African, Caribbean and Pacific Group of States

"COMESA Strategic Plan for Standardisation and Quality Assurance"

"ACP-EU TBT PROGRAMME"

(REG/FED/022-667)

Project code: 015/14

STRATEGIC PLAN

2015 – 02-27

(Revision after Regional Validation Workshop)

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Acronyms

AAS	Atomic Absorption Spectrophotometer
AFRAC	African Accreditation Cooperation
AFRIMETS	Intra-Africa Methodology System
AFSEC	African Electrotechnical Standardisation Commission
AMREF	African Medical Research Foundation (an international African Health Organisation headquartered in Kenya)
AMRH	African Medicines Regulatory Harmonisation Programme
APMP	Asia Pacific Metrology Programme
ARSO	African Organisation for Standardisation
BBN	Burundi Bureau of Standards
BIPM	Bureau International des Poids et Mesures
BMGF	Bill and Melinda Gates Foundation
BNM	Bureau des Normes de Madagascar
CAB	Conformity assessment bodies
CAPA	Corrective Action and Preventive Action
CB	Certification Body
CoC	Certificate of Conformity
COMESA	Common Market for Eastern and Southern Africa
COMESAMET	COMESA Metrology Committee
COMESAMEL	COMESA Legal Metrology Committee
CNTA	National Centre for Food Technology (Burundi)
DAKKS	Germany's National Accreditation Body
DQMS	Domestic Quality Monitoring Scheme
EAC	East African Community
EAC-MRH	East African Medicines Regulatory Harmonisation Programme
EAMET	East African Metrology Systems
EASC	East African Standards Committee
ECAE	Ethiopian Conformity Assessment and Enterprise
EFMHACA	Ethiopian Food Medical Healthcare Administration and Control Authority
ENAO	Ethiopian National Accreditation Office
ESA	Ethiopian Standards Agency
ESI	Ethiopian Standards Institute
FAPAS	Food Analysis Performance Assessment Scheme

FSMS	Food Safety Management System Certification
GC	Gas Chromatography
GDP	Good Distribution Practice
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit (German Cooperation Organisation)
GMO	*Genetically modified* food
GMP	Good manufacturing practices
HACCP	Hazard Analysis & Critical Control Points
IAF	International Accreditation Forum
IB	Inspection Body
ICH	*International Conference on Harmonisation* of Technical Requirements for Registration of Pharmaceuticals for Human Use
IEC	International Electrotechnical Commission
IGAD	Intergovernmental Authority on Development
ILAC	International Laboratory Accreditation Cooperation
IMEKO	International Measurements Confederation
INSP	Testing Reference laboratory for Quality Control of Drugs (Burundi)
IQMS	Import Quality Monitoring Scheme
IRCA	International Register of Certificated Auditors
IRD	Inspection and Regulatory Directorate (Ethiopia)
ISO	International Organisation for Standardization
KCCA	Kampala Capital City Authority
KEBS	Kenya Bureau of Standards
KENAS	Kenya Accreditation Services
KEPHIS	Kenya Plant Health Inspection Services
LACA	Laboratory for chemical analysis of minerals (Burundi)
LGC	Liquid Gas Chromatography
MA	Market authorisation
MOU	Memorandum of Understanding
MS	Member State
MTSH	Minimum Technical Standards of Harmonization
NDA	National Drug Authority (Uganda)
NEMA	National Environment Monitoring Agencies
NEPAD	New Partnership for Africa's Development
NEWMET	North East West Metrology Sub-Region

NAFP	National Accreditation Focal Point
NMI	National Metrology Institute (Kenya)
NMIE	National Metrology Institute of Ethiopia
NMISA	National Metrology Institute of South Africa
NSC	National Standards Council (Ethiopia)
OHSAS	Occupational Health & Safety Advisory Services
OIML	International Organization of Legal Metrology
PICS	Pharmaceutical Inspection Cooperation Scheme
PCR	Polymerase Chain Reaction
PTS	Proficiency Testing Schemes
REC	Regional Economic Community
RVA	Dutch Accreditation Council
SAATCA	Southern African Auditor Training Certification Association
SADC	Southern African Development Community
SADCMET	Southern African Development Community Cooperation in Measurement Traceability
SADMEL	SADC Cooperation in Legal Metrology
SEA	Swaziland Environmental Authority
SIM	Sistema InterAmericano de Metrologia (inter-American Metrology System)
SMAP	Standards & Market Access Programme
SPS	Sanitary and Phytosanitary measures
SQA	Standardization and Quality Assurance
SWASA	Swaziland Standards Authority
TC	Technical Committee
TBT	Technical Barriers to Trade
UKAS	United Kingdom Accreditation Services
UNBS	Uganda National Bureau of Standards
USFDA	US Food and Drug Administration - the federal agency of the United States Department of Health and Human Services
WB	World Bank
ZABS	Zambia Bureau of Standards
ZEMA	Zambia Environmental Management Authority
ZWMA	Zambia Weights and Measures Agency

1. EXECUTIVE SUMMARY

1.1 INTRODUCTION

The Common Market for Eastern and Southern Africa (COMESA) was formed in December 1994 to replace the former Preferential Trade Area (PTA) which had existed since 1981. COMESA (as defined by its Treaty) was established 'as an organization of free independent sovereign states which have agreed to co-operate in developing their natural and human resources for the good of all their people'. The main focus of COMESA is on the formation of a large economic and trading unit that is capable of overcoming some of the barriers that are faced by individual states. Its current Member States are: **Burundi, Union of Comoros, Congo DRC, Djibouti, Egypt, Eritrea, Ethiopia, Kenya, Libya, Madagascar, Malawi, Mauritius, Rwanda, Sudan, Swaziland, Seychelles, Uganda, Zambia and Zimbabwe.**

One of the aims and objectives of COMESA is "to attain sustainable growth of Member States by promoting a more balanced and harmonious development of its production and marketing structures". In order to promote the achievement of this objective, COMESA seeks to eliminate rigidities in the structures of production and manufacturing so as to produce goods and services that are of high quality and are competitive in the COMESA and to adopts common standards, measurement systems and quality assurance practice in respect of goods produced and traded within COMESA.

The activities in the field of Standardization and Quality Assurance derive their mandates from the COMESA Treaty of 1994, which has a provision for cooperation in Standardization and Quality Assurance under Chapter 15 - Standardization and Quality Assurance. Under this Chapter, **Member States recognised the importance of standardisation and quality assurance in the promotion of health, the enhancement of the standard of living, the rationalisation and reduction of unnecessary variety of products, the facilitation of inter-changeability of products, the promotion of trade, consumer protection, the creation of savings in government purchasing, improved productivity, the facilitation of information exchange as well as in the protection of life, property, and the environment.**

Standardization, Metrology and Accreditation and Conformity assessment services (testing, inspection, and product and system certification) are important to an economy in a number of interdependent ways, which support economic development through the production of competitive products, and they enhance the quality of life through promotion health, safety and environment. Consequently, the three pillars of quality infrastructure Standardization, Accreditation and Metrology are vital for sustainable development and regional trade.

The activities on Standardization and Quality Assurance (SQA) were started in 2003 with the setup of the Standardization and Quality Assurance Programme line with the Treaty of 1994. The unit focuses its activities on the following;

- Establishment and Harmonisation of Standards
- Quality Assurance
- Metrology

- Certification
- Laboratory Accreditation
- Cooperation in testing
- Documentation and Procedures
- Training Publicity of Standardisation of Activities and Administrative procedures.

1.2 PURPOSE OF THE PROJECT

The overall objective of the project is to **enhance capacity of COMESA Quality Infrastructure institutions** to coordinate and harmonize regional Technical Regulations, Standards and Conformity Assessment procedures and finally facilitate intra-regional and international trade.

The project takes into account the variable geometry reflected in varying stages of development of Member States, and marked **differences with respect to capacities and capabilities of Quality Infrastructure Institutions**

The Five-Year Strategic Plan is a framework to guide and underpin **activities for Quality Infrastructure, specifically covering Standards Harmonization, Industrial/Scientific Metrology and Legal Metrology, Conformity Assessment, Accreditation, Technical Regulations and Pharmaceutical Harmonization.** It takes into account the common challenges facing Member States in Quality Infrastructure (QI) to meet the requirements of the Customs Union. The priority accorded to the activities is guided by the needs of the Member States, and their capacities to adopt domestic polices and implement agreed activities.

1.3 APPROACH AND METHODOLOGY

The exercise was executed through interviews, questionnaires and review of documents which were supplied by COMESA Secretariat and other stakeholders.

Selected COMESA Member States institutions/organisation, which contribute to trade facilitation and services, were interviewed in order to assess their Quality Infrastructure and find out the gaps in their system. The exercise was executed through interviews, questionnaires and review of documents supplied by COMESA Secretariat and other stakeholders.

The missions to the selected countries were carried out in the period between 27th October 2014 and 6th of December. The countries visited were Burundi, Ethiopia, Kenya, Madagascar, Uganda, Swaziland and Zambia. In accordance with the TOR, the criteria for selection was based on the geographical spread and membership to other RECs and the size of economy with respect to the COMESA region as shown in Table 1 below.

Table 1: Criteria for selection of countries interviewed

	Country	Membership to Other RECs	Economy size
1	Burundi	EAC	Small
2	Ethiopia	-	Large
3.	Kenya	EAC	Large
4.	Madagascar	SADC	Small
5	Swaziland	SADC	Small
6	Uganda	EAC	Medium
7	Zambia	SDC	Medium

The Gap analysis was done based on documental analysis of COMESA SQA documents, EAC SQMT documents and SADC SQAM documents and the findings from the countries that were interviewed vis a vis best practice .

Resulting from the reviews of the COMESA treaty and the COMESA SQA documents and interviews with the selected Member States a needs assessment was conducted and SWOT analysis was performed.

The results of this first step have been delivered in a document “needs assessment & SWOT analysis” report.

The key issues resulting from the needs assessment are as follows

1. Capacity building of Quality Infrastructure institutions – The Quality Infrastructure of most of the of the countries in the COMESA region are rated below average
2. Technical Regulations Framework – there is a need for Member States to develop a framework for technical regulations and to harmonize regulations in COMESA technical regulations
3. Harmonization of Standards and Conformity Assessment Procedures needs to be accelerated in order to increase intra COMESA trade
4. Public Awareness - There is a need to carry out awareness campaigns. There is also a need to have a platform that is available to stakeholders with information on SQA activities and their impact

The Vision and Mission of COMESA SQA were reaffirmed and the Strategic Objectives and Strategies formulated.

The five Strategic Objectives are as follows

- **Strategic Objective 1**: Improve operational efficiency of COMESA SQA Unit

- **Strategic Objective 2:** Enhance capacity of COMESA Quality Infrastructure Institutions in line with international best practice
- **Strategic Objective 3:** Improve Quality of Products
- **Strategic Objective 4:** Eliminate technical barriers to trade
- **Strategic Objective 5:** Resource mobilization

The Strategies for the realization of the strategic objectives were drawn and associated performance measures and indicators are given in the implementation matric in Annex 1.

2. BACKGROUND OF COMESA SQA

2.1 THE MANDATE OF COMESA SQA

The mandate of COMESA SQA as spelt out in the treaty articles 112 is as follows:

a) Evolve and apply common policy with regard to standardization and quality assurance (SQA) of goods produced and traded within the Common Market, the relationships of their National Standards Bodies with regional, international and other organizations concerned with standardization and quality assurance and in the development of activities in standardization and quality assurance for the achievement of the objective of the Common Market

b) Establish within their territories, National Standards Bodies, and develop technical capacities so as to enable them to adequately carry out SQA activities at the national level and co-operate with other Member States

c) Promote and enforce standards relating to public health safety and protection of the environment by applying appropriate standards for goods produced and traded within the Common Market

d) Recognize the African Organization for Standardization (ARSO) as the leading partner in the implementation of provisions of Chapter 15 of the treaty and agree to accede to the Agreement establishing ARSO

2.2 THE ROLE OF COMESA SQA

The role of COMESA SQA is to establish a regional quality infrastructure through its Member States that is aligned to international best practice.

The following are the key roles of COMESA SQA:

1. Facilitate trade within the COMESA region;
2. Increase opportunities for Countries in the Common Market to participate in the interstates, regional, international trade and technology transfer through Standards, Metrology, Conformity Assessment and Accreditation programmes;

3. Strive to conform to the WTO Agreements on Technical Barriers to Trade requirements and obligations;
4. Harmonize COMESA standards, metrology, and conformity assessment and accreditation procedures to reduce costs, reduce waste, enhance compliance and develop trade opportunities;
5. Enhance consumer confidence in the products manufactured in the Member States and limit consumer exploitation by increasing the number of traded commodities, processes and services that conform to established standards; and ensure fair trading and economical practices;
6. Improve product quality and reliability at a reasonable price to enhance the reputation of goods and services traded in the COMESA Region;
7. Protect and improve the health and safety of consumers and the public in general;
8. Protect the environment;
9. Enhance interchangeability, compatibility, better communication and technology transfer; and
10. Capacity building for the purposes of implementing the COMESA SQA policy.

3. SITUATIONAL ANALYSIS

3.1 COMESA Sub Committees

The COMESA SQA Sub committees have been operationalized to spearhead cooperation in various Standardisation and Quality Assurance areas and to assist the SQA Committee in Harmonization of Standards, Accreditation, Industrial and Scientific Metrology and Legal Metrology, Testing and Quality Assurance, and Technical Regulations.

COMESA Member States agreed on a Regional Policy on Standardisation and Quality Assurance, a Mechanism for Development and Implementation of Standards, Modalities for provision of Accreditation services but Modalities for Metrology, Testing and Certification are still under discussion.

3.1.1 Accreditation Sub Committee

COMESA Regional Framework for the provision of Mutually Recognised Accreditation Services has been reviewed. Member States without National Accreditation Bodies are in the process of setting National Accreditation Focal Points.

3.1.2 Standards Harmonization Sub Committee

Harmonisation of standards started with focus on Agricultural and Food Standards. 65 Electrical Standards have been harmonized and adopted. The Eastern Africa Power Pool Interconnection Code and Eight Power Transmission Standards have been validated by Two Technical Working Groups (English and French speaking

respectively) from 13 mainland COMESA Member States, and in consultation with the Southern Africa Power Pool (SAPP). 370 Standards have been interrogated by Member States but no consensus was reached. 165 Standards are undergoing review in accordance with the procedures for development of COMESA Harmonized Standards.

3.1.3 Metrology Sub Committee

Metrology training needs of Member States have been identified on country basis, paving the way for tailor-made assistance at national level to improve implementation

3.1.4 Technical Regulations Sub Committee

The Committee has reviewed the Draft Regional Technical Regulatory Framework and recommended a way forward for implementation.

3.1.5 Testing and Quality Assurance Sub Committee

A Regional Proficiency Testing Scheme has been proposed starting with four products, namely milk, honey, fish and meat for which laboratory facilities are available.

3.1.6 Pharmaceutical Steering Committee

Minimum Technical Standards of Harmonization (MTSH) have been developed but require updating before circulation to the Member States to enable Member States collect information, which is important for charting the way forward.

3.2 TRIPARTITE AGREEMENT

The Tripartite was established in 2005. It is an umbrella organization consisting of three of Africa's Regional Economic Communities (REC's), namely:

- Common Market for Eastern and Southern Africa (COMESA)
- East Africa Community and
- Southern African Development Community (SADC).

The Common Market for COMESA-EAC-SADC comprises 26 countries with a combined population of nearly 600 million people and a total Gross Domestic Product (GDP) of approximately US$1.0 trillion. The main objective of the COMESA-EAC-SADC Tripartite is strengthening and deepening economic integration of the southern and eastern Africa region. This will be achieved through harmonisation of policies and programmes across the three Regional Economic Communities (RECs) in the areas of trade, customs and infrastructure development.

The decision to develop a Tripartite Free Trade Agreement (FTA) Roadmap and to roll out this Tripartite FTA was endorsed by Heads of State and Government at their first Tripartite Summit held in Kampala in October 2008. The main benefit to be secured from the Tripartite FTA is the establishment of a larger market, with a single economic space.

On 12 June, 2011, the Heads of State and Government of the Common Market for Eastern and Southern Africa (COMESA), the East African Community (EAC) and the Southern African

Development Community (SADC) met and signed a declaration launching negotiations for the establishment of the COMESA-EAC-SADC Free Trade Area (FTA).

The Tripartite FTA builds on the FTAs that are already in place in COMESA, EAC and SADC. The Tripartite FTA is intended to cover all 26 Tripartite countries, these being Angola, Botswana, Burundi, Comoros, Democratic Republic of Congo, Djibouti, Egypt, Eritrea, Ethiopia, Kenya, Lesotho, Libya, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Seychelles, South Africa, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

Work Programme for Tripartite (COMESA/EAC/SADC) Technical Working Groups on Technical Barriers to Trade (TBT) was established after an issue of technical discussions in building consensus under COMESA.

The Final Edited Version 1.0 of the document on the Principles and Procedures for the Development and Harmonization of Tripartite (COMESA/EAC/SADC) Standards has been completed, and made available to the 3 RECs.

The final draft on the Tripartite FTA TBT and SPS Annexes have been completed paving the way forward in advancing the tripartite negotiation process.

3.3 CONTINENTAL FREE TRADE AREA

Regional integration has moved further with the just concluded negotiations of the Tripartite (COMESA, EAC and SADC) TBT and SPS Annexes and the soon to come negotiations for the Common Free Trade in Africa (CFTA).

The overarching objective of the Tripartite is to contribute to the broader objectives of the African Union (AU), namely accelerating economic integration of the continent and achieving sustainable economic development - thereby alleviating poverty and improving quality of life for the people of the Eastern and Southern African Region. As such, the Tripartite works towards improving coordination and harmonisation of the various regional integration programmes of its member REC's. These regional integration programmes focus on expanding and integrating trade and include the establishment of Free Trade Areas (FTA's), Custom Unions, Monetary Unions and Common Markets, as well as infrastructure development projects in transport, information and communications technology and energy.

At the 9th AU Conference of Ministers of Trade (CAMOT), the following resolutions were made:

1. All AU members currently not members of ARSO should endeavour to attain membership by the year 2017
2. ARSO and other Pan Africa Quality Infrastructure institutions should refer to the year 2017 as the African Year of Quality Infrastructure
3. The AUC and ARSO should increase awareness and mobilize all stakeholders on the role of Quality Infrastructure
4. The AUC and Quality Infrastructure Institutions should assess the Status of Quality Infrastructure in Africa and develop a strategic plan on quality infrastructure

3.4 NEEDS ASSESSMENT

Using the needs assessment and SWOT analysis Strategies have been identified to use the strengths and opportunities in mitigating threats and weaknesses.

The objective of the assessment was to bring out the following:

- The problems the institutions/organisation have in their operations
- The gaps and needs to be addressed
- Contribution of the National Quality Infrastructure in trade facilitation
- The impact of the COMESA Standardisation and Quality Assurance (SQA) committee and the Steering Committee on Pharmaceutical Harmonization to Government, private sector and regulators in trade facilitation

The above issues affect implementation of harmonized standards, regulations and are major causes of Technical Barriers to Trade (TBT).

The Needs Assessments are based on the perception of the organisations, as it was not possible within the scope of this study to evaluate if the needs identified by the organisations are exhaustive and correct. The details of needs assessment and SWOT analysis are outlined in Annex 1 and 2 respectively.

4 STRATEGIC DIRECTION AND STRATEGIES FOR THE COMESA SQA

4.1 COMESA SQA VISION

To be the global leader in the provision of highly competitive technical services in the fields of standardization, metrology and conformity assessment, thereby facilitating the region's sustained development through economic integration.

4.2 COMESA SQA MISSION

To achieve increased cooperation and integration in the fields of standardization, metrology and conformity assessment in order to facilitate and promote intra and extra COMESA trade.

4.3 STRATEGIC OBJECTIVES

Having analysed the COMESA Member States Quality Infrastructure and performed the SWOT analyses, gap analysis and needs assessment analyses, the following are the proposed Strategic Objectives and Strategies aimed at meeting the Vision of COMESA SQA.

Strategic Objective	Strategies /Activities
Strategic Objective 1 Improve operational efficiency of COMESA SQA Unit	1.1 Strengthen COMESA SQA Unit 1.2 Develop an effective Communication strategy with Member States and other stakeholders 1.3 Promote active participation of Member States and other stakeholders at COMESA SQA Activities
Strategic Objective 2 Establish and strengthen quality infrastructure institutions in COMESA Member States in line with International Best Practice	2.1 Establish COMESA Accreditation System 2.2 Establish and strengthen metrology system in COMESA and Member States 2.3 Establish and strengthen COMESA Standards harmonization system to support regional trade 2.4 Establish a platform for sharing best practices on regulatory strengthening and harmonization of pharmaceutical and health care products - Liaise with WHO to establish a platform for sharing best practice on pharmaceutical regulatory harmonization 2.5 Strengthen a Regional Regulatory Framework in line with WTO-TBT Agreement 2.6 Develop a framework for collaboration with other RECs on regulations of pharmaceutical and health products 2.7 Promote private sector participation in providing recognized conformity assessment services 2.8 Develop and upgrade quality assurance and quality control infrastructure of the national pharmaceutical regulatory Authorities 2.9 Establish and Strengthen Conformity assessment infrastructures 2.10 Establish/strengthen the WTO/TBT/SPS NEP 2.11 Set up SQA Academy
Strategic Objective 3 Improve on quality products in the COMESA region	3.1 Promote implementation of the Quality Management System in Industry 3.2 Establish and Strengthen Product certification schemes and promote use of Quality marks 3.3 Develop a Market surveillance framework
Strategic Objective 4	4.1 Mutual recognition of Conformity assessment activities

Eliminate Technical Barriers to Trade	4.2 Mutual recognition of Member States Quality Marks 4.3 Mutual Recognition Framework (MRF) and Agreement for COMESA National Medicines Authorities (NMRAs) 4.4 Brief overview of COMESA countries and landscape Develop a mutual recognition arrangement with other RECs
Strategic Objective 5 Resource Mobilization	5.1 Attract funding from development partners

5 MONITORING AND EVALUATION

A monitoring and evaluation system is necessary to ensure that progress is tracked and that expected outputs and impact are obtained;

1. Key performance Indicators for the SQA Subcommittees are aligned to the Strategic Objectives
2. Data Collection and reporting will be realized through monitoring of the OVIs
3. The data will be analysed and reviewed for any corrective actions when there is deviation from planned strategic

Expected reports

Annual reports from the SQA and the sub committees and midterm review of the Strategic plan.

6 ORGANIZATION / INSTITUTIONAL ARRANGEMENTS

In order to ensure successful execution of the strategies laid down in this document, it will be necessary to define the responsibilities of the COMESA SQA Unit /Agency and the responsibilities of the Member States and relationships with other organizations.

6.1 Establish a COMESA SQA Unit/ Agency

The COMESA SQA Unit/Agency will:

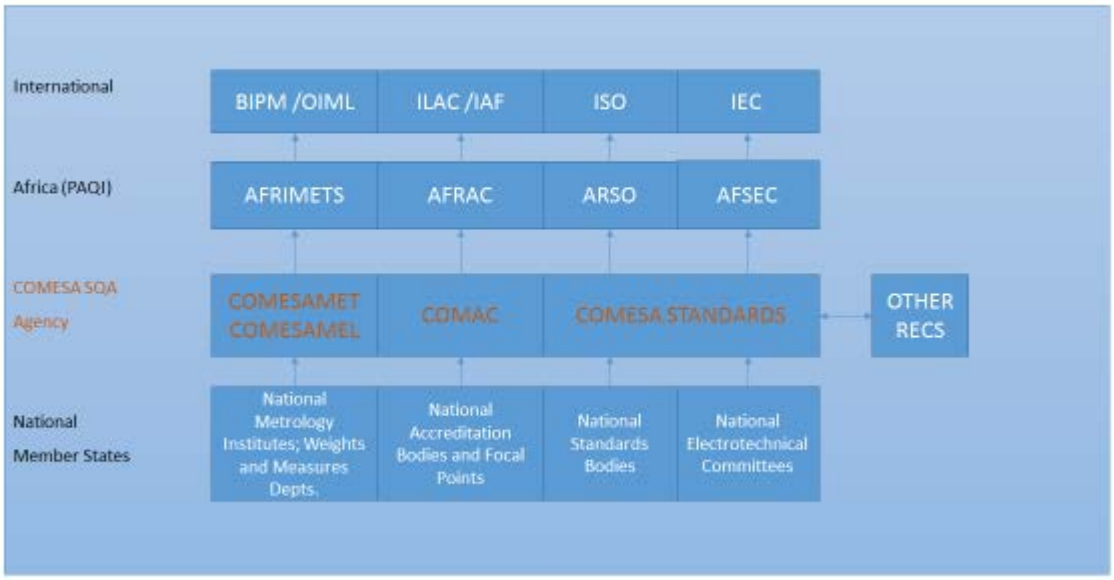
1. Act as focal point where issues of Standards, Metrology, Conformity Assessment and Accreditation are reported and keep abreast with development of Standards, Metrology, Conformity Assessment and Accreditation Activities in the world;

2. Facilitate and provide logistical support for Committee on Standards, Metrology, Conformity Assessment and Accreditation and its Subcommittees in executing their mandates;

3. Provide input into the deliberations of the SQA in establishing priority areas for Committee on Standards, Metrology, Conformity Assessment and Accreditation programmes at the Member States levels;

4. Arrange for the notification of Draft COMESA Standards, facilitate the approval of the drafts as COMESA Standards by the SQA, thereafter present them for declaration to the Council, arrange for the gazetting of the title and scope, and maintain the register and authoritative text of the approved and endorsed COMESA Standards.

6.2 COMESA SQA AGENCY STRUCTURE IN RELATION TO OTHER ORGANIZATIONS



6.2.1 Interaction with other RECs

COMESA SQA Agency shall establish a Mutual Recognition Mechanism with other RECs in order to avoid duplication of work and to save time and resource. RECS will be encouraged to share their work plans.

6.2.2 Resource Sharing

a. Countries with more developed QI should become the reference laboratories and those countries with less developed QI would have contact points. This could be organised by sub-region.

b. There should be a division of work based on specialization and available expertise. Some countries becoming the prime responsible for developing some standards

according to their main businesses (e.g. South Africa for cars as they are the only one with a car industry and Kenya could develop some Standards on Good Agricultural Practice).

6.2.3 Arbitration Mechanism In case of different interpretations of standards (as was the case between Kenya and Zambia on Sugar Standard), it is recommended that an arbitration mechanism hosted by the SQA agency be put in place.

The SQA Agency should have a list of arbitrators, and when there are different interpretations, the two countries would appoint an arbitrator from the list, and the two would appoint a third one. The arbitration would become jurisprudence.

6.3 Establish an SQA Academy

The SQA Academy would have 4 objectives:

- Technical information about new standards (workshops)
- Cursus for future experts
- Popularization of standards through conferences (targeting officials and private sector)
- Knowledge database (Internet)

6.3.1 Technical information about new standards (workshops)

Twice a year, workshops should be organized on a regionalized basis to disseminate information about new standards and review existing standards when there are divergent interpretations. Target audience would be national SQA experts.

6.3.2 Cursus for future experts

The SQA academy will develop a curriculum to train future experts and deliver certificates. Training can be delivered on a regional basis, with teachers travelling to various places.

6.3.3 Popularization of Standards

The SQA Academy will organize conferences to inform officials about the importance of Standards and how to enforce them. Other conferences will target the private sector to inform them about the advantages of standards and train them.

6.3.4 Knowledge database

The SQA Academy will be in charge of building a knowledge database about standards that will be accessible though Internet. It will also include a platform to exchange information and foster cooperation between organizations.

7 IMPLEMENTATION MATRIX

STRATEGIC OBJECTIVE 1*: Improve operational efficiency of COMESA SQA*

Strategies	Activities	Actors	Key responsibilities (tasks)	Period	Objective Verifiable Indicators (OVI)	Priority
1.1 Strengthen COMESA SQA Unit	1.1.1 Recruitment of an SQA Coordinator	COMESA SECRETARIAT	• Develop TORs • Advertise • Interview • Recruit	3 Months	SQA Coordinator appointed	**1**
	1.1.2 Establishment of a Pharmaceutical desk at COMESA Secretariat	COMESA SECRETARIAT	• Develop a paper for establishing the desk • Seek approval from the Council of Ministers	6 Months	A Pharmaceutical desk established at the Secretariat	**1**
	1.1.3 Recruitment of a Pharmaceutical expert	COMESA SECRETARIAT	• Develop TORs • Advertise • Interview • Recruit	6 months	Appointment of a Pharmaceutical expert and a functioning desk	**1**
1.2 Develop an effective Communication strategy with Member States and other Stakeholders	1.2.1 Develop communication strategy	COMESA SQA	• Develop communications strategy • Develop COMESA SQA website • Develop outreach materials • Disseminate to target groups	1 year	Communication Strategy COMESA SQA website Outreach materials developed and disseminated	1
	1.2.2 Share work plans with relevant	COMESA SQA & Standards	• Prepare a schedule for SQA meetings • Prepare Annual work	1 year	Annual work plans	1

	Stakeholders	Harmonization SC	plans • Share the work plans with relevant stakeholders			
	1.2.3 Disseminate harmonized standards, guidelines and other relevant information 1.2.4 Establish/strengthen COMESA Focal Point for SQA matters in Member States with contacts	COMESA SQA AND STANDARDS HARMONIZING SC	• A catalogue of harmonized standards AND Guidelines	1 year	List of Recipient of harmonized standards etc.	1
1.3 Promote active participation of Member States and other stakeholders in COMESA SQA Activities	1.3.1 Develop framework for regular interaction.	COMESA SQA & TR SC	• An annual calendar of meetings • Identify the national experts in respective fields • Develop a platform for internet / web based interaction	1 year	Framework developed and shared with Member States	1
	1.3.2 Schedule and Convene meetings of the SQA Sub Committees	COMESA SQA	• Develop proposals to request for funds • Identify possible development partners	1 year	A calendar of meetings A circulation list	1

STRATEGIC OBJECTIVE 2: *Establish and strengthen quality infrastructure institutions in COMESA Member States*

Strategies	Activities	Actors	Key Responsibilities	Year	Objective Verifiable Indicators (OVI)	Priority
2.1 Establish COMESA Accreditation System	2.1.1. Set up COMAC for cooperation in accreditation	COMESA SQA AND ACCREDITATION SC	• Prepare a paper for the setting up COMAC • Seek approval from Council of Ministers	1 year	A functioning COMAC in place	2
	2.1.2 Establish cooperation with AFRAC, ILAC and IAF	COMESA SQA AND NABS	• Identify requirements for Cooperation/ Membership • Make application to AFRAC, ILAC and IAF	3 years	Cooperation agreements signed	3
	2.1.3 Strengthen Accreditation focal points	Member States (NSBs /NABs) Responsible Ministries	• Identify Accreditation need in Member States • Identify the Focal points with contacts and address	1 year	NABs/ NAFPs in all COMESA Member States	1
	2.1.4 Train assessors and auditors on relevant scopes		• Identify experts in the relevant scopes • Engage a trainer to conduct the training • Organize for regional training of Assessors/ Auditors	2 years	At least 5 assessors trained from each Member State	2
2.2 Established a Metrology Systems in COMESA and Member States	2.2.1 Establish national metrology institutes where they are lacking	Member States Responsible Ministries and NSBs Development Partners	• Prepare proposal for funding • Seek funding from Government and technical assistance from Development partners	3 years	NMIs established	2

	2.2.2	Set up COMESA MET for industrial and Scientific Metrology	COMESA SQA AND METROLOGY SC	• Prepare a paper to request for approval to set up COMESA MET	6 months	COMESAMET Established	1
	2.2.3	Set up COMESAMEL for legal Metrology	COMESA SQA AND METROLOGY SC	• Prepare a paper to request for approval to set up COMESA MET	6 months	COMESAMEL Established	1
	2.2.4	Ensure traceability of measurements	NMIS		4 years	No of members states acquiring membership	2
	2.2.5	Ensure CMCs are posted in the BIPM KCDB	NMIs	• Participate in inter-comparison • Post CMCs	5 years	Evidence of CMCs posted in BIPM KCDB	3
	2.2.6	Establish cooperation with EAMET, SADCMEL, AFRIMETS, OIML and BIPM	COMESA SQA AND NMIs	• Prepare Cooperation agreement with respective organizations • Convene meetings with the organizations • Sign MOUs	3 years	Signed MOUs	3
	2.2.7	Acquire membership in BIPM, OIML AFRIMETS and other Regional metrology organizations	COMESA SQA AND NMIs	• Prepare Cooperation agreement with respective organizations • Convene meetings with the organizations • Sign MOUs	4 years	Signed MOUs	3
2.3 Establish and Strengthen COMESA standards harmonization systems to	2.3.1	Develop criteria for prioritization of harmonization of standards	COMESA SQA AND STANDARDS HARMONIZATION SC	• Identify stakeholder needs • Identify appropriate ARSO/AFSEC THC • Identify experts to participate	1 year	COMESA Standardization System	1

	support regional trade	2.3.2	Establish a standards harmonization system on the basis of stakeholder	COMESA SQA AND STANDARDS HARMONIZATION SC	• Identify stakeholder needs • Identify appropriate ARSO/AFSEC THC • Identify experts to participate	1 year	COMESA Standardization System	1
		2.3.3	Establish cooperation framework relevant regional and international standardization bodies	COMESA SQA AND STANDARDS HARMONIZATION SC	• Draft MOUs / collaboration Agreements • Convene meetings with respective organizations	1 year	Signed MOUs	2
		2.3.4	Acquire membership to relevant organizations	COMESA SQA &NSBS	• Application to relevant Organizations	2 years	No. of new members to the relevant organizations	3
2.4	Establish a platform for sharing best practices on regulatory strengthening and harmonization of pharmaceutical and health care products	2.4.1	Establish forum on regulatory strengthening and harmonization of pharmaceutical and health care products	COMESA PHARMACEUTICAL DESK AND STEERING COMMITTEE	• Establish Regional Expert Working Group (EWG) • Develop harmonized technical guidelines	2 years	Forum Established	1
		2.4.2	Establish forum for other prioritized products			1 year	Forum Established	2
2.5	Strengthen a Regional Regulatory Framework in line with WTO TBT Agreement	2.5.1	Strengthen a Regional Regulatory framework	COMESA SQA TECHNICAL REGULATIONS SC	• Consultation with Regulators • Development of revised RRF	1 year	Review Regional Regulatory Framework	2
2.6	Develop a framework in collaboration with other	2.6.1	Develop a framework in consultation with other RECs (EAC, SADC, EU)	COMESA SQA	• Draft an MOU • Convene meeting with RECs • Sign the MOU	2 years	Inter RECs Framework Number of MOUs signed with other RECs	

	RECs			• Implement			
2.7	Promote private sector participation in providing recognized conformity assessment services	2.7.1 Raise awareness of the private sector on CA services 2.7.2 Provide technical support 2.7.3 Provide incentives	COMESA SQA & COMAC Private laboratories NABs and NAFPs	• Identify potential private CABs • Organize for workshops on 1SO 17000 Series • Assess the CABs for competence	3 years	No of CABs providing services to industry	
2.8	Develop and upgrade quality assurance and quality control infrastructure of the national pharmaceutical regulatory Authorities	2.8.1 Support NMRAs to put in place quality control equipment's, guidelines and procedures	COMESA Pharmaceutical desk and steering committee	• Identify equipment needs for selected countries • Prepare proposals for funding	3 years	No. of NMRAs supported	
		2.8.2 Provide Technical Assistance to ensure Quality Control Laboratories are Accredited	COMESA Pharmaceutical desk and steering committee	• Identify experts in Pharmaceuticals • Train the experts on 17025 • Conduct assessments of the QC Labs • Accredited competent labs	3 years	No. of Pharmaceutical laboratories accredited	2
2.9	Establish and Strengthen Conformity assessment infrastructures	2.9.1 Technical assistance in developing Quality infrastructure in Countries rated below 2 in the needs assessment	Member States and Development Partners	• Develop a proposal for funding • Identify potential development partners	4 years	Improved QI level in the selected Member States	1
		2.9.2 Training of trainers in relevant fields	COMESA SQA, Testing & QA SC Member States	• Engage a Trainer • Develop criteria for training of trainers • Identify potential candidates • Conduct training	2 years	No of Personnel trained	1

	2.9.3 Establish cooperation with conformity assessment bodies (CABs)	Member States	• Identify the CABs within the region • Develop a framework for cooperation	2 years	No. of Cooperation agreements signed	3
	2.9.4 Improve testing skills in selected fields	Testing and QA SC Member States	• Develop an Inventory of Laboratories in COMESA Region • Map the laboratory capabilities • Determine the gaps • Conduct training	3 years	Gap analysis No of training	
	2.9.5 Organize proficiency testing schemes	COMESA SQA Testing and QA SC Accreditation SC Member States	• Identify regional priorities • Identify competent laboratories to run the schemes • Train personnel • Conduct the PT Schemes	3 years	No of PT rounds organized and running	
	2.9.6 Develop harmonized conformity assessment procedures	COMESA SQA Testing & QA Sub Committees	• Assess the existing CA procedures in members states • Determine the gaps • Harmonize procedures • Present for Council of ministers for approval	3 years	Harmonized Inspection procedures	
	2.9.7 Require public procurement to use conformity assessment services	Member States	• Liaise with public procurement authorities • Conduct seminars and workshops on the benefit of conformity assessment	2 years	No of Seminar / Workshops No of Public Institution Standard and Test reports in their tenders	3
2.10 Establish/strengthen the WTO/TBT/SPS NEP	2.10.1 Set up NEPs with contact where required and train NEP personnel	COMESA SQA Member States	• Identify the training requirements of the NEP personnel • Engage a Trainer		No of TBT/SPS NEP established and strengthened	1

			• Train the Personnel			
	2.10.2 Establish TBT/SPS identification and monitoring mechanisms	COMESA SQA SQA Sub Committees NEPs	• Develop a criteria for classification and identification of TBTs and SPS Measures • Harmonize regulations • Promote the use of harmonized regulations	3 years	Monitoring Mechanism in place	1
	2.10.3 Apply for observer status in WTO	COMESA SQA	• Apply to WTO for Observer membership		Membership to WTO	
2.11 Set up of SQA Academy	2.11.1 Establishing the COMESA SQA Academy	COMESA SQA COMESA SQA Sub Committees	• Develop a concept paper • Request for Approval to set up the SQA Academy	1 years	Approval to set up the SQA Academy	2
	2.11.2 Develop and Knowledge database (Internet)	COMESA SQA and Sub Committees	• Identify information for the data base • Develop the data base	2 years	COMESA Academy Web/Internet data base	
	2.11.3 Develop a curriculum for Technical information about new standards (workshops)	COMESA SQA and Sub Committees	• Engage a Consultant to develop curriculum • Develop a TOR for experts • Prepare a calendar of conferences for different target groups	3 years	COMESA SQA Academy Calendar of seminars / workshops	

STRATEGIC OBJECTIVE 3: *Improve on quality product in the COMESA Region*

Strategies	Activities	Actors	Key responsibilities	Year	Objective Verifiable Indicators (OVI)	Budget
3.1 Promote implementation of the Quality Management System (QMS) and Environmental Management system (EMS) in Industry	3.1.1 Develop outreach material on QMS with focus on SMEs	COMESA SQA	• Develop outreach material on QMS with focus on SMEs • Organize for workshops, training and seminars	2 years	No. of Organizations certified	2
	3.1.2 Organize seminars and workshops on the benefits of standards with a major focus on SMEs and Consumer organizations	COMESA SQA Trade Ministries and selected SMEs and Consumer organizations	• Train personnel on administration of the product certification Scheme • Conduct awareness campaigns with focus on SMEs • Administer the Scheme in Member Countries	2 years	No. of products certified	**2**
3.2 Establish / Strengthen Product certification schemes and promote use of Quality marks	3.2.1 Develop / Adopt a Certification scheme with uniform documentation	COMESA SQA Testing and QA SC	• Develop /Adapt a Regional Certification Scheme with special emphasis on SMEs • Develop uniform COMESA documentation • Identify National Certification officers • Train the Certification Officers • Administer the Scheme	2 years	Regional Certification Scheme Uniform documentation for certification and inspection of products Pool of Certification experts in COMESA Region	1

	3.2.2 COMESA Regional Quality Award Scheme	COMESA SQA Testing and QA SC	• Engage a Consultant to Develop a Quality Award Scheme • Market the Scheme to Industry • Train SMEs on the Scheme • Administer the Scheme	3 years	No of Products certified under the scheme	**1**
3.3 Develop a Market Surveillance System	3.3.1 Develop a Regional Framework for Market surveillance (RFMS) including product liability 3.3.2 Strengthen Legal Framework in Member States to handle substandard goods	COMESA SQA & Testing & Quality Assurance Committee Member States Regulators National QI Institutions	• Engage Consultant Prepare a Draft RFMS • Circulate to members for comments • Conduct National Consultations with Stakeholders • Conduct Regional Consolations • Present draft RFMS for adoption and approval by Council of Ministers	2 years	Draft RFMS List of circulation Outcome of National Consultations Outcome of Regional Consultation Approved RFMS	3

STRATEGIC OBJECTIVE 4: *Eliminate Technical barriers to Trade*

Strategies	Activities	Actors	Key Responsibilities	Year	Objective Verifiable Indicators (OVI)	Priority
4.1 Mutual recognition of Conformity assessment activities	4.1.1 Develop a Draft Mutual Recognition Frame work	COMESA SQA AND Sub Committees COMESA SQA, MINISTRIES OF TRADE NQIs	• Engage Consultant Prepare a Draft MRF • Circulate to members for comments • Conduct National Consultations with Stakeholders • Conduct Regional Consolations • Present draft RFMS for adoption and approval by Council of Ministers	2 years	Draft MRF List of circulation Outcome of National Consultations Outcome of Regional Consultation Approved MRF	1
4.2 Mutual recognition of quality marks	4.2.1 Develop a document for peer assessment	Testing & Quality Assurance SC	• Develop TOR • Engage a consultant • Develop the peer assessment document	1 year	Peer assessment Document	1
	4.2.2 Conduct peer assessment in Member States	COMESA SQA	• Develop TOR for assessors • Engage an expert to train assessors • Conduct peer assessment	2 years	No. of trained personnel No. of Countries assessed	
	4.2.3 Notification of MS Quality marks	Members States – Responsible QI	• Identify the National Quality Marks • Notify to COMESA	6 months	No of marks notified	

		Institute	and Member States			
4.3 Mutual Recognition Framework (MRF) and Agreement for COMESA National Medicines Authorities (NMRAs)	4.3.1 Develop MRF & Agreement	COMESA SQA Pharmaceutical Steering Committee	• Engage a Consultant to prepare a draft MRF • Convene National & Regional Stakeholders Meetings on the Draft MRF & Agreement • Present the draft MRF and Agreement to the Council of Ministers for adoption and approval • Conduct collaborative procedures on registration and inspection of pharmaceutical and health	2 years	Free movement of goods Reduction in Technical barriers	1
4.4 Mutual recognition arrangement with other RECs	5.4.1 Develop A Mutual Recognition Mechanism	COMESA SQA , MEMBER STATES, RECS AND PAQI	• Engage an expert to develop the draft MRM • 2 Convene Regional Stakeholders meetings • Present the Draft Mechanism for approval by Council of Ministers	2 years	Draft MRM Outcomes of Regional Stakeholder meetings Approved MRM	1

Strategic Objective 5: *Resource Mobilization*

5.1 Resource mobilization from MS	5.1.1 Encourage Member States to invest in Quality Infrastructure	COMESA SQA MEMBER STATES	• Awareness to Governments / Responsible Ministries on the role of QI • Include QI in activities in National Budgets	Continuous	No of awareness meetings conducted Member States including QI In national budgets	1
5.2 Attract donor funding	5.2.1 Lobby for funding 5.2.2 Develop project proposals	COMESA SQA MEMBER STATES	• Develop proposals to request for funds • Identify possible development partners	Continuous	No. or QI Institutions established / Strengthened	1

ANNEX 1: NEEDS ASSESSMENT

Field	Needs Assessment
Standardisation	1. **Awareness raising to Stakeholders need to engagement in standards development** 2. **Establishment of TBT/WTO enquiry point** 3. **Capacity building in standards information management system, best practices in standards developments** 4. **Awareness of standardisation activities** 5. **Facilitation in attending harmonisation meetings** 6. **Training of Trainers in Management Systems and Standards Implementation** 7. **Upgrading of Training rooms** 8. **Understanding interplay between Technical Regulations and standards** 9. **Training of Chairs and Secretaries of Technical Meetings** 10. **Negotiation skills** 11. **Project Management** 12. **Establishment of Standards Management Committee**
Technical Regulations	**1. Development of a Technical Regulations Framework for COMESA** **2. Harmonisation of Technical Regulations** **3. Understanding interplay between Technical Regulations and standards** **4. Training of Regulators involved in inspection and Market surveillance** **5. Training on TBT and SPS matters**

	6. **Negotiation skills**
Metrology	**Legal Metrology** 1. **Capacity building in weigh bridges verification** 2. **Training on automated road trucks weighing** 3. **Type approval of electronic measurement equipment** 4. **Facilitation of harmonisation of legal metrology regulations** 5. **Specialized training in Legal Metrology especially for the newly established institutions.** 6. **Training in Equipment Maintenance (Instrumentation)** **Scientific/ industrial Metrology** 1. **Capacity building in specialized metrology fields as per country needs including equipment needs** 2. **Facilitation for COMESAMET to harmonize Metrology procedures and best practices in measurements.** 3. **Assistance in acquisition of artefacts for inter-comparisons and facilitation for approval of protocols meetings** 4. **Capacity building in calibration methods, data analysis and results reporting.** 5. **Training in new technologies** 6. **Provision of Spares**
Testing	1. **Assistance in establishment of testing laboratories in the areas of Microbiology, Chemistry, Material and Electronics & Electricals** 2. **Capacity building of testing laboratories in the implementation of ISO/IEC 17025, method validation and measurement uncertainty** 3. **Assistance in accreditation of testing laboratories to ISO/IEC 17025.Assist in harmonisation of testing procedures** 4. **Establishment of Proficiency Testing Scheme (PTS)**

	5. Assistance in acquisition of CRMS 6. Needs or Equipment and provision of spares 7. Awareness on Coordination between Stakeholders and conformity assessment bodies 8. Setting up environmental test facilities
Accreditation	1. Funding for creation of awareness of accreditation, accreditation for selected laboratories and institutions in the Member States. 2. Assist the REC's accreditation bodies in capacity building and in recognition by IAF and ILAC 3. Facilitation in harmonisation work 4. Proficiency testing Schemes 5. Awareness on the need of how accreditation can be used by Conformity Assessment Bodies for regulation. 6. Capacity building in Accreditation Focal Points of Member States
Certification	1. Capacity building of auditors on lead auditors, - 2. Training and mentorship in operationalization of management systems certification to ISO 9001, ISO 14001, ISO 22000, OHSAS 18001 and HACCP assessors and trainers to Certification Standards. 3. Accreditation of certification schemes to ISO/IEC 17021
Quality Assurance, Inspection and Market Surveillance	1. Capacity building of auditors, inspectors for product certification and market surveillance 2. Establishment of product certification scheme to ISO 17065 3. Peer assessment of certification schemes to ISO/IEC 17065 standard 4. Facilitation of harmonizing procedures and regulations for inspection and market surveillance 5. Practical Training in Market Surveillance 6. Need to develop Risk Management System

Pharmaceutical	**1. Capacity building in Pharmaceutical Regulatory Sciences** **2. Technical and Financial Resource Support for participation in harmonization of technical regulations activities** **3. Establish and Sustain National Quality Control Laboratories to ensure Safety and Quality of Pharmaceutical Products in the Market** **4. Establish Sustainable Capacity Building Programmes on Pharmaceutical Regulatory Sciences** **5. Establish a regional Bioequivalence Centre** **6. Harmonisation of Pharmaceutical Technical Regulations and Streamline Registration Processes through Mutual Recognition Framework** **7. Information sharing, networking and joint assessment/inspection activities can help build capacity, confidence and trust and pave the way for mutual recognition.** **8. Implementation of Quality Management System and Risk Based Approaches in Pharmaceutical Registration**

ANNEX 2: SWOT ANALYSIS

STRENGTHS	
Standards and Technical Regulations	• **Established Standards Institutions in most COMESA Member States** • **370 Harmonized COMESA Standards** • **Functional SQA Subcommittee on Harmonisation of Standards** • **COMESA SPS regulations harmonized with EAC and SADC** • **COMESA Member States willing to comply with WTO/TBT requirements** • **Membership to Regional and International Standards setting organisation**
Metrology	• **The COMESA SQA Metrology sub-committee has put in place a structure to operationalize its activities. The structure mirror the AFRIMETS, the EACMET and the SADMET** • **The inter-comparisons has been planned by the sub-committee but not yet executed** • **About two members states are members of BIPM and 5 are associate member of BIPM** • **All the COMESA Member States NMIs have membership in the AFRIMETS with exception of Comoros, Somali, Djibouti and Eritrea**
Accreditation	• **In the COMESA/Tripartite RECs, there exists functional National and Regional accreditation bodies** • **There is a pool of laboratories accredited to ISO/IEC 17025: 2005 and few certification bodies who are accredited to ISO/IEC 17021:2011 in the COMESA REC** • **There are adequate trainers, auditors and assessors on relevant accreditation and certification standards in the region** • **At National level, the accreditation bodies have no competitors**
Testing	• **Good laboratories at Standard bodies, Government and private laboratories**

	• **Competent testing professionals in the COMESA region** • **There are programmed Proficiency Testing (PTs) in the RECs and all competent laboratories are encouraged to participate** • **Some testing laboratories in the RECs are accredited to ISO/IEC: 17025-2005.**
Quality Control, Inspection and Market Surveillance	• **Most of COMESA Member States are carrying out certification of products to ISO 17065:2012** • **Certification marks (Quality marks) being applied and recognized across the borders** • **The COMESA SQA sub-committee on Quality Assurance is carrying out harmonisation of procedures in Quality Control, Inspection and Market Surveillance** • **There are contracted inspection bodies in some Member States carrying out inspection of imports** • **There is a good cooperation between the inspection bodies and the Custom departments**
Certification	• **Pool of experts (auditors and assessors) is in place** • **Trainers on the certification standards (scopes) are available** • **In most Member States Governments is a policy to have its departments certified to ISO: 9001-2008**
Pharmaceutical and Medicine	• **Existence of National Laws and Legal Framework on Pharmaceutical Regulation Activities** • **Autonomy of National Drug Regulatory Authority with few exceptions** • **Harmonization Benefits widely recognized** • **Availability of Regional expertise** • **AU-NEPAD driving continental African Medicines Regulatory Harmonization Initiative** • **Some COMESA Member States participated in EAC Medicines Regulatory Harmonization Initiative (EAC-MRH)** • **Collaboration with International Bodies** • **Existence of EAC Harmonized Guidelines for Registration and Regulation of Pharmaceutical products**

	• **Good progress in domestication and implementation of harmonized EAC Harmonized Technical Regulations and Guidelines**
WEAKNESSES	
Standards and Technical Regulations	• **Insufficient budget/funding standards development and harmonization work** • **Not all Member States attend meetings** • **Irregular harmonisation meetings** • **Lack of experts willing to participate in the harmonisation process** • **Lack of National Regulatory Framework** • **Language barriers** • **Some countries belong to several Regional Economic Communities. This causes confusion and inconsistencies**
Metrology	• **There is insufficient funding of Metrology services and this is common to the other Quality Infrastructure pillars and hence weak or inadequate QI in place in some Member States** • **The QI concept is not fully understood by Governments and other stakeholders in the COMESA Member States**
Accreditation	• **Some Member States have weak accreditation focal points in place** • **Some COMESA Member States have not fully appreciated the role of accreditation of facilities as a trade facilitator** • **Accreditation given no priority in institutions budgets**
Testing	• **Weak funding for public laboratories and hence limited testing scopes and inadequate test equipment** • **Public laboratories not business oriented and efficiency is low**
Quality Assurance, Inspection and Market Surveillance	• **There is non-existence or weak market surveillance regimes in most of the Member States** • **Lack of harmonized inspection procedures existing in the REC** • **Some countries are not accepting imports conformity/test reports issued by the other Member States inspection bodies**

	• **Weak products liability compensation mechanism** • **Negative perception and misunderstanding of the standards**
Certification	• **Slow certification process** • **It is a costly service and many organisations may be discouraged to get certified**
Pharmaceutical	• **Varying capacities across countries** • **Burdensome drug registration processes** • **Country specific requirements** • **Lack of risk-based decision making** • **Lack of effective Management Information System (MIS)** • **Limited Communication and Collaboration between RECs in Pharmaceutical Sector** • **Limited Resources (Human and Financial)**
OPPORTUNITIES	
Standards and Technical regulations	• **Member States willingness to participate in the harmonisation process** • **Information sharing and sharing of expertise and resources** • **Support to the COMESA FTA**
Metrology	• **Metrology services are in demand by Government bodies, private companies and conformity assessment bodies** • **The institution/organisations willing to be certified to Quality management standards ISO 9001, ISO 22000 and ISO 14000 are giving business to Metrology laboratories** • **Little competition in the this field**
Accreditation	• **Business opportunities are plenty for accreditation bodies. There are opportunities for calibration and testing laboratories,**

	certification bodies, inspection bodies and medical laboratories
Testing	• **The scope for testing of commodities is large and need further exploitation** • **Market demand for specialized testing e.g. pesticides residues, soil, metal analysis and food products**
Quality Assurance, Inspection and Market Surveillance	• **The COMESA REC is a large trading block consisting of 19 countries** • **The trading block has good communication network (roads, air transport and telecommunication). It has many water outlets and good harbours which serve other trading RECs**
Certification	• **Certification services are in demand for recognition and confidence of service offered by Certification bodies** • **Procurement and the supply chain have QMS certification as a requirement in their tender document**
Pharmaceutical	• **Political Will** • **Existence of Regional Committee namely COMESA Steering Committee on Pharmaceutical Harmonization to support the initiative** • **EAC Pharmaceutical Regulatory Harmonisation initiative will inform Strategic Plan Development and Establishment of a Pharmaceutical Desk at COMESA Secretariat** • **Existence Harmonized EAC Guidelines and Standards** • **Existence of WHO guidelines and Standards** • **Opportunity for COMESA to invest in untapped areas of infrastructure development**
THREATS	
Standards and Technical Regulations	• **Conflicting Standards with other Regional Economic communities** • **Stronger economies flooding the COMESA region with substandard goods** • **Language problems with some Member States**

	• **Conflicting regulations within the Member States**
Metrology	• **There are very fast changes in technology and equipment are becoming obsolete and there is also need for higher accuracy with very low level of uncertainty of measurements** • **Trained experts leaving the NMIs to other organisations** • **There is mushrooming of commercial laboratories engaged in shoddy calibration and testing activities**
Accreditation	• **National institutions/organisations losing business due to lack of certification and accreditation** • **Integrity of services offered by institution being questioned due to lack of accreditation** • **The changing international trade regulations and requirements**
Testing	• **Competitive market** • **Emerging stringent test requirements by regulators** • **Changing test methods and test equipment technology** • **Costly environmental test conditions**
Quality Assurance, Inspection and Market Surveillance	• **The changing international trade regulations and requirements.** • **Regulators rejecting inspection and test reports other Member States** • **Inability to control counterfeit products and substandard goods in the markets** • **Fraud and mal-practices in trading** • **Under-declarations and unclear certificates of origin**
Certification	• **High competition of the service providers and tough completion on price** • **Unqualified assessors, auditors and trainers**
Pharmaceutical	• **Membership of multiple RECs**

	• **Long timelines for legislative/Policy Change** • **Good progress done in EAC region in harmonisation of standards and guidelines for registration and regulation of pharmaceutical products may result in poor adoption , domestication and implementation of COMESA harmonized technical guidelines** • **Limited human resource capacity (skills and number) and financial resources to execute mandate of regulatory bodies** • **Lack of Regional Systems and Structures to drive the Pharmaceutical Regulatory Harmonization Initiative at COMESA Secretariat i.e. Pharmaceutical Desk** • **Dependency on external bodies to initiate and drive harmonization**