



The Positive Impact of Local Pharmaceutical Manufacturing on Economic Development and Public Health

Tobias Buender, Nazeem Mohamed, Thomas Walter,
Wesley Ronoh, Moritz Fichtl, Rozenn Le Mentec

FEAPM Advocacy Series No. 2

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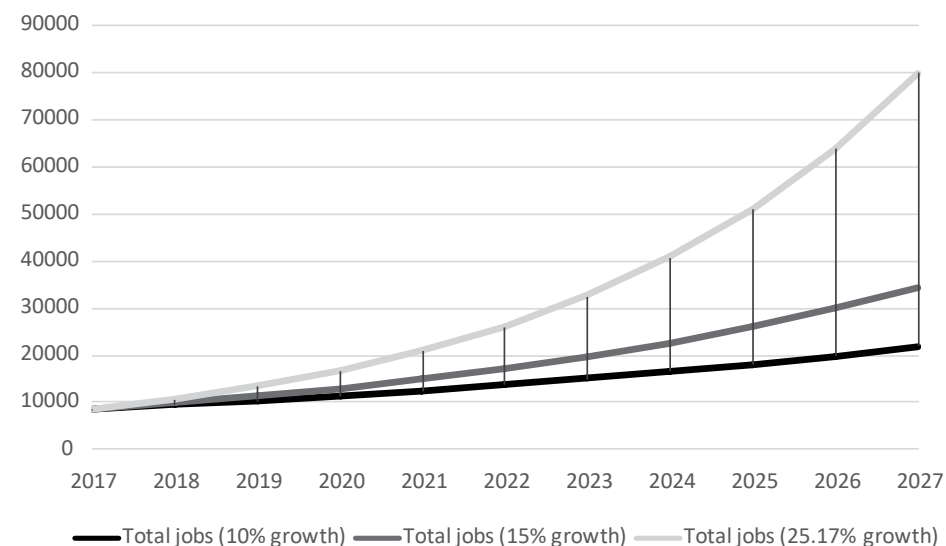
Executive Summary: The Positive Impact of Local Pharmaceutical Manufacturing on Economic Development and Public Health in the EAC

Background: Local pharmaceutical manufacturing is high on the agenda in the East African Community (EAC) and throughout the continent. While there are positive developments with regards to industry growth, political support and increasing demand by international and local procurement, doubts remain whether local manufacturers can produce at sufficient quality and capacity and are able to compete with imported medicines on price. However, this study based on a survey among members of the Federation of East African Pharmaceutical Manufacturers (FEAPM) and local distributors, as well as on a wide literature review shows that the contrary is true. There is evidence that local pharmaceutical manufacturing already has a strong positive impact on economic development and public health alike. With the right support, this effect is projected to grow substantially within the timeline of the Regional Pharmaceutical Manufacturing Plan of Action 2017-2027.

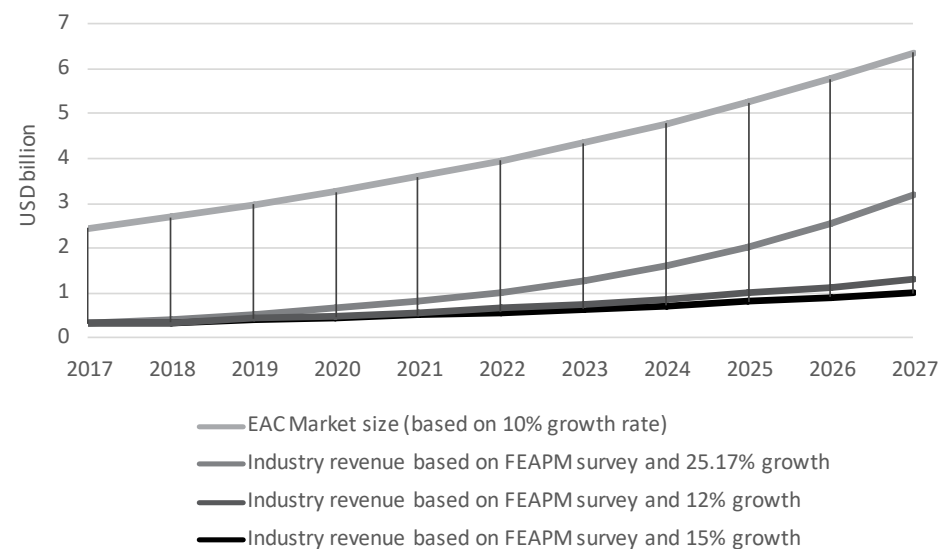
Economic benefit of local pharmaceutical manufacturing:

Revenue and potential for growth	<ul style="list-style-type: none"> • 2017 total EAC industry revenue: USD 323 million • Projected 2027 industry size and market share: <ul style="list-style-type: none"> • growth rate of 12% (2014 estimates): USD 1 bn (16.49% market share) • growth rate of 15% (industry estimates): USD 1.3 bn (20.58% share) • growth rate of 25.17% (RPMPOA target): USD 3.18 bn (50% share)
Employment	<ul style="list-style-type: none"> • 2017 employment EAC total: 8456 jobs (29% university graduates) • Projections for 2027 <ul style="list-style-type: none"> • at 12% growth: 21933 jobs • at 15% growth: 34210 jobs • at 25.17% growth: 79834 jobs • Annual training of ~800 students and interns
Attraction of investment	<ul style="list-style-type: none"> • FDI implemented and schedule since 2010: > USD 130 mio • Planned investment of local industry until 2023: ~USD 140 mio
Trade benefits	<ul style="list-style-type: none"> • Total EAC Exports 2017: USD 140.49 mio (~300% increase since 2006) • Total EAC medicine imports decreased by 10% from 2015-2017
Spill-overs and value-chain effects	<ul style="list-style-type: none"> • 2017: USD 91.29 mio spill-over from pharma industry to EAC value chain. • Salaries made up about USD 45.52 mio

Projections for jobs at different growth rates



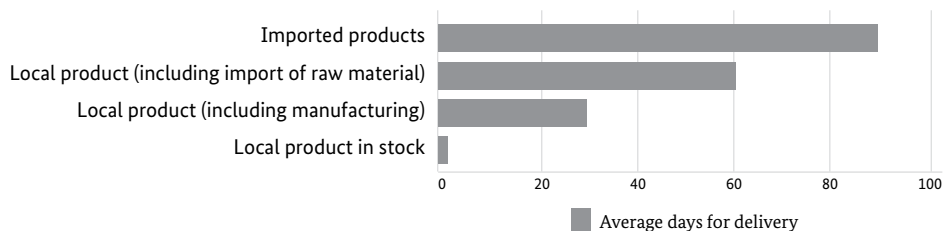
Projections for jobs at different growth rates



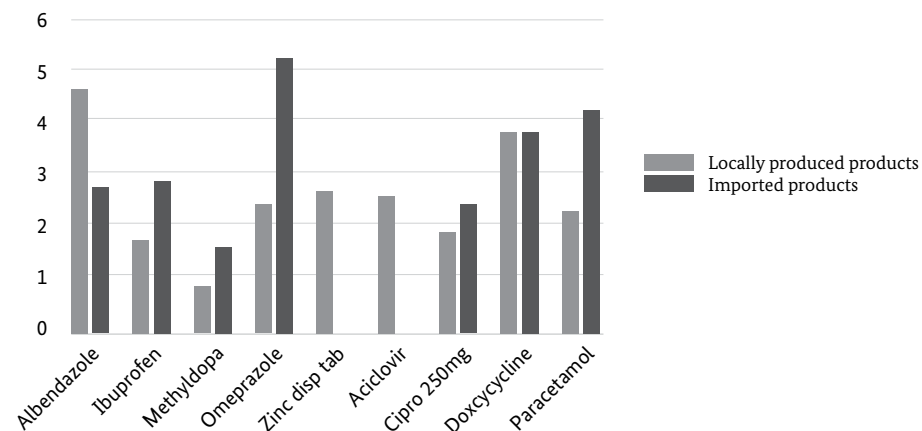
Public health benefits of local pharmaceutical manufacturing

Medicine prices	<ul style="list-style-type: none"> • Price comparisons vary immensely from product to product and between manufacturers • Two Kenyan studies show that if local products exist, procurement prices are lower on average than for imports • KEMSA tender data shows that local manufacturers have become more competitive • Tanzanian study finds that locally made products are cheaper on average than imports
Better quality of medicines	<ul style="list-style-type: none"> • Quality assurance of local products through regulators is very strict • No major difference observed in quality of imports versus locally-made medicines
Higher availability and health security	<ul style="list-style-type: none"> • Lead times of local manufacturers <ul style="list-style-type: none"> • If in stock: 1-2 days • If raw material in stock: 1-4 weeks • If raw material not in stock: 1-2 months • Delivery time for imported medicines: 2-3 months • Survey: 88% of distributors have used local manufacturers to respond to stock-outs in emergencies
Local adaptation of medicines	<ul style="list-style-type: none"> • Adaptations of formulas (e.g. reformulation for rural consumption) • Adaptation of packaging (e.g. information in Kiswahili) • Product development cooperation in international partnerships (e.g. DNDI or CHAI)

Speed of delivery



Patient prices (in median price ratios), Kenyan public sector, individual medicines



Policy recommendations for EAC level

1. Introduce a 25% import tariff on a list of selected medicines, for which sufficient and high quality local production capacity exists. For a suggestion of a list, see Chapter VI.
2. Remove all duties on imports of raw and packaging material, pharmaceutical manufacturing related equipment as well as spare parts for the equipment.
3. Introduce a universal price preference margin of 20% for all pharmaceutical products manufactured in the EAC in all public tenders and remove similar preferences for local importers.
4. Enforce Article 35 of the Common Market Protocol, treating all manufacturers within the EAC as equal with respect to national incentives and preferences in procurement.
5. Harmonise medicine registration procedures within the EAC Partner States.
6. Streamline the implementation of pharmaceutical sector support in an East African Community Pharmaceuticals Management Bill.

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I. Introduction

This is an exciting time for local pharmaceutical manufacturing in the East African Community (EAC). After some uncertain years, in which the globalisation of the generics medicine market created new challenges, manufacturers are looking cautiously optimistic towards the future in 2018. Many companies in Kenya, Uganda and Tanzania are currently expanding their production scale and scope. In Rwanda, two companies have started building new pharmaceutical production facilities and the single producer in Burundi is planning an expansion. Investors from inside and outside the EAC are considering investing in the sector. International and domestic procurement organisations plan to increase their share of EAC-sourced supply. This is first and foremost the fruit of the hard labour invested by the employees and management in East Africa's pharmaceutical industry. Yet, it could not have taken place without a fruitful cooperation between many different EAC governments, civil society and private actors on national and regional level throughout the last years. Together, a new EAC *Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) 2017-2027* was developed and is being jointly implemented along six pillars: Promotion of competitive and efficient regional pharmaceutical production; facilitation of increased investment in pharmaceutical production; strengthening of pharmaceutical regulatory capacity in the region; development of appropriate skills and knowledge for pharmaceutical production; utilisation of WTO TRIPS flexibilities to improve local production of pharmaceuticals in East Africa; and innovation, research and development within the regional pharmaceutical industry. In the RPMPOA, public health and industrial development goals are strongly linked. A successful East African pharmaceutical manufacturing sector will create high-quality jobs, attract international investment and technology transfer, provide export earnings and strengthen the knowledge industry overall. At the same time it can offer high-quality affordable generic medicines to patients, deliver faster than international suppliers and adapt its products to local needs. This dual argument is the reason for growing support for local pharmaceutical manufacturing not only in the EAC, but throughout Africa and the international development community alike.

As part of the RPMPOA, governments are discussing the introduction of supportive industrial policy measures like additional tax

and procurement preferences for the industry or even increased tariffs on specific pharmaceutical products for which sufficient production capacity exists in the region. Understandably, governments and other public health actors want to make sure that this will not negatively affect access to medicines and is worth the political and fiscal investment. This is why the *Federation of East African Pharmaceutical Manufacturers (FEAPM)* has decided to collect and present existing and new evidence for the positive impact on the economy as well as on the public health outcomes of the East African Community population. This study shows that manufacturers in the EAC already play an important role in their local economies, providing thousands of quality jobs, contributions to government finances and investments in further growth. At the same time, public health actors are in need of domestic supplies to meet demand for low-price quality medicines. Evidence shows that local manufacturers are highly competitive on price and speed of delivery, when compared with imports, in many therapeutic fields. Yet, in order to build on this strong foundation, further support from the EAC and its Partner States is needed. This will enable manufacturers to invest into expanding capacities and move into new product categories to meet upcoming health challenges in the Community.

First of all, the study will elaborate on the dual argument for local pharmaceutical manufacturing, drawing links to the evidence from success stories in other developing countries throughout the world. Secondly, it will outline how the pharmaceutical industry currently contributes to employment and economic development of the EAC and what potential it bears for further gains. Thirdly, the study will focus on the performance of the EAC pharmaceutical manufacturers with regards to improving access to medicines by looking at prices, quality, availability and adaption to local health needs. Moreover, two case studies relating to the experience of two FEAPM member companies are presented. Finally, the study will end by outlining proposed policy measures that would help to further strengthen the industry in order to be able to take on new economic and public health challenges.

II. The Benefit of local production

Local pharmaceutical production has gathered much prominent support throughout the African and international policy community. In 2005, the African Union Assembly mandated the AU Commission to develop an overarching Pharmaceutical Manufacturing Plan for Africa (PMPA) and its implementation is in full swing throughout the continent. In the ECOWAS region, the United Nations Industrial Development Organization (UNIDO) and the West African Health Organization (WAHO) work on initiatives like a Good Manufacturing Practices (GMP) Roadmap Framework. The SADC's pharmaceutical business plan supports strengthening pharmaceutical manufacturing in Southern Africa. As mentioned above, the East African Community has been at the forefront of this development having already launched its second Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA), now covering implementation until 2027. Moreover, African regional economic communities have integrated and prioritised pharmaceutical manufacturing as part of their industrialization strategies.

Outside of Africa, many international and development partners have seen the need for a stronger pharmaceutical industry in Africa. UNAIDS Chairman Sidibé, for instance, is a great proponent of African pharmaceutical manufacturing: *"The growth of new pharmaceutical industries...will save lives and deliver measurable returns through increased productivity, longevity and lower long-term health-care costs in the long run. It is a win-win for all."*¹ Other UN institutions like WHO, UNIDO and the UN Conference on Trade and Development (UNCTAD) have all built pharmaceutical sector support programmes within their organizations. On top of that, development partners like the German Ministry for Economic Cooperation and Development, Swissfund, or Finnfund have invested in pharmaceutical capacity building throughout the last ten years. This political commitment has also brought in long-time sceptics of local manufacturing like the Global Fund to Fight AIDS, Tuberculosis and Malaria. It has integrated local suppliers in its 2016-2021 market shaping strategy and hosted a ground-breaking conference with African manufacturers to establish new partnerships. Other international procurement organiza-

tions like PEPFAR or UNICEF equally report that they are increasing their share of medicines made in Africa.

While making medicines in Africa has a long tradition going back to the 1920s², a big push for local pharma arrived as a result of the Doha Declaration on the TRIPS Agreement in 2001: The World Trade Organization and its partner states recognized that Africa needs a strong generic medicines industry to make use of the flexibilities in the TRIPS agreement. This means being able to locally produce low-cost generic versions of medicines that were patent-protected in many industrialized countries and thus unaffordable for the majority of African patients. However, if you look at why African governments and international partners decided to support local manufacturing, you find a much wider argument. What is so special about promoting pharmaceutical manufacturing is that it is a holistic way of undertaking industrial policy; if done right, you may potentially hit two birds with one stone. Not only do you contribute to industrialization and create jobs, but you may improve public health and access to medicines at the same time. This requires strong cooperation and coordination to reach policy coherence among the different departments from industry, trade and finance, to Ministries of Health and their regulatory and procurement agencies.

However, there have been critical voices towards supporting local pharmaceutical manufacturing³, especially during the early years of the discussion. Doubts exist mainly in the public health community and among medicine importers. Some of their representatives argue that prices of imported medicines tend to be cheaper and local producers would not have the necessary capacities to fulfil local demand. On top of that, there is a recurring perception that local manufacturers produce lower quality than manufacturers from outside Africa. Whilst these problems indeed existed and may still occur in some countries and sub-sectors, generally, the African pharmaceutical industry has made critical advancements towards competitiveness both in quality, capacity and price. In this paper, we assemble evidence for this development in the EAC region.

II.I Economic Benefits

Industrial policy used to have a bad reputation among African and international economists after the wide-spread failure of state-supported industrialization in the early post-colonial years⁴. Yet, the neoliberal, hands-off recipe for growth propagated in the 1980s and 1990s did also not lead to much success with regards to the development of competitive industries. At the same time, many Asian economies managed to reach this goal with more sophisticated state-centred industrial policies. This led to a rediscovery of the potential of active industrial policy for structural transformation of African economies from a natural resource focus to stronger manufacturing⁵. Dani Rodrik and other international economists point out that the design of the policy matters. In the past, governments have supported the wrong sectors in the wrong way⁶. In the new wave of industrial policy governments should, amongst other criteria, focus on the sectors that show potential for great knowledge spillover or economies of scale⁷. Pharmaceutical manufacturing has proven to be such a sector. For many countries like India, Bangladesh, Egypt or Ghana, such an active industrial policy has been a success in the sector. Subsequently, such benefits will be discussed.

Local production will stimulate the economy, create jobs and contribute to government finance.

The pharmaceutical sector, like other industries, depends on labour from the local population. In the successful Indian pharmaceutical manufacturing sector, more than 450,000 people have found a high-quality job⁸. In a more local example, the Egyptian industry employs about 100,000 workers⁹. While there are sectors that are more labour-intensive than the production of medicines, the majority of the jobs created can be considered as decent work providing dignity, a fair income and safe working conditions¹⁰. The industry offers opportunities to both high and lower skilled workers ranging from natural science, engineering and research-oriented tasks to more basic production line operations. Due to the high quality standards applied in the industry and international supply chains, the work environment is usually much cleaner and safer than in other sectors.

Moreover, pharmaceutical manufacturing creates spill-over effects into many other industries along its supply-chain. Upstream, it may lead to the

¹ UNAIDS (2017). Believing in African Pharma. Retrieved from http://www.unaids.org/en/resources/presscentre/featurestories/2017/march/20170329_CIPHARM

² Banda, G., Wangwa, S., & Mackintosh, M. (2016). Making Medicines in Africa: An Historical Political Economy Overview. In: Making Medicines in Africa. The Political Economy of Industrializing for Local Health. Basingstoke: Palgrave Macmillan

³ Kaplan W, Laing, R. (2005). Local production of pharmaceuticals: Industrial policy and access to medicines – an overview of key concepts, issues and opportunities for future research. Washington, DC: World Bank.

⁴ Lin, J. (2012). New Structural Economics. Washington, DC: World Bank.

⁵ Rodrik, D. (2004). Industrial Policy for the 21st century. CEPR Discussion Paper 4767; Wade, R.H. (2009). Rethinking Industrial Policy for Low Income Countries. Journal Compilation. Oxford: Blackwell; Altenburg, T. (2011). Industrial Policy in Developing Countries: Overview and lessons from seven country cases. GDI discussion paper; Stiglitz, J., Lin, J., Monga, C. (2016). The Rejuvenation of Industrial Policy. World Bank Policy Research Working Paper No. 6628.

⁶ Rodrik, D. (2004). Industrial Policy for the 21st century. CEPR Discussion Paper 4767

⁷ Norman, A. and Stiglitz, J. (2012). Strategies for African Development. In: Good growth and governance in Africa: Rethinking Development Strategies. Oxford: Oxford University Press.

⁸ Guennif, S., & Ramani, S. V. (2010). Catching up in pharmaceuticals: a comparative study of India and Brazil. UNU MERIT Working Paper.

⁹ Oxford Business Group (2012). Egypt: Regulating pharmaceuticals production. Retrieved from: <https://oxfordbusinessgroup.com/news/egypt-regulating-pharmaceuticals-production>

¹⁰ International Labour Organization (2018). The ILO's Decent Work Agenda. Retrieved from: <https://www.ilo.org/global/topics/decent-work/lang--en/index.htm>

build-up of a strong chemical industry for the production of Active Pharmaceutical Ingredients (API) like in India or China. On top of that, the more labour-intensive packaging industry gets a boost from supplying packaging material. Even the agricultural sector may benefit from the pharmaceutical industry for the production of herbal medicines or plant-based APIs such as artemisinin for malaria treatment. Such economic growth, spill-over effects and increasing wealth of all stakeholders in the industry will pay back any government support through rising corporate, consumption and income taxes, trade levies and other contributions to public finance.

Local production will attract investments

Investors are always looking at the potential of an industry. Pharmaceutical manufacturing faces a growing market in Africa that McKinsey estimates to reach a value of USD 20.8 to USD 65 billion by 2020¹¹. Drivers here are a growing middle class, improving health financing and unfortunately also a change in disease burden with non-communicable diseases (NCDs) on the rise. In combination with strong support for local manufacturing, international companies will look strongly into greenfield investments, joint ventures or other partnerships on the continent to supply the African markets. Moreover, with growing demand, local manufacturers will increasingly mobilize investment resources to improve production capacities and upgrade the capital stock of their local economy.

Local production will save foreign exchange reserves and generate export earnings

All African countries import the majority of their medicine demand. In the EAC Partner States, this share ranges from 99% in Burundi

to around 70% in Kenya. To import medicines, Kenya, for example, required foreign exchange reserves of USD 518 million in 2017¹² alone. This signifies a great potential for import substitution. Bangladesh started off similarly with more than 70% of medicines imported into the country in the 1980s and has decreased that number to only 2% after years of effective support to the industry. After saturating the local market, Bangladeshi firms have moved to exporting to more than 70 countries and generated export earnings of more than USD 80 million in 2017 with the trend pointing strongly upwards¹³. Thus, it is a great opportunity to tap into international markets for African manufacturers.

Local production will contribute to a knowledge society through technology and skills transfer

Pharmaceutical manufacturing is a relatively high-tech and high-skilled industry. In this way, strengthening pharmaceutical production means supporting the transformation towards a knowledge economy in that country. New domestic or foreign investments will often bring in cutting edge development or production technology to the economy, which may spill-over to other sectors. At the same time, working in pharmaceutical manufacturing will create new skills in a workforce making an economy more productive overall. Many pharmaceutical manufacturers run their own workplace trainings or internship programmes to make sure that university or high school graduates are adequately prepared for work in the industry. Thereby, they contribute to capacity-building that will contribute to the wider performance of an economy. Moreover, pharmaceutical companies offer career opportunities for highly educated university graduates reducing the brain drain in developing economies.

II.II PUBLIC HEALTH BENEFITS

Public health is nowadays mostly addressed in a systematic approach. Health systems strengthening makes up an important part of the UN Agenda 2030 for Universal Health Coverage and the G20 global health strategy. While hospitals, pharmacies, medical schools, biomedical research labs and health product supply chains are commonly accepted to be part of a country's health system, there is a strong argument that a local pharmaceutical industry also plays a vital role within a health system. By supporting health-industry linkages, policy makers can contribute to the health systems strengthening agenda and provide a building block for better access to medicines¹⁴. With the right approach, prices may drop, quality can be better assured, and medicines become more available and better adapted to local needs. Moreover, such linkages may build local emergency capacities or increase the pool of the health workforce. The following paragraphs lay out more of these aspects in detail.

Local production will decrease medicine prices

When the discussion about local pharmaceutical production started in the early 2000s, prices of medicines on the international market were still extraordinarily high. Increasing competition through large-scale production of generic medicines in rapidly industrializing countries like India and China has helped to alleviate this problem throughout the developing world. A first-line HIV treatment used to cost about USD 10,000¹⁵ until the early 2000s. This figure has gone down to USD 75 per patient per year¹⁶. While many argue that the Indian and Chinese producers' economies of scale make it harder for other countries to gain price advantages through local production, there still seems to be room for efficiency gains. The

large supply chain of imported medicines, adding intermediate costs and margins, is improved with local manufacturing. Local manufacturers could supply directly to hospitals, reducing costs to patients by between 25% and 50%. In Bangladesh, average medicine prices have decreased by about 80% in real terms since the push for local production in the 1980s¹⁷. Yet, still today, Bangladesh reports that domestically produced medicines are nearly 50% cheaper than imports from neighbouring India¹⁸. African economies could also achieve this, having comparably low labour costs and decreasing costs of business, which will help to raise their competitiveness.

Local production will improve availability of medicines

Stock-outs or delivery delays can cause severe harm if patients cannot access the medicines they need at the right time. Unfortunately, this is a common issue throughout many EAC countries. Local pharmaceutical production capacity can reduce this problem, as their supply is usually faster. Local companies tend to keep stock for stock-out situations or at least keep raw material to manufacture needed medicines within a few days or weeks. In addition, transport times are shorter between factories and warehouses and they may be able to produce smaller batches to cater for fluctuations in demand. International large-scale producers often prefer to ship product only once or twice a year to make use of economies of scale. Then deliveries can take up to three months, not including delays caused by potential administrative issues at customs. The Global Fund has acknowledged this advantage of local production and awards special points to local manufacturers within their tendering procedures

¹¹ McKinsey (2015). Africa: A continent of opportunity for pharma and patients. Retrieved from: <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/africa-a-continent-of-opportunity-for-pharma-and-patients>

¹² International Trade Centre (2018). International Trade Statistics 2001-2017. Retrieved from: <http://www.intracen.org/itc/market-info-tools/trade-statistics/>

¹³ Ibid.

¹⁴ Mackintosh, M., Mugwagwa, J., Banda, G., Tunguhole, J. (2017). Local production of pharmaceuticals and health system strengthening in Africa: An Evidence Brief. German Health Practice Collection. Berlin: BMZ

¹⁵ MSF (2011). Untangling The Web Of Antiretroviral Price Reductions. Retrieved from: https://d2pd3b5abq75bb.cloudfront.net/2012/07/16/14/42/23/52/UTW_14_ENG_July2011.pdf

¹⁶ UNAIDS (2017). New high-quality antiretroviral therapy to be launched in South Africa, Kenya and over 90 low- and middle-income countries at reduced price. Retrieved from: http://www.unaids.org/en/resources/presscentre/press-releaseandstatementarchive/2017/september/20170921_TLD

¹⁷ Amin, Md., & Sonobe, T. (2013). The success of the industrial development policy in the pharmaceutical industry in Bangladesh. GRIPS Discussion Paper 13-07. Chowdury, N. & Kabir, ER (2009). Per pill price differences across therapeutic categories: A study of the essential drug brands marketed by multinational and local pharmaceutical companies in Bangladesh. African Journal of Marketing Management; 1(9), 220-226.

¹⁸ FEAPM (2018) Internal unpublished Report, FEAPM study tour to Bangladesh.

if they can assure rapid delivery. Within a country, local manufacturers also have an incentive to cover the whole market including poorer rural areas. Many producers even develop their own distribution networks for this purpose. Importers tend to focus on the more lucrative urban areas and pockets of wealth. Thus, local production may potentially deliver wider rural availability of essential medicines.

Local production will increase quality of medicines in a country

There is considerable doubt among public health officials that African manufacturers can produce high quality medicines. Whilst not all local manufacturers may have the means to bring their production in line with international standards like the WHO GMP guidelines, local regulatory authorities are mostly very strict to ensure product safety¹⁹. In fact, they can impose much stricter controls on the production environment of local manufacturers than manufacturing sites of companies importing their products from around the world. Even the US FDA, with its relatively high capacity for inspections, is concerned that it is unable to effectively control production quality in India²⁰. Studies claim that about 35% of worldwide sales of counterfeit medicines can be traced back to India²¹. For example, a 2013 report of the Ghana Food and Drug Authority showed that 95% of the medicines to treat postpartum haemorrhage imported from China and India failed quality control²². On top of that, regulatory agencies in export-oriented countries may, from time to time, be less strict with the quality of products destined for export to Sub-Saharan Africa. A recent investigation showed, for instance, that generic drugs exported from India to Africa are of lower quality than those for domestic sales or exports to middle income countries²³.

A major quality scandal in the USA involved Indian manufacturer Ranbaxy. In 2013, Dinesh Thakur, a Ranbaxy executive and whistle-blower in this case, stated that “Ranbaxy took its greatest liberties in markets where regulation was weakest and the risk of discovery was lowest”²⁴. Thus, as long as strict regulatory enforcement is in place domestically, local manufacturing can improve the average quality of medicines in the market.

Local production will create more locally adapted products and medicines for neglected diseases

It is a dilemma for Africa that medicine research is mostly driven by market forces. Thus, effective medicines for many neglected tropical diseases are still missing. For other products, dosage forms, packaging or other specifications may not be appropriate for local conditions. Climate or genetic differences between patients may undermine the effectiveness of a treatment. Even though generic medicines manufacturers do not engage in original medical research, and seldomly conduct their own clinical trials, they are the first step to building up such research capacity. Through local production, more staff gain knowledge of pharmaceutical research methods, universities expand their operations and overall research capacity increases gradually. In India, after years of generic product development and reformulation, some companies currently find themselves in a transition towards a more research-based approach. In Africa, product development partnerships within institutions like the DNDI foster cooperation in innovation between researchers and local manufacturers.

Local production will improve health security

Health security has received much attention lately, often focusing on the threat of epidemics

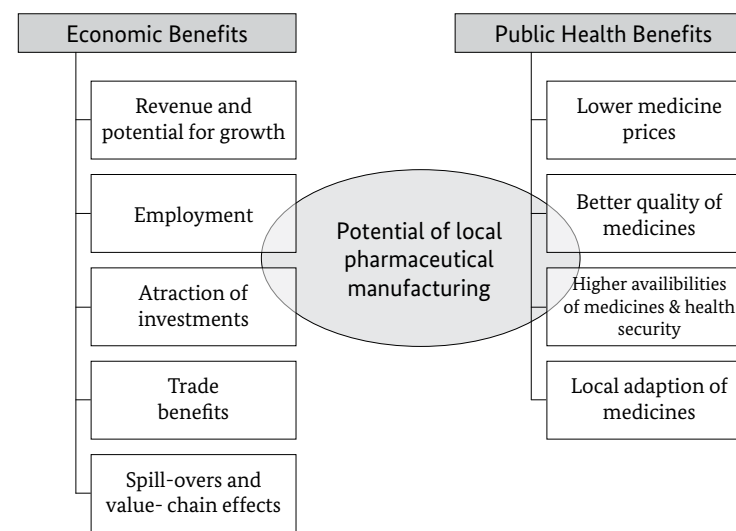
like Ebola. Local production of emergency medication or vaccines can ensure that African countries will not have to wait until everybody else has been supplied. The international flu outbreak of 2009 was such a case, in which all countries held on to their supplies and forbade the export of vaccinations²⁵. However, for local health professionals in many African countries, health security may instead refer to having a security of supply of essential medicines to avoid preventable harm in regular treatment situations like giving birth²⁶. Here, as mentioned above, local manufacturing can help to ensure this safe supply.

III. The Impact of local Pharmaceutical Manufacturing in the EAC

While we have demonstrated that producing medicines locally can have economic and public health benefits in theory and in practical cases from around the world, it is important to check how local pharmaceutical manufacturing in the EAC is doing in comparison. Below, the study summarizes and analyzes evidence for impact along the framework in Figure 1.

The researcher undertook a comprehensive literature and database review to extract relevant data. Additionally, with the support of the Federation of East African Pharmaceutical Manufacturers, a survey was conducted across FEAPM member companies to present a more comprehensive and updated picture of the industry's contributions. Respondents to the survey constitute a major share of the industry. For the share of the industry that did not respond, or is not part of FEAPM, numbers were estimate²⁷ based on extrapolations from the respondents' data with triangulation from FEAPM experts. Thus, final numbers for countries and EAC presented here are a combination of company reports and estimations. To provide anonymity for the companies, data from this survey will be presented on a national or regional level only. Moreover, interviews were held with nine public and private medicine distributors to gather information on the perception of quality, availability and competitiveness of locally made products.

Figure 1: Economic and Public Health Benefits of local pharmaceutical manufacturing



¹⁹ United States Securities and Exchange Commission (2010) Registration Statement under the Securities Act of 1933 [for] Vantage Health. Available at: http://www.faq.s.org/sec-filings/100819/Vantage-Health_S-1/

²⁰ Harris, G. (2014). Medicines Made in India Set Off Safety Worries. New York Times. Retrieved from: <https://www.nytimes.com/2014/02/15/world/asia/medicines-made-in-india-set-off-safety-worries.html>

²¹ Wertheimer, A., & Norris, J. (2009). Safeguarding against substandard/counterfeit drugs: Mitigating a macroeconomic pandemic. *Research in Social and Administrative Pharmacy*, 5, 4-16.

²² United States Pharmacopeial Convention (USP) (2013). Post-Market Quality Surveillance Project: Maternal Healthcare Products (Oxytocin and Ergometrine) on the Ghanaian Market. Retrieved from: http://www.usp.org/sites/default/files/usp_pdf/EN/PQM/ghana-mch_mqm_report_final-mar_27_2013_rdcet.pdf

²³ Bate, R, G Z Jin, A Mathur, and A Attaran (2014), Poor Quality Drugs and Global Trade: A Pilot Study. NBER Working Paper 20469.

²⁴ Eban, K (2013), “Dirty Medicine”, Fortune.

²⁵ Mackintosh, M., Mugwagwa, J., Banda, G. Tunguhole, J. (2017). Local production of pharmaceuticals and health system strengthening in Africa: An Evidence Brief. German Health Practice Collection. Berlin: BMZ

²⁶ Ibid.

²⁷ Respondents for Kenya represent ca. 65% of the industry value (Dawa, Cosmos, Regal, Universal, Biodeal, Laboratory & Allied, Elys); for Tanzania around 90% of the industry value (Shelys, Zenufa, Mansoor Daya, Keko); for Uganda ca. 95% (KPI, CIPLAQCIL, Kwality Afro Asia, Abacus, Rene, Medipharm) of the industry value.

III.I Evidence for Economic Impact

Revenue and potential for growth	<ul style="list-style-type: none"> • 2017 total EAC industry revenue: USD 323 million • Projected 2027 industry size and market share: <ul style="list-style-type: none"> • growth rate of 12% (2014 estimates): USD 1 bn (16.49% market share) • growth rate of 15% (industry estimates): USD 1.3 bn (20.58% share) • growth rate of 25.17% (RPMPOA target): USD 3.18 bn (50% share)
Employment	<ul style="list-style-type: none"> • 2017 employment EAC total: 8456 jobs (29% university graduates) • Projections for 2027 <ul style="list-style-type: none"> • at 12% growth: 21933 jobs • at 15% growth: 34210 jobs • at 25.17% growth: 79834 jobs • Annual training of ~800 students and interns
Attraction of investment	<ul style="list-style-type: none"> • FDI implemented and schedule since 2010: > USD 130 mio • Planned investment of local industry until 2023: ~USD 140 mio
Trade benefits	<ul style="list-style-type: none"> • Total EAC Exports 2017: USD 140.49 mio (~300% increase since 2006) • Total EAC medicine imports decreased by 10% from 2015-2017
Spill-overs and value-chain effects	<ul style="list-style-type: none"> • 2017: USD 91.29 mio spill-over from pharma industry to EAC value chain • Salaries made up about USD 45.52 mio

Industry size and potential for growth

In the Regional Pharmaceutical Manufacturing Plan of Action, EAC reports an estimated pharmaceutical market of **USD 1.84 billion in 2014**²⁸. EAC manufacturers capture about 15% of this market, resulting in an industry size of USD 276 million according to association estimates in 2014. Based on the 2018 FEAPM survey, industry revenue had already grown to USD 323.16 million in 2017. The EAC region has 66 registered manufacturers²⁹, of which the majority are based in Kenya. Thirty-four (34) manufacturers, representing the lion share of the market, are members of FEAPM.

Looking at the market share of local producers, it is important to note that it is much higher among the product categories that local manufacturers can already cover. In Kenya, for instance, local producers fare well in specific sectors: one study found that 59% of chronic disease medicines had been made in Kenya, while only 2% of antiretroviral therapy was made locally³⁰. Another research showed that among medicine categories covered by local manufacturers, they supply around 55% of the Kenyan market³¹. Across the EAC, only an estimated 66% of disease conditions is covered by local manufacturers. Moreover, many have been crowded out from supplying HIV and malaria treatment through the international procurement of the vertical donor programmes like the Global Fund. Their absence in many high-value categories, as well as the loss in the antimalarial and HIV market, decreases the average market share and understates the importance of local manufacturing in their core categories like cough and cold preparations, anti-infectives, antiseptics, analgesics and others.

²⁸ Estimates by manufacturers' associations in EAC (2017). Regional Pharmaceutical Manufacturing Plan of Action 2017-2027. Retrieved from: <http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017%E2%80%932027.pdf>

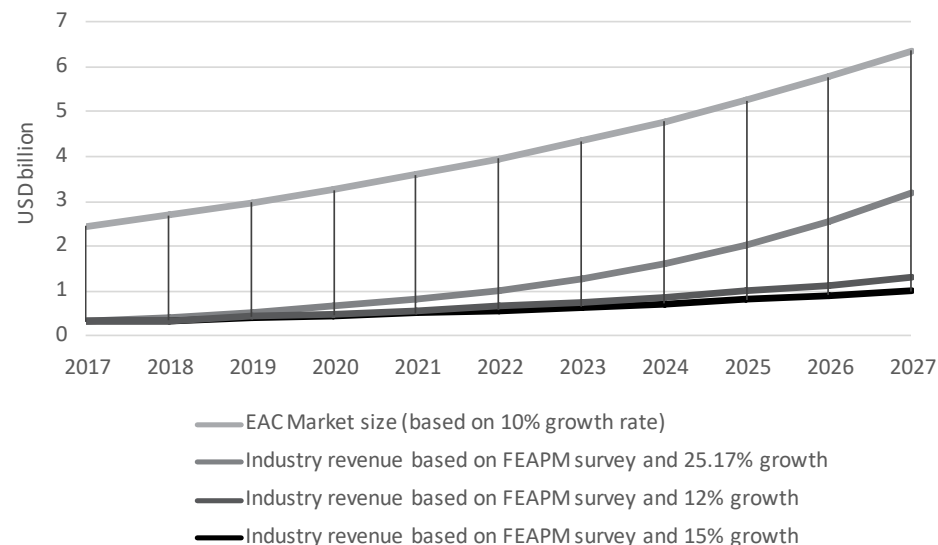
²⁹ ibid

³⁰ Mackintosh, M., Tibandebage, P., Njeru, M., Kungu, J., Israel, C., & Mujinja, P. (2018). Rethinking health sector procurement as developmental linkages in East Africa. *Social Science & Medicine*, 200, 182-189.

³¹ HAI (2018). Prices and Availability of Locally Produced and Imported Medicines in Kenya Report. Retrieved from: <http://haiweb.org/what-we-do/price-availability-affordability/measuring-the-availability-and-prices-of-locally-produced-and-imported-medicines/>

In 2018, the estimated industry size measured in annual revenue stood at USD 339 million. Taking into account an average intermediate consumption of 70%, this corresponds with annual value created of about USD 96.95 million. Moreover, the pharmaceutical market and industry shows great potential for growth. Assuming a continuation of a compound average growth rate of 10%³², EAC market size alone will increase to USD 6.35 billion by the end of the 2nd phase of the RPMPOA in 2027. Figure 2 shows three different projections for the growth of the industry. The grey line is the more conservative estimate of a 12% local industry growth rate, as stated in the RPMPOA. However, FEAPM members reported an expected median growth rate of 15% in the 2018 survey, which is captured by the yellow line. Thus, we may expect an industry revenue between USD 1 billion and USD 1.31 billion in 2027. Even the higher number would only constitute a local market share of 20.58% across the EAC. This shows that at the current growth rates, it is unlikely that the EAC will reach the goal set in the 2nd RPMPOA of 50% locally produced medicines. Thus, increased political support and substantial investments in new manufacturing entities are needed to achieve the 50% target. For this goal, a compound average growth rate of ca. 25% is required (orange line).

Figure 2: Projections for market and industry size



Employment

The pharmaceutical industry employed more than 8800 East Africans on a permanent basis in 2018³³. In times of high capacity utilization, a large number of temporary workers is added to this number. While the industry is not as labour-intensive as other manufacturing sectors, it is notable that about 27%, or 2400 jobs, are occupied by university graduates working in drug development, quality assurance, management or finance (see Figure 3). Approximately 10% of university level employees are trained pharmacists, while the rest have earned other degrees or diplomas, mostly in natural sciences³⁴.

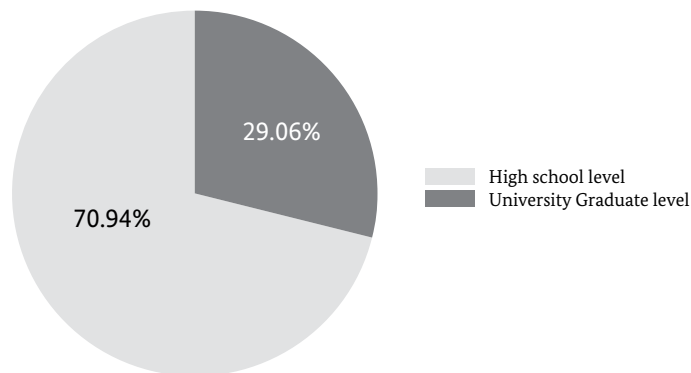
³² EAC (2017). Regional Pharmaceutical Manufacturing Plan of Action 2017-2027. Retrieved from: <http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017%E2%80%932027.pdf>

³³ FEAPM survey

³⁴ Vugigi, S. (2017). Assessment Of The Pharmaceutical Manufacturing Industry In Kenya To Forecast Local Production Sufficiency. PhD thesis in the school of pharmacy of Kenyatta University.

Skilled work makes up a large share of the remainder of the permanent positions, requiring specific additional training following high school education. The quality of each job created in the pharmaceutical industry is thus much higher than in more basic manufacturing. This is also represented by the comparably high income of employees in the industry. In 2017, companies across the EAC spent USD 44.31 million on salaries. This means USD 44.31 million that impacted local economic development through local consumption and private investments. On average, each employee earned about USD 5000 per year, which is far above the average GDP per capita in the EAC region (USD 966 in 2017)³⁵.

Figure 3: Share of employees at different qualification levels

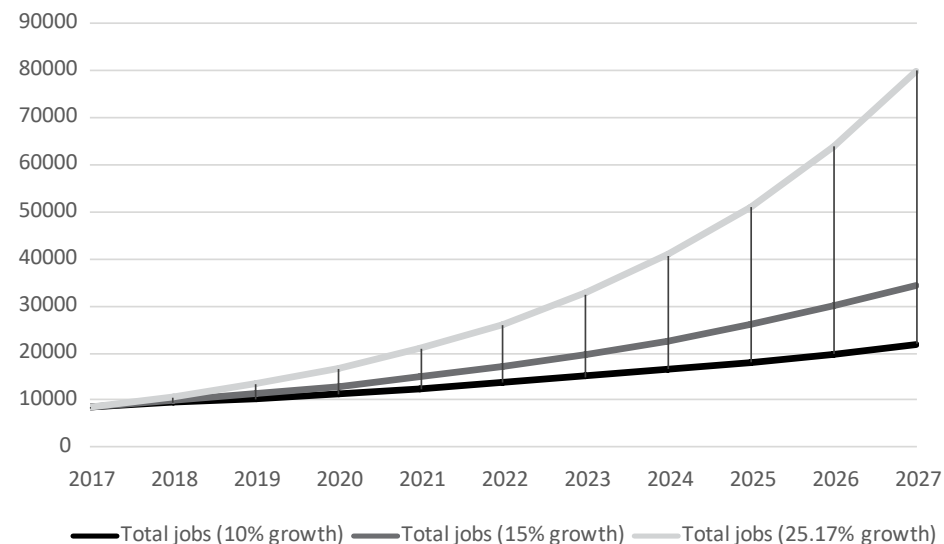


Applying the expected industry growth rate of 15%, we will see employment in the industry rise to more than 34,000 jobs by 2027 (see Figure 4). Taking the desired 25.17% growth rate needed to reach the targets of the RPMPOA, employment will increase to ca. 80,000. Again, this does also not include the jobs created through spill-over effects to the upstream industries like packaging material production or downstream distribution of medicines. Studies of the European pharmaceutical industry showed that each job in the pharmaceutical industry carries another 4.7 jobs in the overall labour market³⁶. For East Africa, this would contribute an additional employment effect of up to 39,750 positions.

³⁵ Data from Wordbank (2017): <https://data.worldbank.org/>

³⁶ European Federation of Pharmaceutical Industries and Associations (2016). The Economic Footprint of Selected Pharmaceutical Companies in Europe. Retrieved from: https://www.wifor.com/tl_files/wifor/PDF_Publikationen/161219_Efpia_EF_report_WifOR_updated.pdf

Figure 4: Projections for jobs at different growth rates



Additionally, every company reports to offer in-house training and capacity development programmes for their employees³⁷. Annually, companies train about 800 students in the region as part of internship or attachment programmes contributing to the overall skill development in the economy and improving employability of graduates. Finally, as the number of pharmacy and pharmacy-related (Pharma technology, microbiology, biochemistry, analytical chemistry, industrial chemistry etc.) university programmes in the EAC region has been increasing, and institutions are producing more graduates every year, the pharmaceutical industry can offer adequate positions for these talents if it continues to grow. Thereby, companies are preventing further brain drain from EAC economies.

Attraction of investments

The local pharmaceutical manufacturing sector has been successful in attracting international investments over the last years. In 2005, at the beginning of the push for more local manufacturing, Finnish development finance company *Finnfund* had bought a 10% share of Universal in Kenya, supplying it with capital and technical support³⁸. In 2016, Indian generic medicine manufacturer, Strides, had taken over a majority shareholding for an investment of almost USD 10 million³⁹. Also in 2005, Ugandan company Quality Chemicals Limited and Indian generic medicine manufacturer CIPLA had formed CIPLAQCIL, a joint Venture to produce ARVs and ACTs under license from CIPLA. In 2013, CIPLA acquired the majority shareholding of QCIL for an additional USD 15 million investment. QCIL has also attracted additional investors, namely TLG Capital Fund (a London-based frontier market investor) in 2009 and Capitalworks International Partnership Fund (an asset management firm specialized in mid-market companies in Sub-Saharan Africa) in 2010⁴⁰. The company is also the first pharmaceutical manufacturer

³⁷ FEAPM survey

³⁸ Finnfund (2016). Drugs producer sets an example for others in Africa. Retrieved from: https://www.finnfund.fi/ajankohtaista/uutiset16/en_GB/universal_corporation_kenya/

³⁹ Strides Shasun (2016). Strides Shasun to acquire controlling stake in Universal Corporation, Kenya. Retrieved from: http://www.stridesarco.com/pdf/pressrelease/2016/ss_universal_press_release.pdf

⁴⁰ CIPLAQCIL (2018). Partners. Retrieved from: <https://www.ciplaqcil.co.ug/partners/>

in East Africa considering to be listed on the stock market, offering 18% of their shares to the public and raising about USD 45 million⁴¹. In this way, CIPLAQCIL could diversify its equity source and contribute to the development of local financial markets⁴². Abacus Parenteral Drugs in Uganda was also successful in attracting a USD 9.5 million investment by SIFEM (Swiss Investment Fund for Emerging Markets), to build a new facility⁴³. Moreover, Aspen Pharma, the leading South African manufacturer, acquired a 60% share in Tanzanian manufacturer Shelys for an undisclosed amount in 2008. In 2012, it took over the remaining shares as well. Also in Tanzania, in 2016 the international development investment fund Catalyst Principal Partners bought a majority stake in Zenufa⁴⁴. The latest addition to this list is the decision by the leading Bangladeshi pharmaceutical manufacturer, Square Pharma, to invest USD 75 million in the first-ever factory abroad with a capacity of about two billion tablets and 60 million bottles of liquid medicines⁴⁵. Medicines will largely be for HIV/Aids, malaria, tuberculosis, diabetes and cardiovascular diseases in phases within five years of starting operations. In Rwanda, where no industrial-scale manufacturing of medicines is taking place at the time of writing, two companies have started building major pharmaceutical production facilities. Moroccan Cooper Pharma has commenced a USD 6 million project in December 2017⁴⁶ and Apex Biotech Ltd, a pharmaceutical manufacturing firm co-owned by Rwandans and Bangladeshi investors followed suit with a USD 18 million project in May 2018⁴⁷. In total this adds up to implemented or committed FDI of more than USD 135 million since 2010.

However, it is important to point out that many established manufacturers are also gathering funds for large-scale investments of their own. All respondents in the FEAPM survey confirmed that they have scheduled major investment projects in the next five years. Overall, the industry estimates to invest about USD 139.7 million until 2023, exceeding the ca. USD 100 million of planned foreign investments mentioned above (Square, Cooper, Apex) by almost 40%. 35% of respondents mentioned that they have scheduled completely new manufacturing facilities. The remainder is looking at capacity expansions, improving their machinery, moving into new product categories or invest in adhering to international WHO manufacturing standards. The success of these investment projects will significantly affect the growth of the local industry. New entrants to the market and established producers entering new markets may drive up the share of local production more than anticipated.

Trade benefits

Increased local production of medicines has the potential to save foreign exchange reserves of more than USD 1.38 billion, which were required to pay imports of medicines to the region in 2017⁴⁸. While this number had been increasing until 2015, imports have decreased by 10% since then. This is the result of the falling value of imports to Kenya and Uganda in the past three years (see Figure 5), where local manufacturing has improved their foothold. Yet, increasing imports to the remaining four partner states weakens the overall trend.

⁴¹ Daily Monitor (2018). Cipla share price rises by 1.2 per cent. Retrieved from <http://www.monitor.co.ug/Business/Markets/Cipla-share-price-rises-by-1-2-per-cent/688606-4769982-80j98cz/index.html>

⁴² Observer (2018). Drugs firm, Cipla to list on Ugandan stock market. Retrieved from: <https://observer.ug/special-editions/58340-drugs-firm-cipla-to-list-on-ugandan-stock-market.html>

⁴³ SIFEM (2014). Abacus Parenteral Drugs. Retrieved from: <http://www.sifem.ch/impact/case-studies/show/abacus-parenteral-drugs-ltd/>

⁴⁴ Catalyst Principal Partners (2016). Catalyst Principal Partners Acquires a Majority Stake in Tanzanian Pharmaceutical Manufacturer. Retrieved from: <https://www.catalystprincipal.com/catalyst-principal-partners-acquires-a-majority-stake-in-tanzanian-pharmaceutical-manufacturer/>

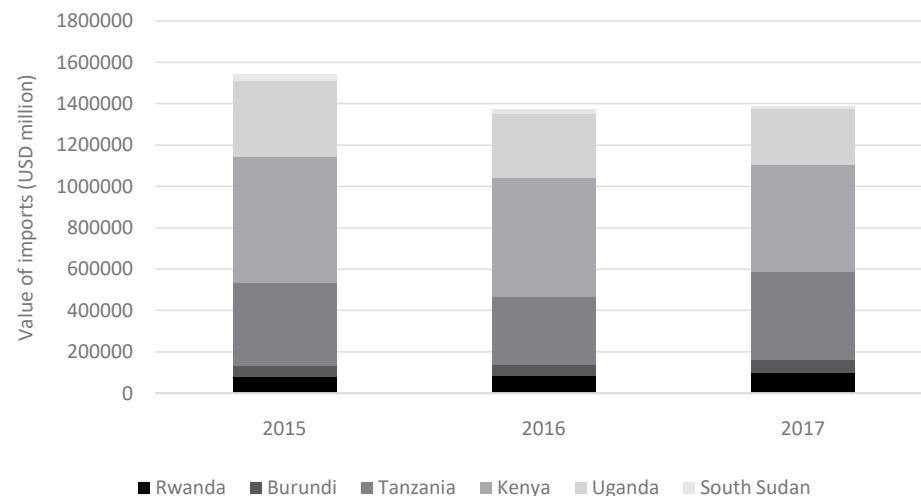
⁴⁵ The Daily Star (2018). Square Pharmaceuticals begins constructing Kenya plant. Retrieved from: <https://www.thedailystar.net/business/global-business/square-pharmaceuticals-begins-constructing-kenya-plant-1517668>

⁴⁶ Rwanda Development Board (2018). RDB, COOPER PHARMA launch Construction of Pharmaceutical plant at the Kigali Special Economic Zone. Retrieved from: <http://rdb.rw/export/hello-world/>

⁴⁷ The New Times (2018). Apex Biotech to open \$18 million drug plant in Kigali. Retrieved from: <https://www.newtimes.co.rw/news/apex-biotech-open-18-million-drug-plant-kigali>

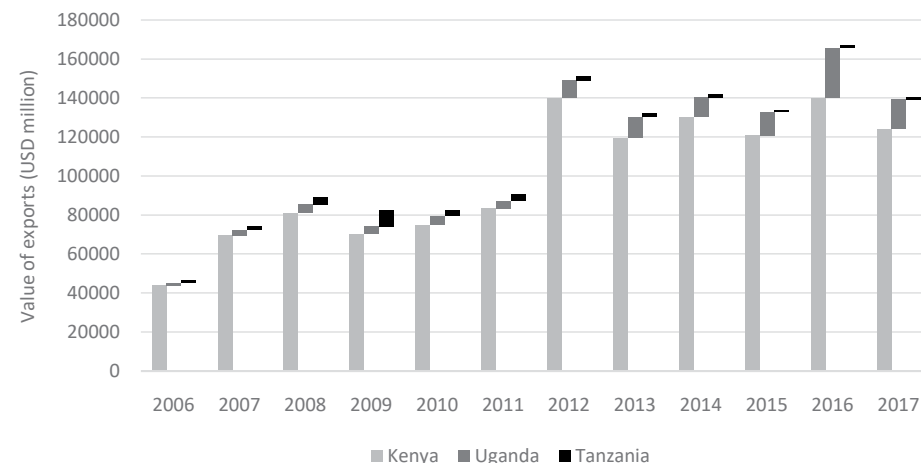
⁴⁸ International Trade Centre (2018). International Trade Statistics 2001-2017. Retrieved from: <http://www.intracen.org/itc/market-info-tools/trade-statistics/>

Figure 5: Pharmaceutical imports of EAC countries



Local manufacturers are also expanding their horizon in exporting medicines and earning foreign currency for their economies. Between 2006 and 2017, exports have almost tripled from USD 46.4 to USD 140.4 million⁴⁹ (see Figure 6). Kenya carries the lion share with about USD 120 million in exports. A recent study found that export makes up about 30% of Kenyan companies' revenues. The leading companies gather about 50% of their income from export activities.⁵⁰ Yet, Uganda's pharmaceutical exports are growing fast as well. Between 2006 and 2017, its exports increased from USD 1.4 to USD 15 million. This shows that with adherence to higher quality and international production standards, companies can exploit export potential.

Figure 6: Pharmaceutical exports of EAC countries



⁴⁹ ibid

⁵⁰ Vugigi, S. (2017). Assessment Of The Pharmaceutical Manufacturing Industry In Kenya To Forecast Local Production Sufficiency. PhD thesis in the school of pharmacy of Kenyatta University.

In terms of geographical reach, about two thirds of exports still remain within the EAC market⁵¹. However, East African medicines have increasingly spread throughout the whole continent. Companies report to have exported medicines to thirteen non-EAC countries in 2017, as shown on the map in Figure 7. Moreover, they have obtained permits and product registrations to drastically expand their export portfolio. East African exports have covered almost all neighbouring countries and are slowly moving further into Southern and West African markets.

Figure 7: Export destination countries for EAC Pharmaceutical Manufacturers



Spill-overs and value chain

Finally, it is important to not only look at the size of the pharmaceutical industry alone, but on the spill-over effects into other sectors. About 30-40% of the industry's total production costs stem from the EAC region, according to the FEAPM survey. This share could be much higher, if supplying industries could improve their capacities. Nonetheless, the current share already signifies a direct spill-over effect from pharmaceutical industry to the rest of the EAC of about USD 91.29 million in 2017 alone. Of these USD 91.29 million, about 49% went directly to East African households through their salary income. Another large benefactor is the packaging industry⁵². A study shows that in Kenya, all outer cartons and more than 50% of plastic bottles used by the local pharmaceutical industry were produced in Kenya⁵³. Yet, there remains potential for growth, as manufacturers struggle to find sufficiently high-quality packaging material for more complicated products like sterile injectables or glass bottles. For non-packaging inputs like excipients or API, the potential for spill-overs is even higher. The established companies in Kenya imported 94% of the APIs and 91.7% of excipients needed for the fabrication of medicines. Additionally, the pharmaceutical industry is a strong contributor to government finances. Applying a uniform corporate tax rate of 30% on revenue across the EAC, the industry transfers up to USD 96 million to national finance ministries. In addition, in 2017 employees will pay income taxes on their salaries of more than USD 45 million. All in all, evidence from other parts of the world shows that for every dollar of gross value created by pharmaceutical manufacturing, an additional value of USD 0.3 (South Africa) to 2.3 (EU) and 2.5 (USA) is created through direct and spill-over effects⁵⁴.

III.II Evidence for Public Health Impact

Medicine prices	<ul style="list-style-type: none"> • Price comparisons vary immensely from product to product and between manufacturers • Two Kenyan studies show that if local products exist, procurement prices are lower on average than for imports • KEMSA tender data shows that local manufacturers become more competitive • Tanzanian study finds that locally made products are cheaper on average than imports
Better quality of medicines	<ul style="list-style-type: none"> • Quality assurance of local products through regulators is very strict • No major difference observed in quality of imports versus locally-made medicines
Higher availability and health security	<ul style="list-style-type: none"> • Lead times of local manufacturers <ul style="list-style-type: none"> • If in stock: 1-2 days • If raw material in stock: 1-4 weeks • If raw material not in stock: 1-2 months • Delivery time for imported medicines: 2-3 months • Survey: 88% of distributors have used local manufacturers to respond to stock-outs in emergencies
Local adaptation of medicines	<ul style="list-style-type: none"> • Adaptations of formulas (e.g. reformulation for rural consumption) • Adaptation of packaging (e.g. information in Kiswahili) • Product development cooperation in international partnerships (e.g. DNDI or CHAI)

⁵² Banda, G., Wangwa, S., & Mackintosh, M. (2016). Making Medicines in Africa: An Historical Political Economy Overview. In: Making Medicines in Africa. The Political Economy of Industrializing for Local Health. Basingstoke: Palgrave Macmillan

⁵³ Vugigi, S. (2017). Assessment Of The Pharmaceutical Manufacturing Industry In Kenya To Forecast Local Production Sufficiency. PhD thesis in the school of pharmacy of Kenyatta University.

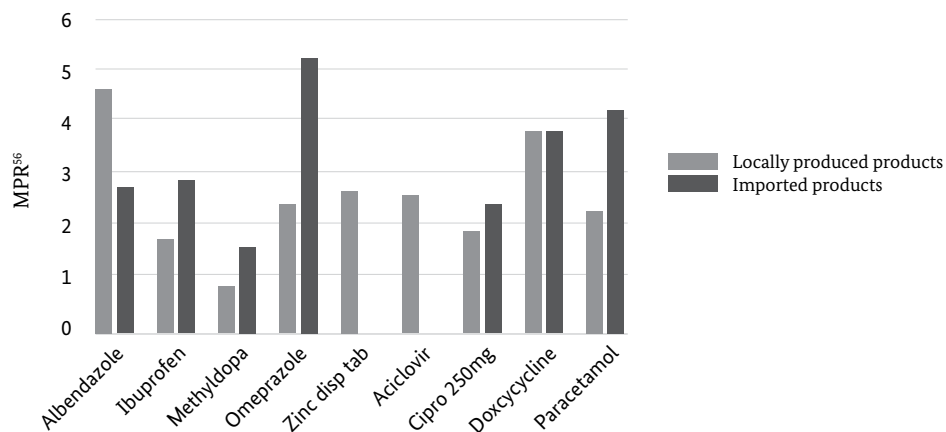
⁵⁴ European Federation of Pharmaceutical Industries and Associations (2016). The Economic Footprint of Selected Pharmaceutical Companies in Europe. Retrieved from: https://www.wifor.com/tl_files/wifor/PDF_Publikationen/161219_Efpia_EF_report_WifOR_updated.pdf; BAK Basel Economics (2015). The Importance of the Pharmaceutical Industry for Switzerland. Retrieved from: https://www.bak-economics.com/fileadmin/documents/reports/The_Importance_of_the_Pharmaceutical_Industry_2015_Interpharma.pdf; Department of Trade and Industry, Republic of South Africa (2017). Portfolio Committee on Economic Development the dti's involvement in the State's procurement of ARV's. Retrieved from: (20<https://www.thedti.gov.za/parliament/2017/Pharmaceuticals.pdf>)

Lower medicine prices

While there is no overall assessment for all products and countries, it can be stated with confidence that local manufacturers can offer competitive prices compared to imports. Otherwise, they would not be able to operate in a free market. Yet, the dynamics of pricing are complicated and need to be looked at on a case to case basis. Thus, the evidence presented here may only give indications towards the more general statement that medicines made in the EAC can, in principle and in practice, compete with imports on price.

A 2018 study on Kenya by Health Action International and GIZ showed that when looking at both patient and procurement prices for a sample of 31 essential medicines, products made in Kenya were generally cheaper than imports⁵⁵. Procurement prices were on average 30 percent (public sector) and 25 percent (mission sector) lower for Kenyan-made medicines. Figure 8 shows that the gap varies widely from product to product.

Figure 8: (HAI STUDY): Patient prices (in median price ratios), Kenyan public sector, individual medicines



However, high mark-ups along the supply chain eat up almost all benefits of cheaper procurement prices for local products. In Kenya, average wholesaler margins make up about 21% of the patient price. In the US, in contrast, this margin lies at only 4%⁵⁷. The data in the HAI study found that median mark-ups between patient prices and KEMSA procurement prices were actually higher for locally produced products (177%) than imports (35%), with wide variation for individual brands. In the mission sector, the mark-ups also inflated prices substantially, but imported products were still 33% more expensive

⁵⁵ HAI (2018). Prices and Availability of Locally Produced and Imported Medicines in Kenya Report. Retrieved from: <http://haiweb.org/what-we-do/price-availability-affordability/measuring-the-availability-and-prices-of-locally-produced-and-imported-medicines/>

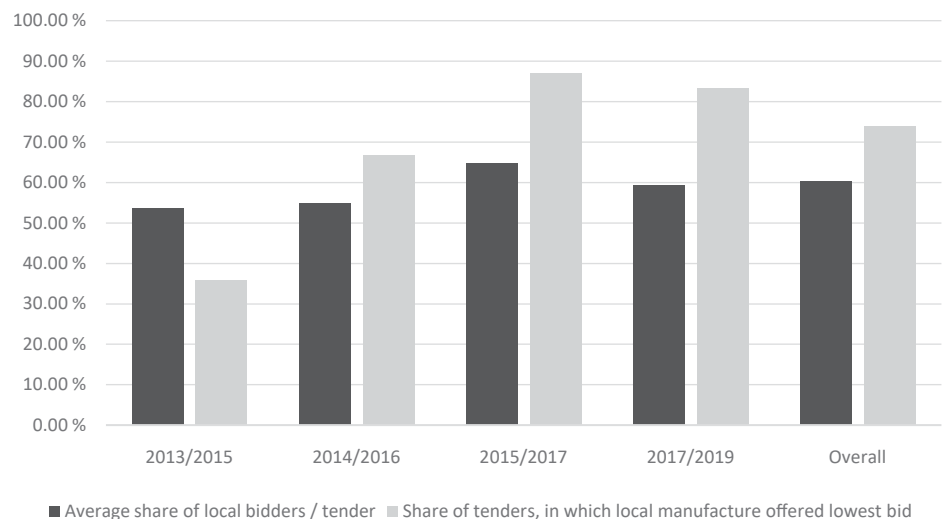
⁵⁶ An MPR is the ratio of the median price in local currency (Kenyan Shilling, KSh) divided by an international reference price converted to KSh. The use of reference prices serves as an external benchmark for price comparisons. An MPR of 1 means the Kenyan price is equivalent to the reference price, whereas an MPR of 2 means the Kenyan price is twice the reference price.

⁵⁷ Sunderji, N. (2018). The essential transformation of supply chains in the sub-Saharan pharmaceutical sector. In: Improving The Quality And Accessibility Of African Medicine. Proparco.

than locally produced medicines. The same pattern holds true in the private sector where patients were paying 48% more for imported products than for locally produced products. A different study confirmed that price competitiveness really depends on the product. In 39.5% of observed pack sizes, a local product beat imports on price, while for 13.2% prices were about similar.⁵⁸

Another indicator that proves the competitiveness of local products with regards to price can be extracted from KEMSA's tender data. Since 2012, KEMSA works with framework contracts that allow manufacturers to deliver smaller batches every three to four months instead of a single large delivery. This makes it easier for local manufacturers to access the public procurement market (see Case Study 2). Figure 9 shows that the share of bids in solid formulation tenders from local manufacturers has increased over the past five years. Moreover, the **share of tenders, in which local manufacturers provided the lowest bid has climbed from 35% to over 80%** in the same time. This underlines the jump in price competitiveness of local manufacturers.

Figure 9: Performance of Kenyan manufacturers in KEMSA tenders (solid formulations, excluding ARVs & ACTs)



Looking at certain categories in the HAI study, one can see that local manufacturers in Kenya compete especially well on antifungal clotrimazole cream, ibuprofen, or omeprazole for stomach and throat conditions. Yet, even medicines for chronic diseases like metformin (diabetes) or methyldopa fare relatively well. For each commonly-used diabetes or cardiovascular product, you may find a lower-priced Kenyan-made generic version.⁵⁹

⁵⁸ Vugigi, S. (2017). Assessment Of The Pharmaceutical Manufacturing Industry In Kenya To Forecast Local Production Sufficiency. PhD thesis in the school of pharmacy of Kenyatta University.

⁵⁹ Satzke, R. (2018). The Contribution Of Local Manufacturing In The Reduction Of Medicine Costs. Cosmos Company Presentation.

Outside of Kenya, there is less data available. Yet, HAI had performed a similar analysis in Tanzania in 2013⁶⁰. Here, locally made products were also cheaper in government procurement. Imports observed were 94% more expensive. However, here as well, higher mark-ups on locally-made products outbalanced cheaper procurement prices and equalized patient prices for local and imported generics in public and private sectors. In the mission sector, patient prices of locally made medicines were still cheaper. Examples of products that were notably cheaper were, for instance, sulfamethoxazole and trimethoprim tablets (antibiotics) or sulpyrimethamine (antimalarial). Here patients could save up to 50% if they bought products made in Tanzania. All producers examined in the FEAPM survey could directly point to products that are cheaper than comparable imports. Tanzanian producers, for instance, mentioned that they beat importers on the price of cough syrups, antiseptic wash, or the antibiotics metronidazole and cotrimoxazole. While there are no official price comparison studies for Uganda as yet, all manufacturers taking part in the FEAPM survey were comfortable to list products in which they outcompete imports on prices. Examples ranged from paracetamol and iodine to amoxicillin and cotrimoxazole. Respondents from Burundi also report to be cost-competitive in similar product categories.

Overall, the common perception that local manufacturers are not competitive with imports on price seems flawed. In some categories where prices have flatlined internationally (e.g. beta lactam antibiotics), they may struggle to compete, but across the board there is evidence that they fare well. One needs to stress that inflated patient prices have little to do with out-of-factory prices, but are a result of unacceptably high retail and distribution margins. Price advantages of local manufacturers are nullified through these added costs. Moreover, there are first reports of Kenyan manufacturers that fear that local manufacturers are even becoming too competitive on price, especially in the public procurement market. In the long-term, this may reduce the number of companies in the market and undermine security of supply. Thus, a sole focus on pushing prices down to an extreme low is also not desirable. This is why some procurement bodies like the Global Fund have gone over to basing tenders not on price alone anymore, but factor in other performance indicators⁶¹. Generally though, there is potential for more affordable medicines in East Africa through local production. Bangladeshi pharmaceutical company Square Pharma explains their investment in Kenya by arguing “that local pharmaceutical production has potential to reduce cost of drugs by 40 per cent and bring about greater access to essential drugs⁶²”.

Better quality of medicines

There are no overarching studies testing the quality or failure rates of locally produced medicines compared to imports. However, there is plenty of anecdotal evidence that local manufacturers have made large progress with regards to quality over recent years. FEAPM reached out to nine public and private medicine distributors across the EAC. The large majority confirmed that local manufacturers have made significant improvements in recent years. If problems occur, they tend to be rather minor issues like cracking tablets or packaging problems. Generally, all respondents pointed out that the regulatory agencies are doing a good job of assuring medicine quality and safety of local manufacturers. In a different study, a respondent working at a Tanzanian health centre underlined the advantage of having local oversight... “the health system will be in a position to monitor right from the primary stage of production, and quality of drugs would be assured right at the factory level⁶³”. Civil society procurement organizations like the NGO Action Medeor or Kenyan MEDS also directly test batches on site or prequalify manufac-

turers through their own experts. Such an approach to direct quality assurance would be more limited with suppliers in Asia⁶⁴. A 2010 study points out that Tanzanian regulators have limited capacity to critically monitor if Indian producers are following all procedures for making safe and effective medicines.

Substandard and falsified medicines are a severe public health threat in the EAC, mainly coming to the region as imports. The Kenyan Association of Pharmaceutical Industries estimates that counterfeit medicines capture 20-25 % of the local market⁶⁵. Other studies show that up to a third of all malaria medicines in Tanzania and Uganda are of substandard quality, mostly imported from India and China⁶⁶. A 2016 study by the World Customs Organisation found that the port of Mombasa belongs to the top four entry points for fake Chinese and Indian medicines to the continent⁶⁷. At the same time, more established, reputable producers from India have gradually retreated from the market, as they struggle with low-price competition from less quality-conscious Indian manufacturers and complained about inadequate enforcement to prevent the sale of substandard medicines⁶⁸. Thus, it must be underlined that international imports are not of a uniform high quality, as was also pointed out by the distributors responding to the FEAPM survey. The variation in quality among imported products is much higher than among medicines produced locally under strict supervision of regulatory agencies.

Another proxy for quality can be found in client satisfaction rates. Exit interviews with medicine purchasers in rural areas in Tanzania showed, for example, that more than 50% preferred Tanzanian-made products over imports for treatments against pneumonia and diarrhoea, while over a third preferred locally-made antimalarials⁶⁹. Asked about the preference of their clients, responding distributors in the FEAPM survey stated that some patients still perceive imported products as being of slightly higher quality. However, there is no clear preference and some even ask directly for locally made products, as they associate local products with stricter quality assurance through the regulator⁷⁰.

Quality improvements among pharmaceutical manufacturers can be seen on multiple levels. Overall, the EAC GMP Roadmap Framework and national GMP roadmaps in Kenya, Tanzania and Uganda lay out a clear path for industry and regulators to bring producers in the EAC up to stringent international production standards within the timeframe of the 2nd RPMPOA 2017-2027. The willingness of companies to support the development of these GMP roadmaps underlines their commitment to quality improvements. Individual companies are leading this process and have already reached WHO GMP levels. Two companies (Universal and CIPLAQCIL) have achieved WHO prequalification for selected ARVs and antimalarials. This allows them to supply to international procurement bodies like Global Fund, PEP-FAR or UNICEF. In addition to the companies' efforts and investments, EAC governments have also improved the quality infrastructure for the pharmaceutical industry as well as regulatory oversight in the last years⁷¹. In this way, the regulatory environment induces a better performance with regards to quality.

⁶⁰ HAI (2016). Prices and Availability of Locally Produced and Imported Medicines in Tanzania Report. Retrieved from: <http://haiweb.org/publication/price-availability-local-vs-imported-meds-in-tanzania/>

⁶¹ Mackintosh, M, Mugwaga, J, Banda, G, Tibandebage, P, Tunguhole, J, Wangwe, S, & Njeru, M. (2018). Health-industry linkages for local health: reframing policies for African health system strengthening. *Health Policy Planning*, 33, 602-610

⁶² Business Daily Africa (2018). Bangladeshi firm breaks ground for Sh7.5bn drugs plant in Athi River. Retrieved from: <https://www.businessdailyafrica.com/corporate/companies/Bangladeshi-firm-breaks-ground-Sh7-5bn-drugs-plant-Nairobi/4003102-4255652-bke8v3z/index.html>

⁶³ Mackintosh, M., Tibandebage, P., Njeru, M., Kungu, J., Israel, C., & Mujinja, P. (2018). Rethinking health sector procurement as developmental linkages in East Africa. *Social Science & Medicine*, 200, 182-189.

⁶⁴ Mackintosh, M, Tibandebage, P, Kungu, J, Njeru, M., & Israel, C. (2016). Health Systems as Industrial Policy: Building Collaborative Capabilities in the Tanzanian and Kenyan Health Sectors and Their Local Suppliers. In: *Making Medicines in Africa. The Political Economy of Industrializing for Local Health*. Basingstoke: Palgrave Macmillan.

⁶⁵ Daily Nation (2017). The poison in your cabinet: Kenya's fake drugs scourge. Retrieved from: <https://www.nation.co.ke/health/Inside-Kenya-fake-drug-scourge/3476990-3997826-aci8bk/index.html>

⁶⁶ Nayyar, G., Breman, J., Newton, P., Herrington, J. (2012). Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa. *The Lancet*, 12, 488-496.

⁶⁷ Daily Nation (2017). Fake China, India drugs put Kenyans at risk. Retrieved from: <https://www.nation.co.ke/business/Fake-China-India-drugs-put-Kenyans-at-risk/996-3955714-e3a55t/index.html>

⁶⁸ Chaudhuri, S., Mackintosh, M. and Mujinja, P. (2010). Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania. *European Journal of Development Research*, 22(4) pp. 451-468.

⁶⁹ Mujinja, P., Mackintosh, M., Justin-Temu, M., & Wuyts, M. (2014). Local production of pharmaceuticals in Africa and access to essential medicines: 'urban bias' in access to imported medicines in Tanzania and its policy implications. *Globalization and Health*, 10:12.

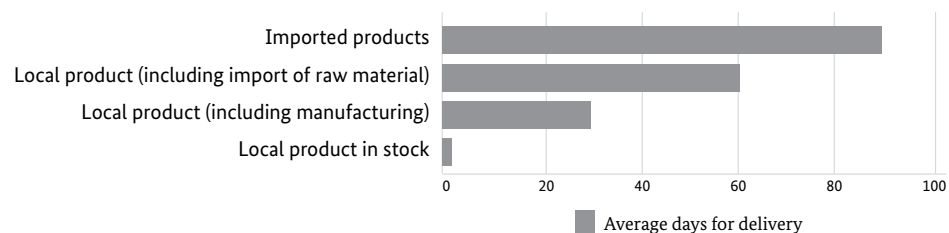
⁷⁰ FEAPM survey

⁷¹ EAC (2017). Regional Pharmaceutical Manufacturing Plan of Action 2017-2027. Retrieved from: <http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017%E2%80%932027.pdf>

Higher availability of medicines and health security

Local producers of medicines in the EAC have a major advantage over manufacturers based abroad in that they can deliver at a much faster and more flexible rate. All distributors in the FEAPM survey noted that local manufacturers supply more rapidly. Most producers across the EAC testify that they keep about one month's stock available, which means they can, on average, deliver a batch within 24-48 hours to local clients. In case of stock-outs or direct orders, lead times including manufacturing and delivery can be between a week and a month depending on the company and the product. Only in the case that API or other raw materials are not in stock, the manufacturing cycle can then extend up to three months. This stands in contrast to the time needed for the delivery of imported goods. Distributors responded in the FEAPM survey that local medicines are usually available within days or few weeks, while imports take between two and three months to arrive (see Figure 10).

Figure 10: Speed of delivery



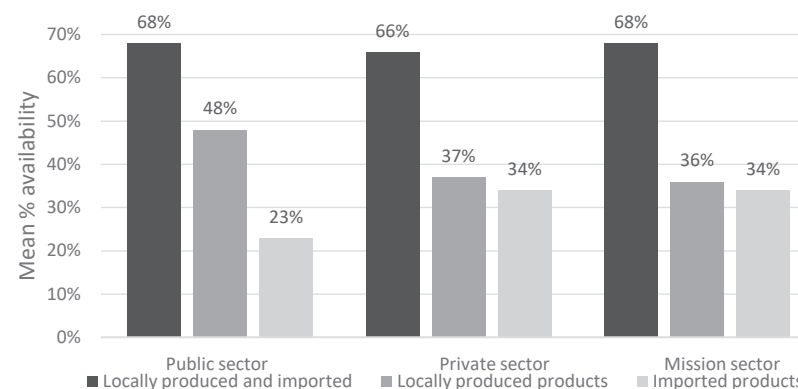
Research shows that this advantage of faster delivery can translate into better availability of locally produced medicines. In Kenya, a HAI study found that medicines made in Kenya were more likely to be found in public sector outlets than comparable imported brands⁷² (see Figure 11). For some products like paracetamol or metformin, the availability gap between imported and locally made medicines was even larger. This supports that local manufacturers can ensure a more reliable or flexible supply-chain. In Tanzania, locally made products are especially relevant for reliable supply in rural areas. For instance, a study found that 66% of tracer medicines in four rural districts were made in Tanzania⁷³. In contrast, imported medicines showed an urban bias, meaning they were more available in urban centres than in rural outlets⁷⁴. Local producers appear to engage more actively in the distribution of their products even to less affluent rural regions, as they rely more heavily on domestic sales than foreign brands. For that purpose, they have built strong distribution networks and partnerships with pharmacies and health centres throughout the EAC countries, which can directly source from the manufacturer. This benefit makes local manufacturing a pro-poor approach to medicine policy, contributing to poverty reduction in rural areas.

⁷² HAI (2018). Prices and Availability of Locally Produced and Imported Medicines in Kenya Report. Retrieved from: <http://haiweb.org/what-we-do/price-availability-affordability/measuring-the-availability-and-prices-of-locally-produced-and-imported-medicines/>

⁷³ Chaudhuri, S., Mackintosh, M. and Mujinja, P. (2010). Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania. *European Journal of Development Research*, 22(4) pp. 451-468.

⁷⁴ Mujinja, P., Mackintosh, M., Justin-Temu, M., & Wuyts, M. (2014). Local production of pharmaceuticals in Africa and access to essential medicines: 'urban bias' in access to imported medicines in Tanzania and its policy implications. *Globalization and Health*, 10:12.

Figure 11: (HAI STUDY): Mean percentage availability / sector (Kenya)



All EAC Partner States are still fighting with stock outs of essential medicines. Here short lead times and flexible production cycles of local manufacturers have helped to alleviate problems. 88% of the interviewed public and private distributors across the EAC stated that they have regularly made use of local manufacturers to overcome shortages in supply. Kenyan faith-based distributor MEDS has built a good reputation for being among the most reliable suppliers in times of emergencies. MEDS management argues that they could achieve this only through flexible contracting with local manufacturers⁷⁵. Similarly, public distributor KEMSA is now using framework contracts with local manufacturers to improve response times. A Tanzanian study showed that local manufacturers are already closing gaps where imports are delayed⁷⁶. In this way, local pharmaceutical manufacturing is improving local health security for EAC Partner States by closing gaps in supply and making sure that medicine availability is more stable.

Local adaptation of medicines

Finally, local manufacturers contribute to public health gains by being better able to cater to local needs and undertake adaptations of their products. With regards to local needs, producers are currently covering about 66% of disease categories, but are actively expanding their portfolio, especially with regard to the change in disease burden towards the need for affordable treatments of non-communicable diseases⁷⁷. They may currently fulfil the demand in many basic product lines like several antibiotics or painkillers. Capacities are often not even fully exhausted and are capable of taking over a larger share of the current demand. For that, diversification is however essential.

With regards to adapting products to local needs, many interviewed distributors, especially in Tanzania and Kenya, argue that it can be a good advantage that locally made products come with labels in the local language. This is predominantly relevant for Kiswahili in rural Tanzania or Kenya. It allows for more reliable medicine use and health education, especially in rural settings. Moreover, the majority of EAC producers stated that they have undertaken in-house reformulation activities to adapt medicines to local standards or requirements. Examples are new formulations that facilitate consumption in rural areas or new forms of sustained release formulations. On top of that, local manufacturers are increasingly involved in international product development partnerships with institutions like *Drugs for Neglected Diseases Initiative (DNDI)* or the Clinton Health Access Initiative.

⁷⁵ Mackintosh, M., Mugwagwa, J., Banda, G. Tunguhole, J. (2017). Local production of pharmaceuticals and health system strengthening in Africa: An Evidence Brief. German Health Practice Collection. Berlin: BMZ

⁷⁶ Chaudhuri, S., Mackintosh, M. and Mujinja, P. (2010). Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania. *European Journal of Development Research*, 22(4) pp. 451-468.

⁷⁷ EAC (2017). Regional Pharmaceutical Manufacturing Plan of Action 2017-2027. Retrieved from: <http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017%E2%80%932027.pdf>

IV. Case Study A: Local Manufacturing and Public Procurement – Collaborating for Lower Prices and Better Availability of Medicines.

A Conversation With Biodeal Laboratories

Biodeal is a family-owned pharmaceutical manufacturer in Kenya with about 230 employees. It started off as a drug distribution company founded in 1976 under the name of Ray Pharmaceuticals. In 1989, Dhirendra Shah moved the company into manufacturing under the current name Biodeal Laboratories Limited. His son Nihal Shah has entered the family business and helped Biodeal to set up a new manufacturing site, expanding their scale.

Q: Why did producers like Biodeal use to have troubles accessing the public procurement market?

Biodeal: Of course, a major challenge was our own capacity. Many producers including ourselves needed to make some progress with respect to competitiveness. However, for us, the biggest hurdle has been the tendering and contracting procedure of KEMSA. It used to be the case that KEMSA would tender one large order of a specific product once every two years. This would bind all of our capacities for a long time and strip us of all cash, as we needed to go in advance for raw material and other costs of production. This is a huge problem, as costs of finance are incredibly high in East Africa. On top of that, payments were often delayed and, thus, our cash flow severely interrupted. Accordingly, we used to be hesitant to commit too much of our capacities to the public procurement market. The private market with its more constant demand was much more attractive to us and other local producers.

Q: So what did change for Biodeal and others to become interested in supplying more strongly to the government?

Biodeal: Well, of course we did our part by investing heavily. We changed our layout to a more efficient production, bought new machines and built a new warehouse for more raw materials. Our general goal in the past years was to improve efficiency and delivery times as well as to increase production capacity and quality. However, in our eyes, the biggest change came through new policies at KEMSA. The introduction of framework contracts in 2012 made a huge difference: KEMSA still tenders for two year periods. However, now, if you win a tender, you may deliver in smaller batches every three to four months with a fixed price. This also means that manufacturers get paid more regularly. Instead of having a huge payment every two years or so, the cash flow is now more stable. This assured market helps us to commit to further long-term investments into our production processes.

Q: What impact do you think local manufacturers can have on public procurement?

Biodeal: Overall, local manufacturers can help to significantly improve the supply and reliability of essential medicines. We are able to deliver medicines faster in some situations, as long as APIs are available. Also KEMSA will be able to act more efficiently when it comes to stocking needs, as they need smaller warehouses and have less logistics costs. Moreover, they can rely on us when it comes to emergency stock outs.

Q: How about the development of medicine prices?

Biodeal: Actually, we have seen a decrease in average medicine prices since the introduction of the framework contracts. The framework contracts have low entry barriers and accordingly, there is strong local competition and various new market entrants comprising of traders as well as manufacturers. From an access to medicines perspective this is a welcome development. Yet, if the prices get too low, some might exit the market again. We personally strongly feel the competitive pressure. While we have won more orders from KEMSA, we also see that local competition has very aggressive pricing strategies. In the solid formulations market (not including ARVs and antimalarials), we find that local manufacturers have won more than 70% of all tenders since the framework contracts exist. Yet, this comes at the cost of vanishing margins. We might be forced to bid more selectively on more complex and higher margin products in the coming years to ensure our long-term viability and quality.

Q: What effect did the framework contracts have on Biodeal's overall business?

Biodeal: The KEMSA orders are definitely increasing. Thus, we are thus again increasing our capacity in various areas. We have investments of about USD 10 million in the pipeline including a new laboratory, a new creams and ointments plant, as well as one for liquid preparations and a pilot production facility for injectables and hormones. Yet, we are still forced to balance public and private markets, as the cash flow is still easier to manage in the private market. Generally, both markets are growing, which means our public procurement quantities will be growing too, albeit, as mentioned above, in a less price aggressive approach.

V. Case Study B: The Investment Case for Local Pharmaceutical Manufacturing

A Conversation with Zenufa Laboratories Ltd. and Catalyst Principal Partners

Zenufa started off in Tanzania as Mimco International, a major pharmaceuticals importer and distributor representing a portfolio of multinational companies such as Pfizer, Pharmacia Upjohn, Glaxo Wellcome and SmithKline Beecham. In 2005, through strategic collaboration with the Belgian Investment Company for Developing Countries (BIO), the company laid the foundation for the construction and commissioning of a cGMP facility in Tanzania under the stringent guidelines set out by the World Health Organization (WHO). After validation and qualification, its production started in mid-2007. Zenufa manufactures most essential drugs listed under the Essential Drugs list of the Ministry of Health, Tanzania in the form of tablets, capsules, oral liquids and dry syrups.

In August 2016, Zenufa became part of Catalyst Principle Partners Group of Companies, Nairobi. Catalyst is a private equity fund that invests in emerging and mid-sized companies with strong growth and profitability prospects. The Group has various operating companies that have diversified interests in many business sectors. They have acquired Zenufa Laboratories Ltd., Dar es Salaam Facility with a 90% equity shareholding.

Q: Why was Catalyst interested in investing into local pharmaceutical manufacturing in Africa?

Catalyst: There is a growing need for high quality, affordable healthcare products and services in East Africa. Generic medications make up an increasingly important part of the local healthcare eco-system. Thus, Catalyst saw an opportunity to earn attractive risk-adjusted returns whilst supporting local manufacturing of high-quality and affordable pharmaceutical medicines for the Tanzanian market.

Q: How did you choose Zenufa as the company to invest in?

Catalyst: Zenufa has the best manufacturing facility in Tanzania with a consistent quality supply of products. Moreover, it has developed a strong nationwide distribution infrastructure in Tanzania. This contributes to improving access to essential medicines outside the main urban areas. Also, the company has the ability to react rapidly and effectively to local market needs. We seem to have made a good decision, as we are expecting the business to double its sales and profitability in the next 2-4 years. Good news for our investors.

Q: Please share how the involvement of a large equity investor has changed the path of the company?

Zenufa: Our company struggled with skyrocketing costs of finance after a Belgian investor had pulled out and we had to rely on bank loans. We are talking about a change from 4-5% to 18% in interest rates. Additionally, management had run into troubles with its previous strategy of focusing on selling unbranded OTC products. When Catalyst came on board, it got involved in the redirection of the strategy from the start. Zenufa now has a strong board composition with two out of six board members being investors and four pharma experts. It is a very active board and influences strategic decisions. Since then, we have increased in volume as well as product ranges - especially in branded generics.

Catalyst: After our investment, a new management team was put in place with stronger focus on the business. We now lay emphasis on the quality of production and breadth of distribution with a product mix of essential and affordable medicines.

Zenufa has invested in its human resource capacities through more effective training and staff development. In addition, production processes and controls have been enhanced to increase the quality and consistency of the manufactured medicines. Over the next 2-3 years, Zenufa is seeking to significantly increase its sale volumes. The business has also been focusing on developing new, more effective product formulations to serve the Tanzanian people better. Finally, there is greater emphasis on developing and supplying drugs that are essential for the treatment of neglected diseases such as Malaria.

Zenufa: We have an agreement with the Drugs for Neglected Diseases Initiative (DNDI) to develop a new antimalarial combination therapy. DNDI transfers technology from Sanofi to Zenufa. The WHO pre-qualification of drug is still in process, but such a cooperation is a tremendous achievement for us and a sign for the advancements of local pharmaceutical manufacturing in the EAC in general.

Q: How is Zenufa working together with the Tanzanian government to make sure that local production is leading to public health gains?

Zenufa: We have a great working relationship with the Tanzanian Ministry of Health, Food and Drugs Authority and other government regulatory bodies to ensure the availability of adequate, quality locally manufactured medication. We have increased our supply to the Medical Stores Department since Catalyst is on board.

Q: Based on the experience with Zenufa, what is needed to make the pharmaceutical sector and Tanzania in general more attractive for investors?

Catalyst: First of all, we need a stable enabling macroeconomic environment. Specifically, government should continue to support local manufacturers, for instance through preferential government procurement or facilitating licensing of new formulations and products developed in Tanzania. Moreover, of course, continued emphasis on effective regulation and maintenance of production standards is a must. For that, it would be good to have appropriate checks and monitoring of imported products to ensure a consistency of quality and parity with local manufacturers. We cannot and do not want to compete with low-quality imports from countries that do not sufficiently control the quality of their exported medicines.

VI. Policy Implications

In order to grow the local pharmaceutical manufacturing industry in the EAC and fully reap its benefits, active Industrial Policy support is needed. The success of the industry in Bangladesh and Ghana is the result of strong government support that created an enabling environment for growth and improvements to quality, scope and scale of production. Figure 12 gives an overview of the tools used in these cases.

Figure 12: Overview of policy tools used in Bangladesh and Ghana to promote local production of medicines

Bangladesh	Ghana
<ul style="list-style-type: none"> • Import ban on medicines if produced by three or more producers at sufficient capacity • Multinationals (defined as companies having headquarters outside Bangladesh) were banned from producing medicines of low complexity like common painkillers, vitamins or antacids • Obligation to have local manufacturing entity or licensed local production for multinationals wanting to market products in Bangladesh • Industrial policy measures combined with price controls on medicines and generic prescription rules for doctors 	<ul style="list-style-type: none"> • Corporate tax exemption for 3 years after establishment • Import ban on 44 medicines produced locally at sufficient capacity • VAT (12.5%) exemption on local medicines • 66 of 200 basic materials required for production are exempted from import duty • Local purchase preference of 15%

On top of that, several countries, including India and Bangladesh, provide export subsidies to their pharmaceutical manufacturers. Companies enjoy a tax rebate on exports of medicines. They pay no income tax on exported products and, thus, can offer prices that are more competitive abroad⁷⁸. Accordingly, the playing field between local producers and importers is not actually level. For the East African Community, FEAPM proposes the following policy measures to support local pharmaceutical manufacturing:

1. Introduce a 25% import tariff on a list of selected medicines, for which sufficient and high quality local production capacity exists.

Rationale: For several medicines, multiple manufacturers have installed capacity that far exceeds demand in the EAC region and offer competitive prices. Yet, many of these products are still being imported to the region at 0% import tariffs. Next to creating unnecessary expenses of foreign exchange reserves, this practice does not take into account the value-addition of locally manufactured medicines. Thus, for non-sensitive (i.e. not life-saving in emergencies) products where no doubt exists that EAC manufacturers can deliver affordable, high quality medicines in sufficient quantity, import tariffs should be raised to the highest CET band of 25%. Initially, FEAPM proposes to start with:

1. Amoxycillin - Capsules and Dry Powder for Suspension
2. Ampicillin & Cloxacillin - Capsules and Dry Powder for Suspension
3. Co-trimoxazole - Tablets and Suspension

4. Paracetamol - Tablets and Suspension
5. Erythromycin - Tablets and Dry Powder for Suspension
6. Metronidazole - Tablets and Suspension
7. Ibuprofen - Tablets and Suspension
8. Ciprofloxacin - Tablets

To be added after validation

9. Dextrose 5% [500ml] and 50% [100ml] - i.v. infusions
10. Normal Saline 0.9% [500ml] - i.v. infusions
11. Ringers Lactate [Hartmanns solution] [500 ml] - i.v. infusions

Expected impact: Imports of protected products will be substituted by local supplies, as imports become too costly. Local manufacturers will have a more secure stream of income allowing them to make more ambitious investments and create quality jobs. Medicine prices and availability will remain stable, as there is ample domestic competition for all products on the list. If any adverse effects are recorded, the list can be easily revised.

2. Remove all duties on imports of raw and packaging material, pharmaceutical manufacturing related equipment as well as spare parts for the equipment.

Rationale: Currently, local pharmaceutical manufacturers face an unfair disadvantage versus importers. Imports of medicines are largely exempt from any kind of taxes or duties. However, several intermediate products for local manufacturing, e.g. packaging material still attracts taxes making it harder to compete with imports on price.

Expected impact: Prices of locally produced medicines will decrease even further. The playing field between importers and local manufacturers becomes more level.

3. Introduce a universal price preference margin of 20% for all pharmaceutical products manufactured in the EAC in all public tenders and remove similar preferences for local importers.

Rationale: Public sector procurement is an effective tool to promote local manufacturing. The 20% margin reflects the additional value-created through the local industry compared with imports.

Expected impact: Public procurement agencies increase their share of locally manufactured medicines. Through long-term engagement between manufacturers and public procurement agencies products and service can be improved, whilst manufacturers have a solid business foundation, on which they may build additional investments.

4. Enforce Article 35 of the Common Market Protocol, treating all manufacturers within the EAC as equal with respect to national incentives and preferences in procurement.

Rationale: Currently, preferences and incentives related to public procurement are implemented for national manufacturers only. However, in order to truly create a common market and provide more opportunity for economies of scale, preferential pricing should be open to manufacturers from any EAC country. This would be in line with Article 35 of the Common Market Protocol.

Expected Impact: Intra-regional trade will increase, as companies begin to compete in tenders in other EAC Partner States. Competitive pressures in a truly common market will keep prices down and market dynamics alive when import barriers on certain medicines are in place. Moreover, companies can build up economies of scale once they cater for the whole regional market.

⁷⁸ FEAPM (2018) Internal unpublished Report, FEAPM study tour to Bangladesh.

5. Harmonise medicine registration procedures within the EAC Partner States.

Rationale: Right now, local manufacturers need to adapt their registration applications to diverging national requirements across EAC Partner States. Harmonising these registration procedures would cut costs for local manufacturers and speed up registration processes. All registered products of any EAC manufacturer that has been jointly inspected by EAC regulatory bodies should automatically be registered in all other EAC countries.

Expected impact: Harmonisation is required to create a truly common market that will allow for economies of scale among local manufacturers. Moreover, due to harmonised registration procedures, medicines will be on the market quicker and reach patients earlier.

6. Streamline the implementation of pharmaceutical sector support in an East African Community Pharmaceuticals Management Bill.

Rationale: Currently, support programmes for the pharmaceutical industry are scattered and are partially of an ad-hoc character. The proposed bill would bundle support mechanisms together and encode them in a legal form.

Expected impact: This strategy will force all necessary public sector actors to work together to implement the programmes specified in the bill. Additionally, progress can be tracked by legislators and corresponding government performance kept in check.

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