugs. African leaders, thus, now know that they need to address critical health challenges facing their countries especially health challenges due to lack of access to quality medicines in furtherance of these global mandates.



In addition to these realities and the global mandates, strengthening the continent's ability to produce high quality, affordable pharmaceuticals across all essential medicines will contribute to improved health outcomes as well as the realization of direct and indirect economic benefits. In addition to increased general output (measured by GDP) of a healthier populace, the sector will contribute to economic growth through enhanced exports, increased intra-African trade, emergence of supportive industries and the reduced reliance on imports that require hard currency.

It is also not inconceivable that some advanced African states with well-developed

manufacturing systems not only wish to reduce their reliance on imports but possibly develop/expand their export markets. By expanding the sector in Africa, we enable these developed manufacturing systems to investigate various products that are off-patent and which Africa-based manufacturers could produce for local consumption and ultimately for export to other developing and developed markets. Some companies in countries such as South Africa and Tunisia have, for example, been certified by American and European regulators to do this.



II. WHY SHOULD WE PRIORITIZE AND GROW THE PHARMACEUTICAL AND HEALTH DEVICES INDUSTRY IN AFRICA?

■ SOCIAL COSTS

A viable pharmaceutical industry in Africa shall not only impact on the African health systems and its capacity to respond to health needs of the people but also will contribute to the overall socioeconomic development of the continent. The consequences of poor-quality drugs include an increase in deaths and morbidity, increased adverse drug reactions (ADRs), and the development of drug resistance, all social costs that can be greatly minimized if package of solutions are enforced to ensure adequate supply of essential medicines. Overreliance on imports cannot meet this need, hence the need for a viable and self-sustaining pharmaceutical industry.



■ ACCESS TO MEDICINE

There is a strong correlation between access to quality medicines and the small size of the local pharmaceutical industry. African manufacturers depend on imports for the bulk of their production inputs, not only inputs but also varied needs along the value chain like machinery, laboratory equipment and reagents, and production raw materials like API, Aluminium foil, labelling materials and even exipients. This reliance on imports for most part of the value chain has a debilitating effect on the ease of doing business and the ability of most government to provide adequate access to Medicine.

■ DEPENDENCE ON IMPORTED MEDICINE

High dependence on imported medicines (estimated to be about 79%) is as a result of its weak pharmaceutical industry. Importation of medicines increases the cost of health care and also may result in an interrupted supply of medicines. With the advent of a pandemic like the present COVID-19 one, the tendency for countries to restrict exports of essential medicines is high and already happening. The main exporters to the continent which is China and India have already placed restriction on some drugs and critical inputs to local manufacturing hence making the drive to increase local production a continental security issue.



■ INSUFFICIENT SUPPLY

There is high demand for the supply of medicines in Africa. As an illustration, according to the Gap Report by UNAIDS and WHO's World Malaria Report 2016, Africa is home to 75% of HIV cases and 90% of malaria deaths. Thus, the continent needs local medicine production to ensure continuous supply of medicines capable of handling the health challenges facing Africa rather than rely on external sources, which may disrupt supply and possibly increase the cost of health care provision. In addition to increasing availability and affordability of medicines, production of quality drugs would lead to reduced infiltration of substandard medicines into the market. It is true that donor funds for provision of essential pharmaceutical products has plugged the gap to an extent, but this is neither sufficient nor sustainable.



III. CONCLUSION

In view of this, local pharmaceutical companies are viewed as being important in bringing sustainable solutions to the health problems in Africa and local pharmaceutical companies in Africa must evolve in their capacity to provide high-quality pharmaceutical products to meet the growing health care need of the continent.

The objective of this paper is to provide an overview of Africa's pharmaceutical manufacturing industry both from the supply side and the demand side noting its potential as well as limitations while recommending enabling policies and initiatives that can help it in sustainably shifting into becoming export-oriented as it aims to meet both domestic and export needs.

This 5-part paper, co-authored by Afrexim Bank, African Union Development Agency (AUDA-NEPAD) and DFS Africa seeks to provide insights into Prioritizing & Growing Pharmaceutical & Health Manufacturing in Africa specifically looking at:



1. An Overview of the African Pharmaceutical Industry
2. Limitations to boosting Local Production
3. Enabling Policies & Initiatives to support Local Production
4. Making Local Pharmaceutical production a sustainable goal, and
5. Conclusive parting notes

PART 2

THE ECONOMIC CASE FOR LOCAL PHARMA MANUFACTURING IN AFRICA

During the last decade, promoting sustainable access to quality and affordable medicines and integrating local production as part of the overall health systems has been of significant concern to African leaders but the conversation must transcend just political will to a critical analysis of possible economic case for local manufacturing.

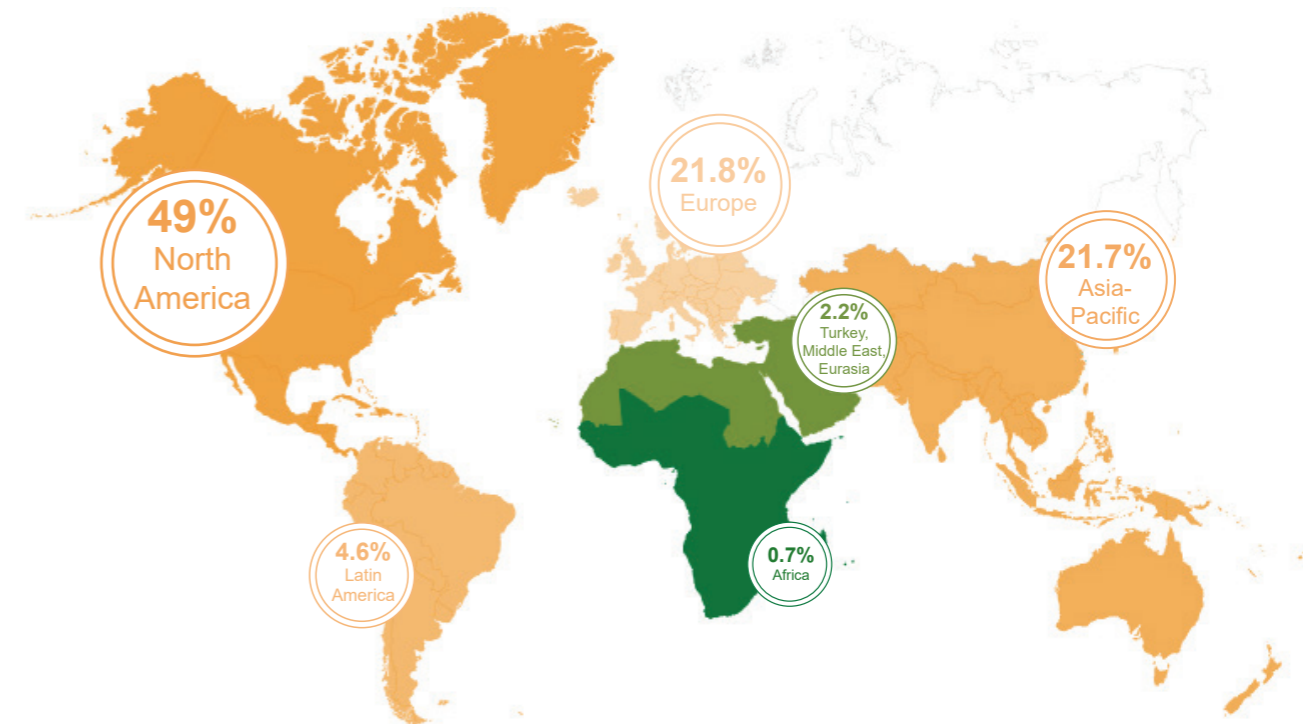


Critical questions bothering on the size of the industry, varied players in it and the market of for varied pharmaceutical products must be asked and answered. While the size of the industry and, especially, its projected growth rate looks good, will the risk tempered returns be comparable to other possible markets and is there enough incentives for capital providers to invest in this industry.

I. SUPPLY SIDE

According to the IFC, in 2016, global pharmaceutical revenues totalled over US\$ 1,105 billion and are forecast to reach US\$ 1,400 billion by 2021 but the African Continent only accounts for 0.7% of this market (ten African countries represent 70% of the Continent's revenues on their own).

AFRICA WITHIN THE GLOBAL PHARMACEUTICAL MARKET



¹ Algeria, Egypt, Kenya, Côte d'Ivoire, Libya, Morocco, Nigeria, South Africa, Sudan, Tunisia

MARKET IS SMALL IN THE GLOBAL CONTEXT

Though the African market accounts for only a small portion of the global pharmaceutical industry, it represents an extremely high growth potential market. In 2007, the International Finance Corporation (IFC) estimated that sub-Saharan Africa accounted for just under 0.6% of the global market or US\$3.8bn, but two critical things must be noted with this market:

The market in North Africa is more developed than its Sub Saharan African counterpart, and about 10 countries (Algeria, Egypt, Kenya, Côte d'Ivoire, Libya, Morocco, Nigeria, South Africa, Sudan, Tunisia) accounts for the largest part of the growth.



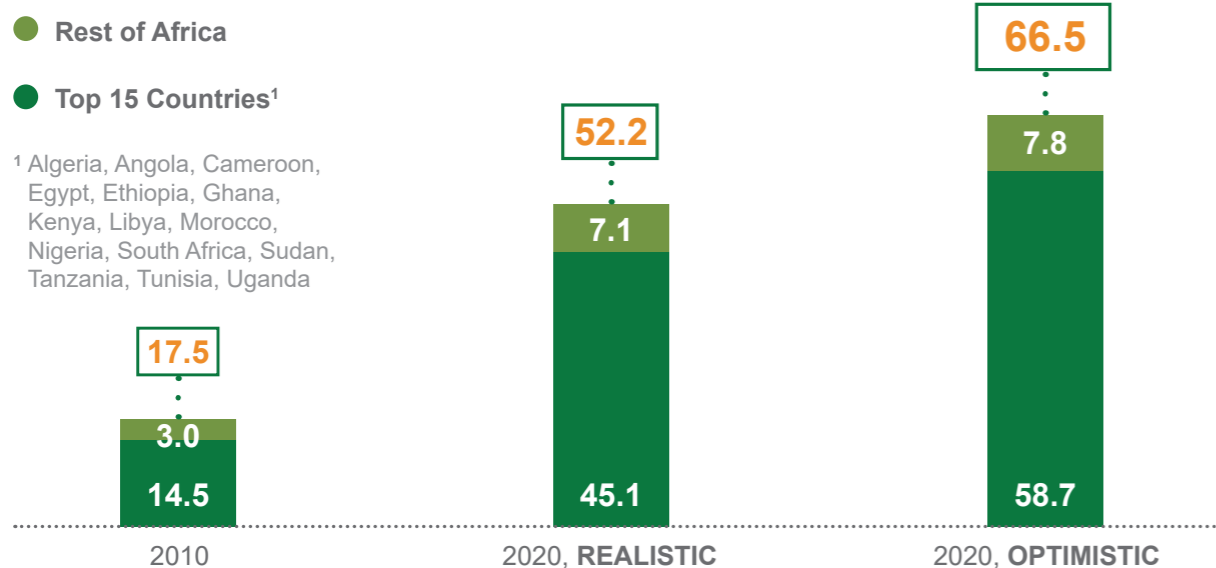
BUT THE AFRICAN PHARMACEUTICAL MARKET IS BOOMING

The African pharmaceutical market was worth US\$ 19.9² billion in 2012 and is forecast to grow to US\$ 50 billion by 2020, driven by the Continent's demographic boom and increasing middle class with better buying power as most consumers on the continents buys out of pocket.

Also, of interest is the segment growth rates. There is growth in all its sub-segments with Over-the-counter drugs (growing at ~6%), generic drugs (growing at ~9%), prescription drugs (growing at ~6%) and medical devices (growing at ~11%) for the same period.

The African Pharmaceutical Market is Booming

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Source: McKinsey, Africa: A Continent of Opportunity for Pharma and Patients, April 2015

² International Financial Company

THIS BOOM HAS ATTRACTED VARIED PLAYERS



Although the African pharmaceutical market is small compared with the global market, it plays host to varied players that differ by size and levels of activity in different segments of the industry. While Africa plays host to some of the leading global innovator and generic manufacturers like Novartis and a growing number of local manufacturers, most of the local manufacturers are small privately-owned companies and a few publicly listed companies (e.g. Ayrton and Starwin in Ghana, Fidson in Nigeria etc.). Also worthy of note are domestic manufacturers that are comparable in size to leading international generic manufacturers, such as Aspen in South Africa, a leading global generic manufacturer and a few public sector manufacturers like Saida (80% state owned) in Algeria and Saphad

in Tunisia, which is also majority government owned. Other public private partnership initiatives exist across the continent like the Kellaphala joint venture in South Africa and the Biovac Institute.

The PMPA business plan estimates only 38 countries as having pharmaceutical manufacturing entities on the continent with Nigerian having 200 registered pharmaceuticals and South Africa, Kenya and Ghana averaging 30 each and other countries like Uganda, Tanzania, Zambia having, though dynamic, an average of five to ten pharmaceutical companies. Countries like Cameroon, Namibia, Swaziland, Lesotho, Malawi and others have just one or two manufacturers.

Despite this range of industry players, the African market remain heavily import dependent market with a disproportionate amounts of state resources spent on importing ~70% to 90% of its pharmaceutical products compared to 5% imports for China and ~20% for India.

There are three other broad group of participants that completes the picture of the present landscape for the pharmaceutical manufacturers on the continent. They are:

Importers and Distributors who import from and represent companies from India and China

Leading Global companies like Ranbaxy, Pfizer, Cipla work through agencies and distributors while GSK and Johnson and Johnson have plants.

Leading global companies also does joint ventures with local manufacturers.

While the number of players varies and seems to cover the whole continent, the large proportion are small family owned manufacturers and importers and they are mostly local oral solid dosage form manufacturers emphasizing the inherent



opportunities for global and local players with sustainable access to market strategies.

In concluding the picture of the industry, we must note that the range of products varies significantly across the countries, with the more developed North Africa countries and South Africa having well developed industries and broader range products than their Sub Saharan counterparts with mostly limited range covering nutraceuticals, cough and cold preparations, simple analgesics, sedatives, older generation antibiotics, anti-helminthics and first generation ant-hypertensives. This mismatch between the Essential Medicines List of most countries and the limited portfolios of most manufacturers represents a significant latent potential market for locally manufactured products in many parts of the continent.



III. CONCLUSION

The uneven high demand and poor supply dynamics signals a great opportunity for Local pharmaceutical production. The fragmented market indicates a cost driven market hence a big emphasis on the use of technology, economies of scale and economies of scope.

It is therefore a reasonable conclusion that Local drug manufacturing will not only improve health outcomes, it will also impact the economic dynamics of the continent: economic diversification, GDP growth and, the impact on the balance of trade. The largest effect would be on the balance of trade. For e.g. If Ethiopia and Nigeria were to increase their local share of production from roughly 15% to 20% to around 40% to 45%, both countries could expect to see their trade balances improve by \$150mn to \$200mn annually.

Additionally, local manufacturing would facilitate cheaper drugs once all the costs are factored. Tablets, capsules and creams produced in Ethiopia and Nigeria tend to be about 5 to 15% cheaper than the landed price of imports from India, which are subjected to freight costs, duties and VAT. Moreover, supporting local incomes and jobs, triggering technology spillovers, addressing new challenges like non-communicable diseases, and helping the sustainability of government medical schemes.

Part 3 of this paper will explore the limitations to boosting local production and policies that have been developed to support local production.



PART 3

LOCAL PHARMA PRODUCTION – LIMITATIONS & SOLUTIONS

In Part 2 of this serialized paper, we look at key industry players and the dynamics of the African pharmaceutical market concluding that, while cost will play a big factor, the uneven tilt towards demand at the expense of supply and the high dependence on imported products presents an opportunity for local Pharmaceutical production.

That said, the present dependence on imported products signals the heavy limitations on the industry and why a tandem of solutions is necessary for it to achieve its full potential. Part 3 of this paper focuses on these limitations and the proffered solutions.



I. LIMITATIONS

■ COMPLEX VALUE CHAIN

The existing pharmaceutical value-chain is complex, and the expertise required for local medicines production extends well beyond absolute manufacturing. It covers areas such as research and development, intellectual property, trade and commerce, tax and tariff policies, drug regulatory and registration issues, finance, raw materials procurement, medicines and marketing.

Currently, there are huge gaps in the continent's technical expertise, resource availability and regulatory architecture. For example, many African manufacturers remain uncompetitive and struggle to match up to internationally recognized regulatory standards, such as World Health Organization (WHO) pre-qualification, a necessary rubber stamp for those supplying drugs to major distributors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Challenges of achieving universal GMP transcends just technical considerations regarding expertise needed in setting up and running high quality plants or even the financial implications to having the ecosystem and infrastructure required to stay compliant.

■ POOR AFRICAN INFRASTRUCTURE

Some of the strong barriers to local pharmaceutical production in Africa primarily exists due to factors such as inadequate infrastructure, skilled human resource constraints, poor regulation, industry fragmentation, and low production quality standards.

The high operating costs of pharmaceutical companies and high cost of local commercial capital coupled with the presence of lower incomes, tax



avoidance and corruption problems further inhibit the local production in Africa. Moreover, weak links between local and international suppliers and lack of foresight on the part of African governments further acts as obstacles to boost local production.

■ SCARCE FINANCING RESOURCES

Pharmaceutical industry is a capital-intensive industry, payback periods are long, and nascent industries need time-limited support from government. African government's budget allocation for procurement of medicines in public healthcare institutions is presently meagre and it is primarily dependent on external funding sources. For e.g. most medicines consumed in Zimbabwe are bought by international donors or the private sector. There are lesser available affordable financing alternatives for the pharmaceutical companies. Moreover, current investment in African pharmaceutical innovation is low. Governments' commitment to financing science and technology research and development are low worldwide, and in African countries, mostly absent.



■ ISSUES RELATED TO POLICY COHERENCE & COORDINATION

African countries are considered as a monolithic cluster for pharmaceutical investments decisions. This neglects and hides the wide contextual differences among the African countries and obscures the country-specific contexts where the opportunities are ripe for advancements in the pharmaceutical sector due to changes and reforms in the institutional underpinnings.

While the EU has an effective pan-European regulator known as the European Medicines Agency, which offers drug companies a centralized marketing authorization across all EU states, Africa has a patchwork of individual regulators offering conflicting rules, standards and approval procedures.

Product approvals take a longer time in execution due to the presence of irregular procedures which are not harmonized throughout the continent. Additionally, each pharmaceutical company has to go to each country or region and pay its fees for product approval which increases that cost that is passed on to the customer. Moreover, fragmented supply chains in Africa have an excessive number of intermediaries between the production facility and the pharmacy where the medicines are sold. Intermediary margins are estimated to be up to ~50% of the final price in Kenya and up to 90% of the price in lesser developed countries - while margins account for only 2% to 24% in the OECD countries.



There is a need for a solid and stable political system for attracting investment to the continent. A recent survey of CEOs from East Africa noted political risk as the single most significant challenge for business in East Africa.

II. SOLUTIONS – ENABLING POLICIES & INITIATIVES

■ REGIONAL INITIATIVES ARE ESSENTIAL TO UNIFY MARKETS



While access to essential medicines is recognized as a universal human right, it is far from being guaranteed to most people in low- and middle-income countries such as most of Africa. Two new mechanisms have emerged that aim to put countries in the driver's seat for access, research and local medicines production. Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) in addition to the African Union Pharmaceutical Manufacturing Plan (PMPA). Many more like this are needed to galvanize and prioritize the African pharmaceutical industry.

Other multilateral bodies are also contributing in making this goal achievable. For example, The United Nations Industrial Development Organization (UNIDO) is working with local manufacturers on a Good Manufacturing Practices (GMP) roadmap to support local companies to be GMP compliant and establish a baseline of the current standards.

It has implemented its GMP roadmap in Kenya and is currently working with the West African Health Organization to develop a GMP roadmap framework for the ECOWAS region.

The Pharmaceutical Manufacturing Plan for Africa whose business plan was adopted by the African Heads of State and Government in 2012 as a roadmap for implementing the Pharmaceutical Manufacturing Plan for Africa (PMPA), endorsed way back in 2007. In 2013, African leaders called for the strengthening of south-south cooperation to scale up investment in Africa's pharmaceutical manufacturing capacity, with a focus on generic essential medicines while In 2014, the Joint United Nations Programme on HIV/AIDS (UNAIDS), UNIDO and WHO came together to appeal to Africa's development partners, especially the BRICS countries, to have a special role in supporting this critical transition scaling up local production. This was further progressed in 2018, when AUDA-NEPAD, in collaboration with private sector operator, DFS Africa convened the maiden edition of the PMPA driven African Pharmaceutical Conference.

At the back of the conference, initiatives that would increase competency across the industry, raise dedicated funds for the industry and curate data of professionals both locally and in diaspora in a bid to encourage cross pollination of ideas was launched.





National initiatives like the Ethiopian's National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025) with the support of the WHO.

Other initiatives worthy of mention is the African Union treaty establishing African Medicines Agency (AMA), which aims to promote and harmonize regulatory policies, standards, and scientific guidelines.

During the past decade, many African countries have shown interest in developing their national health research systems. However, there are only a few African countries have a health research policy in place. Several multilateral and bilateral initiatives exist in Africa to strengthen country capacity for policy formulation

in the science, technology and innovation sector- many coordinated by the African Union and the African Union Development Agency (AUDA-NEPAD).

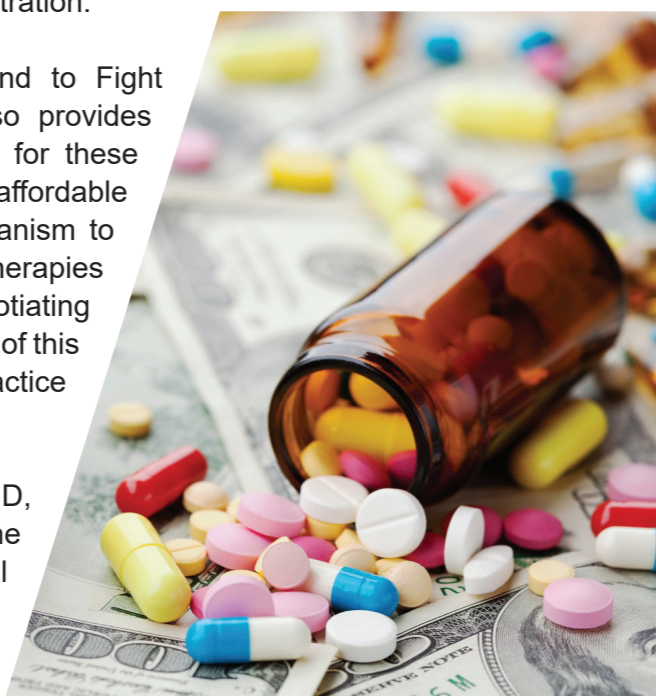
■ INCREASED ACCESS TO FUNDING AVAILABLE

The current investment levels in the African pharmaceutical innovation sphere is low. Governments' commitment to financing science and technology research and development are low worldwide, and in African countries, mostly absent (but this seems to be changing).

Venture philanthropy, such as funds from the Bill and Melinda Gates Foundation, has in the last decade encouraged the creation of public-private partnerships that seek to develop much-needed innovator products, such as new antimalarial drugs or diagnostic tools easy to use in resource poor settings. Funding from the Gates Foundation has facilitated several regional and national initiatives including efforts to strengthen pharmaceutical innovation systems, such as the NEPAD research on innovation systems and the strengthening of regional drug registration.

Other than philanthropic sources, the Global Fund to Fight Tuberculosis, AIDS TB and Malaria (GFATM) also provides funding to enable access to interventions needed for these diseases. The Global Fund has launched the affordable medicines facility for Malaria (AMFm) and a mechanism to expand access to artemisinin-based combination therapies (ACTs) for malaria. Cost reduction is achieved by negotiating a lower price for ACTs, then paying a large proportion of this directly to manufacturers on behalf of buyers (the practice of buyer 'co-payment').

Other special funding mechanisms include UNITAID, which raises funds from a solidarity tax on airline tickets. UNITAID funds facilitate access to essential medicines and diagnostic tools for HIV/AIDS, malaria and tuberculosis. Some venture capital funding is also available for pharmaceutical innovation in



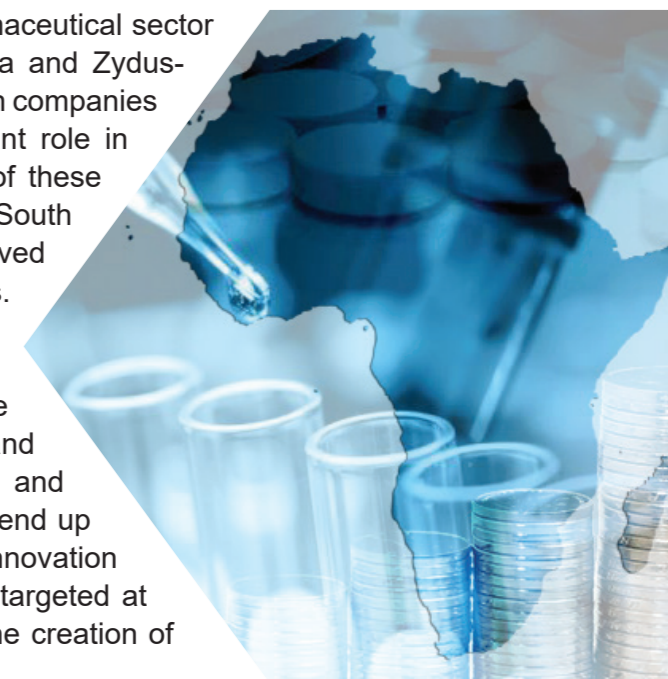
Africa. Examples include Bio-ventures, a South African- based biotechnology and life sciences venture capital fund founded in 2001.

A report by the European Commission and the WHO in 2017 found that China Government authorities and stakeholders have already started to engage in the development of the pharmaceutical sector in the African region. The Chinese Development Bank is undertaking studies and projects, and some Chinese companies have initiated operations, albeit of a limited nature.

A similar report in 2017 that explored India's pharmaceutical sector found that some Indian companies, such as Cipla and Zydus-Cadila have invested in and/or partnered with African companies and that Indian industry already plays a significant role in the South African pharmaceutical market. Some of these firms - like Cadila in Ethiopia, Cipla in Uganda and South Africa and Ranbaxy in Nigeria - are actively involved in manufacturing through foreign direct investments.

The future solution will most probably rely on a combination of mechanisms. Whatever the incentives for strengthening the R&D, production and delivery of the affordable medicines, diagnostics and vaccines needed in African countries, they should end up ensuring a predictable and sustainable funding of innovation for health, an innovation which will be essentially targeted at country self-defined needs and will contribute to the creation of global public goods.

There are many attributes behind boosting local production, but the primary motive is to address the inadequate demand and supply relationship in the pharmaceutical industry across the African continent. Enhancing local production will not only ensure the quality of medicines due to closer and improved governance thereby reducing counterfeit pharmaceuticals but also avoid stock outs.





In Part 3 of this serialized paper, we look at the key critical limitations to boosting local production and the policies and initiatives already in place to mitigate these limitations. Governments and Local manufacturers can look at the plethora of initiatives available to them to take advantage of the demand for medicines in their countries.

Moving forward, the focus needs to be directed towards the pockets of growth. Africa is not one unified market, but 54 distinct ones, with wide gaps between countries in terms of their market size, growth trajectory, macroeconomic landscape, legal structure, and political complexities. Over the past decade, 10 countries have delivered more than two-thirds of Africa's GDP and cumulative growth. However, much of the opportunity lies not at country level, but in cities. ~37% of African consumers are concentrated in 30 cities, which will have more consuming households than Australia and the Netherlands combined by 2025.

To strengthen and improve Local Pharmaceutical production, the following should be considered:

■ FOSTERING TALENT

Building strong local teams is key and requires large investments, effective local marketing and sales teams. That means hiring more pharmacy representatives, building teams' technical skills, and selecting and developing strong local managers to lead them. Sales teams also should be set up in a flexible way that enables them to be responsive to the needs of local markets.

At the back of this, AUDA-NEPAD, in conjunction with DFS Africa, launched the African Pharmaceutical Learning Management System, the APLMS will be the foremost platform for accelerating capacity building and knowledge transfer for Pharma and Biotech in Africa by providing accessible, quality, cost-effective training designed to increase individual and organizational productivity and enrichment.

■ FORGE PARTNERSHIPS

Global pharmaceutical companies need local business partners - manufacturers, packaging companies, and distributors - to help them navigate the continent's many markets, with their widely varying consumer preferences, price points, manufacturing, and distribution infrastructures.

In the absence of a pan-African pharma regulatory body, they also need to invest in local partnerships to understand varying regulatory environments. Partnerships with governments are equally important, whether they involve working with



PART 4

STEPS TO STRENGTHEN LOCAL PHARMA PRODUCTION

medical opinion leaders to guide research priorities and secure funding or collaborating with health ministries and nongovernmental organizations to provide public-awareness campaigns, health screening, treatment, equipment, and training for hospitals and clinics. Johnson & Johnson, for example, has partnered with the South African government to introduce an education program for maternal, newborn, and child health that operates via mobile-phone messaging.

It should not be a one-way traffic, while big pharmaceutical companies are seeking sustainable access models into Africa, local manufacturers with sustained strategies and access models should be reaching out to Big pharma's as they scale their operations.

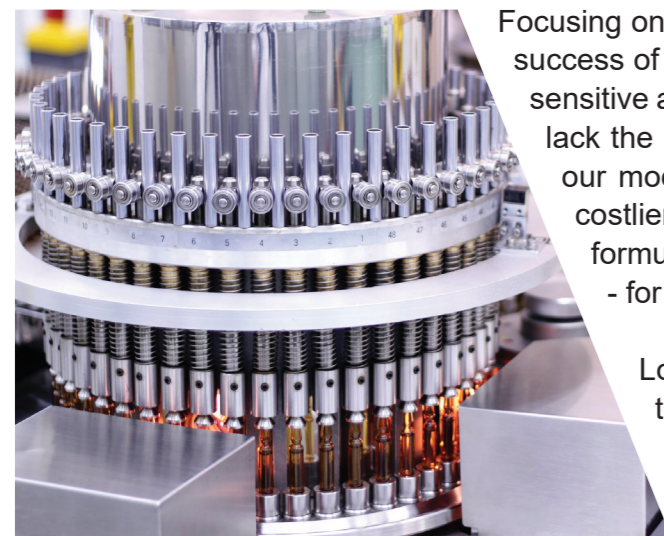
■ ADDRESS SUPPLY AND DISTRIBUTION CHALLENGES

In parts of Africa, supply and distribution mechanisms still pose challenges: regulations are evolving, transport and logistics infrastructures are patchy, and lead times can be long.

The ability to innovate the distribution channel and set up effective operations against this challenging backdrop is critical to capturing growth opportunities. Helpful strategies include locating fixed assets in countries with well-established political and business structures, outsourcing supply chains to third-party operators, and partnering with local logistics providers to identify efficient transport routes.

In the key area of customs and border control, companies should work with the most reliable agents to minimize shipping delays, use only bonded distribution centers, and ensure all customs paperwork is airtight.

■ FOCUS ON DRUG-PRODUCT FORMULATION, BUT KEEP AN EYE ON NEW TECHNOLOGY



Focusing on the right part of the value chain will be critical to the success of a pharma sector in Africa. APIs today are very scale sensitive and hard to manufacture. Most countries in the region lack the requisite chemicals sector for API production, which our modeling suggests would already be 10 to 15 percent costlier than imports from India. That makes drug-product formulation the better bet, while continuing to import APIs - for now, at least.

Looking ahead, this focus could evolve. New technologies could lower API costs - whether by changing the scale economics needed to keep prices competitive, making manufacturing easier, or improving quality.



Indeed, one advantage that Africa has is the opportunity to adopt cutting-edge technologies without worrying about replacing existing technologies in legacy plants.

Some of the most promising technologies on the horizon include improved process chemistry, continuous manufacturing, and modular plant design. Using Ethiopia as an example, employing improved chemical-synthesis processes could reduce costs by approximately 5 to 35 percent, and continuous production could cut costs by another 10 to 25 percent, if the right molecules are chosen for production. In addition, modular plant design could speed construction of these plants and ensure tighter quality assurance.

■ FACILITATE A BETTER BUSINESS ENVIRONMENT

To create a more supportive environment for business, governments should introduce price controls and import restrictions to encourage domestic drug manufacturing; enable country-specific labeling to reduce counterfeiting and parallel imports and tighten laws on import, wholesale, and retail margins. Consolidate pharmacy chains and enable horizontal and vertical integration of these pharmaceutical companies.

Promote mergers and acquisitions, joint ventures, strategic alliances, partnerships, and private-equity deals for further extending Africa's markets. Governments have several potential levers to encourage local production. These include local production incentives in national tenders, subsidies and tax breaks, investment in special economic zones, and talent- and skill-building programs.

The final part of this series will look at current practical steps that the African Union Development Agency (AUDA-NEPAD) in partnership with its consortium and private sector partners are taking to ensure that the growth of the Africa Pharma industry through manufacturing is prioritized.



PART 5

MAKING LOCAL PHARMA PRODUCTION A SUSTAINABLE GOAL – INPUT FROM AUDA-NEPAD

The African Union Development Agency (AUDA-NEPAD) recognize within the context of her mandate that “business-as-usual” advances will not deliver the Africa we want. Therefore, AUDA-NEPAD is actively collaborating and working with member states and stakeholder partners to ensure that the Pharmaceutical Manufacturing Plan for Africa (PMPA) with its associated Business Plan developed by the African Union Commission (AUC) in 2005 is not only realized but also sustainable.



The vision of the PMPA is to develop a stable integrated pharmaceutical manufacturing industry in Africa which is able to respond to the continent’s need for a secure and reliable supply of medicines.

The PMPA was endorsed by the Africa Heads of State and Government at the summit in Accra, Ghana in 2007. The PMPA will contribute to improved access to affordable, safe and efficacious essential medicines for the African people. Strengthening the African continent’s ability to produce high quality, affordable pharmaceuticals across all essential medicines will contribute to improved health outcomes and the realization of direct and indirect economic benefits. In recognition of the need for a conducive regulatory environment for local production and trade in pharmaceuticals on the continent, the AU established the African Medicines Regulatory Harmonization (AMRH).

The overall aim of the AMRH initiative is to improve the fragmented regulatory systems, reducing lead-time associated with meeting different country requirements and contributing to increasing availability of safe, effective, quality essential medicines for priority and neglected diseases. Since 2009, the AMRH has scored a number of successes including the development of the AU Model Law on medical products regulation in Africa that was endorsed at the African Heads of State and Government Summit in Addis Ababa, Ethiopia in January 2016.



Despite these achievements, there still remains significant gaps in the knowledge about the implementation of the AMRH and the PMPA —the framework within which it’s anchored. AUDA-NEPAD efforts in the pharmaceutical value chain, led to the commencement of the Africa Pharma Conference. The event organised in partnership with DFS Africa (a private sector firm with a platform to grow investments into Africa’s leading industries) was initiated to champion the necessary conversations to create the necessary awareness that is critical in accelerating the achievement of the objectives of the AMRH and PMPA.

I. PROGRESS ON AUDA-NEPAD'S WORK IN AFRICA PHARMA

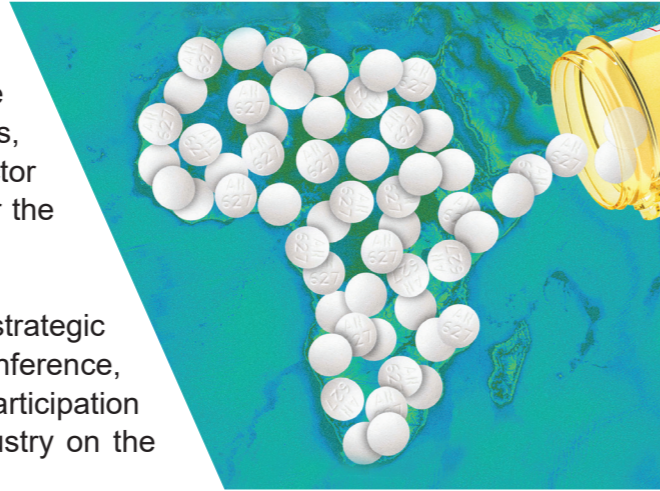
The AUDA-NEPAD created a Pharmaceutical Industry portfolio which is well advanced in its implementation of the PMPA business plan. The portfolio has secured partnerships with UN agencies, Development Finance Institutions and Private Sector organizations to implement its strategic vision over the next 4 years.

The Pharmaceutical Industry portfolio has existing strategic work packages such as the annual Africa Pharma Conference, which is a platform that galvanizes high level participation of critical stakeholders in the Pharmaceutical Industry on the continent and beyond.

The Pharma portfolio has a commitment to implement the following work packages over the next 4 years to support its drive in the development and implementation of PMPA:

1. Set up the APC Secretariat to monitor and manage the 5 work packages within the portfolio;
2. Develop and Implement the African Pharma Best Practices Framework (APBPF)
3. Develop and Implement the African Pharma Learning Management System (APLMS)
4. Develop and Implement the African Pharma Fund (APF)
5. Develop and Implement the Africa Pharma Resource Database (APRD)

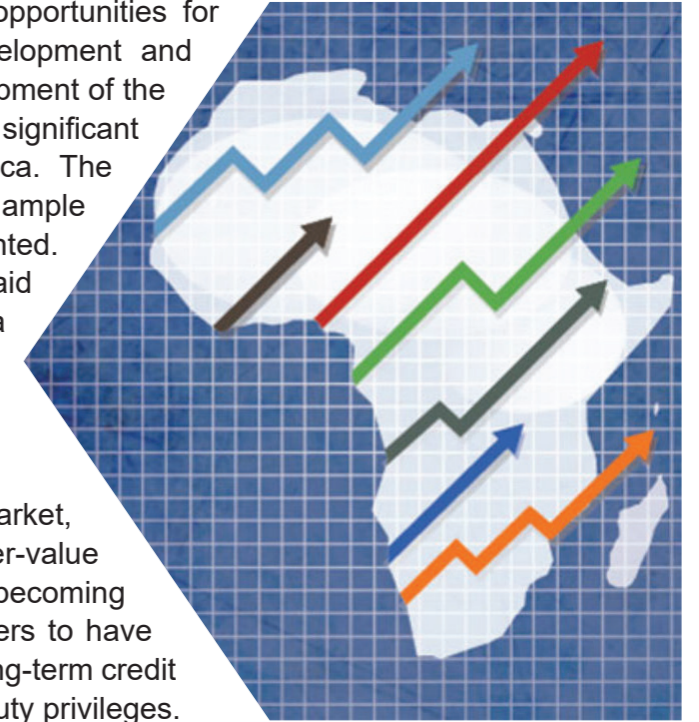
All of the above work packages will be launched at the 2nd Africa Pharma Conference to be held in Nairobi, Kenya at a date to be announced soon.



II. CONCLUSION

The African pharmaceutical market holds vast opportunities for the continent's manufacturers. The export development and industrialization prospects arising from the development of the pharmaceutical sphere are expected to generate significant economic development and growth across Africa. The significantly underpenetrated market represents ample demand despite remaining to be import-oriented. Developing the local manufacturing market will aid in overcoming the key hurdles of not having a comprehensive policy framework for health and health research, science and technology, industry, trade, law and education.

African manufacturers are urged to move up-market, towards more technologically sophisticated, higher-value products with export potential. The transition into becoming an export-oriented sector will enable manufacturers to have easier access to finance; consequently, receive long-term credit with low interest, export incentives and customs duty privileges.





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