JUMUIYA YA AFRIKA MASHARIKI

East African Community




East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012 - 2016)




One People. One Destiny

East African Community
Regional Pharmaceutical Manufacturing
Plan of Action
2012 - 2016

East African Community
One People. One Destiny

East African Community Regional Pharmaceutical Manufacturing Plan of Action: 2012-2016

East African Community

"One People, One Destiny"

Objective:

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

EAC Secretariat,
AICC Building,
Kilimanjaro Wing, 5th Floor,
P.O. Box 1096,
Arusha, Tanzania.
Tel: +255 27 2504253/8
Fax: +255 27 2504255/2504481
E-Mail: eac@eachq.org; health@eachq.org
Website: http//www.eachq.org

Foreword

The East African Community (www.eac.int) is committed to promoting access to affordable quality essential medicines, including those for the treatment of various priority communicable diseases such as HIV/AIDS, Malaria, Tuberculosis as well as various Neglected Tropical Diseases (NTDs) and also non-communicable diseases that include Diabetes, Cardiovascular Diseases, Chronic Respiratory Diseases and Cancers, among others. However, the provision of safe, efficacious and affordable essential medicines and other quality health commodities to the people of the East African Community region remains a major challenge due to inadequate local production of pharmaceuticals and over reliance on importation of finished pharmaceutical products and related health supplies from outside the region.

In order to address this challenge of inadequate supply of essential medicines in the East African Community region, it is crucial to build and strengthen the local pharmaceutical manufacturing capacity. This requires building and strengthening of both national and regional capacity to manufacture affordable, efficacious, high-quality and safe generic essential medicines within the region, which can significantly contribute to simultaneous achievement of public health and industrial development objectives in all the East African Community Partner States.

In this regard, this five-year **"East African Community Regional Pharmaceutical Manufacturing Plan of Action (EACRPMPoA): 2012-2016"**, serves as a roadmap to guide the East African Community towards evolving an efficient and effective regional pharmaceutical manufacturing industry that will supply national, regional and international markets with the requisite medicines.

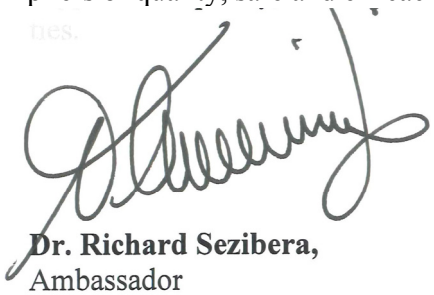
This regional Strategic Plan is designed to achieve the objectives of the Community as set out in Article 118 (g) of the Treaty on the Establishment of the East African Community in which the Partner States agreed to cooperate in the development of specialised health training, health research, the pharmaceutical products and preventive medicines. This Strategic Plan is further anchored within the "**EAC Industrialisation Policy and Strategy"** which has prioritized the development of regional pharmaceutical industry among regional industries to be promoted through collective efforts of the East African Community Partner States. The effective implementation of this Strategic Plan will further complement the ongoing EAC regional initiatives on developing a common regional medicines policy, which will include establishment of quality control capacities, good procurement practices and harmonization of drug registration procedures as stipulated in Article 118 (c) and 118 (d) of the Treaty for the Establishment of the East African Community.

The key strategies to be used in achieving expected results of the East Africa Regional Pharmaceutical Manufacturing Plan of Action and overall five year fourth East African Community Development Strategy objectives for the regional integration in the health sector include among others; promotion of competitive and efficient regional pharmaceutical production; facilitation of increased investment in pharmaceutical production in the region; strengthening of pharmaceutical

regulatory capacity; development of appropriate skills and knowledge on pharmaceutical production; utilization of World Trade Organization - Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS) flexibilities towards improved local production of pharmaceuticals; and mainstreaming innovation, research and development within regional pharmaceutical industry.

The development of the EAC Regional Pharmaceutical Manufacturing Plan of Action which is in line with the African Union Pharmaceutical Manufacturing Plan of Action and the EAC Industrialization Policy and Strategy is an important milestone towards the achievement of universal access to essential medicines for the people of the region and ultimately for the attainment of the United Nations Millennium Development Goals and Targets by 2015. Hence, the successful implementation of the Strategic Plan will require the concerted efforts of all the EAC Partner States, National Ministries of Health, Trade, and Industry as well the National Medicines Regulatory Authorities, the National Procurement Agencies, National Academic and Research Institutions, Pharmaceutical Manufacturers Associations, Pharmaceutical Industries, Private Sector, and International Collaborating Development Partners as well as various Non-State Actors (NSAs) involved in strengthening pharmaceutical systems in the EAC region and Africa as a whole.

In view of the importance of the regional pharmaceutical sector with regard to improvement of the health and overall wellbeing of the people of East Africa and its contribution to industrial development in the region, I wish to call upon the EAC Partner States to take appropriate measures as outlined in the plan for the sustainable development of the regional pharmaceutical industry as suppliers of quality, safe and efficacious essential medicines and other related health commodities.



Dr. Richard Sezibera,
Ambassador
Secretary General
East African Community

Acknowledgement

The development of the **"East African Community Regional Pharmaceutical Manufacturing Plan for Action (EAC-RPMPoA)"** has been a concerted effort of various national, regional and international multisectoral stakeholders. In this regard, the EAC Secretariat wishes to acknowledge the contributions from the East African Community Technical Expert Committee on TRIPS (Trade Related aspects of Intellectual Property Rights) and Access to Medicines (TECTAM) who initiated and expertly steered the development of the Plan of Action (POA).

Further, the Secretariat, wishes to acknowledge the participation, dedication and commitment by the Partner States in the development of EAC-RPMPoA. Key national stakeholders were drawn from local Pharmaceutical Manufacturers, Academia, National Medicines Regulatory Authorities (NMRAs), National Investment Promotion Agencies, National Ministries of Health, National Medicines Procurement Agencies (NMPAs), Pharmaceutical Manufacturers' Associations, National Ministries responsible for East African Community Affairs and Parliamentarians from the East African Legislative Assembly (EALA) and the EAC Partner States' National Parliamentary Departmental Committees on Health under the auspices of the EAC Regional Inter-Parliamentary Forum on Health, Population and Development (EAC-RPF-HPD).

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 coordinated by the EAC-GIZ TRIPS and Pharmaceutical Sector Promotion Project is highly acknowledged and appreciated. Last but not least, the EAC Secretariat recognizes the tireless efforts of the EAC staff from the Health Department on the successful stewardship of the development of the Strategic Plan.

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 in accordance with the relevant provisions of the treaty on the establishment of EAC and the fourth EAC Development Strategy (2012 – 2016).

Jean Claude Nsengiyumva
Deputy Secretary General
(Productive and Social Sectors)
East African Community

Table of Contents

List of Tables

List of Figures

List of Annexes

Abbreviations

ACTs	Artemisinin-Based Combination Therapies
AfDB	African Development Bank
AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
ARV	Anti
AU	African Union
CAMEBU	Centrale d'Achat de Médicaments Essentiels du Burundi
CAMERWA	Centrale d'Achat de Médicaments Essentiels au Rwanda
CVS	Cardio Vascular System
cGMP	Current Good Manufacturing Practice
COMESA	Common Markets for Eastern and Southern Africa
DCs	Developing Countries
EAC	East African Community
EAC-RPMPoA	East Africa Community Regional Manufacturing Plan of Action
ECOWAS	Economic Commission for West African States
EU	European Union
FDI	Foreign Direct Investment
FEAPM	Federation of East Africa Pharmaceutical Manufacturers
GDP	Gross Domestic Product
GSPOA	Global Strategy and Plan of Action
GTZ	German Technical Cooperation
HIV	Human Immune Deficiency Virus
IEC	Information Education Communication
IFC	International Finance Corporation
IHI	Ifakara Health Institute
IPR	Intellectual Property Rights
IRST	Institut de Recherche Scientifique et Technologique
IV	Intravenous
JMS	Joint Medical Stores
KCMC	Kilimanjaro Christian Medical College
KEMRI	Kenya Medical Research Institute

KEMSA	Kenya Medical Supplies Agency
KIST	Kigali Institute of Science and Technology
LDCs	Least Developed Countries
LTEF	Long Term Expenditure Framework
MDGs	Millennium Development Goals
MEDS	Mission for Essential Drug Supplies
MOH	Ministry of Health
MSD	Medical Stores Department
MUHAS	Muhimbili University of Health and Applied Sciences
NEPAD	New Partnership for African Development
NHDP	National Health Development Plan
NIMR	National Institute of Medical Research
NMPAs	National Medicines Procurement Agencies
NMRA	National Medicines Regulatory Agency
NMS	National Medical Stores
NTDs	Neglected Tropical Diseases
OTC	Over the Counter Medicines
PEDs	Priority Endemic Diseases
PHARMESA	Pharmaceutical Manufacturers of Eastern and Southern Africa
PPB	Pharmacy and Poison Board
R & D	Research and Development Board
S & T	Science and Technology
SADC	Southern African Development Community
SEZ	Special Economic Zone
SMEs	Small and Medium Enterprises
SSA	Sub-Saharan Africa
SWOT	Strengths, Weaknesses, Opportunities and Treats
TB	Tuberculosis
TFDA	Tanzania Food and Drug Authority
TRIPS	Trade Related Aspects of Intellectual Property Rights
UIA	Uganda Investment Authority
UK	United Kingdom
UNCTAD	United Nations Conference on Trade and Development
UNHRO	Uganda National Health Research Organization
UNIDO	United Nations Industrial Development Organization
USD	United States Dollars
USA	United States of America
VL	Voluntary Licensing
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive Summary

Integration of the East African Community (EAC) has been advanced by the recent launch of the Common Market, which is expected to promote regional trade and investment, in addition to fostering competitiveness and economies of scale. In a region largely dominated by agriculture this should give a much needed boost to industrial development. Access to affordable, high-quality and efficacious health care products, particularly those used in the treatment of priority communicable and non-communicable diseases, such as HIV/AIDS, Malaria, Tuberculosis (TB), Diabetes, Cardiovascular Diseases, Chronic Respiratory Diseases and Cancers and various Neglected Tropical Diseases (NTDs) is of high national priority in each of the EAC Partner States.

The estimated (2006) pharmaceutical market in sub-Saharan Africa (SSA) was USD 3.8bn, of which local manufacturers accounted for only 25-30%. Additionally, domestic pharmaceutical manufacturers currently capture only a small share of the donor-funded market in sub-Saharan Africa, estimated at between USD 750m and USD 1bn, primarily because donors require product conformity to stringent international quality standards such as prequalification from the World Health Organization (WHO).

Pharmaceutical manufacturers operating from within the EAC region and SSA generally produce at a cost disadvantage to larger generic product manufacturers internationally due to a variety of reasons including scale, expensive asset bases coupled with older technology, higher financing costs plus a lack of integration with active pharmaceutical ingredients suppliers. Other challenges facing the local pharmaceutical production industry in East Africa include shortages of skilled professional personnel and unreliable supporting infrastructure such as electricity, water and transport.

From an industrial policy standpoint, local pharmaceutical manufacture is usually justified by its benefits for the local economy, such as savings on foreign exchange through import substitution, employment creation and the development of exports. From a health policy perspective, the rationale for local pharmaceutical manufacture is largely founded on increasing the access to essential medicines.

Over the past decade, several regional and continental programmes have been initiated towards enhancing capacity utilization of pharmaceutical companies across Africa, increasing access to medicines and boosting formal export markets. Notable amongst these are the African Union (AU) Pharmaceutical Manufacturing Plan, the Economic Community of West African States (ECOWAS) Pharmaceutical Manufacturers Association and the Pharmaceutical Manufacturers Association of the Common Market for Eastern and Southern Africa (PHARMESA).

On the global stage, the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (WTO TRIPS) and Doha Declaration on TRIPS and Public Health provide flexibilities that developing nations could utilize in order to supplement and potentially substitute imported medicines with products that are either manufactured in-country or within neighbouring states.

In light of the foregoing, the EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPoA) has been designed as a results-oriented roadmap to guide Partner States of the EAC towards collective and synergistic evolution of an efficient and effective pharmaceutical production sector, capable of making significant contributions to meeting national, regional and international demand for medicinal products until 2016 and beyond. The action plan is closely aligned to the short, medium and long-term goals and policies of the EAC and individual member states and serves to complement past and present regional economic community and pan-African strategies.

The plan recommends strategic interventions to be applied at firm, institutional, national and regional levels to improve the business environment for pharmaceutical manufacturing, strengthen associated regulatory capacity and further develop human resource capacity through a programmatic approach. Specifically, the plan has set out the following primary strategic objectives:

1. Promotion of competitive and efficient pharmaceutical production regionally;
2. Facilitation of increased investment in pharmaceutical production regionally;
3. Strengthening of pharmaceutical regulatory capacity in the region;
4. Development of appropriate skills and knowledge on pharmaceutical production in the region;
5. Utilization of TRIPS flexibilities towards improved local production of pharmaceuticals, and
6. Mainstreaming innovation, research and development within regional pharmaceutical industry.

The anticipated cost of implementation of the plan of action is approximately USD 45 million, to be raised from EAC Partner States, development partners as well as the regional pharmaceutical industry. The implementation of the EAC-RPMPoA 2012-2016 will be co-ordinated and implemented through the approved EAC structure and will be aligned with health sector strategies. National health and industrial development ministries are expected to support the implementation of the plan by assigning and availing the necessary resources as and when required. The plan will be widely disseminated to EAC citizens, existing and potential development partners. A monitoring and evaluation framework will be put in place to review and assess progress of the plan as per the set milestones and indicators.

Chapter 1: Introduction

1.1 Overview of the East African Community

The East African Community (EAC), like other regional economic bloc, is focused on widening and deepening the integration process among the five Partner States. In this regard, the Community is moving towards the implementation of a Common Market Protocol which came into effect in July 2010 and a Monetary Union by 2012. The region has a total surface area of 1,817.7 thousand square kilometres with Burundi, Tanzania, Uganda, Kenya and Rwanda accounting for 1.5, 51.7, 13.3, 32.1 and 1.4 percent respectively[1].

Figure 1: Map of the EAC Partner States

[1] EAC Facts and Figures, 2009

The EAC midyear population was estimated at 126.6 million by June 2008 with an average annual growth rate of 2.9 percent. The annual infant mortality and child mortality rates range between 52 to 84 and 74 to 137 per 1,000 infants respectively in 2008, while the literacy rate of the region is estimated between 47 and 78 percent in 2008. Overall, the EAC recorded an average per capita of USD 502, with Kenya at USD 794, Uganda at USD 556, Tanzania at USD 525, Rwanda at USD 494 and Burundi at USD 164. The aggregate total GDP for the region amounted to USD 73,338 million in 2008, compared to USD 60,258 million in 2007. The average annual underlying inflation rate increased from 7.6 percent in 2007 to 13.3 percent in 2008. On average, the EAC fiscal deficit, excluding grants, as a ratio of GDP, decreased from 10.5 percent in 2007 to 9.5 percent in 2008[2]. In 2008, Rwanda recorded the highest economic growth of 11.2 percent, followed by Uganda and Tanzania with 9.2 percent and 7.4 percent respectively. Kenya registered a decelerated growth of 1.7 percent compared to 7.1 percent in the previous year, while Burundi continued to return negative real economic growth of 0.025 percent in 2008 compared to 0.029 percent in 2007.

1.2 Project Background

During the 1970s and 1980s, local pharmaceutical production capacity in developing countries was promoted by governments and international organisations for various reasons. The aim was to support the countries' self-sufficiency in medicines supply, to reduce imports and loss of foreign exchange, to improve the quality of medicines, to gain foreign exchange earnings and to create employment and gain national prestige. In the late 1980s, international organisations and donors stopped promoting domestic production. Unfavourable studies on feasibility and potential for local production in developing countries were the basis for this development.

Today, however, perspectives of governments, donors and multilateral organizations are changing. To begin with, the global focus on the priority endemic diseases of HIV/AIDS, Tuberculosis and Malaria articulated in MDG 5 has increased funding for medicines procurement from the international community.[3] Further, in order to scale up in a sustainable manner the achievements in providing medicines to combat priority endemic diseases (PEDs), strengthening local production capacity becomes a viable alternative. Moreover, it is increasingly recognized that the attainment of the other health related MDGs will only be achieved if local innovations, including pharmaceutical production, are supported.[4] Finally, the debate on Intellectual Property Rights (IPRs) and access to medicines within the World Trade Organisation (WTO) has generated awareness of the lack of domestic pharmaceutical production capacity. Due to the deadlines and exemptions around the TRIPs agreement, there is growing concern over the supply of raw materials and generic medicines from China and India and an increasing pressure on Least Development Countries (LDCs) to take advantage of the deadline.

---

[2] http://www.eac.int/

[3] http://www.undp.org/mdg/basics.shtml

[4] Mugabe, J. (2005). Health Innovation Systems in Developing Countries: Strategies for Building Scientific and Technological Capacities, Background Paper Prepared for the Commission on Intellectual Property, Innovation and Public Health, WHO

The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property[5], through its eight elements, seeks to promote access to affordable and quality medicines in developing countries, including availing treatment for diseases that disproportionately afflict these countries' populations. The Global Strategy and Plan of Action (GSPOA) advocates for developing countries to be more involved in solving their health challenges. At the WHO-AFRO 56th Regional Committee Meeting that was held in Maputo (AFR/RC55/10), discussions on strengthening local production of essential medicines emphasized that policy decisions on whether to import essential medicines from reputable sources or to promote local manufacturing should be based on careful situation analysis and realistic appraisal of the technical feasibility and financial viability underpinned by sound regulatory systems. A market size that would ensure sustainability as well as technical and financial viability was considered imperative. The WHO Regional Committee for Africa adopted resolutions AFR/RC/49/R5 and AFR/RC38/R19, which emphasize access to essential medicines, local production of essential medicines and African traditional medicines.

Another noteworthy initiative is the United Nations Industrial Development Organization (UNIDO) global project on strengthening the local production of essential generic drugs in developing countries[6] (DCs/LDCs) through Small and Medium Enterprises (SMEs). business partnerships, investment promotion and South–South cooperation. The project targets interventions at three levels: promoting policy dialogue among stakeholders, strengthening key institutions such as national medicines regulatory authorities (NMRAs) and assisting selected enterprises to develop business plans. Under the AU-EU MDG partnership[7] one of the activities seeks to develop joint strategies to enhance access to affordable quality medicines through enhancing capacity for regional and local production of generic medicine.

Pursuant to the AU Assembly decision 55 taken during the Abuja Summit in January 2005, which mandated the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa within the framework of NEPAD, the AU Conference of Ministers of Health undertook to pursue, with the support of partners, the local production of generic medicines on the continent and to making full use of the Flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health {Gaborone Declaration Doc. CAMH/Decl.1(II) 3 (10 – 14 October 2005)}. They further requested the AU Commission to "accelerate development and facilitation of the implementation of a Pharmaceutical Manufacturing Plan for Africa" {CAMH/Decl.1 (II) 13(ii)}.[8]

At regional level there have been several initiatives aimed at improving access to medicines through strengthening and supporting local production. A UNIDO study on the viability of local production of pharmaceuticals in Nigeria and Ghana recommends a regional approach in developing strategies for local manufacture of pharmaceuticals.[9] [10] The Southern African

[5] Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property , WHA 61.21
[6] www.unido.org
[7] http://www.africa-eu-partnership.org/pdf/ua_ue_mdg_partnership_health_paper_jeg_26th_march.pdf
[8] Third Session of the African Union Conference of Ministers of Health 9 – 13th April, 2007, South Africa.
[9] Harper, J. and Gyansa-Luterodt, M., (2007), The viability of Pharmaceutical Manufacturing in Ghana to Address Priority Endemic Diseases in the West Africa Sub-region, Trade Programme, Sectoral Project Trade Policy, Trade and Investment Promotion , GTZ
[10] Walter, T., Rugumambayu, S. and Wambebe, C., (2008), Pharmaceutical Sector Profile Nigeria, UNIDO

Development Community (SADC) has developed a pharmaceutical business plan (2007 -2013)[11] with an overall goal of ensuring availability of essential medicines including African traditional medicines to reduce disease burden in that region.

In its preamble, the treaty for the establishment of the EAC states that it seeks to strengthen the economic, social, cultural, political, technological and other ties towards a faster, balanced and sustainable development of the region, in addition to guiding the Community towards an economic and political union. On the economic front, the Treaty seeks to promote competitiveness of local industries, and at the same time to attract foreign investment through proactive policies across the Partner States. It is against these global, continental and regional initiatives that the EAC-RPMPoA 2012-2016 has been developed and anchored.

1.3 Project Purpose

Access to affordable, high-quality and efficacious essential medicines, including those for the treatment of diseases such as HIV/AIDS, malaria, tuberculosis and various neglected tropical diseases (NTDs), is of high priority and national interest for all the EAC Partner States. The WTO-TRIPS Agreement and the Doha Declaration on TRIPS and Public Health are the result of the developing countries' fight for a balanced intellectual property rights (IPRs) regime that incorporates public health considerations as regards access to essential medicines.

In order to utilise the WTO-TRIPS flexibilities to their full extent, it is crucial to supplement and possibly substitute imported medicines with products from the region. This requires building and strengthening the capacity to manufacture affordable, high-quality and safe generic essential medicines within the region, which can significantly contribute to achieving public health objectives in all EAC Partner States.

There is therefore a need to develop a Regional Pharmaceutical Manufacturing Plan of Action for the EAC, which lays down the strategic approach for the EAC Partner States to evolve an efficient and effective pharmaceutical manufacturing industry that will supply the national, regional and international markets with medicines.

1.4 Methodology

The development of the EAC-RPMPoA was initiated in September 2009 with an extensive literature review of relevant information. In the months of October to December, 2009, country visits to meet key stakeholders in the five member countries were undertaken. About sixty key industry stakeholders drawn from pharmaceutical manufacturing, academia, regulatory authorities, investment promotion agencies, Ministries of Health and pharmaceutical manufacturers associations among other institutions in the region were interviewed.

[11] SADC Pharmaceutical Business Plan, 2007 -2013, SADC Pharmaceutical Programme, SADC Secretariat

In January 2010, a technical experts committee meeting was convened in Nairobi to critique the EAC-RPMPoA concept document, which was subsequently refined into an initial draft strategic plan presented to a wider stakeholder roundtable meeting in Arusha, Tanzania, in February 2010.

After the input of the roundtable meeting, the revised document was presented to the Session of the Coordination Committee of the 5th Ordinary Meeting of the EAC Sectoral Council on Regional Cooperation on Health on 30th March 2010 in Kigali, Rwanda. The Coordination Committee recommended that National Consultative Meetings be held to give an opportunity to Partner States' experts to review the document holistically and forward their comments to the EAC Secretariat. The National Consultative meetings were held in all Partner States in November, 2010. The Strategic plan was reviewed based on various comments and inputs during the Second Stakeholders Roundtable Meeting held in December 2010. The revised EACRPMPoA was approved upon presentation to the 6th Ordinary Sectoral Council of Ministers of Health Meeting that was held in Bujumbura, Burundi on 1st April 2011.

Chapter 2: Profile of the EAC Pharmaceutical Sector

2.1 Definitions and Concepts

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. According to UNIDO,[12] pharmaceutical production can be viewed along the following continuum:

- No manufacturing facilities and dependency on imported finished medicines;
- Packaging of already formulated medicines and small scale local production of sterile and non-sterile formulation such as Intravenous Fluids (IV)fluids;
- Formulation of drugs in final dosage form and some production from imported intermediates;
- Production from imported intermediates and manufacture of some intermediates from local materials;
- Production of active substances and processing to produce the required pharmaceutical dosage forms.

The whole process requires special technologies, reliable supplies of high-quality raw materials, and dependable provision of top-quality water, energy and other utilities. It also needs adequate human resources with specialist knowledge, such as experts in pharmaceutical development, quality assurance and regulatory processes.

2.2 Pharmaceutical Production in Sub Saharan Africa (SSA)

The estimated 2006 pharmaceutical market in SSA was USD 3.8 billion, of which local manufacturers produced between 20 and 30 percent. Medical supplies and devices accounted for an additional USD 2.1 billion, but less than ten percent of that was locally produced. More than 70% of the estimated USD 1 billion in annual pharmaceutical production in sub Saharan Africa is concentrated in South Africa. Nigeria, Ghana, and Kenya together represent about 20 percent of SSA's pharmaceutical production and of the three countries; only Kenya produces significant volumes for regional export. Between 35 and 45 percent of Kenyan manufacturers' revenues come from exports to other EAC and COMESA countries. Overall, thirty seven sub-Saharan African countries have some pharmaceutical production, with the capacity for formulation of finished dosage forms with twenty five countries limited to packaging or labelling only. Only South Africa has a limited degree of Active Pharmaceutical Ingredient (API) production. Most production outside South Africa consists of non-complex, high volume essential products, such as basic analgesics, simple antibiotics, anti-malarial drugs and vitamins.[13]

[12] Kaplan and Laing, (2005), Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines, HNP Discussion Paper, World Bank

[13] IFC, World Bank, (2007), The Business of Health in Africa. Partnering with the Private Sector to Improve People's Living

SSA manufacturers generally produce at a cost disadvantage compared to the large Asian generic manufacturers. It is estimated that a third of the 30–40% cost disadvantage that a leading African manufacturer suffers versus high-scale Indian manufacturers is attributable to scale. Other causes of production cost disadvantage include a more expensive asset base, often coupled with obsolete technology, high financing costs and lack of integration with API production. Moreover, import difficulties and the fragmentation of distribution networks render shipping to other markets in SSA more expensive than Asia-to-Africa shipping, thus significantly limiting export opportunities. Intra-African imports are often subject to the same import tariffs as intercontinental ones, and manufacturers report that even when there are favourable trade terms between countries, they often do not actually enjoy the benefits (tax breaks), since they either do not extend to pharmaceuticals or are misapplied.

2.3 Local Production: Industrial Policy Versus Health Policy

National governments and regional blocs are faced with multiple responsibilities with regard to procurement, quality control and distribution of pharmaceuticals. The consequences of government policies to improve and promote access to medicines may be in conflict with policies that promote domestic pharmaceutical industry as part of a larger industrial policy. In developing countries there is a great disparity between the demand for medicines to treat endemic diseases and the lack of purchasing power of patients most at risk. The idea to improve access through local production is only attractive if the pharmaceuticals produced are cheaper than the imported products. An industrial policy aiming at optimizing profits, growth and sustainability of the local industry may lead to the production of medicines that are more expensive than those from international markets. This creates tensions between health policy and industrial policy which should be adequately addressed in the national drug policies.

2.4 Structural Characteristics of the EAC Region Pharmaceutical Sector

As in other regions of SSA, the EAC pharmaceutical sector, is characterised by net imports of pharmaceuticals, largely from India and China. The pharmaceutical manufacturing in the region mainly involves the production of non-complex, high volume, essential products, such as basic analgesics, simple antibiotics, anti-malarial drugs and vitamins. The size and complexity of the pharmaceutical sector across EAC varies from country to country. The Kenyan pharmaceutical sector is the most developed among the five countries, while those of Burundi and Rwanda are still in their infancy.

The pharmaceutical sector in the region comprises of manufacturers, distributors, wholesalers, retail pharmacies, hospitals and clinics. The manufacturers are either local or multinational firms. Some multinational firms have local manufacturing units, but most have only scientific and marketing offices. The multinational firms appoint distributors of their products, who in turn sell these products to wholesalers and retailers countrywide. The multinationals deal mainly with branded products and compete in the market through innovation and quality claims. The local

manufacturers may or may not have appointed distributors, but they rather sell their products directly to retailers and compete by selling low-priced generics.

Table 1: Estimated pharmaceutical market sizes and number of licensed pharmaceutical manufacturers in EAC partners states

Country	Pharma industry revenue 2007[14] (million USD)	Market share generics (in %)	Branded (in %)	Revenue forecast 2014 (million USD)	Drugs sourced from local producers in %)	No. of licensed pharmaceutical manufacturers
Kenya	208.6	56	44	557.8	30	31
Tanzania	105	54	46	350	31	8
Uganda[15]	90	NA	NA	270*	5	13
Rwanda	25*	NA	NA	75*	NA	1
Burundi	25*	NA	NA	75*	NA	1

*Key: * - author's estimation of market size, NA - Data not readily available*

The market structure is made up of the public and private sector. The public sector is the largest purchaser of pharmaceuticals and diagnostics in the region; for instance the Kenya public sector budget for purchase of commodities is USD80 million annually.[16] Each of the five EAC countries has a semi-autonomous government agency that deals with the procurement and distribution of pharmaceuticals, non-pharmaceuticals, diagnostics, medical devices and equipment - Centrale d'Achat de Médicaments Essentiels du Burundi (CAMEBU), Kenya Medical Supplies Agency (KEMSA), Centrale d'Achat de Médicaments Essentiels au Rwanda (CAMERWA), Medical Stores Department (MSD), National Medical Stores (NMS), in Burundi, Kenya, Rwanda, Tanzania, and Uganda respectively. Faith-based healthcare organizations control a significant share of private sector market and most make their purchases using a pooled procurement and distribution system; Mission for Essential Drugs and Supplies (MEDS) in Kenya and Joint Medical Stores in Uganda (JMS) being cases in point.

The regulatory regime in the region is characterized by a move towards the creation of semi autonomous government agencies to spearhead the national regulatory affairs. The Tanzania Food and Drug Authority (TFDA) has achieved some notable success towards becoming a semi autonomous regulatory agency, with the Uganda National Drug Authority (NDA) and the Kenya Pharmacy and Poisons Board (PPB) also seeking similar status. The Burundi and Rwanda pharmaceutical regulatory structures are at infancy and currently being set up.

[14] Frost and Sullivan, 2007

[15] Strengthening the Local Production of Essential Generic Drugs in Least Developed Countries (through the Promotion of SMEs, Business Partnerships, Investment Promotion and South-South Cooperation Te/glo/05/015/17-53 Uganda, (2007)

[16] Pharmaceutical Sector Profile: Kenya, (2010),UNIDO

2.5 Research and Development Institutions

The EAC Partner States recognize the critical role of research and development in the promotion of quality health care, and as a result they have supported the establishment and maintenance of research institutions through allocation of resources, with the support of partners. The Ugandan National Health Research Organization (UNHRO) coordinates health research in the country and brings together the activities of eight related organizations. Makerere University is the oldest public university in Uganda and has traditionally focused on health and agricultural sciences. Its medical school has a strong network of collaborations across the globe. In Tanzania, the National Institute of Medical Research (NIMR), the University of Dar es Salaam and Muhimbili University of Health and Allied Sciences (MUHAS) are the leading public health research organizations. Ifakara Health Institute (IHI) and Kilimanjaro Christian Medical College (KCMC) - categorized as private/NGO training and research institutions - are also renowned for their work in biomedical research.

In Rwanda, the Institute of Scientific and Technological Research, also known as the Institut de Recherche Scientifique et Technologique (IRST), was established in 1989. It is the country's premiere medical research institute, including research in phyto-medicine. The National University of Rwanda and Kigali Institute of Science and Technology (KIST) are the other notable institutions in Rwanda involved in biomedical research. The Kenya Medical Research Institute (KEMRI), in Kenya is among the leading health research institutes in Africa. The Institute has a well-established research infrastructure including a critical mass of biomedical scientists. It also has extensive research linkages with leading health research organizations in the world. The University of Nairobi is the oldest and most established university in the country with an active health research programme.

A feature shared by all these institutions in the EAC Partner States is their poor funding by the state, and in most cases the governments only support staff emoluments. As a result, most of the research activities are donor-funded and therefore do not necessarily address regional health priorities. Additionally, most research funding targets basic and operational research which does not necessarily lead to product development. The linkages between academia, research institutes and industry are so weak that they rarely collaborate in research and development.

There is a lot of interest in traditional medicines as potential sources of lead molecules for new treatment of diseases, but there is a lack of capacity in this respect. While most of the Research & Development (R&D) institutions in the region are able to screen plant extracts for activity they are unable to move beyond screening to structure elucidation and optimization because of lack of equipment and expertise in drug discovery. There is a need to build drug discovery platforms in the region.

2.6 Pharmaceutical Sector Value Chain Analysis

A value chain describes the full range and sequence of discrete value-added activities needed to bring a specific product or service from its conception through the different stages of production to its use and final disposal. The value chain approach, describing how producers, processors,

buyers, sellers, and consumers - separated by time and space - gradually add value to products as they pass from one link in the chain to the next, has been intensively used by both private sector agents and government and development agencies to identify options for industry development.[17] This approach must be placed in the context of globalization and trade liberalization policies, which are pushing countries to specialize and produce only those products or commodities for which they have a comparative advantage. Thus, the issue of efficiency and location of an industry becomes a key element for global value chain analysis. This analysis of the EAC pharmaceutical manufacturing sector will focus on the supply of inputs, production and distribution of outputs.

2.6.1 Supply of Inputs

Pharmaceutical manufacturers in EAC source their primary and secondary raw materials mainly from China and India. Over 90 percent of the active pharmaceutical ingredients (APIs) are imported, with India being the leading source.[18] Within the region, a number of enterprises produce packaging materials such as bottles, foils, dispensing packs and unit cartons. However, they do so at a cost disadvantage compared to similar imported products. Additionally, basic ingredients such as water and sometimes sugar and starch are sourced locally. Sugar and starch of pharmaceutical grade is imported by local dealers in bulk quantities and then packaged and resold to manufacturers.

Pharmaceutical plant production technology is not available locally, and is sourced from abroad, including most of the spare parts needed. Plant machinery and equipment are mainly imported from India, China and, in some instances, Europe.

The pharmaceutical manufacturers source their personnel locally, and where there is skill shortage, they recruit expatriates. Some manufacturers and pharmaceutical sector studies[19] in the region report that local personnel are not appropriately trained to carry out pharmaceutical production and business development.

Electricity supply in the region is cited as among the most expensive in the world and in addition, the supply is unreliable, forcing companies to install standby generators and to contend with additional labour costs through adjusting working hours/days to electricity availability.

2.6.2 Production

Most pharmaceutical manufacturers use labour-intensive, step-by-step manual manufacturing; only a few such as Shelys Pharmaceuticals in Tanzania and Universal Corporation in Kenya have undergone extensive expansion and modernization and automated production lines. The large manufacturers have mainly focused on tablets, capsules, powder and liquid preparations. Tableting and liquid lines are the most developed and utilised. Only a few local manufacturers, two in Kenya, one each in Uganda and Rwanda produce parenteral preparations.

[17] UNIDO website - http://www.unido.org/index.php?id=7395
[18] Arichem Limited, bulk APIs importer in Kenya
[19] Losse, K. and Spennemann, C., (2007), The Viability of Local Production in Tanzania, GTZ

The medium and small scale manufacturers focus on the production of liquid preparations, creams and ointments, based on very simple, partly imported technology (water heaters, homogenisers) and local technology using mixers and containers that are locally prefabricated.

2.6.3 Distribution of Output

The private sector pharmaceutical distribution system in the EAC region is largely described as poorly organized and fragmented. The number of intermediaries involved in pharmaceutical distribution is hard to determine and amounts to several thousand. This negatively impacts on product availability, security and the final price and in turn accessibility. As a result, local manufacturers face serious constraints in the distribution of their products and often have to set up distribution companies in order to secure the supply of their products at fair prices in the target market. In other cases, the distribution company is first established and vertical integration into manufacturing comes at a later stage. The distribution through the public sector is much better organized and managed through the national procurement agencies. Global initiatives support these national procurement agencies to ensure access to essential medicines such as ARVs, ACTs and anti-TB drugs.

2.7 Policy, Legal and Regulatory Framework affecting the EAC Pharmaceutical Sector Development

All policy frameworks in the region complement and support global, continental and national initiatives on poverty eradication and the Millennium Development Goals (MDGs). In pharmaceutical manufacturing the following policies are relevant, referred and referenced;

1. The Treaty on the establishment of the East African Community:
2. The fourth EAC Development Strategy: 2012 - 2016;
3. The EAC Industrialization Policy and Strategy;
4. National industrialization policies and strategic plans of EAC Partner States;
5. Investment promotion policies of EAC Partner States;
6. Health sector policies of EAC Partner States, and
7. National medicines policies and strategic plans of EAC Partner States.

In its preamble, the EAC Treaty[20] states that it seeks to strengthen the economic, social, cultural, political, technological and other ties towards a faster balanced and sustainable development of the region, in addition to guiding the Community towards an economic and political union. On the economic front, the Treaty seeks to promote competitiveness of local industries, at the same time attracting foreign investment through proactive policies across the Partner States. The East African Community Industrialization Strategy (2010-2030) is currently being developed. It identifies pharmaceutical manufacturing as one of the key strategic sectors in the region that needs to be supported and promoted in order to become competitive and contribute towards the socio-economic development of the region.

[20] Treaty for the Establishment of the East African Community, 2007

All five EAC member states have an industrialisation policy and/or a strategic plan on industrialization.[21,22,23,24] The common theme across these policies and strategic plans is to strengthen local manufacturing with the aim of increasing substantially the contribution to GDP. Uganda and Rwanda seek to increase the percentage contribution of manufacturing to GDP to 25 percent and 26.5 percent respectively while Kenya targets an annual increase of 10 percent in contribution to GDP by manufacturing sector. The policies and strategic plans focus on improving infrastructure development, promoting public-private partnerships, supporting growth and development of skilled labour, promoting business friendly environment exploiting science, technology and innovation for industrialization, promoting micro and small-scale industries especially in agro-related production and protecting the environment.

The EAC Partner States have investment policies and structures to promote investment in place. The national investment authorities assist investors in obtaining the necessary information on investment; they issue licenses and assist in securing secondary licenses, arranging contacts for investors and seeking joint ventures and linking them with possible funding agencies. The EAC Partner States have taken steps towards improving the business environment nationally and regionally by instituting reforms that have been informed and guided by investment reviews undertaken by development partners such as UNCTAD.

All the EAC Partner States view the health sector as critical for national socioeconomic development, and in this regard they have in place elaborate national health sector policy frameworks and strategic plans that are aligned to national development strategies aimed at poverty reduction and wealth creation as well as global health strategies such as the UN MDGs. These relevant Health Sector policies and strategies include;

1. Government of Rwanda Health Sector policy;

2. Second National Health Sector Strategic plan, 2005 - 2010 (NHSSP II), Ministry of Health Kenya;

3. Health Sector Strategic Plan III (2009 -2015), Ministry of Health and Social Welfare Services, United Republic of Tanzania;

4. National Health Policy (2005 – 2015) and National Health Development Plan (NHDP 2006 – 2010), Ministry of Health, Burundi;

5. Zanzibar Health Sector Reform Strategic Plan II (2006 -2011), Ministry of Health, Zanzibar;

6. Second Health Sector Strategic Plan II (2005 – 2010), Ministry of Health, Uganda.

[21] Republic of Kenya, Ministry of Industrialization, Strategic Plan (2008 – 2012)
[22] Republic of Rwanda, Ministry of Commerce, Industry, Investment Promotion, Tourism and Cooperatives, National Industrial Sector Promotion Policy, 2006
[23] United Republic of Tanzania, Ministry of Industries and Trade, Sustainable Industries Development Policy SIDP (1996 – 2020)
[24] The Republic of Uganda, Ministry of Tourism, Trade and Industry, National Industrial Policy ; A framework for Uganda's Transformation, Competitiveness and Prosperity, 2008

The East African Community is currently in the process of developing an EAC Regional Health Sector Strategic Plan.[25]

2.8 Medicines Regulation

National medicines policies exist within each Partner State as well as a legal frame work that provides for the existence of a National Medicines Regulatory Authorities (NMRAs). Currently only three Partner States within the EAC, namely Kenya, Uganda and Tanzania, have operational NMRAs, while Burundi and Rwanda carry out national medicines regulatory functions within the National Ministries of Health. However, both countries are currently in the process of establishing NMRAs. Zanzibar has a separate NMRA, which relies heavily on the decisions made in mainland Tanzania.

The regulatory regime in the region is characterized by a move towards the creation of semi autonomous government agencies to spearhead the national regulatory affairs. Only three drug quality control laboratories exist in EAC, one of which (Kenya) is pre-qualified by the WHO, while the Uganda and Tanzania are in the process of prequalification and accreditation to meet international standards. Across the EAC Partner States, there is a shortage of skilled human resource in NMRAs.

A detailed situation analysis study covering all EAC Partner States' NMRAs, using the revised WHO assessment tool (2008) confirmed that the national drug registration systems exist.[26] However, there were notable deficiencies, including the drug registration guidelines being incomplete. There is need to improve, and some of the actions required include the restructuring or establishment of NMRAs to enable them to undertake their regulatory activities more effectively, developing and implementing comprehensive guidelines and procedures for drug registration and strengthening human capacity at NMRAs in Partner States.

Some of the measures that have already been undertaken as part of the medicines regulation harmonization include: several regional meetings conducted at various levels to develop the EACs vision for harmonised drug registration; endorsement of the process for harmonizing drug regulation and in particular the proposal to establish the East Africa Medicines and Food Safety commission; regulatory assessments of the NMRAs have been conducted and these are guiding countries to strengthen the NMRAs as well as providing a common approach to the harmonization process; development of an EAC Drugs Regulation Harmonization (DRH) Project proposal and submitted to NEPAD for funding consideration.[27] Officers from the Partner States have participated in the WHO Prequalification Programme in the assessment of dossiers, rotational position in WHO Headquarters and participation in inspections and training, prequalification of laboratories and sampling and testing.

[25] www.eac.int/health
[26] EAC Drugs Regulation Harmonization Project Proposal, 2009
[27] EAC Drugs Regulation Harmonization (DRH) Project Proposal submitted to NEPAD, October, 2009

2.9 Access to Essential Medicines: Constraint Analysis

2.9.1 Demand-Side Analysis

The EAC population currently stands at 127 million and the region is moving towards implementing the Common Market Protocol which came into effect in July 2010. All five countries are among those identified globally as having a high burden of HIV, TB and malaria. In addition to this, the region is faced with other infectious and parasitic diseases with childhood mortality resulting from diarrhoea and upper respiratory tract infections continuing to be unacceptably high. Non-Communicable Diseases pose a growing challenge, and according to WHO, the NCDs in Africa are expected to exceed communicable, maternal, perinatal and nutritional diseases as the most common cause of death by 2030.[28] The majority of the region's population has low purchasing power and can hardly afford to buy medications; women are particularly affected. As a result, the healthcare market is highly price-sensitive in this region. The public healthcare system in the region is characterised by budgetary constraints and largely unable to meet the population's healthcare needs. In all the countries over 50% of individual healthcare needs are met through out of pocket expenses. Donors provide substantial support to the region's healthcare budget, particularly in priority endemic diseases such as HIV/AIDS, tuberculosis and malaria. Due to stringent requirements by donors, manufacturers must adhere to international standards of manufacturing, preventing local pharmaceutical producers from accessing this market. The table below indicates the total need and effective demand in EAC for medicaments against HIV/AIDS, TB and Malaria for 2007 and 2018 respectively.

Table 2: Need and effective demand for medicaments against Malaria, Tuberculosis (TB) and HIV/AIDS within the EAC region

Cases/need/demand[29]	Malaria		TB		HIV/AIDS	
	2007	2018	2007	2018	2007	2018
Number of cases (000s)	141,050	191,463	437	603	3,900	5,338
Total need (USD, 000s)	185,541	309,224	3,516	4,847	218,494	488,893
Effective demand (USD, 000s)	4,391	59,887	1,640	2,805	56,251	131,157

2.9.2 Supply-Side Analysis

The EAC Partner States have made attempts to improve access to medicines in the region and this is captured in various national and regional policies and strategies that are in place or currently being developed and have been cited earlier in this document. Despite these efforts the general business environment is still hostile to healthcare investment in the region. Utilities such as electricity and water are expensive and unreliable compared to other regional economic blocks in Africa and globally. There is a shortage of trained medical staff in the region, and due to low pay there is a loss of highly trained staff to other parts of the world, mainly the UK and the USA.

[28] Global Status Report on Non-Communicable Diseases, 2010; WHO

[29] UNIDO: Opportunities for Producers in Least Developed Countries, Section A – Modelling Demand for Malaria, TB and HIV, Prepared by IMIS for UNIDO, 2008

As mentioned earlier, most of the primary raw materials are imported and transported over unreliable road and rail networks further raising the cost of production. Whilst the regulatory environment is improving in the region, there is still a high incidence of counterfeits in the market and unlicensed medicines outlets and clinics.

Drug distribution in the region is broadly classed into three categories, namely; public, faith-based or not-for-profit and private sector or for-profit. The public sector distribution is through semi-autonomous agencies created by the respective governments and largely supported by donors to strengthen their logistics management capacities. The faith based organizations also receive donor support and have been instrumental in supporting governments' efforts in expanding access to medicines in the region. The private sector distribution is largely fragmented and chaotic, creating a conducive environment for counterfeits and other illegal practices.

2.9.3 WTO-TRIPS Flexibilities and Public Health

According to a 2002 Decision of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Council, based on the 2001 Doha Declaration on the TRIPS Agreement and Public Health, Least Developed Countries are exempted until the 1 January 2016 from implementing, applying or enforcing the TRIPS provisions on patents and the protection of undisclosed information with respect to pharmaceutical products.[30] Among the EAC Partner States, Kenya is the only country that is classified as a developing country by the United Nations while the rest are LDCs. The transition periods for LDCs to implement TRIPS Flexibilities are until 1 July 2013 for all TRIPS obligations and until 1 January 2016 for patents and trade secret protection of pharmaceuticals. In the interim transition period LDC-based producers may use substances that would otherwise be patented and LDC-based traders may import and sell patented ingredients.

Under the TRIPS Agreement, governments in LDCs and DCs are provided with tools to promote access by local producers to patented pharmaceutical ingredients and also to the know-how and the technology to produce patented pharmaceuticals. TRIPS flexibilities for investment in local pharmaceutical production in LDCs / DCs in Africa are important because they increase the amount of knowledge in the public domain, limit exclusive rights and promote competition. TRIPS flexibilities enable generic producers not only to access essential materials but also knowledge, thus allowing them to enter the market. The Doha Declaration on the TRIPS Agreement and Public Health appears as an opportunity to resolve the challenge on the provision of patented medicines to DCs and LDCs as it provides a window for DCs and LDCs to take advantage of the Flexibilities for public health considerations. According to UNCTAD, the future investment in Africa DC/LDC production depends on the implementation of TRIPS flexibilities by host countries.

In 2005, the EAC Secretariat launched its initiative to harmonise its Partner States' policies, legislation and regulations on intellectual property (IP) in order to facilitate regional manufacturing, importation and trade in essential medicines.[31] Towards this end, the EAC mandated several stud-

[30] WTO (2001): Declaration on the TRIPs Agreement and Public Health. Doha Declaration WT/MIN/(01)/DEC/W/2 of 14 November 2001, paragraph 7 [hereinafter Doha Declaration], and the implementing Decision by the TRIPs Council (2002): Extension of the Transition Period under Article 66.1 of the TRIPs Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products. WTO document IP/C/25, 27 June 2002

[31] EAC/SC/01/2005

ies to inform decision making towards harmonization of these policies and regulations in order to improve regional access to essential medicines. In 2007, the EAC Council of Health Ministers directed the EAC Secretariat to facilitate appropriate use of TRIPs flexibilities in the EAC region.

The TRIPS flexibilities of public health importance can be broadly divided into two pre- and post-patent grant TRIPS flexibilities. The pre-grant TRIPS flexibilities include patent term, patentable subject matter; patentability criteria, disclosure of patented information, new use of known products and variations in pharmaceutical composition. The post-grant flexibilities on the other hand include exemptions to patent rights - scientific research exception and Bolar provision, parallel imports, compulsory licensing and government use, competition issues and pharmaceutical test data protection.

A comparative study on the extent to which EAC Partner States' patent laws reflect TRIPS Flexibilities relevant for improving access to medicines was carried out in 2008 with the support of UNCTAD.[32] The objective of the study was to analyse and compare those provisions of national laws which relate to TRIPS flexibilities with a view to identifying areas of need for harmonization in order to improve access to medicines in the EAC region. The study noted that the member states were at various stages of domesticating the TRIPS flexibilities in their national laws. The study made specific policy and legislative recommendations to individual member states. Subsequent to this study the EAC has moved to develop a regional protocol on harmonization of TRIPS flexibilities on public health which is currently under discussion.

There is a low level of awareness of the TRIPS flexibilities in both public and private sectors in EAC. The only known successful use of the TRIPS flexibilities in the region involved the Rwandan government and a Canadian pharmaceutical company, Apotex, in the manufacture of TriAvir, a fixed dose antiretroviral combination therapy. Several other cases involving voluntary licensing (VL) have been tried in the region; for instance a VL was granted to Cosmos by Glaxo SmithKline to produce generic ARVs. Other companies having recently acquired royalty-free licences include Shelys Pharmaceuticals and Zenufa Laboratories in Tanzania as well as Universal Corporation in Kenya. However, such initiatives have not led to the improvement of access to affordable ARVs. Due to other factors the cost of locally manufactured ARV remains significantly higher than those imported from India, and furthermore none of the companies that have obtained VL from innovator companies meet WHO prequalification standards. The WHO bulk prequalification is a prerequisite for accessing the donor market which mainly finances the acquisition of ARVs in the region.

In Kenya, parallel importation under the provision of the Industrial Property Act of 2001 is allowed; however, it is not in harmony with the Pharmacy and Poisons Act (Chapter 244, Laws of Kenya). It should, however, be noted that parallel importation can only achieve the desired objective of increasing access to medicines in an environment where there is strong regulatory and enforcement capacity.

[32] Comparative Study of Provisions of EAC Partner States' Patent Laws Reflecting TRIPS Flexibilities Relevant for the Access to Medicines, EAC Secretariat/UNCTAD/GTZ

2.10 SWOT Analysis of Pharmaceutical Production in EAC

This section presents an overall summary analysis of the strengths, weaknesses, opportunities and threats (SWOT) of the EAC pharmaceutical industry with respect to capacity for production of essential medicines and operating environment.

2.10.1 Strengths

- EAC is a Common Market with effect from 1st July 2010;
- Core cadre of pharmaceutical manufacturing and regulatory expertise exists in the region;
- Established as well as a developing production base exists;
- Public budgets for products addressing priority endemic diseases exist in all member states;
- Existence of an enabling strategic policy context and political will towards strengthening local pharmaceutical production;
- All EAC Partner States region are Members of WTO which automatically makes them signatory to TRIPS Agreement;
- All Partner States have an official or draft national medicines policy, legislations and regulations;
- Positive economic growth and relative socioeconomic stability in all the five Partner States;
- Inflow of foreign and donor funding in support of the health sector in the region.

2.10.2Weaknesses

- High cost of locally manufactured products compared to imports;
- Lack of local supply of active pharmaceutical ingredients and primary raw materials;
- Inability of local manufacturers to meet WHO pre-qualification requirements;
- Lack of regulatory capacities and abilities to ensure quality, safe and efficacious medicines circulating in the market;
- The relevant national laws on pharmaceuticals and intellectual property are not TRIPS compliant;
- Poor and under-funded health infrastructure;
- Over-dependence on imported medicines, both branded and generics;
- Inconsistent medicine regulatory procedures, divergent treatment guidelines and essential drug lists among the Partner States;
- Under utilization of installed manufacturing capacities;
- Poor distribution network for medicines;
- Lack of appropriately skilled local personnel in pharmaceutical manufacturing;
- Lack of timely and accurate market information to aid in decision making;
- Lack of clear incentives and policies that promote local pharmaceutical production.

2.10.3 Opportunities

- Existence of a regional and continental pharmaceutical market for the manufacture and supply of drugs that address priority endemic diseases;
- Public sector preference for generic medicines;

- All Partner States are reviewing/developing policies and/or legislative frameworks that will enhance availability of safe and efficacious medicines in the market;
- Existence of global, continental, regional and national initiatives to promote local pharmaceutical production;
- Support from development partners to improve efficiency in supply chain management systems of pharmaceuticals in the region;
- Some Partner States have well developed regulatory systems and capacity which can be used for building capacities in other member states through trainings and sharing of information;
- Presence of strong and vibrant health R & D in the region;
- Strong focus on mainstreaming African traditional medicines in to national health systems through development of appropriate policies;
- Existence of TRIPS flexibilities that allow Partner States to manufacture pharmaceuticals under patent.

2.10.4 Threats

- Growing threat of counterfeits and diverted medicines;
- Unregulated parallel pharmaceutical trade;
- Inability of local manufacturers to attain WHO prequalification and therefore cannot supply the donor market regionally which is estimated at 80% of PEDs market;
- Poor and unreliable infrastructure – Electricity was cited as relatively expensive and faces erratic supply while water on the other hand was cited as of poor quality and unreliable supply; The poor road and rail networks across the region make it difficult and expensive to deliver raw materials and distribute finished products;
- Chaotic and unregulated distribution system;
- Continued emigration of trained medical personnel;
- Existence of manufacturers that do not meet cGMP standards as set by the local regional regulatory authorities.

Chapter 3: EAC-RPMPoA Strategic Objectives and Actions

The overall goal of the EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPoA) is to ensure availability and access to affordable, high-quality and efficacious essential medicines for the treatment of priority communicable and non-communicable diseases, including HIV/AIDS, Malaria, Tuberculosis (TB), Diabetes, Cardiovascular Diseases, Chronic Respiratory Diseases and Cancers as well as various Neglected Tropical Diseases (NTDs) in the region. The main objective is to improve the capacity of the EAC region to sustainably and competitively produce quality essential medicines for local use and export.

3.1 Specific Objectives

- Promotion of competitive and efficient regional pharmaceutical production;
- Facilitation of increased investment in pharmaceutical production regionally;
- Strengthening of pharmaceutical regulatory capacity in the region;
- Development of appropriate skills and knowledge on pharmaceutical production in the region;
- Utilization of TRIPS flexibilities towards improved local production of pharmaceuticals;
- Mainstreaming innovation, research and development within regional pharmaceutical industry.

3.2 Strategic Action Plan

The EAC-RPMPoA has been developed within the context of global, continental, regional and national policy frameworks, protocols and commitments. Consequently the plan of action will seek to assist the EAC in harnessing, harmonizing and synergizing the existing global, continental, regional and national initiatives on local pharmaceutical production. Based on a SWOT analysis, the plan identifies priority areas and major activities that will be implemented both at regional, national and institutional level to improve availability and access to quality and affordable essential medicines.

In order to achieve the overall goal and objectives the following strategies will be pursued:

3.2.1 Promotion of competitive and efficient regional pharmaceutical production

i. Strengthening of local producers' capacity to meet WHO-GMP and WHO prequalification standards;
ii. Establishment of a regional pharmaceutical manufacturers association;
iii. Promotion of regional and international collaborations including technology transfer
iv. Development and implementation of marketing campaign to promote domestic pharmaceutical producers and products;

v. Effective use of collective purchasing preference schemes by public procurement agencies;
vi. Implementation of pooled procurement of raw materials and other pharmaceutical production inputs by manufacturers;
vii. Regional pharmaceutical demand quantification study for 2011 to 2016;
viii. Baseline survey to determine the regional pharmaceutical production capacity as well as firm level underutilized capacity.

3.2.2 Facilitation of increased investment in pharmaceutical production regionally

i. Promotion of a conducive investment environment in the region;
ii. Feasibility study on identifying suitable long term financing options for pharmaceutical manufacturing in the EAC region;
iii. Sensitizing key stakeholders on the unique pharmaceutical industry dynamics;
iv. Development of national and regional policy framework for pharmaceutical industry clusters and special economic zones;
v. Mapping of existing and potential locations for pharmaceutical industry clusters and special economic zones.

3.2.3 Strengthening pharmaceutical regulatory capacity in the region

i. Strengthen Human Resource capacity in regulatory affairs in the region;
ii. Development/improvement of infrastructure of NMRAs;
iii. Review of national laws for medicines regulation;
iv. Harmonization of regulations for drug registration, licensing of pharmaceutical manufacture, Standard Treatment Guidelines and Essential Medicines List across the region.

3.2.4 Development of appropriate skills and knowledge on pharmaceutical production in the region

i. Identification, equipping and accreditation of training institutions.
ii. Development and implementation of a gender based sectoral human resource development strategy.

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

i. National and regional sensitization on intellectual property rights and public health related WTO-TRIPS flexibilities;
ii. Adoption of a regional policy framework and guidelines to effectively implement public health related TRIPS flexibilities;
iii. Domestication of public health related TRIPS flexibilities within national laws.

3.2.6 Mainstreaming innovation, research and development within regional pharmaceutical industry

i. Pharmaceutical Research and Development capacity enhancement in the region;

ii. Promotion and enhancement on the use of locally sourced inputs (including herbal or natural products) for production of active pharmaceutical ingredients, excipients and final dosage forms;

iii. Structuring and resource mobilization for a regional pharmaceutical innovation fund.

3.3 Implementation Framework

3.3.1 EACRPMPoA Implementation Matrix

STRATEGIC OBJECTIVE 1: PROMOTION OF COMPETITIVE AND EFFICIENT PHARMACEUTICAL PRODUCTION REGIONALLY
OUTCOME 1: A COMPETITIVE AND EFFICIENT PHARMACEUTICAL PRODUCTION REGIONALLY

Activities	Inputs	Outputs	Verifiable indicators	Means of verification	Time-frame	Lead Responsibility	Budget (USD) ,000
1. Strengthening of local producers' capacity to meet WHO-GMP and WHO prequalification standards.	• Industry needs assessment • Technical assistance and advisory support • infrastructure upgrade	At least two local producers achieve WHO prequalification	• Number of GMP compliant producers • Number of producers and products with WHO prequalification	• NMRAs Inspection reports • WHO prequalification records	2012-2016	• EAC Health Secretariat, • National Ministries of Health	8,000
2. Establishment of a regional pharmaceutical manufacturers association in East Africa.	• Consultative meetings • Sensitization and networking seminars • Registration.	Regional Pharmaceutical Manufacturers association established and legally registered.	• Association Secretariat • Register of subscribed members	• Certificate of incorporation • Press articles • Annual General Meetings • Association annual reports	2012-2013	• EAC Secretariat • National Pharmaceutical Manufacturers Associations	200
3. Promotion of regional and international collaboration including technology transfer.	• Sensitization and networking meetings • Match making and brokering	At least three joint ventures and subcontracting negotiations facilitated.	• Number of new joint ventures, PPPs and subcontracting arrangements • Contract agreements	• Investment Promotion Agencies' records • Pharmaceutical Manufacturers annual reports	2012 - 2016	• EAC Secretariat • Regional Pharmaceutical Manufacturers Association • Investment Promotion agencies	150
4. Development and implementation of marketing campaigns to promote domestic pharmaceutical producers and products.	• Baseline survey on perceptions of locally manufactured products. • Consultative meetings • Integrated marketing campaigns • Road shows	• Report on Baseline Survey published and disseminated. • Marketing campaigns to promote use of locally produced pharmaceuticals held in all EAC Partner States.	• Percentage increase in volume of locally manufactured pharmaceuticals prescribed and consumed domestically. • Percentage increase in government tenders awarded to local manufacturers • Percentage reduction in imports as a result of the campaigns	• Pharmaceutical manufacturers sales statistics • Reports on domestic consumption of local pharmaceutical products • Pharmaceutical import statistics	2012-2016	• EAC Secretariat, • National Ministries of Health, • Regional Pharmaceutical Manufacturers Association	650

Activities	Inputs	Outputs	Verifiable indicators	Means of verification	Time-frame	Lead Responsibility	Budget (USD) ,000
5. Effective use of collective purchasing preference schemes by public procurement agencies.	• Consultative meetings • Policy directives on public health procurement.	Harmonized pharmaceutical procurement policies that support preference purchase schemes in place among EAC Partner States.	• Number of locally produced Medicines with prices falling within preference margins. • Number of locally produced medicines restricted for purchase through preference schemes.	• A comparative report on prices of local and imported products. • Manufacturers' sales data • Tender reports by public procurement agencies.	2012-2013	• EAC Secretariat • National Ministries of Health • National public procurement agencies	200
6. Implementation of pooled procurement of raw materials and other pharmaceutical production inputs by manufacturers.	• Survey on commonly used APIs • Consultative meetings • Policy guidelines • MOUs between manufacturers.	• Survey report on commonly used APIs. • MOUs between manufacturers on pooled procurement of commonly used APIs.	• Survey report • Number of raw materials purchased through pooled procurement	• Manufacturers Raw material import reports • Customs data/records • NMRA records	2012 - 2014	• EAC Secretariat • Regional Pharmaceutical Manufacturers Association.	200
7. Regional pharmaceutical demand quantification study for 2012 to 2016.	Survey	Study report	Study report	• Published demand forecast data • Number of stakeholders using the report.	2012-2013	• EAC Secretariat • Regional Pharmaceutical Manufacturers Association • National Ministries of Health • Public pharmaceutical procurement and distribution agencies	200
8. Baseline survey to determine the regional pharmaceutical production capacity as well as firm level underutilized capacity.	Survey	Study report	Study report	• Published study report • Number of stakeholders using the report	2012 - 2013	• EAC Secretariat • Regional Pharmaceutical Manufacturers Association • National pharmaceutical manufacturers associations • National Ministries of Health	200
SUBTOTAL							**9,800**

STRATEGIC OBJECTIVE 2: FACILITATION OF INCREASED INVESTMENT IN REGIONAL PHARMACEUTICAL PRODUCTION
OUTCOME 2: INCREASED INVESTMENT IN REGIONAL PHARMACEUTICAL PRODUCTION THROUGH EXPANSION OF EXISTING FACILITIES AND NEW ENTRANTS

Activities	Inputs	Outputs	Verifiable indicator	Means of verification	Timeframe	Lead Responsibility	Budget (USD) ,000
1. Promotion of a conducive investment environment in the region.	• Consultative meetings • Review of national legislation on relevant tax regimes • Good governance	Reviewed national legislations in all EAC Partner States towards promoting a conducive investment environment.	• Number of reviewed legislations • Number of public sector management reforms • List of Investment incentives • Number of investments recorded	Investment reports Country and regional rankings in annual Doing Business Reports	2012-2016	• EAC Secretariat, • National Ministries of Finance, Trade and Industrial Development • Investment Promotion agencies	350
2. Feasibility study on identifying suitable long term financing options for pharmaceutical manufacturing in the EAC region.	Survey	Survey report	Survey report Number of new investments accessing long-term financing	Policy makers and financial institutions using/implementing survey report. Financial records	2012 -2013	• EAC Secretariat. • Regional Pharmaceutical Manufacturers Associations	150
3. Sensitizing key stakeholders on the unique pharmaceutical industry dynamics.	Consultative and advocacy meetings	At least one stake holder consultative meeting is held in each of the EAC Partner States.	• Number of stakeholders sensitized. • Number of pharmaceutical manufacturers accessing finance. • Number of business proposals financed.	• Financial institutions records • Annual reports of manufacturers	2012-2014	• EAC Secretariat, • Regional Pharmaceutical Manufacturers Associations	150
4. Development of national and regional policy framework for pharmaceutical industry clusters and special economic zones.	Consultative meetings	Regional policy framework in place.	• Policy document on pharmaceutical industry clusters and special economic zones.	Regional\National gazettes establishing economic zones	2012-2014	• EAC Secretariat, • National Ministries of Health and National Ministries of Industrial Development, • Investment Promotion agencies	200
5. Mapping of existing and potential locations for pharmaceutical industry clusters and special economic zones.	Survey	Mapping Report	Mapping Report	Published report	2012- 2014	• EAC Secretariat • National Ministries of Trade and Industry • Investment Promotion agencies	150
Sub total							**1,000**

STRATEGIC OBJECTIVE 3: STRENGTHENING PHARMACEUTICAL REGULATORY CAPACITY IN THE REGION
OUTCOME 3: A STRENGTHENED PHARMACEUTICAL REGULATORY CAPACITY IN THE REGION

Activities	Inputs	Outputs	Verifiable indicators	Means of verification	Timeframe	Lead Responsibility	Budget (USD) ,000
1. Strengthen Human Resource capacity on regulatory affairs in the region	• Review HR capacity • Training Needs Assessment • Survey on gender mainstreaming • Training • Technical assistance	• Report on HR capacity • Training Needs Assessment Report • At least 30% of technical personnel in the NMRAs in all Partner States receive refresher courses	• Report on HR capacity • Report on gender main streaming • Number of personnel recruited • Number of trained and skilled personnel in regulatory affairs	• NMRAs annual reports • International recognition of EAC NMRAs • National and regional HRD plans	2012- 2016	EAC Secretariat, National Ministries of Health, NMRAs	2,600
2. Development\Improvement of infrastructure of NMRAs	• Technical Assistance • Equipment • NMRA Development plans	Technical Assistance and Equipment /infrastructure upgrade in all the EAC Partner States' NMRAs	• Number and type of infrastructural enhancement within NMRAs	• Country reports on NMRAs infrastructure development • NMRA infrastructure inventories	2012 -2016	EAC Secretariat, National Ministries of Health, NMRAs	3, 500
3. Review of national laws for medicines regulation	• Consultative meetings • Technical Assistance	Reviewed/Amended national laws on medicines in all Partner States	• Amendments on national laws • Number of new regulations	• Gazette notices	2012- 2016	EAC Secretariat, National Ministries of Health, NMRAs	1,200
4. Harmonization of regulations for drug registration, licensing of pharmaceutical manufacture, Standard Treatment Guidelines and Essential Medicines List across the region	• Consultative meetings among NMRAs • Development of a regional policy on medicines regulatory harmonization • Review of relevant national legislations	Harmonized Medicines regulations in place in the region	• Number of consultative meetings among NMRAs • Policy and Protocol on harmonization of medicines regulation across EAC Partner States • Mutual Recognition Agreements • Appointment of the regional medicines control and food safety commission	• EAC reports on ratifications and resolutions • Gazette notices	2012-2016	EAC Secretariat, National Ministries of Health, NMRAs	2,000
Sub total							**9,300**

STRATEGIC OBJECTIVE 4: DEVELOPMENT OF APPROPRIATE SKILLS AND KNOWLEDGE FOR PHARMACEUTICAL PRODUCTION IN THE REGION

OUTCOME 4: APPROPRIATELY TRAINED AND SKILLED PERSONNEL IN PHARMACEUTICAL PRODUCTION AVAILABLE IN THE REGION

Activities	Inputs	Outputs	Verifiable indicators	Means of verification	Timeframe	Lead Responsibility	Budget (USD) ,000
1. Identification, equipping and accreditation of training institutions	• TA • Training needs assessment • Curricula development • Technical working group • Consultative meetings • Technical Assistance • Short and long term courses • Centres of Excellence for training	• Training Needs Assessment Report • Training curricula • At least one regional Centre of Exellence in place • Accreditation mechanism in place	• Established institutional framework • Training curricula • Number of accredited training institutions • Number of trainers and trainees • Number of new courses introduced • Number of equipped institutions	• Training institutions' annual reports • Reviewed curricula • Accreditation certificates • Inspection reports	2012-2016	EAC Secretariat, National Ministries of Higher Education	3,350
2. Development and implementation of a gender based sectoral human resource development strategy	• Baseline survey on HR training needs and skills gaps • Baseline survey on gender mainstreaming • Consultative meetings • Technical working group • Short and long term courses • Training scholarships to pharmaceutical production personnel • Industrial attachment for students • Exchange programmes • Pharmaceutical experts Diaspora returnee placement programme	• Baseline Survey Report • HR Development Strategy in place and being implemented	• Survey report • HR development strategy in place • Number of persons trained on elements of pharmaceutical production • Number of EAC Diaspora returnees participating in regional pharmaceutical manufacturing • Number of scholarships awarded to pharmaceutical personnel to upgrade their skills • Number of exchange programmes beneficiaries	• Training institution graduation lists • Personnel records of pharmaceutical manufacturers • Reports from EAC/Higher Education ministries on scholarships awarded	2012-2016	EAC Secretariat, Regional Pharmaceutical Manufacturers Association, Ministries of Health and Higher Education	2,650
Sub total							**6,000**

STRATEGIC OBJECTIVE 5: UTILIZATION OF PUBLIC HEALTH RELATED TRIPS FLEXIBILITIES TOWARDS IMPROVED LOCAL PRODUCTION OF PHARMACEUTICALS
OUTCOME 5: LOCAL PRODUCTION OF PHARMACEUTICALS ENHANCED THROUGH UTILIZATION OF PUBLIC HEALTH RELATED TRIPS FLEXIBILITIES

Activities	Inputs	Outputs	Verifiable Indicators	Means of Verification	Timeframe	Lead Responsibility	Budget (USD) ,000
1. National and regional sensitization on intellectual property rights and public health related TRIPS flexibilities	• Awareness creation seminars • Handbook on utilization of TRIPs flexibilities • Technical assistance	• At least one multi-stakeholder sensitization seminar held in each of the EAC Partner States • At least one country within the EAC exploiting the provisions of public health related TRIPS flexibilities • A regional handbook on utilization of TRIPS flexibilities published	• Number of pharmaceutical companies and countries exploiting TRIPS flexibilities • Number of new products introduced through exploitation of TRIPS flexibilities • Number of sensitization programmes conducted	• Annual reports of pharmaceutical manufacturers and NMRAs • Technology licensing & manufacturing agreements	2012-2016	EAC Secretariat, National patent Offices , Regional Pharmaceutical Manufacturers Association	300
2. Adoption of a regional policy framework and guidelines to effectively implement public health related TRIPS flexibilities	• Consultative meetings • A draft regional policy and protocol	Approved Regional Policy and Protocol	• Regional policy and protocol documents	• Partner States and Institutions using the TRIPS Policy and Protocol • Record of participation in the adoption meeting • EAC Secretariat records	2012- 2013	EAC Secretariat, National Patent Offices	200
3. Domestication of public health related TRIPS flexibilities within national laws	• 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	• National Gazettes • Press articles	2012- 2014	EAC Secretariat, National Patent Offices	200
Sub Total							**700**

STRATEGIC OBJECTIVE 6: MAINSTREAMING INNOVATION, RESEARCH AND DEVELOPMENT WITHIN THE REGIONAL PHARMACEUTICAL INDUSTRY
OUTCOME 6: INNOVATIVE PHARMACEUTICAL PRODUCTS THAT ADDRESS PUBLIC HEALTH NEEDS DEVELOPED IN THE REGION THROUGH A STREGTHENED PHARMACEUTICAL RESEARCH AND DEVELOPMENT PLATFORM

Activities	Inputs	Outputs	Verifiable Indicators	Means of Verification	Timeframe	Lead Responsibility	Budget (USD) ,000
1. Pharmaceutical Research and Development capacity enhancement in the region	• Regional pharmaceutical industry R &D mapping and needs assessment • Consultative meetings • Technical assistance • Training	• R & D mapping and needs assessment report • At least one regional programme for strengthening pharmaceutical R & D in place	Number of programmes in place towards enhancing pharmaceutical industry R & D	Reports by the National Science & Technology Commissions	2012-2016	EAC Secretariat, National Research Institutes, Pharmaceutical companies	4,750
2. Promotion and enhancement of the use of locally sourced inputs (including herbal or natural products) for production of active pharmaceutical ingredients, excipients and final dosage forms	• Technical working group • Database & pharmacopeia for local pharmaceutical materials • Clinical trials and pilot production of local pharmaceutical ingredients • Technical assistance	• Database and pharmacopeia for local pharmaceutical materials • A regional mechanism in place to support product development	Number of new pharmaceutical products from locally sourced inputs	• Intellectual property rights applied for and granted • Submissions for drug registration • Survey reports • Working group reports/recommendations • Pharmacopeia or data base of local raw materials • NMRA register of medicines	2012-2016	EAC Secretariat, National Research Institutes, Pharmaceutical companies NMRAs	3,550
3. Structuring and resource mobilization for a regional pharmaceutical innovation fund	• Management and administration mechanisms • Investor road show	A regional pharmaceutical innovation fund in place	• Final fund close • Number of funding pledges • Number of proposals supported	• Investor subscription agreements • Record of pipeline innovations • Accounts records	2013-2016	EAC Secretariat, National Science and Technology Commissions, Schools of pharmacy, Research institutions and Universities	9,000
Sub Total							**17,300**
BUDGET GRAND-TOTAL (USD)							**44,300**

3.3.2 Key Milestones for EACRPMPoA Implementation

	Year				
	2012	**2013**	**2014**	**2015**	**2016**
Milestones	Regional pharmaceutical manufacturers association established	1. A regional policy framework on pharmaceutical industry clusters and special economic zones in place 2. Adoption of a regional policy framework on approximation and utilization of WTO TRIPS flexibilities with regard to Public Health	1. Establishment of NMRAs in Burundi and Rwanda 2. Regional human resources development strategy on pharmaceutical manufacturing in place	1. Pilot implementation of pooled procurement of raw materials and finished products 2. Accreditation mechanism of training institutions in pharmaceutical manufacturing in place 3. Domestication of TRIPS flexibilities within the national laws	1. Four manufacturers in the region meet WHO-PQ standards 2. Four WHO PQ National Quality Control Laboratories in the region 3. Harmonization of Medicines Registration in the region 4. Establishment of a regional pharmaceutical innovation fund

3.3.3 Organisation

The successful implementation of the plan requires effective coordination mechanisms that will synergize existing and proposed regional and national programmes towards strengthening local production of pharmaceuticals. The EAC-RPMPoA 2012-2016 will be coordinated and implemented through the approved EAC structures. The following will be the necessary institutional arrangements in the implementation framework.

1. EAC Secretariat

The EAC Secretariat will be responsible for the overall coordination of the implementation of the EACRPMPoA. The Secretariat will take a lead responsibility in mobilizing the necessary resources for the successful implementation of the plan. It will advise the Partner States on the policy and institutional reforms required to support the plan. The EAC Secretariat will deploy an EAC Senior Industrial Pharmacist to be responsible for the implementation of the plan.

2. The EACRPMPoA implementation steering committee

An implementation steering committee will be established by the EAC Secretariat to guide the implementation of the plan. The committee members will be drawn from Partner States and will comprise key stakeholders from both public and private sector institutions. The steering committee will establish sub-committees as necessary to assist in the implementation of the strategic objectives

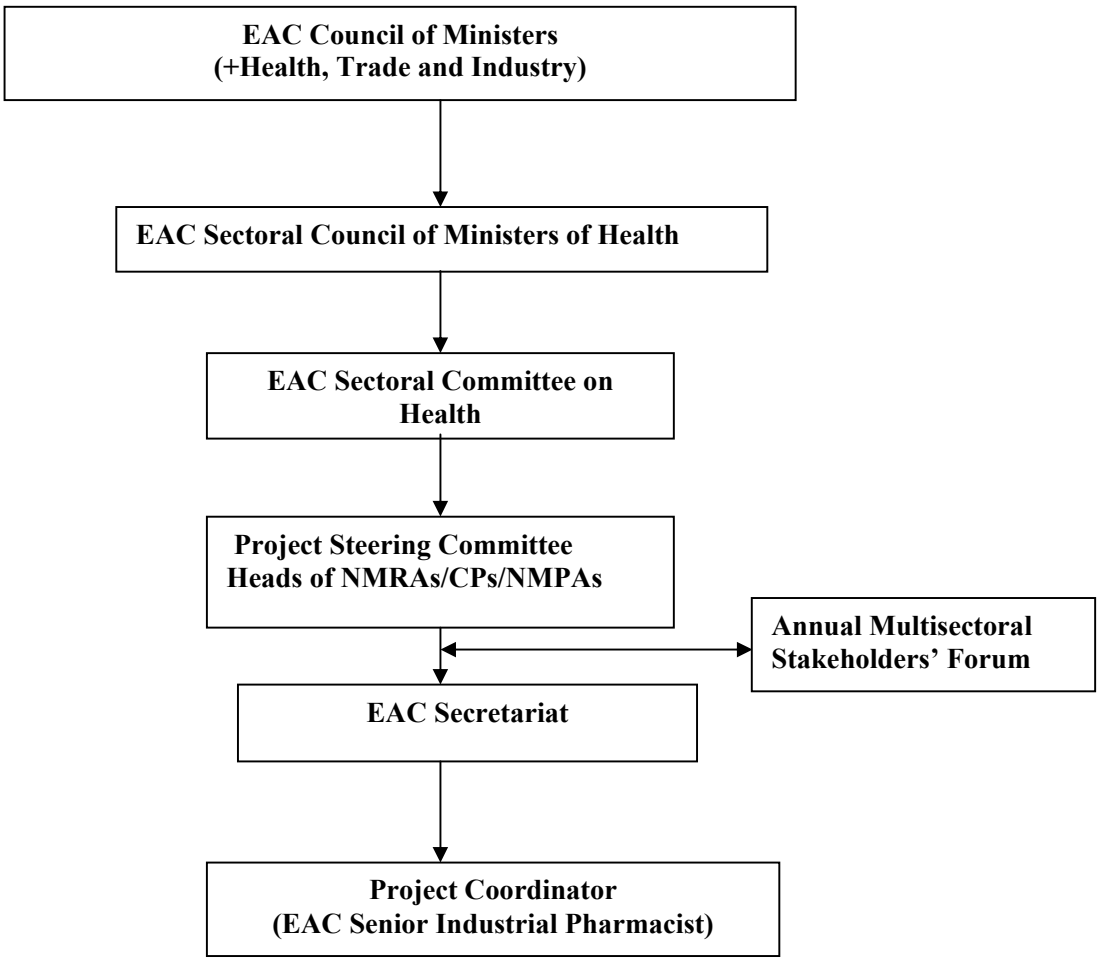
3. National governments

The national governments through the relevant ministries and institutions are expected to support and implement the plan by assisting and availing the necessary resources as and when required. This includes initiating and facilitating the necessary changes in policy and institutions to support the plan.

4. The private sector

The private sector led by the Federation of East Africa Pharmaceutical Manufacturers' (FEAPM) will be crucial in the implementation of the plan. The lead responsibility column in the implementation matrix identifies activities that will be driven through private sector partners. The private sector players will be crucial in playing the advocacy role and committing the required resources for the implementation of the plan.

Figure 2: Proposed Structure of the Implementation of EAC-RPMPoA



3.3.4 Dissemination and Advocacy

The plan will be widely disseminated to key stakeholders in the public, private and civil society organizations as well as to current and potential development partners. It will be crucial to carry out advocacy and fundraising efforts locally and internationally so that the plan receives key multisectoral stakeholder support.

Chapter 4: Budget

The successful implementation of the plan requires substantial financial resources estimated at USD 45 million as detailed in the implementation matrix and further summarized in Table 3 below. Member states will be expected to contribute to the plan to ensure ownership and sustainability. In addition, budgetary support will be sought from local pharmaceutical industry, existing and potential development partners as well as bilateral and multilateral agencies. The EAC Secretariat and the Partner States will make efforts to mobilize the required financial resources.

Table 3: EAC-RPMPoA budgetary allocations

STRATEGIC OBJECTIVES	**BUDGETARY ALLOCATIONS (USD, 000)**					
	2011/2012	2012/2013	2013/2014	2014/2015	2015/2016	**TOTAL (USD, 000)**
Objective 1: Promotion of competitive and efficient pharmaceutical production regionally	600	1,700	2,000	2,500	3,000	**10,000**
Objective 2: Facilitation of increased investment in the regional pharmaceutical production	200	450	150	100	100	**1,000**
Objective 3: Strengthening pharmaceutical regulatory capacity in the region	1,400	1,950	1,950	1,950	2,050	**9,300**
Objective 4: Development of appropriate skills and knowledge for pharmaceutical production in the region	600	1,350	1,350	1,350	1,350	**6,000**
Objective 5: Utilization of public health related TRIPS flexibilities towards improved local production of pharmaceuticals	100	100	200	150	150	**700**
Objective 6**:** Mainstreaming innovation, research and development within the regional pharmaceutical industry	500	1,750	1,750	1,850	11,450	**17,300**
Advocacy and Fundraising	100	200	200	200	200	**900**
TOTALS (USD,000)	**3,500**	**8,500**	**7,600**	**8,100**	**17,300**	**45,200**

The budget lines indicated above are estimates and the primary objective of these funds is to provide an industry stimulus package to strengthen local pharmaceutical manufacturing through deliberate strategic actions as detailed in the implementation matrix.

Chapter 5: Monitoring and Evaluation

A monitoring and evaluation framework will be put in place to review and assess progress of the plan as per the set milestones and indicators. The implementation of the plan will be subject to the established M&E framework of the EAC Secretariat. In particular, the Monitoring and Evaluation Office of the Secretariat will be requested to provide expert support and in house trainings to the staff responsible for the implementation of EACRPMPoA. The M&E activities will focus on the processes, outputs, outcomes and impact as stated in the implementation framework.

5.1 Monitoring

The Project Officer responsible for the implementation of the plan of action will develop annual operational plans (AOPs) derived from the EACRPMPoA. The Officer is expected to generate quarterly, biannual and annual reports to be presented to the steering committee. The committee will review progress reports during regular scheduled and ad hoc meetings and advise the Secretariat accordingly. The project steering committee is expected to meet at the minimum biannually. The Secretariat will take corrective action as necessary to ensure smooth implementation of the plan.

5.2 Evaluation

A baseline survey on the pharmaceutical manufacturing in the region will be commissioned prior to commencement of the implementation of the plan. Subsequently, an external consultant will be recruited to carry out mid-term and terminal evaluation during the implementation phase of the plan of action. The report of the mid-term evaluation will form a basis for strategic decisions necessary to guide the implementation of the remaining period of the plan.

Annex 1: Country pharmaceutical manufacturing snapshots

1. KENYA

- Biggest and most developed pharmaceutical manufacturing sector in EAC region
- Total market size USD 208.6 million in 2007
- Branded and generic market share is 44 % and 56% respectively
- 28% the percentage of market share of locally produced pharmaceuticals
- 35 - 45 % of local production exported to neighbouring countries
- 15% marginal preference scheme for local products by government tenders
- Local production meeting 30% of national demand of pharmaceuticals
- 31 number of registered pharmaceutical manufacturers
- Negative market perception of local manufacturers
- Local production predominantly generic
- Raw materials mostly imported
- Price erosion due to low cost imports

2. **TANZANIA**

- Most developed semi autonomous regulatory authority within EAC region
- Pharmaceutical market size USD 105 million in 2007
- Branded and generic market constituting 46 % and 54% respectively
- 8 number of registered manufacturing sites
- Local production meets 31% of national demand
- India largest exporter of pharmaceuticals to Tanzania
- State and donor market constitute 85% of total pharmaceutical market
- 15% preferential treatment given to local manufacturers in government tenders
- Competition from low cost imports
- Raw materials mostly imported

3. UGANDA

- Estimated total market size USD 90 million in 2005
- 13 registered pharmaceutical manufacturers
- 95 % of medicines imported to meet local demand
- Only 5 % manufactured locally
- Negative market perception of local manufacturers
- Raw materials mostly (over 90 %) imported from India and China
- Pharmaceutical plant production technology imported including spare parts
- Tabletting lines most developed
- Price erosion due to low cost imports

4. **BURUNDI and RWANDA**

- Each has one pharmaceutical manufacturing facility
- National Medicines Regulatory Authorities (NMRAs) are currently being established in both countries
- Estimated pharmaceutical market size for each country is USD 25 million
- Over 95 % of medicines consumed locally are imported
- Rwanda has leveraged use of ICT in management of the medicines distribution and supply systems in the public sector
- Raw materials imported

Annex 2: East African Pharmaceutical Manufacturers

1. BURUNDI

Societe Industrielle Pharmaceutique (SIPHAR), Bujumbura

2. KENYA

1. Aesthetics Limited, Nairobi - *veterinary*
2. Autosterile East Africa Limited, Nairobi
3. Beta Healthcare International Limited, Nairobi
4. Biodeal Laboratories Limited, Nairobi
5. Bioextract EPZ Limited, Athi River
6. Biopharma Limited, Nairobi
7. BOC Kenya Limited, Nairobi - medical gases
8. Cosmos Limited, Nairobi
9. Crown Gases Limited, Nairobi - medical gases
10. Dawa Limited, Nairobi
11. Elys Chemical Industries Limited, Nairobi
12. Gesto Pharmaceuticals Limited
13. Glaxo SmithKline Kenya Limited, Nairobi
14. Infusion Kenya Limited, Nairobi
15. Ivee Aqua (EPZ) Limited, Athi River
16. KAM Industries Limited, Nairobi
17. Laboratory and Allied Limited, Nairobi
18. Mac's Pharmaceuticals Limited, Nairobi
19. Manhar Brothers (K) Limited, Nairobi
20. Medivet Products Limited, Ruiru
21. Noble Gases International Limited - *medical gases*
22. Norbrook Africa EPZ Limited, Athi River - *veterinary*
23. Norbrook Kenya Limited, Limuru
24. Nerix Pharma Limited, Nairobi - *veterinary*
25. Novelty Manufacturing Limited, Nairobi
26. Oss-Chemie (Kenya) Limited, Nairobi
27. Pharmaceutical manufacturing Company (Kenya) Limited, Nairobi
28. PZ Cussons East Africa Limited, Nairobi
29. Regal Pharmaceuticals Limited, Nairobi
30. Sphinx Pharmaceuticals Limited, Nairobi
31. Universal Corporation Limited, Kikuyu

3. RWANDA

Pharmaceutical Laboratory of Rwanda (LABOPHAR), Butare

4. TANZANIA

1. A.A. Pharmaceuticals Limited, Dar-es-Salaam
2. Keko Pharmaceutical Industries (1997) Limited, Dar-es-Salaam
3. Mansoor Daya Chemicals Limited, Dar-es-Salaam
4. Shelys Pharmaceuticals Limited, Dar-es-Salaam
5. Tanzania Oxygen Limited, Dar-es-Salaam - *medical gases*
6. Tanzania Pharmaceutical Industries, Arusha
7. Tanzansino United Pharmaceuticals Limited, Dar-es-Salaam
8. Zenufa Laboratories Limited, Dar-es-Salaam

5. UGANDA

1. Abacus Parenteral Drugs Limited, Mukono
2. Bychem Laboratories Limited, Kampala
3. Kampala Pharmaceutical Industries (1996) Limited, Kampala
4. Medipharm Industries (EA) Limited, Kampala
5. Oxygas Limited, Kampala - *medical gases*
6. Quality Chemical Industries Limited, Kampala
7. Rene Industries Limited, Kireka
8. Uganda Oxygen Limited, Kampala - *medical gases*
9. Uganda Pharmaceuticals Limited, Jinja
10. Joint Medical Stores, Kampala
11. Kisakye Pharmaceuticals Limited, Kampala
12. Mavid Pharmacy, Limited, Kampala
13. Uganda Kwefuga African Industries Limited, Kampala

The "East African Community Regional Pharmaceutical Manufacturing Plan of Action (EACRPMPoA): 2012-2016" serves as a roadmap to guide the East African Community towards evolving an efficient and effective regional pharmaceutical manufacturing industry that will supply national, regional and international markets with high-quality, safe and efficacious medicines.

EAC Secretariat
AICC Building,
Kilimanjaro Wing, 5th Floor,
P.O. Box 1096
Arusha, Tanzania
Tel: +255 27 2504253/8
Fax: +255 27 2504255/2504481
E-Mail: eac@eachq.org; health@eachq.org
Website: http//www.eac.int