East African Community

2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027

A regional roadmap to guide the East African Community towards evolving an efficient and effective regional pharmaceutical industry that can supply national, regional and international markets with efficacious and quality medicines.

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List of Abbreviations

ACT .....Artemisinin Combination Therapy
AMRH.....African Medicines Regulatory Harmonisation
AOP.....Annual Operational Plan
API.....Active Pharmaceutical Ingredient
ARV.....Antiretroviral Therapy
AU .....African Union
CAGR.....Compound Annual Growth Rate
CET .....Common External Tariff
CHAI.....Clinton Health Access Initiative
CRS.....Chemical Reference Substances
CTD.....Common Technical Document
EAC.....East African Community
EAHRC.....East African Health Research Commission
EALA .....East African Legislative Assembly
EML .....Essential Medicines List
EWG.....Expert Working Group
FEAPM .....Federation of East African Pharmaceutical Manufacturers
FGD.....Focus Group Discussions
FKPM .....Federation of Kenya Pharmaceutical Manufacturers
FMD.....Foot-and-mouth disease
FPP .....Finished Pharmaceutical Products
GAP.....Good Agricultural Practices
GCP.....Good Clinical Practices
GDP .....Gross Domestic Product
GIZ.....Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH (German Development Cooperation)
GLP .....Good Laboratory Practice
GMP.....Good Manufacturing Practice
HIV.....Human Immunodeficiency Virus
ICH.....International Conference on Harmonisation
IPR.....Intellectual Property Rights
ISO.....International Organization for Standardization
KEVEVAPI .....Kenya Veterinary Vaccines Production Institute
KPPB.....Kenya Pharmacy and Poisons Board
MA.....Marketing Authorisation
NCD .....Non-Communicable Diseases
NDA .....National Drug Authority
NEPAD.....New Partnership for Africa's Development
NGO .....Non-Governmental Organisation
OECD-DAC .....Organisation for Economic Cooperation and Development - Development Assistance Committee
OOP .....Out of pocket
OTC .....Over the counter
PTB .....Physikalisch-Technische Bundesanstalt Braunschweig
R&D .....Research and Development
REC.....Regional Economic Community
RPMPOA.....Regional Pharmaceutical Manufacturing Plan of Action
SDG.....Sustainable Development Goals
SEZ .....Special Economic Zone
SGR.....Standard Gauge Railway
SHP.....Social Health Protection
SSA .....Sub-Saharan Africa
SWOT .....Strengths, Weaknesses, Opportunities and Threats
TB.....Tuberculosis
TFDA .....Tanzania Food and Drug Authority
THE .....Total Health Expenditure
TM .....Traditional medicines
TOR.....Terms of Reference
TRIPS.....Trade-Related Aspects of Intellectual Property Rights
UHC .....Universal Health Coverage
UNAIDS.....United Nations Programme on HIV and AIDS
UNCTAD.....United Nations Conference on Trade and Development
UNIDO .....United Nations Industrial Development Organization
VAT .....Value Added Tax
WHO.....World Health Organization
WHO-PQ .....World Health Organization Prequalification
WIPO.....World Intellectual Property Organization

Foreword

The EAC Partner States comprising the governments of Burundi, Kenya, Tanzania, Rwanda, Uganda and South Sudan, aspire to develop their pharmaceutical industry as part of the regions', social and political integration agenda. As a region we recognize the strategic importance of developing local production of pharmaceutical products in promoting access to affordable quality essential medicines. It is in this regard that an EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA),2012-2016 was developed to serve as a road map to guide the community towards evolving in to an efficient and effective regional pharmaceutical manufacturing industry. The implementation of the plan along with other regional initiatives such as the EAC Medicines Registration Harmonization (MRH) and the EAC Industrialization Policy and Strategy (which prioritizes pharmaceutical sector) has contributed to the positive development of the sector and progress in harnessing joint economic potential. The implementation period for the first EAC-RPMPOA: 2012-2016 ended in 2016 and there is need for continuation and further improvement. This new plan (EAC-RPMPOA: 2017- 2027) therefore builds on the achievements of the first plan, identifies gains and challenges encountered and; lays down strategic approaches for the EAC and the Partner States. The plan factors in the Sustainable Development Goals (SDG) especially with regard to good health (SDG 3) and industry, innovation and infrastructure (SDG 9).

The key findings in the plan show that while EAC pharmaceutical market is growing rapidly, there is still a high dependency on imported pharmaceutical products and local firms lack capacity to manufacture advance formulation and furthermore most firms in the region are producing below their capacities. Though, locally produced medicines cover majority of the disease conditions, the region lacks the capacity to manufacture advanced formulations with locally produced medicines covering only 66% of the regions' disease conditions. This is attributed to a skills gap on product development and formulation expertise, lack of appropriate and affordable financing for the sector among others. Despite the challenges, opportunities abound in the sector that continues to attract interest. There is a young and growing population with an expanding middle class, an increasing Non-Communicable Disease (NCD) burden and continued prevalence of infectious diseases. Local manufacturers can build on enabling factors such as the existing policy context, improved regulatory environment, larger budgetary allocation to the health sector in the region and the economies of scale created by the Common Market Protocol.

A number of potential niches for expansion of the local product portfolio have been highlighted in the plan such as production of advanced formulations for non-communicable diseases, veterinary pharmaceuticals and development of natural products/traditional medicines. The plan also focuses on supporting production of active pharmaceutical ingredients and excipients as well promoting the sector specific service industry. The plan sets four high level targets for the development of the EAC pharmaceutical sector as follows: reversing dependency on pharmaceutical imports from outside EAC from more than 70% to less than 50%; supporting the expansion of product portfolio of EAC firms to cater for more than 90% of disease conditions; at least 50% of purchases by EAC national medicines procurement agencies is sourced from EAC pharmaceutical manufacturers; and at least five (5) companies to produce more advanced pharmaceutical formulations such as delayed release formulations, small volume injectables, double layered tablets, among others.

To achieve these targets, a number of key strategic activities are to be prioritized which seek to consolidate the gains made in the sector, including putting in place Good Manufacturing Practices (GMP) roadmaps for local manufacturers to upgrade and attain internationally recognized quality standards; developing a platform for sustainable access of pharmaceutical market intelligence data; introducing and implementing incentive packages and appropriate financing schemes for local pharmaceutical manufacturers; promoting policy coherence across sectors at national and regional level; establishing a regional framework for mutual recognition of harmonized medicines registration and GMP inspections; developing and implementing a regional strategy for promoting availability of appropriate skills mix for the local pharmaceutical manufacturing industry; domesticating public health related WTO TRIPS Flexibilities within the national laws of the partner states and putting in place incentive schemes to promote research and development (R&D) in the pharmaceutical industry.

The successful implementation of the plan will require concerted efforts of all EAC Partner States, National Ministries of Health, Trade and Industry as well as National Medicines Regulatory Authorities, the National Procurement Agencies, National Academic and Research Institutions, Pharmaceutical Manufacturers' Associations, Pharmaceutical industries , Private Sector , Non- State Actors (NSAs) and International Development Partners.

In view of the importance of the regional pharmaceutical sector with regards to improvement of health and overall well-being of the people of East Africa and its contribution to industrial development, I urge all the stakeholders to take necessary actions as outlined in the plan for successful implementation of the Plan.

Ambassador Liberat Mfumukeko
Secretary General
East African Community

Acknowledgement

The publication of this second plan of action the **East African Community Regional Pharmaceutical Manufacturing Plan for Action (EACRPMPOA): 2017- 2027** is being availed now coincidentally just just as the EAC winds up its first Industrialization Action Plan (2012-2017). It thus marks an encouraging achievement for the EAC as it begins further steps towards attaining another five (5) year plan all of which envision the implementation of the EAC Industrialization Policy 2012-2032. The EAC Industrialization Policy aims to 'transform the manufacturing sector in EAC through higher value addition and product diversification based on comparative and competitive advantages of the region' and is currently under implementation with the development of the pharmaceutical sector as one of the regions' strategic and priority sector for development. The development of this report is therefore part of the ongoing efforts in the implementation of the regional Industrialization Policy.

In recognition of the important role played by the pharmaceutical sector in the industrialization policy this report was prepared in close consultation with various national, regional and international stakeholders. The report was prepared through a consultative process that took into account the views of stakeholders and ongoing developments in sector in the region. In this regard, the Secretariat, wishes to acknowledge and thank the participation, dedication and commitment by the EAC Partner States in the development of Plan. Key national stakeholders were drawn from National Ministries of Industry, Trade, Health, Finance, Planning and East African Community Affairs; National Medicines Procurement Agencies (NMPAs), National Medicines Regulatory Authorities (NMRAs), National Investment Promotion Agencies, Academia, Pharmaceutical Manufacturers' Associations, local Pharmaceutical Manufacturers and International Development Partners. The support and active participation of the EACRPMPOA focal points and the National Coordination Committee members in the Partner States is also acknowledged.

The invaluable technical and financial support provided by the Federal Republic of Germany through the GIZ Programme of 'Support to the EAC integration process' and implemented by GFA Consulting Group project on Socio-economic Integration in EAC is highly acknowledged and appreciated. Last but not least, the EAC Secretariat recognizes the tireless efforts of the EAC staff from the Industrial Development Department on the successful stewardship of the development of the Plan of Action.

It is envisaged that at the end of the implementation of the plan the local pharmaceutical manufacturing industry will be able to meet local demands as well as increase its presence on the international market, provide more employments and contribute to the availability of foreign exchange through reduced imports. Importantly it is expected that the region's population will be healthier as a result of accessing high quality medicines produced locally.

In conclusion, I wish to emphasize that we will ensure a coordinated and collaborative approach by all the relevant departments of the EAC Secretariat (Health, Industry and Trade), Partner States' National Ministries and Institutions, Pharmaceutical Manufacturers' Associations as well as development partners for the successful implementation of the plan. This coordination will seek to synergize and harness existing national, regional and international initiatives towards strengthening local production of pharmaceuticals. The EAC Secretariat will take the lead responsibility in mobilizing and optimally deploying the necessary resources including personnel for the successful implementation of the plan.

Hon. Christophe Bazivamo
Deputy Secretary General
(Productive and Social Sectors)
East African Community

Executive Summary

There is abundant interest on the part of the EAC Partner States in promoting their pharmaceutical industry. The first EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA): 2012–2016 provided the framework upon which regional and national strategies were aligned in an effort to strengthen the sector. While the implementation of the first plan has achieved several key milestones and contributed to the positive development of the sector, there is need for continuation and further improvement. The current plan (EAC-RPMPOA: 2017–2027) has been developed to build on the achievements and to set out new strategic approaches to surmount the challenges and capitalise on emerging opportunities within the sector.

Key findings from this report show that while EAC pharmaceutical markets are growing rapidly, there is still a high dependency on imported pharmaceutical products and local firms are producing below capacity. Local manufacturers are strongly present in the anti-infectives product category but they miss out in immunological and cardiovascular markets, which have a large market share in the region. Even though locally produced medicines cover 66% of disease conditions, the region lacks the capacity to manufacture advanced formulations. This is attributable to a skills gap in the areas of product development and formulation expertise. Furthermore, there is a lack of appropriate and affordable financing for the sector, with options being limited to short-term loans with high interest rates. From the trade perspective, enhanced cooperation and harmonisation would reduce regulatory barriers and broaden export markets.

Meanwhile, the young, growing population with an expanding middle class, the increasing NCD burden and continued prevalence of infectious diseases will further increase opportunities for local manufacturers on the pharmaceutical market. Local manufacturers can build on enabling factors such as the existing policy context, a pharmaceutical production base and improved regulatory environment, an extension of the use of public health-related WTO TRIPS flexibilities until 2033, a high number of innovator molecules coming off patent, and a larger budgetary allocation to the health sector in the EAC. GMP Roadmaps are under way to guide and support the transition of EAC pharmaceutical firms towards international GMP standards and with that to broader market opportunities beyond the EAC.

In this new plan, a number of potential niches for expansion of the local product portfolio have been highlighted. Non-communicable diseases such as cancer, asthma, and diabetes are strongly on the rise and the gap in access is enormous. This could be a huge opportunity for manufacturers in the EAC; as opposed to the highly competitive markets for HIV, tuberculosis, and malaria drugs. Moreover, traditional medicines and natural products can be a market niche as Africa has a long history of using such products and global market shares are rising. What is more, expanding into veterinary pharmaceuticals by the local manufacturers could be a step towards improving their bottom line and expanding their product portfolio.

This plan also identifies lessons learnt from other countries and regions on how to promote local pharmaceutical production. There is convincing evidence that an industrial policy for the support of local pharmaceutical manufacturing can be successful, both from an economic and a healthcare perspective. Best practice examples from Ghana, India, Bangladesh, Ethiopia and Egypt have shown that access to medicine can be improved, while sub-standard and falsified products as well as dependence on imports can be diminished with the adoption of appropriate policy intervention.

The plan sets four high-level targets for the development of the EAC pharmaceutical sector:

1. Decrease dependency on pharmaceutical imports from outside EAC from more than 70% to less than 50%.
2. Support the expansion of product portfolio of EAC firms to cater for more than 90% of disease conditions.
3. At least 50% of purchases by EAC national medicines procurement agencies to be sourced from EAC pharmaceutical manufacturers.
4. At least five (5) companies to produce more advanced pharmaceutical formulations such as delayed release formulations, small volume injectables, double layered tablets, among others.

To achieve these targets, a number of key strategic activities are to be prioritised, which seek to consolidate the gains made in the sector and include the following:

1. Putting in place a regional GMP Roadmap for local manufacturers to upgrade and attain internationally recognised quality standards.
2. Developing a platform for sustainable access to pharmaceutical market intelligence data.
3. Introducing and implementing incentive packages and appropriate financing schemes for local pharmaceutical manufacturers.
4. Promoting policy coherence across sectors at national and regional levels.
5. Establishing a regional framework for mutual recognition of harmonised medicines registration and GMP inspections.
6. Developing and implementing a regional strategy for promoting availability of appropriate skills mix for the local pharmaceutical manufacturing industry.
7. Domesticating public health-related WTO TRIPS flexibilities within the national laws of the Partner States.
8. Putting in place incentive schemes to promote R&D in the pharmaceutical industry.

Overall, the strategic interventions shall focus on supporting the production of advanced formulations, APIs, veterinary medicines as well as harnessing the potential of traditional medicines and natural products. Specifically, R&D, strategic use of IPRs/benefit sharing and incentives shall be used to attract interest and investment in niche areas.

The implementation period of the plan is divided into three phases, with 2017–2021, 2022–2024 and 2025–2027 being phase one, two and three respectively. Monitoring and evaluation of the implementation of the plan will be informed by baseline data and milestones set to be achieved within specific timelines. In this regard, nineteen (19) key indicators and milestones have been identified to monitor progress and achievements.

Based on the assessment of the previous plan, and lessons learnt from this, a coherent steering structure to support the implementation of the plan should be put in place as well as a clear fundraising and resource mobilisation strategy

01

Introduction

1.1 Background

Ensuring access to essential medicines is a key objective of every health system. Medicines are a critical input in health service delivery, without which many people across the world are denied proper care. Medicines provide important life-saving measures, provide crucial preventive therapies for diseases, provide much-needed relief for chronic illnesses, while prolonging the lifespan and improving quality of life for patients. Thus, equitable access to safe and affordable medicines is necessary for the attainment of the highest possible standard of health[1].

Nevertheless, millions of people, particularly in low- and middle-income countries, still remain without access to quality-assured and affordable medicines. Even today, with an increasing expansion of universal health coverage (UHC), many people have to pay for their medicines out of their own pockets but lack the necessary financial resources to do so. This can result in either non-treatment or disastrous expenditure, especially where there is no generic competition to originator products that can push down the price of medicines for the consumer and government procurement agencies.

Multiple stakeholders, sectors and policy areas need to be involved in this complex process of ensuring access to medicines. The production side of medicines incudes various parameters such as product discovery (research and development), licencing of products and market participants, quality assurance, pharmacovigilance, marketing, pricing, and promotion. The consumption side of pharmaceuticals is influenced by procurement systems, purchasing arrangements, and supply chain management. National pharmaceutical policies, as well as events and reforms in other sectors, such as industrial policy and trade agreements, influence a country's pharmaceutical market. All these parameters and stakeholders interact with each other and have an impact on access to medicines by the consumers.

Effective regulation of medicines is needed to ensure the quality, safety and efficacy of medicines being provided to the population. Effective medicines regulation involves a range of complex processes required to effectively regulate the market, test control samples and inspect companies. In many low- and middle-income countries, however, regulatory authorities and control laboratories tend to be short of funds and lack the technical equipment, human resources and expertise to adequately fulfil their function. This can result in falsified or sub-standard medicines circulating in the market, with potentially harmful effects for the consumer.

One way to improve both availability of essential medicines and their quality is to produce medicines locally. Local production of pharmaceuticals could decrease dependence on foreign suppliers, provide local jobs, increase expertise, and cut transport costs[2]. Local production could also give greater control to African regulators, which are fighting against low-quality drugs, sometimes made in far-off factories that are difficult to monitor[3].

Imports are still dominating the pharmaceutical markets in Africa. Local pharmaceutical production continues to play a relatively minor role: in Sub-Saharan Africa (SSA), only around 30% of the demand can currently be met by local production. Several factors have been identified to be responsible for this situation, including locally manufactured products being uncompetitive over imports; failure of local products to meet internationally accepted quality standards; lack of technical capacity to enable diversification of their dosage form portfolio and product lines; and lack of enabling policies (including policy coherence) among various sectors (both nationally and regionally).

Over the past decade, several continental and international programmes have been initiated towards enhancing local pharmaceutical production across Africa, increasing access to essential medicines and enhancing export opportunities. This includes the African Union (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA), which aims to strengthen Africa's ability to produce high-quality, affordable pharmaceuticals across all essential medicines contributing to improved health outcomes and the realisation of direct and indirect economic benefits[4]. A number of international donors and implementing agencies partner with developing countries to support initiatives towards better access to medicines, improved local production and strengthened regulatory environments. On a global stage, public health-related WTO TRIPS flexibilities could be utilised by developing countries to supplement and potentially substitute imported medicines with locally produced ones.

In the area of local pharmaceutical production, positive developments can be seen in the East African Community. The EAC Secretariat and the Partner States recognise the strategic importance of the pharmaceutical sector in promoting access to quality and affordable essential medicines. It is in this regard that the EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA): 2012–2016 was developed to serve as a roadmap to guide the community towards building an efficient and effective regional pharmaceutical manufacturing industry. The implementation of the plan along with other regional initiatives such as the EAC Medicines Registration Harmonisation (MRH) and the EAC Industrialisation Policy and Strategy (which prioritises the pharmaceutical sector) has contributed to the positive development of the sector.

EAC-RPMPOA: 2017–2027 has been developed to serve as a blueprint for the pharmaceutical sector. The implementation period for the first EAC-RPMPOA: 2012–2016 ended in 2016 and there is need for continuation and further improvement. The new plan (EAC-RPMPOA: 2017–2027) reviews the implementation progress and builds on the achievements of the industry and the public sector, identifies gains and challenges encountered; lays down strategic approaches for the EAC and the Partner States; addresses existing challenges and responds to emerging opportunities. The new EAC-RPMPOA also considers the Sustainable Development Goals (SDG) especially with regard to good health (SDG 3) and industry, innovation and infrastructure (SDG 9).

[1] WHO, 13 March 2009, Statement on Access to Medicines, http://www.who.int/mediacentre/news/statements/2009/access-medicines-20090313/en/ [March 2016].
[2] R. Bate, 2008, Local Pharmaceutical Production in Developing Countries, http://www.libinst.ch/publikationen/LI-LocalPharmaceuticalProduction.pdf
[3] M. Kardas-Nelson, 2015, Can (and should) Africa make its own medicines? The BMJ.
[4] AUC-UNIDO, 2012, Pharmaceutical Manufacturing Plan for Africa, Business Plan (2015).

Local pharmaceutical production as part of the Agenda 2030. Local production of essential medicines contributes to attaining SDG 3.8 ("achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all") in a more sustainable manner than through the delivery of donated drugs to developing countries. This is particularly true in the current turbulent environment where contributions to international organisations are likely to be reduced drastically and funds for medical donations may be cut significantly[5].

1.2 Methodology

An extensive literature review on relevant reports, studies, policies, strategies and country profiles as well as regional and international initiatives was conducted. To guide data collection a questionnaire with both qualitative and quantitative components was developed and where possible it was prefilled by the project team during the desk review. The information gathered was then validated and/or expanded during face-to-face interviews with key stakeholders. The zero draft was presented to a regional expert meeting.

The revised draft with inputs from the experts was presented to a wider audience at national stakeholder workshops held in all Partner States. The draft plan was further revised based on the inputs, suggestions and comments from the national stakeholders.

A final draft was then validated in a regional multi-stakeholder workshop that included public and private sector representatives and civil society organisations from the five Partner States as well as international development partners. Their inputs and comments were included in the final **EAC-RPMPOA: 2017–2027**, which was then presented to the EAC Secretariat. Throughout the duration of the assignment, the consultant team worked closely with the EAC Secretariat staff, the EAC-RPMPOA focal points in the Partner States, and the EAC/GFA team.

1.3 The concept of local pharmaceutical production

The complex process of pharmaceutical production can be divided into three linked activities: manufacture of active pharmaceutical ingredients and intermediates, production of finished dosage forms from active pharmaceutical ingredients and excipients, and final packaging of finished dosage forms or repackaging of bulk finished products. The whole process requires special technologies, reliable supply of high-quality raw materials and dependable provision of high-quality water, energy and other utilities. It also needs appropriately trained personnel with specialist knowledge e.g. in the areas of formulation development, quality assurance, and regulatory processes.

In this Plan of Action, local pharmaceutical production is used to refer to manufacture of pharmaceuticals as described above physically occurring and/or located in any of the East African Community Partner States.

02

Situation Analysis of the EAC Pharmaceutical Sector

[5] https://www.nytimes.com/2017/01/25/us/politics/united-nations-trump-administration.html?_r=0

2.1 EAC socio-economic context

2.1.1 Population and economic status

The East African Community (EAC) is home to about 174.2 million people[6] and comprises six countries: Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda. The EAC is a diverse region, with wide variation across countries both in terms of population and economic status. Among the EAC member states, Tanzania is the most populous with over 52 million inhabitants, followed by Kenya and Uganda. Population growth rates in the EAC countries have been high over the past few decades[7], with a total fertility rate of over 5% in the EAC in 2013[8]. South Sudan with its population of 12.34 million in 2015 has been accepted to join the EAC in 2016 and is estimated to become a full member in another two to three years.

The EAC region has charted significant economic growth over the past decade. At 6.2%, the EAC's average growth rate in the period 2004–2013 is in the top one-fifth of the distribution of 10-year growth rate episodes experienced by all countries worldwide since 1960. This performance is even more remarkable when taking into account that this period encompasses the global economic and financial crisis beginning in 2007[9]. The EAC has fast-tracked regional integration and has seen considerable progress in institutional reforms. The region is experiencing much greater political stability than it has at any point in its recent past; major investments in both national and regional infrastructure have been implemented, or are planned and scheduled to commence shortly[10].

> *The White House (2013): "The EAC is an economic success story, and represents a market with significant opportunity for U.S. exports and investment."*

However, much of the growth in East Africa and the whole continent has been fueled by the extraction of minerals, which may not be sustainable in the longer run[11]. South Sudan is the most oil-dependent country in the world[12]. With the exception of Kenya, which belongs to lower-middle-income economies, all EAC countries are still in the low-income country category [13].

2.1.2 Doing business in the EAC

The EAC Partner States are making efforts to address the challenges faced by businesses in the respective countries with the aim of attracting investments. Reforms range from cutting down on the number of procedures involved in business licence applications to getting electricity and providing access to credit and tax administration. The World Bank 2016 regional report on doing business in the East African Community indicates general improvements in all of the five Partner States. The countries have also made trading across borders faster and easier over the last five years through automation and ICT upgrades. The governments have introduced tools to facilitate trade, including single windows and electronic data interchange systems. In the Northern Corridor, these reforms have led to a reduction in the number of days taken up by transporting cargo from Mombasa to Kampala from 18 to four days, while that of Mombasa to Kigali has been reduced from 21 to five days [14].

Over the last five years the EAC Partner States have made efforts to substantially increase the supply of electricity, but cost of power in the EAC remains high[15]. Kenya has doubled the generation of power from geothermal sources from 158MW in 2009 to 348MW in 2014. In the coming years, Tanzania is expected to substantially scale up power supply from natural gas after the recent discoveries of huge deposits in the country. Despite these improvements, the cost of power in East Africa is still relatively higher than in other countries. For example, as detailed in Annex III, the average unit cost of power for heavy industrial customers was USD 0.128, while that of Egypt and Ethiopia is USD 0.11 and USD 0.09 respectively[16]. The cost of electricity is a significant cost factor in pharmaceutical manufacturing, and anecdotal evidence indicates that for IV Fluids (large volume parenterals) production it contributes up to 5% of the total indirect costs.

Huge investments go into upgrading EAC ports and railway systems. Kenya and Tanzania are making large-scale investments on new berths and facility upgrades at the ports of Mombasa and Dar es Salaam respectively, with the aim of enhancing their efficiency and competitiveness. New ports are being planned in Lamu, Tanga and Bagamoyo along the East African coast. The East African countries are also modernising their railway systems, with SGR construction already under way at both the Northern and Central Corridors. All of these investments as well as reforms on the ease of doing business and the deepening of the regional integration process are expected to make the region more attractive to investors.

In **South Sudan**, the pillars for private sector development are slowly taking shape. These include a policy framework that facilitates an enabling environment to build investor confidence, ensure a level playing field, low administrative barriers, and good economic governance. Policy development has focused on contract law, company law, investment authority and sector-specific laws[17]. The South Sudan government is in the process of implementing business climate reforms in order to attract foreign direct investments (FDI) with the support of development partners. A legal framework for investors has been established to encourage the growth of a nascent private sector and, in the medium term, to substantially attract foreign direct investments into the country[18].

[6] CIA, 2016, "The World Factbook", Retrieved 28 Nov 2016.
[7] UN World Population Prospects, the 2015 revision.
[8] East African Community Facts and Figures, 2014.
[9] IMF Working Paper, How Solid Is Economic Growth in the East African Community? 2014.
[10] https://www.brookings.edu/opinions/africas-powerhouse/
[11] http://www.theatlantic.com/international/archive/2013/07/3-reasons-why-obama-wants-to-expand-trade-with-africa/277493/
[12] http://www.worldbank.org/en/country/southsudan/overview
[13] World Bank data (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups).
[14] http://www.transportworldafrica.co.za/2014/06/30/northern-corridor/
[15] EAC Facts and Figures, 2015.
[16] The World Bank, Benchmarking Africa's Costs and Competitiveness, http://siteresources.worldbank.org/EXTAFRSUMAFTPS/Resources/chapter4.pdf
[17] C. Bartel, 2013, Establishing a framework for trade policy in South Sudan. GREAT Insights, Volume 2, Issue 8. November 2013, Maastricht: ECDPM.
[18] African Development Bank, 2013, South Sudan: A Study on Competitiveness and Cross Border Trade with Neighboring Countries.

Selected accomplishments so far include:

- Enactment of six laws, including an investment promotion act that covers business contracts, limited partnerships, and business entry;
- Finalisation of the process of formulating the Trade Policy;
- Establishment of the South Sudan Investment Authority (SSIA);
- Strengthening of existing business registry by streamlining procedures to enable businesses incorporation within one day;
- Strengthening of customs management and administration;
- Reform of tax regulation and revenue collection through improved transparency and accountability.

2.1.3 Health outcomes and health sector context

The youth is EAC's future. The average life expectancy at birth in the EAC region is 58, albeit with a 13-year gap between Rwanda's life expectancy at birth of 65 years and Burundi's life expectancy at birth of 52 years[19]. The EAC population is very young; in fact, young people constitute the largest segment of the population in the EAC. With over half of its population aged below 15 in 2012, Uganda stands out with one of the world's youngest age structures as a result of lower mortality rates and a high fertility rate of 6.1 children born per female in 2011[20].

East Africa is on the brink of a major epidemiologic transition. HIV/AIDS, lower respiratory infection, and diarrheal diseases are among the leading causes of death in the EAC. In addition, NCDs have risen sharply as a share of the total disease burden across EAC countries. According to the WHO, NCDs deaths due to cancer, diabetes, heart disease and chronic respiratory disease are projected to overtake communicable diseases in Sub-Saharan Africa by 2030. By that year, deaths from NCDs are expected to account for 42% of all deaths, up from approximately 25% today[21].

The rising burden of NCDs, coupled with a young, growing population, means that the region will continue to face a tough battle ahead to provide preventive and long-term care – including access to medicines – to its population, placing a significant burden on the health system to ensure supply-side readiness and resource availability.

2.1.4 Expenditure on health in the EAC

On a per capita basis, total health expenditure (THE) in the EAC varies from about USD 22 in Burundi to USD 78 in Kenya (2014 data). This is very low compared to the global average of USD 1,038 in 2013. General government health expenditure comprises more than half of total health spending in all EAC countries, with high shares of external resources, especially in Burundi (50% of THE). Donor funding plays a significant role in the procurement of medicines, particularly for priority endemic diseases such as HIV, TB and malaria. Private health expenditure (% of THE) varies between 39% in Burundi and 75% in Uganda[22]. The EAC countries are in need of better access to healthcare through social health protection (SHP) programmes; on average, only 25% of the EAC population is covered by some kind of SHP mechanism. Coverage varies from <1% in Uganda to 95% in Rwanda, where coverage is considered effective and moving towards sustainability. In most EAC countries, SHP coverage is limited in benefits, with poor quality of care and under-the-table payment[23].

Table 1: Health expenditure information in EAC countries, 2014

Countries	THE (USD Million)	THE (USD Per Capita)	Funding (%)		Buyers (%)			Population covered by some kind of SHP mechanism (%)
			Govt.	Donors	Govt.	Household	Other	
Burundi	233	22	50	50	53	21	26	65
Kenya	3,500	78	72	28	61	26	13	32
Rwanda	595	52	54	46	38	28	34	95
South Sudan	358	30	58	42	42	54	4	<1
Tanzania	2,700	52	64	36	46	23	30	15
Uganda	2,000	52	N/A	N/A	25	41	34	<1

Source: WHO country profiles and Global Health Expenditure Database, http://apps.who.int/nha/database.

2.2 Pharmaceutical markets in the EAC

2.2.1 Access, affordability and quality of medicines

Ensuring reliable access to affordable and quality-assured medicines in East Africa remains a huge challenge. It is estimated that most medicines in the EAC are purchased through out-of-pocket (OOP) payments by individuals. In the East African countries, OOP payments account for more than 40% of private health expenditure[24]. This is especially critical as the majority of the EAC's population has very low purchasing power. This means the decision to purchase medicines is largely influenced by other competing basic necessities such as food. In addition to pricing and availability issues, the region also faces threats of sub-standard and falsified medicines on the EAC markets. WHO estimates that 10% of medicines bought and sold around the world are counterfeit products; these products are frequently present in low-income countries, as well as in illegal internet commerce.

[19] East African Community Facts and Figures, 2014. [20] Euromonitor International, 2012, Special Report: The World's Youngest Populations.
[20] Euromonitor International, 2012, Special Report: The World's Youngest Populations.
[21] https://globalhealth.usc.edu/2016/04/25/east-african-non-communicable-disease-alliance-convenes-in-kenya/
[22] WHO country profiles and Global Health Expenditure Database, http://apps.who.int/nha/database
[23] EAC Secretariat, 2014, Situational Analysis and Feasibility Study of Options for Harmonization of Social Health Protection Systems Towards Universal Health Coverage in the East African Community Partner States.
[24] WHO Global Health Expenditure Database, 2014, http://apps.who.int/nha/database/Key_Indicators_by_Country/Index/en

2.2.2 Growth rates and market shares

The pharmaceutical sector in the EAC will continue to grow. On average, the pharmaceutical markets in the five countries are expanding rapidly (total EAC pharmaceutical market of USD 1.74 billion[25]), with an estimated compound annual growth rate (CAGR) of over 10%[26] (2007–2014). Kenya has the largest pharmaceutical market (USD 740 million), followed by Uganda (USD 450 million), Tanzania (USD 400 million), Rwanda (USD 100 million) and Burundi (USD 75 million). The fastest-growing market is Kenya, with an estimated year-on-year growth rate of 15%. In South Sudan, political instability will remain a barrier to significant investment in the pharmaceutical and health-care markets. Due to a lack of local production, the majority of pharmaceuticals in South Sudan continue to be sourced from abroad.

Table 2: Overview of key pharmaceutical sector data for the EAC countries

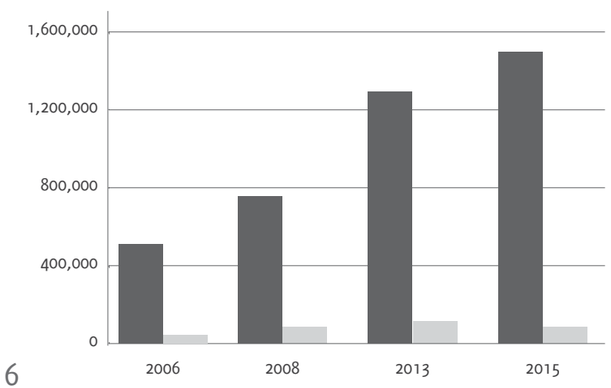
Countries	Burundi	Kenya	Rwanda	S. Sudan (estimates)	Tanzania	Uganda	EAC
Pharma market size (USD million, 2014)	75	740	100	75	400	450	**1,840**
Compound annual growth rate (CAGR) 2007 to 2014	12.85%	15%	16.36%	NVAL	9%	8.5%	**12%**
Market share of locally produced pharmaceutical drugs (% of overall market)	3%	30%	<1%	0	12%	20%	**20%**
Market by segment	(Generic) 56% (Branded) 44%	(Generic) 62% (Branded) 38%	(Generic) 54% (Branded) 46%	(Generic) 60% (Branded) 40%	(Generic) 54% (Branded) 46%	(Generic) 80% (Branded) 20%	**(Generic) 60% (Branded) 40%**
Number of local pharmaceutical manufacturers	1	40	1	0	12	12	**66**
Estimated number of direct jobs	150	6,000	30	0	1,800	1,800	**9,780**

Source: 2014 estimates (industry and associations).

2.2.3 Trends in pharmaceutical import and export

EAC countries heavily rely on pharmaceutical imports, especially for branded and innovator products. The inability of the local pharmaceutical industry to sufficiently meet local demands for low-cost generic production and pharmaceutical innovation has allowed foreign companies to strongly dominate the pharmaceutical markets. The market share for imports in Africa is estimated to be over 70%, with a market share of generics estimated at 62% in Kenya[27] as well as other EAC Partner States. In the EAC, currently over 50% of pharmaceuticals imported into the EAC come from Asia, particularly from India and China[28]. Pharmaceutical imports into the EAC have been rising significantly over the last few years – while the region imported pharmaceutical products estimated at USD 473 million in 2006, import values rose to USD 800 million in 2008 and USD 1.5 billion in 2015. Kenya is the leading importer for pharmaceuticals, followed by Tanzania and Uganda. As shown in Figure 1, over the same period of time (2006–2015), pharmaceutical imports into the EAC increased at a much higher pace than pharmaceutical exports by local firms.

Figure 1: EAC aggregated pharmaceutical imports vs exports



Source: ITC calculations based on UN COMTRADE statistics, 2016.

[25] http://www.ip-watch.org/2015/10/02/policy-coherence-to-boost-east-africa-pharmaceutical-industry/
[26] 2014 estimates by industry associations in the EAC.
[27] BMI, 2012, market report for Q3 2012.
[28] ITC calculations based on UN COMTRADE statistics, 2016.

Kenya leads the East African region in exporting pharmaceuticals, with other EAC countries as focal destinations[29]. EAC export values (aggregation) show a rise from USD 46.7 million in 2006 to USD 84.7 million in 2015, with the largest share of export values on Kenyan local manufacturers, followed by Uganda. About half of the pharmaceutical exports from Kenya go to Uganda and Tanzania[30]. Uganda recorded the strongest rise in export values, from USD 1.4 million in 2006 to USD 12.3 million in 2015. This is partly linked to their WHO prequalification of ARVs, with Uganda now exporting to other African countries such as Namibia and Zambia.
The volumes fade, however, in comparison to total imports from other destinations. The total export and import volumes of all of the five EAC countries are also lower than those of Egypt or South Africa, the leading and most developed pharmaceutical markets in Africa, as shown in Table 3 below.

EAC's export opportunities benefit from proximity to other African markets. Manufacturers based in the region are not only exporting to EAC Partner States but produce for a wider market, reaching out to countries in Central and West Africa[31].

A significant share of exports of EAC manufacturers goes to Congo, Malawi, Zimbabwe, and Zambia as well as to countries in West Africa. This expanded market is an added opportunity available to East African manufacturers by virtue of their proximity to other markets. Export will have to play an increasingly important role for local manufacturers aiming to achieve optimal production efficiency. In Africa, East Africa included, in-country markets are small due to low population sizes coupled with weak purchasing power. The creation of bigger markets for local firms through regional economic blocks can be a solution.

Table 3: Table of pharmaceutical exports and imports (2015) for EAC Partner States as well as Egypt and South Africa

Country	Exports (USD)	Pharmaceutical exports in % of total exports	Imports (USD)
Burundi	28,000	0.02	50,491,000
Kenya	71,200,000	1.20	572,533,000
Rwanda	242,000	0.04	83,123,000
South Sudan	0	0	29,146,000
Tanzania	972,000	0.01	403,125,000
Uganda	12,281,000	0.54	370,962,000
EAC total	**84,723,000**	**0.59**	**1,509,380,000**
South Africa	348,655,000	0.50	1,890,225,000
Egypt	253, 956,000	1.15	2,274,253,000

Source: ITC calculations based on UN COMTRADE statistics, 2016.

The East African Community (EAC) is the most mature trading block from among the four regional economic communities in Africa. Overall, the EAC is Africa's leading Regional Economic Community (REC) in intra-regional trade[32]. The EAC is an important market for each of the Partner States ranking in the top five export destinations for all EAC countries. The EAC Partner States have recognised the importance of the EAC market and its untapped potential by committing to liberalise trade in goods through their common market protocols, which are aimed at eliminating tariffs and non-tariff barriers to intra-regional trade and at harmonising or mutually recognising standards[33].

> *Kenya's President Uhuru Kenyatta: "There cannot be a good reason why it is easier for us to trade with Asia, Europe and the Americas, rather than with fellow Africans."*

With regard to pharmaceuticals, the EAC records the highest pharmaceutical sales growth compared with other regions in the continent[34].

2.2.4 Snapshot on global pharmaceutical market trends and drivers

The global pharmaceutical market will reach USD 1.6 trillion by 2020 while non-communicable diseases are on the rise. The global demand for medicines is rising, as the population increases, ages and becomes more sedentary. In 2011, total pharmaceutical sales were

[29] ITC calculations based on UN COMTRADE statistics, 2016.
[30] South Centre, 2014, Regional pooled procurement of medicines in the EAC, https://www.southcentre.int/wp-content/uploads/2014/09/RP53_Regional-Pooled-Procurement-of-Medicines-in-EAC_EN.pdf
[31] EAC-GIZ Programme, 2011, Baseline Survey of the Local Pharmaceutical Manufacturing Capacity for Human and Veterinary Medicines and Medical Supplies within the EAC Partner States (unpublished report).
[32] Ecobank, 2013, Trade in the East African Community.
[33] EABC, 2016, EAC Common Market Scorecard 2016: Tracking EAC Compliance in the Movement of Capital, Services and Goods.
[34] IMS Market Prognosis, 2012, IMS Health.

worth USD 1.08 trillion and are steadily growing, with nearly USD 1.6 trillion estimated by 2020[35]. The demand for medicines is growing more rapidly in emerging economies such as Brazil, Russia, India, China, Mexico, and Turkey than in industrialised economies. Non-communicable diseases (NCDs) such as cancer, diabetes, and cardiovascular diseases are becoming more prevalent. These diseases are driven by forces that include ageing, rapid unplanned urbanisation, and the globalisation of unhealthy lifestyles. According to WHO, it is estimated that the global NCD burden will increase by 17% within the next ten years, and on the African continent even by 27%[36].

The African continent has huge pharmaceutical market potential. Pharmaceutical expenditure in Africa is growing at a compound annual growth rate (CAGR) of 10.6%, which is second only to Asia Pacific (12.5%) and on par with Latin America (10.5%). Spurred by a convergence of demographic changes, increased wealth and healthcare investment as well as rising demand for drugs to treat chronic diseases, this market potentially represents a USD 45 billion opportunity by 2020[37].

The appeal of Africa's pharmaceutical market lies not in its size but in the dynamics that drive sustainable growth at a time when the major established pharmaceutical markets face a more uncertain future. These dynamics include: greater political and fiscal stability and improvements in pro-business legislation; major demographic shifts that show an increasing number of working-age Africans, a rising middle class that accounts for 34% of the continent's inhabitants, and an urban population expected to exceed that of China and India by 2050[38]. An increase in economic wealth goes along with a notable rise in healthcare spending, which has grown at a CAGR of 9.6% since 2000 (across 49 African countries). Fueled by investments by governments, non-government organisations (NGOs) and the private sector, activities have been largely focused on strengthening health system infrastructure, capacity building, treatment provision, and specialised services[39].

The combination of economic strength and an expanding middle class is already driving demand for medicines across Africa, notably in countries such as Algeria, Morocco, Tunisia, and Kenya.

Trends that are reshaping the pharmaceutical market include shifting healthcare policies and practices that favour generics and biosimilars over patented medicines and growing political support for local pharmaceutical manufacturing. Today, "big pharma" pays increasing attention to market access capabilities in order to capture the growth opportunities offered by emerging markets, in particular for introducing innovative medicines. Challenges to access the emerging markets include:

(i) scarcity of funding,
(ii) infrastructure gaps,
(iii) shortage of trained healthcare professionals, and
(iv) absence of local market data.

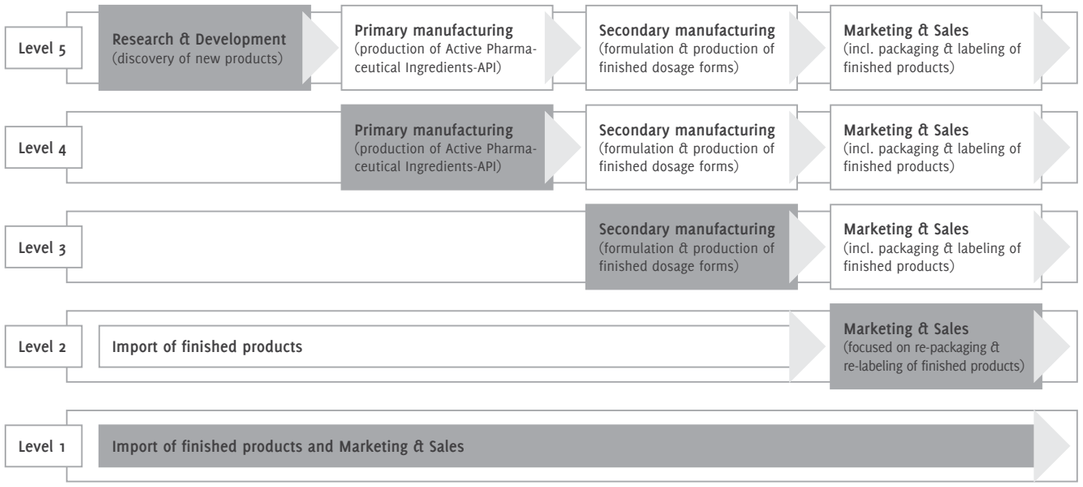
These challenges also hinder access to East African markets, both for local manufacturers and multinational pharmaceutical companies. Pharmaceutical firms may need to shift from marketing and sales models to access-driven models[40].

2.3 Local pharmaceutical production

2.3.1 Pharmaceutical value creation

Pharmaceutical value creation progresses from the mere importation of finished pharmaceutical products (Level 1) to a more sophisticated, research-based pharmaceutical industry (Level 5). Figure 2 shows these different levels of value creation with the typical pharmaceutical value chain steps (the added step at each level is highlighted). There is an increasing level of complexity, value added as well as investment and regulatory requirements moving from Level 1 to 5. From a policy perspective, it is important to note that the pharmaceutical manufacturing sector is supported on its progressive development along the value chain.

Figure 2: Five main levels of pharmaceutical manufacturing



[35] PwC Global, 2012, From vision to decision – Pharma 2020, http://www.pwc.com/gx/en/pharma-life-sciences/pharma2020/assets/pwc-pharma-success-strategies.pdf
[36] WHO, 2013, Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020, http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf?ua=1
[37] IMS HEALTH, 2013, Africa: A Ripe Opportunity. Understanding the Pharmaceutical Market Opportunity and Developing Sustainable Business Models in Africa.
[38] African Development Bank, 2012, Africa in 50 Years' Time: The Road Towards Inclusive Growth.
[39] WHO, 2014, Global Health Expenditure Database.
[40] McKinsey, 2015, Pharma's next challenge, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/pharmas-next-challenge

The majority of the players in the EAC pharmaceutical sector are predominantly at Level 1, with manufacturing activities largely confined to Levels 2 and 3. Local firms are mainly producing finished pharmaceutical products (FPPs) rather than manufacturing active pharmaceutical ingredients (APIs). APIs are the key input for manufacturing FPPs and a substantial cost factor in production. Overall, there is very little pharmaceutical research and development (R&D) in innovator products in the EAC, and no manufacture of biotech products. The production of APIs in the region would require an appropriate mix of knowledge base, acquisition of requisite technology (equipment and skills) and a consolidated local market to justify such investment. India and China have been successful in developing the API manufacturing industry due to a confluence of factors coming together. These include significant domestic demand of APIs, availability of appropriate skills mixes, a strong exports base for finished pharmaceutical products as well as government support.

East Africa can draw lessons from these two countries to develop the local industry towards reaching Level 5. Moreover, the discovery and eventual exploitation of oil in the region will result in the growth of the petrochemical/hydrocarbon industry, which is a precursor for the development of competitive API manufacturing. An established petrochemical industry in East Africa will provide a reliable and affordable source of starting compounds and solvents for the chemical synthesis in API production.

2.3.2 Local product portfolio and market share

Domestically produced medicines remain below 15% of the pharmaceutical market in terms of value (EAC average). With 33 active pharmaceutical manufacturers, Kenya is an important centre for pharmaceutical manufacturing in the EAC region. Kenya's market share for domestic medicines amounts to approx. 30% (value-wise), while in Uganda and Tanzania the share amounts to 20% and 12% respectively. Even though the pharmaceutical sector in Uganda is small and nascent, it has been working towards expanding its local production capacity in recent years. In Tanzania, the domestic share has even decreased over the past few years: while in 2007 Tanzanian manufacturers were supplying about 30% of the products in the market, this figure has decreased to about 12%[41]. Among other reasons, the strong setbacks in public procurement in Tanzania have discouraged local manufacturers from participating in public tenders. However, the Medical Stores Department (MSD) is seeking to revise this trend, having recently granted framework contracts to eligible local manufacturers[42].

Table 4: Top 10 pharmaceutical product classes produced by local firms in Kenya

No	Product class	**No. of Kenyan manufacturers** (out of a total of 32 companies surveyed) **having a product in the class**
1	Cough and cold preparations	18
2	Antiprotozoals (amoebicides, antimalarials)	15
3	Antiseptics and disinfectants	14
4	Antiasthmatics (bronchodilators, respiratory stimulants)	14
5	Antihistamines for systemic use	14
6	Antibiotics and chemotherapeutics, dermatologicals	13
7	Systemic antimycotics, excl. Griseofulvin	13
8	Systemic chemotherapeutics	13
9	Analgesics (narcotics, analgesics and antipyretics, antimigraine preparations)	13
10	Antacids, antiflatulents and antipeptic ulcerants	12

Source: Kenya Drug Index, 2017.

A Kenya pharmaceutical trade data report from the Kenya Pharmacy and Poisons Board as well as a scoping study by the Clinton Access Initiative on the East African pharmaceutical market show that anti-infectives, immunological and cardiovascular agents make up almost 50% of the market share by value. These findings partly explain the strong presence of local manufacturers in the anti-infectives product category in the above table[44]. However, it also shows that they are missing out in immunological and cardiovascular markets, which have a large market share in the region. There is need for local manufacturers to venture into these lucrative product categories.

An estimated 66% of disease conditions are covered by locally produced medicines. A GIZ-EAC survey reports a number of therapeutics lines that are not catered for at all by EAC local manufacturers, as detailed in Table 5. The survey estimates that around 66% of all disease conditions (as per ACT classification scheme) are covered by medicines produced locally in the EAC.

[41] S. Wangwe, P. Tibandebage et al., 2014, Reversing Pharmaceutical Manufacturing Decline in Tanzania: Policy Options and Constraints. REPOA Brief No. 43, Dar es Salaam.
[42] Interview with CEO, MSD, Tanzania.
[43] Kenya Drug Index, 2017.
[44] Clinton Health Access Initiative, 2016, Accelerating Local Manufacture of cGMP Quality Assured Pharmaceutical Products in East Africa, Final Report.

Table 5: Overview of therapeutic lines that are not being supplied by local firms in the EAC

Therapeutic lines not covered by local manufacturers in the EAC	
Alimentary tract and metabolism • Anti-obesity preparations, excl. diet products • Digestives, incl. enzymes • Tonics • Systemic anabolics • Appetite stimulants and other alimentary tract and metabolism products **Blood products and blood-forming organs** • Anticoagulants • Antihemorrhagics • Plasma substitutes and perfusion solutions **Cardiovascular system** • Vasco-protectives **Genito-urinary system and hormones** • Gynecological, such as contraceptives • Urological • Thyroid preparations • Pancreatic hormones	**Systemic anti-infectives** • Immune sera and immunoglobulins • Vaccines **Anti-neoplastic and immunosuppressive drugs** • Cytostatic medicines • Hormone therapy **Muscular-skeletal system** • Muscle relaxants **Central nervous system** • Anesthetics • Other CNS drugs, incl. parasympathomimetics **Various** • Diagnostic agents • Surgical antiseptics • Allergens • Immunosuppressive drugs • General nutrients (protein supplements, infant formulas)

Source: EAC-GIZ survey (2011); Kenya Drug Index (2017).

Local firms in the EAC mainly produce pharmaceutical simple dosage forms, such as plain tablets, hard capsules, lotions and suspensions. Table 6 below shows that local production does not include advanced formulations (sustained release, layered tablets, immune sera) and highly regulated product lines (sterile products, vaccines, diagnostics). Dosage forms that are not being produced in East Africa are highlighted in red. An upgrade of local manufacturing to higher-value medicinal products is currently hampered by a lack of technical expertise and access to finance. In particular, there is a shortage of product development and formulation experts required to upgrade the dosage form portfolio. Moreover, most local firms do not employ business development and market access teams, which can steer investment into advanced technologies. With regard to finance, firms are challenged by a lack of appropriate and affordable funding. At the moment, financing options are limited to short-term loans with high interest rates.

Table 6: Dosage forms that are being produced in East Africa

TECHNOLOGY	BI	KE	RW	SS[45]	TZ	UG	EAC
Plain tablets	✓				✓		✓
Film-coated tablets	✓				✓		✓
Sustained release tablets		✓					✓
Layered tablets		✓					✓
Hard capsules	✓				✓		✓
Soft capsules		✓					✓
Sustained release capsules							
Powders	✓				✓		✓
Dry granules (suspensions)	✓				✓		✓
Suspensions (internal)	✓				✓		✓
Syrups/elixirs/solutions (internal)	✓				✓		✓
Ointments and creams	✓				✓		✓
Lotions and suspensions (external)	✓				✓		✓
Small volume injections (sterile)							
Large volume injections (sterile)			✓			✓	✓
Ophthalmic formulations (sterile)		✓					✓
Ocular formulations (sterile)		✓				✓	✓
Ocular formulations (non-sterile)		✓			✓	✓	
Implants							
Inserts							
Sprays and inhalations							
Medicated dressings							
Immune sera and immunoglobulins							
Vaccines						✓	
Diagnostic agents						✓	

Source: EAC-GIZ survey, 2011.

[45] No pharmaceutical manufacturing in South Sudan.

2.3.3 Local industry capacities and competitiveness

Local firms are producing under capacity. A survey commissioned by GIZ[46] has shown that local firms in the EAC would have sufficient capacity to cater for most of the pharmaceutical needs of the region but underutilise their capacity by up to 60% in some formulations. The only dosage forms that have installed under-capacities are infusions and syrups/suspensions. A self-assessment conducted by the six leading manufacturers in Uganda in 2013 reported underutilisation of installed capacity as shown in Table 7 below, with liquids and creams/ointments being below 40%.

Table 7: Total annual capacity utilisation by six leading Ugandan manufacturers in 2013

Formulation (dosage form)	**Annual installed capacity*** (million)	**Annual utilisation** (million)	**Capacity utilisation** (%)
Tablets	4,800.0	3,100.0	64
Capsules	720.0	530.0	73
Liquids (100ml)	24.5	9.0	36
ORS	32.0	14.0	43
Creams & ointments	7.5	2.5	33

* The installed capacity was calculated based on two shifts per day (eight hours each), 26 working days per month and 12 months of the year.

Similarly, a self-assessment by members of the Federation of Kenya Pharmaceutical Manufacturers (FKPM) in 2013 demonstrated that their installed capacity for a selected list of essential medicines could comfortably meet the national public sector demand for these medicines (see Table 8 below). It is important to note, however, that the overcapacity observed in some of the lines does not necessarily mean that there are no technological niches. As shown in Table 5 above, there is indeed room for investment in high-tech formulations.

Table 8: Total annual capacity of leading Kenyan manufacturers vs annual public sector demand (selected products)

Product description	Annual demand	Annual production capacity
Cotrimoxazole 480mg Tablets	200,000,000 tabs	400,000,000 tabs
Paracetamol Tablets	400,000,000 tabs	800,000,000 tabs
Metronidazole 200mg Tablets	100,000,000 tabs	300,000,000 tabs
Metronidazole 400mg Tablets	250,000,000 tabs	60,000,000 tabs
Ibuprofen 200mg Tablets	1,200,000,000 tabs	240,000,000 tabs
Ibuprofen 400mg Tablets	300,000,000 tabs	600,000,000 tabs
Amoxycillin 250mg Capsules	300,000,000 caps	600,000,000 caps
Amoxycillin 500mg Capsules	50,000,000 caps	100,000,000 caps
Ampicilline & Cloxacillin Capsules 250/250mg	10,000,000 caps	30,000,000 caps
Doxycycline 100mg Capsules	50,000,000 caps	100,000,000 caps
Prednisolone 5mg Tablets	20,000,000 tabs	100,000,000 tabs
Oral Rehydration Salts 0.5 Litre	50,000,000 sachets	100,000,000 sachets
Dextrose 5% 500ml	10,000,000 bottles	20,000,000 bottles
Normal Saline 0.9 % 500ml	10,000,000 bottles	20,000,000 bottles
Ciprofloxacin 500mg Tablets	60,000,000 tablets	120,000,000 tablets
Erythromycin 250mg Tablets	60,000,000 tablets	120,000,000 tablets
Griseofulin 125mg Tablets	5,000,000 tabs	20,000,000 tabs
Griseofulin 500mg Tablets	15,000,000 tabs	20,000,000 tabs
Clotrimazole Cream	3,600,000 tubes	10,000,000 tubes

Source: Self-assessment by members of the Federation of Kenya Pharmaceutical Manufacturers (FKPM) in 2013.

The installed capacity underutilisation is partly attributed to local firms being uncompetitive compared to foreign-based firms that dominate the EAC markets with their imports. According to a study by the Clinton Health Access Initiative (CHAI) on local pharmaceutical manufacturing in the EAC, the main cost drivers are APIs as well as operations management and logistics, including foreign exchange losses[47]. The authors of the study were able to demonstrate that by putting in place cost containment strategies, local companies could be just as competitive as foreign-based players.

[46] EAC-GIZ, 2011, Baseline Survey of the Local Pharmaceutical Manufacturing Capacity for Human and Veterinary Medicines and Medical Supplies within the EAC Partner States (unpublished report).
[47] Clinton Health Access Initiative, 2016, Accelerating Local Manufacture of cGMP Quality Assured Pharmaceutical Products in East Africa, Final Report.

The study recommended that the local firms adopt activity-based costing in order to identify and manage revenue leakages, establish mechanisms to hedge against forex losses and consider pooled procurement of APIs. Similarly, a simulation study comparing Indian and Ghanaian firms demonstrated that with a production volume of 405 million tablets per year, the local firms could price their products to be comparable to imports and still remain profitable[48]. These two studies show that local firms could be just as competitive as foreign-based manufacturers within certain product categories if they adopt lean manufacturing strategies combined with guaranteed market access conditions.

2.3.4 Adherence to international GMP standards

The EAC regulatory environment enables local firms to move towards international quality standards. Adherence to acceptable standards of GMP during production is essential in ensuring that the quality of medicinal products is assured consistently and that the products are safe and efficacious and marketable internationally. In the EAC, local pharmaceutical firms are licenced by national regulators and require GMP certification for the production of medicines. To enforce quality standards, national regulators carry out inspections of companies. The region is moving towards a harmonised medicines regulatory regime and as part of the MRH project, joint dossier evaluations and GMP inspections are being conducted. However, a framework for mutual recognition is not in place and thus any decisions taken through joint activities are non-binding to the individual Partner States. Therefore, it is important to establish a legal framework on which to anchor the medicines regulation harmonisation process at regional and national levels. A fully functional medicines regulatory harmonisation in the region would ease market entry for both innovator and generic formulations and would allow the local industry to take full advantage of the Common Market.

WHO prequalification (WHO PQ) increases the competitiveness and reputation of EAC local manufacturers. Adhering to WHO GMP by companies not only ensures that medicines are produced in the region in a safe and efficacious manner, but also significantly improves the competitiveness of local companies by enabling them to participate in international tenders. The Cipla Quality Chemicals plant in Kampala (Uganda) has already obtained WHO PQ for a number of ARV and antimalaria products. It is the first production plant in Sub-Saharan Africa outside of South Africa to obtain WHO prequalification. In November 2011, Universal Corporation, a Kenyan pharmaceutical company, was granted WHO PQ for Lamizido, a first-line ARV. WHO prequalification allows companies to participate in international tenders, e.g. via the Global Fund to fight HIV/AIDS, TB and Malaria, and to enter international markets. However, with the exception of a few companies that meet global standards, such as the two firms mentioned above, local manufacturers are struggling to access the bulk of the regional donor-funded market for the procurement of medicines for the three priority diseases HIV/AIDS, TB and malaria.

GMP Roadmaps are under way to guide and support the transition of EAC firms towards international GMP standards. Achieving international (WHO) GMP standards is a transition process that requires time. For the upgrading approach to be realistic and achievable it would be essential to develop a stepwise, phased roadmap with clearly defined milestones and targets at the end of each phase, guiding the pharmaceutical sector from the status quo to the targeted WHO GMP compliance. So far, only Kenya has developed a national roadmap to improve WHO GMP compliance of Kenyan companies, but there are plans for an overarching EAC GMP Roadmap. This will require developing national roadmaps for the United Republic of Tanzania as well as for Uganda, which is home to a sizeable pharmaceutical industry. The national roadmap for Kenya will be integrated into a regional framework. Rwanda and Burundi will be able to use the regional roadmap as a guideline for building up their own pharmaceutical industry.

2.3.5 Policy coherence

Pharmaceutical production is the shared objective of industrial and public health policies. Industrial policy supports the development of a competitive pharmaceutical sector that generates employment and contributes to the economy. Health policy seeks to ensure the availability and affordability of healthcare services and commodities, such as pharmaceuticals, in accordance with established standards. Although health and industrial polices share the objective of promoting the pharmaceutical sector, other important policy areas – such as investment laws and incentives, tariffs, education, intellectual property, technology transfer and innovation, government procurement and international cooperation – may influence the achievement of the shared objective. A policy coherence based approach can consolidate the advantages created by some policies, while at the same time addressing certain gaps and inconsistencies in other policies.

The United Nations Conference on Trade and Development (UNCTAD) organised policy coherence capacity building workshops and fact-finding missions in the EAC at both regional[49] and national levels (Kenya, Tanzania and Uganda) in 2014 and 2015, in partnership with the EAC Secretariat, the WHO, and national ministries of health and industry and trade.

The most common challenges cited by the participants and interviewees include the following:

- tariff and VAT policies,
- government procurement,
- resource limitation on part of national medicine regulatory authorities (NMRAs)
- lack of access to credit or alternative financing for projects, and
- shortage of skilled human resources.

Each Partner State also has unique challenges and opportunities with regard to the sector. Compared to Kenya, which is home to 42 pharmaceutical firms, the priority for Tanzania, Rwanda and Burundi is to attract investment and expand existing capacity. The challenge for Uganda includes the implementation capacity for existing policy initiatives, including industrial parks and credit facilities for investment.

[48] S. Chaudhuri and A. West, 2014, Can local producers compete with low-cost imports? A simulation study of pharmaceutical industry in low-income Africa. Innovation and Development, Vol. 5 No.1, pp. 1–16.
[49] UNCTAD, 2015, Policy Coherence for local production of pharmaceutical products and other means to improve access to medicine and medical products in the East African Community and beyond: Workshop Report, 21–23 September 2015, Kampala, Uganda.

The primary advantage provided by the EAC is regional integration based on the Common Market Protocol and the Common External Tariff (CET)[50]. EAC took an important step to provide further integration in the field of public health with the adoption of the Medicines Regulation Harmonization Guidelines (November 2015). The EAC Industrialisation Policy and Strategy has prioritised the pharmaceutical industry. Yet there are gaps with regard to tariff-free imports of raw materials, operationalising Article 35 of the EAC Common Market Protocol, and the adoption of common investment, health, procurement and competition policies. During the EAC-RPMPOA: 2012–2016, work undertaken in the region[51] identified national level policy coherence issues, including tariff and VAT policies, government procurement, as well as access to credit or alternative financing for projects and skills development. Current regional initiatives, such as the development of a regional health policy, medicine policy and Essential Medicine List and the adoption of the EAC Competition Act have the potential to expand the regional market for local manufacturers. EAC can also consider strategic intervention to address bottlenecks for investment and finance, providing market intelligence for investment, integrating Partner States across the value chain, using existing regional mechanisms to build synergies among research projects taking place within EAC in the areas of biotechnology, pharmaceuticals and petrochemicals, and linking them with international partners.

UNAIDS, UNCTAD, the African Union (AU), and the Kenyan and South African governments have signed the *Nairobi Statement on Investment in Access to Medicines*[52] during the World Investment Forum in Nairobi (9 July 2016). The statement emphasises the importance of coherence among African domestic policies related to health, investment, trade, technology and intellectual property and the importance of integrating markets.

2.3.6 Challenges and opportunities of the EAC pharmaceutical industry

The local pharmaceutical industry in the EAC is faced with various challenges. In particular, the supply of electricity and water are often unreliable, and poor roads make transporting goods difficult. Anecdotal evidence indicates that it is cheaper and faster to transport goods from India to Kenya than from Mombasa to Nairobi (within Kenya)[53]. Local manufacturers largely depend on imports of pharmaceutical inputs, such as active pharmaceutical ingredients (APIs), as there is insufficient know-how and capacity for respective R&D and production. Finding appropriately qualified and skilled staff is another problem as local universities and training institutions do not adequately cater for the needs of the pharmaceutical industry and many firms employ highly paid expatriates in key technical and managerial positions. Furthermore, high import costs of inputs and low prices of imported finished products from India, China and other Far Eastern countries with export subsidies, disadvantages the local pharmaceutical sector in the EAC. While the East African Community agreed to a zero-tariff rate on imports of finished medicines, local producers frequently have to pay duties on their imports of inputs for production[54]. To be able to compete and survive, many local firms would need to invest – in R&D, skills development, facilities and equipment. However, access to affordable finance is a challenge in the East African countries. What is more, there is a negative perception regarding locally produced medicines among both prescribers and patients.

On a more positive note, there is abundant interest on the part of the EAC Partner States in promoting their pharmaceutical industry. Accordingly, national strategies for promoting local pharmaceutical production are currently being developed and include the following: Kenya Good Manufacturing Practice Roadmap, Strategy for Promotion of Domestic Production in Tanzania (2013–2023), and the Uganda National Pharmaceutical Sector Strategic Plan (2015–2020). All of these plans/strategies are anchored in the regional and continental plan EAC-RPMPOA: 2012–2016 and the Pharmaceutical Manufacturing Plan for Africa respectively. In addition, massive investments in infrastructure (energy, water, and transport) are on the way[55]. Overall, the young, growing population with an expanding middle class, the increasing NCD burden and continued prevalence of infectious diseases will further increase the opportunities for local manufacturers on the pharmaceutical market. Local manufacturers can build on enabling factors such as the existing policy context; a pharmaceutical production base; an improved regulatory environment; an extension in the use of public health-related WTO flexibilities until 2033; a high number of innovator molecules coming off patent, and a larger budgetary allocation to the health sector in the EAC.

In recent years, the EAC countries have put in place a number of incentive frameworks to support the development of the sector. However, there is still need for improvement: in particular, the real preferential pricing percentage is below expectation, there are long delays in processing VAT reimbursements, and there is no regional preferential pricing. Thus, the implementation of incentive frameworks continues to be work in progress.

[50] The African Development Bank (AfDB), the African Union Commission (AUC) and the Economic Commission for Africa (ECA), 2016, The Africa Regional Integration Index Report 2016. – See more at: http://www.financialnigeria.com/east-africa-is-most-integrated-region-in-africa-sustainable-photovideo-details-399.html#sthash.uZRIGDNg.dpuf
[51] UNCTAD & GIZ, 2015, Policy Coherence for local production of pharmaceutical products and other means to improve access to medicine and medical products in the East African Community and beyond: Workshop Report, 21–23 September 2015, Kampala, Uganda.
[52] http://www.unaids.org/sites/default/files/media/documents/20160721_NairobiStmtAccess Medicines.pdf, accessed online on 28 July 2017.
[53] M. Kardas-Nelson, 2015, Can (and should) Africa make its own medicines? The BMJ.
[54] https://theconversation.com/how-kenyan-and-tanzanian-medicine-producers-deserve-a-shot-in-the-arm-65578
[55] http://www.infrastructure.eac.int/

Table 9: Existing incentive framework for domestic pharmaceutical production in the EAC

PS	Preferential Pricing	Regional Preferential Pricing?	Tax and Custom Incentives for manufacturing inputs	Regional Import Classifi-cation
Burundi	15% for all medicines produced by companies with more than 50% Burundian ownership	Yes, if reciprocity exists with Partner State	All relevant inputs, including raw materials and equipment, are free of customs and taxes	None
Kenya	15% for all medicines produced in Kenya 10% for all imported medicines traded by a company with at least 51% Kenyan ownership. Thus, real price preference for local producers 5%	No	Imported raw and packaging materials are free of customs and taxes. Yet, VAT levied on locally procured products	None
Rwanda	10% for all products produced locally including medical products. Likely to increase to 15%	No	Raw materials and equipment are exempted from VAT	None
S. Sudan	N/A	No	N/A	None
Tanzania	15% for all medicines produced in Tanzania. Factoring in clearance costs of imports, preference is really only 6.5%	No	All relevant inputs free of customs. VAT can be reimbursed up to 8 months later	None
Uganda	15% for all medicines produced in Uganda (implementation problems)	No	Raw and packaging materials are free of customs. Machines and spare parts face 6% customs duty. VAT can be reimbursed later for all goods	None

2.3.7 SWOT analysis and key drivers of pharmaceutical production

Figure 3: SWOT analysis of pharmaceutical production in the EAC

STRENGTHS	WEAKNESSES
• Young, growing population of 174.2m (2016) with expanding middle class • Existing political context and will to strengthen local production • Relative economic and political stability • USD 30bn pharmaceutical spending in Africa with a 10.6% compound annual growth rate (CAGR) • A strengthening regulatory capacity and enforcement • Massive investments in infrastructure (energy, water & transport) • Existence of WHO PQ and PIC/S compliant facilities.	• High production costs (utilities, infrastructure, finance) • Dependency on imports of APIs and other production inputs • Insufficient HR base and skills mix for the pharmaceutical sector • Weak R&D (institutions, resources, capacities) • Insufficient incentives and policies to promote investment • Inconsistent VAT policies • Ineffective and inadequate preferential treatment of locally produced pharmaceuticals in government procurement programmes • Scattered and unreliable market intelligence data • Lack of access to affordable and longer-term finance • Absence of infrastructure such as bio-equivalence (BE).
OPPORTUNITIES	**THREATS**
• Momentum of continental, regional and national initiatives to promote local pharmaceutical production • A larger budgetary allocation to the health sector in the region and expanding access to UHC • Extension in the use of public health-related WTO TRIPS flexibilities until 2033 • Existing pharmaceutical production base and enabling regulatory environment • Larger market in the field of growing NCDs burden and the continued high prevalence of infectious diseases • African traditional and herbal medicines as a market niche • Growing veterinary medicines market • A high number of innovator molecules coming off patent.	• Cheap imports (e.g. from India and China) and SSFFCs on the markets • Poor enforcement by regulatory authorities leading to non-GMP compliant manufacturers actively producing for the EAC market • Unregulated parallel pharmaceutical trade • Negative perception of locally produced products • Brain drain – emigration of qualified and experienced staff • Unregulated distribution systems.

Summary of key drivers for growth of local pharmaceutical manufacturing industry:

- A rising middle class with increasing spending power
- A rise in non-communicable diseases; continued burden of infectious and parasitic diseases means increased demand for chronic care medications
- A notable rise in healthcare investment and spending across the region
- An improved regulatory environment and harmonisation of laws and procedures across the Partner States
- Shifting healthcare policies and practices that favour generics and biosimilars over patented medicines
- Strong political support for the promotion of local pharmaceutical manufacturing
- Extension of the period on the use of public health-related WTO TRIPS flexibilities by least developed countries until 2033
- A high number of innovator molecules coming off patent and thus providing opportunities for generic production.

2.3.8 Niches for expansion of local product portfolio

The neglected epidemics of non-communicable diseases as well as more advanced formulations present opportunities for EAC pharmaceutical producers. Non-communicable diseases such as cancer, asthma, and diabetes are strongly on the rise and the gap in access is enormous. This could be a huge opportunity for manufacturers in the EAC – as opposed to the saturated market for HIV, tuberculosis and malaria drugs, where competition with producers from India and China is stiff[56]. Local producers should also consider targeting more complex products, including sterile preparations, blood products and vaccines. At the moment, these highly regulated products are almost exclusively imported but could be a market niche for those EAC companies that are already more advanced in terms of GMP adherence.

The medical devices sector is currently one of the fastest growing industries in the world and the African market is expected to exceed USD 10 billion by 2020[57]. The regional healthcare market relies almost entirely on imports of medical devices, dental products, laboratory equipment, healthcare IT, clinical chemistry, and diagnostics. Local manufacturers should therefore expand their product portfolio to include medical devices and products (consumables) with priority given to imaging devices, monitoring devices, in vitro diagnostics (IVD) and basic products. East Africa could meet most of its demand for cotton-based products such as bandages, cotton wool and dressings through local production as cotton is grown in the region. The players in the sector should collaborate for knowledge and technology transfer with large global companies. There is a need to develop or adapt technology to market requirements such as low-cost machines that are portable, easy to use and versatile.

Traditional medicines and natural products can be a market niche. Historically, traditional and herbal medicines have always been popular and occupy a high market share in Africa. In fact, an estimated 70 to 95% of the population in Africa, Asia, Latin America and the Middle East use traditional medicine (TM) for primary healthcare. The global market for all traditional medicines (estimated at USD 83 billion annually in 2008) is growing and represents another opportunity for African manufacturers[58,59]. Several well-known medicines that are currently in use are in fact derived from plant sources. These include e.g. Artemisinin, Quinine, Vincristine, and Aspirin. The growing resistance to existing medications by malaria parasites, mycobacteria and other bacterial infections make it imperative to search for new treatments. Traditional medicines and natural products provide good leads in search of new compounds.

The East Africa Community has a rich biodiversity and a strong history in the use of traditional medicines among its population. Yet it remains a challenge to incorporate the knowledge of traditional medicines into modern healthcare and ensure their quality, safety and efficacy standards. The sector suffers from a weak regulatory mechanism as well as strong mistrust between traditional healers on the one hand and physicians and scientists on the other. Developing traditional medicine in East Africa can be a source of foreign exchange earnings and provide solutions to the public health challenges the region is currently facing. In order to fully exploit the full potential of the sector, it will be essential to initiate policy changes to integrate traditional medicine into the mainstream economy. Interventions should be provided across the whole value chain, from domesticating and harvesting medicinal plants through Good Agricultural Practices (GAP) to the standardisation and production of herbal extracts using Good Manufacturing Practices (GMP). Traditional medicine practitioners in the region should be supported to organise themselves through national and regional associations.

The region should draw lessons from India and China, the two countries that have succeeded in having alternative medicines administered side by side with conventional medicines in healthcare settings.

While extracts from natural products are popular materials for basic research across the region's universities, studies rarely progress towards commercialisation even when the results are promising. This is attributable to a lack in adequate funding and know-how as well as poor links between academia and industry. Beyond being potential candidates for APIs, natural products could be used as excipients in the drug formulation process. Gum arabic, which is used as a binder, emulsifier, thickener, stabiliser and adhesive in the formulation industry, is sourced from East African countries, with other leading suppliers being Sudan and Senegal. Aloe vera extract is widely used in the health and cosmetic industry, and the global market is expected to be worth USD 2.4 billion by 2021, growing at a CAGR of 7%[60]. Aloe vera and neem tree extracts are widely used in East Africa for their medicinal and body care properties. In addition to clove oils, Zanzibar is also developing the production and export of a range of essential oils, such as

[56] M. Kardas-Nelson, 2015, Can (and should) Africa make its own medicines? The BMJ.
[57] Presentation by McKinsey at the Euro-Africa Health Investment Conference, March 2013, London, UK.
[58] WHO, 2011, The World Medicines Situation 3rd Edition: Traditional Medicines: Global Situation, Issues and Challenges, Geneva.
[59] SciDevNet, 2016, Traditional Medicine for Modern Times: Facts and Figures, http://www.scidev.net/global/medicine/feature/traditional-medicine-modern-times-facts-figures.html [March 2016]
[60] http://www.researchandmarkets.com/research/d9rhnh/global_aloevera accessed on 25th July, 2017.

lemon grass, eucalyl, and cinnamon leaf. Distillation and export is undertaken by the Zanzibar State Trading Corporation and small private sector players[61]. The global essential oil market exceeded USD 6 billion in 2015 and growth is being driven by changing lifestyles that promote health and beauty[62]. While cottage industries have evolved around these natural products in East Africa, their growth is largely hampered by poor harvesting methods, a lack of standardisation and weak market links.

Veterinary medicines are crucial for the growing African livestock sector. In much of Africa, the livestock sector is evolving in response to rapidly increasing demand for livestock products. Because of the tropical climate, many livestock diseases are prevalent and the availability of veterinary pharmaceutical products is therefore crucial to the sector. In addition, there is increasing incidence of zoonotic diseases, which could pose serious public health challenges if adequate measures are not taken to prevent and control the diseases. The EAC faces problems in providing adequate animal health care, especially in rural areas. Currently, veterinary medicines in the EAC are mainly imported. Tax burdens and the lack of suitable product protection are significant barriers to the development of a local drug manufacturing base for veterinary medicines. Moreover, the large number of informal, unregulated suppliers of veterinary products – at all levels of the supply chain – is a considerable hindrance to legitimate trade[63].

In Kenya, there are 18 facilities manufacturing veterinary medicines, with three exclusively producing veterinary pharmaceuticals. They mainly produce oral dosage forms such as antihelminthics and antibiotics, with sterile formulations being produced under contract manufacturing in India, China and/or European manufacturing sites. Firms such as Dawa Pharmaceuticals are investing in new manufacturing sites, targeting not only the Kenyan market but the whole region as well. The Kenya Veterinary Vaccines Production Institute (KEVEVAPI) produces vaccines for various diseases, including foot-and-mouth disease (FMD) and rabies among others. The establishment of a cadre of veterinary medicines inspectors in Kenya is a positive development to ensure the quality of the products. In Uganda, pilot projects support the production of generic veterinary medicines[64].

Regionally important diseases require research into new veterinary products. The development and registration of new products for diseases that are relevant regionally but not globally is an important issue. For some regionally relevant diseases, there is either no treatment available at all, or the products currently available are inadequate. Regional manufacturers of generic products generally lack the capacity to develop new, improved drugs and vaccines, and while the large, research-intensive multinational companies (MNCs) may have the necessary capacity, they currently have little incentive to develop products targeted at such diseases. Sources of funding must be identified and secured to fund research into these diseases and the development of new treatments – perhaps even to subsidise their production and marketing[65].

Expanding into veterinary pharmaceuticals by the local manufacturers could be a logical step to improve their bottom line and expand their product portfolio. There is a strong case for green field investments in veterinary pharmaceuticals and biologicals in Uganda, Tanzania, Burundi and Rwanda as there are no such production facilities in those countries to date.

The growing pharmaceutical industry also requires a well-established support and service industry. This includes the provision of excipients for pharmaceutical production. Excipients make up the bulk of a solid-dosage form and they play a crucial role with regard to the properties and performance of the finished formulation, such as its stability, drug release, bioavailability, taste, and texture. For example, starch and starch derivatives are widely used excipients in the pharmaceutical industry and are frequently used in oral solid-dosage forms such as tablets, capsules or sachets. At the moment, excipients are mainly imported; the EAC industry may consider producing high-quality excipients to cater for the needs of their growing pharmaceutical industry.

Moreover, packaging materials for pharmaceutical production, such as glass bottles for suspensions or cartons for outer packaging, are increasingly required but still mainly imported. Last but not least, there is a need to strengthen the support service industry for the pharmaceutical sector. In particular, reputable maintenance and repair service providers for pharmaceutical equipment and laboratory instruments are barely available in the region and yet urgently required. The current shortage of such services in the region leads to delays, increases the budget for maintenance and repairs, and extends downtime of equipment, which negatively impacts on the overall competitiveness of the sector.

[61] Market Insider, 2014, Essential oils and Oleoresins, September, 2014 report, International Trade Centre, http://www.intracen.org/itc/market-insider/
[62] Grand View Research, 2016, Essential oil market analysis and segment forecasts to 2024, http://www.grandviewresearch.com/industry-analysis/essential-oils-market
[63] AU/IBAR, 2004, The veterinary pharmaceutical industry in Africa.
[64] http://www.rvo.nl/subsidies-regelingen/projecten/pilot-production-generic-veterinary-medicines-uganda
[65] AU/IBAR, 2004, The veterinary pharmaceutical industry in Africa.

03

Assessment of EAC-RPMPOA: 2012–2016

3.1 Summary of achievements and challenges of EAC-RPMPOA: 2012–2016

Promoting domestic pharmaceutical manufacturing has been identified as a key intervention for ensuring sustainable access to medicines. The ongoing EAC initiatives on the pharmaceutical sector are anchored within the AU Pharmaceutical Manufacturing Business Plan[66]. The continental plan recognises that the pharmaceutical sector is a complex and nascent industry in Africa that requires a multi-sectorial approach.

The EAC and the Partner States are supporting the development of the sector with the twin objective of promoting public health (security of supply of life-saving commodities) and industrial development. Relevant regional and national policies and strategies to support the pharmaceutical sector development are detailed in Annex III.

The EAC-RPMPOA: 2012–2016 was approved by EAC high level policy organs. The EAC-RPMPOA: 2012–2016 was approved by the 6th Ordinary Meeting of the Sectorial Council of Ministers of Health in April 2011 and was launched during a multi-sectorial stakeholder meeting in December 2011[67]. The implementation framework of the plan was such that the EAC Secretariat was to roll out the plan in collaboration with the Partner States. The plan had no allocated budgetary resources but it was expected that the Secretariat and the Partner States would mobilise the necessary resources for the successful implementation of the plan.

Once it was approved, the plan faced two main challenges that slowed down its implementation. One challenge was the set-up and proper functioning of a suitable steering structure for this complex regional endeavour. Like other regional strategies, the plan could only be implemented through the Partner States' institutions. A regional steering committee comprising public and private sector representation was established and their terms of reference (TORs) were approved at the 9th Sectorial Council of Ministers of Health Meeting in April 2014[68]. In the same meeting, the ministers directed EAC health and industry stakeholders to work together in the implementation of the plan, with industry taking the lead. To strengthen the implementation of the plan at the national level, the Sectorial Committee of Industry in its meeting of August 2014 directed that national coordination committees be established[69]. The Ministry of Industry was the lead implementing agency and a focal point was appointed from each of the Partner States. The chairs of the national coordination committees were appointed, with Burundi, Kenya and Tanzania nominating private sector persons, while Uganda and Rwanda choosing public sector appointees.

The other major challenge was related to the resources and funds that were required to implement the specific activities as detailed in the plan. The availability and allocation of resources depended on the development partners' and Partner States' priorities. Thus some of the pillars received sufficient resources to implement the targeted activities, while others lagged behind. Pillar 3 on strengthening regulatory capacity, for example, was the most well-funded, while Pillar 6 on promoting research, development and innovation did not receive any notable direct funding.

The plan had set out six strategic objectives (pillars), each with specific actions to be implemented. In each of the six pillars there were notable successes and challenges, which are highlighted below and summarised in Table 10. A detailed assessment of the implementation matrix is attached as Annex I.

3.1.1 Promotion of competitive and efficient regional pharmaceutical production

A regional manufacturers' association was established to increase lobbying and advocacy efforts of the industry. The regional pharmaceutical manufacturing sector continues to undergo structural transformation in order to remain competitive and to be compliant to the stringent regulatory environment. In the period under review the Federation of East African Pharmaceutical Manufacturers (FEAPM) was legally established and now has 34 paid-up members from the five Partner States[70]. The association has developed position papers[71] and organised round-table discussions in all Partner States as part of its lobbying and advocacy efforts.

At national level, the promotion of local production was prioritised through relevant policies and strategies. Kenya has launched a pharmaceutical sector development strategy, which lays out interventions to be implemented. The Kenya GMP Roadmap, which is a stepwise approach for the pharmaceutical industry to attain WHO GMP standards, is among these interventions[72]. Tanzania has developed a strategic plan (2013–2023) for promoting domestic production; the plan is currently at a draft stage[73]. Uganda has recently launched the National Medicines Policy (2015) and the National Pharmaceutical Sector Strategic Plan (2015–2020)[74]. The Rwanda National Pharmaceutical Policy (2016) has among its policy objectives the promotion of domestic production[75].

[66] African Union Commission, 2012, Pharmaceutical Manufacturing Plan for Africa. Business Plan.
[67] East African Community Regional Pharmaceutical Manufacturing Plan of Action: 2012–2016.
[68] EAC, 2013, Report of the 9th Sectorial Council of Health (EAC/SR167/2013).
[69] EAC, 2014, Report of the Sectorial Committee on Industrialization (EAC/SCI/002/2014).
[70] http://feapm.com/ accessed on 13 June 2017.
[71] FEAPM, 2016, Position paper on East Africa Pharmaceutical Manufacturing Incentive Package.
[72] Kenya Pharmaceutical Sector Development Strategy.
[73] Tanzania Strategy for Promotion of Domestic Production (2013–2023).
[74] Uganda National Pharmaceutical Sector Strategic Plan II: 2015–2020.
[75] Rwanda National Pharmaceutical Policy (2016).

At firm level, companies have expanded their operations and stepped up their quality standards through joint venture arrangements, acquisitions and use of own funds. In Kenya, Tanzania and Uganda, companies have initiated joint ventures/buyouts with leading Indian and South African manufacturers. Examples include joint venture arrangements between Universal (Kenya) and Strides Pharma (India), Quality Chemicals (Uganda) and Cipla (India) as well as Shelys (Tanzania) and Aspen Pharma (South Africa)[76]. Investments in local pharmaceutical companies by private equity funds have also been reported in the region – most notably CDC Capital's investment in Abacus Parenterals Drugs Ltd and the more recent buyout of the majority shareholding of Zenufa Laboratories (Tanzania) by Catalyst Principal Partners[77],[78].

The collection of reliable market data is a challenge. Accordingly, one of the key activities not achieved in this pillar was the collection of reliable market data for demand quantification and production capacity. The challenge was getting companies and regulators to provide up-to-date data, and even when the parties finally collaborated only Tanzania had their baseline data in a digital format. With the support of GIZ and UNIDO, the EAC continues to work on this activity, with the aim of establishing a sustainable and reliable market data collection system in the region.

3.1.2 Facilitation of increased investment in pharmaceutical production regionally

Both the EAC Secretariat and the Partner States have been making efforts aimed at improving the operating business environment in the region. This includes instituting a raft of policy and legislative changes in order to attract investments – including reforming and reconfiguring frontline institutions and infrastructure upgrades, (roads, rail and ports) and electricity supply. As a result, all Partner States have made positive progress in most indicators from the World Bank's Ease of Doing Business reports over the five-year period[79]. The improved business environment is beneficial to all businesses including the pharmaceutical manufacturing sector.

The EAC Secretariat pursued and continues to pursue the full implementation of the Customs Union and the Common Market Protocol. Sectorial Council reports and EABC Non-Tariff Barriers reports suggest improvements in the free movement of goods and services in the region[80]. The Secretariat has also established and institutionalised the Consultative Dialogue Framework that provides a platform for the private sector and civil society to participate in the decision-making process.

The plan has facilitated stakeholder engagements to discuss unique pharmaceutical industry dynamics in all Partner States. In order to implement this, the EAC Secretariat in collaboration with FEAPM organised round-table meetings in all Partner States in 2015. The meetings brought together policy makers and manufacturers to discuss the challenges and propose solutions. In 2016, an international conference on investment in pharmaceutical manufacturing was convened in Nairobi. Key topics included access to appropriate financing, policy coherence and incentivising local industry.

While the plan was aimed at developing a regional and national policy framework for establishing **Special Economic Zones** (SEZs) within the pharmaceutical industry, the sector is considered to be yet too small by the respective Partner States to warrant such an action.

A feasibility study to identify suitable long-term **financing options** for the sector had been proposed but was not conducted. However, the Clinton Health Access Initiative and UNIDO in Kenya have initiated preliminary efforts of bringing together manufacturers and selected financial institutions, with the aim of making the latter get a better understanding of the sector and its specific needs.

Despite improvements in the ease of doing business in the region, challenges persist. Infrastructure such as ports, roads and rail and their interconnectedness remains a weak point in the region. The cost of and access to reliable electricity remains a further challenge in the region. What is more, persistence of non-tariff barriers denies businesses across the region the full benefits of the Customs Union and the Common Market.

3.1.3 Strengthening of pharmaceutical regulatory capacity in the region

Significant gains in strengthening the regulatory capacity have been achieved. The interventions in this pillar set out to strengthen the regulatory capacity through human resource development, NMRA infrastructure improvement, and review of relevant guidelines, procedures, policies and legislation as well as harmonisation of the same across the region. The activities in this pillar were largely implemented through the MRH and PTB projects. The funding (USD 12 million) the EAC received for the implementation of the MRH project enabled the region to make significant gains in strengthening the regulatory capacity. Technical personnel from the national medicines regulatory authorities (NMRA) were trained on dossier evaluation, GMP inspection and QMS. The PTB and GIZ projects on the pharmaceutical sector supported trainings on WHO-GMP and preventative maintenance of critical quality control equipment, targeting both public and private sector personnel. A total of 300 technical personnel were trained with up to 50% of the participants coming from pharmaceutical manufacturing companies.

Through a combination of own funds, exchequer and partner support, the national medicines regulatory authorities have made significant improvements with regard to facilities and equipment.

[76] http://www.stridesarco.com/pdf/pressrelease/2016/ss_universal_press_release.pdf
[77] http://www.cdcgroup.com/The-difference-we-make/Case-Studies/Abacus-Parenteral-Drugs/
[78] http://www.catalystprincipal.com/pe-firm-catalyst-principal-partners-acquires-majority-stake-tanzanian-pharmaceutical-manufacturer/
[79] http://www.doingbusiness.org/reports/~/media/WBG/DoingBusiness/Documents/Profiles/Regional/ DB2017/EAC.pdf
[80] East Africa Trade and Investment Hub, 2016, East African Common Market Scorecard 2016: Tracking EAC Compliance in the movement of Capital, Services and Goods.

The Zanzibar Food and Drug Authority recently established new offices, and both Kenya and Uganda are in the process of expanding their offices and laboratory spaces at KPPB and NDA respectively. Burundi and Rwanda are in the process of establishing fully-fledged NMRAs. The National Quality Control Laboratories of Uganda, Kenya and Tanzania are WHO-prequalified, and Kenya also has ISO17025 accreditation. The MRH project is supporting the establishment of robust ICT/IMIS in all NMRAs and is linking them together. The PTB project is supporting the purchase of minilabs for Burundi, Rwanda and Zanzibar as well as providing user trainings targeted at all Partner States.

The EAC Secretariat and the Partner States are developing/reviewing relevant regional and national policies, guidelines and laws that are aimed at strengthening the regulatory capacity. The MRH project is supporting the EAC Secretariat in the area of harmonising medicines regulations. To this extent, the following harmonised documents have been developed: the Common Technical Document (CTD) and the Guidelines for GMP and QMS guidelines. A total of three (3) joint dossier assessments have been conducted, where 27 applications were reviewed and nine (9) joint GMP inspections took place, involving four facilities in the EAC and five outside the region.

The key challenge encountered in this pillar is that not all NMRAs are at the same level of development, which impedes the full implementation of agreed decisions. A framework of mutual recognition is not in place and therefore joint inspections and dossier evaluation decisions are non-binding to the Partner States. The private sector has raised concerns and recommends that the new guidelines be implemented in a phased approach, taking into consideration the additional budgetary and infrastructural requirements that may be needed.

3.1.4 Development of appropriate skills and knowledge for pharmaceutical production in the region

The interventions in this pillar were aimed at addressing the shortage of appropriately skilled personnel for the region's pharmaceutical industry in a sustainable manner. Two main activities were targeted, which included identifying, equipping and accrediting relevant training institutions as well as the development of a human resource strategy. However, a comprehensive training needs assessment for the region was not carried out. Tanzania, with the support of GIZ, conducted a national needs assessment on pharmaceutical personnel.

The Sectorial Council of Health has issued directives on harmonising the curriculum in pharmacy schools as well as carrying out joint inspections of the facilities. The respective national regulatory authorities/pharmacy councils approve the curriculum for pharmacy schools and accredit them in their respective countries. The GIZ, PTB and MRH projects have contributed significantly to a skills upgrade in the sector by supporting targeted trainings e.g. on dossier evaluation, GMP inspection, proficiency testing, calibration and validation, as well as preventative maintenance of critical quality control equipment. In total, over 300 technical personnel have been trained during hands-on workshops and technical seminars. In collaboration with FEAPM, the GIZ and UNIDO have piloted an academia- industry internship programme that aims to inform the redesign of current pharmacy internships to ensure that training is more responsive to industry needs[81].

Identifying, equipping and accrediting training institutions at regional level presents difficulties – not only because of the costs involved, but also because it requires the development and approval of agreed guidelines for carrying out such an exercise. Due to these constraints, this target has not been achieved in the current phase of the plan. The skills mix of the pharmaceutical manufacturing industry should go beyond pharmaceutical personnel and also include e.g. engineers, chemists, and biologists/ microbiologists. This needs to be taken into consideration in the planned interventions. In conclusion, these targeted activities seem to be misaligned and not comprehensive enough to lead to the attainment of the strategic objective as stated above.

3.1.5 Utilisation of WTO TRIPS flexibilities to improve local production of pharmaceuticals in East Africa

An EAC Regional WTO TRIPS policy and a model law for guidance are in place. The EAC Regional Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities was approved by the 22nd Ordinary Meeting of the Council of Ministers and was published and launched in 2013[82]. In addition, a model law that would guide the EAC Partner States in amending and harmonising their national laws in order to incorporate the public health- related WTO TRIPS flexibilities was developed and annexed in the Regional TRIPS Policy and is part of the EAC Protocol on Regional Cooperation on Health.

Trainings and workshops sensitised EAC stakeholders regarding the use of public health-related WTO TRIPS flexibilities. In collaboration with partners such as GIZ, UNCTAD, WTO and WIPO, the EAC Secretariat conducted several sensitisation workshops and trainings on the use of public health-related WTO TRIPS flexibilities. A three-month blended learning course was organised by UNCTAD, UNIDO and GIZ, with the aim of enhancing participants' understanding of the use of flexibilities under the international intellectual property rules in order to promote local manufacturing of pharmaceutical products and access to medicine. The UNCTAD / EAC / GIZ regional workshop on policy coherence in September 2015 also addressed TRIPS flexibilities. A total of 23 participants were trained, among them members of FEAPM, officials from industry and health ministries of EAC Partner States, as well as researchers and stakeholders from civil society. GIZ and South Centre jointly organised a regional sensitisation seminar for civil society, private sector and public sector representatives from the region as well as EAC Secretariat staff and East African Legislative Assembly (EALA) members. A total of 45 participants attended the workshop. The EAC Secretariat, in collaboration with UN agencies (WIPO, WHO) and WTO, organised a workshop on intellectual property and public health. The workshop brought together FEAPM, EAC Secretariat and Partner States' participants.

[81] FEAPM, 2016, UNIDO - FEAPM report on the pilot academia-industry internship programme.
[82] EAC, 2013, Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation.

Despite the approval of the regional policy and a model law, not all Partner States have made efforts to approximate their national laws in order to take full advantage of the flexibilities[83],[84]. This is mainly attributed to a low level of awareness and a general lack of understanding of IP issues and the public health-related WTO TRIPS, in particular among policy makers and legislators at the national level.

3.1.6 Innovation, research and development within the regional pharmaceutical industry

An East African Health Research Commission (EAHRC) has been established, and pilot projects aimed at promoting the region's pharmaceutical R&D have been implemented. The protocol for the establishment of the EAHRC was signed by the heads of state in 2008 and the institution was set up in 2015. As part of its mandate, the EAHRC is expected to promote and coordinate R&D activities in the region, which also includes R&D in the pharmaceutical sector. Moreover, there have been several pilot projects to promote the pharmaceutical R&D capacity in the region. These include the GIZ support to the Muhimbili School of Pharmacy and the Kilimanjaro School of Pharmacy in setting up a formulation development laboratory and a GMP-compliant pilot production facility respectively. The two facilities were expected to be used by local pharmaceutical manufacturers for formulation development through collaborative arrangements in the region. However, the use of these facilities by the manufacturers has been less than optimal. This can be partly explained by the weak links between industry and academia in the region. Industry stakeholders also reported that universities in the region do not swiftly respond to their queries and are taking their time in meeting their contractual obligations. It appears that academia has not yet adopted a business-oriented approach when servicing industry needs.

A regional innovation fund has not been established, but the Partner States have set up their national innovation funds. While Kenya, Rwanda, Tanzania and Uganda have established such funds, the volumes are modest and are intended to benefit all priority sectors including health, agriculture, climate change, etc. The local pharmaceutical industry focuses mainly on generic medicines production and does not prioritise R&D, and therefore it does not allocate budgets for it. The health R&D landscape in the region is largely donor-funded and focuses on basic research; the priority areas are influenced by the funders. Downstream pharmaceutical product development is not considered a priority area for most donor-funded programmes.

Based on the foregoing, it can be said that the implementation of EAC-RPMPOA: 2012–2016 has achieved certain key milestones that now lay the foundation for the new plan. Highlights include the following:

1. Establishment and operationalisation of a steering structure at both regional and national levels to guide the implementation of the plan;
2. Establishment of FEAPM that has been effective in mobilising local pharmaceutical manufacturers;
3. A strengthened regulatory capacity in the region, with both regulators and manufacturers improving their competence to undertake their respective roles;
4. Harmonised medicines regulation guidelines in place and being implemented at national level;
5. An improved policy and legal environment that is conducive to the promotion of local production;
6. The recognition that the promotion of local pharmaceutical production requires a multi-sectorial approach with industry, health and the private sector closing ranks and coming together for the common good at both regional and national levels.

Despite these achievements, challenges persist, in particular the unfavourable market access conditions for local manufacturers that place them at a disadvantage over imports. The new plan should therefore build on the achievements and set out new strategic approaches to surmount the challenges and capitalise on emerging opportunities within the sector.

[83] South Centre, 2014, The ARIPO Protocol on Patents: Implication for Access to Medicines, South Centre Research Paper.
[84] UNCTAD/GIZ, 2016, A Report on National and Regional Policy Coordination for Pharmaceutical Manufacturing in the East African Community.

3.2 A tabulated summary EAC-RPMP0A: 2012–2016 assessment

In each of the six pillars there were notable successes and challenges, which are summarised in Table 10.
A detailed assessment of the first RPMPOA is attached as Annex I.

Table 10: Summary of main achievements and challenges of the first phase, EAC-RPMP0A: 2012–2016

Strategic objective	Main achievements	Challenges
Promotion of competitive and efficient regional pharmaceutical production	• Local pharmaceutical production is a priority area at both national and regional levels (e.g. policies and strategic plans). • The regional manufacturers' association, FEAPM, has been established and is engaged in lobbying and advocacy activities. • Expanded pharmaceutical operations and improved quality standards of local firms. • Joint ventures/buyouts reported.	Collection of reliable market data for demand quantification and production capacity proved difficult. Key stakeholders were reluctant to provide data.
Facilitation of increased investment in pharmaceutical production regionally	• Round-table advocacy discussions held in all Partner States and a first international high-level conference on investment in pharmaceutical manufacturing (2016). The local pharmaceutical production received attention at the highest level of policy making. • Improved operating business environment in the region has had a positive impact on the pharmaceutical sector.	• Costly and unreliable access to electricity. • Unfavourable market access conditions for local manufacturers.
Strengthening pharmaceutical regulatory capacity in the region	• Strengthened regulatory capacity and infrastructure in the EAC Partner States. • Increased technical cooperation (e.g. common guidelines, joint assessments and inspections, PMS) in the region.	• Varying levels of regulatory capacity among EAC Partner States' NMRAs. • Mutual recognition not in place and therefore decisions from joint evaluation and inspections are non-binding.
Development of appropriate skills and knowledge for pharmaceutical production in the region	• More than 300 technical personnel trained in e.g. PV, PMS, clinical trials, dossier evaluation, GMP inspection, proficiency testing, calibration and validation, preventative maintenance of critical quality control equipment. • Academia-industry internship programme is supported by GIZ and UNIDO.	• High costs for equipping and accrediting regional training institutions. • Skills mix should go beyond pharmaceutical personnel and also include e.g. engineers, chemists, and biologists/microbiologists.
Utilisation of WTO TRIPS flexibilities to improve local production of pharmaceuticals in East Africa	• EAC WTO TRIPS policy and a model law in place to guide Partner States. • Trainings, workshops and blended learning courses sensitised EAC stakeholders on the use of public health-related WTO TRIPS flexibilities.	• Despite the trainings, there is still a lack of awareness and understanding of IP issues and the public health-related WTO TRIPS flexibilities. • Partner States have not approximated their national laws to take full advantage of WTO TRIPS flexibilities.
Innovation, research and development within regional pharmaceutical industry	• The East African Health Research Commission (EAHRC) has been established. • Pilot projects to promote pharmaceutical R&D capacity in the region, e.g. with MUHAS and Kilimanjaro School of Pharmacy, with the support of GIZ.	• Weak links between industry and academia. • A regional innovation fund for the pharmaceutical sector does not exist. • National innovation funds thinly spread their resources to priority sectors. • No significant R&D activities but a focus on generics. • Donor-funded programmes do not prioritise downstream pharmaceutical R&D.

04

EAC-RPMP0A 2017–2027
Strategic Interventions and Actions

4.1 Context: lessons from other countries and regions

There are useful lessons to be learnt from other countries and regions that have implemented deliberate policy interventions to promote local pharmaceutical production. These countries include Ghana, Bangladesh, India, Egypt, and Ethiopia. The specific measures they undertook and results are briefly discussed below.

Ghana's pharmaceutical sector is described as strong; Ghana is a leading exporter to ECOWAS and 30% of demand is met by local production. The strength of the Ghanaian pharmaceutical sector is explained by the following government incentives, which were first introduced in 1989 and included banning the import of about 44 medicines, which either could be manufactured locally or required regulation due to health concerns; 66 of the 200 basic materials required for production were exempt from import duty as well as instituting a raft of tax incentives. As a result, the industry grew strongly and the share of local production increased from 10% to 30% – with 39 local manufacturers in 2014 compared to just nine in 1989. During the specified period, employment in the sector increased tenfold to the current high of 6,500[85].

Prior to the launch of the National Drug Policy in 1982, the Bangladesh pharmaceutical market was dominated by multinational companies, and these were able to set very high prices for live-saving medicines because of their monopolistic power. The respective policy intervention was aimed at lowering prices in order to secure access to essential medicines for all and to promote the local production of medicines. It included three main measures:

- ✓ Prohibition for multinational firms to sell simple formulations that could easily be produced by local firms
- ✓ Restriction of the import of substitutes for finished medicines and intermediate inputs that can be produced by at least two local firms, and
- ✓ Prohibition for multinational firms to advertise brands produced through toll manufacturing.

As a result, multinational firms were incentivised to establish their own factories in Bangladesh. The share of local production increased, and according to current estimates the country meets more than 90% of its essential medicines demand through local production[86]. There was a price drop in real terms of more than 50%, which made medicine more affordable for consumers. Furthermore, the country is now less dependent on imports, and the prioritisation of useful products saved the country approximately USD 600 million[87].

In **India**, following the country's independence in 1947, western MNCs held about 80% of the pharmaceutical market, with the remainder being served by small-scale Indian-owned companies. India heavily depended on imported medicines, prices were among the highest in the world, there was a shortage of essential medicines and there was a crisis in terms of healthcare provision[88]. To overcome this healthcare crisis, India introduced the following measures and incentives aimed at developing the local pharmaceutical industry:

- Large investments to establish public sector enterprises in order to reduce dependence on MNCs
- Inward-looking trade and investment policies: the ensuing "import substitution" policy took the form of a complex system of price controls, high import duties and export subsidies.
- The Indian pharmaceutical industry focused on reverse engineering and process innovation.
- The Patent Act of 1970 included provisions for recognising process patents.
- Price control was introduced in 1970 for a long list of "notified" medicines that were deemed essential, with the objective to curb profit margins and promote access to medicine.

The industrial policy coupled with the dynamic response of local firms to acquire capabilities across all stages of medicine production led to a sharp reduction in import dependence and MNC domination. Today, India is among the top 20 pharmaceutical exporting countries worldwide. Exports have grown at about 19% and Indian medicines are exported to some 200 countries, including highly regulated markets such as the United States and the UK. India's industry has been growing at an annual rate of 10%, while exports have gone up by about 20%. The pharmaceutical industry currently employs about 450,000 people and has contributed significantly in creating a rich talent pool of researchers, scientists, physicians, and project managers[89].

The **Ethiopian** government offers a 25% price preference to local manufacturers in addition to making 30% advance payments on purchases. The balance of 70% was also pre-financed through a loan facility set up by a state bank[90].

Egypt has a well-developed pharmaceutical sector with a strong manufacturing base comprising both local manufacturers and MNCs. The pharmaceutical industry is one of the country's strong manufacturing segments and employs 100,000 personnel. Egypt's domestic production accounts for 82% of the needs of the market, with the remaining share being covered by imports. In terms of market share, MNCs have nearly 30% of local sales through their domestic manufacturing facilities and 35% through licencing agreements with local companies; the remaining 35% belong to generic production by local companies[91],[92].

[85] L. Nixdorf, 2014, Pharmaceutical Manufacturing in Ghana: Lessons Learnt for the East African Community, paper presented to FEAPM AGM in Kampala, Uganda.
[86] Bangladesh Pharmaceutical Manufacturers' Association, 2016, presentation at the Generics Association's exchange workshop, Nairobi, Kenya.
[87] N. Amin and T. Sonobe, 2013, The Success of the Industrial Development Policy in the Pharmaceutical Industry in Bangladesh, GRIPS Discussion Paper, Tokyo, Japan.
[88] S. Guennif, and S.V. Ramani, 2010, Catching up in pharmaceuticals: a comparative study of India and Brazil, UNU MERIT.
[89] Ibid.
[90] National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025).
[91] http://www.oxfordbusinessgroup.com/news/egypt-regulating-pharmaceuticals-production
[92] https://www.researchgate.net/publication/285505960_Pharmaceutical_Pricing_in_Egypt

Table 11: Summary of policy measures undertaken by selected countries and results

Country	Measures	Industry Growth	Quality of Medicines	Employment
Ghana	Import classification and tax incentives	The share of local production increased from 10% to 30%, with 39 local manufacturers in 2014 compared to just nine in 1989.	The quality improved significantly: for example, the share of sub-standard malaria medication in circulation fell from 39% to 3%.	Employment more than ten-folded: currently about 6,500 jobs in the industry.
Bangladesh	Import classification and price ceilings	The share of local production increased from 35% to 97% with more than 170 approved & operating companies in 2013 compared to just 80 active in 1982.	The quality improved significantly. The industry recently started exporting their products to countries in Asia, Latin America and Southern Europe, and also to developed countries including the USA, which has the world's most stringent safety regulations.	Employment: currently about 100,000 jobs in the industry.
India	Import duties and export subsidies	India's industry has been growing at an average annual growth rate of 19%. In 2013, it was the third biggest exporter of medicines by volume.	India is among the world's top 20 pharmaceutical exporting countries. Indian drugs are exported to around 200 countries, including highly regulated markets such as the USA and the UK.	The industry currently employs about 450,000 people and has contributed significantly in creating a rich talent pool of researchers, scientists, physicians and project managers.

4.2 Strategic interventions and actions for the EAC-RPMPOA: 2017–2027

The new plan of action takes into consideration lessons learnt from the first RPMPOA: 2012–2016 as well as experiences from abroad.

The new EAC-RPMPOA: 2017¬–2027 analyses achievements and challenges observed during the first implementation phase (2012–2016). It identifies priority areas for action and designs strategic approaches for implementation at regional, national and firm levels in a coherent manner whilst drawing lessons from the previous plan. Moreover, there is strong evidence in other countries that an industrial policy for the support of local pharmaceutical manufacturing can be successful, both from an economic and a public health perspective. Best practice examples from Ghana, India, Bangladesh, Ethiopia, and Egypt have shown that access to and availability of medicine was increased, sub-standard and falsified products and dependence on MNCs reduced and employment created.

The plan has been developed within the context of a global, continental, regional and national policy environment that is increasingly recognising the critical role of domestic production in promoting public health and industrial development.

Furthermore, the plan considers policy coherence as its strategic approach to maximise the benefits and address the gaps and shortcomings of existing and future national, regional and international initiatives. The interventions listed under each pillar have been designed based on assessments of existing policies and initiatives as well as current trends and market forecasts in a manner that identifies measures that enhance policy coherence. The Partner States will be encouraged to promote coherence among their respective health, industrial, trade, investment and intellectual property policies along the lines of the art of coordination recommended under the UNCTAD-GIZ Tool Box for Policy Coherence on Access to Medicines and Local Pharmaceutical Production[93].

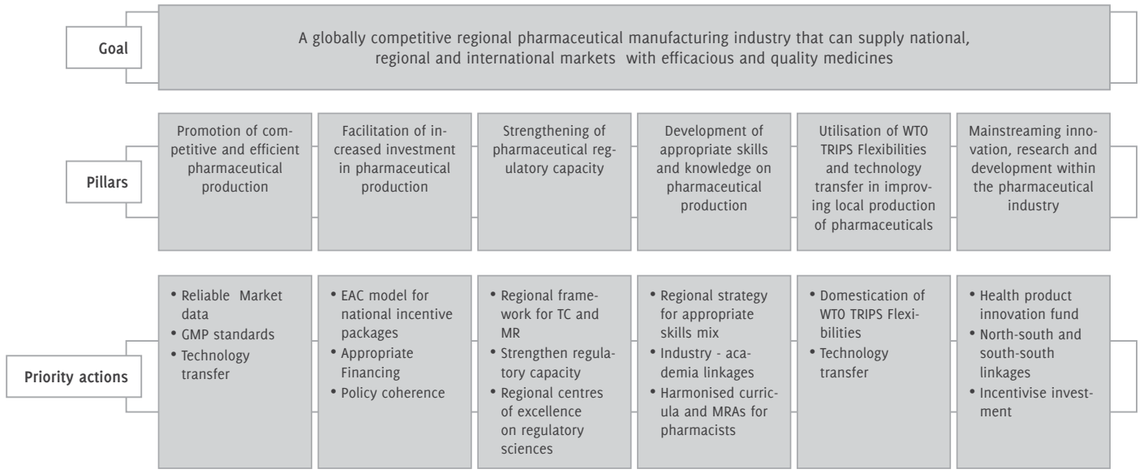
Four high-level targets and key strategic activities have been identified for the sector in order to realise an efficient and effective regional pharmaceutical manufacturing industry that is able to supply national, regional and international markets with efficacious and quality medicines. These include:

1. Reversing dependency on pharmaceutical imports from outside EAC from more than 70% to less than 50%.
2. Support the expansion of product portfolio of EAC firms to cater for more than 90% of disease conditions.
3. At least 50% of purchases by EAC national medicines procurement agencies are to be sourced from EAC pharmaceutical manufacturers.
4. Support local industry in expanding their portfolio. At least five (5) companies to produce more advanced pharmaceutical formulations.

In order to achieve the overall goal and high-level targets, the below key strategic activities under each of the six pillars are to be prioritised. Detailed activities are presented in the performance matrix.

[93] Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production, 2017, UNCTAD.

Figure 4: Goals, strategic interventions and priority actions for the new RPMPOA



Pillar 1: Promotion of competitive and efficient pharmaceutical production:

a) Develop a sustainable platform that provides reliable and up-to-date pharmaceutical market intelligence data. This will improve market access strategies and decisions of local firms as well as policy makers.

b) Support measures to move EAC pharmaceutical production towards international quality standards. This will help manufacturers to export to regulatory stringent destinations and participate in international tenders.

c) Promote regional and international collaboration including technology transfer to achieve advanced pharmaceutical technology production.

Pillar 2: Facilitation of increased investment in pharmaceutical production:

a) Establish an EAC model for national incentive packages for local pharmaceutical production (e.g. tax regime, CET, preferential pricing, public procurement, land allocation for greenfield projects and import classification)

b) Facilitate access to affordable and longer-term finance for investment in appropriate manufacturing facilities, new technologies and expansion of product portfolio.

c) Support policy coherence across sectors at both national and regional levels.

Pillar 3: Strengthening of pharmaceutical regulatory capacity:

a) Develop and implement a regional framework for technical cooperation and mutual recognition of harmonised medicines registration and GMP inspections.

b) Strengthen national and regional regulatory capacity as well as support capacity of industry to meet and sustain GMP compliance.

Pillar 4: Development of appropriate skills and knowledge for pharmaceutical production:

a) Develop and implement a regional strategy for promoting availability of appropriate skills mix for the local pharmaceutical manufacturing industry.

b) Promote industry-academia linkages for skills development.

c) Harmonise pharmaceutical curricula among EAC Partner States and implement MRAs for pharmacists.

d) Establish a regional centre for pharmaceutical sciences and technology.

Pillar 5: Utilisation of WTO TRIPS flexibilities and technology transfer in improving local production of pharmaceuticals:

a) Support domestication of public health-related WTO TRIPS flexibilities within the national laws of the Partner States.

b) Promote technology transfer through use of public health-related WTO TRIPS flexibilities.

Pillar 6: Mainstreaming innovation, research and development within the pharmaceutical industry:

a) Support the establishment of a regional health product innovation fund

b) Promote north-south and south-south linkages on innovation, technology transfer, and research and development.

c) Develop and implement incentives for industry to invest in R&D.

Throughout the pillars, the strategic interventions will prioritise and support local industry towards investing in niche areas described in Section 2.3.8. These include harnessing the potential of traditional medicines and natural products, production of APIs, veterinary medicines as well as strengthening the support and service industry for the sector. A detailed implementation matrix for the activities under each pillar can be found in Annex I.

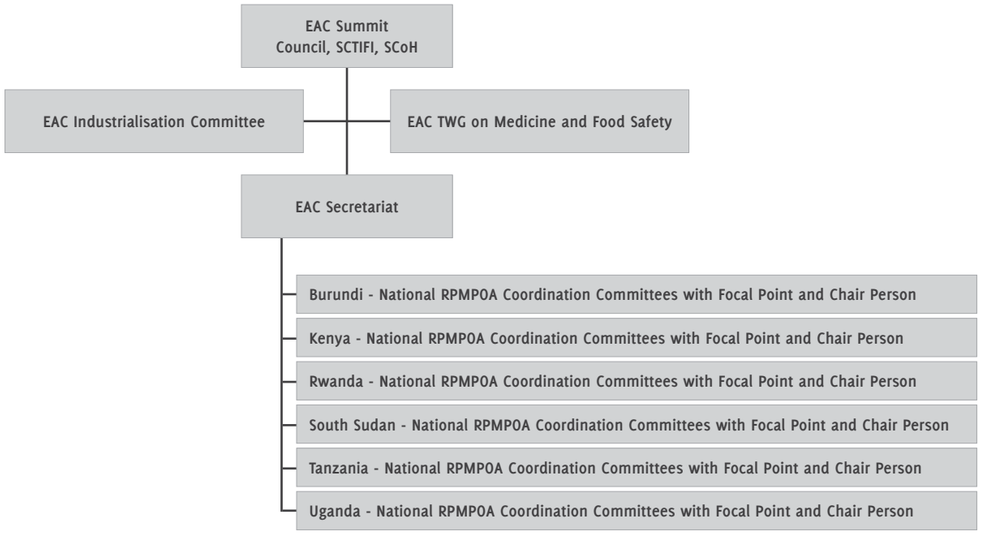
05

Monitoring and Evaluation

5.1 Steering structure and implementation framework

The EAC-RPMPOA is a regional plan that is largely implemented at national level through a multi-sectorial approach. The steering structure takes into consideration the decision-making process of the EAC organs and the multiple actors (regional and national) comprising public and private sector. The Industrial Development Department and the Ministry of Industry are the focal points at the Secretariat and the Partner States respectively. Figure 5 below illustrates the steering structure in detail.

Figure 5: Simplified graph of the EAC-RPMPOA steering structure



An EAC-RPMPOA project implementation officer within the EAC Secretariat Industrial Development Department should be appointed; while at national level the focal points should be appointed substantively to these positions. The project officer will support the national focal points to develop respective annual operational plans.

5.2 Monitoring and evaluation

M&E and control structures have been established. M&E structures are based on the previous EAC-RPMPOA: 2012–2016 and shall be operational right from the adoption and launch of the new RPMPOA. In particular, national and regional steering committees have been set up and will continue their work during the new project phase. National coordination committees with their focal points and chair persons will guide the national implementation process as well as monitoring and evaluation activities at national level. The RPMPOA focal points and project officers will provide reports and inform the RPMPOA steering committee about national initiatives and activities as well as allocated budget lines and investment volumes by the government and private sector respectively. The project officer responsible for the implementation of the RPMPOA will develop annual operational plans (AOPs) derived from the EAC-RPMPOA: 2017–2027. The officer is expected to issue quarterly, biannual and annual reports to be presented to the regional steering committee. Regional steering committee meetings are expected to take place at least once per year. The national steering committees will meet twice per year. The focal points prepare biannual reports to the national steering committees and annual reports to the regional steering committee. The regional steering committee will review the progress reports and advise the Secretariat accordingly. The regional steering committee shall provide regular updates to the EAC policy organs (sectoral committees of industry and health) in their scheduled meetings. The Secretariat will take corrective actions as necessary to ensure smooth implementation of the plan.

Within the framework of the EAC-RPMPOA: 2017–2027, M&E will be conducted by way of systematic and objective assessment of key areas of focus. The aim of M&E will be to determine progress with regard to the goals and targets. The evaluation of the plan will specifically address questions relating to the implementation process and the contribution of the RPMPOA to the overall development of the pharmaceutical sector in the EAC. The evaluation of the EAC-RPMPOA: 2017–2027 will be based on the OECD-DAC evaluation criteria of relevance, efficiency, effectiveness, impact, and sustainability of the various interventions. Evaluations after each of the three phases of the plan of action (2021, 2024 and finally after 2027) are planned to be commissioned. The evaluations will report on implementation and coordination and will also assess achievements against intended outcomes and identify lessons learnt and best practices. The reports of the end-of-phase evaluations will form a basis for strategic decisions necessary to guide the implementation of the remaining period. Overall, the M&E system will endeavour to explore the alignment of the national and regional initiatives, policies and change processes that support development of the EAC pharmaceutical sector towards better access to affordable, efficacious and quality-assured medicines in the region. In particular, the development/amendment of relevant policies and legislation at both national and regional levels will be monitored for coherence and consistency across sectors.

Monitoring and evaluation of progress of implementation of EAC-RPMPOA: 2017–2027 will be largely informed by baseline data and benchmarks for the agreed targets. The ten-year plan will provide specific indicators and milestones with time frames for achieving the short-, medium- and longer-term goals of the EAC-RPMPOA: 2017–2027. Key implementation indicators and milestones are summarised in Table 12 below.

Table 12: Key implementation indicators and milestones

No.	Indicator	2017	2021	2025	2027
1	An EAC GMP Roadmap is in place.	0	In place		
2	A platform for pharmaceutical market intelligence data is established.	0	In place		
3	Number of annual joint post-market surveillance activities in the region.	0	2	2	2
4	EAC Partner States have incentive packages (tax, preferential treatment land allocation, etc.) in place.	0	In place		
5	EAC Partner States have appropriate financing schemes for upgrade of the sector in place.			In place	
6	Number of exchange programmes and initiatives in place towards enhanced pharmaceutical R&D.	0	1	2	3
7	Regional preferential pricing for pharmaceuticals produced in the EAC is in place.	0	In place		
8	Regional centre for production of Chemical Reference Substances.	0	In place		
9	Regional BE centre established.	0	0	In place	
10	Number of local firms investing in renovation and upgrade of existing manufacturing sites.		3	5	7
11	Essential medicines purchased by public procurement agencies from EAC manufacturers (%).		15%	25%	50%
12	Mutual recognition agreements on harmonised medicines registration and GMP inspections in place.	0	1	2	3
13	EAC Partner States have amended national laws to incorporate use of TRIPS flexibilities.	1	3	4	5
14	Number of pharmaceutical firms and countries exploiting TRIPS flexibilities.	0	0	1	3
15	Number of EAC firms with WHO-prequalified products.	2	3	4	5
16	Number of firms producing APIs and higher value-chain pharmaceuticals in the region.	1	2	3	5
17	Dependency on imports from outside EAC.	>70%	65%	60%	50%
18	Level of capacity utilisation at firm level (%).	40%	50%	60%	70%
19	% of disease conditions covered by product portfolio of EAC firms.	66%	75%	80%	90%

06

Budget

6.1 Overall budget for the EAC-RPMPOA 2017–2027

The successful implementation of the EAC-RPMPOA: 2017–2027 requires substantial financial resources estimated at USD 9.95 million for the first period (2017–2021) as detailed in the implementation matrix. For the subsequent phases 2022–2024 and 2025–2027 a headline projected budgetary estimate for each strategic objective (pillar) is provided in Table 13 below. It is expected that at the start of each of these phases a detailed activity-based budget will be developed as part of the evaluation of the implementation progress of the plan. Based on these estimates, the total budgetary requirement for the implementation of the 2017–2027 plan amounts to USD 22.05 million.

Table 13: Budgetary estimations for the EAC-RPMPOA: 2017–2027

Strategic objective	Budgetary estimates (USD)			
	2017–2021	2022–2024	2025–2027	Total
1. Promotion of competitive and efficient regional pharmaceutical production	2,550,000	1,500,000	1,300,000	**5,350,000**
2. Facilitation of increased investment in pharmaceutical production regionally	1,500,000	1,000,000	1,000,000	**2,500,000**
3. Strengthening pharmaceutical regulatory capacity in the region	2,200,000	2,000,000	1,500,000	**5,700,000**
4. Development of appropriate skills and knowledge for pharmaceutical production in the region	1,700,000	1,200,000	1,000,000	**3,900,000**
5. Utilisation of WTO TRIPS flexibilities to improve local production of pharmaceuticals in East Africa	600,000	400,000	400,000	**1,400,000**
6. Innovation, research and development within regional pharmaceutical industry	1,400,000	1,000,000	800,000	**3,200,000**
Total (USD)	**9,950,000**	**6,100,000**	**6,000,000**	**22,050,000**

6.2 Funding and resource mobilisation

The EAC-RPMPOA: 2017–2027 has no specifically allocated financial resources. Just like the previous EAC-RPMPOA: 2012–2016, the new plan is approved by high-level EAC policy organs but no specific financial resources were reserved for it. The implementation framework of the plan is such that the EAC Secretariat is to roll out the plan in collaboration with the Partner States. It is expected that the EAC Secretariat will mobilise the necessary resources for the successful implementation of the plan.

The new plan of action follows on an integrative and comprehensive approach for the development of the pharmaceutical manufacturing in the EAC. Therefore, the new RPMPOA: 2017–2027 comprises (i) initiatives covered under international partners' programmes aimed at improving local pharmaceutical production as well as (ii) relevant initiatives and activities carried out by individual EAC Partner States, and (iii) further required interventions for which financial resources and partners still need to be mobilised.
The plan includes interventions and activities that are covered under specific donor- funded programmes with the EAC, such as:

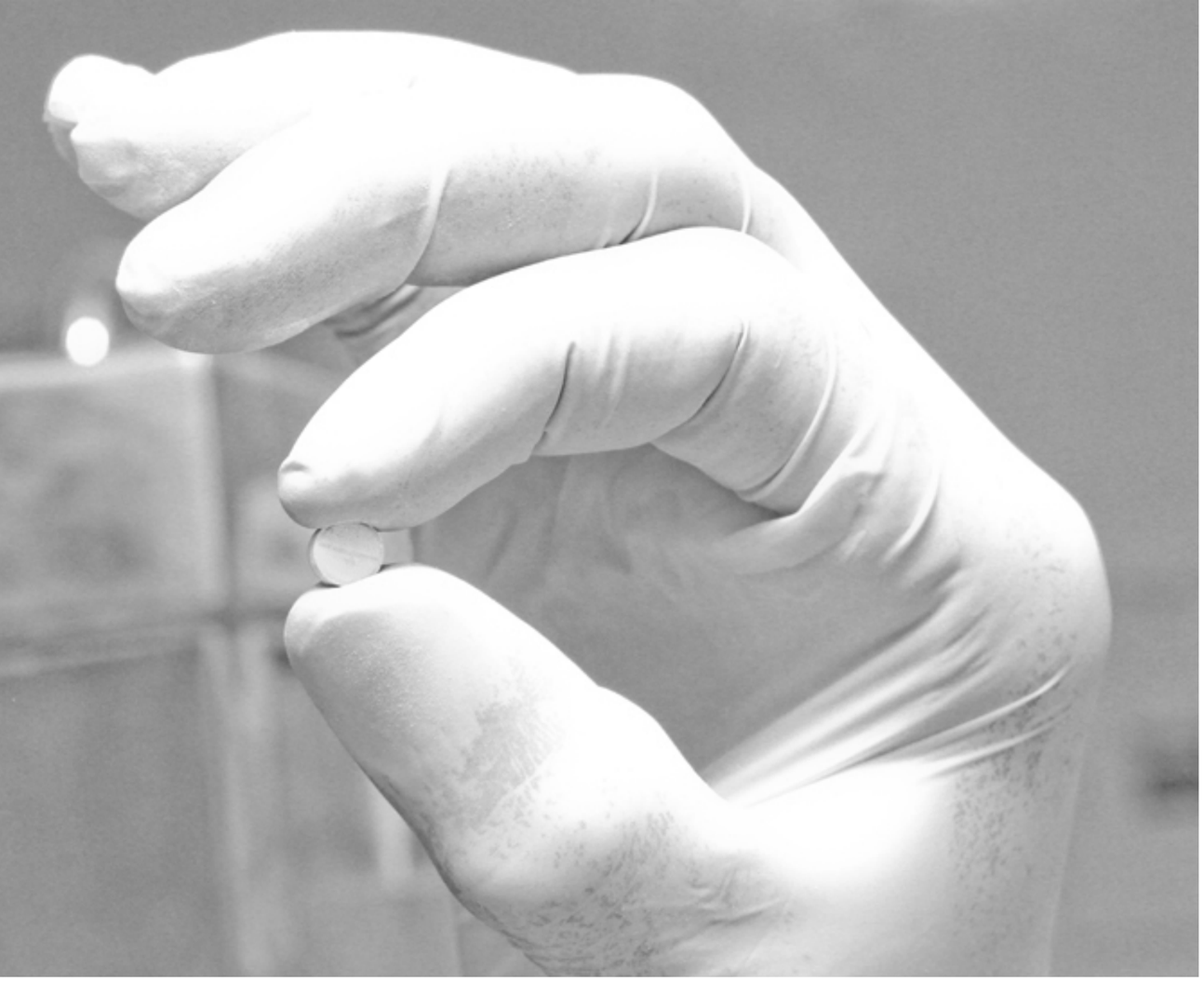
- EAC-PTB project on Quality Infrastructure for the Pharmaceutical Sector; • East Africa Medicines Regulatory Harmonisation (MRH) programme;
- EAC-GIZ Pharmaceutical Sector Promotion Project; • GIZ Polifund project "Access to Medicines";
- UNIDO project to strengthen pharmaceutical production in the EAC

as well as a number of initiatives with other partners. The following interventions are expected to be funded by international partners under their cooperation agreements with the EAC:

- EAC-PTB project on improved regional quality infrastructure
  - Capacity building (focus on quality control, quality infrastructure) • Proficiency testing schemes • PMS strengthening, minilabs
  - Validation and qualification of equipment and processes • CRS availability, support establishment of an EAC CRS centre
  - Maintenance and repair of laboratory equipment.
- EAC-GIZ Pharmaceutical Sector Promotion Project and GIZ Polifund project "Access to medicines"
  - EAC-RPMPOA: 2017–2027 support • Public health-related WTO TRIPS flexibilities (UNCTAD) • Policy coherence (UNCTAD)
  - Capacity development and regulators' platform
  - FEAPM support • EAC GMP Roadmap and national roadmaps for Tanzania and Uganda
- EAC-MRH project
  - Joint inspections and dossier evaluations • Harmonised guidelines • Trainings and twinning programmes
  - Institutional NMRA strengthening • Mutual recognition arrangements
- UNIDO project to strengthen pharmaceutical production in Kenya
- Platform for market intelligence data • Kenya GMP Roadmap follow-up.

In addition, the plan comprises interventions and activities aiming at improved local pharmaceutical production undertaken by individual Partner States. This may include e.g. the following:

(i) national incentive packages and financing schemes to promote the pharmaceutical sectors,
(ii) the establishment of national semi-autonomous NMRAs,
(iii) land allocation for green field projects.



07

Conclusion

There is a high level of political interest across the EAC region to promote and develop the local pharmaceutical manufacturing industry. The implementation of the first plan achieved several key milestones and contributed to the positive development of the sector. The current plan has thus been developed to build on these achievements and sets out new strategic approaches to address existing challenges and to capitalise on emerging opportunities within the sector.

Key findings from this report show that while EAC pharmaceutical markets are growing rapidly, there is still a high dependency on imported pharmaceutical products and local firms are producing under capacity. Even though locally produced medicines cover the majority of disease conditions, the region lacks the capacity to manufacture advanced formulations. This is attributable to a skills gap in product development and formulation expertise and a lack of appropriate and affordable financing for the sector, as options are limited to short-term loans with high interest rates. Furthermore, locally produced medicines compete at a cost disadvantage over imports due to an expensive asset base, high cost of production and unfavourable market access conditions.

In this plan, lessons learnt from other countries and regions on how to promote local pharmaceutical production are identified and adapted to the local context. There is convincing evidence that an industrial policy for the support of local pharmaceutical manufacturing can be successful, both from an economic and a healthcare perspective. Best practice examples from other countries have shown that access to medicine can be improved while sub-standard and falsified products and dependence on imports can be diminished with the adoption of appropriate policy intervention.

A number of potential niches for expansion of the local product portfolio have been highlighted in the plan such as formulations for non-communicable diseases which are new to the region, veterinary pharmaceuticals and development of natural products/traditional medicines. The plan also focuses on supporting the production of active pharmaceutical ingredients and excipients as well as promoting the sector-specific service industry. Priority areas for action and strategic approaches for implementation at regional, national and firm levels have been identified and elaborated in the six pillars.

The successful implementation of the plan will require concerted efforts from all the EAC Partner States' governments, the private sector, international partners and other non-state actors involved in strengthening the region's pharmaceutical sector.

Annex

ANNEX I: Implementation Matrix for Pillars 1–6

The budget indicated in the matrix is for the period 2017–2021.

Pillar 1:
Promotion of competitive and efficient pharmaceutical production

Outcome:
A competitive and efficient pharmaceutical production in the EAC

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
1. Develop and implement national GMP Roadmaps as well as an overarching EAC GMP Roadmap	• Technical assistance; • Assessments of EAC manufacturers; • Trainings; • GMP inspections; • Consultative meetings	• Assessment reports; • CAPA plans; • GMP Roadmap	• An EAC GMP Roadmap is in place; • GMP Roadmaps for Uganda and Tanzania are in place; • Minimum GMP compliance requirements for new facilities in Burundi, Rwanda and South Sudan are in place	• Roadmap report; • GMP inspection reports; • GMP Roadmap monitoring report				• EAC Secretariat; • National ministries; • National medicines regulatory authorities; • FEAPM and national manufacturer associations; • Manufacturers; • International partners	500,000
2. Implement the non-discrimination clause in public procurement of medicines according to Article 35 of the Common Market Protocol[94] regionally	• Consultative meetings; • Policy directives	Uniform implementation of Article 35 of the Common Market Protocol	Procurement laws of the Partner States that are adapted to Article 35 of the Common Market Protocol are in place	Amended national procurement laws				• EAC Secretariat; • National ministries; • Procurement authorities; • International partners	50,000

[94] "The Partner States shall not discriminate against supplies, products or services originating from other Partner States' EAC Common Market Protocol", Article 35 non-discrimination clause.

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
3. Develop a sustainable platform that provides reliable and up-to-date pharmaceutical market intelligence data	• Technical assistance; • Data collection; • Consultative meetings	Market intelligence platform established	Platform for pharmaceutical market intelligence data is in place	Platform for pharmaceutical market intelligence data				• EAC Secretariat; • National ministries; • National medicines procurement authorities; • NMRAs; • National manufacturer associations; • Manufacturers; • International partners	500,000
4. Develop and implement national marketing campaigns to promote locally produced medicines	• Consumer survey; • Stakeholder consultative meetings; • Marketing campaigns	Marketing campaigns to promote use of locally produced pharmaceuticals held in all EAC Partner States	Percentage increase of purchases/ prescriptions of domestically produced medicines	• Survey reports; • Perception survey; • Manufacturers' sales statistics; • Trend reports on ratio of market share of local vs imported				• EAC Secretariat; • National ministries; • Regulators; • FEAPM; • National manufacturer associations; • Health professional associations • Consumer associations; • International partners	200,000

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
5. Implement capacity building measures to move pharmaceutical production and regulation towards international quality standards	• Technical assistance; • Trainings; • Quality infrastructure support	• Capacities for local production of pharmaceuticals in line with international standards have improved; • Sustained compliance with international standards	• Number of facilities complying to cGMP and international quality standards; • Number of personnel trained; • Number of producers and products with WHO prequalification	• Compliance reports; • Trend reports; • FEAPM reports; • WHO-PQ certificates				• EAC Secretariat; • National ministries; • NMRAs; • FEAPM; • National manufacturer associations; • Manufacturers; • National bureaus of standards; • International partners	200,000
6. Assist local industries to expand their product portfolio	• Incentive schemes; • Technical assistance; • Exchange programmes; • Trainings	Expanded product portfolio of local companies to include new formulations	Number of new products/ formulations	• New product registrations/ formulations in the market; • Manufacturers' reports				• EAC Secretariat; • National ministries; • National R&D institutions; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	200,000
7. Implement pilot activities on local production of APIs, excipients, niche products, medical devices and other pharmaceutical inputs and technologies	• Feasibility studies; • Incentive schemes and awareness; • Technical assistance; • Exchange; • Trainings	• Pilot production of selected products; • Capacities for local production of pharmaceutical inputs have improved	Number of locally produced APIs; excipients, primary packaging, pharmaceutical niche products, medical devices, equipment and other inputs	Reports on local production portfolio in the EAC				• EAC Secretariat; • National ministries; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	300,000

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
8. Initiate regional and international collaboration on technology transfer for local pharmaceutical industry	• Industry networking meetings; • Matchmaking and brokering	• New products registered; • New companies established; • Joint ventures and subcontracting negotiations facilitated	• Number of new joint ventures; • Number of PPPs and subcontracting arrangements initiated; • Number of contract agreements in place	• FEAPM reports; • Investment promotion agencies and manufacturers' annual reports				• EAC Secretariat; • National ministries; • Investment promotion agencies; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	200,000
9. Strengthen the capacity of FEAPM to perform its lobbying, advocacy and service delivery role	• Technical assistance; • FEAPM business plan; • Membership recruitment	• FEAPM business plan developed; • New members recruited; • New FEAPM position papers developed	• Number of fully subscribed FEAPM members; • Number of FEAPM lobbying and advocacy activities	• FEAPM annual reports; • New position papers				• FEAPM Secretariat; • National manufacturer associations; • Manufacturers; • International partners	400,000
Subtotal Pillar 1									**2,550,000**

Pillar 2:
Facilitation of increased investment in pharmaceutical production

Outcome:
Increased investment in pharmaceutical production in the EAC

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
1. Develop and implement an EAC model for national incentive packages for local pharmaceutical production[1]	• Market surveys; • Cost-benefit analysis; • Consultative meetings; • Policy directives	• EAC benchmark for national incentive packages developed; • Policy directives issued	• National incentive package in place; • New or amended sector policies in place that take into consideration the incentive scheme	• Survey reports; • FEAPM reports; • Gazette notice				• EAC Secretariat; • National ministries; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	500,000
2. Increase investment in R&D and higher value chain pharmaceutical production in the region	• Trade and industry visits to potential investor countries/firms; • Sector-specific incentives to promote new products; • Policy directives	• Trade visits organised; • Harmonised investment policies and schemes	• Number of investments recorded in the region; • Number of new higher value-chain pharmaceutical products introduced into the market by local manufacturers	• Investment authority reports; • Annual reports of manufacturers; • Procurement agencies' reports				• EAC Secretariat; • National ministries; • Manufacturers; • Investment promotion agencies; • FEAPM; • National manufacturer associations; • International partners	300,000
3. Improve access to finance for upgrade of the sector	• Policy paper on specific financial needs of the industry; • Consultative meetings; • Technical assistance; • Policy directives	Sector-specific financing/loan schemes available	Number of new and existing investments accessing mid- to longer-term financing	• Annual reports of manufacturers; • Financial institutions' annual reports				• EAC Secretariat; • National ministries; • Financial institutions; • National manufacturer associations • Manufacturers; • International partners.	200,000

[95] Incentive packages include tax regime, CET, preferential pricing, import classification and application of verification fee for imports beyond EAC.

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
4. Establish pharmaceutical industry clusters	• Feasibility studies; • Benchmarking visits; • Consultative meetings; • Policy directives	• Policy framework on establishment of pharmaceutical industry cluster; • Cluster established	• Feasibility study report in place; • Policy guidelines on pharmaceutical industry clusters in place	• Gazette notice; • Investment promotion reports				• National ministries; • Export promotion authorities; • Investment promotion agencies; • National manufacturer associations; • Manufacturers	300,000
5. Ensure policy coherence across sectors nationally and regionally	• Policy coherence studies; • Consultative meetings; • Policy directives	Coherent cross-sector policies developed	Number of sectoral policies amended/ developed to promote coherence in local production of pharmaceuticals	• National ministries' reports on policy directives; • EAC reports; • FEAPM annual reports				• EAC Secretariat; • National ministries; • National manufacturer associations; • Manufacturers; • International partners	200,000
Subtotal Pillar 2									**1,500,00**

Pillar 3:
Strengthening of pharmaceutical regulatory capacity

Outcome:
A strengthened pharmaceutical regulatory capacity in the EAC

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
1. Establish a regional medicines regulatory body	• Consultative meetings; • Development of a legal and policy framework for a regional medicines regulatory body; • Council directives	Establishment of a regional medicines regulatory body	• National incentive package in place; • New or amended sector policies in place that take into consideration the incentive scheme	• EAC reports; • Council/policy directives				• EAC Secretariat; • National ministries; • NMRAs; • International partners	500,000
2. Establish a regional framework for mutual recognition of and technical cooperation on harmonised registration of medicines and other regulatory decisions	• Consultative meetings; • Development of a regional policy on mutual recognition of technical cooperation agreements; • Review of national legislation	Mutual recognition of regulatory decisions between Partner States	• Number of investments recorded in the region; • Number of new higher value-chain pharmaceutical products introduced into the market by local manufacturers	• EAC reports; • NMRA reports				• EAC Secretariat; • National ministries; • NMRAs; • International partners	300,000
3. Establish regional bioequivalence and chemical reference substances centres	• Feasibility studies; • Consultative meetings; • Development of business plans for the EAC BE and CRS centres; • Budget allocation	BE and CRS centres established	Number of new and existing investments accessing mid- to longer-term financing	• EAC reports; • NMRA reports; • FEAPM annual reports; • Manufacturers' reports				• EAC Secretariat; • National ministries; • NMRAs; • NQCLs; • National research institutes; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	400,000

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
4. Strengthen national and regional regulatory capacity and upgrade quality infrastructure in order to meet and sustain GMP compliance	• Trainings and technical assistance; • Exchange platforms between stringent regulatory authorities with EAC NMRAs and among themselves; • Industry and regulator exchanges; • Setting up self-sustainable NMRAs; • Government vote and subvention; • Exchange visits and placement of QC/QA personnel in more established manufacturing facilities outside the region	• Twinning and mentoring programmes; • Trainings; • Improved staff competence at both NMRAs and manufacturing facilities; • NMRA guidelines for risk management and enforcement developed; • Exchange visits	• Feasibility study report in place; • Policy guidelines on pharmaceutical industry clusters in place	• EAC reports; • NMRAs annual reports; • FEAPM and manufacturer reports on the service delivery of the respective NMRAs				• EAC Secretariat; • National ministries; • NMRAs and QC laboratories; • Manufacturers; • National bureaus of standards; • International partners	500,000
5. Strengthen pharmacovigilance and post-market surveillance activities in the region	• Trainings; • EWG meetings; • Joint PMS and PV activities; • Information sharing	• Increased reporting; • Number of joint PMS and PV activities; • Number of EWG meetings held	Number of sectoral policies amended/ developed to promote coherence in local production of pharmaceuticals	• EWG meeting reports; • NMRAs annual reports; • Manufacturers' reports				• EAC Secretariat; • National ministries; • NMRAs; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	300,000
6. Develop a harmonised framework for regulation of traditional medicines	• Technical assistance; • Situation analysis of the TM sector in the region	A harmonised framework for regulation of TM developed	• National incentive package in place; • New or amended sector policies in place that take the incentive scheme into consideration	NMRA reports				• EAC Secretariat; • National ministries; • NMRAs; • TM practitioner associations	200,000
Subtotal Pillar 3									**2,200,000**

Pillar 4:
Development of appropriate skills and knowledge for pharmaceutical production

Outcome:
Appropriately trained and skilled personnel in pharmaceutical production available in the EAC

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
1. Develop and implement a regional strategy for promoting availability of appropriate skills mix for the local pharmaceutical manufacturing industry	• Skills gap analysis; • Consultative meetings; • Trainings and industrial attachments; • Exchange programmes (north-south and south-south linkages); • Pharmaceutical industry experts' diaspora returnee programme; • Identify and designate regional training centres for the required pharma skills mix	• Gap analysis conducted; • HR development strategy in place and being implemented; • Database of local pharmaceutical experts in the diaspora	• Gap analysis report in place; • Number of personnel trained; • Number of exchange programmes; • Number of expert diaspora returnees; • Number of identified and designated training centres	• Gap analysis report; • Training reports; • Returnee programme reports; • Training centres' reports				• EAC Secretariat; • National ministries; • Schools of pharmacy, physical sciences and engineering; • FEAPM; • National manufacturer associations; • International partners	500,000
2. Harmonise curricula for personnel required in pharmaceutical manufacturing	• Survey on relevant courses; • Technical assistance; • Consultative meetings; • Policy directives	Harmonised curricula	Number of institutions adopting harmonised curricula	• Reports on use of new curriculum; • EAC reports				• EAC Secretariat; • National ministries; • Academic and research institutions; • International partners	300,000

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
3. Establish a mutual recognition agreement for pharmacists	• Consultative meetings; • Negotiations; • Signing of MRA as per the provisions of the CMP	Signed MRA for pharmacists	• Number of consultative meetings; • Number of pharmacists being registered and licensed to practice in Partner States other than their home countries as a result of MRA	• EAC reports; • Regulator reports; • National pharmaceutical professional society reports				• EAC Secretariat; • National ministries; • NMRAs/pharmacy councils; • Pharmacy professional associations; • International partners	200,000
4. Strengthen industry-academia linkages for skills development	• Consultative meetings; • Exchange programmes; • Structured internship programmes	Exchange programmes and structured internship programmes	• Number of joint trainings; • Number of exchange programmes; • Number of internships offered by industry	• Training reports; • Manufacturers' annual reports; • Exchange programme reports				• EAC Secretariat; • National ministries; • NMRAs; • Academia; • Manufacturers; • International partners	300,000
5. Develop and implement incentive schemes for local industry to participate in training and nurturing the necessary pool of skills mix at national level	Consultative stakeholder meetings	Guidelines for the incentive schemes	Policy directive on incentive schemes in place	Number of firms making use of the incentive scheme				• EAC Secretariat; • National ministries; • Academia; • National manufacturer associations; • Manufacturers; • International partners	100,000
6. Establish a regional centre for pharmaceutical sciences and technology	• Feasibility studies including needs assessment; • Consultative meetings; • Develop an agreed framework for designating/ establishing such centres	• Regional framework for establishment of an EAC centre for pharmaceutical sciences and technology; • Centres designated/ established	• Number of centres designated/ established; • Number of trained personnel from these centres	• Training certificates; • EAC reports; • NMRA reports; • Manufacturer training reports				• EAC Secretariat; • National ministries; • NMRAs; • International partners	300,000
Subtotal Pillar 4									**1,700,000**

Pillar 5:
Utilisation of WTO TRIPS flexibilities and technology transfer in improving local production of pharmaceuticals

Outcome:
Local production of pharmaceutical enhanced through utilisation of public health-related TRIPS flexibilities in the EAC

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
1. Promote awareness and utilisation of public health-related WTO TRIPS flexibilities in the Partner States	• National and regional sensitisation workshops; • Technical assistance; • Online platform and publications	Awareness created and flexibilities utilised	• Number of firms using TRIPS flexibilities for product development; • Number of new products introduced through exploiting TRIPS flexibilities	• Workshop reports; • NMRA product licencing register; • Manufacturers' annual reports				• EAC Secretariat; • National ministries; • National patent offices; • Regional patent office (ARIPO); • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	200,000
2. Use public health-related WTO TRIPS flexibilities as part of the incentive framework for technology transfer	• Investor briefs; • Technical assistance; • Online platform and database; • Matchmaking and brokering; • Pilot projects on technology transfer and product development using TRIPS flexibilities	• Use of TRIPS flexibilities for technology transfer to local firms is achieved; • Database of potential technology transfer candidate molecules developed	• Number of pharmaceutical firms engaged in technology transfer; • Number of pilot projects	• Consultative meeting reports; • Technology licencing & manufacturing agreements; • Manufacturers' reports				• EAC Secretariat; • National ministries; • National patent offices; • Investment promotion agencies; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	200,000
3. Domesticate public health-related WTO TRIPS flexibilities within the national laws of the Partner States	• Consultative meetings; • Review and enactment of relevant laws	Amended national laws to accommodate public health-related TRIPS flexibilities	Number of amended national laws to accommodate TRIPS flexibilities	• Gazette notices; • Amended national laws				• EAC Secretariat; • National patent offices; • National ministries of justice and AG offices; • International partners	200,000
Subtotal Pillar 5									**600,000**

Pillar 6:
Mainstreaming innovation, research and development within the pharmaceutical industry

Outcome:
Innovative pharmaceutical production through strengthened R&D in the EAC

Activities	Inputs	Outputs	Indicators	Verification	Time frame 2017 to 2021	Time frame 2022 to 2024	Time frame 2025 to 2027	Responsibilities	Budget (USD) Est. 2017–2021
1. Promote north-south and south-south linkages, twinning and exchange on innovation, technology transfer, research and development	• Consultative meetings and visits to selected host institutions and partners; • Exchange programmes (north-south and south-south linkages); • Study visits and placements; • Technical assistance	Exchange programmes established	Number of exchange programmes and initiatives in place	• Exchange programme reports; • EAC reports; • FEAPM reports				• EAC Secretariat; • National ministries including higher education; • FEAPM; • National manufacturer associations; • Manufacturers; • International partners	400,000
2. Support set-up of regional and national innovation funds	• Technical assistance; • Consultative meetings; • Operational and utilisation framework of the fund	Framework for set-up of a regional innovation fund in place	Regional and national innovation funds in place	• EAC reports; • Gazette notices; • Reports on grant applications and awards				• EAC Secretariat; • National ministries; • EADB; • FEAPM; • International partners	200,000
3. Promote industry-academia linkage in product development and technology transfer	• Consultative meetings; • Exchange programmes; • Joint pilot projects on product development	Industry-academia cooperation programmes established	• Number of cooperation programmes and initiatives in place on joint product development/ pharmaceutical R&D; • IP policies for the use & protection of publicly funded research in place; • Number of pilot projects	• EAC reports; • Programme reports; • Manufacturers' reports				• EAC Secretariat; • National ministries including higher education; • Academia; • National manufacturer associations; • Manufacturers; • International partners	400,000
4. Develop and implement incentive schemes for industry to invest in R&D	• Introduce R&D incentive schemes; • Interactive R&D platform to link R&D institutions, industry, policy makers and consumers; • Consultative meetings; • Technical assistance; • Policy directives	Incentive schemes for R&D	• Number of manufacturers investing in R&D; • Number of new products and formulations developed by local industry	• Report on incentive policies; • Gazette notices; • Report on R&D investment by local firms				• EAC Secretariat; • National ministries; • National manufacturer associations; • Manufacturers; • Academia; • International partners	200,000
5. Promote R&D synergies in biotechnology, pharmaceuticals and petrochemicals in the EAC	• Mapping current research activities; • Establishing coordination mechanisms; • Determining priority areas for building synergies	Platform for exchange of information and collaboration in R&D	Number of collaborative R&D projects between the three sectors	• EAC reports; • Publications in relevant journals				• EAC Health Research Commission; • National research institutes; • National science commissions; • Academia; • International partners	200,000
Subtotal Pillar 6									**1,400,000**

Grand Total (Pillars 1–6)									**9,950,000**

ANNEX II: Country-Specific Challenges and Priority Intervention Areas

Each EAC Partner State has its own unique challenges and opportunities that influence its priorities for the pharmaceutical sector. All the EAC Partner States have established a national health sector policy, health sector strategic plans, a medicine policy and a relevant institutional framework (Ministry of Health, medicine regulation and procurement agency), as well as a national Essential Medicines List (EML) and regulations. Burundi and Rwanda, however, still have no autonomous medicines regulatory authorities in place. In Burundi, insufficient capacity of medical stores and inadequate supply and distribution chains are critical factors that need to be addressed in the short term. This is also true for inefficient stock monitoring and procurement planning to prevent stock-outs in Uganda. All countries lack strategies to promote investment, access to finance, R&D capacities, technical expertise and qualified HR required for a local manufacturing upgrade. Country-specific challenges include:

➔ Burundi
- Security constraints
- No adequate regulatory framework for medicines
- Lack of a national strategy for the pharmaceutical sector
- Long registration timelines for pharmaceutical companies
- Lack of sufficiently skilled personnel and knowledge in the pharmaceutical industry
- High cost of production and transport
- Inadequate national quality control and reference laboratory services
- Lack of appropriate infrastructure, utilities and support systems
- Inadequate policy & legislative framework for strengthening local manufacture of pharmaceuticals.

➔Rwanda
- No autonomous medicine regulatory authority in place
- High cost of production and transport
- Lack of a strategy to promote investment
- Limited access to finance
- Need to identify niche area across the pharmaceutical sector's value chain in the mid to long term
- Lack of sufficiently skilled personnel and knowledge in the pharmaceutical industry
- Lack of information on market size.

➔South Sudan
- Poor health commodities security (pharmaceuticals and equipment)
- There is no local production of pharmaceuticals
- Inadequate and poorly managed pharmaceutical storage capacity and network across the country
- Uncoordinated drug donations and parallel supply chain system
- Inadequate national quality control and reference laboratory services
- Low and progressively declining public sector health budget and difficulties in accessing the approved budget
- Over-reliance on oil as the main source of revenue for government health financing
- Limited legislative and regulatory capacity
- Underdeveloped infrastructure – poor road network and unreliable electricity supply

➔Tanzania
- Insufficient incentive frameworks and financing schemes to support pharmaceutical investment
- Need to scale up and benefit from existing R&D
- Strong competition from imports
- High cost of upgrading and maintaining GMP
- Lack of appropriate infrastructure, utilities and support systems
- Lack of sufficiently skilled human resources
- Inconsistent tax policies.

➔Kenya
- Insufficient access to credit for further upgrade of the sector
- Insufficient R&D for the pharmaceutical sector development
- Lack of comprehensive incentive packages including preferential procurement of locally produced medicines
- Lack of stratification of knowledge and skills required in pharmaceutical sector
- Inadequate policy & legislative framework for strengthening local manufacture of pharmaceuticals.
- Lack of information and ineffective monitoring of patented products
- Weak collaboration between industry and academia in leveraging the benefits inherent in TRIPS flexibilities
- Unclear attraction and retention strategies for direct foreign investment and local re-investment.

➔Uganda
- Insufficient incentive frameworks and financing schemes to support pharmaceutical investment
- Insufficient R&D for the pharmaceutical sector development
- Lack of framework for interaction between industry, policy makers and regulation
- Limited access to pharmaceutical inputs, raw materials and support services
- Weak connection between industry, policy makers and regulation.

All Partner States face their own unique challenges in promoting local pharmaceutical production, which need to be articulated and prioritised within the wider framework of the regional plan. The following section highlights the priority interventions for each of these countries.

Burundi	1)	Develop and implement a national policy and strategy for the pharmaceutical sector development
	2)	Put in place a legal framework and establish a semi-autonomous NMRA
	3)	Establish a school of pharmaceutical sciences
	4)	Provide incentives for establishment of domestic pharmaceutical manufacturing facilities
	5)	Exploit the public health-related WTO TRIPS flexibilities to support the growth of the local pharmaceutical industry
Kenya	1)	Mobilise resources for the implementation of all components in the Kenya Pharmaceutical Sector Development Strategy.
	2)	Establish comprehensive pharmaceutical legislation for the control of medicines and health technologies to include API, biologicals, new technologies, herbal medicines and veterinary medicines.
	3)	Streamline and strengthen the regulation of biologicals, new technologies, herbal medicines and veterinary medicines in order to support investment in the sector.
	4)	Establish remedies against imports benefitting from export subsidies that disadvantage locally produced medicines.
	5)	Implement the Kenya GMP Roadmap.
	6)	Develop and implement a comprehensive incentive package to support growth and consolidation of the local pharmaceutical manufacturing industry, including preferential procurement of locally produced medicines.
	7)	Encourage and support local industry to increase R&D activities and expand their portfolio to include high-tech products such as delayed release formulations, vaccines, and biosimilars.
	8)	Support the domestic production of APIs, excipients and primary packaging materials.
	9)	Establish a pharmaceutical industry cluster and/or SEZ.
	10)	Support the local industry to access markets in EAC and beyond.
	11)	Support access to credit for upgrade of the sector.
	12)	Assess & develop stratification of knowledge and skills required in the pharmaceutical sector.
	13)	Maintain a database of information and monitor patented products.
	14)	Strengthen collaboration between industry and academia in leveraging the benefits inherent in TRIPS flexibilities.
	15)	Streamline strategies for attracting and retaining direct foreign investment and local reinvestment.
Rwanda	1)	Establish a semi-autonomous National Medicine Regulatory Authority.
	2)	Develop and implement a pharmaceutical sector development strategy.
	3)	Provide incentives for the establishment of domestic pharmaceutical manufacturing facilities.
	4)	Exploit the public health-related WTO TRIPS flexibilities to support the growth of the local pharmaceutical industry.
	5)	Support domestic manufacturing of niche pharma products for the regional market.
	6)	Assessment of the local pharmaceutical manufacturing industry and development of GMP Roadmap.
	7)	Develop a platform for pharmaceutical market intelligence data.
	8)	Develop and implement a drug coding database.
	9)	Full implementation of Customs Union and Common Market Protocol.
South Sudan	1)	Develop and implement a national policy and strategy for the pharmaceutical sector development.
	2)	Provide incentives for the establishment of domestic pharmaceutical manufacturing facilities.
	3)	Establish a school of pharmaceutical sciences.
	4)	Establish a national quality control laboratory and strengthen quality assurance mechanisms.
	5)	Strengthen medicines supply chain systems in the country.
	6)	Provide incentives for establishment of domestic pharmaceutical manufacturing facilities.
	7)	Exploit the public health-related WTO TRIPS flexibilities to support the growth of the local pharmaceutical industry.
Tanzania	1)	Finalise and implement the strategy for promotion of domestic pharmaceutical production in Tanzania (2013–2023).
	2)	Develop and implement a comprehensive incentive package to support growth and consolidation of the local pharmaceutical manufacturing industry, e.g. tax incentives, price preference, reintroduction of local tenders, and introduction of a "positive list" of medicines that are to be produced locally and not imported.
	3)	Develop and implement a Tanzania GMP Roadmap.
	4)	Develop and implement measures to revive and support closed or underutilised production facilities.
	5)	Support local industry to scale up R&D and expand their portfolio to include high-tech products such as delayed release formulations, vaccines, and biosimilars.
	6)	Support domestic production of APIs, excipients and primary packaging materials.
	7)	Establish a pharmaceutical industry cluster and/or SEZ.
	8)	Support the local industry to access markets in EAC and beyond.
	9)	Promote business linkages.
	10)	Establish affordable long-term investment finance.
Uganda	1)	Support access to finance for upgrade of the sector.
	2)	Increase competitiveness with imports (e.g. review of tax regimes, import classification, subsidies, tax exemptions on machinery and equipment).
	3)	Improve access to inputs and raw materials (e.g. incentives to set up manufacturing of raw materials, APIs, excipients, primary packaging materials in the country).
	4)	Improve access to support services such as calibration and maintenance.
	5)	Develop and implement a Uganda GMP Roadmap.
	6)	Support local industry to increase R&D and expand their portfolio to include high-tech products such as delayed release formulations, vaccines, and biosimilars.
	7)	Establish a pharmaceutical industry cluster and/or SEZ.
	8)	Support harmonisation of drug registration and legislation in the region, e.g. through centralised registration and mutual recognition, to increase market opportunities in the EAC region and beyond.

ANNEX III: EAC Key Policies and Initiatives for the Pharmaceutical Sector Development

The EAC and Partner States are supporting the development of the sector with the twin objective of promoting public health (security of supply of life-saving commodities) and industrial development. The EAC Industrialisation Policy and Strategy has prioritised the development of the regional pharmaceutical industry among other regional industries to be promoted through collective efforts by the Partner States[96,97]. The strategic objectives of the EAC Development Strategy (2012–2016) include: harmonisation of policies, strengthening of local production of medicines and health institutions as well as enhancing competitiveness[98]. In an effort to strengthen and institutionalise health sector interventions, the Secretariat has developed the EAC Regional Health Policy on Cooperation in Health[99], the EAC Health Sector Strategic Plan (2015–2020)[100], and the EAC Medicines and Health Technologies Policy[101]. The EAC Vision 2050 acknowledges the pharmaceutical industry in the EAC as crucial for structural transformation and diversification of the EAC industrial base and emphasises the need for more policy coherence, R&D, and capacity building for the sector. **These policies and strategies entail explicit statements on the development of domestic pharmaceutical production and on incentivising local industry.**

Not all relevant policies and strategies have been approved and implemented yet. Several important EAC health-related policies and strategies that call for enhanced access to essential medicines and health technologies have not been put into practice yet and await approval from EAC policy organs. For the EAC Common Market and Customs Union, many of the national procurement laws of the Partner States have not fully complied with the Common Market Protocol despite the commitment of heads of state. In addition, there are several key tax- and trade-related regimes and policies that are not harmonised across the region yet, with negative effects for local manufacturers aiming at EAC export market opportunities.

The Partner States have also put in place policy and strategic interventions that seek to promote domestic pharmaceutical production – in response to and in compliance with their continental and regional commitments.

The **Burundi** National Strategy for Industrial and Commercial Development (2014–2020) seeks to improve the business environment, modernise infrastructure and create economic, technological and industrial zones[102]. The pharmaceutical sector is prioritised in the National Industrial Policy, and the Burundi Poverty Reduction Strategy Paper II includes the strengthening of the manufacturing sector as part of the recommended interventions[103]. A ministerial decree is in place to regulate manufacturing, trade and practice of pharmacy. However, a proposed law that seeks to establish an autonomous regulatory agency is still in parliament at a draft stage.

The **Kenya** Sessional Paper (2010) on National Pharmaceutical Policy[104] has the expansion of domestic pharmaceutical production as one of the key pillars of its policy framework. With the support of the United Nations Industrial Development Organization (UNIDO), Kenya has made some significant progress in promoting domestic production. Notably, the Ministries of Health and Industry have worked together to develop the Kenya Pharmaceutical Sector Development Strategy (2012)[105], which lays out a series of strategic interventions to be implemented in order to support the sector. These two ministries have also developed the Kenya GMP Roadmap[106] – a stepwise approach for the pharmaceutical industry to attain WHO GMP standards.

The **Rwanda** Health Sector Policy (2015) has prioritised access to safe and affordable medicines for the population[107]. The policy also identifies the private sector as a key partner in achieving this objective. The Rwanda National Pharmaceutical Policy (2016) has among its policy objectives the promotion of domestic production and, in particular, putting in place incentives to create manufacturing capacity for health commodities and technologies[108]. The National Industrial Policy (2011) identifies the pharmaceutical sector as part of the cluster of industries to be considered for medium-term development[109].

The **South Sudan** Health Sector Development Plan, 2012–2016 (HSDP)[110] provides the strategic direction for all health sector work in the country. It is a shared vision of health development between the Ministry of Health (MOH) and sector stakeholders. It builds upon the Health Policy, 2007–2011, and on the achievements since the formation of the interim government in 2005. South Sudan has developed national policies, standards, guidelines and regulations aimed at streamlining the pharmaceutical sector. However, enforcement is still weak and compounded by a shortage of qualified staff in both the public and private sectors. A Food and Drug Control Authority (FDCA) has been established through an act of parliament (2012) by the same name. The country continues to reform its national laws and policies in order to attract investments[111]. These include e.g. the design of investment and trade policies as well as business licencing and registration.

The **Tanzania** Sustainable Industries Development Policy (1996–2020) and Integrated Industrial Development Strategy (2025) have identified policy and strategic objectives aimed at transforming the manufacturing sector of the country[112,113]. Interventions include e.g. fiscal incentives, improving the investment environment, setting up industrial clusters, and Special Economic Zones (SEZs). A strategic plan for promoting domestic production in Tanzania (2013–2023) is at a draft stage[114]. The plan seeks to put in place strategies such as provision of land and long-term credit facilities to potential investors and promote technology transfer and skills development.

Uganda recently launched the National Medicines Policy (2015)[115] and the National Pharmaceutical Sector Strategic Plan III (2015–2020)[116], which prioritise domestic production as part of the overall initiative to improve access to medicines.

The EAC Partner States have made several legal changes to their national laws in order to strengthen the pharmaceutical sector. Kenya is seeking to establish a food and drugs authority and has developed a draft bill, which is awaiting parliamentary debate before adoption. Burundi and Rwanda have also made changes to their national laws to facilitate the establishment of national medicines regulatory authorities in the respective countries. In January 2013, Rwanda published a gazette notice on the introduction of a law regarding the establishment of the Rwanda Food and Medicines Authority.

Summary of EAC policies and strategies supporting the development of the pharmaceutical sector:

- **EAC Treaty, Chapter 21, Article 118** – calls for a common regional medicines policy, which includes the establishment of quality control capacities, good procurement practices, and the harmonisation of drug registration procedures.
- **EAC Treaty, Article 79 on industrialisation** – calls for self-sustaining and balanced industrial growth. Aims at improving the competitiveness of the industry sector so as to expand trade. ➔ ***Industrialisation is a high priority for EAC and Partner States.***
- **EAC Common Market, Article 35** – entered into force on 1 July 2010. Stipulates that Partner States shall not discriminate against suppliers, products or services originating from other Partner States, for purposes of achieving the benefits of free competition in the field of public procurement. ➔ ***Still, many of the national procurement laws of the Partner States have not adapted to the regulation of the Common Market Protocol despite commitment of heads of state.***
- **EAC Customs Union Act – adopted in 2006.** Aimed at liberalisation and promotion of intra-EAC trade for the mutual benefit of all Partner States. The EAC Common External Tariff (CET) covers all pharmaceutical products; they attract 0% CET. ➔ ***Still, attainment of free movement of goods is hampered by retention of internal borders. Several key tax- and trade-related regimes and policies are not harmonised yet.***
- **Agreement on establishment of Tripartite Free Trade Area** – seeks to establish a FTA comprising COMESA, EAC and SADC; a population of 400 million. ➔ ***Negotiations still ongoing.***
- **EAC Industrialisation Policy and Strategy 2012–2032** – identifies the pharmaceutical sector as among the six priority sectors to be promoted through collective efforts by EAC Partner States. Additionally, an EAC industrial upgrading programme focuses on promoting linkages between SMEs and large companies. ➔ ***Currently under implementation.***
- **EAC Development Strategy 2012–16** – aimed at harmonising policies, strengthening local production of medicines, and strengthening regional health institutions. Supports linkages between MNCs and SMEs; enhances competitiveness. ➔ ***New strategy 2016–2019 currently under development.***
- **Draft EAC Regional Health Policy** – calls for enhanced access to essential medicines and health technologies. Aimed at promoting and supporting the development of local manufacturing of health products and technologies including vaccines. ➔ ***Awaiting SCH approval, same as EAC Health Sector Strategic Plan 2015–2020.***
- **EAC Vision 2050** – acknowledges the pharmaceutical industry in the EAC as crucial for structural transformation and diversification of the EAC industrial base. Calls for more policy coherence, R&D, and capacity building.
- **EAC Medicines Registration Harmonisation Initiative** – launched in 2012 with a focus on the development of a harmonised medicines registration system. Achievements include guidelines developed for medicines evaluations, GMP inspections, and a regional IMS being developed. Joint evaluations and inspections now being conducted.
- **Regional Intellectual Property Policy** – calls for utilisation of public health-related exceptions provided under the WTO Agreement on TRIPS as a key tenet of the EAC's strategy to produce more quality medicines locally.
- **EAC Medicines and Health Technologies Policy** – entails explicit policy statements on domestic pharmaceutical production, strengthening GMP, incentivising local industry, skills development, QA systems, medicines financing, and TRIPS flexibility. -> Currently being subjected to stakeholder discussions in the Partner States.
- **EAC Health Research Commission** – mandated to coordinate health sector research, conduct research to inform policy interventions, and prioritise research that seeks to address public healthcare needs in the region. ➔ ***Status: the Secretariat has been established and staff has been recruited.***
- **EAC Anti-Counterfeit Bill (2013)** – potential of supporting the efforts against substandard and falsified medicines. Efforts have been made to align the Anti-Counterfeit Bill and TRIPs policy to avoid contradictions between the two documents.
- **Establishment of FEAPM** – founded in 2011, it is the industry's voice within the EAC. ➔ ***Advocacy and lobbying capacity of FEAPM still needs to be strengthened.***

[96] The EAC Industrialisation Policy: 2012–2032. [97] The EAC Industrialisation Strategy: 2012–2032. [98] EAC Development Strategy: 2012–2016.
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[115] Uganda National Medicines Policy (2015).
[116] Uganda National Pharmaceutical Sector Strategic Plan II: 2015–2020.

ANNEX IV: Stakeholder Overview

The pharmaceutical sector is multidimensional and involves various stakeholders, sectors, policy areas, and processes. Overall, the pharmaceutical sector is influenced by national (and regional) pharmaceutical policies, as well as activities and reforms in other sectors, such as industrial policy and trade agreements. The supply side (production) of pharmaceutical products includes parameters such as product discovery (research and development), licencing of products and market participants, pricing, quality assurance, pharmacovigilance, marketing, and promotion – as well as the respective stakeholders such as the private sector, NMRAs, quality control laboratories, and research institutions. The demand side of the pharmaceutical market (consumption) is influenced e.g. by procurement agencies and purchasing arrangements, supply chain management, distributors and wholesalers. All of these factors and stakeholders interact with each other and have an impact on eventual access to medicines by patients. The table below provides an overview of the main stakeholders and key institutions that support the development of the pharmaceutical sector in the EAC.

Country	Main stakeholders	Roles and responsibilities
EAC level	EAC Summit, Council, SCTIFI, SCoH	Provide strategic policy direction and make decisions aimed at deepening and widening the integration process as per the EAC Treaty.
	EAC Industrialisation Committee	Receive technical reports from the EAC Secretariat and advise/make recommendations to the Secretariat and SCTIFI as appropriate.
	EAC TWG on Medicines and Food Safety	Receive technical reports from the EAC Secretariat and advise/make recommendations to the Secretariat and SCoH as appropriate.
	EAC Secretariat (Health and Industry)	Overall coordination of the implementation of the EAC-RPMPOA: 2017–2027. Lead responsibility in mobilising necessary resources. Advise Partner States on policy and institutional reforms required to support the plan.
	EAC RPMPOA Regional Steering Committee	Support the EAC Secretariat and Partner States in the implementation of the EAC-RPMPOA: 2017–2027.
Partner State level	National RPMPOA Coordination Committee	Support the implementation of the EAC-RPMPOA: 2017–2027 at partner state level.
	Ministries of Health, Industry,	Overall stewardship of the sector, and provision of policy and strategic guidance.
	Regulatory authorities	Responsible for enforcing compliance with the set regulatory requirements for the production, distribution and sale of medicines within the respective countries.
	Quality control laboratories	Support regulatory authorities in pre- and post-market surveillance activities that are aimed at enforcing regulatory compliance.
	Procurement agencies	The national procurement agencies purchase medicines for public health facilities. As their budgets are considerable, they could play an important role in promoting local production of medicines through innovative procurement.
	Investment authorities	Their mandate is to attract investments to their respective countries through various strategies including the provision of incentive schemes.
	Academic training institutions	Provide the appropriate skills mix to the industry.
	Research institutions	Support product development and process improvement through R&D.
	Bureaus of standard	Enforce standards and also provide services to the industry, e.g. calibration.
	Manufacturers	Make the necessary investment decisions and mobilise resources for medicines production.
	Pharmaceutical associations	The industry's voice, it serves as a lobby group and advocate in articulating key concerns of the industry to policy makers and other stakeholders.
	Distributors, wholesalers	Deliver medicines from manufacturing facilities to patients through their networks and business arrangements.
International partners	GIZ, GFA, PTB, UNIDO, WHO, World Bank, USP, NEPAD, UNCTAD, MRH project, BMGF, UNAIDS, AUC, ADB	These partners play a key role in supporting the EAC Secretariat and the Partner States in developing and implementing policies and strategies aimed at promoting the pharmaceutical sector and/or improving access to affordable quality medicines.

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