Chapter 2
Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania

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Abstract This chapter outlines the example of a regional effort to improve access to medicines through regulatory harmonization in the East African Community.

The East African Community (EAC) consists of five Partner States: Burundi, Kenya, Uganda, Rwanda, and Tanzania. The Republic of Southern Sudan was recently admitted to the EAC as the sixth Partner State on March 2, 2016. The East African Community Medicines and Health Technologies Policy is under development to complement provisions of EAC Treaty, Article 118, Chapter 21 on regional cooperation on health and EAC Common Market Protocol in which integration in the health sector is the main policy priority. An assessment of medicines' policies and pharmaceutical legislation was undertaken in all five EAC Partner States in May–June 2015. Key findings indicated that all Partner States have medicine policies, and three Partner States with updated medicine policies. Constitutional changes are driving the policy reform with human rights principles underpinning policies. Implementation planning, together with monitoring and evaluation, are areas requiring support across the EAC. The recommendation for the regional pharmaceutical policy is to guide action in three areas, namely, access, quality, and rational use. The scope of the regional policy needs to include pharmaceuticals for human and veterinary use plus medical devices, health technologies, food, and cosmetics. All Partner States have pharmaceutical legislation in place; however, this is outdated and is in need of reform to align to the regional harmonization initiatives and allow countries to implement their policies in a timely and efficient manner. The slow pace of legislative reform is a barrier to improve access to essential medicines and health commodities across the region. In terms of the medicines' regulatory harmonization

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agenda, legal frameworks for mutual recognition and information sharing are key. Considering the different stages of development across the EAC Partner States and the enablers, together with regional goals and aspirations, a phased approach to implementation of the regional policy and legislation is recommended. First, adopt a stepwise approach to regional collaboration in the pharmaceutical sector starting with implementation of national policies. Second is to establish the East African Community Medicines and Food Safety Commission. Alongside these developments, information sharing activities should increase and continue.

2.1 Background

The East African Community (EAC) is an intergovernmental organization made up of the Republics of Burundi, Kenya, Rwanda, the United Republic of Tanzania, and the Republic of Uganda [1]. The Community was established by the EAC Treaty and has its headquarters in Arusha, Tanzania. At the time of writing this chapter, the terms of admitting another country, Republic of Southern Sudan, is being negotiated. EAC has a combined population estimated at more than 143.5 million people, spanning a land area of 1.82 million sq km and a combined Gross Domestic Product of $110.3 billion [1].

The aim of the EAC is to strengthen cooperation among the Partner States for their mutual benefit, especially in the political, economic, and social fields. The Community plans to become a Political Federation of East African States. It has established a Customs Union and is now working toward a common market.

The organs of the EAC are captured in Box 2.1. These organs oversee the implementation of the EAC Treaty allowing EAC citizens to benefit from a common market, while also sharing in the responsibilities needed to attain the overall goal.

Box 2.1 EAC Organs

- *Summit*: Heads of the Partner States
- *Council*: Ministers responsible for EAC affairs in the Partner States; Attorney Generals of Partner States and any other minister nominated by the Partner States.
- *Coordination Committee*: Permanent Secretaries for East African Community affairs in each Partner State and such other Permanent Secretaries of the Partner States as each Partner State may determine.
- *Sectoral Committees*: consists of nominated representatives from Partner States for thee specific sector, eg. Education, Health etc.
- *East African Court of Justice*: This Court, established under Article 9 of the Treaty for the Establishment of the East African Community, ensures adherence to law in the interpretation and application of and compliance with the EAC Treaty by the Partner States.
- *East African Legislative Assembly*: This Assessmbly, established under the Treaty, is intended as the independent Regional Parliament. It is made up

of nine members elected by each Partner State; ex-officio members consisting of the Minister or Assistant Minister responsible for the East African Community Affairs from each Partner State; the Secretary General and the Counsel to the Community.
- *Secretariat*: The executive organ of the EAC, and consisting of the Secretary General, Deputy Secretaries, General Counsel to the Community, and other offices as may be deemed necessary by the Council.

It is important to acknowledge that while the EAC wants to move toward a common market with the free movement of people, services, and trade, the Community also recognizes the sovereignty of the individual Partner States. This principle guides how the countries work together.

First, areas of cooperation for mutual benefit are identified. This is followed by assessing existing policies, practices, and regulations, with the aim of harmonizing the instruments that will facilitate cooperation and collaboration. In addition, platforms are established to allow for the sharing of information and adopting best practices for strengthening systems and efficiently using limited resources. The EAC Secretariat works closely with the representatives from Partner States and external partners to achieve the agreed objectives.

2.1.1 Focus of This Chapter

With the above background in mind regarding the EAC, this chapter discusses regional harmonization in the pharmaceutical sector focusing on medicines regulation within the overall context of improved access to health. This chapter first presents the Health System of the EAC followed by an overview of pharmaceutical systems, including medicines policies and pharmaceutical legislation, across the EAC Partner States. It goes on to discuss, briefly, the regional intent regarding a regional pharmaceutical policy and medicines regulatory harmonization. This chapter does not extend to other areas of medicines issues including the selection; procurement and use as regional approaches to these areas have not yet been addressed. This chapter ends with a few challenges and recommendations on regional integration and harmonization as an approach to improve access to essential medicines and health commodities.

2.1.2 Health System of the EAC (Health System and Health Indicators)

The EAC does not have one uniform health system. The five Partner States have different systems guided by national policies, legislation, regulations, and delivery structures. As governance systems are being strengthened across the region, Partner States are acknowledging the right to health in their constitutions. There is also a

move toward having a single national health framework with an overarching health policy and development plan addressing key health development goals for the individual countries [1].

EAC Partner States are also at different levels of development. Kenya has recently been classified as a lower middle-income country, while the remaining States are classified as low-income [3]. All Partner States also face many constraints in ensuring adequate access to sustainable, equitable, and affordable healthcare services. In this regard, other nonstate actors like the Churches have become involved with the provision of care. The private sector is growing rapidly across the region. There is a long established system of services provided by the not-for-profit sector driven mainly by Churches. Donors have also played a key role in providing and funding services through different mechanisms. It is beyond the limits of this chapter to describe in detail the individual Partner States and their health systems. The focus of this chapter will be on the regional Community.

Health is a key social sector where the EAC has agreed to collaborate and work together as part of the wider development of the Community. Article 118 of the EAC Treaty spells out the areas of cooperation among the Partner States in this regard. Box 2.2 summarizes these nine areas of cooperation in the health sector.

Box 2.2 EAC Areas of Cooperation in the Health Sector Among EAC Partner States [4]

(a) Disease prevention and control of noncommunicable, communicable, and vector-borne diseases prioritizing HIV-AIDS, cholera, malaria, hepatitis, yellow fever including mass immunization, and other public health campaigns.
(b) Health systems strengthening.
(c) Improved pharmaceutical quality control capacities and good procurement practices.
(d) Harmonize drug registration procedures for medicines.
(e) Information exchange regarding health policies and regulations.
(f) Research and Development of herbal and traditional medicines.
(g) Specialized heath training and health research in areas of reproductive health, pharmaceutical product development, and preventive medicine.
(h) Nutritional standards and popularization of indigenous foods.
(i) Controlling and eradicating the trafficking and use of illicit and banned drugs.

The Partner States of the EAC include four low-income countries and one middle-income country. These countries face many challenges in the development and sustainable delivery of health services. This is reflected in the health statistics of the countries as shown in Table 2.1.

Overall, EAC infant mortality rate and child mortality rate stood at 67% and 89%, respectively, in 2011 [6]. Even with more recent figures unavailable, these rates are higher than the overall infant mortality rate for Africa which stood at 55 in 2015 [7], pointing to weak health systems in the EAC region. However, it is important to note that presently there is no standardized approach to data collection from

Table 2.1 EAC Partner States Statistics [5]

Indicator	Burundi	Kenya	Rwanda	Tanzania (Mainland)	Uganda
Total population (2013)	10,633,00	44,354,000	11,777,000	49,253,000	37,579,000
Gross national income per capita (PPP international $, 2013)	820	2,250	1	1,750	1
Life expectancy at birth m/f (years, 2013)	54/58	60/63	64/67	61/65	57/61
Probability of dying between 15 and 60 years m/f (per 1,000 population, 2013)	312/244	299/250	246/196	312/244	380/307
Total expenditure on health per capita (Intl $, 2013)	62	101	162	126	146
Total expenditure on health as % of GDP (2013)	8.0	4.5	11.1	7.3	9.8

the Partner States regarding health statistics. For this reason, data held at the EAC Secretariat is generally out-of-date.

All EAC Partner States have Ministries of Health [8–12]. The individual Health Ministers constitute the regional Sectoral Council of Ministers. Within the framework of the EAC Treaty, the Sectoral Council on Health will decide on key matters of integration for the health sector.

Secretariat staff, with the support from development partners, facilitate the work of technical working groups consisting of experts from Partner States to develop harmonized frameworks, policies, and regulations supporting regional activities in the health sector. Once proposals, reports, and draft policies are validated by these technical working groups and Partner States, these are presented for decision-making by the Sectoral Council which then advise the relevant organs of the EAC prior to implementation. By understanding the operations of the Community, it becomes clear that processes are inclusive and also lengthy.

2.2 Pharmaceutical Situation of the EAC

The EAC, like other sub-Saharan countries, relies largely on imports for pharmaceuticals. These imports are mainly from China and India. Where pharmaceutical manufacturing does occur, this involves the production of noncomplex, high-volume, essential products such as basic analgesics, simple antibiotics, and vitamins. Kenya has the most developed pharmaceutical manufacturing sector in the region [13].

The regional pharmaceutical sector consists of manufacturers, distributors, wholesalers, retail pharmacies, hospitals, and clinics. Pharmaceutical manufacturers are either local or multinationals. Few multinationals have local manufacturing plants; rather there are local agents who distribute their products. Multinational pharmaceutical companies also have scientific and marketing offices. Multinational firms generally have brand name products in the market, while local manufacturers provide lower priced generics.

Below is a snapshot of the pharmaceutical sector of the EAC Partner States as extracted from the EAC Regional Manufacturing Plan of Action (2012–2016) [13].

Box 2.3 Pharmaceutical Sector Snapshot of EAC Partner States

Kenya

- Biggest and most developed pharmaceutical manufacturing sector in EAC region
- Branded and generic market share is 44% and 56%, respectively
- 28% – the percentage of market share of locally produced pharmaceuticals
- 35–45% of local production exported to neighboring countries
- 15% marginal preference scheme for local products by government tenders
- Local production meeting 30% of the national demand of pharmaceuticals
- Number of registered pharmaceutical manufacturers: 31
- Negative market perception of local manufacturers
- Local production predominantly generic
- Raw materials mostly imported
- Price erosion due to low cost imports

Tanzania

- Most developed semiautonomous regulatory authority within the EAC region
- Branded and generic market constituting 46% and 54%, respectively
- Number of registered manufacturing sites: 8
- Local production meets 31% of national demand
- India is the largest exporter of pharmaceuticals to Tanzania
- State and donor market constitute 85% of total pharmaceutical market
- 15% preferential treatment given to local manufacturers in government tenders
- There is competition from low-cost imports
- Raw materials mostly imported

Uganda

- 13 registered pharmaceutical manufacturers
- 95% of medicines imported to meet local demand
- Only 5% manufactured locally
- Negative market perception of local manufacturers
- Raw materials mostly (over 90%) imported from India and China
- Pharmaceutical plant production technology imported including spare parts
- Tableting lines most developed
- Price erosion due to low-cost imports

Burundi and Rwanda

- Each has one pharmaceutical manufacturing facility
- National Medicines Regulatory Authorities (NMRAs) are currently being established in both countries
- Estimated pharmaceutical market size for each country is US$ 25 million
- Over 95% of medicines consumed locally are imported
- Rwanda has leveraged use of ICT in the management of the medicines distribution and supply systems in the public sector
- Raw materials imported

Source*: EAC Manufacturing Plan of Action, 2012–2016.*

2.3 EAC Medicines Policy, Legislative and Regulatory Environment

All countries, apart from Rwanda, have distinct national medicines policies (NMPs). Rwanda's policy is embedded in the National Health Policy. Burundi, Kenya, and Tanzania (Zanzibar) have updated NMPs. Tanzania (Mainland) has a draft policy that was presented in 2014, but has not yet been approved. Uganda is currently revising its NMP, which is expected to be completed in 2015. Rwanda started work on its NMP in 2009, but this is yet to be approved [14].

The time taken for the review and approval of NMPs is long. Timelines span 24 years, that is, 1991–2015 (Tanzania – Mainland); 13 years, that is, 2002–2015 (Uganda); 6 years, that is, 2009–2015 (Rwanda). Kenya has managed to produce three revisions over the period 1994–2012; Tanzania (Zanzibar) has produced two NMPs from 1991 to 2014; Uganda is on its third revision; and Rwanda is still developing its first policy. These timelines highlight the varying capacities and challenges faced by the Partner States in the development, review, and revision of NMPs.

The scope of existing NMPs of Partner States generally covers pharmaceuticals for human and veterinary use,[1] as well as herbal products. The updated policies of Kenya and Tanzania (Zanzibar's) have extended scopes to also include medical devices and technologies, food products, tobacco products, cosmetics, and emerging health technologies.

Generally, the components of the NMPs in Partner States are based on the WHO-recommended components of NMPs:

- Selection: evidence-based, focusing on morbidity patterns, EMLs
- Supply: local production, procurement mechanisms, distribution and storage, disposal of unwanted or expired medicines
- Rational use: STGs, Medicines Information, rational medicine use for training, education, promotion
- Affordability: taxes or tariffs on essential medicines, pricing, use of generics, TRIPs mechanisms
- Financing: user charges, health insurance, donor assistance
- Human resource development: education, training, continuing education
- Monitoring and evaluation: baseline surveys, indicators for monitoring, periodic monitoring, independent external evaluation
- Research
- Technical cooperation among countries
- Legislative and regulatory framework: Drug Regulatory Authorities, good governance for medicines, legislation and regulation, medicines registration and licensing, quality assurance (inspection and enforcement), regulation of prescription and distribution

All Partner States have legislation in place to support the implementation of their policies. However, such legislation and regulations are often outdated and not enabling; in some instances, the legislation is the bottleneck for implementation. For example, in Uganda, the legislation places the National Drugs Authority as the overall body responsible for both the policy and the regulator. The situation is unique in Uganda, when in most countries the NMPs remain within the policy arm of Ministries of Health, and not with the regulatory authorities [15].

Kenya's Pharmacy and Poisons Act of 1957 (Chapter 244) regulates both the products and the practice, while the policy calls for the separation of these functions. Kenya's Pharmacy Practice Bill, 2012, proposed amendment to the Pharmacy and Poisons Act (Chapter 244). It also allows for the separation of the Pharmacy and Poisons Board from the Ministry of Health. However, current legislation also contributes to confusion regarding the autonomy of the regulatory body as it places the Chief Pharmacist of the Ministry of Health as the Registrar and the Director of Medical Services as the Chair of the Board. Therefore, in Kenya, the provisions in the 2012 policy to elevate the status of pharmaceutical services from under the medical directorate cannot be achieved within the existing legislation.

[1] Normally vaccines, blood products, and other biologicals are considered to be within the framework of medicinal products for human use. This also true for herbal products for human use.

In Burundi and Rwanda, existing pharmaceutical laws have to be changed to ensure semiautonomous status of the regulatory authorities, as these currently are based within Ministries of Health. Rwanda has already enacted a law in 2013 for establishing autonomous institution to regulate medical products; hence, it has not been stated here.

There is a move across the region toward the creation of semiautonomous government agencies to spearhead the national medicines regulatory affairs.

It is only in Tanzania (Mainland), through the Tanzania Food and Drugs Authority, and Uganda, through the Uganda Drugs Authority, that semiautonomous authorities exist. In the remaining Partner States, the regulatory authorities are all within the Ministries of Health. In Kenya, this is the Pharmacy and Poisons Board. In Rwanda, it is the Pharmacy Task Force. In Burundi, no actual structure exists even though registration of medicines occurs under a decree. While changes are being discussed in Partner States to establish semiautonomous structures, progress is slow. In Kenya, the Kenya Food and Drugs Authority Bill remains pending. The Rwanda Food and Medicines Authority (RFDA) Bill was approved in 2013; due to policy changes, this Bill was revoked and a new proposal is being considered where the RFDA will be an institution under the Rwanda Inspectorate and Competitions Authority (RICA) within the Ministry of Commerce.

There are three WHO prequalified drug quality control laboratories in EAC: Tanzania, Kenya, and Uganda. Across the EAC Partner States, there is a shortage of skilled human resource in NMRAs.

Table 2.2 presents an overview of pharmaceutical legislation and the agencies responsible for implementation for the EAC Partner States.

The EAC, unlike the Southern African Development region, does not have a regional mechanism for procurement of medicines. Nor does it have a regional list of essential medicines or regionally standardized treatment guidelines. These are areas for future development. Whereas, the initial focus is on regional harmonization concentrating on policy development and medicines regulation.

2.4 Conclusions: Summary and Way Forward

The pharmaceutical sector of EAC Partner States encompasses research, products, trade, personnel, and services – all linked in a complex and dynamic matrix of health, economics, and politics. There are many stakeholders involved, each with their own agenda, which do not always align with the overall public health goal of improving access to essential medicines and health commodities.

National Medicines Policies (NMPs) have been accepted by all Partner States as the policy instrument to guide the national pharmaceutical sector. In terms of regional harmonization, the existing NMPs of Partner States allow for technical and regional cooperation. This component of the national policies serves as an enabler for the regional regulatory harmonization initiatives.

There is strong support for the regional harmonization agenda by Partner States and partners. Two key gaps present the bottlenecks. First, the Regional Pharmaceutical

Table 2.2 Summary of pharmaceutical legislation and implementing agencies across EAC Partner States

Country	Burundi	Kenya	Tanzania (Mainland)	Tanzania (Zanzibar)	Rwanda	Uganda
Pharmaceutical legislation	Bill regulating the practice of pharmacy in Burundi	Pharmacy and Poisons Act of 1957 (Chapter 244)	Medicines and Food and Cosmetic Act, Pharmacy Council Act, Traditional Medicine Act, Patent Act, Procurement Act, Industrial and Consumer Chemical Act	Zanzibar Food, Drugs, and Cosmetics Act, 2006	2013 law on Inspection of Pharmaceutical Products RICA Bill Pharmacy Law 2013	Drug Policy and Authority Act, 2000
Implementing agencies	Under a Ministerial Decree	Pharmacy and Poisons Board	Tanzania Food and Drugs Authority	Zanzibar Food and Drugs Board (under MoH)	Pharmacy Task Force (in MoH)	National Drug Authority

Policy is long overdue. The Policy is needed to guide the harmonization process as well as providing the platform for collaboration and cooperation in the pharmaceutical sector. Second, the national and regional regulatory and enforcement mechanisms are missing, which has in fact resulted in countries participating in the regional initiatives but not always using the regional decisions into local national policies and in regulatory instruments and frameworks.

At the regional level, the pharmaceutical programme has been strengthened with the appointment of principal technical officers for Medicines and Food Safety as well as for the EAC-Medicines Registration Harmonization project.

At the Partner States level, while progress has been made, the pace is slow and it affects regional harmonization and cooperation. The slow pace is due to some of the following issues:

- Inappropriate institutional structures for policy direction and governance that fail to recognize and address the complexities of the manufacturing supply and also issues related to use of medicines. The Office of the Chief Pharmacist, generally tasked with the NMP, is not supported to fulfill this mandate.
- Outdated medicine laws which fail to provide the NMRAs with the legal instruments to address and adapt to new trends.
- Limited resources or political will to enforce pharmaceutical legislation.
- Policy development and implementation not evolving with other national and regional developments. This has resulted in underperformance and stagnation.
- Conceptualization of pharmaceutical services limited to procurement and supply, and up to some extent to prescribing and dispensing.
- Lack of sustainable strategies for implementation, weak management, and programming of pharmaceutical services.

The directives under Article 118 of the EAC Treaty, the Common Market Protocol, the EAC-MRH project, and the Manufacturing Plan of Action provide opportunities for fast-tracking the harmonization agenda. These directives are also helpful to build technical and management capacity, in building trust through joint activities. These initiatives will definitely benefit the people of the EAC.

References

1. East African Community. One people one destiny. www.eac.int. Accessed 12 Jan 2016.
2. East African Community. (2010). *EAC common market protocol*. Arusha: EAC.
3. http://data.worldbank.org/country. Accessed 12 Jan 2016.
4. East African Community. (2002). *The treaty for the establishment of the East African Community*. Arusha: EAC.
5. WHO. http://www.who.int/countries. Accessed 10 Jan 2016.
6. EAC. http://www.eac.int/statistics. Accessed 12 Jan 2016.
7. WHO. http://www.who.int/gho/child_health/mortality. Accessed 12 Jan 2016.
8. Ministry of Health Burundi. https://www.minisante.bi. Accessed 13 Jan 2016.
9. Ministry of Health Kenya. www.health.go.ke. Accessed 13 Jan 2016.

10. Ministry of Health Rwanda. www.mog.gov.rw. Accessed 13 Jan 2016.
11. Ministry of Health Uganda. www.health.go.ug. Accessed 13 Jan 2016.
12. Ministry of Health, Community Development, Gender, Elderly and Children, United Republic of Tanzania. www.moh.go.tz. Accessed 13 Jan 2016.
13. East African Community. (2012). *EAC regional manufacturing plan of action, 2012 – 2016*. Arusha: EAC.
14. hera. EAC medicines policy, legal and regulatory frameworks. Report. Sept 2015.
15. National Drug Policy and Authority Act 1993. Chapter 206. http://www.ulii.org/ug/legislation/consolidated-act/206. Accessed 15 July 2016.

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