



4TH ANNUAL SADC INDUSTRIALISATION WEEK

EAC PHARMACEUTICAL VALUE CHAINS REGIONAL APPROACH: LESSONS LEARNT

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About the East African Community-Health Context

- Home to about 174.2 million ;
- Young population > half of its population aged below 15 in 2012;
- Leading causes of death - HIV/AIDS, lower respiratory infection, and diarrheal diseases. NCDs have risen sharply (approx. 25% of all deaths);
- By 2030, deaths from NCDs (cancer, diabetes, heart disease and chronic respiratory disease are projected to overtake communicable diseases) are expected to account for 42% of all deaths, up from approximately 25% today;
- ☐ High donor funding (especially TB, Malaria, HIV) and out-of-pocket expenditure for medicines;
- ☐ Need for better access to healthcare through social health protection (SHP) programs; on average, only 25% of the EAC population is covered by some kind of SHP mechanism;
- ☐ Domestically-produced medicines remain below 15% of the pharmaceutical market in terms of value (EAC average);
- ☐ Over 50% of the products are generics not branded; simple dosages

Pharmaceutical Market in EAC

Countries	Burundi	Kenya	Rwanda	Tanzania	Uganda
Pharma market size (US\$ million, 2014)*	75	740	100	400	450
Compound Annual Growth rate (CAGR) 2007 to 2014**	12.85%	15%	16.36%	9%	8.5%
Market share of locally produced pharmaceutical drugs (% of overall market)*	3%	30%	<1%	12%	20%
Market by segment**	56% Generic, 44%, Branded	62% generic, 38 branded	53.9% Generic, 46.1% Branded	Generic 54%, Branded 46%	Generic 80%, Branded 20***
Number of local pharmaceutical manufacturers	1	34	1	12	14

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Policies Supporting Local Production in EAC

No	Policy	Key Points
1.	EAC Regional Pharma Manufacturing Plan of Action (RPMPOA 2017-2027	<p>Premised on six pillars: competitive and efficient regional pharmaceutical production; increased investment : regulatory capacity; appropriate skills and knowledge; WTO TRIPS flexibilities and innovation and research.</p> <p>Targets: Imports from outside EAC reduced from >70% to < than 50%; Expand product portfolio of EAC firms to cater for more than 90% of disease conditions; at least 50% of purchases by EAC national medicines procurement agencies is sourced from EAC manufacturers; and at least five (5) companies produce more advanced pharmaceutical formulations.</p>
2.	EAC Industrialization Policy and Strategy; 2012-2032	Pharmaceutical sector is prioritized
3.	Regional Health Policy; 2015-2020	Enhanced access to essential medicines and health technologies
4.	EAC Medicines Registration Harmonisation Initiative	Regional guidelines developed for medicines evaluations, GMP inspections, and a regional IMS being developed. Joint evaluations and inspections now being conducted; Less time for registration
5.	EAC Regional WTO Regional Policy on the Utilisation of Public Health-Related policy and a model law, 2015	Enables the region to take advantage of TRIPs Flexibilities
6	Others	EAC Development Strategy; EAC Vision ; EAC Treaty; Customs Union; Common External Tariff; among others



Achievements/Lesson learnt

- Joint Steering/ Coordination structure established between health sector/ Industrial development sector and private sector; Enabling policies developed in Partner States
- Increased investments: Joint ventures/buyouts with leading Indian & South African manufacturers e.g. between Universal (Kenya) and Strides Pharma (India), Quality Chemicals (Uganda) and Cipla (India); Shelys (Tanzania) and Aspen Pharma (South Africa). Investments by private equity funds e.g.. CDC Capital's investment in Abacus Parenterals Drugs Ltd and buyout of the majority shareholding of Zenufa Laboratories (Tanzania) by Catalyst Principal Partners ;
- Strengthened regulatory capacity in the EAC Partner States; Increased technical cooperation (e.g. common guidelines, joint assessments and inspections, PMS) in the region.
- Good Manufacturing Practices enhanced through a Regional Framework-Corrective Actions to be undertaken;
- Harmonised documents have been developed: the Common Technical Document (CTD) and the Guidelines for GMP and QMS guidelines. A total of three (3) joint dossier assessments have been conducted, where 27 applications were reviewed and nine (9) joint GMP inspections took place, involving four facilities in the EAC and five outside the region; joint assessments undertaken reducing time by 30-40%; Median time for dossier submission reduce by 40-60% ; 7 months from 1-2 years

ACHIEVEMENTS/ LESSONS LEARNT ON THE REGIONAL ACTION PLAN contd.

- ❑ The regional manufacturers` association, FEAPM, is established and engaged in lobbying and advocacy activities.
- ❑ Quality Infrastructure improved : More than 300 technical personnel trained in PV, PMS, clinical trials, dossier evaluation, GMP Inspection, Proficiency Testing, Calibration and Validation, preventative maintenance of critical quality control equipment and others.
- ❑ Academia- industry internship programme established with the support of GIZ and UNIDO.
- ❑ EAC WTO TRIPS policy and a model law to guide Partner States in place and trainings.
- ❑ East African Health Research Commission (EAHRC) has been established.
- ❑ Pilot projects to promote Pharmaceutical R & D capacity in the region, e.g. with MUHAS and Kilimanjaro School of Pharmacy (GIZ).

Incentives to attract investments

- Market Access via price preference: A preferential margin of 20% for all regionally produced medicines and medical devices in public tenders according to Art. 35 of the Common Market Protocol.;
- No duties on imports of raw and packing material, pharmaceutical manufacturing related equipment as well as spare parts for this equipment.
- Classification of medicines according to the production capabilities of local manufacturers. Medicines that can be produced locally will be taxed or even restricted from import.
- Common External Tariff: Tariff raised for Negative list which have been identified where region has capacity to produce namely;
 - Amoxycillin - Capsules and Dry Powder for Suspension;
 - Ampicillin & Cloxacillin - Capsules and Dry Powder for Suspension;
 - Co-trimoxazole - Tablets and Suspension;
 - Paracetamol - Tablets and Suspension;
 - Erythromycin - Tablets and Suspension;
 - Metronidazole - Tablets and Suspension;
 - Ibuprofen - Tablets and Suspension; and
 - Ciprofloxacin – Tablets.



Thank you

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