

IMPROVING ACCESS TO ESSENTIAL MEDICINES THROUGH GOVERNMENT-INDUSTRY- UNIVERSITIES/RESEARCH INSTITUTIONS JOINT PARTNERSHIP

The Scinnovent Centre;

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EXECUTIVE SUMMARY

Research and Development (R&D) is a critical aspect of innovation that is necessary for economic development and prosperity. Product development process is lengthy and costly, and adherence to strict regulatory requirements is mandatory. Public-Private Partnerships (PPPs) have been identified as one of the solutions for addressing challenges in pharmaceutical innovation where capacity in research by the private sector is deemed insufficient. Industry-research institution partnerships should be established in the EAC region. EAC partner states should stimulate PPPs by directing the R&D agenda, funding pharmaceutical research and formulating policies that encourage product development.

INTRODUCTION

Pharmaceutical production is unevenly dispersed globally, with majority of the manufacturing work concentrated in a few sites, mostly in developed countries. According to the World Health Organization (WHO) World medicines situation outlook, two-thirds of the value of medicines produced globally is accounted for by firms with headquarters located in just five countries- the USA, Japan, Germany, France and the UK.

The research-based multinational pharma companies from these countries have continued to spend, on average, ~17% of their revenues for R&D work to develop new medicines to save human lives. From such investments, tremendous reports on new formulations to address several ailments have been highlighted.

The US Food and Drug Authority (US-FDA), through their Center for Drug Evaluation and Research (CDER), revealed that about 28 novel drugs were approved in the period 2005 – 2015, giving hope for hard-to-treat diseases¹. Additionally, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) show that there were 2.5 million AIDS-related deaths in 2005 compared to 1.1 million in 2015².

This was attributed to introduction of ARVs which were new at the time. Due to increase in the burden of non-communicable diseases (NCD), research-based pharma industry has also recognised this challenge and is committed to carry out research in this area.

WHO has also identified 17 neglected tropical diseases (NTDs) that affect many people, predominantly from the poor setting, and have rallied all players, including pharma to develop products to address the scourge. Considering that development of pharmaceuticals and new therapies is costly, there is need to leverage on partnerships.

This will allow for concerted effort to ensure end-products are affordable. In this case, the support and funding for R&D for NTDs is mainly through collaborations and partnerships that bring together expertise from academia, industry, private foundations and governments, and funded by philanthropic organisations in the research-based industry.

In 2014, the research-based industry invested over US\$ 543 million for NTDs research work. This demonstrates that industry-academia synergistic partnerships, enabled by sound policies and regulatory systems are fundamental for development and funding of robust health systems³. This in turn creates a conducive climate for investment in the pharmaceutical sector. As such, forming

¹CDER January 2016 summary report

²The Pharmaceutical Industry and Global Health, Facts & Figures 2017

³Local production of pharmaceuticals and health system strengthening in Africa; An Evidence Brief; A publication in the German Health Practice Collection.

strategic partnerships with different organisations is a crucial part of our research and development process. For instance, GlaxoSmithKline (GSK) has over 500 research partnerships with universities and academic institutions globally, and provides support for science students through fellowships to advance scientific understanding and research capacity. GSK's approach is drawn from historical happenings of the 1940s when the transformation of the US pharmaceutical industry happened, because government partnered with 17 manufacturers to produce penicillin, which was urgently needed⁴.

Just like in the US, India's pharmaceutical industry experienced meteoric growth when government proactively crafted policy interventions like tax, partnerships, technology, and legal provisions for the manufacturing sector⁵, which has made their pharma industry the largest provider of generic medicines globally. In India, R&D is realised through partnerships and joint ventures (JVs). This has led to growth of the domestic market that is projected to increase from an estimated US\$11 billion in March 2009 to approximately US\$30 billion by 2020.

On the other hand, African countries produce approximately 30% of the national's medicines requirement; yet of the more than two billion people worldwide that have sub-optimal access to the medicines they need, majority reside in Africa. The low investment of manufacturing in Africa is a function of many aspects that include technical capacity, human resource, financing and conducive policy environments for pharma manufacturing. Nonetheless, Africa Pharma have demonstrated some level of expertise and currently produce various products, i.e. finished products such as tablets, capsules, creams and ointments for various therapeutic uses. More supportive policies and local partnerships can help bolster the small gains achieved so far.

The Government of Ethiopia is leading the way in demonstrating this through their industrial policy and health policy attributes that have accelerated growth of local pharmaceutical producers (LPP)⁶. Learning from previous policy lapses, the current policy under implementation is more progressive with positive successes in industrial development, including improved quality infrastructure and availability of quality medicines.

Similar efforts have been seen in Uganda, Tanzania and Kenya even though proactive research partnerships remain low. Furthermore, EAC governments have not been able to create a framework within which government priority needs are linked to industry/research/academia groups. This has been attributed to a weak policy advocacy environment- both in the public and private sector.

In view of the above, ACTs project was conceptualised to establish the innovation capacity of the East Africa pharmaceutical manufacturing industry, to identify the barriers to Public/-Private partnerships and establish a framework for an impactful pharmaceutical cross-sector partnership system for improved access in essential medicines.

The main objectives of the study were;

1. To determine the level of production competence of the pharmaceutical industry in East Africa region regarding manufacture of national essential medicines.
2. To identify factors that contribute to the product gap between the national essential medicines lists and medicines that are manufactured in the region.
3. To establish mitigation strategies to reduce the product gap between the national essential medicines lists and medicines that are manufactured.
4. To explore how collaborations, financing, research links, and technology transfer can be

harnessed to not only boost local production of quality essential medicines in the EAC region, but also increase access to affordable medicines.

From the study, this policy brief was developed. It proposes a clear pathway and mechanisms for the enhancement of engagements across several industries, including research institutions in the EAC region.

APPROACHES AND RESULTS

A survey was conducted in the pharmaceutical manufacturing industry, universities and research institutions in the EAC region. Information was obtained through comprehensive literature review, use of questionnaires, and formal meetings with key stake holders including the pharmaceutical manufacturing industry, Ministry of Health and Ministry of Trade and Industry.

Local Pharmaceutical Production in EAC Region

There are about 60 pharmaceutical manufacturers in EAC and Ethiopia, and majority produce non-sterile products – both beta and non-beta lactams; thus, demonstrating their level of competence in production of medicines. The major focus is on solids (capsules/tablets). The industry is limited in the capability of manufacturing a whole range of essential medicines. This is mainly due to lack the technical, financial and human capacity to manufacture these products. Pharmaceutical

³Local production of pharmaceuticals and health system strengthening in Africa; An Evidence Brief; A publication in the German Health Practice Collection.

⁴Younkin, P. (2008). Making the Market: How the American pharmaceutical industry transformed itself during the 1940s. University of California, Berkeley, Berkeley, November 2008.

⁵Global pharma looks to India: Prospects for growth; PWC Report.

⁶Pharmaceutical Sector Assessment in Ethiopia December 2017 WHO and World Bank

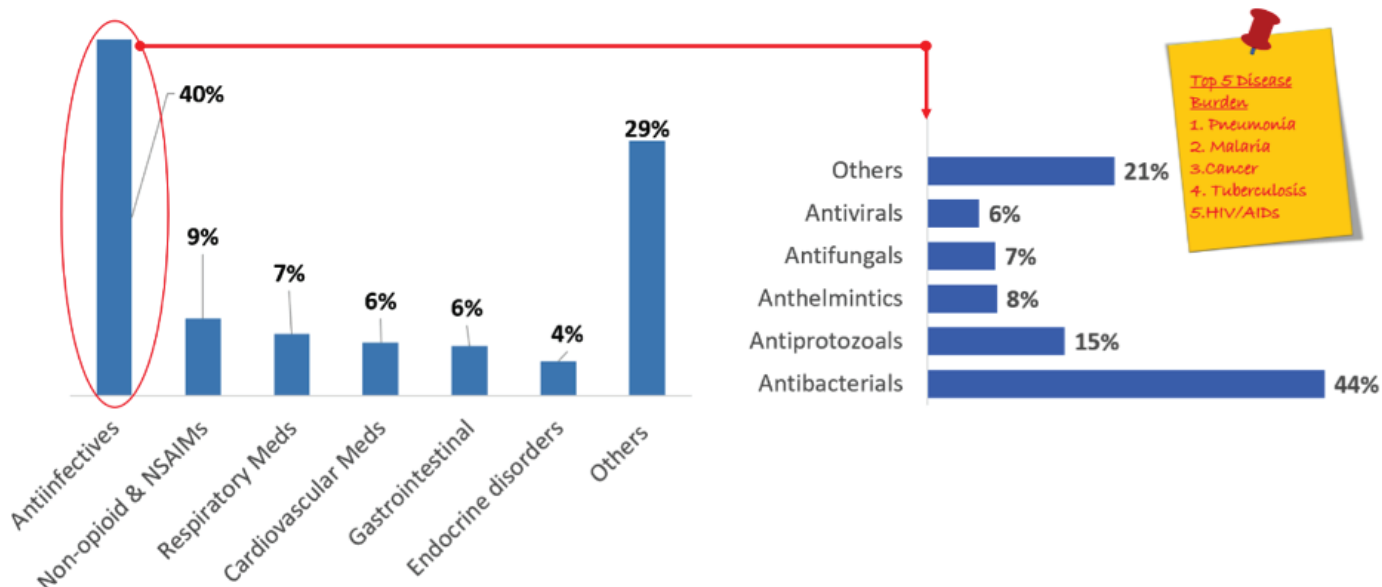


Exhibit 1: Pharmaceutical products manufactured in Kenya

partnership is a great collaborative strategy that manufacturers can use in order to exploit synergies in the application and utilisation of knowledge and resources, in order to help increase the range of products that are manufactured. Technology transfer and joint ventures are initiatives that can be harnessed to improve access to essential medicines. Examples of successful technology transfer enterprises in the region are Universal Corporation Limited/Strides-Shasun Merger (Kenya) and CIPLA/Quality Chemical Industries Limited (Uganda).

Like many African countries, Kenya lacks sufficient technical, financial and human capacity to produce adequate medicines to meet the country's demand. This study established that the local pharmaceutical manufacturers in Kenya produced only 28% of the national essential medicines.

Notably, LPPs in Kenya focus on few therapeutic categories (Exhibit 1) at the expense of the bigger need, as per the disease burden profile of the EAC region and country. It is also noteworthy that LPPs are hesitant to engage in new molecule development that have high potential safety risks and/or narrow therapeutic indices. They also have a high product

development costs. Most companies indicated that their product portfolio was based on market demand, and not necessarily on the need to develop new products to address government priorities, mainly because they are unsure of government priorities and support. The industry's main agenda was tailored towards profit and not the needs of the country in regard to essential medicines.

There is potential for growth in pharma research in the region. There are efforts to promote R&D work at Muhimbili School of Pharmacy, the Kilimanjaro School of Pharmacy in Tanzania supported by GIZ and the Kenya Medical Research Institute (KEMRI) but they are at the nascent stages. Furthermore, the region has many universities with schools offering courses in biological and other sciences, chemistry and more than 10 schools of pharmacy that can collaborate with the pharma industry and work towards achieving the national research and medicines agenda.

However, the universities and research institutions in EAC have made no effort to create linkages with the pharmaceutical industry. Most of the research that is performed is for academic publishing and has not resulted in innovation that is useful

for the pharma industry. There is a glaring disconnect between academia, research institutes, the pharmaceutical industry and the government. The LPPs focus on a narrow set of products is an indication that there is no connection between the disease profile in the country and pharma manufacturing sector in terms of key priorities to address the national disease burden. The disease burden of the country should determine the priorities in selection of products to be developed and the subsequent product quality requirements.

Partnerships Proposed by the Pharmaceutical Sector

A symbiotic partnership is required (Exhibit 2). There is need to ensure that each player/stakeholder is benefiting from the partnership and this way it will be sustainable, in the following ways:

- The industry registers their needs with research institutions, for example product optimisation and new formulations among others.
- Research/academic institutions use their research facilities to carry out trial for the work requested by the industry.

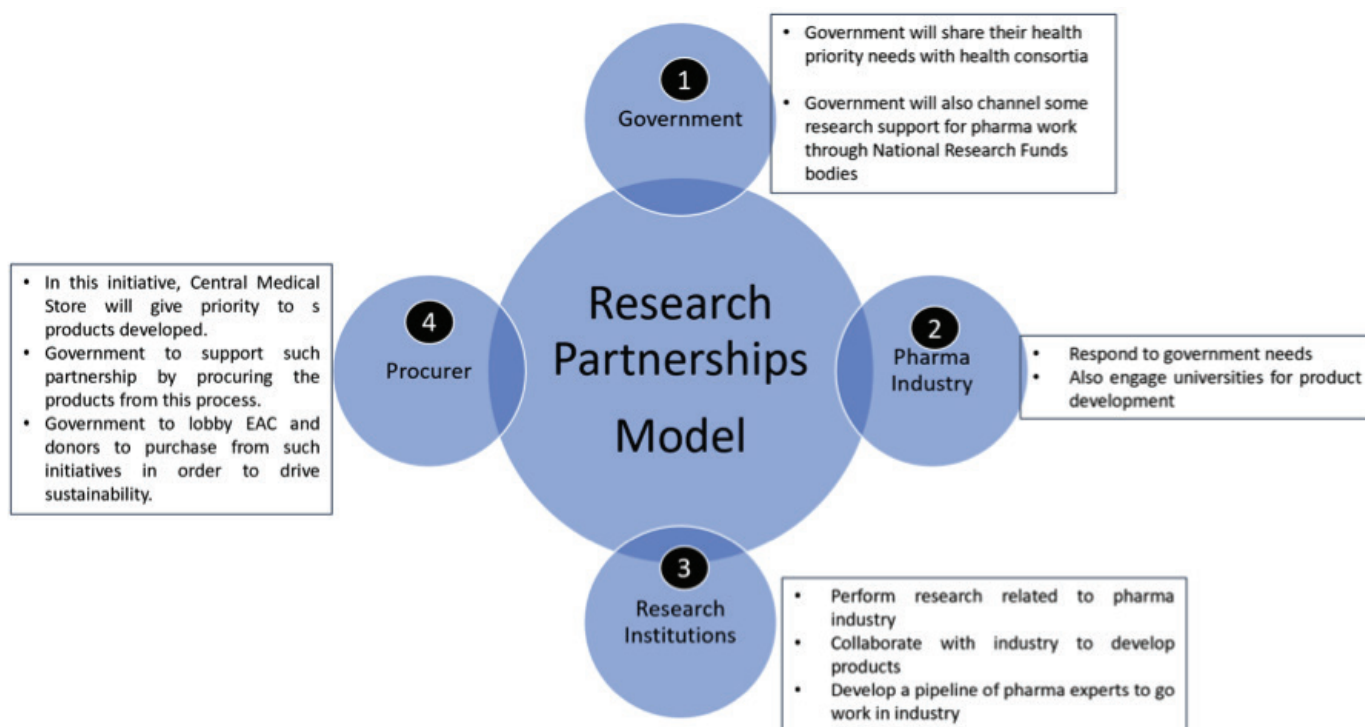


Exhibit 2: Proposed Academia-Industry-Government Model

- Once it is optimised and ready to be batch-tested, the researchers send the compounds (test products) to the pharma company to use their R&D facilities to initiate the tests at a production site.
- If the product does well and the process is optimised, it is then scaled up to commercial scale production.
- To ensure its success and sustainability, the government shall commit to buy xx% of the FPP ensuing from this process.
- On their part, the private sector will contribute back ~xx% of their sales per unit that will be committed to the R&D resource pool that supported the above work. The resource pool shall include already existing research funds from the National Research Fund targeted at health programmes
- The above cycle is repeated all through on a continuous basis.

Policy Implementation

There are several policy documents in Kenya which are consistent with vision 2030, an economic, social and political

roadmap to move Kenya’s economic status to a middle-income country. They include the Universal Health Care, the Kenya Industrial policy and Kenya National Pharmaceutical policy. The driver for implementation in the pharmaceutical sector is the Kenya Pharmaceutical Sector Development Strategy (KPSDS). The KPSDS is a holistic approach encompassing seven strategic components namely, setting out a roadmap for industry to achieve GMP Standards, strengthening mechanisms for quality assurance of medicines in the distribution chain, strengthening regulatory capacity, accessing necessary financing for investment in the sector, devising time-limited incentives for industry, developing necessary human resources and developing common support services for the local pharma industry.

There are lost opportunities when policy and implementations are not coherent. For example; in the 1990s, Kenya had several manufacturers producing anti-malarial products. Due to massive resistance to chloroquine and later Sulphadoxine – Pyrimethamine in

early 2010s, there was a deliberate change in therapy to the artemisinin-based combination therapy (ACT). However, the local production of antimalarial products decreased substantially as a result of this change⁷. This is because Artemether/Lumefantrine (AL) procurement by the government is donor-funded. Most local manufacturers however are not eligible due to international prerequisites that participation is open only to manufacturers with WHO prequalification (PQ) status. Malaria at that time was the leading cause of morbidity. There were no initiatives for local sources for AL or other recommended therapies for malaria. Meri Koivusalo and Maureen Mackintosh cite malaria as one of the failure vertical programs⁸ for lack of integration with other strategies. It is important to recognise that changes

⁷Sarah Vugigi et al. Production Capacity of Pharmaceutical Manufacturing Industry in Kenya. East Cent. Afr. J. Pharm. Sci. 20, 2017, 3.

⁸Global public action in health and pharmaceutical policies: politics and policy priorities IKD Working Paper No. 45 February 2009 Meri Koivusalo and Maureen Mackintosh

in policy at international fora may be detrimental to an unprepared local industry.

The current disconnect between the national priorities and the local pharmaceutical industry arises from the fact that government is not driving the industry towards manufacturing products according to the public sector needs. The weaknesses stated herein may be mitigated through the following actions, for enhancement of medicines access through pharmaceutical partnerships in the region.

IMPLICATIONS AND RECOMMENDATIONS

- A high level government advisory panel on pharmaceuticals development should be established to collect, collate and disseminate data that is necessary to attract investment in the sector. It will also provide a forum to bring government, industry and academic/research institutions to identify national priority needs which are relevant to the pharmaceutical manufacturing industry.
- Establish industry-research institution partnership for product innovation and research in line with the public health needs, especially essential medicines. This should include exploring traditional medicines as a source of medicines. This partnership shall run on the strength of product development, intellectual property agreements and assurance. Respective institutions and national governments should encourage, motivate and wherever possible, facilitate the agreements and guarantees, especially those related to LPPs and disease burden.
- The region should harness the potential of their research institutions capabilities to develop new products through structured collaborations and partnerships that can be funded by the public to address the

priorities in line with the national disease burden. This structured approach should ensure that the positive outcomes of these research/development work benefits the citizenry.

- Develop additional incentives and harmonise the incentive regime in order to catalyse growth and expansion of LPP scope to address the UN Sustainable Development Goal No.3 and disease burden. For example, the need to consider tax rebates for LPP that invest in quality improvements and R&D and also fund basic research in this industry.

CONCLUSION

The government should derive the R&D agenda for the pharmaceutical industry. There is need to establish a structured process to collect, synthesise and disperse data that is vital to guide industry and academic/research institutions on national priority R&D needs. This necessitates a symbiotic linkage between universities/research institutions and the pharma industry on collaborative arrangements and sharing of knowledge in health and pharmaceutical research priorities for development targeted towards improved access to essential medicines.



The Scinnovent Centre
Second Floor, Karen Plains Arcade
P.O. Box 52486 - 00100, GPO, Nairobi, Kenya

Website: <https://scinnovent.wordpress.com>; Tel: +254 020 2173433