

Local Manufacture of Pharmaceutical Commodities in Sub-Saharan Africa: An Empirical Literature Review

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ABSTRACT

This is a literature review that entails prioritised areas of research in order to unpack local/regional manufacture of pharmaceutical commodities in sub-Saharan Africa. The specific objectives of the study shall entail: establishing the key research questions that need to be asked to inform governments if they want to develop their local manufacturing capability; determining the key research questions that need to be asked by regional bodies if they want to develop regional manufacturing capability; establishing the steps that governments should take if they want to develop their local manufacturing capability; determining the key research questions for regional bodies as they develop regional manufacturing capability; and, developing a prioritised research framework of key considerations for governments and regional bodies as they develop local manufacturing capability. The research output is expected to be a comprehensive knowledge repository for governments, regional bodies and private sector investors with interests in local/regional manufacturing hubs in Eastern, Western, Central and Southern African regions is highly recommended. This hubs could begin with pharmaceutical commodities such as tablets, capsules and general antibiotics with emphasis on importation of APIs.

Key words: Local Manufacture; Regional Manufacture; Pharmaceutical commodities

INTRODUCTION

The study is seeking for expert opinions on the way forward in local manufacturing of pharmaceutical commodities in sub-Saharan Africa. The desire and passion for sub-Saharan Africa to manufacture her own drugs has been in existence for over the past 20 years. However, there hasn't been much achieved, towards that objective. The continent still imports close to 97% of its pharmaceutical commodities. Covid-19 pandemic exposed the risks of overdependence on imported medicines as a result of the disruptions in the global supply chains that was experienced as well as certain countries restricting export of medicines. The disruption of global supply chains with container and worker shortages as well as port congestion resulted in difficulties accessing most of the medicines and pharmaceutical products imported from Europe, especially the antiretroviral drugs for AIDS/HIV patients. This then begs the question as to why local/regional manufacture of pharmaceutical products has not reached its full potential.

The literature review should form a basis for documenting information useful to governments, private entities and regional bodies with interest in establishing local/ regional manufacture of pharmaceutical commodities in sub-Saharan Africa. From literature review, it is evident that a lot of studies have been done on local manufacture of pharmaceutical commodities in Africa (Mackintosh et.al 2016; Banda et. al. 2021; McKinsey & Co. 2019). There is however, no studies that provide comprehensive framework on areas to give priority when making considerations for local/ regional manufacture of pharmaceutical commodities in sub-Saharan Africa. The study further proposes the use of document analysis from websites of key stakeholders in public health to seek for grey literature on local / regional manufacture of pharmaceutical



commodities in sub-Saharan Africa.

The article explores the passion and drive for sub-Sharan Africa to manufacture its own pharmaceutical commodities. There are some progress already made towards this end, however, the question that abounds is how can sub-Saharan Africa build on this progress and/ or expedite it? There is need to provide governments and regional bodies in the pharmaceutical space with a prioritised framework regarding local/ regional manufacture of pharmaceutical commodities in sub-Saharan Africa. It is important to explore issues that relates to why the viability and desirableness of sub-Saharan African domestic pharmaceutical manufacture have been heavily contested in academic and policy circles (Mackintosh, et. al., 2016). To be discussed also are the diverse opinions on local/regional manufacture of pharmaceutical commodities in sub-Saharan Africa, hence, the study endeavours to gather a comprehensive opinion from all the experts and stakeholders identified for the roundtable discussions.

Literature has documented a number of issues with regard to local manufacture of health commodities in Africa ranging from lack of capacity, high production costs, poor quality as well as sub-standard products. However, through expert opinion from literature review and expert opinion, the study aims to develop a more comprehensive framework of the prioritised areas for local manufacture of pharmaceutical commodities in sub-Saharan Africa. The authors also suggests the use of unpublished literature complementing grey sources from public health stakeholders such as world health organisation (WHO), United States Development Agency (USAID), Africa Resource Centre (ARC), Bill and Melinda Gates Foundation, Ministries of Health for respective countries as well as Regulatory bodies for respective countries. The overall aim of the review is to develop a research framework that contains prioritised areas of research for local/regional manufacturing. The specific objectives for the study entails: To establish the key research questions that need to be asked to inform governments if they want to develop their local manufacturing capability; To determine the key research questions that need to be asked by regional bodies if they want to develop regional manufacturing capability; Establish the steps that governments should take if they want to develop their local manufacturing capability/industry; Determine key considerations for regional bodies as they develop regional manufacturing capability; Develop a prioritised research framework of key considerations for regional bodies and countries as they develop local manufacturing capability; and, Document a prioritised research framework of key considerations for governments, regional bodies and private entities for use as they develop their local manufacturing capability.

THEORY AND LITERATURE ANALYSIS

The literature review is intended to point out issues already in public domain through published papers from both academic and non- academic sources. The review therefore helps bring into picture a validation of these issues as well pointing out at those that may not be available in published literature.

Overview of local manufacture of Pharmaceutical commodities in sub-Saharan Africa

The viability and desirableness of African domestic pharmaceutical manufacture have been heavily contested in academic and policy circles as has been espoused by Mackintosh, et. al. (2016). A survey conducted in 2005 revealed that 37 of 46 African nations tested positive for certain pharmaceutical production capabilities (Berger *et. al.*, 2009). This gives reason to investigate further why very little progress has been made towards that end. According to Sadie, Yong Li, and Chan (2014), Africa continues to be dependent on imported drugs and other medical equipment, which is a perilous condition in a region with the highest prevalence of HIV in the world. Eighty percent of the antiretroviral medications used by the over 30 million Africans with HIV who are currently receiving antiretroviral treatment and the millions more who are waiting depend on imports from other countries (Sadie, Yong Li and Chan, 2014). The delivery of antiretroviral in most sub-Saharan countries was almost halted during the early stages of covid-



19 pandemic as a result of the disruptions in supply chains. These events highlighted the need for sub-Saharan Africa to be less dependent on the importation of pharmaceutical products from other countries.

Research findings suggests that depending on the country, there is potential for local pharmaceutical commodities production in sub-Saharan Africa. According to an analysis conducted by Mckinsey and Company (2019), which focused mostly on North Africa and Sub-Saharan Africa (Nigeria, Ghana, Kenya, Zimbabwe, and South Africa), increasing local medication manufacturing is achievable given the demand that is currently forecast. The roundtable discussions should shed light on the issues of regional regulations and different government policies with regard to the procurement policies and the willingness of countries to buy pharmaceutical commodities from each other. The issue of quality and sub-standard pharmaceutical commodities from local manufacture also keeps arising and should be addressed. According to the WHO, 13.6 percent of all medications in low- and middle-income countries (LMICs) may be of inferior quality or fake, which could have a negative impact on patient outcomes, cost money, and increase the development of antibiotic resistance (Baite and Tuck, 2020). As a result, it is important to consider whether quality must be prioritised when it comes to the production of pharmaceuticals locally (or regionally).

There is the need for the manufacture of pharmaceutical commodities in sub-Saharan Africa to focus on a review of: development of regional hubs; drug product formulation; and value chain effects (WHO, 2011; McKinsey and Company, 2019). One of the key indicators of successful local production of pharmaceutical products is impact and feasibility. The demand for pharmaceutical products in the region is already established both from the huge burden of HIV treatment and other ailments such as Malaria, Tuberculosis, Pneumonia and sickle cell anaemia. The study should therefore shed some light on the need for respective sub-Sahara African governments creating a conducive environment through implementation of the right policy frameworks. Research supports having countries in sub-Sahara Africa considering at the initial stages of production a mixed model that involves Active Pharmaceutical Ingredients (API) importation and local formulation. It is important to consider if this model is relatively cost effective as compared to the full-import model as illustrated in the McKinsey and Company report of 2019. The focus for local production is the attainment of the economies of scale in order to optimise the costs of production, hence the ability to be competitive enough.

Important areas of focus on local manufacture of pharmaceutical commodities in sub-Saharan Africa.

Issues highlighted in literature to be discussed entails: product quality; development of regional hubs; and, drug formulation. The grey literature on regional manufacture of pharmaceutical commodities in sub-Saharan Africa was sought from the websites of non-academic institutions currently active in the public health space. These institutions included but not limited to the following: world health organisation (WHO), United States Development Agency (USAID), Africa Resource Centre (ARC), Bill and Melinda Gates Foundation, Ministries of Health for respective countries as well as Regulatory bodies for respective countries

Product quality and standardisation of pharmaceutical commodities in sub-Saharan Africa.

The success of pharmaceutical products manufacturing in sub-Saharan Africa generally would require a focus on quality as has already been pointed out. According to Ekeigwe (2019), the high incidence of substandard and falsified pharmaceuticals in West Africa is a result of a number of multiple and intricate reasons. Among these is the fact that this activity has very high financial returns because of the huge demand for medications, which is partly brought by the significant burden of disease. The stark disparity between the price at which these substandard falsified (SF) medications are sold and the expense of making them is another factor in this (they are usually sold at the same price as the equivalent quality medicines).



Development of manufacturing regional hubs in sub-Saharan Africa

Sub-Sahara African nations could cooperate to support a small number of internationally competitive industry clusters given the minimal production requirements and the limited number of nations where pharmaceutical manufacturing is practicable. The likelihood of these clusters producing affordable, high-quality medications is higher than it would be if resources were spread thinly across more subscale investment attempts across the continent (McKinsey and Company, 2019). The issues to considered entails an analysis of whether smaller nations might benefit from shorter lead times and more responsive supply chains thanks to proper regulatory harmonisation because they could be supplied by domestic rather than foreign vendors.

Drug product formulation as an alternative in sub-Saharan Africa

It is important to consider the reason why today's Active Pharmaceutical Ingredients (APIs) are difficult to manufacture and extremely scale sensitive. There is need to consider if indeed it is true that the majority of the countries in sub-Saharan Africa do not have the necessary chemical industries to produce API, which would already be 10 to 15 percent more expensive than imports from India and China. As a result, drug product formulation is preferable while continuing to import APIs—at least for the time being (McKinney and Company, 2019). Is it in order to advise sub-Saharan countries that during the early years of local manufacture they could import APIs as they develop the capacity to carry out clinical studies, and conduct testing? A critical analysis shall be required to explain why in sub- Saharan Africa, developing local pharmaceutical manufacturing capabilities to produce APIs and maintaining compliance with international standards, which differ significantly throughout the continent, may remain as a challenge in the years to come. Is it also a possibility that if the required policy framework are put in place sub-Saharan Africa has the potential to grow a strong indigenous pharmaceutical manufacture of pharmaceutical commodities to be viable.

CHALLENGES FACING LOCAL MANUFACTURE OF PHARMACEUTICAL PRODUCTS.

Ekeigwe (2019) claims that the following factors make it more difficult for West Africa to have a reliable and continuous supply chain: inadequate infrastructure, including inadequate transportation, communication, and electricity infrastructures (The African Union Commission, 2012); The health care industry is heavily dependent on medicines, vaccines, medical equipment, and diagnostics produced and imported from outside sources, particularly from China and India, which limits opportunities for local learning curves; Most of the raw ingredients and equipment required to produce medicines in West Africa are imported. In Ghana, there is only one small-scale producer of active medicinal components (West African Health Organization 2018). The capacity to produce any equipment or raw materials is quite limited (The African Union Commission, 2012).

Due to technical and financial limitations, manufacturers in the West African region are having trouble obtaining WHO (World Health Organization) pre-qualification (United Nations Industrial Development Organization 2015). Technical limitations include, but are not limited to, the need for qualified employees, necessary tools, and reference materials. Resources (local capital formation) are limited, and foreign exchange rates are biased against imports, meaning that local currencies have very low equivalent rates to currencies used in international trade. These two factors combine to create financial restrictions. Additionally, there is a lack of qualified technical workers in the medication development and production fields (The African Union Commission 2012). Because capital preferentially flows to places with large



returns on investment under capitalism, making medicines for West Africa is a difficult business with very slim profit margins. Otherwise, intervention is required (West African Health Organization 2014). There are no clinical research organisations or bioequivalence facilities in the West African region. This makes it more difficult to introduce branded and high-quality generic medications to the market (The African Union Commission 2012)

The Tanzanian market is relatively open, and changes in the key international market segments are promptly felt in Tanzania's local and regional markets. A tipping point appears to be developing due to a number of structural and technological pressures that are getting worse. The first has to do with market placement and scale. Tanzanian pharmaceutical companies mostly produce over-the-counter products like cough syrups and basic, needed generic medications. The manufacture of active pharmaceutical ingredients (APIs) benefits greatly from economies of scale, which are limited for basic formulations (Chaudhuri and West, 2014). Tiny businesses can therefore compete in the formulations market, but because they purchase small API amounts from Asian suppliers, some of which also create formulations, they are structurally at a disadvantage versus huge Indian exporters. Demand is the "main restriction in this sector," according to one producer. If businesses can't make a profit, they can't expand, and they require their home market as a foundation for growth (Tibandebage et. al. 2016).

For Tanzanian policymakers to prioritise and actively engage in selective support of particular industrial sectors, they must adopt a different mindset. The national security concerns resulting from weaknesses in the importation of fake goods are among the justifications for giving pharmaceuticals priority. Losing the ability to meet a basic demand for its people increases the country's reliance on exporters, particularly those from India, who might not be long-term dedicated to producing for this market (Chaudhuri et. al., 2010). Can this industry be improved? According to Tibandebage et al. (2016), two major mindset and policy behavior shifts are necessary for a turnaround: acceptance of the need for well-designed industrial protection mechanisms and their effective implementation in stable and understandable rules, as well as active and sustained engagement with current firms and their suppliers in a determined effort to deepen and strengthen the local pharmaceutical production system. Tanzanian businesses have been particularly vulnerable to these rising barriers to domestic and international market entry due to a combination of a shallow industrial structure with few supportive links, a highly liberalised market, a policy "tilt" towards incentivising imports, and a largely passive industrial policy approach.

Finally, Tanzanian pharmaceutical enterprises significantly rely on donors for mentorship for both the initial manufacture of new products in response to prospective new markets and the quality upgrading in response to explicit conditions. Tanzania was a desirable location for committed mentoring for a variety of reasons. Tanzania was exempt until 2021 as a least developed nation, and thereafter 2023 is the deadline to avoid implementing patent obligations for pharmaceutical items. (UNAIDS 2013), making it a feasible location for the manufacturing of recently developed medications (Chore, 2019).

On the other hand, when Kenya's government unveiled a modest plan to provide ARVs in the late 1990s, it was anticipated that the medications would be imported. Although it was a modest market, the development of this new one was enough to inspire three of the biggest local pharmaceutical businesses, who typically manufactured straightforward medications requiring minimal technological skill, to learn how to make ARVs. With the Kenyan Pharmacy and Poisons Board, Cosmos Pharmaceutical Limited, Universal Corporation, and Laboratory & Allied (Lab & Allied) had successfully registered ARVs by the year 2002. One of Kenya's oldest and most reputable pharmaceutical companies, Cosmos, which was founded in the 1980s by a pharmacist of Indian descent named Prakash Patel and is still family-owned, was at the forefront of these initiatives. Cosmos stated their intention to take part in a government procurement for ARVs in September 2003 (Kimani, 2003). The Cosmos proposal was praised as a "brave step" that "placed Kenya in the category of India and Brazil," two developing nations praised for their domestic pharmaceutical



industries (Okwembe, 2004). A few months later, Cosmos won a \$1 million tender to launch Kenya's first public HIV/AIDS treatment project, taking home a 30% share of the money (Okwembe 2004)

Donors and development organizations helped East African pharmaceutical enterprises undergo a significant transition by giving markets, oversight, and mentoring. As a result, they created more complex medications and aimed for higher quality standards. The desired WHO PQ was successfully attained by two businesses, Universal in Kenya and QCIL in Uganda, while other businesses were able to pass European audits. And even companies that failed such inspections learned how to make new pharmaceuticals using better standards than were mandated by law just by trying to pass them. Regarding PIC/S training in Kenya, a local consultant stated that it "not only was a nice experience, it created a [huge] rise in the quality" of the industries involved (Chore, 2019).

In the DRC, just 10% of pharmaceutical commodities consumed in the country are manufactured locally (World Bank, 2019), and the capital city, Kinshasa is home to 21 of 30 Local Pharmaceutical Manufacturing (LPMs) (DNB—). Local pharmaceutical manufacturing in the nation is reliant on imported pharmaceutical materials and industrial machinery. As a result, the levies incurred due to importations raise prices and reduce price competitiveness, which discourages local manufacturing since only wealthy LPMs can sustain the high costs of importation and dominate the market, making local manufacturing relatively unattractive(World Bank, 2019). Other challenges that LPMs encounter in the DRC include unsatisfactory and costly utilities, rising transportation expenditures, and corruption (Okereke, 2022).

Pharmacy owners are reluctant to stock locally made medicinal products because customers think they are of lower quality (World Bank, 2019). As a result, the nation is compelled to depend on the importation of pharmaceutical products like APIs. For background, a 10-year review showed that the number of pharmaceutical items imported into the DRC increased by 842 percent, from 10,955.7 in 2010 to 103,206.665 in 2020, as a result of a lack of production capacity that would have otherwise been able to satisfy local demand (CEIC). It is unlikely that indigenous manufacturers in the DRC will significantly increase their supply-side contribution given the severe constraints they now face. Lack of ability to achieve quality requirements is the main barrier for regional manufacturers (World Bank, 2019). The DRC must now consider the lessons learnt from the past ten years as well as the COVID-19 epidemic in order to intensify its efforts to improve its domestic pharmaceutical production capabilities (Okereke, 2022).

In Africa, developing local pharmaceutical manufacturing capabilities to produce APIs and maintaining compliance with international standards, which differ significantly throughout the continent, may remain challenges in the years to come. However, if the required policy framework are put in place, the DRC, together with other East African nations, West Africa and South African nations have the potential to grow a strong indigenous pharmaceutical manufacturing sector.

PROPOSED RESEARCH APPROACH

Research philosophy, design and data analysis

The study shall be anchored on the phenomenological research philosophy being of a qualitative nature with a focused group discussion (FGD) approach (Cooper and Schidler, 2019; Kothari, 2019; Silverman, 2011; Babbie and Mouton, 2011). Other possible alternatives to FGD would be the use of Delphi technique, interview schedule, interview guide as well as document analysis. The issues raised shall be grouped into themes and content analysis used to generate the findings and areas for further research. The study proposes to use NVIVO software (or any other appropriate software) for the analysis of the themed responses generated by the panellist in the roundtable discussion.



Table 1.0: Summary of issues involved in FGD techniques

ACTIVITY	ISSUES TO CONSIDER
Planning focus groups	1.Ethical issues
	2.Budget constraints
	3.Selection of participants
	4. Group structure
	5. Group size and discussion quality
	6.Number of focus groups
	7. Criteria for evaluation.
Conducting focus groups	1.Introducing the focus group
	2.Begginning discussion
	3. Substantive discussion.
Data coding and analysis	1. Frequency counts and categorical data analysis
	2. Feedback.

Source: Lee, T.W (1999).

Focus groups consists typically of 8 to 10 members with a moderator leading the discussions for about 2 hours on a particular topic. In this study the themes and highlighted talking points shall guide the moderator in leading the discussions. Members (respondents) in this case are generally chosen on the basis of their expertise in the topic on which information is sought (Tables 2.0). In this study they shall be chosen on their expertise on local/regional manufacture of pharmaceutical commodities in sub-Saharan Africa.

Justification for using FGD

Focus group discussions on a specific topic at a particular location and at a specified time provide the opportunity for a flexible, free flowing format for the members. The unstructured and spontaneous responses are expected to reflect the genuine opinions, ideas, and feelings of the members about the topic under discussion. FDG are relatively inexpensive and can provide fairly dependable data within a short time frame (Sekaran, 2006). This as well forms a good basis for generating grey literature.

Analysis and the nature of data obtained through FGD

It should be noted that content analysis of data obtained through FGD provides only qualitative and not quantitative information. The data also can be analysed using computer based software like NVIVO as already stated (Cooper and Schidler, 2019). There will be need for segmentation of panellists for the focus group discussions as highlighted in table 2.0. According to Lee (1999), there are two tactics for data



analysis in FGD. First coding schemes are typically applied, and this often results in frequency counts. Methods of categorical data analysis may be applied as well. Second, a portion of the focus group sessions might be devoted to the moderator's soliciting the participants' perception of what they have learned, or what others might learn from the discussion. For example, indicators of a topic's importance can be: the number of groups that mention the topic; the number of people within a group that mentions the topic; and, verbal descriptions about how much energy and enthusiasm the topic generated.

These data can be provided back to the FDG members as feedback during this designated period, and their interpretations sought. Such interpretations should help augment, confirm, or falsify the researcher's current understanding. In addition, participants might be provided with some quantitative information, such as a rank ordering or rating of the importance of the various topics discussed. A system could be set up whereby the various topics mentioned during the focus group's discussion could be counted as the discussion goes on, then immediately analysed with categorical methods (possibly by a research team member using a computer). These statistics could then be fed back to the participants, and their reactions recorded.

Proposed respondents for the study

It is the respondents views and opinions that shall be captured and analysed using content analysis or NVIVO software as is proposed. Research suggests that a good size for a FGD is between 8 to 10 individuals (Sekaran, 2006), hence, this study proposes to have a roundtable discussions of 10 members each. The first roundtable discussion shall consist of ten (10) expects from international and local pharmaceutical firms currently operating in sub-Saharan Africa.

Table 2.0: Study respondents (Roundtable panellists)

Respondents	Sample size
-International pharmaceutical firms with presence in the African continent. – Identified local/ regional pharmaceutical firms in Africa.	10
 -Government departments (MOH and Pharmacist cadres, Trade and Industry bodies, Treasury). -Representatives from regional bodies such as: EAC, SADC, COMESA, AU 	10
-Relevant private sector board and other stakeholders to be identified – Identified donors	10
 -Identified academics from Universities and research institutes in Africa. – Representatives from Supply chain professional bodies in Africa 	10

Scope and Limitations of the study

Much of the implementation of the research will involve the good will of the respective governments in the East African region. These is through creating a favorable environment for local production of pharmaceutical products by initiating the right policy frameworks.



Justification for the study: Cost benefit analysis

These shall entail a critical analysis of the costs involved in establishing the plant via a vis the benefits that would accrue from the project. From a wider scope, the benefits accrued that entails saving human life and enhancing the quality of life would outweigh the costs involved in establishing a pharmaceutical plant. This involved undertaking a SWOT analysis in order to ascertain the viability of the project.

Project strengths

- Enhance availability of medicine in all the health facilities in the region;
- Accelerate achievement of universal health coverage
- Enhance quality of life especially among the low income households
- Reduce infant mortality rates mainly due to non-availability of proper Medicare for expectant mothers
- Employment opportunities for health workers in the region
- Contribution to the country's GDP

Project weaknesses

- Availability of cheap imports from outside the country, especially India.
- Inadequate number of local scientists well versed in production of pharmaceuticals.

Opportunities afforded by the project

- Opportunity to be a leader in the provision of pharmaceutical products.
- Employment opportunities to a large number of unemployed medical personnel in the country.
- Contribution to payment of tax, thus enhanced GDP

Threats to the project.

- Delayed approvals for the commencement of the project as a result of government bureaucracy.
- Quality assurance mechanisms to enhance consistency in the pharmaceutical products produced by the plant
- Establishing confidence among the citizens on the locally manufactured products.

Ethical implications of the study

There shall be need for ethical clearance from the responsible authorities in the respective countries, universities and/ or research institutes. The study shall observe all the research protocols with respect to informed consent, anonymity and confidentiality. All the respondents to the study will have to sign informed consent forms and since some of the issues addressed in the study involve high level government policy, confidentiality will be considered a priority in the study.

Recommendations with policy implications on regional production of pharmaceutical products.

It is technically feasible to have a manufacturing plant for production of pharmaceutical products. However, it is critical that the firm deployed to do the construction should be sourced competitively. It is also important that the facilities required for the plant to be competitively sourced as well. These process should be open to public scrutiny in order to ensure accountability in expenditure of the funds. An effective monitoring and evaluation process would help ensure that the project is completed within time and on budget. Partnerships across the supply chain is extremely vital in ensuring viability of the resources and materials for the construction and equipping of the plant. The establishment of regional manufacturing hubs



in Eastern, Western, Central and Southern African regions is highly recommended. This hubs could begin with pharmaceutical commodities such as tablets, capsules and general antibiotics with emphasis on importation of APIs.

CONCLUSION

The study is expected to provide insight into the pharmaceutical production landscape in sub-Saharan Africa. The information should provide a prioritised framework for governments, private entities and regional bodies with a desire to invest in local/regional production of pharmaceutical commodities in sub-Saharan Africa. This shall relieve Sub-Saharan Africa from the burden of importing most of its medications from Europe, India and China, which currently stands at close to 97%. The suggestions from literature is that the countries could start with creating regional hubs in order to create economies of scale. Research also reveals that the countries could start with importation of API and undertake the formulation locally / regionally.

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