HEALING THE GREAT RIFT:

Investing in the East African Pharmaceutical Sector to close the Medicines Supply Gap

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EXECUTIVE SUMMARY

As the East African population expands, the health sector in Kenya, Uganda, Tanzania and Rwanda is under extreme strain, both financially and organisationally.

Across the region's government and private (for-profit and not-for-profit) health sectors, over 90% of all drugs are imported, both legitimately and in the "grey" market. The majority are generics from India which are extremely price competitive, but erratic in terms of supply.

Stock-outs at pharmacies and hospitals are a recurring problem, especially but not exclusively in rural areas. These include drugs already in high demand such as antibiotics, but also drugs where demand is accelerating fast such as antidiabetics and antihypertensives, and medical sundries such as cotton wool, absorbent gauze, cannulas and giving sets. The gap between demand and supply is ubiquitous.

In diagnostic equipment, much of it is in need of repair and consequently out of use, sometimes for prolonged periods. Such equipment is always imported, meaning service support and maintenance is difficult. Even where technical support is available, supply of spare parts is often problematic.

These problems are widespread, systemic and highly detrimental to the health of the population. Without action they will get worse.

The role of the private sector in addressing this challenge is central. The East African Community (EAC) has published a second Regional Pharmaceutical Manufacturing Plan for 2017-2027 which argues for industrial policies to support local manufacturing at the national level. There is already zero duty on imports of raw materials and manufacturing equipment.

However, such policies have not yet had significant traction, partly because of the problems of access to capital but also perceptions of restrictive or burdensome regulation. Some of these perceptions are well-founded but not all, and the EAC regulatory harmonisation initiative is progressively improving the regulatory environment.

There is a lack of raw material and component suppliers and comprehensive support services for both pharmaceutical and medical equipment manufacturing. This problem is compounded by the lack of secure, temperature-controlled logistics and storage in many areas.

However, the upside is that these sub-sectors themselves, together with production of some of the simpler pharmaceutical products, medical equipment and devices, offer significant opportunities for inward investment. This would enable the necessary injection of capital and important technology transfer, at the same time as providing a bridgehead for foreign investors into the region.

With the right policy and regulatory framework in place, this could in turn help to stimulate economic growth, improve population access to medicines and address the mounting challenge of non-communicable diseases (NCD's) such as diabetes, hypertension and heart disease.

The most immediate foreign direct investment (FDI) opportunities are likely to be in the following sub-sectors:

- **Contract manufacturing of selected high volume products such as antibiotics, antidiabetics and antihypertensives**
- **Intravenous (IV) infusions, and potentially eye drops**
- **Pharmaceutical packaging**
- **Medical sundries and accessories**
- **Small scale diagnostic equipment (eg. ophthalmoscopes) and equipment maintenance/support services**
- **Healthcare data and logistics systems**

The key research findings by country are summarised overleaf.

Kenya:

- Of the four countries studied, Kenya has the most well-developed pharmaceutical manufacturing and distribution sector. The state-owned Dawa Pharmaceuticals was acquired by the distributor Medisel in 2004, and along with other domestic players has seen considerable growth since.

- However, overall inward foreign direct investment to Kenya declined markedly between 2018 and 2022. Then in 2023 GSK decided to close its manufacturing operation for prescription drugs. This followed Sanofi withdrawing from Kenya in favour of a distributor model in 2021.

- Several leading pharmaceutical companies in Kenya are nevertheless owned by foreign investors, and Mauritius and Japanese investors have recently been moving into the sector (completing deals with the distributor Harleys and the syringe manufacturer Revital).

- Medicines procurement and distribution in the government sector are problematic. There have been efficiency issues related to the Kenyan Medical Supplies Agency and some in the industry believe more competition should be introduced.

- The industry argues it will continue to be at a disadvantage versus imports unless tariffs are increased, a differential levy is imposed on products which are also manufactured in Kenya and product registration fees are increased for suppliers outside the East African Community (EAC).

- However, this may not build the necessary domestic capacity in the supply chain without investment in packaging and other input industries, and improvements in logistics, procurement and inventory management systems.

- In 2023 significant new legislation was introduced to advance universal health coverage, widening access to the national health insurance fund. This is likely to be a positive change for investors.

Uganda:

- Uganda experienced a marked growth in overall inward foreign direct investment between 2018 and 2022, and this is expected to continue with the recent discovery of significant oil reserves.

- Key inward investors include the Indian generics manufacturer Cipla which acquired Quality Chemicals and was in turn acquired by Africa Capitalworks in 2023. The company recently launched two new oral antidiabetics which they claim will be price competitive with imports.

- A further major manufacturer, Kampala Pharmaceuticals, is owned by the Investment Promotion Services arm of the Aga Khan Foundation.

- However, the current regulatory structure is considered by many commentators to be out of date. A large number of drug shops have developed, ostensibly to sell Class C (OTC) medication, but which also often sell prescription medication secured through the illegitimate or grey market.

- The private for-profit health sector is growing but underfunding of government health facilities has led to hospitals and clinics incurring problems with basic issues such as water supply. Without significant economic growth this is likely to get worse as international donor funding reduces.

- Procurement and distribution channels are less efficient in the government sector than in the private sector. Even drugs produced in Uganda can be in short supply, and simple products such as malaria testing strips can be unavailable in rural areas.

- There are gaps in planning and logistics, with deliveries of drugs to government facilities being missed or not having the right combination of drugs. Improved management information and tracking systems, as well as additional production capacity, represent an investment opportunity.

- Notwithstanding the recent success in attracting FDI, regulatory reform and prioritisation of the key pharmaceutical and medical supplies sub-sectors will be important in opening the market up further for inward investment.

Tanzania:

- Tanzania has the second largest economy in the region (after Kenya), but its pharmaceutical industry has not shown growth for some years, despite earlier innovations and growth in overall inward investment.

- Per capita spend on healthcare declined between 2017/18 and 2021/22 because, whilst the population has expanded, the proportion of government expenditure on health has remained constant at c7%.

- Domestic manufacturers are given a 15% advantage in government tenders for drug procurement. In 2016 a UNDP report also recommended the Tanzanian government should provide attractive credit terms to local manufacturers wanting to establish GMP-compliant plants, but this has not translated into increased investment in the sector.

- A network of Accredited Drug Dispensing Outlets (ADDO's) was established to improve access to a limited list of drugs in local, mostly rural, communities. However, regulation of these outlets has not been strong and many dispense prescription medication without the authority to do so.

- Several interviewees felt regulation by the Tanzanian Ministry of Health and the Medicines & Medical Devices Authority was too lax in some areas and too restrictive in others. However, Zanzibar (a semi-autonomous region) has less of a delay in registering new products than other countries in East Africa.

- There are problems with the planning, financing and logistics of supply to both government and private sector health facilities. Additional private sector investment to enable improved planning and delivery is critical to stabilising the health system and addressing the challenge of NCD's.

- Zanzibar, with its own Ministry of Health, distribution system and sector regulator but with strong links to policies in mainland Tanzania, could provide a valuable pilot territory for investors.

Rwanda:

- Rwanda has a much smaller territory than the other countries in this study. That may partly explain why it has the most efficient drug ordering and delivery system, although inventory management by importers is still a problem.

- Regional supply warehouses, emergency deliveries by drone and better data and communication systems all support the effective distribution of medicines, although according to the Ministry of Health the order fill rate for supplies is still only 72%.

- Stock-outs are less of a problem in Rwanda than in the other countries, but issues with diagnostic, specifically optical, equipment are still significant. The absence of any optical equipment manufacturing in the region means supplies are imported from a wide variety of countries, with associated time delays, import costs and problems with maintenance.

- Rwanda Medical Supply exercises a “procurement preference” which confers a 10% price advantage on locally manufactured products but there has not been a significant pharmaceutical manufacturing sector.

- The country has recently attracted greenfield pharmaceutical FDI from Morocco (Cooper Pharma) and Germany (BioNTech) in a Special Economic Zone outside Kigali. However, there have been difficulties, including legal action by the government against LEAF Pharmaceuticals from the USA.

- There is a network of state-owned district pharmacies developing and Community Health Workers and Eyecare Nurses are being deployed across the country. Their role includes public health screening which will be important for the diagnosis and treatment of NCD’s, especially diabetes.

- The Ministry of Health has an ambition to digitise the whole supply chain in Rwanda. Together with the high level of health insurance coverage, this is likely to present opportunities for investors.

Across the region there is a general policy question about whether it would be worth governments paying a modest premium over imports for certain locally/regionally produced products in order to develop the regional industry. There might be a trade-off between price on the one hand and industrial development and security of supply on the other. This could be important for delivery of the EAC Pharmaceutical Manufacturing Plan.

For inward investors, there is a huge and growing market opening up. Government funding is constrained but in all four countries there is an expanding middle class and health insurance coverage is improving.

Moreover, insurance organisations, both state-backed and private, have a direct interest in supporting the treatment of NCD's in order to avoid the downstream cost consequences of untreated conditions such as diabetes and hypertension, the prevalence of which is growing fast.

The policy environment is becoming more supportive of FDI. In addition to regulatory harmonisation and procurement preferences given to local producers, the EAC has been working towards monetary union and a common currency. This was initially intended to happen by 2023 but was delayed until 2027. Monetary union would be a further incentive for inward investment in the wider market opportunities presented by the whole EAC.

Foreign investment in targeted areas of the supply chain (as identified on p3 above) is likely to be a key mechanism to start closing the medicines supply gap.

1. INTRODUCTION

1.1 Research Objectives

The overriding purpose of the research was to identify ways of improving access to medicines in four countries of East Africa:

Kenya
Uganda
Tanzania
Rwanda.

The specific objectives were:

a) To identify and understand the specific barriers to more effective supply of medication and related medical supplies (particularly in optometry), in each individual country and across countries
b) To assess how common these barriers are in rural as compared to urban settings and in the private (both not-for-profit and for-profit) sector versus the government/ public sector
c) To understand any differences between therapeutic categories and the key trends affecting those differences
d) To understand the role foreign direct investment (FDI) might make in improving medicines supply and access for the populations concerned
e) To identify possible policy actions that could support this.

1.2 Research Methodology

This was a cross-sectional qualitative study comprising:

- Desk research into current policies and other recent reports on medicines supply, distribution and regulation, including optometric supplies (July-Aug 2023)
- Semi-structured, in-person interviews with a pragmatic sample of over fifty key players at different points of the supply chain – manufacturers, importers, wholesalers, distributors, hospitals, clinics and pharmacies (Sept-Oct 2023)
- Semi-structured, in-person interviews with government policy-makers and supplies agencies in the health sector and with inward investment promotion authorities (Sept-Oct 2023)
- Detailed review with academic and other sector experts (Nov-Dec 2023).

2. HEALTH SYSTEMS CONTEXT

2.1 Overview

The combined population of Kenya, Uganda, Tanzania and Rwanda is approximately 185 million, and growing at over 2% per year.
Eastern Africa Population 2023 (worldpopulationreview.com)

This places considerable strain on health systems, resulting in serious gaps between the demand and supply of medicines. National Health Accounts are not available on an annual basis for most sub-Saharan countries, but variations between budgeted and actual expenditure are common.

These variations are independent of the COVID-19 pandemic, although the pandemic clearly required some urgent and significant readjustments in health systems. The timing of this research was designed such that the fieldwork (September-October 2023) would enable an assessment of the post-pandemic state of medicines supply and the current opportunities for improvement.

Of the countries studied, Kenya has had the highest level of health spending per capita for many years, fuelled by the strongest growth in GDP per capita. In 2021, the latest year reported by the WHO, health spending was $95 per capita.

By contrast, Tanzania's health spending per capita was only $37 and Uganda's $43. Rwanda's health spending per capita was $60.
Global Health Expenditure Database (who.int)

All four countries have a mix of government, private for-profit and private not-for-profit healthcare facilities. The last category includes a large number of NGO and faith-based organisations.

Government facilities are divided into levels or tiers, with the more local Level I and II clinics and dispensaries staffed mainly by nurses, the highest primary care facilities usually being Level IV. The level of funding and provision varies by tier, the most comprehensive being referral hospitals such as Kisumu Hospital in Kenya and Mulago Hospital in Uganda (both visited as part of this research).

In Uganda, the government is responsible for 70% of the country's healthcare facilities, with private not-for-profit organisations responsible for c20% and for-profit organisations for c10%. This is similar to the situation in the other three countries and it presents significant challenges in terms of nationwide distribution.

All the health systems have a high dependence on donor funding, especially for malaria, HIV and TB programmes. However, this is anticipated to taper down in the near future and there is an open question over the sustainability of current provision without such funding. This is especially challenging as all governments in East Africa try to move towards universal health coverage.

In October 2023 a new funding mechanism was introduced in Kenya with the aim of improving access to healthcare and advancing health insurance coverage. The new legislation includes provision for 100,000 community health promoters, although critics have questioned the training and regulation of this new workforce.

In Rwanda a mobile phone based system of Community Health Workers has been established at local (village) level, and other countries are considering similar systems. There is also a network of district pharmacies developing under the umbrella of Rwanda Medical Supply.

There are public sector pharmacies in government hospitals and clinics in all the countries, but outpatients often have to buy their medicines in the community. This is sometimes funded or co-funded by insurance, but insurance currently is well short of universal.

In Tanzania, public health insurance covers around a third of the population, under four different schemes, but this is set to grow. In Uganda, a national health insurance scheme was introduced in 2021, although patients' out of pocket costs still account for c40% of total health expenditure.

In Rwanda community-based health insurance covers c85% of the population. The Rwanda Ministry of Health also collects good data on drug supply and distribution, but elsewhere in the region data availability is patchy.

Community pharmacy is very active across the four countries with multiple private chains, wholesalers, distributors and importers. One interviewee in Kenya estimated there might be 20,000 pharmacy outlets in the country, although only 9,000 are registered. In 2018 the Kenya Pharmacy and Poisons Board raided and closed down 83 unlicensed chemists in the central, upper and lower Eastern regions of the country.

In Uganda, a large number of drug shops have developed in addition to more heavily regulated pharmacies. These are ostensibly to sell Class C (OTC) medication, but in fact prescription medication, including morphine, is often also available through these outlets, sometimes supplied through unregulated channels.

In Tanzania, a network of 20,000 Accredited Drug Dispensing Outlets (ADDO's) was established nearly twenty years ago to improve access to a limited list of drugs in local, mostly rural, communities. ADDO's are staffed by pharmacy technicians (qualified through a 1 year training certificate in Pharmacy) and are privately owned.

However, some interviewees argued ADDO's have been poorly regulated, with high levels of counterfeit drugs being dispensed and legitimate drugs finding their way to ADDO's from supplies intended for hospitals. In a study by the Tanzanian Ministry of Health, 85% of antibiotics dispensed in the ADDO sample were not against a prescription.

Zanzibar, as a semi-autonomous region of Tanzania, has its own Ministry of Health, Central Medical Stores (CMS) and medicines regulator separate for mainland Tanzania. Interviews were conducted with the Ministry Chief Pharmacist and CMS as well as several community pharmacies, and although there are differences many policies echo those in place on the mainland.

In Rwanda, there is a network of state-owned district pharmacies developing under the umbrella of the Ministry of Health and Rwanda Medical Supply. This may be easier than in the other countries because of Rwanda's smaller geographical scale and its high population density, one of the highest in Africa.

Public health screening is not widespread but is most advanced in Rwanda. Each of the thirty districts in Rwanda also has at least one hospital with a Vision Centre, originally established by the NGO One Sight but now under the Ministry of Health.

In Tanzania, routine eye screening is being rolled out and a higher than 50% prevalence of refractive errors has been found.

Insurance to cover eye conditions is not yet comprehensive. In Kampala a basic sight test (visual inspection and refraction only) costs in the region of UGX30-50,000 ($8-13), which in light of the average salary of UGX12,000,000 ($3,000) in the capital is not affordable for many of the population.

However, optometric screening will become more important with the growth of diabetic retinopathy. At the private City Eye Hospital in Nairobi, diabetic retinopathy has overtaken cataracts as the biggest disease area in both in-patients and out-patients.

2.2 Drug Supplies & Distribution

Across the government and private sectors combined over 90% of all drugs in East Africa are imported, the largest group being generics from India. This research also identified products from China, Pakistan, Bangladesh, South Africa, Turkey, Egypt, Cyprus and several other countries but the informal benchmark price is often set by Indian generics.

All government facilities receive drug supplies from a public sector wholesaler – National Medical Supplies (NMS) in Uganda, the Kenyan Medical Supplies Agency (KEMSA) in Kenya, the Medical Stores Department (MSD) in Tanzania, and Rwanda Medical Supply (RMS) in Rwanda.

These organisations mostly purchase drugs from importers and distributors, but also sometimes from local manufacturers and from other wholesalers such as those which supply the private not-for-profit sector (including JMS in Uganda and NMS in Kenya). However, the Central Medical Stores in Zanzibar has to date only been responsible for storage and distribution, not for procurement.

Drug supplies to government facilities are usually delivered on a “push” system, with the composition of each monthly or bi-monthly delivery determined by previous patterns and trends in demand. However, the demand data is sometimes more than a decade out of date.

Facilities at higher levels of the public system can sometimes exert some “pull” on what they receive. There is a drive towards more effective “pull” systems generally, but this is dependent on forward demand planning, and efficient ordering and inventory management systems at the individual institution level. Mulago Hospital in Kampala works within a “pull” ordering system, but a consultant there estimated they have 50% or less of the drug supplies they need.

For-profit hospitals purchase from private wholesalers or distributors, and are generally funded through insurance schemes. There are moves in all four countries to establish universal health insurance, which would enable more of these facilities to supplement the government provision of care, but this is not yet comprehensive. Insurance schemes also tend to restrict the medication that can be prescribed, which concentrates demand on particular products and can result in specific availability issues if that demand exceeds supply.

Several interviewees mentioned the lack of effective forecasting for drug demand, especially in the government sector. If an importer over-orders, the likelihood of stock going past its expiry date increases (though some importers will sell stock close to expiry at cheaper prices), and it ties up working capital. A common problem is then reduced importer stocks in the next cycle, the importer not wanting to take the inventory risk again – a “pendulum swing” which results in out of stocks at individual health facilities.

Out of stocks are a recurring problem in community pharmacies across most of East Africa, including in the major cities. The most commonly mentioned stock-outs in Kampala and Dar Es Salaam were found to be in antibiotics, antidiabetics, antihypertensives, anticoagulants, and to a lesser extent analgesics. This was less pronounced but still problematic in the major cities in Kenya (Nairobi, Kisumu and Mombasa).

The JMS interviewee in Uganda felt they had enough supplies of simpler antibiotics, although this wasn’t always borne out by front line interviews at health facilities. He felt the challenge was more to do with second and third line antibiotics and sundries such as absorbent gauze and cotton wool.

Although a number of drugs are not available in government hospitals, supplies for the treatment of schistosomiasis, a condition extremely rarely seen in urban centres, continue to be delivered in Kampala. There is clearly a policy issue involved, but also potentially one of corruption, favouring the supplier of schistosomiasis medication at the expense of more essential treatments.

Out of stock issues were much less evident in Kigali, but the Rwandan Ministry of Health reported their order fill rate was still only 72%. There is a widespread shortage across the region of mental health, neurology and oncology treatments.

On the other hand, the optical laboratory visited at the University of Rwanda appears to function very effectively, providing spectacles to order to all the government eye departments in the country based on blank lenses that are imported. However, it does not supply drugs or sundries.

The problem of sundries supply and out of stocks was also identified by a leading wholesaler in Kigali and a number of other interviewees across the four countries including the Central Medical Stores in Zanzibar (CMS).

Although CMS in Zanzibar puts in requests to the Ministry of Health for medication and sundries supplies, it has not so far been responsible for their procurement. This has led to a lack of coordination which has exacerbated the stock-out problem. It may be remedied through new arrangements currently being developed, but it is still a handicap in terms of reliable supply.

2.3 Inventory Management

There was a recurring theme of poor inventory management in all the health systems studied.

Generally, the private (especially for-profit) sector appears to handle inventory management more effectively than the government sector. However, at the private Saifee Hospital in Dar Es Salaam the senior pharmacist said the whole distribution system was let down by its inventory management. The hospital has to order six months in advance in order to ensure delivery, and price variation against a fixed price agreed with insurers for up to two years ahead leads to insecurity.

Saifee hospital has to use a large number of unregistered drugs, especially in ICU, because they do not believe the government registration lists are adequate (although these drugs may of course be authorised at the EAC level). The interviewee also suggested that for certain tablet formulations there could be larger containers supplied (eg 1,000 tablet volume), which would reduce the number of deliveries needed and potentially reduce costs.

Good Life Pharmacy, a major pharmacy chain in Kenya (130 branches), said one problem in inventory management is if the importer or distributor is not moving product quickly enough so it gets too close to its expiry date. This is obviously most often the case for drugs which are naturally slower moving, but because of the disaggregated nature of each national system it remains a problem.

Some supplies also arrive very close to their expiry date. This exacerbates the problem of inventory management because many patients visiting a pharmacy cannot afford to buy a whole course or pack of medication, so the pharmacist sells them one or two strips of tablets. The result is that it can take longer than it should for the full pack to be dispensed, with the risk of stock going out of date. In addition, if the patient doesn’t take a proper course of antibiotics it builds up antibiotic resistance with no therapeutic benefit.

The inventory management problem was echoed by many other interviewees ranging from community pharmacists in Kigali to the Dean of Public Health at Dodoma University in Tanzania.

2.4 Planning & Organisational Delivery

At both the strategic and operational levels there is sometimes a public sector "planning versus delivery gap". In rural Uganda, cycles of drug delivery, supposed to be every two months, are sometimes completely missed, even consecutively. A Level III Health Centre at Patongo in Northern Uganda was consequently short of basic supplies such as malaria testing strips.

The government in Uganda is also keen to be the sole supplier of Yellow Fever vaccine, but the vial has ten doses, which means the unused doses go out of date. At an NGO clinic in Jinja, this was a source of frustration because the clinic felt funds were being wasted.

As part of this research, a one-day workshop was attended in Tanzania on the next Strategic Plan for the National Eyecare Programme (2023-26). The objectives of the previous plan (2016-22) were discussed, including reducing the prevalence of severe-moderate visual impairment and the incidence of avoidable blindness, but there were no metrics available on whether these objectives had been achieved.

This will inevitably compromise strategic planning and delivery of the next programme, which will not be launched until 2024 (two years after the end of the previous plan). Performance metrics on the quantitative objectives of the 2016-22 plan were still not available at the end of 2023.

In Uganda there is a 5-year strategic plan for the eyecare sector (2020/21-2026/27) but until recently the focus has been on ophthalmology and optometrists were not included. They have recently been included but some interviewees felt more use could be made of the optometric workforce.

There is wide recognition across all four countries that drugs for NCD's (especially diabetes and hypertension) are rapidly becoming more important as populations adopt more Western diets and enjoy longer life expectancy. In Rwanda, a Ministry of Health official explained the highest mortality rate (40%) is now from cardiovascular disease rather than communicable disease and plans need to be developed to address this.

A dramatic rise in demand for antihypertensive and antidiabetic drugs was anticipated by all the interviewees. The private Ampola Hospital in Zanzibar is already experiencing a rise of 20% pa in their demand for antidiabetics, but even without this growth there are supply problems across the whole region.

The focus of public health policy is consequently starting to move away from malaria, HIV and TB, although malaria continues to present a significant challenge in particular parts of the region. Severe anaemia, often related to malaria, and malnutrition are still common in rural populations and amongst the urban poor.

In October 2023 Kenya launched an initiative to distribute 15.3 million insecticidal nets across 22 counties considered at high risk of malaria. A domestic producer in Kenya, Universal Corporation, has also recently received WHO approval for its SPAQ malarial prophylactic drug in children. Previous supplies of the drug were limited to imports.

Dysentery and respiratory tract infections, both of which are common, place additional demands on supplies of antibiotics. Policy-makers are aware that antibiotic resistance is increasing, but measures to combat it are minimal.

The Rwanda Ministry of Health identified curbing antimicrobial resistance as one of its twelve strategic objectives in its National Pharmaceutical Sector Strategic Plan 2018 – 2024, but progress on this is unknown. Reducing stock-outs and promoting development of the pharmaceutical industry were also identified as objectives. The Plan set a target of improving the percentage of products available at the central medical warehouse from 55% to 90% by 2024.

2.5 Workforce Issues

Workforce numbers were generally not considered a significant barrier in terms of improving drug supply. The professional healthcare workforce is nevertheless small in relation to the countries' populations.

TABLE 1: Physician and Pharmacist Workforces

	Physicians per 10,000 population	**Pharmacists per 10,000 population**
Kenya	2.3	0.2
Uganda	1.6	0.4
Rwanda	1.2	0.7
Tanzania	0.5	0.3
USA	*35.6*	*10.6*
UK	*31.7*	*8.5*

World Population Review 2023
Doctors per Capita by Country 2023 (worldpopulationreview.com)

Although healthcare demand is increasing, there is a reasonable supply of trained professionals with a number of new university courses being opened in recent years. The University of Dodoma opened its first Bachelor of Pharmacy degree course in October 2023, the fifth university in Tanzania to do so.

The challenge for the public sector in all four countries is how they can afford to employ the health professionals that are trained. One reason for the large number of community pharmacies across East Africa (in urban areas sometimes six or eight in the same street) is the supply of qualified pharmacists, which exceeds the capacity of the government to employ them.

At pharmacy schools in Kenya, represented at a conference attended at Kabarak University, there is a high level of enthusiasm for the profession, but a realism about the lack of public sector funding. From one pharmacy school six years ago, there are now nine schools in Kenya and it is unclear where these graduates will find employment.

In Tanzania the Pharmaceutical Society estimates there are 3,500 pharmacists currently unemployed, including industrial pharmacists who in theory could be employed by the manufacturing sector if that were to grow.

In optometry, the Ophthalmic Training School in Jinja, Uganda, believes it is hampered by being under the Ministry of Education rather than the Ministry of Health. This inhibits its ability to obtain drug supplies, including basic antibiotics, and essential equipment, but there was also criticism of a lack of coordination in workforce planning and funding.

According to the eyecare charity CBM, based in Nairobi, a mismatch between labour supply and workforce affordability in the government sector applies in optometry as it does in pharmacy.

Key areas where there are skills shortages in the workforce are procurement, especially in the government sector, and equipment maintenance and repair. Government procurement of medication is hampered by the challenges of corruption (evidenced by the allegations against KEMSA and the unnecessary supplies to Mulago Hospital in Uganda) and the lack of coordinated forecasting and procurement systems.

According to a leading community pharmacist in Kigali, there is also a shortage of pharmacy technicians in Rwanda. Across the region there is a shortage of pharmaceutical product development and production engineering expertise.

For the health systems of all the countries to be sustainable with less donor funding but accelerating demand for treatment of NCD's, improved planning, procurement and coordination systems need to be developed, and the production and supply chain needs to be upgraded to enable higher volumes across a wider range of products.

The role of the private sector is critical to this. However, the lack of capital in the region and all the countries' high interest rates (typically in the high teens for bank borrowing) point towards inward foreign direct investment (FDI) as potentially a key "breakthrough" factor to enable the improvements needed.

3. MANUFACTURING IN THE REGION

3.1 Regional Overview

The East African Community (EAC) has published two Regional Pharmaceutical Manufacturing Action Plans (2012-2016 and 2017-2027).

In the most recent plan, the EAC argues that local manufacturers are strongly present in the anti-infectives market but they “miss out” in the large immunological and cardiovascular markets. The report says the region lacks the capacity to manufacture advanced formulations because of a skills gap in product development and formulation, and a lack of appropriate and affordable investment capital.

5fda325febf52608148429_8f16115940.pdf (eacgermany.org)

The report highlights the challenge and opportunity associated with NCD’s and argues there is convincing evidence that industrial policies supporting local pharmaceutical manufacturing can be successful from both an economic and a healthcare perspective. It sets a target of reducing East African pharmaceutical imports to less than 50%, from an estimated 70% currently (though some commentators put the current percentage at 90%+ because of private sector supply chains).

In the present research, the EAC interviewee expressed disappointment that no pharmaceutical manufacturer in the region had grown by more than 15% in the six years since the start of the latest Pharmaceutical Manufacturing Action Plan. His view was the main difficulties lie in access to investment capital to enable growth and the lack of sufficient technology transfer.

Both of these difficulties could potentially be addressed through foreign direct investment.

Overt government support for local manufacturing while it is still developing (and which falls short of long term protectionism) is difficult. When the Tanzanian government banned the import of metronidazole because it was being produced locally, they found the local product wasn’t in the right dosage for many NGO’s, who suddenly found they had no supply.

More proactive support for the industry often requires funding, through development grants or loans, fiscal incentives (potentially leading to a loss of tax revenue) or preferential drug registration or procurement (potentially leading to higher procurement costs).

Nevertheless, the EAC's 2017-2027 plan identifies a goal of having at least five regional companies producing more advanced products such as delayed release formulations, small volume injectables and double layered tablets. It makes eight recommendations for "strategic interventions" to enable this, including introducing appropriate financing schemes for local manufacturers and a regional framework for mutual recognition of harmonised medicines registration and GMP inspections.

It suggests some of the technical know-how to set up and run GMP-compliant manufacturing operations may come from India. In fact, as part of this research, Laboratory & Allied, Cosmos and Revital, three of the largest GMP-certified manufacturers in Kenya, were found all to have strong links with India. Revital employs nearly all its operations managers from India.

All manufacturers in the region have to import their active pharmaceutical ingredients (API), which typically account for over 50% of the total production cost of a drug. China is by far the world's largest producer of API and the prospects for any local API production in East Africa are extremely daunting.

There may also be a misconception that more local manufacturing would improve the security of supply. In fact, not only would the API have to continue to be imported, so would many of the other raw materials (excipients, coatings, gelatine capsules etc).

Potentially, one effect of generating more local production would be to substitute a single product supply chain for multiple supply chains for all the component parts, which would have the perverse effect of making supply more vulnerable. GSK in Kenya, for example, incurred a significant production risk when they were unable to source the necessary foil for their blister packs from anywhere in East Africa.

Increasing local production might therefore just transfer the supply risk from that associated with a finished product to that associated with all the raw materials for that product from API onwards. There was also some evidence in this research that stock-outs were at least as prevalent with locally sourced products as for imports.

On the other hand, in selected product areas there is enormous growth expected. Kampala Pharmaceuticals has experienced 1,000% pa growth in metformin, with gross profit of up to 80%. They believe it is possible 30% of the East African population is pre-diabetic, and manufacturing products with lower ingredient complexity, such as metformin, offers significant commercial opportunities.

In Kenya, Revital already exports its syringes, giving sets and other medical accessories to thirty different countries (including India) and is further developing its manufacturing capacity for rapid testing diagnostic kits. Its product range competes very effectively with low priced imports.

Meanwhile, the Africa Health & Economic Transformation Initiative (AHETI) was launched in January 2023. AHETI is a collaborative among Catholic and non-faith based health and social justice networks aimed at eradicating poverty diseases endemic in Africa. It has a specific objective of "promoting efforts and policies to ramp up local production of pharmaceuticals in Africa".

Africa Health Economic Transformation Initiative – Ramping up Pharmaceutical Production in Africa (aheti.org)

3.2 Existing Pharmaceutical Capacity

Kenya

There are over thirty pharmaceutical manufacturers already located in Kenya. Most are small scale, but all face intense price competition from imports. On the other hand, they know the demand to treat NCD's is going to grow hugely and want to position themselves as offering high quality products to address that need.

Laboratory & Allied, one of the longest established manufacturers in the region (founded in 1968), produces a range of products that covers over 70% of the WHO Essential Medicines List. They have a 300,00 sqft facility in Nairobi from which they produce over 3 billion tablets and 34 million capsules (including large volumes of penicillin), 3.4 million litres of fluid and a million tubes of ointment per month.

They are aware of the growth of NCD's but new product launches are hampered by delays in market authorisation. Their view is full regulatory harmonisation within the East African Community is overdue.

This echoes comments made in the 2020 diagnostic report on the pharmaceutical industry by the Kenyan Ministry of Health and the Ministry of Industrialization, Trade & Enterprise Development. The report said there was a need to "accelerate adoption of cross-recognition of common regulatory standards and practices" within the EAC.

Cosmos Pharmaceuticals, based in Nairobi, produces a range of products including drugs for hypertension (such as amlodipine and furosemide), type 2 diabetes

(metformin, gliclazide, dapagliflozin, sitagliptin and gliclazide) and heart disease (atorvastatin). The Cosmos interviewee recognised the growth of NCD's but warned that because of poor inventory control by county governments in Kenya and KEMSA, demand from the government sector is very erratic.

Cosmos currently imports many of its raw materials, including bottles, cartons, foil and process machinery, from India. However, it is looking to partner with more local producers to reduce the supply chain risk. This could represent an important new development for the sector.

Regal Pharmaceuticals in Nairobi also manufactures and distributes a wide range of products including antibiotics, antimalarials and analgesics, but nothing in diabetes, hypertension or heart disease.

Dawa Life Sciences is the result of the 2004 acquisition of the state-owned Dawa Pharmaceuticals by the Nairobi based pharmacy business Medisel. The deal was unusual partly because it was based on funding from local banks.

There have been further acquisitions since and Dawa now has over 1,000 generic product lines, including antihypertensives but not antidiabetics or statins. Dawa has sales in eleven different countries and annual revenues exceeding US$60 million.

The Federation of Kenyan Pharmaceutical Manufacturers has argued that product registration fees should be increased for companies outside the EAC for any product already manufactured in Kenya. The Federation also argues for higher import tariffs.

The 2020 diagnostic report on the pharmaceutical industry found that although workforce costs are relatively low, local firms rely on expatriates which pushes up the overall cost of the workforce. Other significant barriers include the high cost of utilities and transport, and the high dependence on imported production inputs.

Uganda

Kampala Pharmaceutical Industries (KPI) manufactures a comparable number of products to Cosmos on three production lines – capsules, tablets and creams & ointments. There is a dedicated line for paracetamol tablets. Gross margins are highest on capsules (penicillin can be up to 80%)

KPI is 100% owned by the Investment Promotion Services arm of the Aga Khan Foundation which provides capital not only for development but also for operating expenditure when necessary.

The Indian generics manufacturer Cipla acquired a majority stake in the Ugandan firm Quality Chemicals in 2017, before floating it on the Ugandan stock exchange the following year. Cipla completed its acquisition of the human medicines business in 2020 and sold a majority stake to Africa Capitalworks, based in Mauritius, in 2023. Cipla has a substantial manufacturing facility at Luzira near Kampala and is the leading local producer of antimalarials.

In October 2023, Cipla launched Flozicard XR, a combination of two oral antidiabetics. Importantly, the company has stated its intention to sell Flozicard at less than the typical imported competitor price of UGX10,000. However, it issued a profits warning for the half year to September 2023, associating a decline in gross profit with a change in the company's product mix.

Rene Industries started as an importer and distributor in Uganda but now manufactures antidiabetics (metformin and glibenclamide), as well as the beta blocker propranolol, some CNS drugs, and a range of antibiotics and antimalarials. They produce 2.8 billion tablets per month across 140 different product lines, but they do not produce antihypertensives or statins.

Investment capital for manufacturing is clearly constrained. However, the Cipla investment in Uganda could be a model, with the initial capital coming from the Indian parent company followed by private equity finance. Cipla's listing on the Ugandan stock market in 2018 was not regarded by the Cipla interviewee as the most efficient form of capital raising. The acquisition of a majority (51.18%) stake by Africa Capitalworks in 2023 valued the company at $48 million.

Across the region there is minimal contract manufacturing for international pharmaceutical companies. However, Kampala Pharmaceuticals decided to close its liquid production line because of the cost and commercial risk of manufacturing original products and move to a contract manufacturing model. The Kakamega County Minister for Health in Kenya suggested there were also contract manufacturing opportunities in antibiotics and antihypertensives.

The JMS interviewee in Kampala mentioned the fact that East Africa produces its own cotton, but cotton wool is imported. Supplies were identified from China (Medisafe) and

India (Tulsi) as well as from Kampala itself (Advance, and contract manufactured by Royal in Nairobi), but quality is variable.

There is some vertical integration in the industry. Mavid Pharmaceuticals in Uganda and a few other producers have wholesale as well as manufacturing operations, and occasionally a retail arm as well, but this is not widespread.

Tanzania

In Tanzania, local pharmaceutical production has declined since 2005, mostly because of the costs of imported raw materials and the difficulty of achieving economies of scale. In 2016, a UNDP report found that that several Tanzanian pharmaceutical manufacturers were operating at as low as 25% capacity because it was not financially viable for them to do more due to government policies that favoured importation.

Tanzania_Local_Production.pdf (adphealth.org)

The UNDP report also recommended that the Tanzanian government provide attractive credit terms to local pharmaceutical manufacturers wanting to establish and run GMP-compliant manufacturing plants. It does not appear this recommendation has been implemented.

The government Medical Stores Department (MSD) has, according to its website, a specific mandate to “collaborate with [the] private sector to open local manufacturing industries as provided in Public Private Partnership Act, 2010. MSD envisages that this will enable the country at large to source essential medicines and medical supplies locally and therefore reduce importation costs and lead-time as well as storage costs”.

Unfortunately, the present research could find no substantive evidence of this kind of collaboration.

One of the most important existing manufacturers in Tanzania is Shelys Pharmaceuticals, frequently mentioned by pharmacy interviewees. The Shelys subsidiary, Beta Healthcare based in Nairobi, manufactures OTC products. Shelys was the first company in Tanzania to produce penicillin, and their product range also includes antihypertensives, antidiabetics and cardiovascular drugs. It was also the first company in East Africa to invest in European standard Modular Clean Room Panels.

In 2012 Shelys was acquired by the South African based Aspen Pharmacare which is listed on the Johannesburg Stock Exchange. The London-based private equity and venture capital firm Aureos Capital had previously had a stake in Shelys.

Rwanda

Rwanda does not have a long established pharmaceutical manufacturing sector.

The inward investors BioNTech (Germany) and Cooper Pharmaceuticals (Morocco) are still in the early stages of production in the Kigali Special Economic Zone, for vaccines and antibiotics respectively. They represent significant greenfield investments in the sector.

At the start of construction of the Cooper plant in 2018, the Rwanda Development Board said it would “help reduce the amount of foreign exchange we use to import drugs while at the same time creating more job opportunities for the youth in the country”.

PharmaLab, also in Kigali, manufactures consumables such as specimen collection tubes, as well as being a distributor of medical and laboratory equipment. (Laboratory equipment was not specifically considered in the current research.)

The US company Zipline has established a base at Muhanga in central Rwanda, from where it operates an effective drone delivery service for emergency drug and other low bulk medical supplies. The ordering and despatch system is digitised, and larger drones are planned, but it has clear capacity limits on volume.

Several interviewees mentioned the lack of packaging suppliers in Rwanda, which is also an issue in other East African countries.

3.3 IV Infusions and Eye Drops

Rwanda Medical Supply started manufacturing its own intravenous (IV) infusions, but there were significant problems with GMP compliance and production stopped.

Nevertheless, a senior pharmacist in Kigali reported the RMS IV pouches were superior to the bottles imported from Uganda and India, although more expensive. Quality and efficiency in clean room production play a key role, but also scale in order to keep unit costs down.

IV infusions are also produced in Kenya and Tanzania as well as Uganda, and some of the larger hospitals produce their own. However, Kenyatta Hospital in Nairobi discontinued their own production because of the low cost of imports, and Turiani Hospital in central Tanzania did likewise because of problems in sourcing the necessary

equipment. So cost competitiveness is a critical factor, even on higher margin products such as infusions.

IV infusions are generally considered to be at the easier end of the production spectrum, and there is a particular need for infusions that remain stable at higher ambient temperatures. There is also new technology available in the blow/fill/seal systems which enable an end-to-end production process, increasingly used in the manufacture of IV infusions.

Abacus Pharma, which is primarily a regional distributor, already employs blow/fill/seal technology at its site near Kampala. It uses US-sourced equipment to produce 20 million units of large volume parenteral solutions and 45 million units of low volume parenteral solutions annually.

Several interviewees mentioned the market opportunity in eye drops. These are currently produced by a number of East African manufacturers including several in Kenya, plus some health facilities themselves such as Ruharo Mission Hospital in Uganda. This last development required investment of cUS$30,000, which the hospital funded from its reserves.

The eyecare charity CBM started an initiative with Sight Savers International to produce eye drops locally, but found the lack of appropriate skills and refrigeration facilities were significant barriers. They currently import eye drops from India, but remain anxious about meeting demand.

The incidence of eye conditions, including allergic reactions to dust and other allergens, dry eye syndrome and optical problems associated with diabetes, is growing significantly, and a number of interviewees took the view that eyedrop volume needed to expand.

There does not seem to be a significant shortage of spectacle lenses or frames, many of which are imported from India. More upmarket spectacles come from Europe, and distributors such as Sima and Optical Supplies Africa, both based in Kenya, are growing as economic growth and expansion of the middle classes continues.

3.4 Medical Equipment

There is currently no manufacturing of medical equipment in the East African region, and very little manufacturing of smaller medical devices. There are no producers of

radiology, ultrasound or optical diagnostic equipment although the use of these technologies is growing. Nairobi X Ray Supplies, a major distributor in Kenya, sources most of its equipment from Japan.

In 2021 the journal *Africa Health* reported that in Uganda there were 15.5 units of radiology equipment per one million people, compared to the minimum WHO recommendation of 20 units per one million. The only other East African country included in the same study was Tanzania, which also fell short of the WHO recommended minimum.

Anudha in Dar Es Salaam imports and distributes medical equipment and consumables from a variety of countries, but no specific optometric appliances or equipment.

Blanks for spectacle lenses are sometimes imported to the region, but capacity for finishing them is limited, especially in Uganda. The great majority of spectacles are imported as finished products.

There is some potential for local manufacturing of simpler optometric diagnostic equipment such as ophthalmoscopes at relatively low cost, if there was sufficient volume. This could in turn stimulate the provision of the technical support and maintenance services which are sorely needed.

There are large amounts of optical equipment currently unused in all the countries studied because it is in need of repair, but no technician is available in the country. Slit lamps for example often come from suppliers in India, Pakistan and Japan who have no local agents in East Africa. In Rwanda, the two eye hospitals visited often have to wait up to 12 months for spare parts or pay for a technician to fly from Nairobi.

This problem is most often found with donor-funded equipment, but it extends to other equipment as well – including an ultrasound machine in a rural hospital near Kitale in Kenya that had not been working for over a year because it was in need of repair.

This points to the need for planned preventive maintenance strategies at the institutional level, including the provision of specialist workshops and a supply chain for spare parts. It also suggests an opportunity for the development of equipment support services.

In Rwanda, PharmaLab is a distributor of medical and laboratory equipment as well as being a manufacturer of medical consumables. The problem for the company’s expansion in support services, as with many other companies in the region, is access to investment capital.

The syringe manufacturer Revital in Kenya overcame this problem in 2013, five years after its establishment, with $4 million funding from the Bill & Melinda Gates Foundation.

The company has since extended its product range considerably and in 2021 signed agreements with Japanese investors Asia Africa Investment & Consulting and Ohara Pharmaceutical Co. Revital is now developing a capability in rapid testing diagnostics, in partnership with USAID. In 2023 it signed a Memorandum of Understanding with Mitsui O.S.K. Lines, the Japanese company originating in the shipping industry, for a $3.3 million development of its plant in Kilifi.

A visit was also made to Viebeg Technologies in Kigali. The company imports a wide range of medical equipment from a variety of countries, and provides a full suite of warranty, maintenance and support services, including flexible payment plans. It has also developed a health demand simulation model to forecast demand for its equipment and improve logistics and inventory management.

Viebeg has secured investment from a US venture capital firm (Beyond Capital Ventures) and in 2023 received funding from Johnson & Johnson Impact Ventures, part of the Johnson & Johnson Foundation. The foundation has a particular interest in strengthening the medical supply chain in Africa.

Foreign investment has been critical to the growth of both Revital and Viebeg. However, the timeframe for return on capital may be more suited to FDI in a distribution based business than pharmaceutical manufacturing, unless it involves acquisition of an existing operation, because the break-even point tends to be much earlier in a distribution business.

Kampala Pharmaceuticals said they would not expect a new factory to break even within five years, and Revital said their importation of major production equipment would sometimes not generate a return on investment within ten years.

Nevertheless, it is clear that external capital is frequently required to enable business expansion in the sector. This is often most successful when it is not conventional debt but sourced from a foundation, a venture capital firm or another inward investor. This need not mean outright acquisition (which tends to be by foreign investors). Even after equity dilution, the founders of Viebeg will still own 30% of the company. There is currently a debt to equity ratio of 1, but they are looking to expand that to 1.1.

Like Revital, Viebeg is overcoming the capital access barrier to developing the business. Both companies depend on government procurement for a similar, minority

proportion of their sales (Viebeg 40%, Revital 35%), but Viebeg has a higher proportion in the local NGO sector while Revital exports more.

Viebeg and Revital are both relatively young companies with a strong entrepreneurial approach which could provide a model for effective investment.

4. INWARD INVESTMENT CONTEXT

4.1 Overall Trends

All the countries studied have government agencies responsible for promoting inward investment. However, there is significant variance in their success over the last five years with Uganda doing particularly well and Kenya, whilst it is the largest economy in the region, finding it more difficult.

TABLE 2: Inward Flows of Foreign Direct Investment (all sectors, $US million at current prices)

	2018	2019	2020	2021	2022	FDI change 2018-2022	GDP 2022 (US$ bn)
Uganda	1055	1274	874	1100	1526	**+44%**	49
Tanzania	972	1217	944	1033	1111	**+14%**	77
Rwanda	382	354	274	399	399	**+4%**	13
Kenya	1139	1098	717	463	759	**-33%**	116

World Investment Report 2023; UNCTADstat

The African Continental Free Trade Area (AfCFTA), involving over fifty African countries and connecting 1.3 billion people, will progressively remove tariff barriers to trade over the next decade. Import duty on goods traded between member states is already zero.

The longer established, eight-country East African Community (EAC) is likewise removing tariff barriers within the region and introducing a common 25% tariff on selected pharmaceutical products to promote local manufacturing.

The EAC is also on the path to monetary union and introduction of a common currency across the region, but progress is slow, as it is on full regulatory harmonisation.

The AfCFTA and the EAC will almost certainly have a positive impact on foreign direct investment (FDI), but to date there has been only modest inward investment in the pharmaceutical and medical supplies industries.

Uganda's recent discovery of oil reserves, expected to produce up to 230,000 barrels per day starting in 2025, may change the FDI picture in that country. The biggest oilfield is being developed by the Ugandan National Oil Company together with Chinese and French investors.

The Uganda Investment Authority has also promoted the argument that it has the lowest labour cost for skilled production operatives in the region and lower electricity costs than Kenya.

There are examples of recent greenfield investment in the pharmaceutical sector in Rwanda (BioNTech and Cooper Pharma), but the majority of FDI has been M&A based. 2023 saw two significant acquisitions by companies based in Mauritius (Harleys in Kenya and Cipla in Uganda).

The domestic Rwandan pharmaceutical sector is at an earlier stage of development than that in the other three countries, but the German company BioNTech has invested $150 million in a modular mRNA vaccine production facility in the Kigali Special Economic Zone (SEZ), It is the first such facility in Africa, with a primary focus on malaria, TB and COVID-19 vaccines. BioNTech said the plant would eventually become part of a wider supply network spanning several African nations, and all the vaccines produced by the company in Africa are intended for use in African populations.

Cooper Pharma, a Moroccan generics manufacturer, is currently nearing completion of its US$6 million production facility in the Kigali SEZ, concentrating on production of IV fluids and antibiotics. In addition, Apex Biotech, a generics firm co-owned by Rwandans and the Bangladeshi investor Health City is expected to open a further new factory in the SEZ in 2025.

The Apex factory will reportedly have capacity to produce up to 800 million tablets, 200 million capsules, 5 million powder sachets for suspension, and 8 million bottles for liquid formulations per year, focused on NCD’s as well as HIV, TB and hepatitis. The investment is worth $18 million in two phases.

Interviews were held as part of this research with senior staff at the Rwanda Development Board, the Uganda Investment Agency and the Zanzibar Investment Promotion Authority. The Kenya Investment Authority and the Tanzania Investment Centre were unresponsive to enquiries.

4.2 Sector Challenges and Changes

It has proved more difficult to stimulate inward investment in the medicines supply chain than in private sector hospital infrastructure. There have also been a number of specific challenges and setbacks.

In 2022 the Rwandan Government sued LEAF Pharmaceuticals, based in Massachusetts, for $40 million for allegedly misleading the Rwandan Social Security Board (RSSB). The RSSB claimed LEAF mischaracterised certain pharmaceutical patents in order to promise it could turn Rwanda into a pharmaceutical research hub. As a result, the RSSB invested in LEAF's nascent operations in the country. Legal action is continuing.

Apex Biotech is also rumoured to have been in dispute with the Rwandan government about banning imports of the products which their plant will produce.

Another negative for the East African region is the recent withdrawal of some pharmaceutical multinationals from production operations there.

GSK decided in 2023 to exit Kenya as part of an overhaul of its global business. It will maintain its stand-alone consumer healthcare business Haleon but move its pharmaceutical business to a distributor model. GSK has been operating in Kenya for over sixty years, but had previously announced it was cutting back many of its operations in Africa.

Similarly, Sanofi announced in 2021 that it would be moving its business to the distributor E.P.Dis in many African countries including Kenya and Uganda. The role of local distributors, who have exclusive rights to the products they distribute, is critical in the East African pharmaceutical sector, although combined with importers it increases the complexity of the supply chain.

Some distributors are quite large and diversified businesses. Phillips Pharma Group which started in Kenya now employs 1,300 people across nine sub-Saharan countries, providing warehousing and cold storage, marketing, technical and regulatory services as well as product distribution. In 2022 it formed a strategic partnership with the French Piex Group, but Piex say on their website the lack of skilled labour and the unreliability of supplies are still significant barriers to investment in the region.

Nevertheless, several other major distributors in Kenya have been acquired by foreign investors in recent years. Laborex was acquired by the French based Eurapharma in 2004, and Surgipharm was acquired by Imperial Logistics of South Africa in 2017.

In 2023 another Kenyan distributor, Harleys, was acquired by IBL Group. IBL is a multinational conglomerate led by Mauritian businessman Arnaud Lagesse. The consortium includes Proparco, a subsidiary of Agence Francaise de Developpement

(AFD). These deals may provide a welcome injection of capital and valuable technology transfer which will enable further business development.

Private equity groups are increasingly active in the region. Abacus Pharma, one of the leading distributors in the region with 60 wholesale branches in Kenya, Tanzania, Uganda, Rwanda and Burundi, and a production facility for IV fluids, plus eye, ear and nose drops in Uganda, was acquired by the US private equity firm Carlyle Group in 2018.

Cipla in Uganda, Shelys in Tanzania and Revital in Kenya have all received investment from private equity groups. This has funded not just expansion of production capacity but also the development of local workforce skills.

The US drone operator in Rwanda, Zipline, has raised considerable funding from three US venture capital firms, Katalyst Partners, Andreessen Horowitz, Sequoia and The Rise Fund, as well as the investment house Baillie Gifford. In 2023 Zipline expanded into Kisumu County, Kenya.

Pharmaceutical, raw material and equipment imports have to be purchased in dollars, but access to US$ currency is difficult and exchange rates have been working against East African importers, distributors and manufacturers. They consequently have to ensure they have foreign exchange cover, but banks in the region often do not have enough hard currency to sell to them. Inward investment can sometimes offer a way through this if the foreign investor has access to such currencies and an effective treasury management function.

4.3 Special Economic Zones

A new Special Economic Zone was launched in Nairobi in 2023. This is reported to be the first SEZ in East Africa with a gazetted customs control area.

The Kenyan government's 2020 diagnostic report on the pharmaceutical sector argued that access to low cost, reliable infrastructure, especially utilities, could be enabled by making common user facilities available in an SEZ, export processing zone or industrial park. The cost and poor quality of utilities is recognised as a barrier to investment both in Kenya and elsewhere in the region.

Tanzania has also established Special Economic and Export Processing Zones (plus five in Zanzibar) to attract FDI, but with a minimum $5 million investment threshold to qualify for the relevant incentives.

Rwanda established the Kigali Special Economic Zone specifically to encourage inward investors such as BioNTech and Cooper Pharmaceuticals. All these zones offer 100% access to the domestic market, subject to import and export duties.

In Uganda there are both Free Zones, which are not subject to customs duties on either imports or exports, and Industrial Parks where firms are offered renewable land leases at a discounted rate. In both types of zone, companies over a certain investment threshold are given a ten year corporate tax holiday, but Free Zone firms are only allowed to supply 20% of their output to local markets, including all EAC countries.

In 2020 the International Growth Centre at the London School of Economics issued a Policy Note on Uganda in which it said “fiscal incentives do not appear to play an important role in explaining either the performance of special economic zones or attracting FDI in African countries”.

Instead, basic infrastructure, trade-related infrastructure and services, and efficient, non-burdensome regulation were considered more important. The report also argued for an SEZ policy at the regional (EAC) level.

Microsoft Word - Special Economic Zones in Uganda 28.01.20 format.docx (theigc.org)

The East African market for pharmaceutical and related products is obviously expanding, with associated opportunities in downstream activities such as consumables, packaging, logistics and data management. The question is whether policies can be developed to make maximum use of foreign direct investment to improve supply, and consequently improve access to healthcare for the regional population.

5. FDI AND THE BARRIERS TO IMPROVING SUPPLY

Ensuring a reliable supply of legitimate, effective medicines is hampered by three types of barrier. Each of these could potentially be reduced through targeted inward investment, in systems as well as in selected manufacturing capacity.

5.1. Supply Chain Barriers

Because of the length and complexity of the supply chain, there are numerous points at which supply can be lost or diverted. Some of this is unavoidable, but there is also the risk of procurement inefficiency. The most notorious recent example of this is the two recent scandals at KEMSA (the Kenyan Medical Supplies Agency).

KEMSA is the sole supplier of drugs to District health facilities in Kenya. It purchases, stores and delivers medicines to public health facilities, which are obliged to use it. There are fines and even jail sentences for public officials who do not use KEMSA for their supplies. However, the Kenya Ethics and Anti-Corruption Commission found that KEMSA lost KES1.5bn in suspect procurement deals for COVID-19 personal protective equipment, and in May 2023 it is alleged to have mishandled a KES3.7bn tender for the purchase of mosquito nets.

There have been unfavourable comparisons made between KEMSA and MEDS, a smaller but similar agency which supplies private non-profit organisations in Kenya. This is similar to the relationship between National Medical Stores (which supplies government institutions) and Joint Medical Stores (originating with faith-based NGO's) in Uganda.

The Federation of Kenyan Pharmaceutical Manufacturers has called for the KEMSA central procurement system to be revamped.

In Tanzania, government facilities are not obliged to use the equivalent organisation, MSD, but there are still problems with product availability and many interviewees were critical of how supplies are handled and distributed. In Dodoma, the capital of Tanzania, emergency supplies can take 2-3 days to arrive.

This issue is being tackled in Rwanda with a National Supply Chain Assessment undertaken in 2017 and the introduction of a coordinated procurement and distribution system run by Rwanda Medical Supply. A drone delivery system run by Zipline is used for blood products and emergency supplies including medication with capacity for up to 500 flights per day.

Zipline drones currently have a range of only 160km and Rwanda is much smaller than the other three countries studied, but regional depots are being rolled out elsewhere and there may be learnings from this initiative for other parts of East Africa. Zipline is US owned but started in Rwanda in 2016 and is expanding into Kenya, Nigeria, Ghana and Cote d'Ivoire.

Uganda's population is 74% rural, Kenya's 71% and Tanzania's 63%, which exacerbates the distribution challenge.
(World Bank 2022; https://data.worldbank.org/indicator/SP.RUR.TOTL.)

The County Minister for Health in Kakamega, Kenya, also cited the lack of temperature control in transport as a problem, and KAMU Medical Centre, in Eastern Uganda, sometimes has to use non-air conditioned taxis over long distances to ensure supplies arrive. In Nairobi, motorbikes are sometimes used because of the traffic congestion, although they are obviously limited in the volume they can transport (as are drones).

Several interviewees also mentioned security problems in transit and the poor state of many of the roads in the region, especially in Kenya, Uganda and Tanzania.

Storage is an equally serious problem. The lack of temperature control in the storage of drugs in all the four countries causes problems; the pharmacy store at Kalongo Hospital in Northern Uganda regularly has temperatures exceeding 30 degrees Centigrade. The lack of appropriate storage facilities also means many health facilities order on a "just in time" basis, which inevitably incurs a price premium.

In November 2023, the ARCH Cold Chain Solutions Fund announced its intention to build a state of the art pharmaceutical storage facility in Nairobi, with a $15 million contribution from the European Investment Bank. However, most drugs do not need a full cold chain and can be stable with just conventional air conditioning, but this is often not available.

Import delays were mentioned by several interviewees, with specific criticism of importers' poor inventory management in Kenya and Rwanda. Pharmacies and distributors can of course hold buffer stocks, but they often don't have the working capital to be able to do so.

Consequently, stock-outs are a perennial problem across large parts of Kenya, Uganda and Tanzania. Even regular supplies of antibiotics are problematic - a Level IV Health Centre in Uganda said they didn't have enough to treat cases of pneumonia or skin

infections (metronidazole was in particularly short supply, although some of it is produced by Kampala Pharmaceuticals).

Products such as ACE inhibitors, and drugs for mental health and neurological conditions, are generally unavailable even in the major hospitals, unless they are high end for-profit facilities. Several interviewees also mentioned supply problems with giving sets, canulas, syringes and IV fluids, even saline.

Most out of stock issues last for a few weeks or months, but in Dar Es Salaam, the largest city in Tanzania, one eye unit had been out of stock on nepafenac eye drops for two years. This placed a serious constraint on their ability to perform cataract surgery.

At the Turiani government hospital in central Tanzania, 24 out of 107 items ordered in one month in 2023 were out of stock at the wholesalers. In February 2023 it was 35 items out of stock. Long delays in the delivery of orders are common.

Of the four countries studied, Rwanda has the fewest problems with stock-outs. However, at the specialist eye unit at Kabgayi Hospital in central Rwanda they often experience a delay of several months in obtaining eye drops, even though they order direct from the manufacturer in India rather than through Rwanda Medical Supply (RMS).

As well as other products, RMS supplies anaesthetics and analgesics, and some anaesthetic gases are produced in Rwanda. However, at the Rwanda Charity Eye Hospital in Kigali, over 25 drugs which they use are not on the RMS registered list.

Optical equipment at the hospital comes from a wide range of countries including China, Korea, India, Dubai, Sweden, Germany, Switzerland and Lithuania. This makes procurement and the acquisition of consumables and spare parts complex to manage, and it means hospital staff have to deal with numerous different types of manual. The costs of importation in Rwanda include a 2% tax on medical equipment, plus costs for the customs agent and warehousing etc.

Because of the length of the supply chain there are regular maintenance problems on all types of hospital equipment in each of the countries studied. Much equipment is out of service for long periods because of the need for repair. Mulago Hospital in Kampala sends many of its patients to a private sector imaging centre, with consequent costs, despite having equipment of its own, because it is so often out of service.

Some interviewees commented that supply channels in the private sector (for-profit and not-for-profit) generally work better than those in the government sector. The private

wholesaler Kamcare Pharma will deliver every few days in Kampala and accepts orders via its app. MedSource, a subsidiary of the NGO Management Sciences for Health, provides a digital procurement platform for its members, mostly in Kenya.

The Rwanda Ministry of Health has an ambition to digitise the supply chain for all medical supplies and connect it with the patient electronic medical record database, to enable better forecasting. The need for this kind of linkage was echoed by the Dean of Public Health at the University of Dodoma in Tanzania.

If the Rwandan initiative proves successful, it could offer a model for other countries in the region, and could be combined with other system improvements such as in inventory management and planned preventive maintenance for equipment.

Some interviewees suggested that more use should be made of the private sector to enable safe and reliable transport and storage. The costs of this might be offset by the increased efficiency of drug distribution.

Inward investment in systems and logistics, combined with supply chain knowledge transfer from the private sector, could enable a step change in these areas.

5.2 Price & Procurement Barriers

Low drug prices, which all countries in East Africa need, in principle represent a disincentive for inward investment. However, there are pockets of opportunity which could potentially be expanded.

Almost all drugs are generics, mostly imported from India, plus sometimes China, Pakistan, Bangladesh, Egypt, Turkey and Cyprus. The products are generally satisfactory, but there are occasions when, for example, omeprazole is sourced without a sugar coating. Patients decide it tastes bitter and refuse to take it.

This is essentially a failure of procurement systems for not specifying exactly what is required. Specification detail varies by product and country across the region. In Tanzania there is a comprehensive standard for absorbent cotton wool for medical purposes developed by the Hospital Textiles Committee and covering eighteen technical attributes, plus packaging, marking and testing, but this level of specificity is not universal.

Training in effective procurement and the introduction of efficient procurement systems, with in-built safeguards against supply diversion and corruption, would be a significant step forward.

Some patients, especially in Uganda and Kenya, also distinguish drugs by country of origin. A generic produced in Europe is generally viewed more favourably than one produced in the Indian subcontinent or in East Africa, although it will be more expensive. Public attitudes to this will take some time to change.

Rwanda Medical Supply exercises a “procurement preference” which confers a 10% price advantage on locally manufactured products, although one pharmacy interviewee said the EAC had recommended a 20% advantage. There are also exemptions from import duty for products on the national Essential Medicines list, which indirectly supports importation rather than local manufacture.

The Federation of Kenyan Pharmaceutical Manufacturers (FKPM) has proposed, as in Uganda, a 12% levy should be imposed on imported products that are also manufactured in Kenya, and a 2% levy on all other imported products, in order to give domestic manufacturers a procurement advantage. Currently in Kenya there are no customs costs on imported pharmaceuticals and the import levy is only 0.75% (2% in Uganda and Tanzania).

In Tanzania, local suppliers are given a 15% advantage, and in Uganda NMS issues some national tenders which are only open to domestic suppliers.

One advantage of national procurement tenders limited to domestic suppliers is the producer retains legal liability for the product. This is in contrast to an imported product, for which the supplier has no, or very limited, legal liability for the product in the destination country and the government has to assume that liability. So procurement from a domestic supplier in principle reduces government liability.

A 2016 UNDP report recommended that the Tanzanian Medical Stores Department (MSD) consider a two stage procurement process, the first stage of which would only be open to companies manufacturing in Tanzania. However, there is no evidence of this recommendation having been implemented.

Tanzania_Local_Production.pdf (adphealth.org)

In the present research many interviewees thought the economies of scale, workforce advantages, supplier networks and sector infrastructure associated with production in India are likely to confer a price advantage on imports for some years to come. One

interviewee also claimed there was also some product dumping by Chinese manufacturers.

However, investment in more robust and efficient procurement systems, with the pros and cons of domestic versus imported supply being better understood, would pay dividends in terms of improving access to medicines.

The interviewee from the East African Community felt national drug procurement was mainly influenced by price (imports often being cheaper), but also by the lack of capacity in the sector regionally. Capacity could potentially be expanded, with the associated economies of scale, if government procurement treated it as a strategic priority and access to capital was improved (eg. through inward investment).

A related question is whether there is a price premium worth paying for more domestic production of key products, in order to generate local economic growth and employment. In certain categories, scale is also important to unit costs, so more local procurement could potentially reduce the price gap versus imports.

In Rwanda, a pharmacist at a Kigali polyclinic suggested margins even in the public sector would allow up to a 50% premium, so there could be some “headroom” in terms of price competition versus imports. In Kenya, wholesalers typically work on a 15-20% gross margin over the importer’s cost (although the KEMSA margin is higher), but it was felt there might be some headroom on selected products, especially infusions, sundries, surgical accessories and medical devices.

This is obviously a policy issue and there may be trade-offs between the procurement benefits of lower prices and the wider economic benefits of more domestic supply. However, most interviewees, especially policy-makers, were keen to reduce the country’s dependence on imports. In Kenya and Uganda, governments use the slogans “Buy Kenya. Build Kenya” and “Buy Uganda. Build Uganda” which are obviously relevant.

One interviewee asked if the East African Community should initiate some sort of pooled procurement for drugs. Other projects have explored questions related to this, including the African Union’s non-profit Africa Medical Supplies Platform developed in response to the COVID-19 pandemic and the Commonwealth Price Sharing Database initiated by the Commonwealth Pharmacists Association.

However, at present the challenges of implementing cross-country pooled procurement in any particular product category would be significant without full regulatory harmonisation including common or mutually recognised standards.

5.3 Regulatory Barriers

The East African Community (EAC), headquartered in Arusha, Tanzania, has been pursuing a Medicines Regulatory Harmonisation (MRH) initiative since 2012.

Funded primarily through donor funds, this has enabled joint product assessments, plant inspections and other collaborative processes. In 2019 the initiative developed standard operating procedures for the joint processing of product variations and renewals, in response to requests from manufacturers. However, manufacturers still have to pay individual country registration fees, and mutual recognition of new product registrations and marketing authorisations is not complete.

The EAC interviewee indicated the median delay between EAC regional authorisation and national registration for a new drug is approximately 270 days but it can be up to 550 days (Burundi). Zanzibar has the shortest time lag between these two procedures.

In 2020, a scholarly article reported that the MRH initiative had reduced the time it took to register medicines in individual countries by about half, but that there was more work to be done.

Eight years of the East African Community Medicines Regulatory Harmonization initiative: Implementation, progress, and lessons learned | PLOS Medicine

There is also an East African Health Research Commission (EAHRC) which is the principal advisory institution to the EAC on health research and development. This is intended to support the cross-border transfer of know-how and technology, alongside a publicly accessible online compendium of health information.

In the current research the interviewee from the EAC felt the new African Medicines Agency, to be headquartered in Kigali under a treaty signed in 2021, is likely to focus on evaluating more complex products and supporting capacity-building for national medicines regulatory authorities. So this of itself may not simplify the regulatory burden for manufacturers seeking to launch less innovative but essential products across the EAC.

Nevertheless, the African Development Bank has recognised the importance of regulatory and policy harmonisation in its Strategy for Quality Health Infrastructure 2022-2030. The strategy also seeks to strengthen health information systems and support innovation in the sector.

In Tanzania the Medicines & Medical Devices Authority (TMDA) was criticised by several interviewees for the length of time it takes to register a drug. Some pharmaceutical companies consequently don't consider it worth trying to register a drug for smaller therapeutic markets in Tanzania.

In addition, many hospitals depart from the official list of registered drugs because they don't believe it offers the therapeutic options they need. It is unclear why registration in the EU, US or elsewhere is not acceptable.

The interviewee from the Ugandan National Drug Authority (NDA) admitted the regulatory framework was "out of date". They thought c70% of the supply problems with antibiotics and antimalarials could be solved with more local production. However, a leading community pharmacist near Kampala felt the challenge was more to do with restrictive regulation, which in turn limits access to medicines, than the lack of local production.

In Rwanda there is only one producer (Kampala Pharmaceuticals) registered to supply acetazolamide, even though there are several other producers in East Africa who are GMP and ISO certified. There is also a question over whether the GMP Guidelines most recognised should be those of the WHO or the EU (currently they tend to be WHO), and how other producers can secure registration.

There were numerous examples in all the countries studied of prescription drugs being available over the counter, probably originating in unofficial channels of supply.

Many interviewees believed KEMSA in Kenya, NMS in Uganda, MSD in Tanzania and RMS in Rwanda could be good systems to enable reliable and well regulated public sector supply, if completely de-coupled from government. It was suggested there should be some competition to KEMSA to avoid complacency and improve efficiency.

Lack of competition was a recurring theme in the research, even in areas such as production of IV fluids, sometimes because of registration barriers. Guardian Health, one of the largest retail pharmacies in Kampala, said they need "another Cipla" (one of

the most successful local manufacturers). The lack of effective competition may be one factor behind the strength of the grey market for pharmaceuticals across the region.

Rwanda Medical Supply buys some products from Cipla, whose plant in India is pre-qualified. However, the Cipla plant in Uganda is not prequalified, with the result that products are imported from India rather than a neighbouring country in East Africa.

Harleys Pharmacy, one of the largest pharmacy distributors in Kenya, with some operations in Tanzania and Uganda as well, depends like all other players in the supply chain overwhelmingly on imports. But they estimate 25% of total imports are in the grey market - unregulated product crossing borders, stolen product and parallel imports. At the private MP Shah Hospital in Nairobi the Chief Pharmacist believes up to 30% of total drug supplies could be counterfeits.

In optometry, there are potential resources that are not currently being used because of regulatory barriers. For example, optometrists in Tanzania are not allowed to undertake retinal screening or fundascope diagnosis or to treat glaucoma. Patients have to be referred to an ophthalmologist, who may be a long distance away (there are only twenty ophthalmologists in the whole of Tanzania). But with an appropriate short course, existing optometrists could be trained to diagnose and treat the glaucoma population, at lower cost, with earlier intervention.

On the other hand, in Uganda optometry has recently come under the regulatory oversight of the National Bureau of Statistics. The President of the Optometrists Association felt this would be a significant driver of improved standards by clamping down on illegitimate providers.

In Rwanda, the importation of optical equipment is hampered by the need for registration which limits the equipment available and the complexity of the import process. For example, one requirement is that all equipment should have at least two thirds of its lifespan remaining, but this is usually completely unknown. This requirement may be a misunderstanding of WHO recommendations, which in this case apply to consumables but not equipment.

As part of the East African Customs Union, no country imposes import tariffs on goods from other EAC countries, and full implementation of a single customs territory is one of the EAC’s priorities for 2022-2026.

Although it is yet to get off the ground, the African Medicines Agency is intended to support the growth of pharmaceutical manufacture in the continent, evaluate medicines

for the treatment of priority diseases and “inspect, coordinate and share information” about products authorised for marketing. It is meant to work in concert with the nascent African Continental Free Trade Area.

At a global level, the 2001 Doha Declaration on TRIPS and Public Health provides some flexibility in terms of enabling the manufacture and supply of pharmaceutical products still under patent protection. There are particular patent law exemptions for countries on the UN list of Least Developed Countries, which includes Uganda, Tanzania and Rwanda (but not Kenya).

It could be argued that more use should be made of these exemptions in East Africa. This would be of benefit to inward investors as well as existing producers, and could stimulate more interest in downstream pharmaceutical manufacturing investment.

6. CONCLUSIONS

6.1 The Challenge Overall

There is a critical need for affordable medication and medical supplies, but gaps between demand and supply are ubiquitous. One official at the Ugandan Ministry of Health said they have, at most, 50% of the supplies they need.

Antibiotics continue to be in high demand, but antimicrobial resistance is increasing. Many pharmacies in the region find it difficult to get supplies of antidiabetics other than metformin, antihypertensives (especially higher dose formulations), drugs for mental health and neurological conditions, and anything for osteoarthritis other than analgesics. Anticoagulants and beta-blockers and were also found to be in short supply.

A consultant at the Mulago referral hospital in Kampala suggested there should be regional drug stores, similar to the existing regional blood banks, to improve distribution efficiency in the government sector. This idea was echoed by interviewees in Tanzania and parts of Kenya (Kisumu, Kakamega and Mombasa).

Even though a regional distribution system already exists in Uganda, Kenya and Tanzania, it does not appear to be able to respond to regional needs. In Rwanda, possibly because of the smaller national territory or because of more efficient systems (including an electronic management information and ordering system which accommodates regional differences), the distribution system appears to be more responsive to need.

Rwanda Medical Supply also has regional warehouses. The lack of adequate storage in other countries is a severe constraint on supply, perversely resulting in higher costs because of the need for a rapid response from manufacturers.

In rural areas, access to medication is generally much worse, partly because of logistics and partly because of funding. At the NGO hospital visited in Kalongo, Northern Uganda, essential drugs such as artesonate for the treatment of malaria were often in short supply, as were thiamine and oral morphine. The same was true in rural Western Kenya. Some counterfeits were also reported in antibiotic tablets.

There are severe funding constraints across the region and all government health facilities are chronically short of money. Patients often have to pay for their own analgesics, and sometimes anaesthetics and even surgical sutures.

In 2014 Mulago Hospital, the largest government hospital in Uganda, was disconnected from its water supply for not having paid its bill. Two years later it was on the verge of being cut off again. The hospital director was reported in the press as saying they just did not have the money to pay the bill. He said the hospital's water budget was underfunded by UGX 2bn ($0.5m).

Even in the growing private sector cashflow problems are endemic, largely because of delays in payment from state-backed insurance organisations. Malolo hospital in Tanzania had its medicines supply suspended by a key wholesaler because of delayed payment. Credit lines are difficult to negotiate.

Government healthcare spend per capita in Tanzania actually declined between 2017/18 and 2021/22, but the challenges of providing care for a population which is expanding and enjoying increased life expectancy are accelerating fast.

One response to this funding shortfall is for health facilities to prioritise medication that has a direct link to mortality outcomes. So analgesics for example, apart from paracetamol, are frequently unavailable.

All interviewees agreed there is a wave of diagnosis of diabetes and hypertension about to hit all the countries studied. They also felt there were currently very large undiagnosed populations with these conditions which, when diagnosed, will put enormous further pressure on medicines supply. Currently, the under-diagnosis of hypertension and diabetes is leading to kidney problems, for which there is often no adequate treatment.

The exception is Rwanda, where the Rwanda Biomedical Centre (RBC) has undertaken two national prevalence surveys of NCD's. The most recent survey in 2021-22 indicated a diabetes prevalence of approximately 3%, a figure which has remained unchanged since 2012-13 but which is expected to climb in the near future.

Rwanda is generally the country with the most effective medication supply. However, at a polyclinic in Kigali the sudden discontinuation of a metformin combination therapy due to supply problems has meant frequent changes of therapy. This obviously interrupts treatment and adds complexity to patient management. Even when supply is not discontinued, volume is often insufficient, especially in rural areas, across the whole East African region.

The 2021-22 RBC survey in Rwanda found that 52% of the sample of 5,676 had never had their blood pressure checked. Whilst of some concern, this was down from 80% in the 2012-13 survey.

The current research found there was limited attention paid to hypertension and coronary heart disease across all the countries. However, both can be expected to increase in the near future in line with increases in life expectancy and lifestyle changes reflecting greater economic affluence.

There is also a need to reduce dependence on programme donations, historically focussed on Malaria, HIV and TB. It was widely agreed donor funding does not represent a long term solution.

Mental health and neurological conditions currently are often undiagnosed. When more attention is paid to these areas it will add further to the financial strains in the healthcare system.

6.2 Developing Production Capacity

Kenya has the most well developed domestic pharmaceutical manufacturing sector. The main barrier to further development of this in all four countries is **access to investment capital**. With interest rates in the high teens in all the countries studied, domestic investment is severely constrained.

There are some forms of commercial project finance available from international lenders, but these are rarely used as providing adequate loan security is difficult. The investment promotion agencies therefore have a crucial role to play in enabling further development of production capacity in specific areas.

Pharmaceutical materials and packaging suppliers are not well established in the region. GSK could not find a local producer of specialist bottles or foil for its blister packs, and many topical creams have to be imported pre-packaged for a similar reason.

This and other sub-sectors, in addition to medicines production for the growing **NCD markets (especially diabetes and hypertension)**, represent genuine opportunities for inward investors. The Kenyan government's Diagnostic Report on the sector also identified significant needs in immunological and cardiovascular therapy areas.

However, there are barriers in terms of **drug and equipment registration** (which often takes far too long or is restricted to too few products), the **technical skills base** available (which is why Revital in Kenya employs engineers and managers from India) and the **healthcare infrastructure**. Power outages regularly affect production facilities and storage facilities, many of which lack temperature control.

Transport logistics are also unreliable. There is hardly any temperature tracking for drugs in transit. Investment in more sophisticated logistics systems would pay dividends, and some experts recommend opening up both logistics and the wider distribution system more to the private sector.

In **diagnostic equipment**, there are limited opportunities for local manufacturing with the current skills base and raw materials, but simple ophthalmoscopes would be possible. In order to improve the effective utilisation of equipment, much of which is out of service because it needs repair, it may be useful to expand the availability of leasing arrangements.

This would obviously have an impact on the acquisition of donor-funded equipment and the accounting used by health facilities, but it could provide essential services support. As equipment becomes more complicated and sophisticated, often with a software component, it is less and less possible for repairs to be made by health facilities staff.

That support itself represents an investment opportunity, either through the stand-alone provision of such services (which increasingly have to be equipment-specific) or the development of more leasing-based models.

However, there remains some **economic and political uncertainty** across the region which is inhibiting inward investment. This is despite development of both the East African Community and the new African Continental Free Trade Area, and the imminent establishment of the African Medicines Agency in Kigali.

Regulatory harmonisation and reform through these and other channels, together with reassurance from international agencies on the economic and political environment, will be essential in overcoming investors' hesitation. This could create a step change in FDI and the associated injection of investment capital and technological know-how.

6.3 The FDI Opportunity

Foreign direct investment can provide both capital for growth and technology transfer into the regional pharmaceutical, diagnostic and medical supplies sectors.

The opportunity presented to potential inward investors by the growing demand in these sectors will be considerably magnified when **full regulatory harmonisation** is achieved within the East African Community, including common or mutually recognised standards. This will enable far easier access to the wider regional market with a population approaching 200 million and increasing life expectancy.

Local pharmaceutical manufacturers currently have to import almost all their raw materials, including much of their **specialist packaging**. More production within the region of blister packs or specialist bottles, for example, would be of considerable benefit to manufacturers and to the wider growth of the sector.

GSK cited the lack of regional prescription medicines packaging suppliers as a factor in their withdrawal from Kenya. There is also an appetite amongst other regional manufacturers for more locally sourced packaging.

One of the most often mentioned FDI opportunities was in **sundries and accessories** - in particular catheters and giving sets, absorbent gauze, cotton wool and bandages.

These may appear to be low value product categories. However, according to a senior pharmacist in Kigali, elastic adhesive bandages, which are almost always imported, carry a c30% margin for the pharmacy. There is also substantial unmet demand in all these categories. Shortage of supply was mentioned even in Kisumu, the third largest city in Kenya.

Other areas of medical accessories could also be attractive. The number of local manufacturers of masks increased hugely during the COVID pandemic, but Venturi masks are still in short supply. The growth of the Kenyan syringe and diagnostics manufacturer Revital could offer a model for further development of this sector.

Product categories such as packaging, sundries, accessories and simpler medical devices are often valuable bridgeheads for investors into new geographic markets.

In general, most medicine stock-out issues relate to drugs which are in high demand but not particularly difficult to manufacture, especially if set up by an overseas partner or investor with the necessary experience, systems and materials availability.

There are significant opportunities in **IV infusions** which are often in short supply.

Some are produced by local manufacturers such as Kampala Pharmaceuticals and Abacus in Uganda and Laboratory & Allied in Kenya. They have also been produced by a number of hospitals across the region, but there are challenges at the hospital level in terms of materials cost, supply and economies of scale with the investment required in GMP-compliant clean rooms.

Nevertheless, several interviewees said there was genuine potential in IV fluids and more competition in supply would be widely welcomed. These products tend to generate higher gross margins (c60%) than many others because the inputs are relatively low in number and the finished product is sold straight to the hospital from the manufacturer, or sometimes the wholesaler, with no retail margin involved.

A leading pharmacist suggested IV fluids should be developed that are stable at ambient temperatures above 30 degrees Centigrade. Given the climatic conditions of the region, there would be considerable demand for such products.

A number of interviewees also mentioned the growing demand for **eye drops. T**he raw material and production skill challenges in this area have been overcome by Abacus in Uganda and several smaller producers. The larger regional manufacturers have not so far taken a dominant share of the eye drop market, and this could offer a niche opportunity.

As a way into further development of the regional industry, some interviewees felt contract manufacturing for international pharmaceutical companies was a way forward, especially in **antibiotics and antihypertensives, plus antidiabetics, statins** and potentially **asthma medication**. Senegal has had significant success with contract manufacturing in recent years.

Contract manufacturing would introduce more competition in the relevant markets, whilst managing the financial risk for local producers, with the overseas owner of the drug supporting investment in additional capacity. Increased supply of antidiabetics and antihypertensives, plus possibly statins, via this route would also be in line with the increasing life expectancy in the region and the fast-growing demand for treatment of NCD’s.

Some interviewees commented that abolishing VAT on raw materials and packaging for pharmaceutical and medical supplies production would be a significant step towards support for the domestic industry. Kenya’s exemption from VAT for selected medical

equipment, including production machinery, oxygen and some consumables, in the 2022/23 budget has been very positively received.

However, having **visibility on market demand and the price at which products will be bought** were considered more important for strategic planning in manufacturing.

Historically, donor funded programmes in HIV, malaria and TB have carried both assured demand and guaranteed prices (and consequently they have supported the growth of producers such as Cipla in Uganda). This is less likely to be the case with NCD's.

However, as health insurance expands to cover more of the population in each country, state-backed insurance schemes could play a highly influential role. They will be in a position to confirm demand for medication is areas such as diabetes, hypertension and heart disease. These all have significant downstream costs if not treated in their earlier stages, so there is an economic incentive to improve the availability of antidiabetics, antihypertensives and statins.

The **diagnostics sector** is also underdeveloped.

The large number of different countries from which optical equipment is sourced creates a particularly challenging supply picture in that sector. But it also represents an opportunity for potential local manufacturers, particularly for relatively simple equipment such as ophthalmoscopes.

As with IV infusions and medical sundries, ophthalmoscopes could be an attractive entry point in order to expand local production capacity. Rapid test diagnostic kits, such as those being developed by Revital in Kenya, could also offer potential.

Equally important are the opportunities for effective, responsive **equipment maintenance and repair services**. These could potentially be included in leasing agreements, which might be more appropriate as equipment becomes more technically complex.

The equipment distributor Viebeg in Rwanda has demonstrated the commercial value of preventive maintenance and responsive support services. This is likely to grow substantially as health systems across the region use increasing amounts of technologically advanced equipment.

Finally, there are opportunities in **data and logistics systems.** There is a clear need for better data collection and analysis in determining the composition of "push" medical

supplies in the government sector and in monitoring epidemiological trends to enable better demand forecasting.

The opportunity to better connect procurement, supply and distribution information with patient and epidemiological data is significant. This could improve the efficiency of warehousing and inventory management, as well as reducing the number of stock-outs of medicines and other supplies.

In logistics, Zipline represents a potentially game-changing development for the delivery of emergency supplies in Rwanda, and could provide a model for other countries in the region. Along with Kisumu County, Kenya, where Zipline is collaborating with the county government, a relatively self-contained region such as Zanzibar could be a pilot for its further roll-out in the region.

System improvements such as these are directly in line with the African Development Bank's 2022-2030 Strategy for Quality Health Infrastructure. It is hoped this report can contribute to the delivery of that strategy as well as the EAC's Regional Pharmaceutical Manufacturing Plan 2017-2027.

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