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DEVELOPMENT REIMAGINED

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MAKING AFRICA'S PHARMACEUTICAL AMBITIONS A REALITY:

Part 1 – History, Trade and Hubs

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1. ACKNOWLEDGEMENTS

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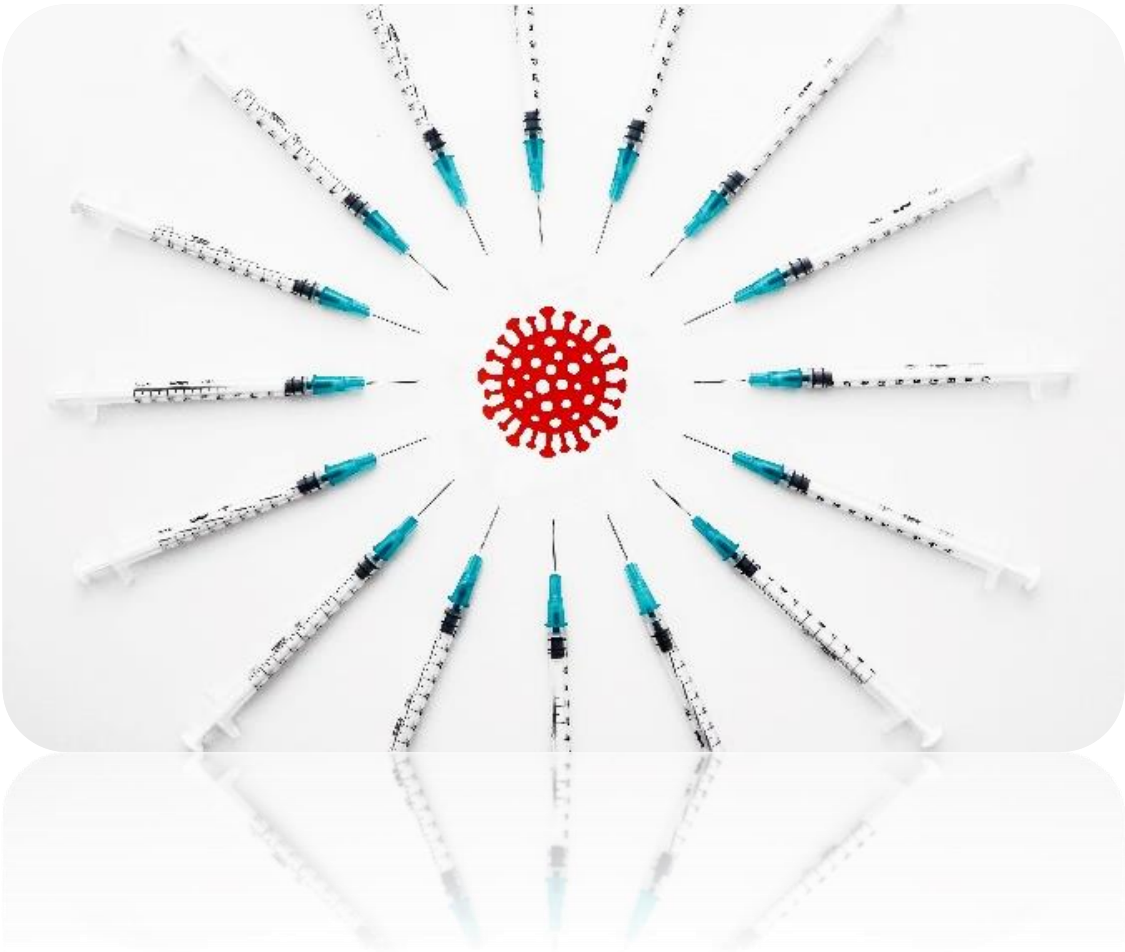


2. INTRODUCTION

Africa is the world's fastest growing continent: the consolidated value of its developing economies is estimated at 2.6 trillion USD, while its youthful demographic, expanding middle class and an estimated 1.3 billion population position the continent favorably in the global consumer market arena.

Despite these positive points, Africa only accounts for 3% of global GDP, struggles with its infrastructure deficit and with a World Bank estimate of its purchasing power parity (PPP) at 4.82 trillion in 2021 (compared to India at 10.2 trillion USD and China at 27.3 trillion USD), the continent is still in its developmental stage: this includes all the attendant difficulties with building the necessary sectors to support its growth, such as its pharmaceutical sector.

Valued up to an estimated 65 billion USD, the pharmaceutical sector in Africa is primed to grow rapidly but is faced with multiple challenges: infrastructure and regulation gaps, unequal manufacturing capacity spread, a fractured internal pharmaceutical market and a shifting pharmaceutical needs base (from infectious to non-communicable diseases), among other issues. Integrating the existing expertise on the continent and closing the gaps is key to Africa harnessing its full potential and taking its place in the global market for pharmaceuticals and in self-sufficiency for medicines – a goal that has become more pressing in the wake of the COVID-19 pandemic and the undeniable inequity experienced by the continent in accessing much needed vaccines.

This paper is the first of a three-part series of Development Reimagined reports on the pharmaceutical industry, intended to offer insights into – and provide actionable recommendations for – the decolonization and sustainable improvement of Africa's pharmaceutical sector.

This paper assesses the pharmaceutical sector from a historic standpoint, highlighting the issues and attendant opportunities – from infrastructure gaps, the pharmaceutical needs of the continent, to initiatives that can be scaled to provide bigger benefits, and finally presents the argument for pharmaceutical manufacturing hubs in Africa – a move that will provide economies of scale for local manufacturing, add value, and return on investments.

The bulk of this report draws from desk research, including but not limited to: data scraped from the web, reports, and research by Development Reimagined, as well as white papers by international organizations and news publications.

This paper was written to be read and understood by pharmaceutical sector experts across the world in Africa, China and India, including: manufacturers, researchers, investors, boards of regulatory bodies, local and international organizations in the sector and state leaders, among others.

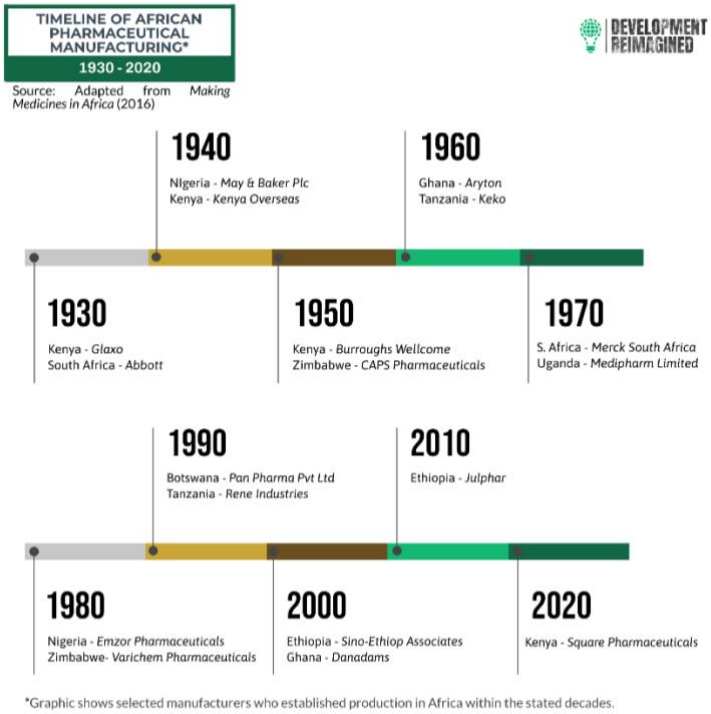
3. A HISTORY OF THE AFRICAN PHARMACEUTICAL INDUSTRY

Records of pharmaceutical manufacturing in Africa can be traced as far back as 1930[1], when multinational corporations began to set up subsidiary operations in African colonies at the time. The historically leading countries for these pharmaceutical manufacturing start-ups were Kenya (Glaxo, 1930), South Africa (Abbott, 1935), Nigeria (May and Baker, 1944) and Zimbabwe.

Mackintosh et. al. (2015) explored the slow increment of multinational investment in African manufacturing in the 1930s – 1960s, in tandem the rise in other industrial sectors for agro-processing and mining, changes which have been linked to the logistics fluctuations for essential materials experienced by colonial powers during World War II.

In Figure 1 below, there are several instances of fluctuating activity in the development of Africa's pharmaceutical manufacturing sector: an investment burst in the 1970s (when multiple countries began to secure their Independence), a slowdown in the 1980s into the early 90s (coinciding with the economic downturn of the time, the adoption of IMF structural adjustment programs by African states in exchange for fiscal support and the subsequent deindustrialization across much of Africa) then another rise in the late 1990s until the present day (driven mostly by local investors returning to the continent with experience gained in foreign pharmaceutical industries).

Figure 1: Timeline of African pharmaceutical manufacturing start-ups (1930 - 2020)



[1]Mackintosh, M., Banda, G., Wamae, W., & Tibandebage, P. (2015). *Making Medicines in Africa: The Political Economy of Industrializing for Local Health (International Political Economy Series)* (1st ed. 2016 ed.). Palgrave Macmillan. https://doi.org/10.1007/978-1-137-54647-0

3.1 Historical Trade Data in Africa

An exploration of Africa's trade data from the World Bank's World Integrated Trade Solution (WITS)[2] shows a skew towards imports of mixed drug classes, with little export between 1970 – 2020 (Figure 2, 3).

These circumstances translated to a trade deficit on pharmaceuticals in the continent, valued at up to 2 billion USD in some countries in 2019 (Figure 4).

As cited by Chaudhuri in Making Medicines in Africa (2015), most pharmaceutical manufacturers in Africa were large multinationals – changes in their market strategy over the decades leaned towards a focus on established and more lucrative markets in other regions, which lowered local production and pushed the continental dependency on drug imports to the fore.

Figure 2: Export – Import Balance of Pharmaceuticals in Africa (1970 – 2020)

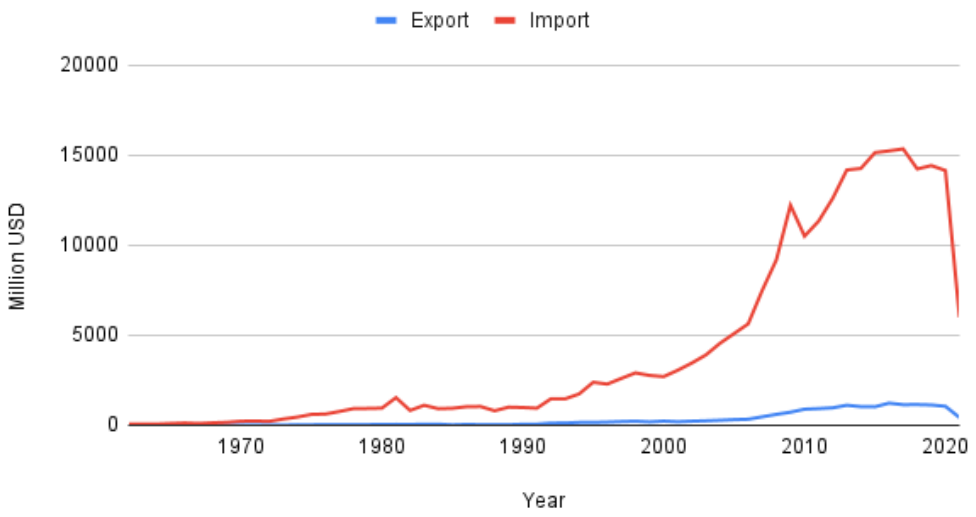


Figure 3 shows a breakdown of the pharmaceutical products that made up most of the imports into Africa; where medicaments with mixed or unmixed products for therapeutics made up the largest deficit, representing imports of measured dose (or finished and packaged) drugs, typically for retail sale.

[2]World Bank. (n.d.). *WITS Home*. World Integrated Trade Solution. Retrieved June 6, 2022, from https://wits.worldbank.org/WITS/WITS/Restricted/Login.aspx

Figure 3: Trade Balance of Pharmaceutical Products in Africa (1990 – 2020)

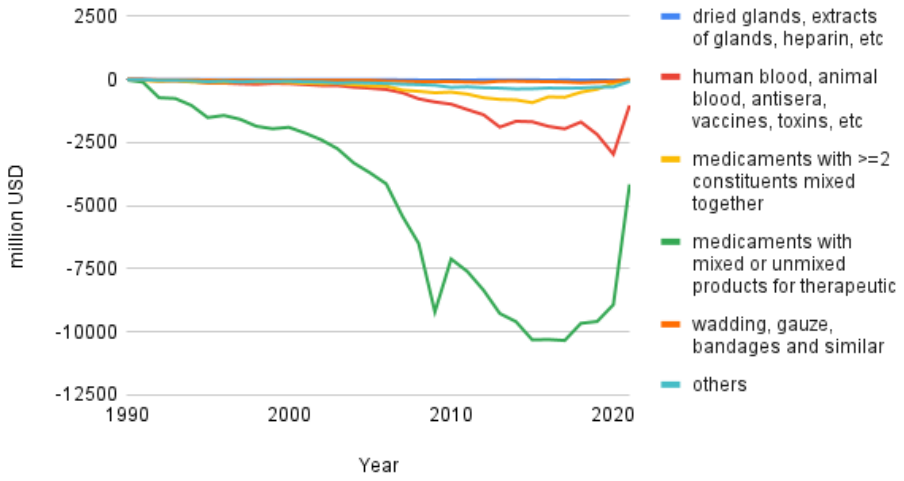
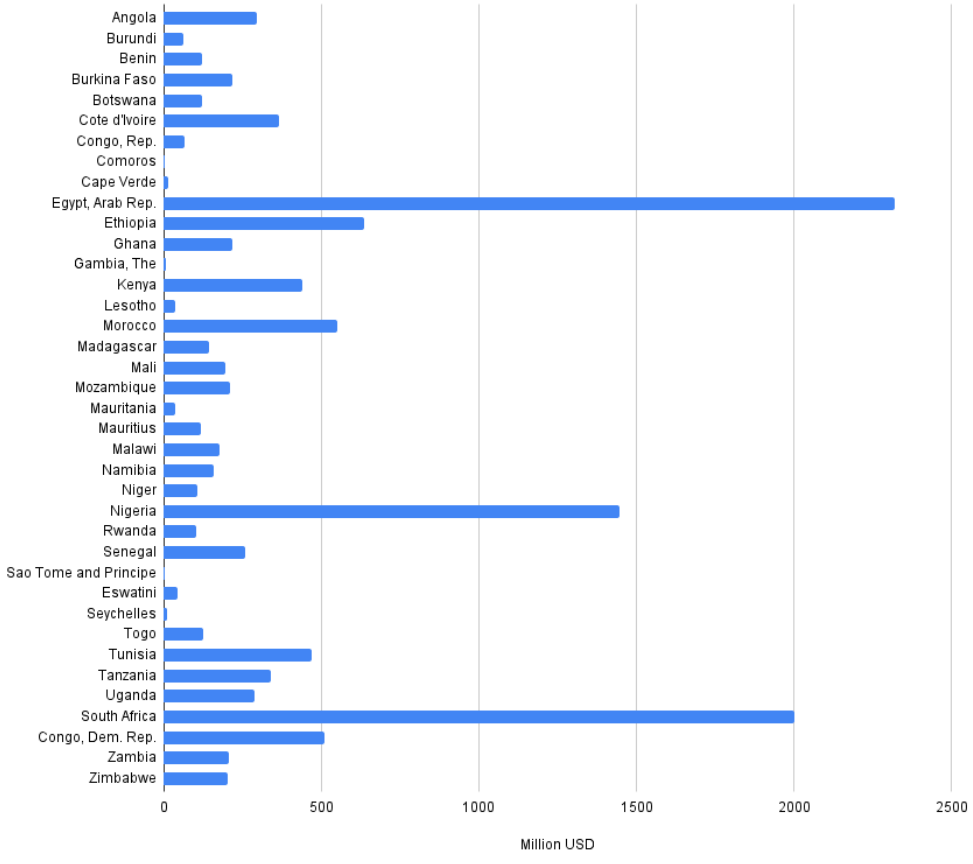


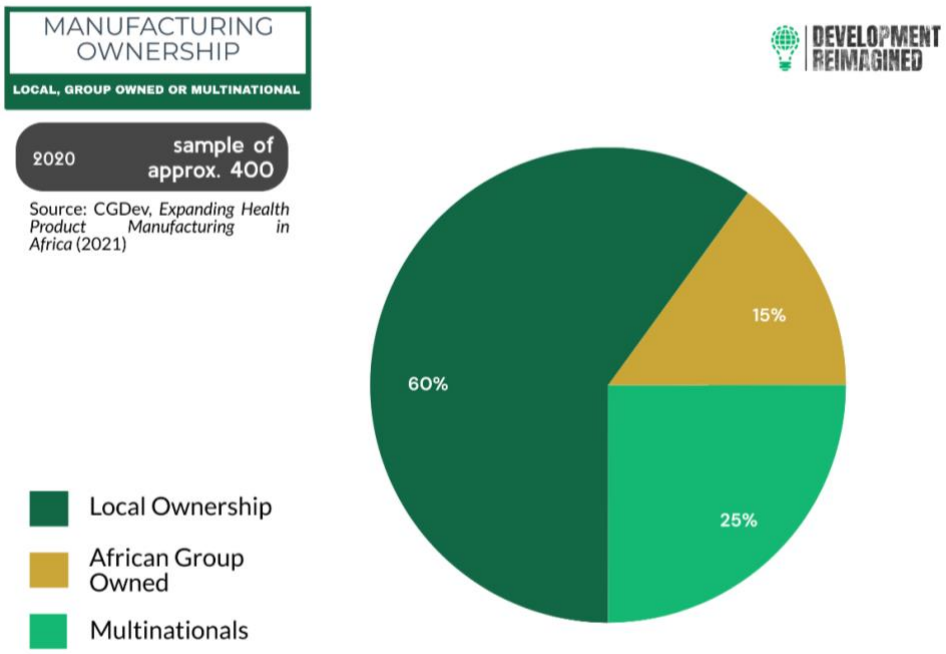
Figure 4 shows that every African country with available data has a trade deficit in pharmaceuticals, with some countries' deficit exceeding 2 billion USD. This is notable, as the top 3 countries registering the most deficit (Egypt, Nigeria, and South Africa) are also among the continent's largest economies and have significant pharmaceutical manufacturing capacity (see Figure 9).

Figure 4: Trade Deficit on Pharmaceuticals in Africa (2019)



Recent data from a CGDev 2021 assessment of a selected sample of 400 manufacturers shows more local ownership of pharmaceutical companies in Africa (Figure 5), indicating an increase in African-owned pharmaceutical manufacturers, representing over 50% of the sample, with a still sizeable multinational company section at 25%.

Figure 5: Pharmaceutical Manufacturer Ownership in Africa (2020)



4. STATE OF THE AFRICAN PHARMACEUTICAL INDUSTRY

Today, Africa represents only 3% of global drug production and imports greater than 80% of its consumed pharmaceutical goods[3], whereas India comparatively imports only 5% of its need[4], generating most of its required medicines internally. Some countries in Africa, such as Morocco and South Africa, produce just over 70-80% of their needs, but some countries in Central Africa import over 90% of their drug consumption.

These drugs are also more expensive than they need to be. Intermediary costs – the added drug costs incurred from the distribution chain – can go as high as 50% added to the price paid by the final consumer in some African countries[5], whereas these costs range from 2 – 24% in the OECD, as cited in Evo (2021). Even before the COVID-19 pandemic disruptions in drug supplies, supply disparities were common due to stock-by-demand, which often led to drug stock-outs, shortages[6] and increased risk of counterfeit drugs.

Still, growth in Africa's pharmaceutical markets reaches every segment, given that between 2017 and 2030, prescription drugs are forecast to grow at a compound annual growth rate of 6.5%, generics at 10%, over-the-counter medicines at 7.1%, and medical devices at 12.1%[7].

This surge is suggested by Mackintosh et. al. (2015) to be driven primarily by expanded health insurance schemes, enhanced investments, an improved business climate, a maturing regulatory environment, and increased confidence in generic products.

There is also increasing interest in investment from foreign countries (such as China and India) as well as international organizations including the International Finance Corporation[8], the Africa Development Bank[9] the European Investment Bank[10] and many others targeting infrastructure growth to support local production.

[3] Evo, F. (2021, June 17). *Strengthening efforts to support the pharmaceutical sector in Africa*. ID4D. https://ideas4development.org/en/support-pharmaceutical-sector-africa/
[4] Conway, M., Holt, T., Sabow, A., & Sun, I. Y. (2019, January 10). *Should sub-Saharan Africa make its own drugs?* McKinsey & Company. https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs
[5] Barbière, C. (2018, March 28). *Africa takes steps to make medicine more affordable*. Euractiv. https://www.euractiv.com/section/development-policy/news/africa-takes-steps-to-make-medicine-more-affordable/
[6] Buckholtz, A. (2021, June). *Inside Africa's Push to Make its Own Medicines*. International Finance Corporation. https://www.ifc.org/wps/wcm/connect/news_ext_content/ifc_external_corporate_site/news+and+events/news/cm-stories/africa-pharma-manufacturing-hubs-en
[7] Goldstein Market Intelligence. (2020, April 24). *African Pharmaceutical Market Report: 2017–2030 (2020 Edition)*. Goldstein Research. https://www.goldsteinresearch.com/report/africa-pharmaceutical-industry-market-size-forecast
[8] To scale up the manufacturing of COVID-19 vaccines in Africa, IFC announced a collaboration with the Institut Pasteur de Dakar (IPD), a vaccine maker and non-profit healthcare foundation mandated to support public health improvements in Africa. https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=26493
[9] The African Development Bank (AfDB) has said it would invest 3 billion dollars to build Africa's pharmaceutical industry in the next 10 years. https://www.vanguardngr.com/2021/05/afdb-invest-3bn-in-africas-pharmaceutical-industry/
[10] The European Investment Bank launches a 50 million Euro pharmaceutical manufacturing scheme for Africa. https://www.eib.org/en/press/all/2020-377-eib-launches-eur-50-million-africa-pharmaceutical-manufacturing-initiative

4.1 Local Pharmaceutical Production in Africa – Challenges and Opportunities

The challenges hampering local pharmaceutical production in Africa are both domestic and international, and include:

- a lack of affordable financing and modern technology,
- inadequate infrastructure,
- small and fractured markets in Africa,
- subsidised / free medicine imports from international aid organizations which crowd out local manufacturers, and
- weak regulatory frameworks as well as inadequate expertise to sustain production and drive innovation.

In 2019, a McKinsey assessment on the challenges and opportunities of drug production in Africa posited that most African countries are in the earliest stages of pharmaceutical industry development and are limited to packaging: purchasing pills and other finished drugs in bulk and repackaging them into consumer-facing packs.[11]

A World Bank report from 2005 also noted the industrial potential of several African countries, namely South Africa, Kenya and Nigeria and Zimbabwe to produce some drugs for export or for domestic consumption. In the face of what some would argue would be diminishing supply of generic medicines from the major producers, the report further noted that if the economic cost of creating local production capacity is excessive or the quality of the products is doubtful, this "local production solution" would be no solution at all[12].

A current example showing the need for the operationalization of these principles – particularly of local procurement – is the case of South African manufacturer Aspen Pharmaceuticals, which as at May 2022[13] is considering halting production of its COVID-19 vaccine due to receiving no orders – neither locally nor for export.

Aspen's experience precipitated a call by African leadership to those purchasing COVID-19 vaccines for Africa on a global scale – in this case, international bodies such as the World Health Organization (WHO) and the Global Alliance for Vaccines and Immunization (GAVI) – to improve on their procurement strategy by prioritizing purchases from African manufacturers[14]. Establishing production is only part of the struggle – the market for these drugs must be supported by policy as well.

[11] Conway, M., Holt, T., Sabow, A., & Sun, I. Y. (2019, January 10). *Should sub-Saharan Africa make its own drugs?* McKinsey & Company. https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

[12] Kaplan, Warren; Laing, Richard (2005). Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines, An Overview of Key Concepts, Issues and Opportunities for Future Research. Health, Nutrition and Population (HNP) discussion paper; World Bank, Washington, DC. © World Bank. https://openknowledge.worldbank.org/handle/10986/13723 License: CC BY 3.0 IGO.

[13] Ryder, H., & Omosigho, O. (2022, May 30). *Aspen debacle shows global vaccine funds must buy African*. African Business. https://african.business/2022/05/agribusiness-manufacturing/aspen-debacle-shows-global-vaccine-funds-must-buy-african/

[14] Al Jazeera. (2022, May 5). Africa CDC calls for COVID vaccine orders from S Africa's Aspen. *Coronavirus Pandemic News | Al Jazeera*. Retrieved July 1, 2022, from https://www.aljazeera.com/news/2022/5/5/update-1-africa-cdc-urges-covid-19-vaccine-buyers-to-order-from-s-africas-aspen

The United Nations Industrial Development Organization (UNIDO) (2015) states that there are several benefits to be gained from local manufacturing[15], which include:

- assured quality of medicines,
- preventing stock issues,
- local incomes expansion and jobs generation,
- triggering technology spill-over,
- improved capability to internally manage challenges like non-communicable diseases, and
- sustaining government health schemes.

Efforts to fill this essential manufacturing gap should account for the financial, infrastructure, expertise and regulation challenges while sustainably supporting local manufacturing of affordable and quality medical products.

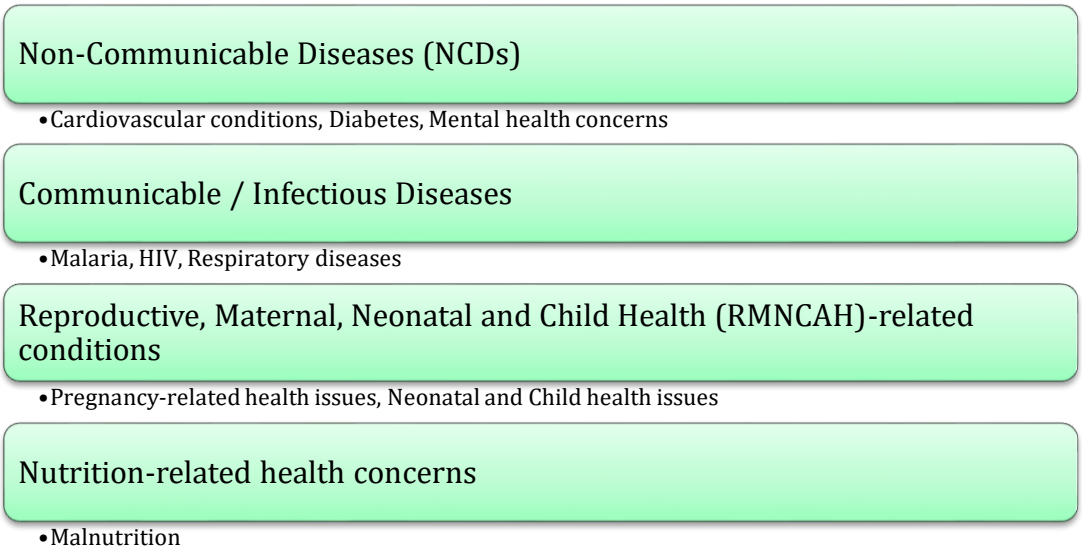
[15] Supporting Pharmaceutical Production in Africa (2015). United Nations Industrial Development Organization. https://www.unido.org/sites/default/files/2015-05/PRINT_Pharma_Brochure_SPREADS_0.pdf

5. AFRICA'S PHARMACEUTICAL NEEDS – DISEASE BURDEN AND PRIORITISATION

Projections from the Global Burden of Disease Study (2019) indicated the most pressing health concerns of the continent are non-communicable diseases (such as cardiovascular diseases, diabetes, and cancers), which have overtaken infectious diseases as the largest driver of disability, accounting for 66%[16] of the continent's disease burden. Other disease classes of concern are communicable and parasitic diseases, maternal, neonatal, and nutrition-related conditions, and injuries (Figure 6).

Investment in African health systems and public health interventions – and in the necessary medications to treat them – needs to prioritize the diseases and risk conditions that reflect the current reality, not of past records which focused heavily on mitigating infectious diseases.

Figure 6: Disease Burden in Africa (order by decreasing priority)



In addition, Africa will also require a steady supply of locally manufactured COVID-19 and other vaccines – the pandemic is still ongoing and new variants of concern continue to emerge. For Africa to avoid being left behind in essential vaccine supply in future pandemics, as was noted in the early period of the COVID-19 outbreak[17], local manufacturing of vaccines needs to be established and grown.

5.1 Pharmaceutical Products Manufacturing in Africa

Most local manufacturing in Africa involves the production of fill-and-finish medicines and generics (copies of innovator-branded medicines) with a dependency on the importation of active pharmaceutical ingredients (APIs) and excipients, mostly from

[16] Liverpool School of Tropical Medicine. (2020, December). *Sub-Saharan Africa and the 2019 Global Burden of Disease Study: celebratory with a note of caution.* LSTM. https://www.lstmed.ac.uk/news-events/blogs/sub-saharan-africa-and-the-2019-global-burden-of-disease-study-celebratory-with-a

[17] Development Reimagined. (2022, April 19). *Can African countries rely on vaccines to manage COVID-19?* https://developmentreimagined.com/2022/04/19/canafricancountriesrelyonvaccines/

India and China[18], where the industrial capacity to produce key chemicals and reagents is established.

For APIs production in Africa to grow beyond the limited current state, it will require more multinational partnerships and investment, such as the European Investment Bank's API for Africa Initiative[19] and the agreement between Nigerian manufacturer, Emzor and Indian manufacturer Mangalam Drugs and Organics Ltd, towards the production of APIs for malaria treatments in Nigeria.[20]

It has been suggested that investment in this underserved sector could prove beneficial for Chinese pharmaceuticals and industry leaders – filling an essential manufacturing gap in the continent, while promoting cooperation and the sharing of technical skills.

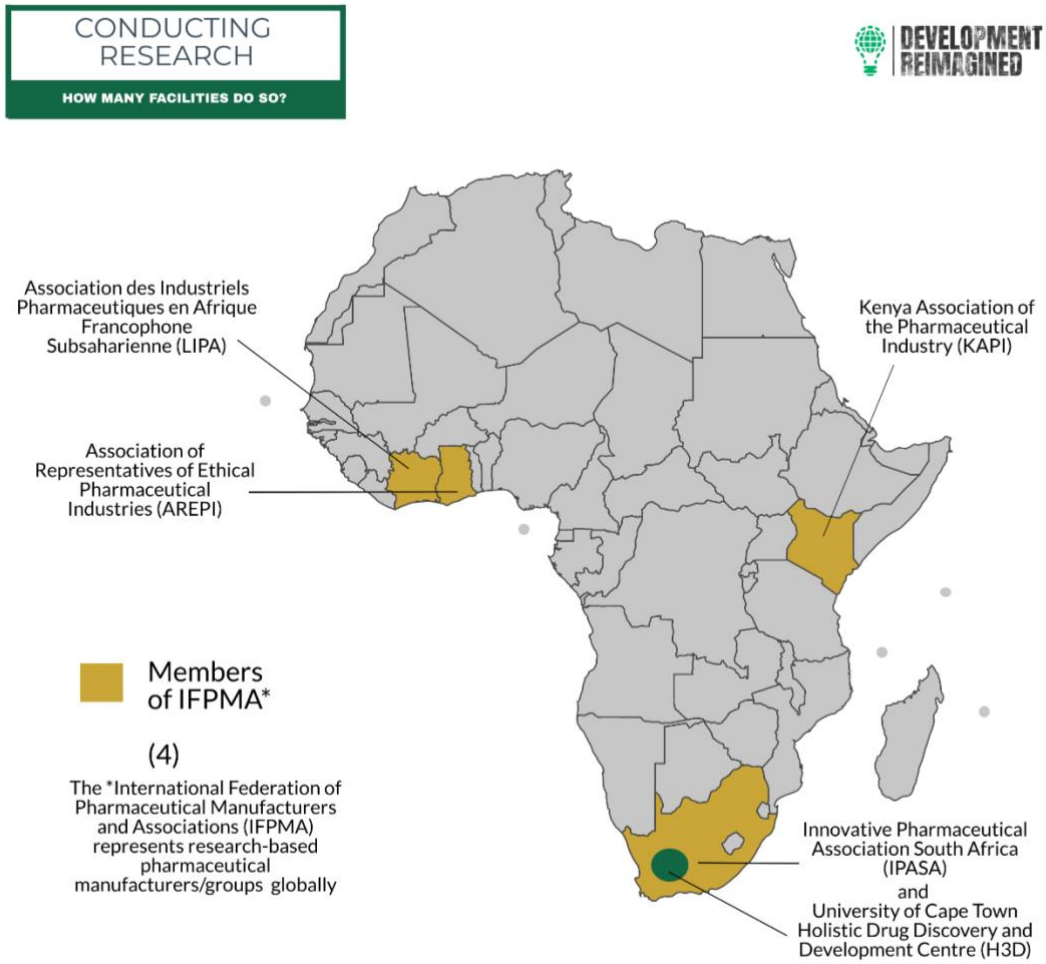
5.2 Research and Development

Research and Development (R&D) feeds industry – R&D for pharmaceuticals in Africa is overseen by least four (4) International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)-approved organizations in Cote d'Ivoire, Ghana, Kenya and South Africa[21]. Given the essential nature of R&D to innovation in the pharmaceutical sector, more of these supervisory bodies are required – and they need to be of global standard, properly funded and staffed with skilled personnel, attended by the necessary policies and regulation to support the sector.

Cooperating with – and learning from – established research regulatory bodies in nations with more advanced pharmaceutical sector regulation – such as the National Medical Products Administration (NMPA)[22] in China or the Indian Council of Medical Research (ICMR)[23] – would prove beneficial for the African pharmaceutical research sector.

[18] Buckholtz, A. (2021b, June 30). *COVID-19: Why Africa must strengthen its own drug supply*. World Economic Forum. https://www.weforum.org/agenda/2021/06/covid19-africa-drug-supply-health/
[19] *API for Africa*. (n.d.). API for Africa. https://www.covidx.eu/API_for_Africa
[20] Onyenucheya, A. (2021, August 28). *Emzor to manufacture APIs for treatment, prevention of Malaria*. The Guardian Nigeria News - Nigeria and World News. https://guardian.ng/news/nigeria/national/emzor-to-manufacture-apis-for-treatment-prevention-of-malaria/
[21] *Associations* – International Federation of Pharmaceutical Manufacturers and Associations (2015, November 25). IFPMA. https://www.ifpma.org/who-we-are/our-membership/full-members/associations/#!/
[22] *National Medical Products Administration*. (n.d.). NMPA. http://english.nmpa.gov.cn/
[23] *Indian Council of Medical Research | Government of India*. (n.d.). Indian Council of Medical Research. https://main.icmr.nic.in/

Figure 7: IFPMA-affiliated Research Associations in Africa



5.3 Pharmaceutical Manufacturing Plan for Africa (PMPA)

The Pharmaceutical Manufacturing Plan for Africa (PMPA)[24] is a business plan agreed upon in 2012, between AU heads of state, aiming to improve access, quality and affordability of pharma products, while supporting sustainability, competitiveness and self-reliance in the industry. Some of the proposed solutions include strengthening the regulatory systems and establishing a one-stop-shop for information, data and business intelligence for industry players—governments, the private sector, Regional Economic Communities and so on.

To boost local pharmaceutical production and improve public health outcomes, the PMPA business plan strongly encourages the procurement of medical products from Africa-based companies and recommends the use of pooled procurement to incentivize local manufacturers to address local health challenges.

[24] Pharmaceutical Manufacturing Plan for Africa. https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-africa

5.4 African Medicines Agency (AMA)

Adopted in 2019, the African Medicines Agency (AMA)[25] was conceptualised to enhance the regulation capacity of medical products by State Parties and AU recognized Regional Economic Communities (RECs) to improve their quality, safety, and efficacy. The AMA Treaty was entered into force on November 5th in 2021 and is currently signed by 26 member states[26].

The agency is intended to build on the efforts of the African Medicines Regulatory Harmonization (AMRH) initiative, which is led by the Africa Union Development Agency – the New Partnership for Africa's Development (AUDA-NEPAD). The AMA will be the second specialized health agency of the African Union after the Africa Centres for Disease Control and Prevention (Africa CDC).

5.5 Pooled Procurement – Africa Medical Supplies Platform

Devised to procure medical goods, the African Union launched the Africa Medical Supplies Platform[27] in 2020: an e-commerce initiative to promote the distribution of African-made key medical goods (test kits, PPEs, clinical equipment and more), as well as global procurement of essentials during the COVID-19 pandemic.

The initiative served to fill the medicines and products gap created by logistical upheaval during the pandemic; providing a coordinated means to gather the needed resources from local producers and supporting their businesses, as well as securing supplies from established providers as a group, with the aim of cutting down on costs.

This development serves to build towards cross-border cooperation that can mitigate single buyer market issues, offering benefits such as reduced purchase prices, lower operating cost and less losses to procurement corruption; improved quality assurance and standardization; increased equity between purchasing members and overall, improved access to essential medical products in member states[28].

[25] African Medicines Agency Treaty is established. https://au.int/en/pressreleases/20211109/treaty-establishment-african-medicines-agency-ama-enters-force

[26] Algeria, Benin, Burundi, Cameroon, Chad, Cote d'Ivoire, Egypt, Gabon, Ghana, Guinea, Madagascar, Mali, Mauritius, Morocco, Niger, Rwanda, Republic of Congo, Sahrawi Arab Democratic Republic, Senegal, Seychelles, Sierra Leone, Tanzania, Togo, Tunisia, Uganda and Zimbabwe.

[27] Africa Medical Supplies Platform. https://amsp.africa/

[28] Huff-Rousselle M. (2012). The logical underpinnings and benefits of pooled pharmaceutical procurement: a pragmatic role for our public institutions? *Social science & medicine (1982)*, *75*(9), 1572–1580. https://doi.org/10.1016/j.socscimed.2012.05.044

6. PHARMACEUTICAL REGULATION ACROSS AFRICA

6.1 Harmonization Of Standards

Standardized regulation of pharmaceutical production in Africa will be key to boosting investor confidence; as 42% of reported global counterfeit drugs for the period 2013 – 2017 came from Africa, according to WHO records cited by Millar (2019)[29].

In that regard, the African Medicines Regulatory Harmonization (AMRH) initiative was devised by AUDA-NEPAD in 2009 to provide guidance to AU recognized RECs and Regional Health Organizations (RHOs), *to facilitate harmonization of regulatory requirements and practice among the national medicines authorities (NMRAs) of the AU Member States*[30]. The AMRH initiative also designates 11 Regional Centers of Regulatory Excellence (RCOREs)[31] *to facilitate regulation across the continent with 8 functions*; the 8 countries hosting the selected boards and facilities are Burkina Faso, Ghana, Kenya, Nigeria, South Africa, Tanzania, Uganda and Zimbabwe.

The AMRH collates information on each AU member state pharmaceutical regulation bodies to ease cross-border regulation. Its key mechanisms are continental cooperation on production, trade and regulation of medical goods will require unifying regional regulation and establishing subsidized manufacturing hubs, as well as supporting intra-African markets for these in-continent medications to be traded. Integrating national Chambers of Commerce could also feed into this, as not all African countries have established such organizations, but could benefit from the expertise (Figure 8).

Figure 8: African Chambers of Commerce

[29] Millar, A. (2019, December 20). *The rise of fake medicines in Africa*. Pharmaceutical Technology. https://www.pharmaceutical-technology.com/analysis/counterfeit-drugs-africa/

[30] *AMRH Annual Report: 2020 | AUDA-NEPAD*. (2020). AUDA-NEPAD. https://www.nepad.org/publication/amrh-annual-report-2020

[31] *Regional Centres of Regulatory Excellence (RCOREs) | AUDA-NEPAD*. AUDA-NEPAD. https://www.nepad.org/publication/regional-centres-of-regulatory-excellence-rcores

6.2 Intellectual property (IP) in African countries

i. The TRIPS Agreement

The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed into effect by the World Trade Organization (WTO) in 1995, is almost 25 years old – it was intended as an IP protection measure, and later modified to affirm that patent rules should be flexibly implemented to promote public health and medicine access for all[32].

The Agreement, as it exists today – with its provisions for compulsory licenses, which are government-granted licenses that permit an entity to bypass the restrictions on a patented product and allow them to manufacture the product for an agreed fee – came about because of the HIV medicine tumult of the late 1990s, when South Africa's government was sued by a coalition of HIV patent holder companies for its legal changes that aimed to make low-cost drugs more available.

With considerable pressure from CSOs, NGOs and activists, the eventual TRIPS Agreement modification between 1999 and 2000 saw improved HIV medicine availability globally, bringing prices down due to the increased options for generic versions of patented treatments[33]. There are presently 44 African countries which are members of the WTO, and thus accede to the TRIPS Agreement.[34]

ii. African Pharmaceuticals and IP

Regarding IP within Africa, Motari et. al. (2021) assessed intellectual property rights in the WHO Africa region[35] covered patenting trends and legislative implementation around TRIPS, finding that patenting is generally low in African countries.

First, the main diseases covered by African patents were HIV/AIDS, cardiovascular diseases, cancers, and tumors. Second, that most African countries have legislation allowing for compulsory licensing and parallel importation of medicines, but the least legislated flexibilities were explicit exemption of pharmaceutical products from patentable subject matter, new or second use of patented pharmaceutical products, imposition of limits to patent term extension and test data protection. Third, thirty-nine countries have applied TRIPS flexibilities, with the most common being compulsory licensing and least-developed country transition provisions.

[32] *WTO | Intellectual property (TRIPS) - TRIPS and public health*. (n.d.). WTO. https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm
[33] Hoen, E. '., Berger, J., Calmy, A., & Moon, S. (2011). Driving a decade of change: HIV/AIDS, patents and access to medicines for all. *Journal of the International AIDS Society*, *14*, 15. https://doi.org/10.1186/1758-2652-14-15
[34] Grinsted, P., & Eguegu, O. (2021, May). *China's Model of Innovation: Are there Lessons for African Countries?* CGDev. https://www.cgdev.org/sites/default/files/China-model-of-innovation-lessons-for-Africa.pdf
[35] Motari, M., Nikiema, J. B., Kasilo, O., Kniazkov, S., Loua, A., Sougou, A., & Tumusiime, P. (2021). The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement. *BMC Public Health*, *21*(1), 490. https://doi.org/10.1186/s12889-021-10374-y

What this means is that most African countries are employing the flexibilities afforded by the Agreement to produce generic medicines, while aiming to build capacity to fully implement IP protection requirements specified in the agreement – this is good news for generic manufacturer investors, as there is ample space in the market for growth in this direction. However, the least-developed status of several African countries means that the regulation around patenting of IP in Africa is minimal, not necessarily due to cost, but due to low registration and only one specialized IP court to oversee cases (in South Africa)[36]. This could be extrapolated into uncertain returns or security of R&D investment in locally researched drug products; improved awareness, regulation and legal infrastructure around IP issues would check this and promote investor confidence.

iii. COVID-19 and Patents

TRIPS has again come under scrutiny in the wake of the ongoing COVID-19 pandemic, as the challenges the agreement was meant to handle persist – protecting IP rights while negotiating public-health promotion in the face of high patented medicine costs, delayed market entry of generics and market exclusivity.

The COVID-19 pandemic highlighted the limitations of patent-based restrictions, where the hesitancy of large multinational pharmaceuticals in releasing knowledge to produce necessary medications and products left most low-income nations far behind richer countries in both procuring and producing vaccines for local use.[37]

Delays in getting vaccines quickly enough during the pandemic prompted the tabling of a TRIPS waiver by India and South Africa in October 2020, which originally suggested the suspension of multiple IP restrictions to spur the production of essential COVID-19 therapies, technology, and associated materials where they are needed.

Negotiations resulted in the application of limitations (on the IP that could be waived and country eligibility) to the original suggestion, with hedging agreement by the US and the EU.[38]

As at May 2022, African countries are eligible – where eligibility of beneficiary countries is based on developing country classification as well as being a country which manufactured and exported less than 10% of the world's vaccines in 2021. This would allow African countries to utilize the waiver's vaccine patent-only IP suspension, but more room to maneuver is still needed, given the disappointing conclusion to the June 2022 WTO negotiations[39], where

[36] Spoor and Fisher. (2022, May 10). *Filing Intellectual Property (IP) in Africa with ARIPO and OAPI*. Spoor & Fisher. Retrieved July 2, 2022, from https://spoor.com/filing-intellectual-property-ip-in-africa-with-aripo-and-oapi/
[37] Morten, C., & Header, M. (2021, June 9). *We Can't Trust Big Pharma to Make Enough Vaccines*. The Nation. https://www.thenation.com/article/world/covid-vaccines-pharma/
[38] Green, A. (2022, March 17). *TRIPS waiver compromise draws mixed response*. Devex. https://www.devex.com/news/trips-waiver-compromise-draws-mixed-response-102860
[39] Amnesty International. (2022, June 17). *Covid-19: WTO ministerial decision on TRIPS Agreement fails to set rules that could save lives*. https://www.amnesty.org/en/latest/news/2022/06/covid-19-wto-ministerial-decision-on-trips-agreement-fails-to-set-rules-that-could-save-lives/

an additional 6-month postponement was applied on the point requesting the inclusion of COVID-19 therapeutics and diagnostics IP in the waiver.

African leaders will need to shore up their negotiation strategies by partnering with other disaffected countries or regions, form stronger blocs and push for better deals at the table of international governing bodies.

iv. Regulation of IP

Regulators of IP processes in the continent are the African Regional Intellectual Property Organization (ARIPO)[40] and Organization Africaine de la Propriété Intellectuelle (OAPI)[41], which are inter-governmental organizations (IGOs) that facilitate cooperation among African member states on intellectual property matters.

These organizations were founded in 1976 and 1977 respectively, with the objective of pooling financial and human resources in Africa, and seeking technological advancement for economic, social, technological, scientific, and industrial development.

With 21 and 17 AU registered member states respectively, both organizations jointly cover up to 35 African countries; and continue to build their capacity and reach across the continent regarding patents and trademarks.

[40] African Regional Intellectual Property Organization. https://www.aripo.org/
[41] Organization Africaine de la Propriété Intellectuelle. http://www.oapi.int/index.php/fr/

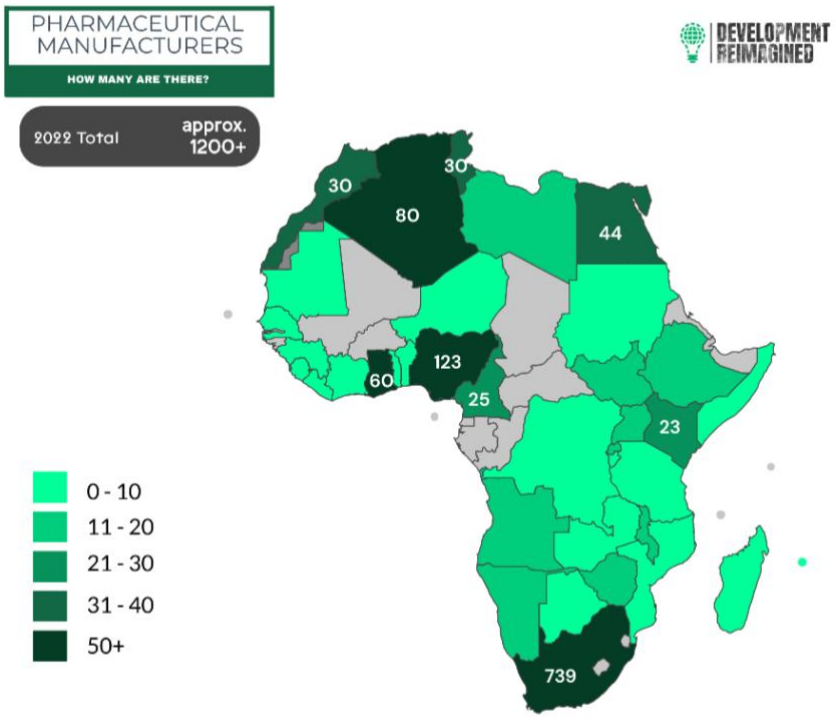
7. PHARMACEUTICAL MANUFACTURERS IN AFRICA – THE CASE FOR MANUFACTURING HUBS

There are approximately 600 – 1000 pharmaceutical manufacturers in Africa, concentrated in three North African states (Egypt, Morocco and Algeria), two West African states (Ghana and Nigeria), and one East African (Kenya) and South African state (S. Africa) each.

Africa's population of 1.3 billion persons is served by approximately 600 – 1,000 pharmaceutical manufacturers, compared to India's 5,000 and China's 10,500 manufacturers respectively for an equivalent population[42]. These African manufacturers are clustered in a handful of countries (over 80% of manufacturers are in only 8 countries. Available data suggests almost 40% of African countries have little significant local production, with 60% of countries having some level of production (Figure 9).

Figure 9: Map of African Pharmaceutical Manufacturers

(Source: Web scraped data, Pharmaceutical Sector Reports and Literature)



Given this concentration of manufacturers in key locations across regions, regional manufacturing hubs could improve manufacturing in the continent.

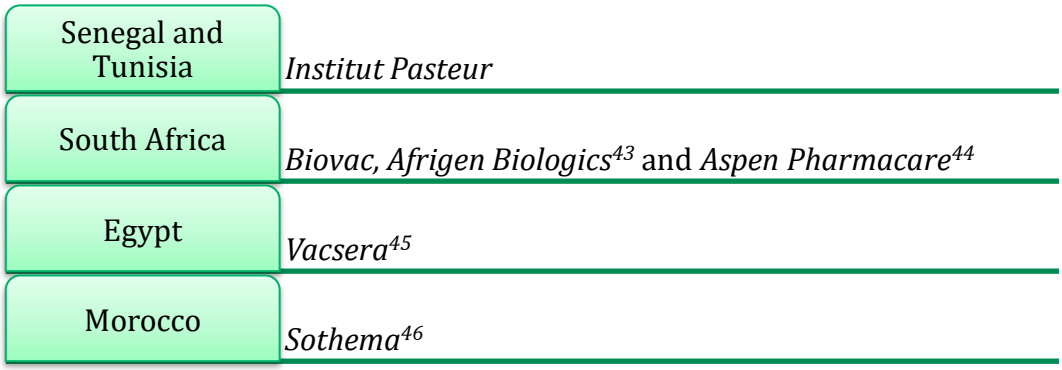
[42] Kaufman, J., Glassman, A., & Yadav, P. (2021, February 10). *Expanding Health Product Manufacturing in Africa: Ideas for Development Finance Institutions, Procurers, and Policymakers*. Center for Global Development | Ideas to Action. https://www.cgdev.org/blog/expanding-health-product-manufacturing-africa-ideas-development-finance-institutions-procurers

Regional manufacturing hubs are a recommended option to boost local manufacturing in Africa – promoting economies of scale in production and reducing manufacturing costs. More databases covering data on African manufacturers will be key to broadening understanding of the scope of gaps in African pharmaceutical manufacturing.

7.1 Developments in Vaccine Manufacturing

Several African countries manufacture vaccines[43], often in partnership with multinational companies, as can be seen in Figure 10 below, and Figure 11 on the following page.

Figure 10: The five (5) African countries and companies manufacturing COVID-19 vaccines[44454647]



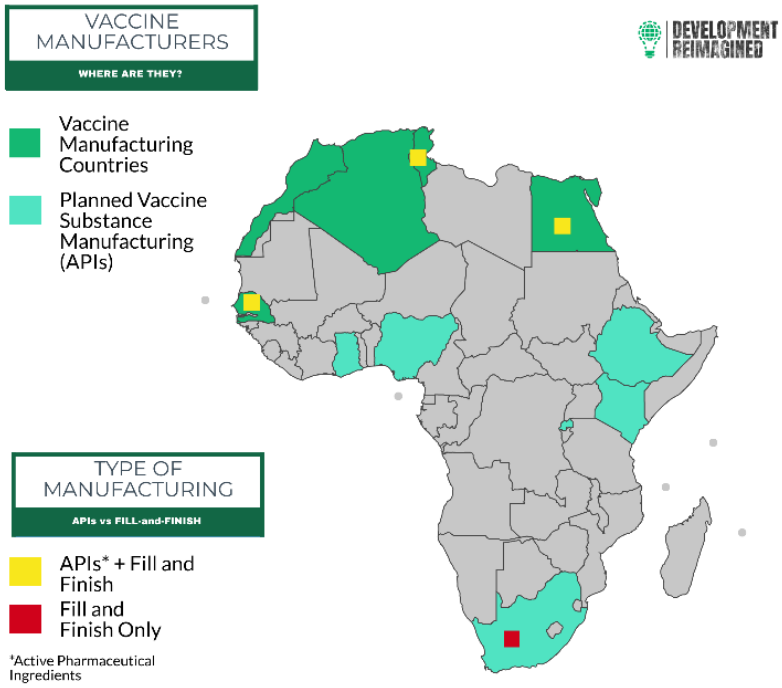
In relation to the WHO-recommended rollout of GlaxoSmithKline's *Mosquirix* malaria vaccine[48] in Africa, another set of promising clinical trials are underway[49] in Malawi, Kenya and Ghana for the *R21*, a malaria vaccine intended for local production.

In addition, BioNTech has expressed interest to Rwanda and Senegal to begin local trials to produce mRNA malaria and tuberculosis vaccines in 2022.[50]

Overall, these examples highlight the growing interest of foreign manufacturers in vaccine production in Africa, an as-of-yet untapped market for locally produced vaccines.

[43] Schwikowski, M. (2021, September 10). *Is Africa ready to produce a malaria vaccine?* DW.COM. https://www.dw.com/en/is-africa-ready-to-produce-a-malaria-vaccine/a-59145349
[44] Afrigen Biologics is the continent's first mRNA technology Hub. https://www.afrigen.co.za/
[45] Aspen Pharmacare produces the J&J COVID-19 vaccine. https://www.aspenpharma.com/2021/06/14/aspen-statement-on-manufacture-and-supply-of-covid-19-vaccines/
[46] Vacsera aims to make Sinovac's COVID-19 vaccine. https://www.reuters.com/world/middle-east/egypt-ramps-up-local-vaccine-production-with-eye-exports-2021-08-31/
[47] Sothema aims to manufacture Sinopharm's COVID-19 vaccine in partnership with the Swedish company, Recipharm. https://www.reuters.com/business/healthcare-pharmaceuticals/moroccos-sothema-produce-chinas-sinopharm-vaccine-2021-07-05/
[48] GlaxoSmithKline. (2021, June 10). *GSK welcomes WHO recommendation for broad roll-out of its RTS,S/AS01e (RTS,S) malaria vaccine | GSK*. GSK. https://www.gsk.com/en-gb/media/press-releases/gsk-welcomes-who-recommendation-for-broad-roll-out-of-its-rts-sas01e-rts-s-malaria-vaccine/
[49] R21, a prospective made-in-Africa malaria vaccine. https://doi.org/10.1038/d44148-021-00051-y
[50] BioNTech interested in malaria vaccine production in Rwanda and Senegal. https://www.dw.com/en/biontech-mulls-producing-malaria-jabs-in-rwanda-senegal/a-59005220

Figure 11: Vaccine Producing Countries in Africa



Of note is the considerable overlap between figures 9 and 11 – these maps highlight the countries with the largest number of pharmaceutical manufacturers and those with current or proposed vaccine production, reflecting expertise and resource concentration.

This data reflects possible locations for these manufacturing hubs, pending further feasibility assessments.

8. CONCLUSION

Africa will require partnerships to build its pharmaceutical sector – these partnerships must be built on trust, transparency and mutual cooperation, with the intent to exchange knowledge and should be approached with an understanding of the issues on ground.

Cooperation on the African pharmaceutical industry will involve steady investment and agreement between manufacturers and regulators from Africa and countries with similar developmental paths, such as China and India. To ease this cooperation, we **recommend**:

- The **building of a continental or regional database on African pharmaceutical manufacturers** is key; listing their products and scale to identify gaps in local / regional production and to better target investment or partnership niches. This should be taken up by African regulatory bodies such as the African Union African Medicines Agency in cooperation with national pharmaceutical regulatory bodies.
- **There is sufficient demand on the continent for Africa's local pharmaceutical producers to prioritise the continent's own current disease burden, while looking to future demand burdens and eventually international demands.** The former is presently led by non-communicable diseases such as diabetes and followed by infectious and communicable diseases, such as malaria and HIV respectively. Future investors in African pharmaceuticals should heed the continental disease burden for targeted development and aim to build capacity for local vaccine manufacturing.
- **Consolidation of pharmaceutical regulation across the continent is necessary and** will ease production and make trade of internally manufactured medical products feasible; further integration of differing national regulatory processes in the continent is key to developing this sector and will require the input of African regulatory bodies – especially the African Medicines Agency, national legal bodies and national Chambers of Commerce, learning from – and in partnership with – international regulators in countries of a similar developmental path, such as India or China.
- **Manufacturing hubs are necessary for the development of the sector**: current manufacturing locations are skewed to too few countries; manufacturing hubs should ideally be present in each African region to reduce infrastructure costs, encourage multinational resource pooling and ease logistics. Future investors should consider targeted partnerships for pharmaceutical hub construction between multiple countries. This process can be supported by African organizations such as the AU, as these principles feed into the operationalisation of the AfCFTA.

- **Local procurement must be institutionalised as a policy in global health funds and institutions:** African governments and global partners should push for and support procurement of locally manufactured pharmaceuticals to bolster local production. One method could involve African governments negotiating with the WTO to institute trade policies that require certain percentages of all procured medicines and products for use in their countries be locally manufactured; while international bodies like GAVI should modify their procurement policies to reserve a specified amount of their supply contracts for African manufacturers.