EAST AFRICAN COMMUNITY MEDICINES AND HEALTH TECHNOLOGIES STRATEGIC PLAN (2018-2022)

FINAL

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Abbreviations and Acronyms

AMRH	African Medicines Regulatory Harmonisation
EAC	East African Community
EACMFSC	East African Community Medicines and Food Safety Commission
EAC-MRH	East African Community Medicines Regulatory Harmonisation
EML	Essential Medicines List
EU	European Union
FEAPM	Federation of East African Pharmaceutical Manufacturers
HIA	Health in Africa Initiative
ICH	International Conference on Harmonisation
IFC	International Finance Corporation
IMS	Information Management System
eIMS	Electronic IMS
MA	Marketing Authorisation
MoH	Ministry of Health
MRA	Medicines Regulatory Authority
NMP/NPP	National Medicines Policy/National Pharmaceutical Policy
NMRA	National Medicines Regulatory Authority and equivalent institutions
NEPAD	New Partnership for Africa's Development
PS	Partner States
RPP	Regional Pharmaceutical Policy
SFC	Sub-Standard Falsified and Counterfeit Drugs
STG	Standard Treatment Guidelines
WHO	World Health Organization

DEFINITION OF TERMS

Active Pharmaceutical Ingredient (API)

An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Alternative medicine
A practice that is put forward as having the healing effect of medicine, but not founded on evidence gathered using the scientific method. I consists of a wide range of health care practices, products and therapies

Bio-therapeutics
Any pharmaceutical drug product manufactured in, extracted from, or semi synthesized from biological sources. Different from chemically synthesized pharmaceuticals, they include vaccines, blood, blood components, allergenic, somatic cells, gene therapies, tissues, recombinant therapeutic protein, and living cells used in cell therapy. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living cells or tissues. They are isolated from natural sources iehuman, animal, or microorganism.

Clinical Trial
Research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people.

Commission
A regional health and related institutions of the Community established under Articles 4 and 5 of this Protocol

Community
East African Community established by Article 2 of the Treaty

Complimentary Medicines
A range of medical therapies that fall beyond the scope of scientific medicines but may be used alongside it in the treatment of diseases and ill health. Examples include acupuncture, reflexology, massage, meditation, art therapy, psychotherapy counselling and yoga.

Coordination Committee
Coordination Committee established by Article 9 of the Treaty

Council
Council of Ministers of the Community established by Article 9 of the Treaty

Drug

1. Also called Medicine is a substance used in the diagnosis, treatment or prevention of a disease or a component of a medication

2. A chemical substance, such as narcotics or hallucinogen, that affects the central nervous system, causing changes in behavior and often addiction

3. (Informal) any substance that can be abused for its stimulant, depressant, euphoric or hallucinogenic effects

E-Health
Means the use, in the health sector, of digital data - transmitted, stored and retrieved electronically- in support of health care, both at the local site and at a distance.

E-Health for health-care delivery
e-Health applications that directly support prevention, patient diagnosis and patient management and care. These applications include tele-consultations, tele-referrals, forward-storage concepts (e.g. tele-radiology and tele-prescriptions), and electronic patient records (EPR).

Gazette
An official Gazette of the Community

Harmonization
Process of standardizing policies, laws, regulations and practices to facilitate EAC integration in social, cultural, economic and political sectors.

Head
Chief Executive Officer of a member institution by whatever name called.

Health
A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

Health Practitioner
Individual accredited by a professional body upon completing course of study and usually licensed by Government agency to practice a health related profession such as dentistry, nursing, medicine, occupational health.

Health Technologies
Applications of organized knowledge and skills in the form of devices, procedures and systems developed to solve a health problem and improve quality of lives.

Herbal Medicines
Herbal medicine, also called botanical medicine or phytomedicine, refers to

using a plant's seeds, berries, roots, leaves, bark, or flowers for medicinal purposes.

Market Authorization Holder
Is a person resident ordomiciled to each of the EAC Partner States who holds authorization to place a medicinal product in the EAC Partner States and is responsible for that product

Manufacturer
A manufacturer is a natural or legal person with responsibility for manufacturing of a medicinal product or active pharmaceutical ingredient. It involves operations such as production, packaging, repackaging, labeling and relabeling of pharmaceuticals

Medical Device
Any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease

Medicinal Products
Any susbstance or combination of substances which may be used in or administered to human beings either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

Medicines *(Synonyms:- medication, medicament, drug, , pharmaceutical)*

Medicines are medications, drugs, substances used to diagnose, treat, cure or prevent diseases and promote health.

National Institution
Means a body established under the relevant laws of a Partner State mandated to provide health or related services for and on behalf of the respective Partner State

Partner States
Means the United Republic of Tanzania, the Republic of Kenya, the Republic of Uganda, the Republic of Burundi, the Republic of Rwanda and any other country granted membership to the Community under Article 3 of the Treaty

Pharmaceutical product
A pharmaceutical product (also referred to as a pharmaceutical, pharmaceutical drug, pharmaceutical preparation, medicinal product, medicine, medication, medicament or drug) is a drug used to diagnose, cure, treat or prevent diseases.

Pharmacovigilance
A science and activities relating to the detection, assessment, understanding

and prevention of adverse effects or any other drug related problem

Post-Market Surveillance
The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance.

Public Health means the effort of society to protect, promote and restore the people's health through health-related activities in order to reduce the amount of diseases, premature death, and reduce discomfort and disability in the population

Quality Assurance
A concept covering all matters that individually and collectively influence the quality of a medicinal product. It involves development, quality control, production, distribution and inspections.

Quality Control (QC)
A procedure or set of procedures intended to ensure that a manufactured product or performed service adhere to a defined set of quality criteria or meets the requirements of the client or customer.

Quality System
Organizational structure, responsibilities, procedures, processes and resources needed to implement quality management.

Quality Management System
A quality management system (QMS) is a formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct organizations activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

Secretary General
Secretary General of the Community provided for under Article 67 of the Treaty

Sectoral Committee
The Sectoral Committee established by Article 20 of the Treaty

Sectoral Council
The Sectoral Council provided for under Article 14 of the Treaty

Stakeholder
Means a person, legal or natural, governmental or non-governmental

conducting business with any of the regional institutions of the Community established under Articles 4 and 5 of this Protocol

Traditional Medicines
Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Traditional Health Practitioners
People who use the total combination of knowledge and practices, whether explicable or not, in diagnosing, preventing or eliminating a physical, mental or social disease and in this respect may rely exclusively on past experience and observation handed down from generation to generation, verbally or in writing, while bearing in mind the original concept of nature which included the material world, the sociological environment whether living or dead and the metaphysical forces of the universe;

Treaty
The Treaty establishing the East African Community and any annexes and protocols thereto.

Message from the EAC Sectoral Council of Ministers of Health

The development of the five-year East African Community Medicines and Health Technologies Strategic Plan (EACMHTSP 2017-2021) is an important milestone towards the achievement of universal access to essential medicines and the attainment of the United Nations Sustainable Development Goals and Targets.

The plan have been developed inline with EAC Treaty, Chapter 21, Article 118, EAC Health Sector Strategic Plan and 4th EAC Development Strategy and it provides a roadmap for the Partner States pharmaceutical sector contribution to health goals by defining key interventions to be undertaken over the next five years within the framework of East African Community Medicines and Health Technologies Policy. With this plan, partners and stakeholders involved or interested in supporting EAC pharmaceutical sector, have a comprehensive guide to systematically address pharmaceutical sector priorities.

The implementation of the strategic plan will be coordinated by the EAC Secretariat through the EAC Technical Working Groups (TWGs) for Medicines, Health Technologies and Food Safety, EAC Sectoral Committee on Health and guided by the EAC Sectoral Council on Regional Cooperation on Health as established by the 4th Ordinary Session of the EAC Council of Ministers on 13th September 2002.

We, the Ministers responsible for Health of Governments of the Republic of Kenya, the Republic of Rwanda, the Republic of Burundi, the Republic of Uganda and The United Republic of Tanzania wish to provide leadership to ensure the EAC population have access to affordable, safe, efficacious and quality medicines and health technologies at all times.

We express our full commitment and dedication to the implementation and realization of the set goals and targets as enshrined in this strategic plan.
This was done at Kampala, Uganda, on this 24th day of March, Two Thousand and Fifteen.

HON. SARAH OPENDI (MP)
MINISTER OF STATE FOR HEALTH
REPUBLIC OF UGANDA

HON. DR. DIANE GASHIMBA
MINISTER FOR HEALTH,
REPUBLIC OF RWANDA

HON. DR. JOSIA NIJIMBERE
MINISTER FOR PUBLIC HEALTH AND FIGHT AGAINST AIDS,
REPUBLIC OF BURUNDI

HON. DR. CLEOPA MAILU
CABINET SECRETARY FOR HEALTH,
REPUBLIC OF KENYA

HON. DR. RIEK GAI KOK
MINISTER OF HEALTH
REPUBLIC OF SOUTH SUDAN

HON. UMMY ALLY MWALIMU (MP)
MINISTER FOR HEALTH, COMMUNITY
DEVELOPMENT, GENDER, ELDERLY AND CHILDREN
UNITED REPUBLIC OF TANZANIA

FOREWORD

The East African Community is committed to promoting equitable access to safe, efficacious, affordable and quality essential medicines and health technologies for treatment of both communicable and non-communicable diseases.

Provision of safe, efficacious, quality and affordable essential medicines and health technologies to the EAC population remains a major challenge due to a number of factors including among others low domestic pharmaceutical production capacity, limited institutional capacity to enforce regulations, limited human resource and weak infrastructure to ensure quality control and quality assurance of medicines and health technologies in EAC market.

The Plan is designed to achieve the objectives of the Community as set out in EAC Treaty, Chapter 21, Article 118 (c), (d), (e), (f), (g) and (i) where Partner States agreed to cooperate to develop common drug policy, quality control capacities and good procurement practices; harmonise drug registration procedures; promote exchange of information; promote research and development in traditional, alternate and herbal medicines; develop pharmaceutical products and control or eradication of trafficking and consumption of illicit or banned drugs.

Successful implementation of this strategic plan will require joint efforts of EAC Partner States, National Ministries of Health, Trade, Commerce, Industry, Education, Environment and Information Technology; Government Health Agencies such as National Medicines Regulatory Authorities, the National Medical Stores Department, National Procurement Agencies and Bureau of Standards; Pharmaceutical Industries and Pharmaceutical Manufacturers Associations; Academia; National Medical Research Organizations; Private sector; Civil Society and Community; National Parliaments; East African Legislative Assembly and EAC Policy Organs; Regional or Continental Bodies and Organizations; and International Development Partners.

EAC Secretariat has put in place tools to assess the status of implementation of the regional priority interventions and provides opportunity for Partner States to learn from each other.

The Strategic Plan have outlined strategic interventions in line with the main components of the EAC Medicines and Health Technologies Policy to address challenges facing EAC Partner States in accordance with the functions and mandate of the EAC Secretariat and previous directives of the Sectoral Council of Ministers responsible for regional cooperation on Health.

The strategic plan development adopted an inclusive, participatory and appreciative approach that involved extensive engagement and consultations with and sharing of experiences and learning among the diverse EAC Partner States' stakeholders both at the national and regional levels. The strategic plan covered all the EAC Partner States namely Burundi, Kenya, Rwanda, United Republic of Tanzania and Uganda.

Improvement in the quality of life and social well-being of the East African people depends on the successful implementation of this plan. EAC is engaged in a number of initiatives to strengthen medicines and health technology sector;

- EAC Industrialization and Pharmaceutical Sector Promotion Programme;
- East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme
- EAC/GAVI/Kfw Immunization Programme
- EAC Center of Excellence for Vaccines, Immunization and Health Supply Chain Management (HSCM)
- African Vaccines Regulatory Forum (AVAREF)
- Pharmaceutical Quality Infrastructure Programme
- African Union Pharmaceutical Manufacturing Plan of Action

I would like to acknowledge the work of the EAC Expert Working Group on Pharmaceutical Policy, Legal and Regulatory Reforms and all stakeholders from various sectors for their valuable contribution during development process and call upon all Parties to support implementation of strategic interventions outlined in this plan.

Amb. Liberat Mfumukeko
EAC Secretary General

EXECUTIVE SUMMARY

The East African Community (EAC) is the regional intergovernmental organization comprised of the Republics of Burundi, Kenya, Rwanda, South Sudan, Uganda and the United Republic of Tanzania. The EAC aims at widening and deepening co-operation among the Partner States in, among others, political, economic and social fields for their mutual benefit.

The EAC Secretariat through the Medicines Regulatory Harmonization (MRH) Programme has developed this strategic plan to highlight activities planned to be implemented in five years' time beginning 2018. The plan defines implementation strategies as delineated in the *Medicines and Health Technologies Policy* which has been finalized. The Policy has the following objectives:

- To ensure equitable access to medicines, health technologies and pharmaceutical services
- To regulate quality, safety and efficacy of medicines and health technologies
- To promote rational use of medicines and health technologies
- To promote domestic pharmaceutical production
- To facilitate research and development
- To increase collaboration and cooperation between different sectors

The Plan articulates important milestones towards the achievement of these objectives to ensure universal access to essential medicines and the attainment of the United Nations Sustainable Development Goals.

The Plan is divided into six chapters to include details on results of the situational analysis of the pharmaceutical sector conducted by external consultants, goal, objectives and monitoring and evaluation framework. It also summarizes in form of a table a list of strategies, outputs indicators, interventions, actors, estimated costs and the timeframe for implementation for each output.

Strategies in resources mobilization are also highlighted including engaging development partners in implementation of the Plan. The monitoring and evaluation framework has also been detailed to guide on periodic reviews of the Plan to measure realization of set goal and objectives.

Hon. Christophe Bazivamo
EAC Deputy Secretary General
Productive and Social Sectors

INTRODUCTION

The East African Community (EAC) is the regional intergovernmental organization comprised of the Republics of Burundi, Kenya, Rwanda, South Sudan, Uganda and the United Republic of Tanzania. The EAC aims at widening and deepening co-operation among the Partner States in, among others, political, economic and social fields for their mutual benefit.

The EAC coordinates development of policies, strategies, programmes and guidelines that enable Partner States to collectively address regional development challenges. Whereas the EAC Secretariat directly implements a limited set of interventions especially those focused on border areas, it is the responsibility of Partner States to implement the bulk of the interventions agreed upon in regional policy instruments as they are the ones that have the relevant agencies and requisite resources on the ground.

The first East African Community Regional Health Sector Strategic Plan 2015-2020 was adopted and approved for implementation by the 11th Ordinary Meeting of the EAC Sectoral Council of Ministers of Health on 24th March 2015. The Plan serves to establish and maintain a sustainable regional platform for joint cooperation between and among the Partner States in addressing common priority health challenges in the region.

The EAC Health Sector Strategic Plan sets out objectives that address health challenges to ensure access to safe, effective, affordable and quality health products and technologies. In line with the EAC Health Sector Strategic Plan, the EAC Medicines and Health Technologies Strategic Plan (2018-2022) was developed to articulate the EAC's strategic direction on how to address issues related to:

- Equitable access, availability and affordability of medicines, health technologies and pharmaceutical services.
- Quality, Safety and Efficacy of all Medicines and Health Technologies
- Rational Use of Medicines by Health Professions and Consumers.
- Collaboration between Public and Private Sectors, Civil Society, Regional and International Agencies and
- Human Resource for the Pharmaceutical Sector

Implementation of the EAC Medicines and Health Technologies Strategic plan will guide the region towards strengthening the sector to ensure access to safe, efficacious, quality and affordable medicines and health technologies to the EAC population.

CHAPTER ONE: SITUATIONAL ANALYSIS IN THE EAC PARTNER STATES

This chapter highlights the overall socio-economic and demographic data in health and provides the status of the EAC medicines and health technology sectors relevant to this strategic plan.

1.1 Socio-economic and Demographic Data

The population in the EAC as at 2015 is estimated to be 145.5 million. According to the world population report (UNFPA 2014), the average annual population growth rate is high ranges from 2.7% per annum in Kenya and Rwanda to 3.1% per annum in Uganda.

The EAC has a combined GDP of US$ 147.5 billion. The maternal and child mortality rates ranges between 477/100,000 and 75/1000 respectively. The total expenditure for health and the total budget allocated for health is.....respectively. The average cost of medicines and health technologies amongst all EAC partner states was recorded at USD 539 Million while the average health sector budget allocation is at USD 445 Million. Other key demographic indicators are summarized in **Table 1** below.

Table 1: Key Demographic Indicators in the EAC

Area	Uganda	Rwanda	Burundi	Kenya	United Republic of Tanzania		South Sudan
					Mainland	Zanzibar	
Population	36,743,900 (2016)	11,809,295	10,000,000	42,000,000	43,628,923	1,303,569	12,340,000
GDP (Current) in 2016	US$ 25.528 Bil.	1,817 billions RWF	3Billions of USD	70.529 Billion USD	US$ 50.5 Bil	US$860Mil	US $ 20.423 Bil
Maternal Mortality Ratio	368/100,000	2.1/1000	712/100,000	510/100,000	556/100,000	195/100,000	789/100,000
Child Mortality<5	66/1,000	50/1000	60.4/1000	59/1000	67/1,000	56/1,000	102/1,000
Total Expenditure for Health	US$ 1.376 Bil.	$ 125 per capita	7.5% of the GDP		US$.1.911 Mil. (2014/15)		
Budget Allocation for Health Sector	US$ 511 Mil.	$ 341,297,402.42	-		US$. 483 Mil (2017/18)		
Number of Pharmacists	800	717	150	3,000	1563	46	250
Number of Pharmacy Universities	3	2	0	5	4	0	0

/School							
Pharmacist to Patient Ratio	1:46,000	1/16,171	1:70,000 0		1: 29,914	1:28,96 8	
Number of Pharmaceutical Industries (Public and Private)	13	2	1	35	12	0	0
Number of Pharmaceutical Industries WHO Prequalified	1	0	0	1	0	0	0
Cost of Medicines	US$ 854 Mil.				US$ 22I.9 Mil	US$ 3.18 Mil	
Financing of the Pharmaceutical Sector by Government	US$ 64 Mil.				US$ 116.6		US$12 Mil
% of Medicines and Health Technologies imported	80%	95%	More than 95%	88% in 2017	80%	100%	100%
% of Medicines and Health Technologies exported	10%	0%	-	16.7% in 2017		0%	0%
Medicines and Health Technologies Market Size	US$ 450Mil.			US$ 894.4	US$. 538.1		
Number of Tenders provided to Local/Domestic Pharmaceutical Manufacturers	60% of GoU funding	5%				0	
% Disposal of Medicines and Health Technologies	0.35%	0.93%			25%	1.3%	2%
Cost of disposal of	US$ 200,000	$ 39,730.28			US$ 2.9 Mil		US$12, 000

medicines							
% of Donor Funding for Medicines and Health Technologies	70%				45.6%		90%
% of substandard, falsified and counterfeit medicines	2%						5%
Number of Quality Control Laboratories for Medicines and Health Technologies which are WHO Prequalified /ISO Certified	1	0		2	1	0	0

2.2 Assessment of the EAC Medicines and Health Technology Sector

2.2.1 Policy, Legal and Regulatory Frameworks

All Partner States have explicit National Medicines Policies (NMPs). Burundi, Kenya, Rwanda, Uganda and Tanzania (Zanzibar) have updated NMPs. Tanzania (Mainland) has a draft policy that was presented to Cabinet Secretariat in 2014 but is not yet approved. **Table 2** below summarizes the status of EAC Partner States National Medicines Policies.

Table 2: Status of EAC Partner States Medicines Policies

Criteria	Burundi	Kenya	Rwanda	United Republic of Tanzania (Mainland) (Zanzibar)		Uganda	South Sudan
Availability of NMP	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Latest update	2012	2012	2016	1991 2016 (draft)	2014	2015	2007
Implementation plan	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Legislation for enforcement	No, under Ministerial Decree	Yes	Yes	Yes	Yes	Yes	Yes
Monitoring & Evaluation plan	Yes	Yes	Yes	Yes	Yes	Yes	Yes

2.2.2 Legal and Regulatory Framework

The assessment of this component revealed that most partner states had legislation related to medicines and health technologies as highlighted in **Table 3** below.

Country	Burundi	Kenya	Tanzania (Mainland)	Tanzania (Zanzibar)	Rwanda	Uganda	South Sudan
Pharmaceutical Legislation	Bill for Regulating the Practice of Pharmacy in Burundi incorporated in the Health Code.	Pharmacy and Poisons Act of 1957 (Chapter 244) Health Act, 2017 Kenya Medical Supplies Authority Act (2013) NACOSTI Act KEMRI Act	The Tanzania Food, Drugs and Cosmetics Act, Cap 219 The Pharmacy Act, Cap 311 The National Institute for Medical Research Act of 1993 The Traditional and Alternative Medicines Act of 2002 Medical Stores Department Act of 1993	Zanzibar Food, Drugs, and Cosmetics Act No. 2 2006 and its amendment Act No. 3 of 2017 Public Procurement and Disposal of Assets, Act (2005) Traditional and Alternative Medicine Act, 2008 The Establishment of the Chief Government Chemist Laboratory Act,No 10 of 2011	Law No. 47/2012 of 14/1/2013 relating to regulation and Inspection of Food and Pharmaceutical Products Law No. 74/2013 of 9/2013 Establishing Rwanda Food and Medicines Authority and Determining Its Mission, Organization and Functioning Law No. 45/2012 of 14/1/2013 on Organization, Functioning and Competence of Council of Pharmacists	National Drug Policy and Authority Act, 2000 National Medical Stores Act (1993) Public Procurement and Disposal of Assets, Act (2003) Uganda National Health Research Organization Act of 2011	Drug and Food Control Authority Act No. 37 of 2012 Central Medical Stores Bill South Sudan General Medical Council Act Public Procurement Act, 2006 Research Council Act, 2007

Implementing agencies	Department of Pharmacy Medicines and Laboratories(DPML);	Pharmacy and Poisons Board (PPB); Kenya Medical Supplies Authority (KEMSA)	Tanzania Food and Drugs Authority (TFDA); Medical Stores Department (MSD)	Zanzibar Food and Drugs Agency(ZFDA); Traditional and Alternative Medicines Council Procurement Management Unit, Central Medical Stores Chief Government Chemist Laboratory Agency	Pharmaceutical Services Division, MoH CAMERWA	National Drug Authority (NDA), National Medical Stores	Drug and Food Control Authority(DFCA) MOH Central Medical Stores

The Table above shows that most Partner States have legislation for regulation of medicines but not health technologies. The pharmaceutical legislation in Burundi is still under development. A draft Bill with the name 'Bill Regulating the Practice of Pharmacy in Burundi' dated 2014 has been incorporated in current draft of public health code. This law will regulate the manufacturing and registration of medicinal products and medical devices, as well as the distribution and retail activities in pharmacies. Currently the regulatory work is based on a ministerial decree.

All the Partner States have legislation on procurement and procurement agencies have been established to manage the supply chain.

2.2.1.2 Supply Chain Management

Availability of medicines and health technologies remains a challenge in the EAC Public sector. Limited health financing compounds this[1] as the region strives to drive universal health coverage agenda. Improving health financing is key to ensuring that all people can use promotive, preventive, curative, rehabilitative and palliative health services they need. Patients often have to pay out of pocket to purchase medicines from the private sector due to non-availability or unreliability of supply in the public health facilities.

[1] http://www.who.int/healthsystems/topics/financing/en/

The overall selection, procurement, distribution and use of medicines and health technologies across the EAC remain weak resulting in non-availability of essential medicines, high prices and irrational use.
Partner States have developed and implemented Essential Medicines Lists (EMLs) and Standard Treatment Guidelines (STGs). Both EMLs and STGs are considered essential tools to ensure the rational selection, procurement and use of medicines and health technologies. However, due to capacity and information constraints, Partner States' EMLS and STGs are not updated on a regular basis. These instruments are also not adopted for use by the private sector.

Best procurement practices recommend that national EMLs guide the procurement of essential medicines and health technologies to prevent wastage and irrational procurement. However, quantification of requirements remains weak, further contributing to wastage.

2.2.1.3 Quality Assurance

Quality Assurance Infrastructure including Quality Control Laboratories in the Regulatory Authorities and Pharmaceutical Manufacturing Sector across EAC Partner States is generally weak. Surveillance and testing systems for substandard and falsified (SF) medicines circulating in EAC market is not conducted regularly due to limited human resources capacity and testing equipment. EAC Post-Marketing Surveillance Systems needs to be strengthened or established to ensure safe and quality medical products are available in the market.

Additionally, enforcement of regulatory guidelines regarding the promotion and advertising of allopathic and traditional medicines is non-existent. Clinical trials oversight is also weak because of non-existent of legislation and/or poor enforcement[2]. Reports from studies supported by partners across the EAC Partner States indicate that, sub-standard and counterfeit medicines are circulating in the national markets.

Chapter 21, Article 118 (c) of the EAC Treaty, calls for EAC Partner States to establish and strengthen Quality Control Capacities and Good Procurement Practices to ensure safety and efficacy of medical products circulating in the EAC Market.

Out-dated legislation, weak or non-existent enforcement and limited access for testing of medicines means that citizens are at risk of being harmed from unethical practices as well as using sub-standard s, spurious, falsified, falsely labeled, counterfeit (SSFFC) medicines.

2.2.1.4 Rational Use of Medicines and Health Technologies

Inappropriate use and over-use of medicines leads to wastage of resources, often out of pocket payments by patients and results in significant harm to patients in terms of poor patient outcomes and adverse drug reactions. Worldwide, 50% of all Medicines are prescribed, dispensed, or sold

[2] Draft EAC Medicines and Health Technologies Policy

inappropriately, while 50% of patients fail to take them correctly[3]. Common types of irrational medicines use include too many medicines per patient (poly-pharmacy), inappropriate use of antimicrobials, inadequate dosage, over use of injections over oral medications and failure to prescribe based on clinical guidelines.

The major step towards rational use of medicines was taken in 1977, when WHO established the 1st Model List of Essential Medicines to assist countries in formulating their own national lists. All EAC Partner States have adopted the essential medicines concept and have national essential medicines lists (EMLs) and selection committees are in place to support development of national Standard Treatment Guidelines (STG's).
The National Medicines Policies of Partner States also require that, STGs be used in the training of health professionals. However, capacity for developing evidence-based STGs, reviewing and updating STGs as well as adoption and use of STGs by the private sector is lacking.

Additionally, EAC Partner States with the exception of United Republic of Tanzania and Republic of Uganda do not have independent medicines information centers that can be used by prescribers, dispensers and consumers on issues related to rational use of medicines. Tanzania has a programme for training and accrediting informal drug sellers; however, it is not the norm to train informal drug sellers on rational use in all the Partner States.

Lack of access to medicines and inappropriate doses result in serious morbidity and mortality, particularly for childhood infections and chronic diseases such as hypertension, diabetes, epilepsy and mental disorders. To address irrational use of medicines, prescribing, dispensing and patient use should be regularly monitored in terms of types, amount and reasons. EAC Partner States should also established National Medicines Information Centres to educate the Public on rational use of Medicines.

2.2.1.5 Medicines Financing and Pricing

Despite the EAC region registering relatively high levels of economic development as demonstrated by year on year economic growth rates of about 5%, the share of the EAC's population below the poverty line is 38% while the share of government budget devoted to health in the region is 9% .The proportion of EAC's population covered by any form of health insurance is 25% but varies from 1% in Uganda to 15% in Tanzania, 32% in Kenya, 65% in Burundi and 95% in Rwanda[4]. Table 5 summarizes the status of health financing in the EAC Partner States.

[3] WHO Policy Perspectives on Medicines: Promoting Rational Use of Medicines, Core Components, September 2012
[4] EAC.2014.Situational Analysis and Feasibility Study of Options for Harmonization of Social Health Protection Systems Towards Universal Health Coverage in the East African Community Partner States.

Table 7: Overall Status of Health Financing in the EAC Partner States in 2013

Indicator	Burundi	Kenya	Rwanda	Uganda	Tanzania
Per capita total expenditure on health at average exchange rate (US$)	27	66	71	59	49
General Government Expenditure on Health as a proportion of General Government Expenditure (GGHE/GGE)	14	6	22	9.6	11
Percentage of THE that is out-of-pocket payments	20	45	18	49	33
Percentage of population covered by health insurance	65	32	95	1	15

Public financing for implementation of National Medicines Policies across the EAC Partner States is inadequate. All countries still rely on donor support for the procurement of essential medicines for key communicable diseases such as HIV and AIDS, Malaria and Tuberculosis.

EAC Partner States with the exception of the Republic of Uganda and United Republic of Tanzania (Zanzibar) are implementing National or Social Health Insurance Schemes. Schemes exists for co-payment by patients; and, in most instances, out of pocket payments are high and unaffordable for the poor and vulnerable.

The Republic of Rwanda is implementing pricing Policy for the public health facilities while other Partner States have no policy that promote affordability of essential medicines and improve transparency in the supply chain.

2.2.1.6 Traditional and Complementary Medicine

EAC Treaty, Chapter 21, Article 118 (f) calls for EAC Partner States to "co-operate in promoting research and the development of traditional, alternate or herbal medicines". Traditional medicine (TM) has been an important source of health care for much of the world, and many populations use and value TM not only as the source of their primary health care but also as part of their spiritual and cultural belief systems. Worldwide, people have increasingly embraced TM, also referred to as complementary and alternative medicine (CAM), by using herbal medications to complement their standard health care.

Attractive features of TM practices include greater accessibility in many parts of the world, cultural acceptance in low and middle-income countries, comparatively low cost and, often, a lesser need for modern technology. In developed countries, CAM is used for preventing disease and maintaining wellness, in addition to complementing conventional care for chronic and acute health conditions.

Although TM/CAM has a great influence on health care practices, there is wide variation from country to country in policies, laws, and regulations

governing the safety, quality, and efficacy of TM/CAM therapies in EAC. Many consumers use herbal products to treat themselves often without a health practitioner's knowledge or advice[5].

The EAC population makes use of traditional, herbal and complementary medicines to treat illnesses. The United Republic of Tanzania (Tanzania Traditional Medicines Council and Zanzibar Traditional and Alternative Medicines Council) regulates the practices and products for traditional, herbal and complementary medicines while the Republic of Rwanda regulates products only. The Republic of Uganda regulates herbal products, other EAC Partner States have no regulatory mechanisms for both products and practices. This result in possible harm to people using these products and services.

EAC Consumers and practitioners may not be adequately informed about potential adverse effects, drug interactions, and how to use herbal medicines safely. Lack of regulations on quality standards and evaluation for safety and efficacy of these products may cause problems, resulting in the marketing of unsafe or ineffective TCM products.

EAC Partner States that already have a strong pharmaceutical regulatory structure in place should adapt their existing systems to include herbal medications, and countries that lack regulatory standards should work toward setting up a national system that encompasses both pharmaceuticals and herbal medicines. All Partner States should have some framework in place to review and monitor herbal medicines, including a regulatory agency, a national advisory committee, and a system to monitor adverse reactions from herbal medicines.

Expanding the credibility and integration of Traditional Medicines and CAM will require developing an evidence base for safety and efficacy, which means consolidating data from existing national and international studies and supporting new research to fill evidence gaps.

Since, there are few standards exist to control the labeling and advertising of herbal medicines. The regulatory framework for TCM products should also include guidelines on how to educate the public, including restrictions on information and advertisements. Such regulations can be issued either by national authorities, in the form of enforceable controls, or by local organizations, such as professional groups, in the form of voluntary controls. These kinds of regulations help secure the trustworthiness of the information, prevent false health claims and misleading advertisements, and ensure the appropriate labeling of TCM products.

EAC Consumers also need to be reminded that information on the Internet is not easily controlled or regulated and that special attention is needed when evaluating online information.

2.2.1.7 Human Resource Capacity and Development for the Pharmaceutical Sector

[5] Chapter 5: Traditional and Complimentary Medicines Policy, http://apps.who.int/medicinedocs/documents/s19582en/s19582en.pdf

The development, production, distribution and appropriate utilization of medicines, as well as the supportive functions of regulation, operational research, and training require the involvement of competent pharmaceutical professionals. The successful execution of these activities is essential to strong health system and therefore, population.

Pharmacy workforce per capita varies considerably between countries and regions and generally correlates with country level economic development indicators. Countries and territories with lower economic indicators, such as those in Africa, tend to have relatively fewer pharmacists and pharmacy support workers[6]. This has implications for observed inequalities in access to medicines and medicines expertise.

EAC Pharmaceutical workforce faces challenges of performance productivity, capability and ability to adapt to new roles in the increasing dynamic environment of new technologies and innovation, rising health care costs, increased demand for health services and increased burden of chronic diseases.

The EAC region requires good leadership, strategic frameworks and policies to develop pharmacy workforce through multi-stakeholder processes involving Ministries of Health, Health Professionals Boards and Councils, regulators and Academicians to achieve both competence and practitioner excellence for health service delivery. Investment in transforming and scaling up pharmacy profession and retention strategies will provide the opportunity for pharmacists to use their professional skills to provide safe, high quality, and cost effective pharmaceutical services for the benefits of the EAC population.

To support free movement of people, goods and labor as per provisions of EAC Common Market Protocol, Pharmaceutical Human Resource continue to be a priority for the EAC Health Sector. EAC Partner States Pharmacy Boards and Councils in collaboration with Pharmacy Universities also needs to develop a harmonized guide for titles of different Pharmaceutical Cadres and Mutual Recognition of Pharmacy Professions.

2.2.1.8 EAC Domestic Pharmaceutical Production

Poor performance of EAC health sector is contributed by shortage of essential medicines and health technologies, which could be produced within the region with EAC industrial sector. 75% of the EAC pharmaceutical market demand is met through importation of medical products and health technologies while 25% is covered by local pharmaceutical production[7].

Currently, there are sixty five (65) pharmaceutical companies in the East Africa region and only two (2) of pharmaceutical manufacturers are pre-qualified by the World Health Organization WHO cGMP and produced prequalified products. EAC pharmaceutical manufacturing sector focus on

[6] International Pharmaceutical Federation (FIP), Human Resources - the 2012 FIP Global Pharmacy WorkforceReport,http://www.fip.org/files/fip/PharmacyEducation/2012/2012_Workforce_report_english.pdf

[7] EAC Pharmaceutical Manufacturing Plan of Action (RPMPoA 2012-2015)

producing finished pharmaceutical products (FPP) and few produced Active Pharmaceutical Ingredient (API), medical devices and veterinary biotechnology manufacturing facilities.

The East African health supplies market is large and expanding, but is not benefitting locally based manufacturers due to high percentage of imported medical products; rising barriers to market entry for domestic pharmaceutical manufacturers; increasing import price competition, power and infrastructure constrains; limited human resource skills and knowledge to cope with innovation and technology development; duties and tariffs discourage domestic pharmaceutical manufacturers; limited involvement of Pharmaceutical Manufacturers in national procurement and public sector support; and regulatory approval delays[8].

EAC domestic pharmaceutical manufacturers are key players to achievement of UN Sustainable Development Goals, however, the sector is still at infant stage due to weak physical and quality infrastructure, lack of conducive policy environment and policy coherence across sectors health, industry, trade, commerce/customs and poor surveillance and testing systems for substandard, spurious, falsified, falsely labelled, counterfeit (SSFFC) medicines leading to the EAC market being flooded by SSFFC medical products .

Table 8: Pharmaceutical Manufacturing Opportunities in East Africa Region

Country	Number of Pharmaceutical Manufacturers	Population	Ratio
India	30000	1.2 billion	1:60,000
East Africa: 5 Countries	**65**	**145 million**	**1:2,153,000**
Comesa: 20 Countries	< 200	400 million	1:2,000,000
Africa: 54 Countries	< 500	1.1billion	1:2,200,000

Opportunities exist for EAC Pharma sector as indicated in Table 6. The EAC market is expanding and pharma sector should capitalize the available market and ensure medical products produced domestically are safe, efficacious and of high standards to build customer trust and confidence inline with the theme of the 1st EAC Manufacturing Business Summit of ***"Buy East African-Build East Africa (BEABEA)"***.

A stepwise approach should be taken by the Pharma sector towards implementation and domestication of the EAC harmonized GMP Standards[9] to ensure domestic pharmaceutical industry stays competitive at regional and international level. Additionally, the East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme[10] provides incentives to the EAC Pharmaceutical Manufacturing Sector. Single launch of application

[8] Minutes of Roundtable Discussions on Pharmaceuticals Value Chain: 1st EAC Manufacturing Summit, 1st September 2015
[9] EAC GMP Compedium of, 2014
[10] EAC-MRH Programme Document,2009. www.mrh.eac.int

for registration of domestically produced medical products to be marketed in all five Partner States, EAC joint dossier evaluation and EAC Joint GMP inspections reduce duplication of efforts, costs and time to the EAC Pharma sector.

2.2.1.9 Health Technologies Research, Development and Innovation

Effective research and development, technology and innovation are key requirements for growth of the EAC pharmaceutical sector and improving access to medical products and health technologies. Whilst all Partner States have undertaken several attempts to promote Research and Development (R&D) and technology transfer, these have been met with limited success.

Factors that hamper progress include limited funding, weak intellectual property regimes [11]and inadequate frameworks to support innovation and technology transfer.

The EAC Industrialization Policy, 2012 – 2017, has Technology and Innovation as one of its key policy areas[12]. EAC Medicines and Health Technologies Policy [13]is aligned to EAC Industrialization Policy to strengthen capacity, development and use of innovation and technology for the mutual benefit of the EAC region.

Additionally, operational research is critical in assessing the impact of pharmaceutical policy interventions on the health system. The research helps to facilitate implementation, monitoring and evaluation. Innovation, Technology Transfer, Research and development for the Pharmaceutical Sector remains weak in all EAC Partner States and opportunities for skills and technology transfer have not been exploited.

East African Health Research Commission (EAHRC) became operational in July 2015 after all EAC Partner States deposited the instruments of ratification for the Protocol to the EAC Secretary General's Office. The EAHRC have been established as a regional body to coordinate regional research activities however, regional research priorities for the pharmaceutical sector are lacking.

There is need to support the development of operational and scientific research in strategic areas of pharmaceutical sector, development of harmonized regulatory framework and guidelines for control of Clinical Trials, strengthen information sharing and establishment of Pharmaceutical Observatory as a resource for evidence-based decision making.

2.2.1.10 Administrative and Institutional Framework

Good Governance is broad concept that implies a system which is consensus oriented, accountable, transparent, responsive, equitable and inclusive,

[11] EAC TRIPS Policy and Approximation of Public Health Intellectual Property
[12] EAC Industrialization Policy 2012-2017
[13] Draft EAC Medicines and Health Technologies Policy 2016-2021

effective and efficient, follows the rule of law, and is participatory [14]. An estimated amount of US $ 5.3 trillion is spent worldwide in providing health services and 25% of the total health expenditure is spent on Pharmaceuticals [15,16]. However, due to lack of transparency in decision making, lack of accountability for decision made are some of the opportunities that create opportunities for corrupt practices and increase likelihood of governance breakdown.

Good governance within health systems and accountability of service providers are essential for functioning health systems to deliver preventive and curative services. The Pharmaceutical sector is highly lucrative due to high market value but also increasingly vulnerable to corruption and unethical practices. Recognizing that good governance matters for improved health outcomes and return on development investments, global institutions like the World Bank, the World Health Organization (WHO) Good Governance for Medicines Programme (GGM), the Global Fund for HIV/AIDS, Tuberculosis, and Malaria (Global Fund), and the UK Department for International Development (DFID) through the Medicines Transparency Alliance (MeTA) have launched a number of initiatives in the past decade[17].

In EAC region, the capacity and performance of the public sector dealing with pharmaceutical matters is generally low resulting in inadequate implementation of policies and strategies. Constraining factors include poor governance and ineffective monitoring and evaluation frameworks. There is also weak coordination of policies, strategies and programmes; weak capability to design, monitor and implement policies as well as weak management systems; weak incentives for improvements and performance; challenges with private sector engagement; and challenges to use information, communication and technology for improved public sector delivery.

2.2.1.11 Linkages and Collaboration

The pharmaceutical sector is a specialized, economic entity with linkages across several sectors. It operates in a highly globalized and interconnected manner. Multi-sector and international collaboration and cooperation are essential to comprehensively address the intricate and complex issues and to safeguard public health and safety.[18]

Across the EAC Partner States, there is also a lack of a shared understanding and subsequent collaboration between key Ministries i.e. health, trade and industry. The line Ministries executes its mandate in silos leading to duplication of efforts, limited focus and scope, which has negative

[14] What is good governance? http://www.unescap.org/pdd/prs/ProjectActivities/Ongoing
[15] Spending on health. Fact Sheet No. 319. Geneva, World Health Organization, 2004. Available at:

[16] The world Medicine Situation 2011. Good Governance the Pharmaceutical Sector, Jillian Clare Kohler and Guitelle Baghdadi-Sabeti
[17] Why the MDG's need good governance in pharmaceutical systems to promote global health, Jillian Clare Kohler, Tim Ken Mackey and Natalia Ovtcharenko, BMC Public Health 2014.
[18] Adopted from Kenya's Sessional Paper No 4 of 2012 on National Pharmaceutical Policy

impact to equity and access of medicine and health technologies.

Due to poor implementation, or a narrower focus, no platforms exist in the Partner States for structured dialogue between policy-makers, regulators, private sector and civil society to address the challenges facing the pharmaceutical sector.

2.5 SWOC Analysis of the EAC Medicines and Health Technology Sector

This section presents an overall summary analysis of the strengths, weaknesses, opportunities and challenges (SWOC) of the EAC medicines and health technology sector.

2.5.1 Strengths

- Existence of the EAC Integration Pillars i.e Common Market and Customs Union
- Harmonization Initiatives in the EAC Pharmaceutical Sector
- EAC Partner States have National Medicines Policies, Legislation and Regulations
- Existence of human resource with technical skills in pharmaceutical regulation, production, quality control, procurement, research and development
- Existence of semi-autonomous institutions to oversee safety and quality of medicines and health technologies in some Partner States
- Existence of an enabling strategic policy context and political will towards strengthening domestic pharmaceutical production at African Union and EAC Level.
- Positive economic growth in all the five Partner States and relative socioeconomic stability.
- Inflow of foreign and donor funding to support EAC pharmaceutical sector

2.5.2 Weaknesses

- Inadequate access to medicines and health technologies
- Some Partner States have outdated pharmaceutical policies, legal and regulatory frameworks
- High prices of medicines especially for domestic produced medical products and health technologies
- Limited domestic pharmaceutical manufacturing capacity leading to reliance on importation
- Lack of domestic supply of active pharmaceutical ingredients, excipients and packaging materials.
- Domestic manufacturers unable to meet WHO pre-qualification requirements due to limited resources (human, infrastructure and technology)
- Poor investment environment due to lack of clear incentives and policies that promote domestic pharmaceutical production.
- Limited research, innovation and development for the Pharmaceutical Sector

- The relevant laws on pharmaceuticals and intellectual property are not TRIPS compliant.
- Limited public health financing
- Divergent treatment guidelines and essential medicines lists across Partner States
- Poor distribution network for medicines and health technologies.
- Lack of timely and accurate market information to aid in decision making.

2.5.3 Opportunities

- Existence of regional and continental efforts on Medicines Regulatory Harmonization
- Some Partner States have well developed regulatory systems and domestic production which is used to build capacity of less resourced NMRAs
- EAC Partner States are in the process of reviewing their Medicines Policies and Legislative instruments to enhance access to safe and quality medicines and health technologies
- Regional Models for Joint Registration of Medical Products, Joint Inspection of Pharmaceutical Manufacturers and Pooled Bulk Procurement save on time, resources and improve efficiency.
- Support from Development Partners for the EAC Pharmaceutical Sector improves service delivery and positive impact to health outcomes
- Presence of Strong and Vibrant health Research Institutions to support Research & Development for the Pharmaceutical Sector

2.5.4 Challenges

- Political Instability for Some Partner States will delay integration and harmonization in the pharmaceutical sector
- Lack of regional institution to sustain medicines regulatory harmonization
- Different levels of development of EAC Partner States NMRAs
- Introduction of substandard and falsified medicines into the market
- Inefficient pharmacovigilance and post market surveillance systems
- Unregulated supply chain system (procurement, selection, pricing, prescribing, distribution, dispensing and use)
- Inability of domestic pharmaceutical manufacturers to meet regional demand
- Poor investment environment due to unreliable infrastructure for water, electricity and transport
- Lack of human resource retention strategies for the pharmaceutical sector

2.6 Introduction of the EAC Medicines and Health Technologies Strategic Plan (2018-2022)

The EAC Medicines and Health Technologies Strategic Plan (2018-2022) was developed to articulate the EAC's strategic direction on how to address issues related to:

- Equitable access, availability and affordability of medicines, health technologies and pharmaceutical services.
- Quality, Safety and Efficacy of all Medicines and Health Technologies
- Rational Use of Medicines by Health Professions and Consumers.
- Collaboration between Public and Private Sectors, Civil Society, Regional and International Agencies and
- Human Resource for the Pharmaceutical Sector

The strategic plan have outlined strategic interventions in line with the main components of the EAC Medicines and Health Technologies Policy to address challenges facing EAC Partner States in accordance with the functions and mandate of the EAC Secretariat and previous directives of the Sectoral Council of Ministers responsible for regional cooperation on Health.

The strategic plan development adopted an inclusive, participatory and appreciative approach that involved extensive engagement and consultations with and sharing of experiences and learning among the diverse EAC Partner States's stakeholders both at the national and regional levels.The strategic plan covered all the EAC Partner States namely Burundi, Kenya, Rwanda, South Sudan, Uganda and United Republic of Tanzania.

3.0 CHAPTER THREE: STRATEGIC AGENDA

3.1 Goal

The goal of the EAC Medicines and Health Technologies Policy is to ensure an adequate and reliable supply of safe, efficacious, quality and affordable medicines and health technologies to all people of the EAC and their rational use by prescribers, dispensers and consumers.

The Strategic Plan (2018-2022) serves as a guide to EAC Partner States in promoting the following Policy objectives:

- Equitable access to medicines, health technologies and pharmaceutical services.
- Quality, safety and efficacy of medicines and health technologies.
- Therapeutically sound and cost-effective use of medicines by health professionals and consumers.
- Rational use of medicines
- Promote domestic pharmaceutical and health technologies production
- Facilitate research, innovation and development in the pharmaceutical and health technologies sectors
- Increased collaboration and cooperation between public, private, civil societies and regional and international agencies.
- Timely and relevant implementation strategies that include developing and retaining skilled human resources, dealing with emergencies and evidence-based decision-making.

Strategies outlined in this plan addresses all factors that could compromise effective utilisation of medicines, health technologies and pharmaceutical services to ensure provision of good quality services in line with legitimate needs of the consumers.

3.2 Strategic Priorities

The EAC Medicines and Health Technologies Strategic Plan (EACMHTSP 2018-2022) outlines implementation strategies as provided for in the EAC Medicines and Health Technologies Policy. The Policy has identified the following priority areas:

- Legal and regulatory framework
- Medicines and health technologies supply chain management
- Quality Assurance
- Rational use of medical products and information
- Medicines financing and pricing
- Traditional, herbal and complementary medicines
- Human Resource capacity and development for the pharmaceutical and health technology sectors
- Domestic production of medical products and health technologies
- Health technologies innovation, research and development

- Information systems
- Administrative and institutional framework
- Linkages and collaboration

3.2.1 Legal and Regulatory Framework

During the period of implementation of this Strategic Plan, emphasis will be placed on development of regional legislation and regulatory frameworks to address challenges of outdated legislation in EAC Partner States; support establishment of independent national and regional regulatory authorities and promote cooperation and eventual mutual recognition agreements amongst Partner States NMRAs and other regulators.

Policy Objectives	1. To develop a regional legal and regulatory framework to ensure access to safe, efficacious, affordable and quality assured medicines and health technologies to the EAC citizens. 2. To develop a regional legal and regulatory framework for pharmacy and health technology professionals and practices to ensure high standard of quality services.
Indicators	1. Number of established autonomous or semi-autonomous NMRAS 2. Number and percentage of Partner States with revised legislative frameworks 3. Number of Partner States NMRAs implementing EAC Cooperation Framework Agreement 4. Number of Partner States NMRAs implementing EAC Mutual Recognition Agreements 5. Existence of the EAC Medicines and Food Safety Agency (EACMFSA)
Baseline	1. Four (4) Semi- autonomous NMRAs (Kenya-PPB, Uganda-NDA and United Republic of Tanzania (TFDA & ZFDA); 2. Draft EAC cooperation framework Agreement
Targets (2022)	1. The Republic of Rwanda and Republic of Burundi to have semi-autonomous NMRAs 2. EAC Medicines Agency to sustain regulatory harmonization activities established 3. Mutual recognition agreements between two or more partner states implemented

Strategies

1. Enact or amend, enforce and harmonize the legislation required to enable effective regulation of medicines, health technologies and pharmaceutical service and professionals

2. Develop, update and harmonize EAC guidelines on regulation of medicines and health technologies

3. Establish new and strengthen existing autonomous national and regional medicines regulatory authorities

4. Support implementation of harmonization initiatives for medicines and health technologies in the EAC region.

Strategy 1: To enact or amend, enforce and harmonize legislation required to enable effective regulation of medicines, health technologies and pharmaceutical services/practice						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1) EAC Pharmaceutical Law developed and adopted by Partner States by December 2019	Partner States legislations	1. Number of Partner States adopting EAC Pharmaceutical Law	1. To review the EAC partner states Pharmaceutical legislation for regulation of medicines and health technologies; and pharmaceutical services/practice 2. To develop regional legislation for Partner States to regulate medicines and health technologies; and pharmaceutical services/practice 3. Conduct consultative meetings to validate EAC Pharmaceutical Law 4. To support Partner States to domesticate EAC Pharmaceutical Law	Partner states Governments, Ministry responsible for Health, Legal and Judicial Affairs, Livestock and Agriculture, EAC National Medicines Regulatory Authorities, East African Legislative Assembly (EALA), EAC Policy Organs, WHO, CSO's, NGO's, Private Sector, Development Partners and Media	**424,600**	2018-2022
Strategy 2: Develop, update and harmonize EAC guidelines on regulation of medicines and health technologies.						

Output (s)	Baseline (s)	Indicator (s)	Interventions/activities	Actors	Estimated costs in USD	Timeframe
1) EAC Joint GMP Inspections sustained between 2018 to 2022 2) All existing EAC harmonized guidelines reviewed by December 2020 3) Guidelines for regulation of medical devices and diagnostics harmonized by June 2022 4) EAC guidelines on Pharmacovigilance and post-marketing surveillance harmonized by June 2022 5) EAC guidelines for control of clinical trials harmonized by June 2022 6) EAC guidelines on import and export	EAC harmonized Guidelines	1. Number of Partner States that have adopted and domesticated EAC Guidelines 2. Number of EAC Joint Assessments and inspections conducted	1. To conduct a desk review of existing guidelines 2. To organize regional workshops to draft the guidelines 3. To conduct consultative stakeholder meetings to validate the draft guidelines 4. To organize EAC policy organ meetings to approve the guidelines. 5. To print and disseminate guidelines 6. To conduct EAC Joint activities on assessments, GMP, GCP, GLP, PV, PMS and Clinical Trial protocol reviews at national,	Partner States Governments, Ministry responsible for Health, Legal and Judicial Affairs, Livestock and Agriculture, EAC National Medicines Regulatory Authorities, WHO, AU-NEPAD, BMGF, WB, Stringent NRAs, other Development Partners, Media	**833,800**	2018-2022

of medicines and health technologies harmonized by June 2022 7) EAC guidelines on registration of veterinary medicines domesticated and implemented by June 2022 8) EAC harmonized guidelines for registration of human medicines, GMP inspection and QMS adopted by the Republic of South Sudan by December 2019 9) EAC Mutual Recognition Agreement (MRA) for NMRAs and pharmacists executed by June 2022			regional and international level 7. To support the implementation of the MRAs			
Strategy 3: To establish new and strengthen existing autonomous National and Regional Medicines Regulatory Authorities						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in**	**Timefra me**

					USD	
1) EAC Medicines and food safety Agency (EACMFSA) established by December 2019 2) Burundi semi-autonomous NMRA established by June 2019 3) EAC Partner States NMRAs strengthened by December 2022	Four (4) Semi-autonomous NMRAs existing in EAC Draft protocol for Establishment of EAC Medicines and Food Safety Agency	1. Bill for establishing EAC Medicines and Food Safety Agency 2. Republic of Burundi to have a functional and autonomous institution to oversee regulation of medicines and health technologies 3. Republic of Rwanda to operationalize the NMRA	1. To develop a concept Note for establishing EACMFSA adoption by EAC Council of Ministers 2. To draft the protocol for establishing EAC Medicines and Food Safety Agency 3. To conduct consultative meetings to validate the draft Protocol for establishing EACMFSA at national and regional level, East African Community Parliamentary Committee on Health and Population and EALA 4. To support approval of the protocol through policy organs of the EAC 5. To support operationalization of the EACMFSA 6. To conduct assessment	Partner States Governments, Ministry responsible for Health, Legal and Judicial Affairs, Livestock and Agriculture, EAC National Medicines Regulatory Authorities, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, Stringent NRAs, other Development Partners, Media	1,350,000	2018-2022

			of Policy, Legislative and institutional requirements for establishing semi-autonomous NMRAs for the Republic of Burundi 7. To mobilize resources (technical, financial, infrastructure and human) to support establishing of NMRAs of the Republic's of Rwanda and Burundi			
Strategy 4: To support implementation of harmonization initiatives for medicines and health technologies in the EAC region.						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1) EAC harmonization programmes sustained and implemented by EAC Partner States NMRAs by December 2021 2) EAC-MRH Scope expanded to include	EAC-MRH Programme	1. Number of EAC Joint Assessments and EAC Joint GMP Inspections conducted 2. Number of activities for EAC on harmonization and strengthening of pharmacovigilance	1. To develop sustainability strategy for EAC harmonization programmes for medicines and health technologies 2. To mobilize resources to support implementation of EAC harmonization programmes	Governments, Ministry of Health EAC National Medicines Regulatory Authorities, EAC Policy Organs, East African Community Parliamentary	**676,500**	2018-2022

Pharmacovigilance and Post Market Surveillance, regulation of Clinical Trials and Medical Devices by December 2021		systems for medical products, Vaccines and Health technologies conducted. 3. Number of activities for EAC on harmonization of regulatory frameworks for control of clinical trials for medical products, vaccines and health technologies conducted 4. Number of activities for EAC programme on harmonization of regulatory framework for regulation of medical devices and diagnostics conducted 5. Number of activities for EAC programme on strengthening post market	3. To implement EAC programme on harmonization and strengthening of Pharmacovigilance systems for medical products, Vaccines and Health technologies conducted. 4. To implement EAC programme on harmonization of regulatory frameworks for control of clinical trials for medical products, vaccines and health technologies 5. To implement EAC programme on harmonization of regulatory frameworks for regulation of medical devices and diagnostics 6. To support implementation of EAC programme on strengthening post market surveillance	Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, Stringent NRAs, other Development Partners, Media National medical Research Institutes National Health Ethical Committees Sponsors, Principal Investigators, Clinical Research Organizations (CROs) AVAREF		

		surveillance (PMS) systems conducted	systems			
				TOTAL	**3,284,900**	

MEDICINES AND HEALTH TECHNOLOGIES SUPPLY CHAIN MANAGEMENT

Effective and Efficient supply chain management system in the EAC region will ensure availability and accessibility of cost-effective and quality medicines and health technologies for treatment of priority diseases to the EAC population including the poor and vulnerable.

This plan will put emphasis on systems for strengthening selection, quantification, forecasting, procurement, storage, distribution and disposal of medicines and health technologies.

Policy Objective	To strengthen supply chain management of medicines and health technologies
Indicators	1. Percentage availability of essential medicines in the Public supply chain 2. Number of EAC Partner States with reliable systems for regular and accurate quantification and forecasting of medicines and health technologies at all levels of the health systems. 3. Percentage of unfit medicines and health technologies disposed annually 4. Number of legislation governing procurement of medicines and health technologies enacted and implemented in the partner states 5. Number of EAC pooled bulk procurement for essential medicines and health technologies
Baseline	None. To be determined in 2018
Targets (2021)	1. EAC Pooled Bulk Procurement for Medical Products and Health Technologies operationalized by December 2021

Strategies

1. Develop EAC guidelines, tools and standards in line with essential medicines concept to ensure rational selection, procurement, storage, inventory, use and disposal of medicines and health technologies in the region.

2. Establish and/or Strengthen EAC Partner States Systems for Effective and Efficient Procurement of Medicines and Health Technologies and Quantification Capacities.

3. Establish and Operationalize EAC Pooled Bulk Procurement Mechanisms for medicines and Health Technologies

Strategy 1: Develop EAC guidelines, tools and standards in line with essential medicines concept to ensure rational selection, procurement, storage, inventory, use and disposal of medicines and health technologies in the region.						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1) EAC Guidelines on Good Procurement Practices for Medicines and Health Technologies developed by March 2019 2) EAC Guidelines to respond to Pharmaceutical Emergencies and donated Medicines and Health Technologies developed by June 2019 3) EAC guidelines for recall and safe disposal of expired and unwanted Medicines and Health Technologies developed by March	Partner States Procurement guidelines and tools	1. Number of guidelines developed 2. Number of Partner States adopting EAC Guidelines, tools and Standards for rational selection, procurement, storage, use and disposal of medicines and health technologies	1. Conduct a desk review of existing guidelines 2. To organize regional workshops to draft the guidelines 3. Conduct consultative stakeholder meetings to validate the draft guidelines 4. Organize EAC policy organ meetings to approve the guidelines. 5. Printing and dissemination of guidelines	Partner states Governments, Ministry of Health, National Medical Stores Departments, WHO, CSO's, NGO's, Private Sector, Development Partners, Media Ministry of Finance	**700,000**	2018-2022

2019 4) EAC guidelines on good distribution and storage practices developed by June 2019						
Strategy 2: Establish and/or Strengthen EAC Partner States Systems for Effective and Efficient Procurement of Medicines and Health Technologies and Quantification Capacities.						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. EAC Procurement (including bulk procurement mechanisms) legislation and regulations enacted by June 2022 2. EAC Centre of excellence for procurement and supply chain management established by December 2021 3. Integrated Logistics Management	None KEMSA-Kenya MSD-Tanzania CAMERWA-Rwanda NMS-Uganda CAMEBU-Burundi EAC Centre of	1. EAC procurement legislation in place 2. EAC Centre of excellence for procurement and supply chain management in place 3. Number of Partner States with automated system for quantifying needs for medicines and health technologies	1. To review existing legislation and systems in the Partner states 2. To conduct meetings of experts to draft the legislation 3. To organize consultative stakeholder meetings to validate the draft legislation 4. To approve the legislation within the EAC 5. To assess the central	Partner states Governments, Ministry of Health, Ministry of Finance, Public Procurement Agency/Regulatory Authority National Medical Stores Departments, WHO, CSO's, NGO's, Private Sector, Development Partners and Media	**945,400**	2018-2022

system(ILMS) developed by December 2021 4. Supply chain management systems(SCMS) in the partner states strengthened by June 2022	excellence on immunization and supply chain management for vaccines-Rwanda	4. Number of personnel trained on Good Procurement Practices and Quantification Methods	medical stores of the partner states to be designated as centre for excellence 6. To support EAC Partner States to establish and maintain an Integrated Logistics Management system(ILMS) 7. To build capacity of EAC Partner States on Good Procurement Practices and Quantification 8. To strengthen Supply chain management systems(SCMS) in the partner states			
Strategy 3: To establish and operationalize EAC Pooled Bulk Procurement Mechanism for Medicines and Health Technologies						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. EAC pooled Bulk procurement feasibility study conducted by December 2018. 2. EAC Essential	Draft Proposal on Pooled Bulk Procurement	1. Feasibility study report in place 2. 45% of the public sector pharmaceutical	1. To conduct a feasibility study on pooled bulk procurement for medicines and health technologies in the EAC region	Partner states Governments, Ministries responsible for Health, Trade and industry National Medical	**1,100,900**	2018-2022

medicines and health technologies list for pooled bulk procurement developed by June 2019 3. EAC pooled Bulk procurement mechanism established by June 2020.	11 essential medicines identified for pooled procurement through feasibility study of 2007 67% of the medicines were procured above lowest international reference prices(IRP) in 2007	purchases made through EAC Pooled Bulk Procurement Scheme 3. 45% Active Pharmaceutical Ingredients and packaging materials used in the Public and Private Domestic Pharmaceutical Manufacturing Sector procured through regional pooled bulk procurement scheme 4. EAC EML in place 5. EAC EML tracer medicines in place	2. To identify the essential medicines and health technologies to be considered for pooled bulk procurement. 3. To coordinate and oversee the EAC pooled bulk procurement program 4. To build national and regional capacity to coordinate and implement EAC Pooled Bulk Procurement program	Stores Departments, medicines and health technologies manufacturing industries, Global Fund, UN Agencies, CSO's, NGO's, Private Sector, Development Partners and Media		
				TOTAL	**2,746,300**	

QUALITY ASSURANCE

Quality Assurance infrastructure including Quality Control Laboratories in Regulatory Authorities and Pharmaceutical Manufacturing Sector across EAC Partner States is required to ensure safe and quality medicines and health technologies are available to the population. The focus of this plan will be to strengthen quality assurance systems in the entire spectrum of the medicines and health technologies sector.

Policy Objective	To establish and strengthen quality assurance infrastructure and capacities to ensure safety, quality and efficacy of medicines and health technologies to protect and promote public health in the EAC region.
Indicators	1. Number of ISO certified NMRAs, procurement agencies, health institutions and professional councils 2. Number of Quality Control Laboratories accredited by the World Health Organization (WHO) and International Standards Organization (ISO) 3. Number and percentage of substandard and falsified medicines and health technologies detected in the EAC market 4. Number of qualified professionals in the medicines and health technologies sector.
Baseline	1. One (1) NMRA and two (2) procurement agencies are ISO certified 2. Three (3) Quality Control Laboratories are WHO prequalified
Targets (2022)	1. All NMRAs procurement agencies and professional councils to be ISO certified 2. Three (3) Quality Control Laboratories to be prequalified by WHO and ISO Certified 3. EAC Medicines and Food Safety Agency operational 4. EAC region free of substandard and falsified medicines and health technologies 5. EAC Centre for Chemical Reference Standards operational

Strategies

1. To develop and strengthen quality assurance systems and quality control capacities for the EAC medicines and health technologies sector.

2. To enhance efficiency and effectiveness of regulatory and procurement agencies to enforce regulations for safety, quality and efficacy of medicines and health technologies.

Strategy 1: To develop and strengthen Quality Assurance Systems and Quality Control Capacities for the EAC medicines and health technologies sector.						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1) EAC quality assurance systems implemented by June 2022 2) EAC Centre of Excellence for Chemical Reference Standard established by June 2018	EAC harmonized guidelines and common technical documents 7 NMRAs and quality control laboratories	1. EAC medicines and food safety agency in operation 2. Number of NMRAs implementing quality assurance activities 3. Number of NMRAs and Quality control laboratories ISO certified and prequalified by WHO respectively 4. Number of Partner States utilizing services of EAC Centre for Chemical Reference Standards 5. Number of joint activities conducted in EAC region	1. To recruit and train staff of the EACMFSA 2. To conduct joint evaluation and inspection to verify compliance to GMP, GCP, GLP, GDP and GSP requirements 3. To conduct PMS programs to identify SF in the EAC market 4. To conduct PV activities to detect unsafe medicines and health technologies. 5. To control importation and exportation of medicines and health technologies in the EAC region. 6. To control the conduct of clinical trials in the	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities, Government Chemists, Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs,	**1,845,700**	2018-2022

			EAC region 7. To control advertisement and promotion of medicines and health technologies in the EAC region. 8. To support National Medicines Regulatory Authorities and Quality Control Labs to attain ISO certification and WHO prequalification 9. To procure and supply chemical reference standards for QC labs and pharmaceutical industries in the EAC region	other Development Partners, Media		
Strategy 2: To enhance efficiency and effectiveness of regulatory and procurement agencies to enforce regulations for professional services, safety, quality and efficacy of medicines and health technologies.						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timefra me**

1) The EAC Centers of excellence for registration of medicines, pharmacovigilance and PMS, GMP, CRS, Vaccine, immunization and Health Supply Chain Management strengthened by June 2019 2) EAC Clinical Research Organization(CRO) for conducting bioequivalence studies established by June 2022 3) EAC action plan for combating substandard and falsified products (SFs) developed and implemented by December 2020 4) EAC plan for combating	Existing centres of excellence National action plans for combating AMR	1) EAC CRO in place 2) Action plan for combating AMR and SFs in place. 3) Number of personnel trained at the centres of excellence	1) To support (technical and financial) to the Centers of excellence in performance of their functions 2) To conduct training of EAC experts at the Centers of excellence 3) To support establishment of the EAC CRO for Bioequivalence studies 4) To review the Partner states national action plans on SFs and AMR 5) To organize meetings to draft the EAC action plans for SF and AMR. 6) To conduct stakeholder consultative meetings to validate the draft action plans 7) To conduct joint EAC PV and PMS activities	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media	**956,900**	2018-2022

antimicrobial resistance(AMR) developed and implemented by June 2020 5) EAC health professionals authority established			8) To support Partner States to establish and strengthen QA infrastructure.			
				TOTAL	**2,802,600**	

RATIONAL MEDICINES USE AND INFORMATION

The focus of the Strategic Plan will be advocate for establishment and strengthening Partner States Therapeutics and Poisons Information Centers/Committees use affordable health technologies and ensure patients to receive correct medicines at the right time in adequate doses at a price they can afford together with appropriate information on how to use the medicines.

Policy Objective	To promote rational and safe use of medicines and health technologies by prescribers, dispensers and patients as well as facilitating access to unbiased sources of medicines information.
Indicators	1.% Reduction in Antimicrobial resistance 2. Number of ADRs reported in the region 3. % of adherence to the Standard Treatment guidelines
Baseline	1.Pharmacovigilance canters of the United Republic of Tanzania(Mainland & Zanzibar), Republic of Uganda, Republic of Kenya and Republic of Burundi 2. Standard Treatment guidelines and Essential medicines lists in partner states 3. Rational Use Medicines Communication strategy for the United Republic of Tanzania and Republic of Uganda
Targets (2022)	1.Functional Pharmacovigilance Information Centre 2. STGs and EMLTs reviewed every three years

Strategies

1. Promote rational use of medicines and health technologies by consumers, dispensers, prescribers and other healthcare workers
2. Establish and integrate a system for managing of drug abuse, overdose, poisoning, and adverse drug reactions into health care delivery services.
3. Develop a mechanism for regular monitoring of antimicrobial resistance and ensure enforcement of prescribing and dispensing practices

Strategy 1:. Promote rational use of medicines and health technologies by consumers, dispensers, prescribers and other healthcare workers						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1.Prescribing and dispensing practices improved by June, 2022 2. Awareness in rational use of medicines created in communities of all EAC partner states by June, 2022	1.None 2.Moi Teaching hospital in the Republic of Kenya Rational Use Medicines Communication strategy for the United Republic of	1. % reduction in medication errors 2. Number of hospitals implementing patients individualized dosage 6. % increase in awareness of rational use medicines in partner states	1. To conduct baseline assessment on prescribing and dispensing practices in the EAC region. 2. To review STGs and EMLs in all partner states 3. To print and disseminate the STGs and EMLs to healthcare providers 4. To strengthen Medicines and Therapeutic Committees in health facilities 5. Train and Promote patient tailor made dosage practices in partner states 6. To monitor the use of	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM,EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, hospitals,MTCs, EALA WHO, AU-NEPAD, BMGF, WB, PTB,	**537,200**	2018-2022

	Tanzania and Republic of Uganda 2. Standard Treatment guidelines and Essential medicines lists in partner states		STGs and EMLs in health facilities 7. To develop RUM communication strategies in other EAC partner states 8. To conduct community awareness programmes on medicines and health technologies use in the EAC region.	GIZ, UNIDO, Stringent NRAs, other Development Partners, Media Health Professional boards and councils Consumers Associations Government Chemists		
Strategy 2.Establish and integrate a system for managing of drug abuse, overdose, poisoning, and adverse drug reactions into health care delivery services.						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**

1Pharmacovigilance/poison/call center established/strengthened in the region by June,2022	Existing centers in EAC partner states.	1. Number of centers in the EAC –Partner states 2. % of the budget funded 3. Number of report shared	1. Conduct a baseline survey to identify the gaps 2. Mobilize resources to operationalize/ strengthen the centers 3. Monitor the implementation of activities 4. Share the information/ reports amongst partner state	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media and Local communities	**125,500**	2018-2022
Strategy 3: Develop a mechanism for regular monitoring of antimicrobial resistance and ensure enforcement of prescribing and dispensing practices						

Output (s)	Baseline (s)	Indicator (s)	Interventions/activities	Actors	Estimated costs in USD	Timefra me
1. Antimicrobial action plan established and implemented in EAC partner states by 2022 Mechanism of monitoring AMR available in all partner states by 2022	Existing Action plans in the EAC region	1. Number of partner states implementing the EAC mechanism for monitoring AMR 2. Number of reports on antimicrobial resistance in the EAC partner states	1. Support the development/strengt hening of antimicrobial action plans in partner states. 2. Develop EAC mechanisms for regular monitoring of anti-microbial resistance 3. Support establishment of mechanism to monitor AMR. 4. Monitor and evaluate the implementation of Antimicrobial Action Plan in EAC partner states 5. Share information on	Ministries of Health, Vertinary and Agricultures, NMRAs, Research Institutions, Universities and Hospitals		

			AMR amongst EAC partner states			
					TOTAL	**662,700**	

MEDICINES AND HEALTH TECHNOLOGIES FINANCING AND PRICING

Public financing for implementation of National Medicines Policies across the EAC Partner States is inadequate. Efforts will be made to ensure resources available are effectively utilized and equitably shared. It is imperative additional resources are identified and reduce out of pocket expenditures on medicines. EAC Partner States with exception of the Republic of Uganda and United Republic of Tanzania (Zanzibar) are implementing National or Social Health Insurance Schemes. National health insurance if implemented within the strategic period, will contribute to bridging the gap.
The Republic of Burundi is implementing pricing policy for the public health facilities while other Partner States have no policy that promote affordability of essential medicines and improve transparency in the supply chain.

Policy Objective	1. To establish mechanisms for control of pricing of medical products and health technologies; 2. To advocate for implementation of social health insurance schemes in all EAC Partner States;. 3. To encourage EAC Partner States to mobilize financial resources for medical products and health technologies and ensure optimum utilization
Indicators	1. Per capita expenditure on medicines, 2. Reduced percentage of out of pocket expenditures 3. Percentage of partner states using Universal Health coverage
Baseline	Existing Per capita expenditure for medicine, Health Insurance Schemes and out of pockets in the partner states
Targets (2022)	

Strategies

1. To sustainably mobilize resources for financing the procurement of quality essential medicines and health technologies
2. Establish and maintain systems for the efficient utilisation and tracking of funding for medicines and health technologies
3. Develop cost-containment strategies and price regulation and monitoring of medicines and health technologies for both public and private sector.

Strategy 1: To sustainably mobilize resources for financing the procurement of quality essential medicines and health technologies						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Adequate financial resources made available for essential medicines and health technologies by 2022 3. Social Health Insurance Schemes established/ strengthened in the Partner states by December 2022	EAC – Partner states budgets	1. % Increase of per capital expenditures for medicines and health technologies 2. % of health Insurance schemes revenue that go for Medicines and health technologies allocation 3. Number of clients on National Health Insurance Schemes	1. Advocate for EAC Partner States to increase budget allocation medicines and health technologies 2. Partner states to mobilize financial resources to cover the budget gap for medicines and health technologies 3. Advocate for EAC Partner States to implement National/Social Health Insurance Scheme 4. Enact legislation for National/ Social	Partner States Governments, Ministry of Health, Ministry of Finance, Public Procurement Regulatory Authorities, EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM,EAC Policy Organs, East African Community	**258,400**	2018-2022

			Health Insurance 5. Review the national/social health insurance scheme to provide adequate coverage for essential medicines and health technologies	Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Insurance Companies ,Stringent NRAs, other Development Partners, Media		
Strategy 2: Establish and maintain systems for the efficient utilisation of funding for medicines and health technologies						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Systems for efficient utilisation of fund are established/strengthened by June, 2022	None	1. Number of Partner States with a monitoring and tracking system in place	1. To establish systems for monitoring and tracking of funds allocated for medicines and health technologies 1 Support Partner States to establish/ and or strengthen systems for effective monitoring and tracking of funds	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers,	**130,000**	2018-2022

			allocated for medicines and health technologies	FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
Strategy 3: Develop cost-containment strategies ad price regulation and monitoring of medicines and health technologies for public and private sector						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1.EAC guidelines on pricing control developed and implemented by June 2020 2 TRIPS flexibility utilized in partner states by June 2022	Partner states price catalogues 2. Insurance	1. EAC guidelines in place 2. Regional price indicator catalogue published 3. Number of partner states utilizing Intellectual Property	1. Conduct a comprehensive costing and pricing survey for the public and private not for profit sectors – EAC PS.	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities,	**295,300**	2018-2022

	schemes price catalogues	Rights and Public Health Intellectual Property and Innovation	2. Publish indicator prices and price mark for commonly used essential medicines and health technologies 4. EAC Secretariat to advocate for enactment laws on medicines and health technologies price control. 5.Promote transparency in the pricing structure of medicines and health technologies by pharmaceutical manufacturers, distributors and health service providers. 6. Monitor and share information on consumer prices 7, To implement the Global Plan of Action on Trade	Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		

			Related Intellectual Property Rights and Public Health Intellectual Property and Innovation			
				TOTAL	**683,700**	

TRADITIONAL AND COMPLEMENTARY MEDICINES

The EAC population relies on traditional and complementary medicines (TCMs) as their first treatment or last treatment option when conventional medicines treatment fails.

Regulation of quality, safety and efficacy of TCMs is weak and not harmonized in the EAC region. The focus of this strategic plan will be to strengthen policy oversight and regulation of TCMs and TCM practice.

Policy Objective	To maximize the benefits of TCMs in public health.
Indicators	1. Number of registered domestic TCMs 2. Number of Partner States with regulatory mechanism for TCM practice 3. Number of registered TCM practitioners
Baseline	1. List of registered TCMs 2. Number of licensed premises for TCMs 3. Partner States with regulatory mechanism for TCM practice 4. 80% of the population relies on TCMs for primary health care
Targets (2022)	1. All TCMs registered 2. All Partner States implementing regulatory mechanism for TCM practice

Strategies

1. Promote, coordinate and monitor the implementation of multi-sectoral TCM activities and practice in the EAC Partner States
2. Establish systems for regulating TCMs and TCM practice
3. Promote research and development and preserve TCM knowledge, innovation and practices in the EAC region

Strategy 1: Promote, coordinate and monitor the implementation of multi-sectoral TCM activities and practice in the EAC Partner States						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Guidelines for integration of TCM in the health care system developed by 2020 2. TCM Boards and Councils established/strengthened in each Partner State by 2020 3. Regional formulary of nationally approved TCMs developed by 2020 4. Regional platform for exchange of information on TCM established by 2019	1. TCM Council of the URT 2. Guidelines in place 3. Traditional Health Practitioners Bill (Kenya) in place	1. Guidelines for integration of TCM in the health care system in place 2. Functioning boards and councils 3. Regional TCM formulary in place 4. Funding proposals for establishment of coordination office 5. EAC database of TCM products, practitioners and practices	1. Develop guidelines for integration of TCM in the health care system 2. Enact legislation to establish TCM boards and councils 3. Operationalize the boards and councils 4. Mobilize resources for the operations of the boards and councils 5. Develop regional formulary for TCMs 6. Mobilize resources to support EAC Partner States to operationalize coordination office for TCM in the ministries of health 7. Establish/and or strengthen regional mechanisms for the exchange of information, experiences and	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities, WHO, Domestic Pharmaceutical Manufacturers, TCM Practitioners, FEAPM,EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA	**350,000**	2018-2022

			practices on TCM at regional and international level 8. Develop, disseminate and enforce EAC regulations on TCM practice 9. Establish an EAC database of TCM products, practitioners and their practices			
Strategy 2: Establish systems for regulating TCMs and TCM practice						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. System for regulating TCMs established in NMRA by 2021 2. System for regulating TCM practice established in Councils and Boards by 2021	1. NDA, PPB, TFDA and ZFDA have mandate to regulate TCMs 2. TCM Council of the URT in place 3. Traditional Health Practitioners Bill (Kenya) in place	Number of Partner States with capacity to regulate TCMs and TCM practice	1. Review/enact legislation for regulation of TCMs and TCM practice by NMRAs 2. Mobilize resources to support establishment/ and or strengthening national regulatory authorities/councils to regulate quality, safety and efficacy of TCMs 2.To Develop harmonized guidelines, standards and tools for the regulations of the TCMs 3.Adopt and domesticate	Partner States Governments, Ministry of Health EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community	**550,000**	2018-2022

			harmonized guidelines, standards and tools for regulation of TCMs 4.Conduct surveillance on the quality, safety and efficacy of TCM in EAC and take regulatory action 5.Develop an EAC TCM Pharmacopeia 6.Develop EAC harmonized regulations for TCM practice 7.Support Partner States to establish and/or strengthen a system for registration of TCMs 8.Develop EAC guidelines for inspections and licensing of manufacturing premises for TCMs and conduct EAC joint inspections 9. Train staff in the regulation of TCMs and TCM practice	Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
Strategy 3: Promote research and development and preserve TCM knowledge, innovation and practices in the EAC region						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timefra me**

1. Regional COE in research and development for TCMs established by 2020 2. Intellectual property rights for TCMs innovation protected/promoted by 2020	EAC Health Research Commission is in place	1. Regional COE designated 2. Number of Domestic Pharmaceutical Manufacturers commercializing local TCMs 2. Number of patented TCM products	1. Conduct assessment of national research institutes' capacity to host a regional COE for R&D in TCMs 2. Select and operationalize the regional COE 3. Enact legislation on intellectual property rights for TCM Promote and support relevant research into all aspects of TCM in EAC region. 4.Support domestic pharmaceutical manufacturers of TCM products in research, innovation and development 4. Conduct advocacy meetings for use of intellectual property protection for EAC THCM 5. Incorporate TCM in the curricular of medical teaching institutions	Partner States Governments, Ministry of Health, Industry, Trade, Commerce, EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media	**150,000**	2018-2022
				TOTAL	**1,050,000**	

HUMAN RESOURCE CAPACITY AND DEVELOPMENT FOR THE PHARMACEUTICAL AND HEALTH TECHNOLOGY SECTOR

Investment in development of human resource for the pharmaceutical and health technology sector will be a priority during the period of the strategic plan implementation. Capacity building will focus on soft and hard skills and strengthening of tertiary education for the pharmaceutical and health technology sector.

Policy Objective	To develop and retain pharmaceutical and other health technologies personnel in the health care system
Indicators	1.Number of health professionals in the pharmaceutical and health technologies per 100,000 population 2.Number of training institutions offering pharmaceuticals and health technologies professionals 3. Number of pharmaceutical and health technology councils in EAC region
Baseline	.....complete –Insert baseline of Pharmacists including Biomedical Engineers, Laboratory Technologists, Radiographers Registered
Targets (2022)	Achieve WHO recommended target - Figure

Strategies

1. Develop a strategic plan for human resource development, identifying needs and opportunities for training institutions and retention
2. Establish the EAC Pharmacy and health technologies network of bodies and councils and harmonization of education programs
3. Facilitate establishment of academic centers of excellence to support the development of skills and expertise for the EAC pharmaceutical and health technology sector
4. Establish a regional accreditation system for pharmacy schools/ Universities and licensing of all categories of pharmacists and health technologies

Strategy 1: Develop EAC Strategy for Human Resource Development for the Pharmaceutical Sector and facilitate rationalization and harmonization of pharmacy education programmes and titles. Develop a strategic plan for human resource development, identifying needs and opportunities for training institutions and retention						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Comprehensive Human Resource Development Plan for the EAC Pharmaceutical Sector established. 2. EAC harmonized pharmacy curriculum for diploma and degree developed	review	1. Implementation of comprehensive HRD strategy. 2. EAC guidelines and tools for inspection of pharmacy schools/universities in place 3. EAC regional accreditation system for pharmacy and health technologies schools/universities established	1. Establish and implement a multi-stakeholder process for the development and costing of the AC HRD Plan for the Pharmaceutical Sector 2. Mobilize resources to implement HRD plan 3. Strengthen the EAC Network of Pharmacy Boards and Councils 4. Support Twinning and Technical Exchange Programmes for the different cadres of pharmacy profession (regulators, manufacturers, inspectors, quality	Partner States Governments, Ministry of Health, Industry, Ministry of Education, Pharmacy Universities/Schools, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community	**754,600**	2018-2022

			control/assurance etc) 5. Review and harmonize code of ethics for pharmacists, health technologists and other professions that are involved with issues related to the Medicines and Health Technologies Policy 6.Rationalize and harmonize pharmacy and health technology education programmes relevant to the sector. 7. Establish a regional accreditation system for pharmacy and health technology schools/universities with the EAC Inter-University Council and the licensing of all categories of relate professionals. 8.Strengthen collaboration with the domestic pharmaceutical manufacturing sector for the placement and training of professionals.	Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		

			9. Facilitate the establishment of centres of excellence to support the development of essential skills and expertise for the EAC pharmaceutical and health technology Sector. 10.Institute structured platforms for engagement amongst medicines regulatory authorities, professional registration councils, private sector including domestic pharmaceutical manufacturers, and civil society. 1.			
Strategy 2: Establish and/or strengthen of EAC Centres of Excellences (CoE) to support the development of essential skills and expertise for the EAC pharmaceutical Sector.						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
EAC Centre of Excellence established by 2019		1. Number of in-service training programmes 2. Number of capacity building programmes conducted for	1. Develop training packages for the CoE 2. Conduct continous training programme	Partner States Governments, Ministry of Health, Industry, Ministry of Education,	**85,400**	2017-2021

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		pharmaceutical industry staff		Pharmacy Universities/Schools, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, Domestic Pharmaceutical Manufacturers, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
				TOTAL	**840,000**	

DOMESTIC PRODUCTION OF MEDICINES AND HEALTH TECHNOLOGIES

Opportunities for investment in the EAC medicines and health technologies manufacturing sectors exist. During the period of this strategic plan implementation, the focus will be on: creation of conducive policy environment for investment; implementation of the EAC Pharmaceutical Manufacturing Plan of Action (RPMPoA 2017-2027) and promotion of development and growth of the domestic production of medicines and health technologies of assured quality, safety and efficacy.

Policy Objective	1. Support development and growth of the EAC Partner States manufacturing sector for medical products and health technologies 2. Facilitate development of policy coherence across sectors of health, industry, trade, finance , commerce and customs 3. Create conducive environment to encourage investment in manufacturing of medical products and health technologies
Indicators	% (financial value) of medicines manufactured in EAC Number of pharmaceutical and health technologies industries established in the EAC region
Baseline	75% of EAC Pharmaceutical market demand is met through importation while 25% is covered by local pharmaceutical production
Targets (2022)	45% of EAC Pharmaceutical market demand is met by local pharmaceutical production

Strategies

1. Promotion of competitive and efficient regional pharmaceutical production
2. Facilitation of increased investment in pharmaceutical production regionally
3. Utilization of WTO-TRIPS Flexibilities to improve local production of pharmaceuticals in East Africa

Strategy 1: Promotion of competitive and efficient regional pharmaceutical production						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Gap analysis, CAPA plans in place by 2018. 2. Membership contributions, FEAPM interventions (including position papers, trainings) by 2020. 3. Article 35 of the Common Market Protocol is implemented by 2022. 4. Market intelligence platform established by 2018.	75% of EAC Pharmaceutical market demand is met through importation while 25% is covered by local pharmaceutical production	1. An EAC Roadmap is in place. 2. FEAPM is self-sufficient and advocates for EAC pharmaceutical industry needs. 3. Procurement laws of the partner states have adapted to the regulation of the common market protocol. Free competition in the field of public procurement. 4.Platform for pharmaceutical market intelligence data is established.	1. Develop and implement an EAC GMP Roadmap 2. Support FEAPM towards self-sustainability. 3. Implement Article 35 of the Common Market Protocol 4. Develop a sustainable platform that provides reliable and up to date pharmaceutical market intelligence data	Partner States Governments, Ministry of Health, Industry, Trade, Commerce, Education, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-	**1,700,500**	2018-2022

				NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
Strategy 2: Facilitation of increased investment in pharmaceutical production regionally						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Harmonized incentive policies established by 2020. 2. Harmonized investment policies established by 2020 3. Infrastructure upgrade policies by 2022 4. Policy framework for access to finance established by 2020	None	1. Regional preferential pricing for pharmaceuticals produced in the EAC is in place. 2. Number of investment incentives. Number of investments recorded in the region. 3. Number of projects on infrastructure upgrade reported.	1.Develop and implement a harmonized incentive package for local pharmaceutical production (tax regime, preferential pricing, land allocation for green projects and import classification) 2.Promote increased investment in R&D and higher value chain pharmaceutical production in the region. 3.Support infrastructure upgrade 4.Support access to finance for upgrade of the sector.	Partner States Governments, Ministry of Health, Industry, Trade, Commerce, Education, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC	**105,800**	2018-2021

				Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
Strategy 4: Promote price preferences for regionally produced medicines and health technologies in public tenders according to Article 35 of the EAC Common Market Protocol						
Strategy 3: Utilization of WTO-TRIPS Flexibilities to improve local production of pharmaceuticals in East Africa						
Output (s)	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timefra me**
Amended national laws to accommodate public health related TRIPS flexibilities by 2022.	None	1. Number of amended national laws to accommodate TRIPS flexibilities. 2.Number of pharmaceutical firms	1.Support stakeholder sensitization on the use of public health related WTO TRIPS flexibilities 2.Support pilot projects on the use of public health related WTO TRIPS	Partner States Governments, Ministry of Health, Industry, Trade, Commerce, Domestic	**1,125,000**	2018-2022

		and countries exploiting TRIPS flexibilities 3.Number of new products introduced through exploiting TRIPS flexibilities.	Flexibilities	Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
TOTAL					**2,931,300**	

MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES, INNOVATION, RESEARCH AND DEVELOPMENT

The EAC region intends to promote evidence based decision making in service delivery interventions and thus the strong research focus proposed in this plan. Strengthening collaboration with Universities, Research Institutes and other institutions of learning will be vital to further the agenda. Operational research will also be prioritized during the strategic plan implementation period.

Policy Objective	1. To promote innovation, technology transfer, research and development for the pharmaceutical and health technology production sectors in the EAC region.
Indicators	Number of researches related to medical products and health technologies conducted and published Percentage increase in budgetary allocation for research on medicines and health technologies
Baseline	Existing published research studies on medicines and health technologies in EAC Partner States
Targets (2022)	Increase in budgetary allocation for research in medicines and health technologies

Strategies

1. Facilitate implementation of collaborative R & D programs
2. Facilitate establishment of a centre of excellence in research on medicines and health technologies
3. Enhance budgetary resource allocation for research in medicines and health technologies

Strategy 1: Facilitate implementation of collaborative research and development programs						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Capacity for research scientists built by 2022 2. Research on medicines and health technologies regulated by 2022 .	None	1.Number of operational and scientific research carried out during the strategic plan implementation period 2.Number of capacity building programmes conducted on scientific and technological research 3.Number of Centers of Excellence (CoE) to promote technology adaptation and transfer for medicines and health technologies 4.EAC harmonized regulatory framework and guidelines for control of Clinical Trials implemented	1. Conduct trainings 2. Create a database of research experts for medicines and health technologies 3. Create a platform for sharing information on research on medicines and health technologies 4. Enact or review legislation on research on medicines and health technologies 5. Develop harmonized guidelines, standards and tools for research on medicines and health technologies 6. Monitor research conducted in the EAC region and take appropriate regulatory action	EAC Health Research Commission Partner States Governments, Ministry of Health, Industry, Trade, Commerce, National Institutes of Medical Research , Clinical Research Organization, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC	**945,500**	2018-2022

				Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
Strategy 2: Facilitate establishment of a centre of excellence in research on medicines and health technologies						
COEs in research on medicines and health technologies established by June 2020	Existing research institutes in the EAC region	COEs in research on medicines and health technologies in operation	1. Conduct assessment of the existing research institutes to host the COEs 2. To select and mobilize resources for operationalizing the COEs 3. To conduct research including operational research	EAC Health Research Commission Partner States Governments, Ministry of Health, Industry, Trade, Commerce, National Institutes of Medical Research , Clinical	**845,500**	2018-2022

				Research Organization, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
Strategy 3: Enhance budgetary resource allocation for research in medicines and health technologies						

Resources for research in medicines and health technologies mobilized by 2022	1% in URT (Mainland), 4% in Kenya (figures pertain to all research)	1. Percentage increase in funds allocated to research in medicines and health technologies	1. To budget for research activities 2. Write proposals for funding and submit to potential donors 3. Pooling of resources for research 4. Establish an innovation fund for research	EAC Health Research Commission Partner States Governments, Ministry of Health, Industry, Trade, Commerce, National Institutes of Medical Research , Clinical Research Organization, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on		2018-2022

				Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
TOTAL					**1,791,000**	

INFORMATION SYSTEMS

Electronic Information Management Systems is a powerful tool to collect information and data in the medicines and health technologies sector and make informed policy decisions. EAC Partner States are at different levels of development of the Information Management Systems (IMS)By 2022, it is expected a robust medicines and health technology information systems will be in place and information generated will be used continuously to improve access to medicines and health technologies. Integrated information Management system (IMS) for National Medicines Regulatory Authorities (NMRAs), Medical Stores Departments and other medicines and technology sectors will be established and strengthened to allow free flow of information. It is envisaged all the systems will be electronic to ensure accuracy, timeliness and easyaccess. ..

Policy Objectives	1. To establish systems to collect, store , secure and manage information on all medicines and health technology, personnel, and practices in line with the sectors information needs. 2. To facilitate integration and harmonization of Electronic Information Management System , in healthcare system in the region 3. To ensure that data from all Medicines and health technology information systems are available, accessible and utilized at all levels of the health sector
Indicators	Integrated and Harmonized e-Information Management Systems for supply chain management. EAC data base for professionals in medicines and health technology sector
Baseline	EAC Integrated Information Management System (IMS) for NMRAs
Targets (2022)	Fully functioning EAC IMS in the region. e-Platform established for medicines and health technology sector. Efficient information exchange on medicines and health technology.

Strategies

1. Establish and maintain systems to collect, collate, process, analyze , secure and share data on various aspects of medicines and health technologys and
2. Promote use of electronic systems in medicines and health technology sector

Strategy 1: Establish and maintain systems to collect, collate, process, analyze , secure and share data on various aspects of medicines and health technology .						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Electronic information management System for Supply chain management created and integrated by june 2022 Electronic information management System for professionals created and integrated by june 2022 Electronic information management System for NMRAs strengthened by june 2022	e-LIMS in all partener States None None Harmonized eIMS for NMRAs	1. Integrated and Harmonized e-Information Management Systems for Medicines and Health Technology in place. Number of reports updated in the system	1. Develop EAC requirements for e-IMS for supply chain management 2.design or procure a software for e-IMS for supply chain management 3 Procure hardware to support e-IMS for supply chain management 4 Install and conduct training of users 5 Maintain the system 6 Develop EAC requirements for e-IMS for professionals in medicines and health technology sector 7 Design or procure a software for e-IMS for	Partner States Governments, Ministries responsible for Health, Industry, Trade, Commerce,and Information technologyNational Statistical Centres, National Institutes of Medical Research, Clinical Research Organization, Domestic Pharmaceutical	**900,500**	2018-2022

			health professionals in medicines and health technology sector 8 Procure hardware to support e-IMS for health professionals in medicines and health technology sector 9 Install and conduct training of users 10 Maintain the system 11 Maintain and ensure interporabillity of EAC IMS for NMRAs 12 Recruite ICT expert to operate and maintain the electronic system 1 To share information on regulatory activities amongst EAC parterstates NMRAs 2 To conduct training of expert in NMRAs 3 To finalize and intergrate the eIMS for the NMRAs of the Republics of Burundi,South Sudan and United Republic of Tanzania-Zanzibar 4 To review and upgrade the system	Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		

			sector 2 6			
TOTAL					**900,500**	

ADMINISTRATIVE AND INSTITUTIONAL FRAMEWORKS

A meaningful contribution of medicines and health technologies sector towards progressive realization of universal health coverage and one health approach will only be possible with good governance, strong leadership and institutional systems. Efforts will focused at promoting good governance and leadership and establishing structures and systems for effective coordination, monitoring and evaluation of implementation of medicines and health technologies sector policies and programmes.

Policy Objective	1. To support the establishment of structures for effective governance and policy direction of the medicines and health technologies sector
Indicators	Number of Partner States with Directorate of medicine and health technology in the structure of Ministries of health
Baseline	Existing Directorates/Divisions/Sections/Departments in the Ministries of Health responsible for medicine and health technology matters
Targets (2022)	Efficient structures established for effective governance and policy direction of the pharmaceutical sector.

Strategies

1. Establish institutional frameworks to coordinate and monitor implementation of the EAC medicines and health technologies policy and this strategic plan

Strategy 1. Establish institutional frameworks to coordinate and monitor implementation of the EAC medicines and health technologies policy and this strategic plan						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Medicines and health technologies Directorates established within the Ministries of Health of the Partner State by June 2022 2. Activities of the Directorates coordinated and effectively implemented by June 2022	Directorate of Pharmaceutical and medical supplies of the Republic of South Sudan	1. Number of Directorates established 2. Number of staff recruited to support implementation of the Policy 3. relevant institutional structures in place 4. structures for effective governance and policy direction of the medicines and health technologies sector in place	1. To review the existing structures of the Ministries of health of the EAC in the Partner State 2. To engage the decision makers at ministerial level to incorporate the Directorate in the structures of the Ministries 3. To draft and approve the proposed structures **2.** To mobilize reorces for effective implention of strategic plan ..To coordinate ,monitor and evaluate the	Partner States Governments, Ministry of Health, Industry, Trade, Commerce, National Institutes of Medical Research , Clinical Research Organization, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines	**890,000**	2018-2022

			implementation of strategic plan 2. Support Partner States to upgrade Pharmacy Division to Directorate Level for efficient implementation of the Policies and Strategies, 3. Mobilize resources to ensure capacity to coordinate and oversee implementation of the Policy at national and regional level.	Regulatory Authorities, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
Strategy 2: Coordinate monitoring and review of the Policy and its strategies						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timefra me**
1. Functional M & E systems established 2. 1 medicines and health technologies		1. Number of Partner States with functional M & E institutionalized into medicines and health technologies	1. Establish and/or strengthen organizational Monitoring and communication structures and partnership in M & E	Partner States Governments, Ministry of Health, Industry, Trade,	**750,000**	

data used for decision making available		Programmes/Directorates 2. Number of M & E reports	2. Develop and implement costed M & E work plan 3. Institutionalize and operationalize M & E activities within medicines and health technologies Directorate at national and regional level 4. Conduct bi-annual reviews of the progress of implementation of the EAC Medicines and Health Technologies Policies 5. Regularly prepare and disseminate high quality reports on implementation of the EAC Medicines and Health Technologies at Regional and Partner States Level	Commerce, National Institutes of Medical Research , Clinical Research Organization, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC Policy Organs, East African Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs,		

				other Development Partners, Media		
TOTAL					**1,640,000**	

LINKAGES AND COLLABORATION

Multi-sectoral collaboration is crucial for implementation of this strategic plan due to the nature of interventions that have been defined. Every effort will be made to ensure that there is strong linkages and efficient work mechanisms with all stakeholders and Partners in the medicines and health technologies Sector. The EAC will harness the synergies and opportunities available at national, regional and international collaboration to support implementation of EAC Medicines and Health Technologies Policy and Strategic Plan.

Policy Objective	To facilitate and sustain a platform for the engagement of all stakeholders involved in the medicines and health technologies sector.
Indicators	
	Number of networks established in EAC region Number of meeting conferences workshop symposia held annually in the EAC region Number of cooperation agreements signed by stakeholders related to medicines and health technologies
Baseline	Cooperation Framework Agreement for NMRAs
Targets (2022)	Stakeholder networks for medicines and health technologies established

Strategies

1. Promote collaboration and exchange of information, skills, expertise and experience with international, regional, national agencies and institutions.

Strategy 1: Promote collaboration and exchange of information, skills, expertise and experience with international, regional, national agencies and institutions.						
Output	**Baseline (s)**	**Indicator (s)**	**Interventions/activities**	**Actors**	**Estimated costs in USD**	**Timeframe**
1. Regional and international collaboration strengthened by June 2022.	Existing networks amongst partner states and International Agencies	1. Number of networks established in EAC region	1. Conduct mapping of stakeholders to support implementation of EAC Medicines and Health Technologies Policy 2. Conduct regular meetings, workshops, symposia and conferences in the medicines and health technologies sector 3. To establish and maintain networks and exchange programmes in medicines and health technologies with relevant regional and international bodies: RECs, UN agencies (WHO, UNIDO, UNDP, FAO etc), Afican Union Commission (AUC), AU-NEPAD Agency, BMGF, World Bank, DFID, GIZ, PTB, TradeMark East Africa 4.	Partner States Governments, Ministry of Health, Industry, Trade, Education Commerce, National Institutes of Medical Research , Clinical Research Organization, Domestic Pharmaceutical Manufacturers, Pharmacy Boards and Councils, EAC National Medicines Regulatory Authorities, FEAPM, EAC Policy Organs, East African	**95,000**	2018-2022s

				Community Parliamentary Committee on Health and Population, EALA WHO, AU-NEPAD, BMGF, WB, PTB, GIZ, UNIDO, Stringent NRAs, other Development Partners, Media		
TOTAL					**95,000**	
GRAND TOTAL (USD)					**19,428,000**	

CHAPTER FOUR: IMPLEMENTATION ARRANGEMENT

The implementation of the EAC Medicines and Health Technologies Strategic Plan is a shared responsibility of the EAC Secretariat and Partner States.

Collaboration in implementation will be fostered among all stakeholders including development partners

The roles and responsibilities of implementing entities are further described below:

1. **The EAC Secretariat** will provide leadership and have the overall responsibility for the implementation of EAC Medicines and Health Technologies Strategic Plan (EACMHSP 2018-2022). The officer in charge of the docket of Medicines and Food Safety Unit within the EAC Health Department will take the lead in providing guidance, coordination, monitoring and evaluation of the interventions of all actors involved in the implementation plan. Resource investments (Human, technical and financial) will be made during the strategic period to ensure EAC Medicines and Food Safety Unit has the requisite capacity to fulfil its mandate. It is expected that the position of Principal Health Officer of the Unit will be established and institutionalized into the EAC Commission. The Strategic Plan will be translated into annual work plans, which will provide further guidance for the year on year activities. Quarterly reviews will be organized to discuss performance, set priorities and utilise information.

2. **EAC Partner States** Ministries of Health and Agencies such as National Medicines Regulatory Authorities, National Medical Stores, Research Organizations/Institutions and Pharmacy/Health Professional Councils will provide leadership and overall responsibilities for guiding implementation within their specific areas of jurisdiction and mandate.

3. **Government Ministries and Agencies** including the Ministry of Finance Planning and Economic Development; Ministry of Industry, Ministry of Trade and Commerce, Ministry of Education; Ministry of Water, Sanitation and Environment; Ministry of Information Technology; Public Procurement

Agencies, the National Environment Management Authority (NEMA), and National Bureau of Standards (NBS) will have a role to guide and support the sector on cross cutting issues.

4. **Private Sector** entities including manufacturers, importers, distributors, wholesalers and retailers are key in implementation of the plan and will contribute in various aspects of the plan to achieve the key milestones.

5. **Academia** particularly Pharmacy and health technology training institutions and universities are key to ensuring that the human resource entering the market is able to support effective implementation of the plan. These institutions are also crucial in furthering the sector's research agenda.

6. **The Entire Health Service Delivery System** including district health departments, hospitals, lower-level health facilities, Village Health Teams (VHTs) and Community Health Extension Workers (CHEWs) will be part of the implementation process.

7. **Civil Society and Communities** have a key role to play in advocacy and implementation of interventions. Effective support for community engagement through multi-pronged capacity building strategy will be required.

8. **Private for Profit (PFP) and Private Not for Profit (PNFP)** health service providers have a key role to play in ensuring medicines and health technologies are available to all seeking health services and that they are safe, of good quality, affordable and appropriately used. They also have a role to support Governments efforts to ensure full compliance with the law and regulations.

9. **National Parliaments and East African Legislative Assembly**
   will be responsible for enactment of various Laws and Regulations related to this strategic plan.

10. **Regional and International Partners** will be engaged in various aspects of

implementation of this plan particularly in provision of technical expertise, research, harmonisation, development of guidelines /standards and support for other resources (infrastructure and financial).

IMPLEMENTATION PRINCIPLES

Achievement of the overall targets set out in this plan will be guided by the following broad principles:

1. The EAC Health Department/Medicines and Food Safety Unit shall coordinate the consultative planning, implementation and monitoring and evaluation of the defined interventions;

2. Development Partners wishing to support the EAC medicines and health technology sector shall be guided by interventions outlined in this plan and where a different set of priorities are identified guidance shall be sought from EAC secretariat

3. All partners involved in activities in the medicines and health technology sector will be required to share information on their contribution as well as the results of their interventions.

CHAPTER FIVE: MONITORING AND EVALUATION

Existing EAC monitoring and evaluation mechanisms will be used to assess the progress of implementation of the strategic plan. A monitoring and evaluation tool will be developed as a framework to assess implementation of strategic interventions and achievement of key targets of this plan.

EAC Technical Working Group for Medicines, Health Technologies and Food Safety will provide administrative, advisory and technical oversight role and report progress to the EAC Sectoral Council of Ministers of Health.

Quarterly and annual reports will be prepared by the EAC Secretariat in conjunction with the Partner States and submitted to the respective TWG and EAC Sectoral Committee on Health before being considered and adopted by the EAC Sectoral Council of Ministers of Health.

Continuous and systematic collection and analysis of information will be instituted at national and regional level in order to inform the EAC Secretariat and key stakeholders of the extent to which progress against stated goals and objectives have been achieved.

The EAC Medicines and Food Safety Unit of the EAC Secretariat will take a lead role in monitoring the strategic plan.

Evaluation of the plan will involve periodic surveys to provide baseline data and impact evaluation of key strategic areas. The evaluation will build on the monitoring process by identifying the level of short to medium term outcomes and longer-term impacts achieved. Lessons learnt will be packaged and disseminated.

Main evaluations will be conducted during the mid-term and end of the plan.

CHAPTER SIX: RESOURCE MOBILIZATION

Human, technical, infrastructure and financial resources will be required to implement EAC Medicines and Health Technologies Strategic Plan 2018-2022. Given the low budget allocation for EAC Medicines and Food Safety projects and programmes from EAC joint funding, domestic resources mobilization will be prioritized. Funding for strategic plan will also largely depend on support from Development Partners.

Table 5 summarizes costing of activities based on the Policy objectives as covered in this plan for the period of 2018 to 2022.

Table 5: Summary of costing for strategic objectives of the Plan

S/NO.	Policy Objectives	ESTIMATED COST(US $)
1.	To develop a regional legal and regulatory framework to ensure access to safe, efficacious, affordable and quality assured medicines and health technologies to the EAC citizens.	3,284,900
2.	To develop a regional legal and regulatory framework for pharmacy and health technology professionals and practices to ensure high standard of quality services.	
3.	To strengthen supply chain management of medicines and health technologies	2,746,300
4.	To establish and strengthen quality assurance infrastructure and capacities to ensure safety, quality and efficacy of medicines and health technologies to protect and promote public health in the EAC region.	2,802,600
5.	To promote rational and safe use of medicines and health technologies by prescribers, dispensers and patients as well as facilitating access to unbiased sources of medicines information.	662,700

6.	To establish mechanisms for control of pricing of medical products and health technologies	683,700
7.	To advocate for implementation of social health insurance schemes in all EAC Partner States;.	
8.	To encourage EAC Partner States to mobilize financial resources for medical products and health technologies and ensure optimum utilization	
9.	To establish mechanisms for control of pricing of medical products and health technologies;	
10.	To maximize the benefits of traditional, herbal and complimentary medicines in public health	1,050,000
11.	To develop and retain pharmaceutical and other health technologies personnel in the health care system	840,000
12.	Support development and growth of the EAC Partner States manufacturing sector for medical products and health technologies	2,931,300
13.	Facilitate development of policy coherence across sectors of health, industry, trade, finance, commerce and customs	
14.	Create conducive environment to encourage investment in manufacturing of medical products and health technologies	
15.	To promote innovation, technology transfer, research and development for the pharmaceutical and health technology production sectors in the EAC region.	1,791,000
16.	*T*o establish systems to collect, store , secure and manage information on all medicines and health	900,500

	technology, personnel, and practices in line with the sectors information needs.	
17.	To facilitate integration and harmonization of Electronic Information Management System , in healthcare system in the region	
18.	To ensure that data from all Medicines and health technology information systems are available, accessible and utilized at all levels of the health sector	
19.	To support the establishment of structures for effective governance and policy direction of the medicines and health technologies sector	1,640,000
20.	To facilitate and sustain a platform for the engagement of all stakeholders involved in the medicines and health technologies sector.	95,000
	GRAND TOTAL	**19,428,000**

The EAC financial rules and regulations as specified by Article 14 (3 (G)) and Article 135 (1) of the Treaty, funding in-favor of the strategic plan will be backed-up by a funding agreement. The funding agreement between the EAC and the Funding agency will be signed by the Secretary General who is also the accounting officer of all funds managed by the EAC. The funds will be managed by the EAC Finance and Administration office. A separate project account may be opened for each funding organization in line with EAC procedures.

In accordance with EAC procedures, all funds remitted to EAC for implementation of the Strategic Plan will be incorporated in the EAC Medium-Term Expenditure

Framework (MTEF) budget. This will then be presented to the Finance and Administration Committee, the Council of Ministers and EALA for perusal and approval. Once approved, the funds will be ready for implementation.

The Technical and financial reports will be produced on an annual basis and submitted to the office of the Deputy Secretary General for Planning and Infrastructure (DSG-PI). The reports will be deliberated by the Council of Ministers, shared with contributing partners and inform the EAC 5th Development Strategy