



1st International High Level Multi-Stakeholder Conference

*On Promoting Pharmaceutical Sector Investments
in the East African Community (EAC) Region*



Nairobi, Kenya

2nd – 4th November, 2016

CONFERENCE BOOKLET AND PROGRAMME

CONFERENCE PARTNERS



THE WORLD BANK



World Health
Organization



UNITED NATIONS
UNCTAD



german
cooperation

DEUTSCHE ZUSAMMENARBEIT

giz

Deutsche Gesellschaft
für Internationale
Zusammenarbeit (GIZ) GmbH



Messen ■ Forschen ■ Wissen



Consulting Group

BILL & MELINDA
GATES foundation



1. INTRODUCTION

The pharmaceutical spending in Africa is currently estimated at US\$30 billion and this value is driven by a 10.6% compound annual growth rate (CAGR) second only to Asia Pacific (12.5%) and in line with Latin America (10.5%). Spurred by a convergence of demographic changes, increased wealth and healthcare investment and rising demand for medicines to treat chronic diseases, this market potentially represents a US\$45 billion opportunity by 2020¹.

The East African Community (EAC) is the most mature trading block among the four regional economic communities in Africa.

The EAC has the highest pharmaceutical sales growth compared with other regions in the continent with an estimated CAGR of 12.4% over the next five years and the market is currently estimated at USD 5.3 billion.

The East African Community Secretariat and the Partner States recognizes the strategic importance of the pharmaceutical sector in promoting access to affordable quality essential medicines as well contributing to industrial development.

The Secretariat in collaboration with the Partner States and development partners have put in place several programmatic measures to support the development and growth of the sector.

' Spurred by a convergence of demographic changes, increased wealth and healthcare investment and rising demand for medicines to treat chronic diseases, the African market potentially represents a US\$45 billion opportunity by 2020'

The measures that have been put in place include the development of an EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA): 2012-2016 as well as the inclusion of the

pharmaceutical sector as among the six priority intervention areas in the EAC Industrialization Policy and Strategy (2012-2017) and the on-going EAC Medicines Registration Harmonization Project.

Despite these developments, the pharmaceutical manufacturers operating from within the EAC region generally produce at a cost disadvantage to larger generic product manufacturers internationally due to a variety of reasons including scale, expensive asset base coupled with older technology, higher financing costs plus a lack of integration with active pharmaceutical ingredients suppliers.

This situation makes locally manufactured medicines uncompetitive compared to imports and the regional pharmaceutical market is therefore dominated by imports with local manufacturers producing less than 30% of the medicines demand.

There is need therefore to support the growth of the sector by engaging and addressing the concerns of the local pharmaceutical manufacturers and potential investors.

It is in this regard that the EAC Secretariat in collaboration with the EAC Partner States will hold the **"1st International Conference on Promoting Pharmaceutical Sector Investments in the East African Community (EAC) Region"** which is being held in Nairobi, Kenya from 2nd to 4th November 2016.

The conference brings together key stakeholders in the Partner States including Ministries of Health, Finance and Industry, National Medicines Regulatory Agencies (NMRAs), National Procurement Agencies (NMPAs), other Regional Economic Communities (RECs), NEPAD, World Health Organization (WHO), UNCTAD, UNIDO, UNAIDS and the private sector (local and international pharmaceutical manufacturers) as well as international development partners and investors among others.

The stakeholders will deliberate and propose viable and practical strategies for promoting growth and investment in the local pharmaceutical manufacturing industry.

1.2 CONFERENCE OBJECTIVES

The overall objective of the workshop is to develop a common and shared vision for promoting investment in the regional pharmaceutical manufacturing sector.

Specific objectives:

- a.) To sensitize pharmaceutical manufacturers on the EAC Regional Harmonized Medicines Registration Procedures/guidelines and address their concerns;
- b.) To discuss and propose the most viable incentive schemes for promoting local pharmaceutical manufacturing;
- c.) To make recommendations for consideration by the Partner States' governments on promotion of local pharmaceutical manufacturing industry;
- d.) To promote and foster dialogue between the policy makers, regulators and pharmaceutical manufacturers.



1.3 CONFERENCE AGENDA

The agenda of the conference will include the following:

- a.) Updating stakeholders and in particular pharmaceutical manufacturers on the EAC Regional Harmonized Medicines Registration Procedures/Guidelines;
- b.) Make recommendations on incentives that will promote local pharmaceutical manufacturing;
- c.) Provide a platform for industry/regulators/policy makers exchange as well as networking and business linkages.

PROGRAMME

Wednesday 2nd Nov.	DAY ONE
08.30 - 09.00hrs	Arrival and Registration
	OPENING SESSION
09.00–11.00hrs	<p>Welcoming Remarks: Dr. Nicholas Muraguri Principal Secretary of Health, Kenya</p> <p>Welcoming remarks: Mr. Julius Korir , Principal Secretary, Industry, Trade and Cooperatives, Kenya</p> <p>Remarks: Mr. Nazeem, Mohamed, Chairman Federation of East African Pharmaceutical Manufactures (FEAPM) and CEO Kampala Pharmaceutical Industries</p> <p>Remarks: International Development Partners</p> <p>Opening Remarks: Amb. Liberat Mfumukeko, EAC Secretary General</p> <p>Remarks by Hon. Dr Josiane NIJIMBERE, Minister for Health and Fight Against AIDS , Republic of Burundi</p> <p>Speech and opening of the conference by Guest of Honour: Hon. Phyllis Kandie, Cabinet Secretary, East African Community, Labour and Social Protection, Kenya</p> <p>Key Note address : Dr. Ibrahim Mayaki, CEO, NEPAD</p> <p>Opening Session Moderator: Dr Stanley Sonoiya, EAC Secretariat</p>
11.00 –11.30hrs	TEA BREAK
SESSION I: IMPLEMENTATION OF EAC MEDICINES REGULATION AND HARMONIZATION GUIDELINES	
11.30–13.00hrs	<ol style="list-style-type: none">1. Ms. Margareth Ndomondo-Sigonda, Pharmaceutical Coordinator, NEPAD; African Medicines Regulatory Harmonization Programme and African Union Model Law on Medical Products Regulation2. Dr Stanley Sonoiya, EAC Principal Health Officer; Promoting local pharmaceutical production for Public Health and Industrial Development

3. John Patrick Mwesigye, EAC Senior Health Officer; Progress on implementation of EAC Medicines Regulation and Harmonization guidelines
 4. Mr. Hiti Silo, Director General, Tanzania Food and Drug Authority (TFDA); Roll out of the MRH guidelines by the Regulator
 5. Dr. Rogers Atebe, Federation of East Africa Pharmaceutical Manufacturers (FEAPM) and Company Pharmacist, Regal Pharmaceuticals; Private sector View on Harmonized guidelines
 6. Mr. Pierre Claver, Sipha Pharmaceuticals Burundi; Private sector experience on complying with the Guidelines
- Chair of session: Dr Fred Sioyi , Kenya Pharmacy and Poisons Board

13.00-14.00hrs

NETWORKING LUNCH

SESSION II: IMPLEMENTATION OF EAC MEDICINES REGULATION AND HARMONIZATION GUIDELINES (INDUSTRY- REGULATOR EXCHANGE)

14.00– 16.00hrs

1. Ms. Jane Mashingia, EAC Senior Health Officer; Overview of EAC regional pharmaceutical policy and regulatory framework
 2. Mr. Daniel Murenzi, EAC e-health Officer; Overview of EAC MRH IMS architecture
 3. Mr. Joseph Kabetende, Head Pharmacy Unit, MOH Rwanda; Overview on Harmonized guidelines for Medicines Evaluation and Registration
 4. Ms. Kate Kikule, NDA, Uganda; Overview on Harmonized guidelines on Good Manufacturing Practices
 5. Dr Wiberforce Wanyanga, UNIDO; The Kenya GMP Roadmap: Current status, Experience and Lessons for scale up
- Chair of Session: Dr Samuel. Azatyan, World Health Organization

16.00 – 16.30

TEA BREAK

SESSION III : CAPACITY BUILDING ON PHARMACOVIGILANCE AND POST-MARKET SURVEILLANCE FOR THE LOCAL PHARMACEUTICAL INDUSTRY

16.30–17.30hrs

1. Dr. Christabel Khaemba, Kenya Pharmacy and Poisons Board; Overview of the EAC Pharmacovigilance and Post-Market Surveillance systems

2. Dr. Ndinda Kusu, USAID/SIAPS Support for Pharmacovigilance Systems in the EAC
 3. Dr. Gaddu Gabriel, USP; Capacity building on Good Manufacturing Practice to promote domestic pharmaceutical manufacturing
 4. Dr Robert Miano, GSK; The role of manufacturers in strengthening PV and PMS systems
 5. Prof. Gibson Kibiki, Executive Secretary, EAHRC; East African initiative to support health Research and Development
- Chair of session: Ms. Kushemererwa Donna, Executive Director, NDA, Uganda

Thursday 3rd Nov.

DAY TWO

SESSION IV : INCENTIVES FOR LOCAL PHARMACEUTICAL MANUFACTURING

09.00–11.00hrs

Keynote 1 : Mr Nazeem Mohamed, Chairman, FEAPM & CEO Kampala Pharmaceutical Industries; Proposed East African Pharmaceutical Manufacturing Incentive Package

Keynote 2 : Mr Emmanuel Alenga, Ernst and Young Kenya; Promoting growth of local manufacturing industry: Lessons from other sectors

Panelists:

- Permanent Secretary Ministry of Finance ,Rwanda
- Permanent Secretary Ministry of Finance, Uganda
- Permanent Secretary Ministry of Finance, United Republic of Tanzania
- Permanent Secretary Ministry of Finance, Burundi
- Principal Secretary Ministry of Finance, Kenya
- Ermias Biadgleng, Legal Officer, UNCTAD

Chair of session: Eng. Jennifer Gache , EAC Secretariat

11.00 –11.30hrs

TEA BREAK

SESSION V : POLICY COHERENCE FOR PHARMACEUTICAL SECTOR DEVELOPMENT IN EAST AFRICA

11.30–13.30hrs

Key Note 2 : Mr Ermias Biadgleng, Legal Officer, UNCTAD;
Policy coherence approach in promoting local
pharmaceutical manufacturing

Panelists:

- Permanent Secretary, Ministry of Industry & Trade, Burundi
- Permanent Secretary , Ministry of Industry & Trade, Uganda
- Permanent Secretary, Ministry of Trade & Industry , Rwanda
- Permanent Secretary, Ministry of Industry & Trade,
United Republic of Tanzania
- Principal Secretary, Ministry of Industry, Trade and
Cooperatives Kenya

Chair of session: Dr Wilberforce Wanyanga, UNIDO, KENYA

13.00-14.00hrs

NETWORKING LUNCH

SESSION VI : INCENTIVES FOR LOCAL PHARMACEUTICAL MANUFACTURING ACCESS TO APPROPRIATE FINANCING

14.00– 16.30hrs

Keynote 1: Dr Geoffrey Banda, University of Edinburgh,
Co-author of the book "Making Medicines in Africa"
Financing African Pharmaceutical Production

Keynote 2 : Mr. Amitabh Mehta, Director, Innovative
Financing Solutions, Fundraising Strategy & Corporate
Partnerships, Indus Blue Consulting, Geneva; Exploring
Innovative Mechanisms for Financing Local Manufacturing.

- Open Panel Debate: Lessons from the input presentations

Moderator: Ms. Elizabeth Maloba

- Panel

- Dr Geoffrey Banda, University of Edinburgh
- Mr. Amitabh Mehta, Indus Blue Consulting
- Mr. Martin Nicholson, UNIDO
- Ms. Martha Osier, Catalyst Principal Partners
- Mr. Nihal Shah, Biodeal Laboratories
- Mr. Rohit Kumar Singh, Group Executive Director,
Corporate & SME Banking, Equity Bank

Chair of session: George Ndira , EAC Secretariat

16.30 – 17.30

TEA BREAK AND NETWORKING SESSION

Friday 4th Nov.

DAY THREE

SESSION VIII : PARTNERS SUPPORTING THE EAC PHARMACEUTICAL SECTOR

09.00–10.15hrs

1. Mr. Tobias Diergardt - PTB project on support to quality infrastructure in the pharmaceutical sector
 2. Dr. David Mukanga, B&MGF- EAC Medicines Regulatory Harmonization
 3. Mr. Martin Nicholson, UNIDO Project on Strengthening the Local Production of Essential Medicines in Developing Countries
 4. Mr. Wesley Ronoh, GIZ/GFA project on Pharmaceutical Sector Promotion
 5. Dr Jantine Jacobi, UNAIDS Country Director Kenya
 6. Dr. Franklin Keter, Clinton Access Initiative (Pharmaceutical Manufacturing)
- Chair of session: Prof. Gibson, Kibiki, EAC Health Research Commission

SESSION IX: INVESTING IN EAST AFRICA PHARMACEUTICAL MANUFACTURING SECTOR:
AN INVESTOR PERSPECTIVE

10.15–11.15hrs

1. Mr Palu Dhanani, CEO, Universal Corporation/Strides JV, Kenya
 2. Mr Neil Bradford, CEO, Quality Chemicals/CIPLA, Uganda
 3. Harvinder Singh Alag, CEO, Zenufa Pharmaceuticals, Tanzania
 4. Pierre Claver Nivonizigiye, SIPHAR Pharmaceuticals, Burundi
- Chair of session: Dr Robert Karanja, CEO, VILLGRO KENYA

11.15 -11.45hrs

TEA BREAK

SESSION X: WORKSHOP RECOMMENDATIONS AND CLOSING CEREMONY

11.45– 13.00hrs	1. Workshop report and recommendations 2. Closing ceremony
13.00 – 14.00	LUNCH
14.00–17.00hrs	BUSINESS LINKAGES AND NETWORKING

HIGHLIGHTS OF THE EAC PHARMACEUTICAL SECTOR PROJECTS



1. EAST AFRICAN COMMUNITY MEDICINES REGULATORY HARMONIZATION (EAC MRH)

Introduction

The six EAC National Medicines Regulatory Authorities (NMRAs) are developing and implementing medicine registration procedures that are compatible with internationally accepted standards. The project is coordinated by the EAC Secretariat and implemented by the Partner States with technical support from NEPAD and WHO.

Overall goal

To have a harmonized and functioning medicines registration and regulation system within the East African Community in accordance with the national and internationally recognized standards and best practices.

Benefits

Reduction in timelines to introduce new medicinal products in the EAC market, Cost savings by EAC Governments, Reduction in duplication of efforts and improved efficiency of NMRAs through work and information sharing.

Achievements

Three compendiums have been developed and are being implemented; EAC Medicine Evaluation and Registration (MER), Good Manufacturing Practices (GMP) and Quality Management Systems (QMS) compendiums. The EAC Information Management System (IMS) has been developed within the framework of EAC-MRH.

MRH Partners

- Bill And Melinda Gates Foundation
- World Health Organization (WHO)
- African Union and NEPAD
- The World Bank
- The United Kingdom Development Agency (DfID)

For more information please visit: www.mrh.eac.int

2.0 EAC - PTB PROJECT ON ESTABLISHMENT OF A REGIONAL QUALITY INFRASTRUCTURE FOR THE PHARMACEUTICAL SECTOR

Objective

The quality infrastructure in the EAC is developed to satisfy the demand of the pharmaceutical sector



Approach

To ensure availability of affordable and qualitatively good medicines on the EAC Market, Quality Infrastructure services are needed by pharmaceutical manufacturers and by institutions which are in charge of regulating and controlling the pharmaceutical sector.

Project activities are therefore aiming to strengthen the private as well as the public sector and to meet common challenges. These challenges are the insufficient availability of appropriate calibration services, affordable chemical reference substances, regular interlaboratory comparisons and reliable maintenance services for laboratory equipment.

Within the framework of the project, comparison measurements will be introduced to the region enabling laboratories to compare their performance and take remedial action where necessary. Together with the National Metrology Institutes, the scope of calibration services will be extended according to the needs of the pharmaceutical sector.

In order to improve access to chemical reference material, EAC will be supported in setting up a regional centre. Quality Assurance experts from industry, regulatory authorities and QI institutions will be trained on quality management systems and maintenance of laboratory equipment.

Impact

The improved access to quality infrastructure services for the pharmaceutical sector enables manufacturers and control authorities to better meet internationally accepted quality standards like the WHO prequalification or the ISO/IEC 17025 laboratory standard.

This opens up new growth opportunities for manufacturers beyond their national borders and ensures better controls against substandard medicines by regulatory authorities. Hence, the accessibility of safe and affordable medicines for all EAC citizens improves.

Further development of the pharmaceutical sector is a strategic priority of the EAC Secretariat and through the project, important framework conditions for this development are set.

The project is an integral part of the German development program "Support to the EAC integration process" and cooperates closely with Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ).

For more informations, please Contact:

EAC Secretariat & Tobias Diergardt, PTB Project Coordinator East Africa

tobias.diergardt@ptb.de

3.0 POLICY COHERENCE FOR PHARMACEUTICAL SECTOR DEVELOPMENT IN EAC

Pharmaceutical production is the shared objective of industrial and public health policies of EAC and its Partner States. Industrial policy supports the development of a competitive pharmaceutical sector that generates employment and contributes to the national and regional economy. Health policy seeks to ensure the availability and affordability of pharmaceutical products that satisfy the quality, safety and efficacy requirements.

The Nairobi Statement on Investment in Access to Medicines, signed in July 2016, among UNAIDS, UNCTAD, the African Union (AU), and the Kenyan and South African governments emphasized the importance of coherence among domestic policies related to health, investment, trade, technology and intellectual property and the importance of integrating markets.

A policy coherence approach, as a methodology, can help to ensure that various policies work together to achieve their shared objectives. It seeks to consolidate the advantage created by some policies, while at the same time addressing the gaps and inconsistencies in other policies. Important policy areas, including investment laws and incentives, tariffs, education and skill development, intellectual property, technology transfer and innovation, government procurement and international cooperation can influence the achievement of the shared objective.



EAC: Regional Approach and Policy Coherence

The EAC Industrialisation Policy and Strategy has prioritized the pharmaceutical industry. The Pharmaceutical Manufacturing Plan of Action (2012 – 2016) has been the regional roadmap for developing the sector, which is now currently subject to renewal.

The primary advantage provided by the EAC region is its integration based on, among others, the Common Market Protocol and Common External Tariff (CET). EAC took an important step to provide further integration in the field of public health with the adoption of the Medicines Regulation Harmonization Guidelines (November 2015). Yet there are gaps in tariff, public procurement, and regional investment, health, procurement and competition policies.

The United Nations Conference on Trade and Development (UNCTAD) had conducted capacity building activities in the EAC region, at regional level and national level (Kenya, Tanzania and Uganda) during 2014 and 2015, in partnership with the EAC Secretariat, GIZ, WHO and national ministries of health, and industry and trade, science and technology as well as generic manufacturers' associations.

During this Conference, UNCTAD will contribute to the discussion on policy coherence for local pharmaceutical manufacturing.

For further information, please contact, Ermias Biadgleng, Legal Affairs Officer, UNCTAD, at Ermias.biadgleng@unctad.org.

4.0 UNIDO PROJECT TO STRENGTHEN PHARMACEUTICAL PRODUCTION IN KENYA

UNIDO's global project is focused on *"Strengthening the local production of essential medicines through advisory and capacity building support"*.



Healthcare benefits can be attained through improved access and continuous availability to safe and efficacious medicines with assured quality. Local pharmaceutical production plays a key role in ensuring a sustainable and consistent source of quality medicines, preventing discontinuities in the supply chain and saving time and money compared to the long and costly procurement mechanisms inherent with importation.

It is necessary to recognise that pharmaceutical production is enshrined in a set of complex challenges, therefore a holistic approach is desirable. It is also important to state that the solutions are not achievable overnight and prioritization is essential. A risk based approach is necessary given the nature of both pharmaceutical production, and the healthcare market it serves.

UNIDO's project in Kenya commenced with a comprehensive study of the sector, to gain a better understanding of its status, strengths, weaknesses and opportunities. All key national stakeholders were engaged in order to develop a clear perspective of the sector. Several key policy documents provide insight into this, in particular Vision 2030: Kenya Pharmaceutical Policy and Kenya Industrialization Policy.

A number of factors can be seen as limiting the capability of local manufacturers to serve their home national and regional markets. One significant factor relates to donor funded medicines where WHO prequalification is a prerequisite in order to meet procurement requirements. Another important issue relates to different levels of compliance to GMP, and calls for a level playing field for both imported and locally produced medicines. Whilst not an exhaustive list, these realities, together with regulatory factors, impact greatly on the commercial environment that local manufacturers operate within.

Having a better understanding of the pharmaceutical market terrain, the next step was to seek and develop solutions. The Kenya Pharmaceutical Sector Development Strategy (KPSDS) is a product of concise engagement through round table discussions with key stakeholders and the balance between public health and economic impact required careful consideration. Seven strategic components were developed that, taken together, offer a holistic approach to strengthening the sector.



One inherent factor in the process was building capacity alongside implementation. In order to ensure all players were on same page, various trainings were undertaken including demystification of GMP, improving operational efficiency and supporting and strengthening regulatory functions relevant to the sector strategy.

The Kenya GMP Roadmap represents a pivotal strategic component for implementation of the KPSDS as a whole. Both the industry and regulators were in agreement that this formed a rational and practical stepwise approach to development of the local pharmaceutical sector, towards achievement of WHO GMP standards. The Roadmap was launched in 2014 with an ambitious five year plan, involving a two pronged approach focusing on both site- and QMS-related GMP, and covering the 17 WHO key quality elements.

Categorization of the industry according to their compliance with WHO GMP involved application of a risk-based matrix developed by the UNIDO pharmaceutical team. The related GMP assessment was the most sensitive part of the process for industry and was conducted by one of three UNIDO international GMP experts who, accompanied by a PPB GMP inspector, took part in a two-day site visit to each company. This portion of the Kenya project was supported by GIZ.

Each manufacturer received a written report following the assessment, and thereafter was responsible for development of a Corrective and Preventive Action (CAPA) plan. UNIDO supported this process through conductance of a 'CAPA clinic' which involved bringing together the GMP Experts with industry in order to review, one-by-one and confidentially, their draft CAPA plans to ensure these met requirements.

The assessment and CAPA review processes not only provided objective measurements to determine the gaps between each manufacturer and WHO GMP, but also gave opportunities for skill-based training to both the industry and regulator. This approach has been acknowledged by participants as being comprehensive, technically sound and highly valuable.

It was also necessary to set up a governance structure for the KPSDS as a whole. The Pharmaceutical Technical Committee (PTC) reviews and determines actions required to address technical issues arising from implementation of the KPSDS and GMP Roadmap. The Pharmaceutical Steering Committee (PSC) has overall oversight of the KPSDS, provides guidance on policy issues, and importantly briefs the Cabinet in order to ensure continued high level Governmental awareness and support of the project.

Currently, on the industry side CAPA implementation is on-going and number of companies are making significant progress towards the attainment of WHO level GMP.

Dr. W.O. Wanyanga
National Pharmaceutical Expert, UNIDO

"The EAC has the highest pharmaceutical sales growth compared with other regions in the continent with an estimated CAGR of 12.4% over the next five years and the market is currently estimated at USD 5.3 billion" (**IMS HEALTH, Africa**)

www.eac.int