Working Brief

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Pharmaceutical manufacturing in Kenya:

key trends and developments

Watu Wamae and Joan Kariuki Kungu

Introduction

The improvemnet of health sector performance requires a holistic approach that addresses the wide ranging challenges that many African countries face: lack of adequated and highly skilled medical personnel; limited access to essential medicines and equipment; lack of access to affordable universal healthcare etc.

Local capacity to manufacture essential pharmaceutical products is one way to catalyse national health sector performance. It has the ability to lower the costs of healthcare, to expand access and to stimulate research and innovation in the development of curative and preventive medicines for the region's specific diseases. It also has the ability to induce the training of highly skilled medical personnels and to contribute to their in-country retention by leveraging public , private and civil society resources.

This Working Brief presents some key trends and developments of the Kenyan pharmaceutical industry. It highlights the fact that whilst the local industry has great scope for improving health sector performance in Kenya, this is yet to be achieved. Strengthening policy synergies between the health sector and the pharmaceutical industry is an important way of contributing to better health.

Pharmaceutical production in Kenya

Kenya's pharmaceutical production grew at an average annual rate of 21 per cent between 2007 and 2013 (see Figure 1). In that period total production of tablets, capsules, liquid preparations for oral use and creams/ ointments alone increased from US$ 34.1million to US$ 154 million.

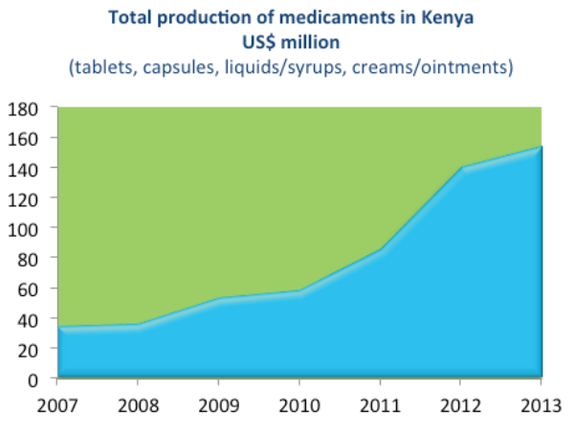

Figure 1

Key issues:

- Share of local production in domestic sales could be improved

About 75 to 80 per cent of local production is sold in the domestic market. However, it meets only about ¼ of the local demand.

- Kenyan exports contribute only 0.2 to 0.3 per cent of COMESA's needs

Kenya may be the largest producer of pharmaceutical products in the COMESA region - an estimate of about 50 per cent of the region's production. However, Kenya's capacity to address a sizeable share of COMESA's needs is small.

- Capacity utilisation a challenge

Average annual capacity utilisation is only about 60 per cent for the manufacture of most dosage forms. Furthermore, Kenya has relatively small total production capacity.

- Limited diversifcation of the industry's activities

Diversification of the industry in terms of both product portfolio and the range of knowledge intensive activities should be addressed to enhance the industry and better catalyse health sector performance.

- Foreign-owned local firms can deliver greater technological benefits

Greater collaboration or linkages between foreign and local firms can contribute to knowledge intensification in the local industry.

There are about 40 pharmaceutical manufacturers in Kenya. At the time of data collection (February 2014) there were 39 Pharmacy and Poisons Board (PPB) registered manufacturing firms. 34 of these manufactured human health pharmaceutical products whilst the remaining five were wholly focused on animal health products. Local pharmaceutical manufacturing is thought to have the potential for substantial growth to address both local and regional demand.

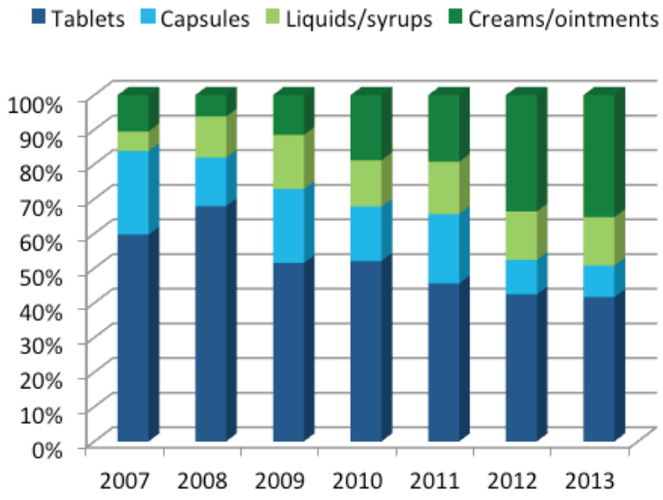

Figure 2

Pharmaceutical manufacturing in Kenya can be traced back to the 1940s; Kenya Overseas Company limited was set up in 1947 and began local production two years later. Some of the other pharmaceutical firms that pioneered local production include: Sterling Winthrop (US), 1953; Burroughs Wellcome (East Africa) ltd (UK), 1955; Aspro-Nicholas (EA) ltd (Australia), 1961. Until the late 1990s, local production was primarily by foreign owned multinational firms. Only one multinational firm continues to engage in some level of local production. Currently, there are about twenty multinational firms with local presence in the country undertaking activities, which include: marketing, clinical trials and clinical studies.

Local production is now predominately undertaken by locally owned firms. The vast majority of pharmaceutical manufacturing companies in Kenya are engaged solely in formulation activities i.e. converting manufactured bulk substances into final usable forms and packaging (see Table 1).

The tablet is the most common dosage form of pharmaceutical products: Kenya also manufactures capsules; topical preparations (creams, gels, ointments, or pastes); liquid preparations for oral use (including syrups); injectable infusions (small and large volume parenteral preparations) and; ophthalmic formulations. Topical preparations have seen significant growth between 2007 and 2013 (see Figure 2).

Among the different formulations, sterile products, particularly injectable infusions are usually technologically more complex and demanding in terms of meeting standards (safety, efficacy and quality). Injectable infusions and ophthalmic formulations require sterilisation. There are 3 local firms that manufacture injectable infusions.

Manufacturing of bulk pharmaceutical products is an area that is yet to be penetrated. At present, there is one firm that is developing capabilities for local manufacturing of active pharmaceutical ingredients (APIs). There are, however, about three local firms that process raw materials used to manufacture bulk pharmaceutical products. These raw materials are 100 per cent destined for export as the local

Research & Development (R&D)	Conversion of organic and natural substances into bulk pharmaceutical substances or ingredients			Formulation, mixing and compounding	Packaging operations only	No. of manufacturing firms (34 of the 39 registered in Feb 2014 produced human health medicaments)
Discovery & product dev.	Extraction	Fermentation	Chemical synthesis	Formulation	Repackaging	
Single stage processes						
√						0
	√					0
		√				0
			√			0
				√		30
					√	2
Multiple stage processes						
√	√	√				1
				√	√	1

Table 1

capacity for manufacturing APIs is underdeveloped.

Research and Development activities (R&D) is in its infancy in the industry. Only one firm undertakes R&D activities. However, a number of the more technologically progressive firms do have dedicated laboratories that undertake extensive product development.

Key trends of pharmaceutical exports

Growth of Kenya's pharmaceutical exports is driven by the sub-Saharan African market (see Figure 3). Sales outside sub-Saharan are mainly purchases made by donor organisations headquartered in Europe such as the United Nations Children's Fund.

Growth of Kenyan exports has had a positive trend particularly since 2002. Kenya's export share of domestic production ranges between 15 and 20 per cent. In absolute terms, however, these figures remain very modest (see Figure 4).

The Common Market for Eastern and Southern Africa (COMESA) is the main export destination for Kenya's pharmaceutical exports. In fact, Kenya is hyped as the largest producer of pharmaceutical products in the COMESA region; it is estimated that Kenya supplies about 50 per cent of the region's production. In relative terms, however, this translates into a minute share of the COMESA market (see Figure 5). Kenya's exports contribute to well under 0.5 per cent of COMESA's market. Prospects for increasing Kenya's contribution to both the domestic and regional market need to be reviewed.

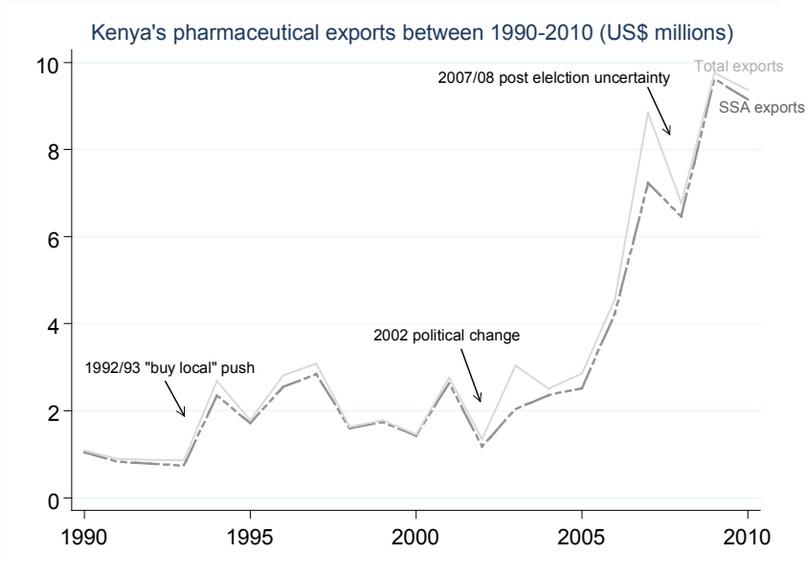

Figure 3

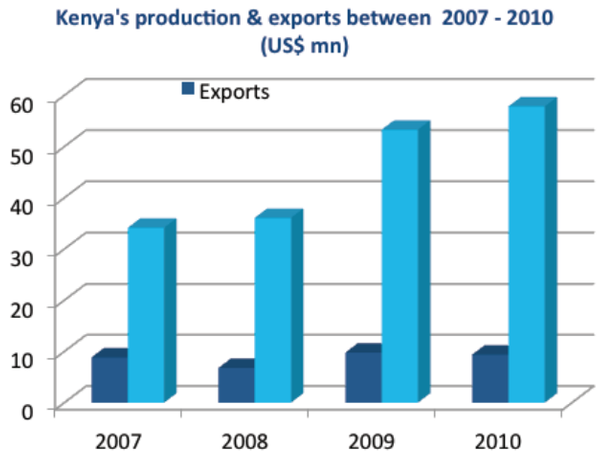

Figure 4

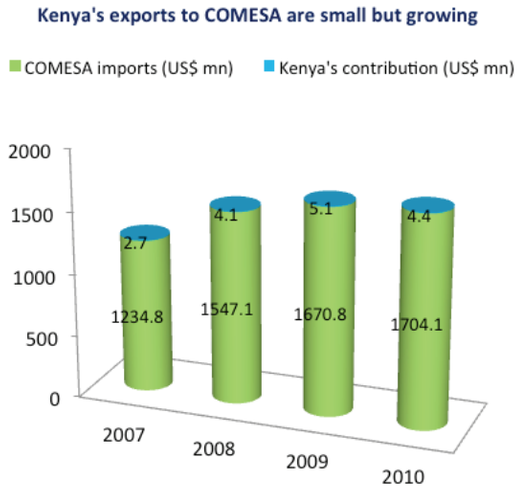

Figure 5

With respect to the main importers of Kenya's pharmaceutical product, Uganda has remained a significant market over a number of decades. Somalia and Sudan have also seen significant growth of Kenyan products, particularly over the last two decades (see Figure 6).

Kenya's contribution to the composition of Tanzania's imports of pharmaceutical products varies between 1 and 3 per cent. Kenya accounted

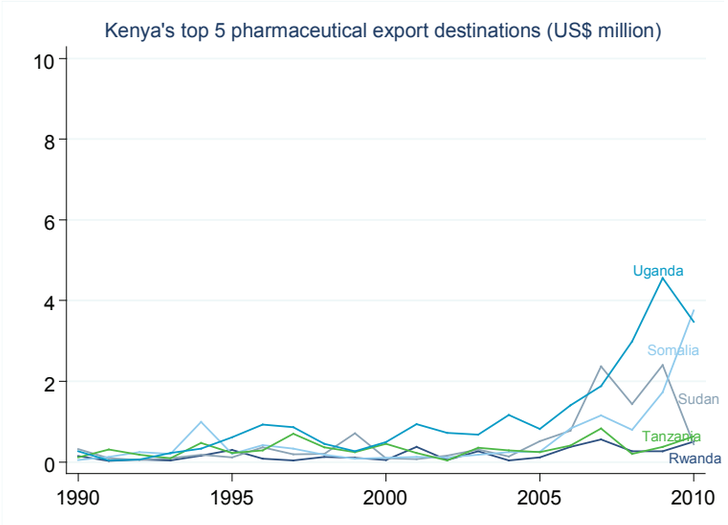

Figure 6

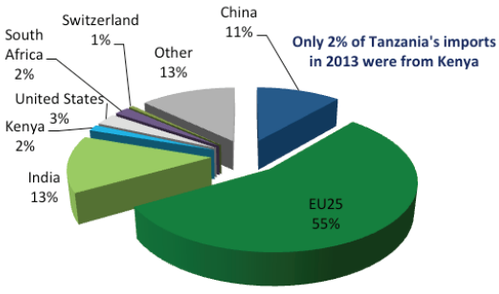

Figure 7

for 2 per cents of Tanzania's imports in 2013 (see Figure 7).

Non-medicaments (wadding, gauze, bandages and similar articles as well as blood-grouping reagents) have been by far the main Kenyan products that find their way to the Tanzanian market (see Figure 8).

Fairly small amounts of: vitamins, antibiotics, alkaloids, hormones and glycosides from Kenya also entre Tanzania's market.

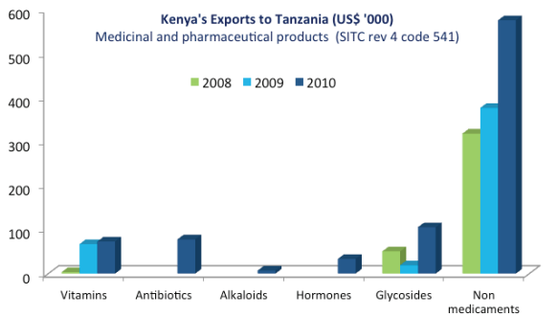

Figure 8

Capacity utilisation in Kenya's pharmaceutical industry

The sector is fairly sensitive to domestic political and economic or policy factors. For example, the 1992/93 "buy local" push by the government gave great impetus to local manufacturing and particularly locally owned firms. This period coincided with significant divestment by multinational firms from the industry. The 2007/2008 post-election violence depressed the industry.

The sensitivity of the sector to domestic political and economic factors means that slight policy changes – fiscal (e.g. VAT), industrial, regulatory – can have significant impacts on the sector.

Local pharmaceutical manufacturing is thought to have the potential for substantial growth in the region. The growth of the industry is however constrained by a number of challenges. A key challenge is the industry's heavy reliance on imported raw materials. Local availability of raw materials meets only five per cent of the total industrial requirement. One of the main sources of raw materials (especially for essential medicines) is India, which has a highly dynamic and competitive vertically integrated pharmaceutical industry. India is also a major source of finished pharmaceutical products for Kenya.

If Kenya's pharmaceutical industry is to achieve significant market access in the region, opportunities for a shift towards advanced manufacturing should be evaluated. A feasibility assessment of product innovation, upgrading and diversification in the sector is urgently needed. Such an assessment would help shed light on factors or policy incentives needed to trigger the growth or emergence of new ancillary sectors. Auxiliary sectors are critical in attaining improved efficiency: they also create opportunities for firms to engage in *non-price competition*, which offers prospects for shifts within the industry towards more knowledge intensive activities. Knowledge intensive activities hold the key to long terms growth and competitiveness of the industry.

Changing regional climate and demographics are occasioning changes in disease and helath patterns. Only a knowledge intensive industry is best able to adapt to these changes. However, a shift to a knowledge intensive industry requires, among others, a high growth technological trajectory as has been the case in emerging economices of India, China and Brazil.

Capacity utilisation in Kenya's pharmaceutical industry is a major challenge. On average, annual capacity utilisation is only about 60 per cent for the manufacture of most dosage forms. Only injectable infusions experience higher capacity utilisation, (between 85 and 100 per cent). A number of reasons for this underutilisation of capacity include: the functioning state of machinery and equipment; delays in sourcing spare parts from abroad and specialised maintenance support from machinery and equipment suppliers; human resource issues and in particular highly specialised skills in some critical areas such as product development; perceptions of locally manufactured products by some market segments and; lack of policy coherence. Some of these challenges have a direct impact on the competitiveness of locally manufactured products.

About 75 to 80 per cent of local production is sold in the domestic market. However, it only caters for about ¼ of the local demand. Similarly, although Kenya is the leading COMESA region's supplier of pharmaceutical products, it only meets about 0.2 to 0.3 per cent of COMESA's needs.

Moving towards a more dynamic and diverse local industry

It is noteworthy that within each dosage form, local manufacturers are progressively developing the capability to manufacture products that may vary in the composition of technological requirements (see Table 2). For example, most local firms have the capability to manufacture plain tablets, but a number of them have made inroads into the manufacture of modified release and sustained release tablets.

Dosage forms	Technology composition	Local manufacture
Tablet	Plain tablet	√
	Film coated tablet	√
	Layered tablet	√
	Others Tablets	
	• soluble tablets;	√
	• dispersible tablets;	√
	• effervescent tablets;	√
	• chewable tablets;	√
	• modified-release tablets	√
	• Sustained release tablets	√
Capsule	Hard capsule	√
	Soft capsule	
	Sustained release capsule	√
	Modified-release capsules	√
Liquid preparations (for oral use)	Powder (suspension)	√
	Dry granules (suspension)	√
	Suspension (internal)	√
	Syrups/elixirs/solutions (internal)	√
Topical semi-solid dosage forms	Ointments and creams	√
	Lotion and suspensions (external)	√
Parenteral preparations	Small volume injections (sterile)	√
	Large volume injections (sterile)	√
Ophthalmic preparations	Ophthalmic formulations (sterile)	√
API		
Others	Implants	
	Inserts	
	Sprays and inhalations	
	Medicated dressings	√
	Immune sera and immunoglobulin	
	Vaccines	
	Dialysis solutions	√
	Diagnostic agents	√

Table 2

To attain better health through strengthened policy synergies between health sector performance and local industrial production, a broad perspective is crucially important. For broader national health outcomes and its sustainability, the pharmaceutical industry in Kenya should be interested in two things:

- raising the productivity and increasing the efficiency gains with the aim of driving price competitiveness for consumers
- product innovation, diversification and upgrading (i.e., product, process, services and business model innovation).

To achieve this, a number of fundamental issues that underpin a forward looking perspective should be considered. They include:

(i) Technological capabilities in local production

The level of technological capabilities in local production should be evaluated. Specifically, an assessment of how technological capabilities can be strengthened to encourage an evolution towards advanced pharmaceutical manufacturing as a pathway for better health for Kenyans is necessary. Technological capabilities, particularly in the form of specialised pharmaceutical manufacturing and product development skills lie at the heart of the diversification of the industry. Such diversification may be with regard to product portfolio and/or the range of knowledge intensive activities beyond formulation activities in the industry. It may include local production of raw materials (active pharmaceutical ingredients and excipients), which are for the most part imported.

Inputs such as packaging materials are another area requiring attention with regard to achieving competitive pharmaceutical products (price and quality). Increasing the range that is locally available inputs should also be considered. Technological capabilities underpin competitiveness and diversification of inputs.

Extending and deepening technological capabilities

Policies that create incentives for extending and deepening technological capabilities are critically important if the local industry is to transition towards a high growth technological trajectory.

Policies that promote learning within and between firms would be particularly helpful in this respect.

(ii) Knowledge intensive ancillary *activities*

Kenya needs to strike a right balance between the activities of foreign owned pharmaceutical firms and locally owned ones – where each participate within the product value chain and how they relate to each other. At the moment, it is not entirely clear that the current 'division of labour' between foreign and domestic firms is based on competencies and capacities. It appears to be more a legacy or arbitrary political decision making and state induced 'market capture' of particular activities within the pharmaceutical product chain.

Broadly speaking, presently, most locally owned firms engage in manufacturing and distribution while most foreign firms engage in clinical studies, trials and product marketing. Given the state of development of the Kenyan pharmaceutical industry, it is not clear that this division of labour is the best option either for the overall national welfare in Kenya or the most mutually beneficial for either domestic or foreign firms. A cost benefit analysis of policies governing the participation of both foreign and locally owned firms in the Kenyan pharmaceutical industry might be helpful. An assessment of the impacts of the country's fiscal, industrial and educational policies on the manufacturing capacity of the local pharmaceutical industry might also be helpful.

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Contact author:
Dr. Watu Wamae, African Centre for Technology Studies
E-mail: wwamae@acts-net.org

Contact ACTS: www.acts-net.org