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PRIVATE SECTOR BRIEF
RWANDA HEALTH SYSTEM STRENGTHENING (RHSS) PROJECT

LOCAL MANUFACTURING: A CASE FOR GENERICS PRODUCTION IN RWANDA

This Private Sector Brief examines the potential for the local production of medicine in Rwanda taking into consideration potential risks and benefits, the current situation in the country, and key elements of success identified in the literature. It concludes with recommendations for decision-makers in Rwanda.

I. OVERVIEW OF THE POTENTIAL BENEFITS OF LOCAL PRODUCTION

Local manufacturing of medical products can have a long-term positive impact on a national healthcare system and a country's economy (resulting in savings) if the cost of local production is lower than the cost of imports. If this is the case, local production can free up resources that can be utilized to strengthen health outcomes. Even if the cost is the same, local production may bring qualitative benefits, such as reliability and better access to essential medicines, as well as other positive externalities, such as job creation and an increased tax base. Local production, however, is not without risks and can drain resources, if not carefully managed. These risks will be discussed later.

II. THE RWANDAN CONTEXT: OVERVIEW ON LOCAL MANUFACTURING OF MEDICAL PRODUCTS

A recent survey found that the vast majority of African countries have some pharmaceutical manufacturing capability.[1] In Rwanda, the sector is fledgling, characterized by a small number of producers that operate at a limited capacity, manufacturing non-complex products such as suspensions, infusions, ointments and suppositories. Local producers include the Pharmaceutical Laboratory of Rwanda (LABOPHAR), a government institution operating under the Rwanda Biomedical Center, which has the capacity to produce medicines at sterile and non-sterile facilities[2], the Bureau des Formations Medicales Agréées du Rwanda (BUFMAR), a not-for-profit, faith-based wholesaler; and other small private companies.

A situation analysis the United States Agency for International Development (USAID) funded Rwanda Health Systems Strengthening Project conducted identified several challenges that hinder the development of a robust pharmaceutical industry in Rwanda.[3] These issues include an underdeveloped regulatory framework coupled with inadequate regulatory capacity,[4] a lack of harmonization between industrial and health policies, a cumbersome and unclear procurement process for key inputs, he necessity of importing raw materials or active pharmaceutical ingredients (APIs),[5] and high water and energy costs, that increase the overall cost of production.

Despite these challenges, the country enjoys some advantages that can be exploited to benefit local production. Rwanda is a member of the lower income countries (LICs) the World Trade Organization gave a grace period until 2033 to disregard patents. Also, Rwanda has properly trained personnel at LABOPHAR facilities that are strategically located near the National University of Rwanda in the city of Butare.[6] And, LABOPHAR's good manufacturing practice (GMP) compliant, sterile drug factory is capable of satisfying national demand for infusion medicines.[7]

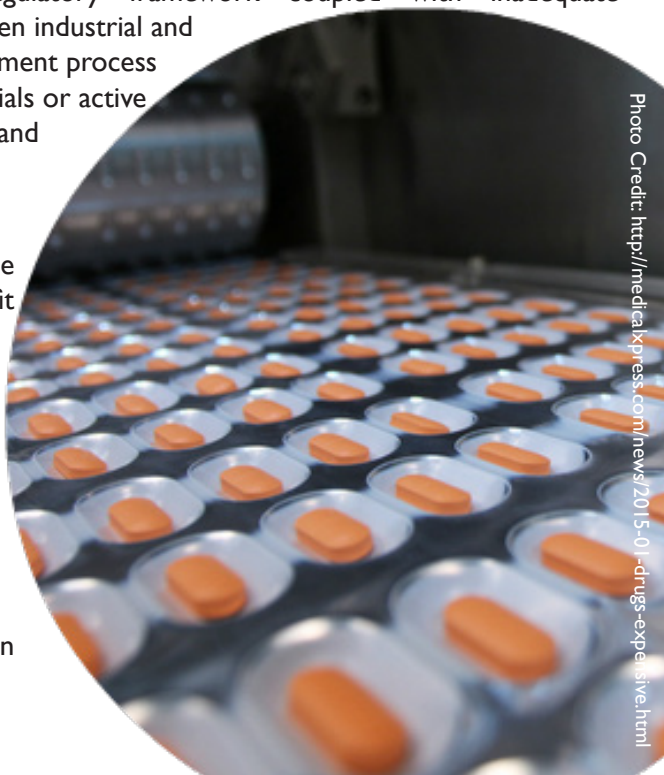

Photo Credit: http://medicalxpress.com/news/2015-01-drugs-expensive.html

III. Summary of International Literature Review

Many African countries have struggled to address infrastructural weaknesses, skills gaps, deficient utilities and other challenges to developing a home-grown pharmaceutical sector. The literature review identified five key success factors that have enabled some countries to overcome these challenges.

1. **Phased Development.** Not all countries have had the capacity and capability to embark on the full spectrum of pharmaceutical production, innovation and research and development all at once. Successful African firms have progressed from basic production (tablets and capsules) to more complex production (such as layered and sustained-release tablets) over time.

Kenya: Import Duties and Tax Holidays

The government of Kenya aligned policies, such as the removal of import duties on key inputs and tax holidays for local producers, to incentivize the growth of local manufacturing

2. **Multinationals' Involvement.** From 1930 until the present a number of multinational pharmaceutical firms have partnered with local entities to spur production in countries as diverse as South Africa, Nigeria, Kenya, Zimbabwe, Tanzania, Botswana, Uganda, Ethiopia and Ghana.

3. **Specialization.** Most African countries have specialized in producing generic medicines and importing APIs and excipients, primarily from India and China. Only South Africa and Ghana currently produce APIs, which are more complex and require higher quality standards.

4. **Supportive Policies.** The development and alignment of different types of policies (fiscal, investment, industrial, and health) that incentivize local manufacturing have played an important role in growing the sector.

5. **Joint Ventures.** Evidence suggests that the use of joint ventures is one of the catalysts for the development of the pharmaceutical industry in Africa. They not only contributed to the growth of the pharmaceutical industry, but they also transferred skills and technology. Countries such as Kenya, Tanzania and Ethiopia benefited from this type of partnership. Today most of these joint ventures are wholly locally-owned private firms.

Public Private Partnerships

In Kenya, Infusion Medicare began producing infusions in the mid-1970s as a joint venture between the government-owned, Industrial and Commercial Development Corporation and Hoechst E.A, a German pharmaceutical producer.

IV. Summary of Recommendations for Decision-Makers

Taking into consideration the challenges and success factors identified, a sustainable, local pharmaceutical manufacturing sector can be encouraged with:

Photo Credit: Sumitomo Chemical http://sumivector.com/about-us/olyset-net-manufacturing-in-africa

1. **Strategic Partnerships.** With the advent of the new Public-Private Partnership (PPP) law, Rwanda can benefit from past African experiences to explore a strategic PPP that will leverage the resources and expertise of a multi-national partner in the pharmaceutical sector.

2. **Generics Production.** Due to less stringent technical requirements, generics production is frequently the most expedient entry point into the local production of medicines. Rwanda should build on LABOPHAR's experience and infrastructure to facilitate the development of a strategic PPP with a multinational.

3. **Prospective Investors.** As a starting place, a potential LABOPHAR PPP should explore a partnership partnership with one of the leaders in generics manufacturing in Africa, such as Starwin in Ghana, Saidal in Algeria, Universal in Kenya, Aspen in South Africa, or the Indian-firm Cipla, which has operations in Nigeria.

4. Next Steps. The development of a generics manufacturing PPP will require identifying the contract authority (ministry in charge) and a potential investor; conducting a feasibility analysis (including a cost-benefit analysis)[10]; implementing some policy changes to avoid problems identified in the literature, and structuring a partnership model that can address some of the potential issues identified in the situation analysis (Please refer to the text box for more details). As stated in the new PPP Law, a Steering Committee composed by the Minister of Finance, the Minister of Infrastructure, the Chief Executive Officer of the Rwanda Development Board, and the representative of the contract authority will lead (and decide jointly) the approvals of each step of the procurement process.

Potential Issues that a PPP Must Address

- Lack of appropriate technology
- Import dependency on raw materials and technology sources
- Lack of skilled personnel for operating and maintenance of machinery
- Scarcity of spare parts and consumable materials in the local market
- Lack of prequalification by the World Health Organization
- Lack of local knowledge on how to submit GMP applications
- High costs due to duties on raw materials/ high utility cost
- Limited capacity for troubleshooting and management

1 Palgrave Mackmillan (2016). Making Medicines in Africa.
2 This non-sterile facility has been temporarily suspended due to the lack of compliance with GMP requirements.
3 Please refer to Cabrera, Enrique. Investment in the Manufacturing of Medical Products in Rwanda. Situation Analysis. Rwanda Health Systems Strengthening Project. 2015, for more details on these challenges.
4 The agencies that will be responsible for inspection and quality control, National Food and Medicines Regulatory Authority and the National Medicines Quality Control Laboratory, have not been created.
5 Active pharmaceutical ingredients account for 40-50% of the final cost of generic medicines. Janet Bumpas and Ekkehard Betsch (2009). Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines.
6 LABOPHARM has a intern program to bring university students to work at their facilities.
7 Estimated at 300,000 to 500,000 liters annually. Source: LABOPHARM.
8 Ibid. Footnote 3
9 Northern African countries, such as Egypt, also have developed strong pharmaceutical sectors.
10 The proposed PPP will benefit from developing a cost-benefit analysis to determine risks and potential quantitative and qualitative advantages to Rwanda.

Implementing Partner:

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