EAC MEDICINES AND HEALTH TECHNOLOGIES POLICY

FINAL

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LIST OF 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 State
RPP	Regional Pharmaceutical Policy
SFC	Sub-Standard Falsified and Counterfeit Drugs
STG	Standard Treatment Guidelines
WHO	World Health Organization

DEFINITION OF TERMS

Biopharmaceuticals
A biopharmaceutical, also known as biologic (al) medicinal product, biological, or biologic is any pharmaceutical 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. Biopharmaceuticals 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 ie human, animal, or microorganism.

Clinical Trials
A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care

Community
East African Community established by Article 2 of the EAC Treaty

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

Complementary/Alternative Medicines (CAM)
The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system.Examples include acupuncture, reflexology, massage, meditation, art therapy, psychotherapy counselling and yoga.

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

Domestic Manufacturing
Medical products and health technologies that are only produced in the EAC Partner States

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

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

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 medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations.

Herbs: crude plant material such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

Herbal materials: in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages or other materials.

Herbal preparations: the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.

Finished herbal products: herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be

Information Management System
Information Management System (IMS) is a general term for software designed to facilitate the storage, organization and retrieval of information.

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

Medical Product
1. Also called medicine or drug 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 behaviour and often addiction; and
3. (Informal) any substance that can be abused for its stimulant, depressant, euphoric or hallucinogenic effects

Medical Device
Any instrument, apparatus, implement, machine, appliance, implant, in vitro or in-vivo reagent or calibrator, diagnostic, 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 diseases.

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

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 quality of a pharmaceutical product or medical device after it has been released on the market and is an important part of the science of pharmacovigilance.

Public Health
Public Health is defined as “the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society” (Acheson, 1988; WHO).

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

Quality Control
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

Sectoral Council
The Sectoral Council provided for under Article 14 of the EAC 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 the EAC Common Market Protocol.

Traditional Medicine
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

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

1.0 PREAMBLE

Medical products and health technologies form a key component of the health care system and efforts should be geared towards ensuring that they are accessible, safe, of good quality, efficacious and cost effective. A situation

analysis carried out in all the EAC Partner States in 2015, brought to the fore the status of the pharmaceutical sector and challenges identified included limited regulatory capacity, human resource shortage, weak procurement and distribution and limited finances among others.

The Treaty for the Establishment of the East African Community, Chapter 21, Article 118 (c), calls for EAC Partner States to develop " a common drug policy which would include establishing quality control capacities and good procurement practices", leading to the development of the EAC Medicines and Health Technologies Policy.

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

This Policy provides a guide to EAC Partner States, Private Sector Civil Society and Development Partners in priority settings and implementation. Therefore, the EAC Sectoral Council of Ministers of Health invites all Partner States and other stakeholders to join hands and support the implementation of the Policy.

SIGNED on this …….....Day of ……by the EAC Sectoral Council of Ministers of Health

Hon. Sarah Opendi.	**Hon. GASHUMBA Diane**	**Hon. Dr. Josiane Nijimbere**	**Hon. Dr. Cleopa Mailu**	**Hon. Dr. Riek Gai Kok**	**Hon. Ummy Ally Mwalimu**
Minister of Health	**Minister of Health**	**Minister of Health**	**Cabinet Secretary**	**Minister of Health**	**Minister of Health**
Ministry of Health	**Ministry of Health**	**Ministry of Public Health & Fight Against Aids**	**Ministry of Health**	**Ministry of Health**	**Ministry of Health, Community Development, Gender, Elderly and Children**
REPUBLIC OF UGANDA	**REPUBLIC OF RWANDA**	**REPUBLIC OF BURUNDI**	**REPUBLIC OF KENYA**	**REPUBLIC OF SOUTH SUDAN**	**THE UNITED REPUBLIC OF TANZANIA**

2.0 ACKNOWLEDGEMENT

The EAC Medicines and Health Technologies Policy is a document, which will serve as a guide to ensure equitable, adequate and reliable supply of safe, quality, efficacious and affordable medical products and health technologies to the region.

I would like to express my profound gratitude to the East African Community (EAC) Experts Working Group (EWG) on Pharmaceutical Policy, Legal and Regulatory Reforms for their tireless efforts and commitments in developing the Policy.

The East African Community extends its appreciation to the African Medicines Regulatory Harmonization (AMRH) Programme Partners, namely the World Health Organization (WHO) for their technical support; the Bill and Melinda Gates Foundation (BMGF), the United Kingdom Department for International Development (DFID) and the World Bank, for their financial assistance and African Union New Partnership for Africa's Development (AU-NEPAD) for policy advocacy role.

Participation of stakeholders drawn from Ministries of Health, EAC Affairs, Industry, Trade, Judicial and Commerce; Government institutions including National Medicines Regulatory Authorities, Quality Control Laboratories and National Bureau of Standards; Pharmacy Schools/Universities, Profession Boards/Councils/Associations that participated in reviewing and validation of the Policy is very much appreciated.

I would like to make special recognition of the contribution and dedication of EAC Secretariat staff towards development of the Policy and leadership role of the Steering Committee for the East African Community Medicines Regulatory Harmonization Programme.

Finally, I take cognizant of the role of the EAC Technical Working Group on Medicines, Food Safety and Health Technologies and EAC Sectoral Council of Ministers of Health for deliberation and final approval of the Policy.

Ambassador Liberat Mfumukeko
Secretary General
EAC Secretariat

3.0 EXECUTIVE SUMMARY

The East African Community (EAC) is a regional inter-governmental organization of six Partner States namely Republics of Burundi, Kenya, Rwanda, South Sudan, Uganda and the United Republic of Tanzania with an estimated population of over 150 million people. The mission of the EAC is "to

widen and deepen economic, political, social and cultural integration in order to improve the quality of life of the people of East Africa through increased competitiveness, value added production, trade and investment.

The EAC Secretariat and EAC Partner States are in the process of undertaking regional and national pharmaceutical policy, legal and regulatory reforms aimed at deepening regional cooperation and integration in the health sector amongst the Partner States. A regional assessment of the medicines' policies, legislation and regulatory instruments of EAC Partner States was undertaken as part of the wider reform process. The findings of the assessment had revealed major gaps in the pharmaceutical sector ranging from inequitable access to medicines, irrational use of medicines, existence of substandard and falsified medicines, over-reliance to imports, weak financing mechanisms, lesser human resources capacity and inadequate governance structures. This necessitated the development of this regional policy, herein referred to as the *EAC Medicines and Health Technologies Policy*.

The goal of this EAC Medicines and Health Technologies Policy is to ensure an adequate and reliable supply of safe and cost-effective medicines and health technologies to all people of the EAC and their rational use.
The document covers all the relevant components of a medicine policy as recommended by World Health Organization (WHO) and it has widened the scope to cover not only medical products but also health technologies which embraces products like medical devices and diagnostics. Other products such as cosmetics, blood and blood products, radiopharmaceuticals, traditional medicines and veterinary products are also covered. The intention here is to comprehensively set-up systems for their effective regulation to ensure protection and promotion of public health in a wider scale.

The objectives of this policy document include:

- Advocating for equitable access to medicines, health technologies and pharmaceutical services.
- Ensuring quality, safety and efficacy of medicines and health technologies
- Managing supply chain to ensure therapeutically sound and cost-effective use of medicines by health professionals and consumers.
- Promoting rational use of medicines and health technologies
- Promoting domestic pharmaceutical and health technologies' production
- Facilitating research, innovation and development in the pharmaceutical and health technology sectors
- Ensuring timely and relevant implementation strategies that include developing and retaining skilled human resources and evidence-based decision-making.
- Increasing collaboration and cooperation amongst public and private sectors, civil societies and regional and international agencies.

In each component, the policy issue, objective and statements are outlined as depicted from the findings of the situational analysis conducted in the region

and validated by Partner States.

To ensure effective implementation, the EAC Secretariat in collaboration with Partner States will mobilize resources and engage all stakeholders to realize the objectives set-forth in this Policy document. A Strategic Plan will be formulated to chart-out a clear pathway towards coordination and implementation of the policy. Development partners, the private sector and other key stakeholders will be engaged during implementation. Monitoring and evaluation strategies have also been outlined in the document.

4.0 INTRODUCTION

The East African Community is a regional inter-governmental organization of six (6) Partner States: Republics of Burundi, Kenya, Rwanda, Uganda, South Sudan and The United Republic of Tanzania, of, with its headquarters in Arusha, Tanzania.

The EAC has an estimated population of over 150 million people, land area of 2.47 million square kilometres and combined GDP of $ 163.9billion and GDP per Capita of $ 909.7.
The objectives of the EAC are to develop policies and programmes for widening and deepening co-operation among the Partner States in political, economic, social and cultural fields, research and technology, security, legal and judicial affairs for their mutual benefit[1]. The EAC envisages accelerated, harmonious and balanced development and sustained expansion of economic activities.

Chapter 21, Article 118 of the EAC Treaty provides the priorities and focus for regional cooperation and harmonisation in the area of health, including medicines and regulatory policies. Clause(c) of the Treaty specifically calls for the development of a common drugs policy as one instrument to strengthen integration and cooperation in the pharmaceutical sector.
The EAC Partner States have national medicines policies but not harmonized in the region and furthermore the area of health technologies is currently handled on adhoc basis which compromises their quality and safety. This impacts negatively on the investigative and treatment processes in the management of various diseases.
The EAC region imports 75% of its medicines requirements and there is very limited capacity for the local production of medical products and health technologies.

This policy will facilitate the harmonization and improvement of access to safe, efficacious, quality and affordable medicines and health technologies to the population of the EAC.

To facilitate harmonisation of pharmaceutical policies, legislation and regulatory frameworks, the EAC Council of Ministers (EAC/CM9/Decision 61 and EAC/CM9/Directive 29) adopted the recommendation of EAC Partner States' Ministries of Health and National Medicines Regulatory Authorities (NMRAs) to review and harmonise medicines policy, legislation and regulatory frameworks, procurement, distribution and management across the EAC.

It is within this context that the Medicines and Health Technologies Policy for the East African Community has been developed.

For the purposes of this Policy, medicines and health technologies cover medicines for human and veterinary use including vaccines, blood products, biopharmaceuticals, cosmetics, herbal products, traditional and complimentary medicines and medical devices.

[1]Treaty for the Establishment of the East African Community (As amended on 14th December, 2006 and 20th August, 2007).

2.1 EAC-SOCIO ECONOMIC AND DEMOGRAPHIC INDICATORS

Mid-year population in the EAC increased by 2.9% from 139.4 million persons in 2012 to 143.5 million persons in 2014[2]. 64.2% of this population is aged 0-24 years, with Uganda having the highest percentage (70.4%) and Rwanda having the lowest (61%). Life expectancy in 2013 ranged between 50 and 65 years with Rwanda having the highest life expectancy at 64.5 years while Uganda the lowest at 50 years.

During the period 1990 and 2013, maternal mortality ratio reduced by 76% in Rwanda, 55% in the United Republic of Tanzania, (provide Zanzibar data) 53% in Uganda, 41% in Burundi and 17% in Kenya compared to by 45% globally[3]. The absolute maternal mortality ratio ranges from 210/100,000 live births (LBs) in Rwanda to 360/100,000 in Kenya, 360/100,000 in Uganda; 410/100,000 in the United Republic of Tanzania; and 500/100,000 in Burundi.

On the other hand, the annual rate of reduction in under-five mortality in the United Republic of Tanzania and Rwanda were 5.1% and 4.6 per annum respectively during the period 1990 and 2013, well above the required average rate of 4.4% per annum[4].

The total health expenditure per capita in the EAC is USD 45 as opposed to USD 86 recommended to deliver an essential package of services within the context of Universal health Coverage (UHC)[5].

Although per capita total expenditure on health increased From 7 to 21 in Burundi, 19 to 45 in Kenya, 9 to 71 in Rwanda, 19 to 59 in Uganda and 10 to 49 in the United Republic of Tanzania between 2000 and 2013, much of this improvement has been outstripped by high population growth rates, high burden of communicable and non-communicable diseases and healthcare inflation (reference as 5).

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[6].

Medicines and Health Technologies are a key input for health service delivery and for addressing the disease burden of communicable and non-communicable diseases that the East African Community (EAC) Partner States (PS) face. In order to be beneficial, medicines and health technologies available on any market need to be safe, effective, affordable and of assured quality, which is a key responsibility of National Medicines Regulatory Authorities (NMRAs).

Within this context, the EAC Secretariat and EAC Partner States undertook

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[2]EAC Facts and Figures 2014

[3]Trends in Maternal Mortality: 1990 to 2013. Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division

[4]UN Inter-agency Group for Child Mortality Estimation (IGME) 2013

[5]Report on Sustainable Financing Analysis for Universal health and HIV Coverage the EAC Region

[6]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.

regional and national medicines and health technologies policy, legal and regulatory reforms aimed at deepening regional cooperation and integration in the Health Sector. At service delivery level, these reforms are meant to facilitate free movement of health goods and services between the countries in line with "EAC Common Market Protocol".[7]

2.2 SITUATIONAL ANALYSIS OF MEDICINES POLICIES IN EAC PARTNER STATES

In an effort to address equitable access to essential medicines and health technologies, EAC Secretariat in collaboration with Partner States, have implemented regional policies, strategies and initiatives to address existing gaps and challenges in the sector at both national and regional level. The EAC policies, strategies and initiatives include:

- EAC Health Sector Policy
- EAC Health Sector Strategic Plan (2015-2020)
- EAC Pharmaceutical Manufacturing Plan of Action[8] 2012.
- EAC Medicines Regulatory Harmonization (MRH) Programme, 2012;
- EAC Pharmaceutical Quality Infrastructure Programme;
- EAC/GAVI/Kfw Immunization Cooperation;
- EAC Centre of Excellence for Vaccine, Immunization and Health Supply Chain Management;
- EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation[9] 2013.

Partner States have also adopted National Medicines Policies (NMPs) as a guide to strengthen Medicines and Health Technologies sector. Partner States recognised that the NMP is part of the overall National Health Strategy and are working towards this integration.
At the regional level, the EAC Health Sector Policy was considered by the 12th Ordinary Meeting of the EAC Sectoral Council of Ministers of Health and approved for domestication by Partner States by 34th Ordinary Meeting of the Council of Ministers.

The scope of existing Partner States NMPs generally includes medicines for human and veterinary use,[10] as well as herbal products. There is a move towards including vaccines/biopharmaceuticals, blood and blood products, medical devices and diagnostics, radiopharmaceuticals, food products, tobacco products, cosmetics and emerging health technologies into NMPs.

7EAC Common Market Protocol 2010
[8] EAC. East African Community Pharmaceutical Manufacturing Plan of Action (2012 - 2016).
[9]EAC Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation. EAC, 2013.
[10]Normally vaccines, blood products and other biologicals are considered to be within the framework of medicinal products for human use. This is also true for herbal products for human use.

This Policy is based on the analysis of the Partner States' NMPs as listed in the table 1 below:

Table 1: Status of Implementation of Components of National Medicines Policy (NMP)

Component	Burundi	Kenya	United Republic of Tanzania (Mainland) (Zanzibar)	Rwanda	Uganda
Selection	Y	Y	Y	Y	Y	Y
Affordability	Y	Y	Y	Y	Y	Y
Pricing	Y	Y	Y	N	Y	Y
Financing	Y	Y	Y	Y	Y	Y
Supply systems	Y	Y	Y	Y	Y	Y
Regulations & QA	Y	Y	Y	Y	Y	Y
Rational Use	Y	Y	Y	Y	Y	Y
Local Production	Y	Y	Y	Y	Y	Y
Research	Y	Y	Y	Y	Y	Y
Human Resources	Y	Y	Y	Y	Y	Y
Governance: Institutional & Administrative Framework	Y	Y	Y	Y	Y	Y
Regional & International Collaboration	Y	Y	Y	Y	Y	Y
Health Technologies & Innovation	Y	Y	Y	Y	Y	Y
M&E	Y	Y	Y	Y	y	Y

Key: Y- Yes; N- No

Overall, all Partner States are facing challenges with the implementation of NMPs. There are inadequate institutional, operational, legislative and oversight mechanisms to implement NMPs and enforce legislation and regulations. Due to irregular monitoring and evaluation of NMPs, planning and programme management of the pharmaceutical sector remains weak. 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. These challenges stem from a limited or narrow

conceptual understanding of the complex and dynamic nature of the pharmaceutical sector.

EAC Partner States have to critically analyse the underlying factors for the slow progress in the implementation of NMPs and address the bottlenecks. The situational analysis of the status of implementation of the components of the National Medicines Policy for each Partner States is covered in the EAC Strategic Plan for Medicines and Health Technologies 2018-2027.

3 RATIONALE, GOAL, PRINCIPLES AND BENEFITS OF THE POLICY

3.2 Rationale

As outlined in Chapter 21 of the EAC Treaty, Health is a key area of cooperation within the EAC Partner States. Article 118 of the Treaty advocates for development of a Common Drug Policy.In recognition of the gaps in the pharmaceutical and health technology sector and persuant to the EAC Council of Ministers (EAC/CM9/Decision 61 and EAC/CM9/Directive 29) adopted the recommendation of the 7th Meeting of the EAC Health Committee to develop the EAC Medicines Policy, herein after referred to as the Medicines and Health Technologies Policy for the East African Community.

3.3 Goal

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

3.4 Objectives

The Objectives of the Policy include:

- Equitable access of medicines, health technology[11] and pharmaceutical services.
- Quality, safety and efficacy of all 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 Technology Production
- Facilitate Research, Innovation and Development in the Pharmaceutical and Health Technology Sectors
- Increased collaboration and cooperation between public, private and civil society, 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.

Specific objectives derived from the main objectives are stated in each policy subsection.

3.5 Principles

The EAC Medicines and Health Technologies Policy is underpinned by the core

[11]Health technology refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. http://www.who.int/topics/technology_medical/en/. Accessed on 24 July 2015.

principles of the EAC Treaty and Constitutions of Partner States, including:

- Human Rights
- Essential Medicines Concept
- Good Governance
- Effective Partnership and Collaboration among Partner States

3.6 Benefits

The benefits of the EAC Medicines and Health Technologies Policy are through enabling Partner States to:

- Optimise the EAC populations' access to safe, efficacious, quality and affordable medicines and health technologies including medical devices; as well as related services.
- Widen public domain by ensuring safe, efficacious, quality and affordable medicines and technologies to the EAC population .
- Achieve Public Health objectives.
- Promote domestic manufacturing inline with EAC Industrialization Policy and EAC Vision 2050
- Control Substandard and Falsified (SF) Medicines and Health Technologies.
- Encourage regional research, development and innovation
- Enhance knowledge and information sharing
- Improve cooperation in the Common Market for their mutual benefit.

3.7 Scope

The policy will cover pharmaceutical and health technology products, practice, systems and services. Products include medical products, biological products including vaccines, medical devices and diagnostics, cosmetics, veterinary medicines, radiopharmaceuticals and Traditional, Herbal and Complimentary Medicines (THCM) and new treatment regimes.

Practice: All pharmaceutical personnel and other cadre of professionals that support the pharmaceutical and health technology sector

Systems & Services:- All systems and services within the pharmaceutical and health technology sector

4 POLICY STATEMENTS

4.2 Legal and Regulatory Framework

4.2.1 Policy Issues

EAC Partner States have pharmaceutical legislation however, the legislation and regulations do not adequately address the existing gaps in the dynamic nature of pharmaceutical and health technology sector. Lack of regional Medicines Policy, legislative and regulatory framework pose a limitation in the development of the EAC pharmaceutical market.

The Republic of Kenya, United Republic of Tanzania, Republic of South Sudan and Republic of Uganda have national medicines regulatory bodies that oversee the safety and quality of medical products, use of medicines and licensing of premises. Pharmacy and Poisons Board (PPB) of the Republic of Kenya regulates products and pharmacy practice. For the Republic of Rwanda and Republic of Burundi, regulatory functions are executed by the Ministry of Health. Current institutional arrangements are inadequate in facilitating implementation of Partner States' NMPs. There is need for EAC Partner States to separate functions of medicines policy oversight, medicinal product regulation and pharmacy practice.

There is weak regulatory framework for pharmaceutical and health technology professionals and practices in the EAC region while in some countries products and professionals are regulated by NMRAs.

4.2.2 Policy Objective

To develop a regional legal and regulatory framework for medicines, health technologies and to ensure access to safe, affordable and quality-assured medicines to the EAC citizens.

To develop a regional legal and regulatory for pharmacy and health technology professionals and practices to ensure high standard of quality services

4.2.3 Policy Statements

- Develop the regional legislation for Partner States to comprehensively regulate medicines and health technologies
- Support the establishment of new and strengthen or existing semi-autonomous national and regional medicines regulatory authorities.
- Implement the EAC Cooperation Framework for EAC NMRAs to facilitate intra-trade between Partner States inline with the Common Market Protocol.
- Facilitate development, domestication and use of harmonized regulatory guidelines, standards and tools for medicines and technologies.
- Develop the regional legislation and regulatory frameworks for

pharmacy and health technology professionals and practices
- Identify, establish and strengthen regional training centres of excellence on medicines regulation and quality control.

4.3 Medicines and Health Technologies Supply Chain Management:

4.3.1 Policy Issues

There are challenges with availability of medicines and health technologies in the EAC Partner States. The overall selection, quantification, procurement, storage, inventory management and distribution of medicines and health technologies across the EAC is ineffective resulting in non-availability of essential medicines, stock pilling, high prices, irrational use and wastage of resources through disposal.

All EAC Partner States have adopted the essential medicines concept and have national essential medicines lists (EMLs). Partner States have also developed and implemented 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, in some Partner States, EMLS and STGs are not updated on a regular basis based on emerging diseases and new technologies due to capacity and budget constraints. These instruments are also not adopted for use by the private sector.

Good procurement practices further recommend that national EMLs guide the procurement of essential medicines and health technologies to prevent wastage and irrational procurement. However, procurement in EAC Partner States is not limited to the products on the EMLs. Quantification of requirements remains weak, further contributing to wastage.

4.3.2 Policy Objective

To strengthen supply chain management of medicines and health technologies.

Policy Statements

- Strengthen good governance for supply chain management
- Develop regional guidelines for reviewing and updating EMLs.
- Develop a regional EML and institute periodic review mechanisms.
- Develop and implement separate guidelines for selection of traditional, herbal and veterinary medicines.
- Promote and support the development and implementation mechanisms for cooperation in medicines procurement.
- Facilitate the establishment of the Regional Network of Pharmaceutical and Health Technologies Procurement and Supply Chain Management
- Establish and implement strategies for joint procurement (Pooled Procurement)for priority medicines and health technologies and

harmonize procurement regulations.

- Strengthen capacity to assess and quantify regional needs for medical products, vaccines and health technologies.
- Promote the development of a regional platform for procurement information sharing and pooled negotiations.
- Developing mechanisms to respond to pharmaceutical and health technology emergencies during epidemics and other health and environmental disasters.
- Strengthen public-private partnerships in procurement, storage, ,distribution and disposal of medicines and health technologies.
- Develop regional guidelines for the safe disposal of expired or unwanted medicines and health technologies.

4.4 Quality Assurance

4.4.1 Policy Issues

Physical and Quality Assurance Infrastructure including Quality Control Laboratories in Regulatory Authorities and Pharmaceutical Manufacturing Sector across EAC Partner States is weak. There is poor surveillance and testing systems for substandard and falsified (SF) medical and health technology circulating in EAC market. In all EAC Partner States, Post Marketing Surveillance Systems needs to be strengthened to ensure safe and quality medical products are available in the market.

Enforcement of regulatory guidelines regarding the promotion and advertising of allopathic and traditional medicines is non-existent. Oversight of clinical trials is also weak because of non-existence of legislation and/or poor enforcement. Studies conducted across the EAC Partner States indicated that sub-standard and falsified medical products and health technologies are circulating in the national markets posing a risk to the population.

Currently, EAC Partner States are at different levels of developing quality control infrastructure and capacities for medical products and health technology and institutions need to be strengthened to meet the international standards inline with provisions of EAC Treaty, article 118 which calls for EAC Partner States to establish and strengthen Quality Control Capacities to ensure safety and efficacy of medical products and health technologies circulating in the EAC Market.

Assessment of EAC Partner States quality assurance and control systems for medical products and health technologies conducted in July 2017, indicated that some quality control laboratories are not integrated into the NMRAs organizational structures which lead to costly outsourced services, there is also limited infrastructure and human resource capacity among others.

EAC Partner States Quality Control Laboratories are more advanced in analyzing medicines and gaps exist for other products such as bio therapeutics and health technologies. In addition, monitoring safety and quality of medical products and health technologies is still weak due to lack of enforcement and

adherence to Pharmacovigilance and Post Market Surveillance Legislations/Regulations by all stakeholders.

4.4.2 Policy Objective

To establish and strengthen EAC Partner States quality assurance infrastructure and capacities to ensure safety, quality and efficacy of medical products and health technologies to protect and promote public health in the EAC region.

4.4.3 Policy Statements

- Establish the EAC Medicines and Food Safety Agency/Commission
- To develop and strengthen Quality Assurance Systems, procedures and standards in the entire spectrum of Pharmaceutical and health technology Sector.
- Determine capacities of quality control laboratories and facilitate access and testing of medical products, vaccines, cosmetics, bio therapeutics, medical devices, diagnostics and other health technologies.
- Support strengthening of national quality control laboratories and facilitate WHO and ISO accreditation.
- Support the review and updating of national legislation for advertising and promotion of medicines, clinical trials and pharmacovigilance
- Establish regional regulatory framework for medical devices, diagnostics and other health technologies.
- Ensure compliance to good manufacturing practices (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practices (GDP) inspections and law enforcement.
- Establish and strengthen EAC Centres of Excellences on regulatory matters
- Establish a regional platform for sharing regulatory information

4.5 Rational Use of Medical Products and Information

4.5.1 Policy Issues

Evidence from EAC Partner States indicate that some patients do not receive the 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. There is wide spread self-medication, drug abuse and emerging trends of anti-microbial resistance in all Partner States.

EAC Partner States medicines and health technologies information centers that can be used by prescribers, dispensers and consumers are still weak. Some countries lack these centers and the coordination among the professional council is poor. In addition, the EAC Partner States health systems lacks

centralized point where patients can report and seek guidance incase of drug overdose and poison.

There is low adherence and enforcement to Good prescribing and dispensing practices in all Partner States due weak national governance structures. Standard Treatment Guidelines and formularies are also not updated and printed on regular basis and to assist in prescribing and dispensing of 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.

4.5.2 Policy Statements

- Develop a regional strategy and work plan for strengthening the rational use of medicines and health technologies in the EAC
- Promote rational use of medical products and health technologies by consumers, dispensers and prescribers
- Develop and promote harmonised regional STGs for priority and neglected diseases for both human and veterinary.
- Develop and promote a regional Essential Medicines List (EML) and formulary.
- Support the establishment of medicines information centres and/or the provision of unbiased medicines information.
- Develop EAC mechanisms for regular monitoring of anti-microbial resistance
- Establish and integrate a system for managing of drug abuse, overdose and poisoning into health care delivery services.
- Ensure enforcement of the law in prescribing and dispensing of medical products and health technologies

4.6 Medicines Financing and Pricing

4.6.1 Policy Issues

Partner States financing for implementation of NMPs across the EAC Partner States is inadequate.
All EAC Partner States except 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 majority and vulnerable. Health financing[12]is still a challenge in the EAC region, yet it drives universal health coverage agenda. Therefore improving health financing is key to ensuring that all people can use promotive, preventive, curative,

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

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. The percentage of out of pocket is at 20% in Burundi, 45% in Kenya, 18% in Rwanda, 49% in Uganda and 33% in United Republic of Tanzania[13].

In all EAC Partner States with exception of Republic of Burundi, there is no pricing control mechanisms to ensure access to affordable essential medicines and health technologies by the population. .

4.6.2 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*

4.6.3 Policy Statements

- Sustainably mobilise resources for financing the procurement of quality essential medicines and health technologies and systems for their equitable access and appropriate use
- Establish and maintain systems for the efficient utilisation and tracking of finances for medicines and health technologies
- Promote Utilization of TRIPS Flexibilities
- Develop a regional policy framework for cost-containment strategies, including use of generic medicines, sustainability of financing mechanisms and price regulation and monitoring for both Public and Private sector.
- Facilitate information sharing on supplier prices.
- Promote transparency in the pricing structure of medicines and health technologies by manufacturers, distributors and health service providers.
- Strengthen financial management and pharmaceutical supply systems to enable effective operation and monitoring of resource utilization.

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4.7 Traditional, Herbal and Complementary Medicines

4.7.1 Policy Issues

Many citizens of the EAC make use of traditional, herbal and complementary medicines to treat illnesses. The regulation of traditional, herbal and

[13] EAC Social Health Protection Study

complementary medicines is generally weak and not harmonized in all EAC Partner States.

The United Republic of Tanzania have established Traditional and Alternative Medicines Council that regulates the practices and products while herbal products are regulated by Tanzania Food and Drugs Authority. Other EAC Partner States NMRAs of the Republic's of Burundi, Kenya, Rwanda, Uganda and South Sudan regulates herbal products and in some countries, the law gives powers to NMRAs to regulate traditional and alternative medicines. The current institutional arrangement in some Partner States does not provide proper enforcement of regulatory oversight for both traditional, herbal and complementary medicines and there is a need to separate regulatory oversight for both products and practices.

4.7.2 Policy Objective

To maximize the benefits of traditional, herbal and complementary medicines where possible and desirable and protect the EAC population against their negative effects.

Policy Statements

- Establish Traditional Medicines Council/ and or Boards to oversee the practice and profession in traditional and complementary medicines;
- Develop strategies for promoting the appropriate use of traditional and complementary medicines in the EAC.
- Establishing harmonized systems for regulating traditional, herbal and complimentary medicine by NMRAs.
- Encourage EAC Partner States to Promote and Protect Intellectual Property Rights Copy Rights for Traditional Medicine Innovation
- Establish a regional centre for research and development for herbal, traditional and complementary medicine
- Develop and implement guidelines for integration of traditional medicine in health care system
- Develop a regional database of indigenous plants that have been screened for efficacy and toxicity by national regulatory authorities.
- Compile a regional formulary of nationally approved herbal, traditional and complementary medicines
- Integrate traditional and complementary medicines in university curricula

4.8 Human Resource Capacity and Development for the Pharmaceutical and Health Technology Sector

4.8.1 Policy Issues

The pharmaceutical sector is dynamic and requires personnel that can adapt to the ever- changing landscape. The role of the pharmacy profession is evolving in the health care setting moving away from the original narrow focus of supply and distribution to broader public health roles of ensuring pharmaceutical and health technology outcomes and programme

management.

All EAC Partner States suffer from inadequate numbers of trained personnel and limited training capacity to meet national and regional needs. There is also inequitable distribution of pharmaceutical personnel with the majority concentrated in the private sector and in urban areas. EAC Pharmacy Boards and Councils in collaboration with Pharmacy Schools/Universities needs to develop harmonized guidelines for mutual recognition of professions to facilitate free movement of pharmacy profession in the region.

Some Partner States have limited workforce with soft and hard skills that are essential for promoting sustainability of the pharmaceutical sector. Public spending on human resource development within all Partner States is inadequate whilst the cost for skills development in tertiary institutions is increasing. Furthermore, non-tariff barriers on the free movement of personnel across borders still exist between Partner States.

Overall, the EAC lacks alignment of training to the needs and trends of the pharmaceutical sector. Gap analysis studies for skills required for the key areas of the pharmaceutical policy areas have not been conducted in the region. These challenges are further affected by the lack of retention strategies for pharmaceutical personnel. The same challenges also affects experts in the veterinary, medical devices, diagnostics and traditional medicine fields who support the pharmaceutical sector.

4.8.2 Policy Objective

To develop and retain pharmaceutical and other health technologies personnel in the health care system

Policy Statements

- 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
- Establish and support the EAC Network of Professional Boards and Councils
- Rationalize and harmonize pharmacy and health technology education programmes relevant to the sector.
- Enhance linkages between pharmaceutical and health technology services, (Government, community and industry) and training institutions to align the training programmes to the needs of the sector.
- Develop a strategic plan for human resource development, identifying needs and opportunities for training institutions.
- 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 related professionals.
- Strengthen collaboration with the domestic pharmaceutical manufacturing sector for the placement and training of professionals.
- Facilitate the establishment of academic centres of excellence to support the development of essential skills and expertise for the EAC

pharmaceutical and health technology Sector.

- Institute structured platforms for engagement amongst medicines regulatory authorities, professional registration councils, private sector including domestic pharmaceutical manufacturers, and civil society.
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4.9 Domestic Production of Medical Products and Health Technologies

4.9.1 Policy Issues

Shortage of essential medical products and health technologies have contributed to low performance of the health sector in EAC. The provision of essential medicines and other quality health commodities remains a major challenge in the EAC due to inadequate domestic production and over reliance on importation of finished pharmaceutical products from outside the region. The pharmaceutical market in EAC region is largely dependent on importation estimated at 75% and 25% is covered by domestic production.

To address these challenges, the EAC Secretariat in collaboration with Partner States have put in place several strategic interventions including implementation of the EAC Regional Pharmaceutical Manufacturing Plan of Action (EACRPMPOA2012-2016); and Action Plan for the Implementation of the EAC Industrialization Policy and Strategy, 2012-2017.

Nationally, EAC Partner States have policies where domestic manufacturers are given an average of 15% preference over other suppliers of medicines, however this has not impacted on the dynamics of pharmaceutical market demand in the region.

Opportunities for investment exist in the manufacture of drugs for the treatment of diseases of Public Health Importance, the provision of family-planning services, and the manufacture of medical equipment's and sundries. Further, the rich biodiversity of the region provides additional opportunities for the production of herbal medicines. However, there is lack of conducive policy environment and policy coherence across sectors of health, industry, trade, commerce and customs.

4.9.2 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

4.9.3 Policy Statements

- Facilitate the development of programmes to upgrade domestic manufacturers of medical products and health technologies through capacity building and adoption of new technologies and innovations
- Advocate for consistent and long term fiscal Policies for Investors
- Facilitate Implementation of EAC and AU Pharmaceutical Manufacturing Plan of Action.
- Facilitate the establishment of a regional information portal on local manufacturers to provide regular information on business potential, market opportunities and access to finance.
- Support regional and national efforts to improve Good Manufacturing Practices by domestic manufacturers.
- Provide conducive environment for investing in production of raw materials for producing medicines and health technologies
- Coordinate the implementation of TRIPS Flexibilities to improve access to essential medicines across the EAC.
- Promote preferential margin of 20% for all regionally produced medical products and health technologies in public tenders according to Article 35 of the EAC Common Market Protocol.
- Encourage technology transfer and international accreditation of local manufacturers to enhance their competitiveness.
- Strengthen regional and national pharmaceutical manufacturers associations
- Establish mechanisms to minimize imports of essential medicines that can be manufactured domestically in a sufficient quantity and at competitive prices.

4.10 Research, Innovation and Development

4.10.1 Policy Issues

Effective research and development, technology and innovation are key requirements for growing the pharmaceutical and health technology 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 and inadequate frameworks to support innovation and technology transfer.

The EAC region have established institution, policies and strategies to promote research, technology and innovation and this include East Africa Health Research Commission (EAHRC), EAC Health Sector Policy 2016-2020 and EAC Industrialization Policy, 2012 – 2017. However, research in Pharmaceutical and Health technology sector is still weak and resources are inadequate to build EAC Partner States capacity to conduct scientific and operational research.

4.10.2 Policy Objective

To promote innovation, technology transfer, research and development for the pharmaceutical and health technology production sectors in the EAC region.

4.10.3 Policy Statements

- Build basic pharmaceutical scientific and technological research capabilities in universities and technology centres through the appropriate training of scientists, biomedical engineers and technologist to ensure a critical mass of skills needed for pharmaceutical sector industrialization.
- Promote and mainstream research in pharmaceutical and health technology in EAC Health Research Commission agenda.
- Enhance budgetary resource allocation for pharmaceutical research, technology and innovation initiatives.
- Facilitate implementation of collaborative Research and Development programmes.
- Facilitate the establishment of centres of excellence to promote technology adaptation and transfer for the pharmaceutical and health technology sector.
- Support the development of operational/scientific research and knowledge management and use for evidence based policy formulation.
- Support development of harmonized regulatory framework and guidelines for control of Clinical Trials

4.11 Information Systems

4.11.1 Policy Issues

Electronic Information Management Systems is a powerful tool to collect information and data in the pharmaceutical and health technology sector and make informed policy decisions. EAC Partner States are at different levels of development of the Information Management Systems (IMS). Although efforts are ongoing in the EAC region to strengthen and establish integrated IMS for NMRAs to support Medicines Regulatory Harmonization, the rest of the medical products and health technologies sector are not covered.

Policy Objectives

1. *To establish systems to collect, store, secure and manage information on all medical products and health technologies, personnel, and practices inline with the sectors information needs.*
2. *To facilitate integration and harmonization of eIMS in health care system in the region*
3. *To ensure that data from information systems are available, accessible and utilized at all levels of the health sector.*

4.11.2 Policy Statements

- Develop and strengthen national and regional information systems, security and quality assurance for collection, collation, processing, analysis, dissemination and use of data on various aspects of medicines and health technology sector
- Strengthen Human Resource Capacity in Information Management Systems (IMS)
- Ensure information gathered is disseminated to all stakeholders for decision making
- Develop, review and deploy harmonized systems for information sharing and ensure interoperability with other existing systems in the health care settings

4.12 Administrative and Institutional Framework

4.12.1 Policy Issues

The impact of effective policies depends on the capabilities of the technocrats and structures established to facilitate and oversee engagement with stakeholders and implementation.

Overall, the capacity and performance of the public sector dealing with medicines and health technologies matters is generally low resulting in inadequate implementation of policies and strategies. Constraining factors are related governance issues and ineffective monitoring and evaluation frameworks.

4.12.2 Policy Objective

To support the establishment and strengthening of structures for effective governance and policy direction of medicines and health technologies sector

Policy Statements

- Facilitate Partner States to establish or strengthen semi-autonomus institutions to oversee regulation of medical products and health technologies
- Enhance the technical and management capacities of national and regional institutions to implement, review and monitor this Policy and related strategies and regulations.
- Facilitate the attainment of the goals and objectives of this Policy by establishing the necessary institutional framework for its

implementation.

- Developing and regularly reviewing strategies to guide implementation of this Policy provisions.
- Fostering collaboration between the national pharmaceutical systems and other partners and stakeholders involved in its implementation;

4.13 Linkages and Collaboration

4.13.1 Policy Issues

Medical products and health technology is a specialized sector operating in a highly globalized and interconnected manner. Across the EAC Partner States, there is also a lack of a shared understanding and subsequent collaboration between Ministries of Health, Agriculture, Commerce, Finance, Trade and Industry. This lead to duplication of efforts and has negative impact to equity and access to medical products and health technologies. Multi-sector and international collaboration and cooperation are essential to comprehensively address the intricate and complex issues and to safeguard public health and safety.

4.13.2 Policy Objective

To facilitate and sustain a platform for the engagement of all stakeholders involved in the medical product and health technology sector.

4.13.3 Policy Statements

- Support planning and negotiations for international and inter-governmental agreements related to the Policy
- Strengthen collaboration between health, trade, commerce, agriculture, livestock, industry, education, water, environment and other sectors including and their respective agencies
- To facilitate participation in regional and global initiatives related to the the Policy.

5 IMPLEMENTATION AND REPORTING ARRANGEMEMTS

The implementation of the EAC Medical Products and Health Technologies Policy is a shared responsibility of the EAC Secretariat, Partner States and the Private sector. Collaboration in implementation will be fostered among all stakeholders including development partners.

EAC Technical Working Group for Medicines, Food Safety and Health Technologies will provide oversight role for the implementation of the Policy on annual basis.

At the national level, National Medicines Policy (NMP) committees will spearhead domestication of this Policy by relevant stakeholders.

The EAC Secretariat will be responsible for coordinating implementation of the EAC Medical Products and Health Technologies Policy and report progress to EAC Policy Organs.

6 RESOURCE MOBILIZATION

Effective implementation of the Policy will require substantial resources both at EAC and Partner States level. Currently, Partner States are experiencing resource constrains due to competing priorities. In this regard, it is necessary to establish a sustainable financing mechanism.

The EAC Secretariat in collaboration with Partner States will mobilize resources to support to support implementation of the Policy.

7.0 MONITORING AND EVALUATION

Existing EAC monitoring and evaluation mechanisms will be used to assess progress of implementation of the Policy. Monitoring and evaluation tool will be developed as a framework to assess implementation of the Policy and achievement of key targets.

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

Annual reports will be prepared by EAC Secretariat and 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 on progress of implementation of the policy will be instituted at regional in order to inform the EAC Partner States and other key stakeholders.