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# **REGIONAL POOLED PROCUREMENT OF MEDICINES IN THE EAST AFRICAN COMMUNITY**

Nirmalya Syam



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**Nirmalya Syam\***

**SOUTH CENTRE**

**SEPTEMBER 2014**

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## TABLE OF CONTENTS

I.	INTRODUCTION .....	3
II.	THE EAST AFRICAN COMMUNITY: AVAILABILITY OF MEDICINES .....	4
III.	ORGANS AND INSTITUTIONS OF THE EAC .....	6
IV.	DISCUSSIONS ON REGIONAL POOLED PROCUREMENT IN THE EAC.....	7
V.	OTHER DEVELOPMENTS IN THE EAC .....	11
V.1	The EAC Common Market Protocol .....	11
V.2	The EAC Customs Union .....	12
V.3	The EAC Regional Pharmaceutical Manufacturing Plan of Action, 2012-2016.....	12
V.4	EAC Regional IP Policy on the Utilization of Public Health-Related WTO TRIPS Flexibilities.....	13
V.5	EAC Medicines Regulatory Harmonization Project.....	13
V.6	EAC Anti-Counterfeit Law .....	16
VI.	LEGAL FRAMEWORK ON PROCUREMENT OF MEDICINES IN THE EAC PARTNER STATES	17
VI.1	Burundi.....	18
VI.2	Kenya .....	19
VI.3	Rwanda.....	24
VI.4	Uganda .....	25
VI.5	United Republic of Tanzania and Zanzibar .....	29
VII.	CONCLUSIONS AND RECOMMENDATIONS .....	32
VII.1	Recommendations .....	36
	BIBLIOGRAPHY.....	39





## ABBREVIATIONS AND ACRONYMS

ACAME	African Association of Central Medical Stores
AIDS	Acquired Immunodeficiency Syndrome
ARMP	Public Procurement Regulatory Authority (Burundi)
ARVs	antiretrovirals
CAMEBU	the national medical stores (Burundi)
CAMERWA	Rwandan Central Medicines Store
CET	Common External Tariff
CHAI	Clinton Health Access Initiative
CMS	Central Medical Store (CMS) and nine Zonal Medical Stores
DNCMP	National Procurement Monitoring Directorate (Burundi)
DPML	Directorate of Pharmacies, Medications and Laboratories
EAC	East African Community
EACJ	the East African Court of Justice
EAC-MRH	EAC Medicines Regulatory Harmonization
EALA	the East African Legislative Assembly
EMHL	Essential Medicines and Health Supplies List
EML	essential medicines list
EWG	Expert Working Group
FEAPM	Federation of East African Pharmaceutical Manufacturers
GDP	Good Distribution Practices
GMP	Good Manufacturing Practice
GPP	Good Pharmaceutical Procurement
HIV	Human Immunodeficiency Virus
HSSP III	Third Health Sector Strategic Plan 2009-2015 of Tanzania
HSSP	Health Sector Strategic Plan
JMS	Joint Medical Stores
KEDL	Kenya Essential Drugs List
KEMSA	Kenya Medical Supplies Agency
LABOPHAR	the Pharmaceutical Laboratory of Rwanda
LDCs	Least developed countries
MEDS	Mission for Essential Drugs and Supplies
MSD	Medical Stores Department (Tanzania)
NARP	National Pharmaceutical Governing Authority (Burundi)
NDRA	National Drug Regulatory Authorities
NHDP II	National Health Development Plan 2011-2015
NMPA	National Medicines Procurement Agencies
NMRAs	National Medicines Regulatory Authorities
NMRL	National Medical Referral Laboratory (Rwanda)
NMS	the National Medical Stores (Uganda)
NQCL	National Quality Control Laboratory (Kenya)
NTB	National Tender Board
OECS	Organization of Eastern Caribbean States
PEPFAR	The US President's Emergency Plan for AIDS Relief
PPDA	Public Procurement and Disposal of Assets Authority
PPOA	Kenyan Public Procurement Oversight Authority
PSS II	the Pharmaceutical Services Section (Tanzania)

PTF	Pharmacy Task Force
RBC	Rwanda Biomedical Centre
RFMA	Rwanda Food and Medicines Authority
RPMPOA	Regional Pharmaceutical Manufacturing Plan of Action
RPPA	Rwanda Public Procurement Authority
STG	standard treatment guidelines
TCM	World Health Organization Department of Technical Assistance for Essential Medicines
ToRs	Terms of Reference
TWG	Technical Working Groups
UCG	Uganda Clinical Guidelines
UNMHCP	Uganda National Minimum Healthcare Package
WHO	World Health Organization
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

## ABSTRACT

This paper explores the current discussions in the East African Community (EAC) with regard to the establishment of a regional pooled procurement mechanism for essential medicines.

In 2008, the EAC Council of Ministers has approved the establishment of a regional pooled bulk procurement mechanism for essential medicines with a group contracting model based on the recommendations of a feasibility study carried out by the WHO in 2007 at the request of the EAC. However, there has not been much progress towards the implementation of the regional procurement mechanism by developing a plan of action for the same.

Discussions on implementation of the regional pooled procurement mechanism must be expedited to complement progress made in the EAC with regard to other policy initiatives on facilitating regional pharmaceutical manufacturing, full utilization of TRIPS flexibilities and regional cooperation on medicines registration. The issue of establishment of a regional pooled procurement mechanism for essential medicines has been largely discussed within the EAC Sectoral Council on Health and has been distinctly absent from the discussions in the East African Legislative Assembly (EALA). Implementation of a regional pooled procurement mechanism must be given prominence in the discussions of EALA as it is necessary to develop an EAC wide legal framework for pooled procurement of medicines in order to effectively implement such a mechanism. Though there is a lot of homogeneity in the procurement laws and regulations of EAC Partner States, due to the lack of any specific law for regional pooled procurement, diverse interpretations of national and international legal obligations might give rise to potential conflicts.

It will be necessary for all EAC Partner States to have specific regulations on procurement of medicines under the general procurement laws. The laws of all Partner States should ensure that in the event of a conflict between the domestic law and the regional law, the regional law shall prevail.

It will be necessary to ease nationality-based restrictions on preference and reservation schemes and expand their scope to include nationals of any EAC Partner States.

The existence of parallel systems of procurement in the form of public procurement by the central medical stores as well as procurement by ministries of health under donor funded programmes with different requirements adds to the complexity of the implementation of a regional pooled procurement mechanism. It will be desirable for the regional pooled procurement mechanism to have sole sourcing of procurements through the suppliers selected by the pooled procurement mechanism. All procurement, including donor funded procurement activities, should be conducted under a common set of rules and quality standards. Quality standards for medicines registration in the region should be developed as appropriate to the unique circumstances of the region and ensure that local and generic manufacturers are not prevented from participating in the regional pooled procurement mechanism due to the adoption of regulatory standards that are promoted as definitive international standards by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use under the influence of multinational pharmaceutical companies and regulatory authorities from developed countries.



## I. INTRODUCTION

Ensuring affordable access to quality medicines remains one of the biggest public health challenges before governments of developing and least developed countries which face increasing burden of patients afflicted with communicable and non-communicable diseases and overwhelming reliance on import of most of their required medicines. Though the cost of medicines in the private sector is unaffordable for most of the population in these countries, the lack of adequate supply of affordable and quality medicines in the public health facilities compels patients to purchase medicines from the private sector to the extent that out of pocket expenditure on medicines constitutes one of the leading contributory factors towards increased impoverishment. As governments in various countries aim to achieve universal health care in their countries, it becomes imperative to ensure that public health facilities always have adequate stock of quality medicines at affordable price. Therefore, an efficient mechanism of procuring medicines is one of the most critical factors for ensuring universal access to medicines.

Pooled procurement of medicines is an innovative approach for ensuring a consistent and sustainable supply of appropriate medicines at the country, regional as well as global levels.<sup>1</sup> Pooled procurement of medicines is a mechanism of purchasing medicines in bulk by a procurement agency on behalf of a group of facilities, health systems or countries. Participating members agree to purchase certain drugs exclusively through this mechanism. Pooled procurement of medicines creates economies of scale resulting in low transaction costs and better leverage in pricing negotiations with pharmaceutical companies.<sup>2</sup> Through bulk procurement involving purchase of medicines on a large scale, the procuring entities participating in this mechanism are able to get significant price discounts from suppliers. A regional pooled procurement mechanism could also attract major medicines suppliers by offering a large regional market compared to smaller national markets.<sup>3</sup> Moreover, pooled procurement can lead to elimination of wasteful expenditure, unnecessary purchase and stock outs. For example, the Organization of Eastern Caribbean States (OECS) reported an average cost saving of 37 per cent for 25 selected medicines over a five year period by using a regional pooled procurement mechanism.<sup>4</sup>

In addition to cost savings through price negotiations with pharmaceutical companies, regional pooled procurement of medicines can also facilitate a potential increase in local pharmaceutical manufacturing by generating greater demand within the regional market. A

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<sup>1</sup> Health Systems for Outcomes (2009), *Innovative Medicines Procurement: A Review of Multi-County, Regional, International and National Approaches to Procurement*, p. 2, available at [http://www.hha-online.org/hso/system/files//library\\_protected/2009/10/innovative\\_medicines\\_procurement\\_pdf\\_17294.pdf](http://www.hha-online.org/hso/system/files//library_protected/2009/10/innovative_medicines_procurement_pdf_17294.pdf) (Last visited 18 June 2014).

<sup>2</sup> Zafar Mirza (2010), "Pooled Procurement of Medicines & Allied Commodities", Presentation at the Joint WHO, WIPO, WTO Technical Symposium on Access to Medicines: Pricing and Procurement Practices, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/techsymp\\_july10\\_e/mirza\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/techsymp_july10_e/mirza_e.pdf) (last visited 17 June 2014).

<sup>3</sup> UN Millennium Project (2005), *Prescription for Healthy Development: Increasing Access to Medicines*, Report of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Essential Medicines (Sterling, VA: Earthscan), p. 77, available at <http://www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf> (last visited 18 June 2014).

<sup>4</sup> WHO (2007), *Multi-country Regional Pooled Procurement of Medicines: Identifying key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and the Pacific Island Countries*, Meeting Report, Geneva, 15-16 January 2007, p.15, available at <http://www.who.int/medicines/publications/PooledProcurement.pdf> (last visited 14 July 2014).

pooled procurement mechanism may also be attractive for donors and development partners by enabling them to centralize their funding mechanisms and makes it administratively easier to manage procurements supported by donor grants instead of overseeing multiple single-country procurements. Moreover, pooled procurement also facilitates the creation and use of common quality assurance standards, use of standardized essential medicines list and treatment protocols, harmonization of drug registration and common standards for prequalification of suppliers.<sup>5</sup>

A number of countries have expressed interest in or have established regional pooled procurement mechanisms to improve the availability, quality and affordability of essential medicines. Some examples of existing regional pooled procurement mechanisms are the PAHO Strategic Fund for Essential Public Health Supplies,<sup>6</sup> African Association of Central Medical Stores (ACAME),<sup>7</sup> Gulf Cooperation Council Group Purchasing Programme,<sup>8</sup> Pacific Island Countries,<sup>9</sup> the WHO Global Drug Facility for TB,<sup>10</sup> etc.

This paper analyses the implementation of a regional pooled procurement mechanism in the East African Community (EAC) region. The EAC Secretariat has been exploring the issue of establishment of a regional pooled procurement mechanism over the past few years. However, in spite of this sustained interest, legal and policy frameworks at the regional and national levels for the establishment of a pooled procurement mechanism for medicines is yet to be established. Nevertheless, there have been some developments, which can be considered to be supportive towards the establishment of a regional pooled procurement mechanism. This paper seeks to explore these recent developments in the legal and policy regimes at the regional and national levels, pertaining to the establishment of a regional pooled procurement mechanism in the EAC, and identify areas of further work.

## II. THE EAST AFRICAN COMMUNITY: AVAILABILITY OF MEDICINES

The East African Community is a regional intergovernmental organization of five countries from east Africa – Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania and Zanzibar. The EAC was established by a treaty in 1999. Its Secretariat is based in Arusha, Tanzania. The objective of the EAC is to develop policies and programmes for widening and deepening cooperation on political, economic, social and cultural fields, research and technology, security, legal and defence affairs. In pursuit of these objectives, EAC Partner States have agreed to establish among themselves a Customs Union and a Common Market, to be followed by a Monetary Union and ultimately a Political Federation.<sup>11</sup> In this context, Partner States have an obligation to plan and direct their policies and resources for creating conditions favourable for the development and achievement of the objectives of the EAC and

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<sup>5</sup> Health Systems for Outcomes (2009), *supra* note 1, pp. 2-3.

<sup>6</sup> PAHO, PAHO Strategic Fund, available at [http://www.paho.org/hq/index.php?option=com\\_content&view=category&layout=blog&id=1159&Itemid=986&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=category&layout=blog&id=1159&Itemid=986&lang=en) (last visited 14 July 2014).

<sup>7</sup> Mirza (2010), *supra* note 2.

<sup>8</sup> *Ibid.*

<sup>9</sup> *Ibid.*

<sup>10</sup> Stop TB Partnership, Global Drug Facility, available at <http://www.stoptb.org/gdf/> (last visited 14 July 2014).

<sup>11</sup> EAC Treaty, Article 5.

implementation of the provisions of the Treaty. Therefore, Partner States have to coordinate their policies through the institutions of the EAC and abstain from any measures likely to jeopardize the same.<sup>12</sup>

The EAC region has a high burden of HIV, TB and malaria, and also faces significant burden of other infectious and parasitic diseases as well as non-communicable diseases. However, the patients from the EAC Partner States have low purchasing power and cannot easily afford to buy medicines. Government budgets are insufficient to meet the healthcare needs and almost 50 per cent of individual healthcare needs constitute out-of-pocket expenses.<sup>13</sup> This makes the healthcare market extremely price-sensitive. Donor funding plays a significant role in the procurement of medicines, particularly for priority endemic diseases such as HIV, TB and malaria. However, donors require suppliers to meet stringent quality standards, which is a major constraint for local pharmaceutical manufacturers.<sup>14</sup>

The local pharmaceutical industry in the EAC Partner States remains generally weak. These countries are net importers of medicines, particularly from India and China. Pharmaceutical manufacturing in the region involves production of non-complex, high volume formulation products like basic analgesics, simple antibiotics, anti-malarial drugs and vitamins.<sup>15</sup> Local production is at a very small scale among the EAC LDCs. Among these, Mainland Tanzania and Uganda are the only countries that have at least 10 local pharmaceutical companies of varying capacity. Burundi and Rwanda each have only 1 local pharmaceutical company.

Though most of the medicines for the treatment of HIV/AIDS, TB and malaria in the region are imported under donor funded programmes like the Global Fund, the Clinton Health Access Initiative (CHAI) or the US President's Emergency Plan for AIDS Relief (PEPFAR), the limited budget of these programmes can only treat a small percentage of the population in these countries who need treatment.<sup>16</sup> In fact, the high price of essential medicines like ARVs charged by multinational pharmaceutical companies, rather than import tariffs, is the predominant reason for the high cost of medicines. While the availability of generic medicines from countries like India can make the drugs more affordable, this may not be the case for drugs required for second and third line treatment for HIV/AIDS, or the need for new medicines to combat increasing drug resistance, as generic production of these drugs could be blocked by the existence of patents.<sup>17</sup>

Therefore, the EAC Partner States have to pursue policies to support the development of a local pharmaceutical industry which can supply affordable and quality medicines in the region. Ownership of production facilities by local nationals may offer several advantages including continuity of production and supply in the face of changing economic

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<sup>12</sup> Ibid., Article 8.

<sup>13</sup> EAC (2011), *East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016)*, EAC Secretariat, Arusha, Tanzania, p.25, available at [http://feapm.com/fileadmin/user\\_upload/documents/EAC\\_Regional\\_Pharmaceutical\\_Manufacturing\\_Plan\\_of\\_Action.pdf](http://feapm.com/fileadmin/user_upload/documents/EAC_Regional_Pharmaceutical_Manufacturing_Plan_of_Action.pdf) (last visited 21 April 2014).

<sup>14</sup> Ibid.

<sup>15</sup> Ibid., p. 17.

<sup>16</sup> Olulomire Oguniye, *et. al.* (2009), *AIDS, Africa and ARVs: Domestic Production as a Solution To The Treatment Gap*, p. 9, available at <https://blogs.commons.georgetown.edu/globalsolvercommunity/files/Domestic-Production-as-a-Solution-to-the-Treatment-Gap.pdf> (last visited 30 June 2014).

<sup>17</sup> Ibid. p. 11.

circumstances which can avoid disruptions in the pharmaceutical supply chain, building domestic technological capacity and skill development, securing a competitive market environment that may constrain the pricing power of multinational suppliers.<sup>18</sup>

### III. ORGANS AND INSTITUTIONS OF THE EAC

The EAC has an executive, legislative and a judicial organ along with a permanent secretariat. The executive arm of the EAC is comprised of the Summit of Heads of State of EAC Partner States, the Council of Ministers from each Partner State responsible for EAC affairs, and the Coordination Committee of Permanent Secretaries from each Partner State. The East African Legislative Assembly (EALA) is the legislative branch of the EAC and the East African Court of Justice (EACJ) serves as the judicial branch. For the purposes of harmonization of law and policy among EAC Partner States, the executive and legislative branches of the EAC are most relevant.

In the executive branch, the Summit of Heads of States meets annually and reviews reports from the Council of Ministers and provides general directions and impetus to the achievement of the objectives of the EAC.<sup>19</sup> The Council acts as the policy organ of the EAC and meets at least twice a year. The Council is responsible for taking major policy decisions, introducing bills in the EALA, gives directions to the Partner States and all subordinate organs and institutions of the EAC except the Summit, EALA and EACJ. It can also make regulations, issue directives, take decisions, make recommendations and give opinions in accordance with the Treaty. It can also establish Sectoral Council of Ministers on specific matters under the Treaty as well as Sectoral Coordination Committees.<sup>20</sup> Thus, on specific subjects like health, education, etc., the Council can establish Sectoral Council of Ministers responsible for these departments in the Partner States, as well as Sectoral Coordination Committees of secretaries from these departments in the Partner States. The regulations, directives and decisions of the Council are binding on the Partner States and all organs and institutions of the EAC except the Summit, EALA and EACJ.<sup>21</sup>

The Coordination Committee submits reports and recommendations to the Council or Sectoral Council for approval, and implements the decisions of the Council. It also coordinates the functions of the Sectoral Councils.<sup>22</sup> Sectoral Committees can be established by the Council on the recommendation of the Coordination Committee.<sup>23</sup> In respect of their relevant sectors, the Sectoral Committees are responsible for developing a comprehensive implementation programme and priority setting subject to the directions of the Council. It is also responsible for monitoring and reviewing implementation of the programmes of the EAC

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<sup>18</sup> Frederick M. Abbott (2011), Trends in Local Production of Medicines and Related Technology Transfer (World Health Organization, Geneva), p. 13, available at <http://apps.who.int/medicinedocs/documents/s19063en/s19063en.pdf> (last visited 27 June 2014).

<sup>19</sup> EAC Treaty, *supra* note 11, Article 11 and 12.

<sup>20</sup> *Ibid.*, Article 14 and 15.

<sup>21</sup> *Ibid.*, Article.

<sup>22</sup> *Ibid.*, Article 18.

<sup>23</sup> *Ibid.*, Article 20.



in relation to that sector, and submit reports and recommendations to the Coordination Committee on implementation of the provisions of the Treaty in relation to that sector.<sup>24</sup>

The EALA is comprised of nine members elected by the legislative bodies of each EAC Partner States and ex-officio members comprising Ministers and deputy or assistant ministers from each of the EAC Partner States as well as the Secretary General and Counsel of the EAC.<sup>25</sup> The elected members of the EALA are not representatives of their national legislative bodies but they represent as far as feasible the diverse political entities represented in each national legislative body.<sup>26</sup> The EALA maintains liaison with national legislative assemblies of Partner States on EAC related matters, and it can make recommendations to the Council as it may consider appropriate on implementation of the EAC Treaty.<sup>27</sup> Any bill that is discussed in the EALA is also laid before the respective national legislative assemblies of Partner States, and records of debates of national Assemblies on such bills are to be transmitted to EALA.<sup>28</sup> A bill passed by EALA becomes an enactment when it receives the assent of all Heads of State of EAC Partner States. A Head of State may return such a bill to the EALA for reconsideration. If the reconsidered bill is passed by EALA but it still does not receive the assent of the Head of State, then the bill lapses.<sup>29</sup>

A bill may be initiated in the EALA by the EAC Council of Ministers under Article 14 (3) (b) of the EAC Treaty or a member of the EALA may introduce a bill through a motion under Article 59 (1) of the Treaty. Under Article 8 (4) and (5) of the Treaty, Community laws enacted by the EALA shall take precedence over similar national laws on matters pertaining to the implementation of the Treaty.<sup>30</sup> Thus, there is an opportunity to enact Community laws to implement the EAC policies for ensuring access to medicines in respect of full utilization of the public health related WTO TRIPS flexibilities, support local production of pharmaceutical products and also create a legal framework for regional pooled procurement of medicines. However, so far there has not been any discussion in the EALA on community laws that could be adopted to support implementation of the EAC policies pertaining to access to medicines.

#### **IV. DISCUSSIONS ON REGIONAL POOLED PROCUREMENT IN THE EAC**

The EAC has been considering the issue of regional pooled procurement for nearly a decade. Cooperation on health issues among EAC Partner States is mandated by the EAC Treaty itself. Article 118 of the EAC Treaty expresses the commitment of Partner States to take joint action for prevention and control of communicable and non-communicable diseases, control pandemics and epidemic of communicable vector-borne diseases such as HIV/AIDS, cholera, malaria, hepatitis and yellow fever. In this context, Partner States are committed to develop a

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<sup>24</sup> Ibid., Article 21.

<sup>25</sup> Ibid., Article 48.

<sup>26</sup> Ibid., Article 50.

<sup>27</sup> Ibid., Article 49.

<sup>28</sup> Ibid., Article 65.

<sup>29</sup> Ibid., Article 63.

<sup>30</sup> Resume on EAC Legislation, available online at [http://www.eac.int/index.php?option=com\\_content&view=article&id=1272&Itemid=225](http://www.eac.int/index.php?option=com_content&view=article&id=1272&Itemid=225) (last visited 3 September 2014).

common drug policy, which would include establishing quality control capacities and good procurement practices, and harmonize drug registration procedures to achieve good control of pharmaceutical standards.<sup>31</sup>

In 2005, a new EAC Development Strategy 2006-2010 was formulated to ensure systematic implementation of the EAC Treaty, focusing on economic cooperation and regional development with health identified as a priority area.<sup>32</sup> Prior to this, in 2002 the EAC Council of Ministers had established the Sectoral Council of Ministers of Health to guide the Community on issues related to the initiation and strengthening of regional collaboration in sectoral health programmes and projects in east Africa pursuant to Article 118 of the EAC Treaty.<sup>33</sup> At the first meeting of the Sectoral Council on Health in July 2005, the Coordination Committee received a report and recommendations from a meeting of EAC Partner States' National Regulatory Authorities and Experts on pharmaceuticals and medical products. The recommendations were that the EAC Secretariat should recruit a pharmaceutical officer to coordinate the sector in the EAC, and a situational analysis should be conducted on medicines policy, legal and regulatory framework, procurement, distribution and management in the EAC Partner States. The terms of reference (ToRs) suggested for the situational analysis included reviewing the capacity of national drug regulatory authorities (NDRA), examine the capacity of EAC Partner States to respond to the WTO TRIPS flexibilities to maximize access to essential medicines in the region, make recommendations on strengthening existing NDRA and come out with a way forward for the possible establishment of a Food and Drug Regulatory Authority for the region.<sup>34</sup>

Pursuant to this, the Sectoral Council established a Pharmaceutical Programme Office under the EAC Health Desk and approved the ToRs for a situational analysis study on the development of a common medicines policy, regulatory and legal framework, including joint procurement, distribution and management of essential medicines within the EAC Partner States, the capacity of EAC Partner States to achieve a harmonized regional policy on legislative, regulatory, administrative, procurement and distribution framework for generic essential medicines in east Africa, and to examine the capacity of EAC Partner States to respond appropriately to the WTO TRIPS flexibilities to maximize access to essential medicines in the region.<sup>35</sup> Thus, the issue of pooled procurement was addressed by the Council as a priority issue in relation to access to medicines in the region, along with related issues such as harmonizing drug regulations and utilizing TRIPS flexibilities.

The situational analysis was presented at a meeting of EAC regional stakeholders in Zanzibar in November 2006, which recommended the establishment of a task force or a Technical Steering Committee to develop a position paper on the way forward for the EAC on pooled procurement of antiretroviral (ARV) drugs and also to ensure that the agenda of

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<sup>31</sup> EAC Treaty, *supra* note 11, Article 118.

<sup>32</sup> WHO (2007), *A Situational Analysis and Feasibility study on Regional Pooled Bulk Procurement of Essential Medicines and other Health Supplies in the East African Community Partner States*, p.25, available at [http://www.eac.int/health/index.php?option=com\\_content&view=article&id=52&Itemid=117](http://www.eac.int/health/index.php?option=com_content&view=article&id=52&Itemid=117) (last visited 17 June 2014).

<sup>33</sup> EAC Secretariat (2002), Report of the 4th Ordinary Session of the East African Community Council of Ministers, EAC/CM/4/2002.

<sup>34</sup> EAC Secretariat (2005), Report of the 1st Meeting of the EAC Sectoral Council on Health, 8 July 2005, EAC/SC/01/2005, p.10, available at [http://www.health.eac.int/index.php?option=com\\_docman&task=cat\\_view&gid=22&Itemid=144](http://www.health.eac.int/index.php?option=com_docman&task=cat_view&gid=22&Itemid=144) (last visited 17 June 2014).

<sup>35</sup> *Ibid.*, p. 11.

pooled procurement will continue to remain a high health care priority in the EAC. The meeting also agreed that the Group Contracting model of procurement should be a potential medium-term goal for the EAC.<sup>36</sup> At the 2nd meeting of the Sectoral Council of Ministers of Health in 2007, the Sectoral Council approved these recommendations and also approved the establishment and ToRs of an EAC Regional Technical Working Group (TWG) on Medicines and Food Safety.<sup>37</sup> Thus, a Technical Steering Group was established on the issue of procurement, and a Technical Working Group was established on medicines and food safety.

Following this, in 2007 the EAC Secretariat requested the WHO Department of Technical Assistance for Essential Medicines (TCM) to conduct a situational analysis and feasibility study for implementing a mechanism of regional pooled procurement of medicines as part of efforts by the EAC to address issues of accessibility and affordability of essential medicines in the region. The WHO undertook a study that analyzed the legal and regulatory framework on procurement of pharmaceutical products and other essential medical supplies in the public sector in the EAC Partner States, determined the feasibility of pooled procurement, recommended specific models of pooled procurement and identified a potential target commodity for bulk purchasing, and sought to develop guidelines and recommendations for the implementation of the recommended model of pooled procurement. The study recommended the Group Contracting model as the most feasible model for pooled procurement for the EAC region. In the Group Contracting model, participating countries jointly negotiate prices and agree to purchase the medicines through selected suppliers, but the member countries conduct the purchase of the medicines individually.

The WHO study focused on six components essential for pooled procurement – political commitment, appropriate procurement legislation, robust supply systems, harmonized regulatory procedures, adequate and predictable financial resources, and opportunities to acquire greater pricing efficiency through bulk purchasing. With regard to procurement legislations and policies, the study found that procurement legislations and institutional framework in the EAC Partner States is relatively homogenous and provides the basis of establishment of Good Pharmaceutical Procurement practice for the adoption of regional pooled procurement. However, due to the lack of any specific law for regional pooled procurement, diverse interpretations of national and international legal obligations might give rise to potential conflicts which will have to be addressed. These issues include the role of local manufacturers in regional pooled procurement, lack of mutual recognition of decisions of respective National Medicines Regulatory Authorities (NMRAs) on registration of medicines. For implementation of the project, four Technical Working Groups (TWG) have been established under the Project Steering Committee on the development of a common technical document, information management system, Good Manufacturing Practice (GMP) inspection, and quality management system.

Based on the recommendations in the WHO study, the 15th session of the EAC Council of Ministers in 2008 approved the “Regional Group-Contracting Bulk Procurement

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<sup>36</sup> UNDP (2006), Report of Stakeholders Meeting on Bulk Procurement of ARVs and Essential Medicines in the East Africa Community (EAC), 13-15 November 2006, available at [http://api.ning.com/files/7RdsitIYYj-V8iV-BVf66TnrI5c8kIAO\\*6uF355X4rPIfkO2oCsQ-MOBtrn8lkhDnRGkKKk9vLo419\\*2sFzJ2OLBMLvbu6kG/EACReportBulkprocurementZanzibarwshop13\\_15Nov2006.doc](http://api.ning.com/files/7RdsitIYYj-V8iV-BVf66TnrI5c8kIAO*6uF355X4rPIfkO2oCsQ-MOBtrn8lkhDnRGkKKk9vLo419*2sFzJ2OLBMLvbu6kG/EACReportBulkprocurementZanzibarwshop13_15Nov2006.doc) (last visited 17 June 2014).

<sup>37</sup> EAC Secretariat (2007), Report of 2nd Ordinary Meeting of EAC Sectoral Council of Ministers of Health, 24-27 September 2007, EAC/SR/30/2007, available at [http://www.health.eac.int/index.php?option=com\\_docman&task=cat\\_view&gid=22&Itemid=144](http://www.health.eac.int/index.php?option=com_docman&task=cat_view&gid=22&Itemid=144) (last visited 17 June 2014).

Model” for priority essential medicines in East Africa.<sup>38</sup> The EAC Secretariat embarked upon developing a Draft Strategic Plan of Action and multi-year budget for implementation of the proposed group contracting bulk procurement mechanism in collaboration with EAC Partner States’ ministries of health, National Medicines Procurement Agencies (NMPA) and National Medicines Regulatory Authorities (NMRA). The 3rd meeting of the EAC Sectoral Council on Health in 2008 directed the EAC Secretariat to coordinate this work taking into account the development of a costed regional work plan for pooled bulk procurement to address gaps and build model for pooled bulk procurement, strengthening the capacity of the EAC Secretariat in coordinating pooled bulk procurement, identification of relevant structures at country level for coordinating pooled bulk procurement activities like forecasting, quantification, financing and price monitoring, simultaneous implementation of regional work plan for pooled procurement and mechanism development, and development of contractual, binding and funded agreement to be signed among the EAC Partner States for the implementation of pooled bulk procurement.<sup>39</sup> The Sectoral Council also appointed members of the expert task force that was approved by the Sectoral Council in 2007. The Sectoral Council also urged EAC Partner States to operationalize national task forces for pooled bulk procurement of essential medicines and inform the EAC Secretariat by December 2008.<sup>40</sup>

The reports of the 4th and 5th meetings of the EAC Sectoral Council on Health are not available on the website of the EAC. The reports of the 6th and 7th meetings of the Sectoral Council makes no mention of progress regarding the development of a plan of action and budget for establishing a regional pooled bulk procurement mechanism since the decision of the 3<sup>rd</sup> meeting of the Sectoral Council in 2008, though the report of the 6th meeting of the Sectoral Council generally noted the ongoing progress in implementation of the decisions of the past meetings of the Sectoral Council. Moreover, the report of the 8th meeting of the Sectoral Council is also not available on the EAC website.

The most specific reference to the work being pursued on pooled procurement in EAC since the 3rd meeting of the Sectoral Council on Health in 2008 appears in the report of the 9th session of the Sectoral Council held on 17 April 2014. In that meeting, the Sectoral Council took note of the progress made in developing a draft proposal and mobilization of resources from development partners to support implementation of the initial phase of activities on pooled bulk procurement through group contracting mechanism.<sup>41</sup> In this context, the Sectoral Council directed the EAC Secretariat to operationalize an Experts Working Group (EWG) on EAC regional pooled bulk procurement initiative with members drawn from national procurement agencies, national medical stores and department of pharmaceuticals of ministries of health of EAC Partner States. The Sectoral Council further directed the EAC Secretariat to convene the EWG meeting to review the draft proposal and develop a roadmap for implementation of the initiative, and also mobilize additional resources to support pooled bulk procurement initiative.<sup>42</sup>

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<sup>38</sup> EAC Secretariat (2008), Report of the 3rd Meeting of the EAC Sectoral Council of Ministers of Health, 22-26 September, 2008, EAC/MS/01/2008), p. 15, available at [http://www.health.eac.int/index.php?option=com\\_docman&task=cat\\_view&gid=22&Itemid=144](http://www.health.eac.int/index.php?option=com_docman&task=cat_view&gid=22&Itemid=144) (last visited 17 June 2014).

<sup>39</sup> *Ibid.*, p.16.

<sup>40</sup> *Ibid.*

<sup>41</sup> EAC Secretariat (2014), Report of the 9th Ordinary Meeting of the EAC Sectoral Council of Ministers of Health, 17 April 2014, EAC/SCM/HEALTH/001/2014, p. 33, available at [http://www.health.eac.int/index.php?option=com\\_docman&task=cat\\_view&gid=22&Itemid=144](http://www.health.eac.int/index.php?option=com_docman&task=cat_view&gid=22&Itemid=144) (last visited 17 June 2014).

<sup>42</sup> *Ibid.*

Thus, it seems that since the approval of the proposal for establishing a regional pooled bulk procurement mechanism on the group contracting model by the Council of Ministers in 2008 and the direction by the Sectoral Council to the Secretariat to develop a draft plan of action and budget for implementing this mechanism, there has been very limited progress, if any. In this context, more information is required to assess what are the constraints that have delayed the development of this plan of action. It is learnt from one expert involved in this issue in the EAC is because other issues like medicines registration harmonization had to be addressed first.<sup>43</sup>

## **V. OTHER DEVELOPMENTS IN THE EAC**

Though the plan of action on implementing a regional pooled procurement mechanism has not progressed substantially, there have been other developments in the EAC which can complement and support a regional pooled procurement mechanism. These are the entry into force of the EAC Common Market Protocol, the establishment of the EAC Customs Union, the development of a draft EAC TRIPS policy and protocol, and the adoption of the EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA). However, the implementation of a regional pooled procurement mechanism could be undermined significantly by the draft EAC anti-counterfeit law which is currently being discussed in the EAC.

### **V.1 The EAC Common Market Protocol**

The EAC Common Market Protocol came into force in July 2010 following ratification by all five EAC Partner States. With the implementation of the Common Market Protocol a number of trade barriers between the EAC Partner States have been eliminated which would render cross-border supply of medicines between EAC Partner States much more convenient. It could also facilitate greater harmonization of laws and policies among EAC Partner States. Some of the provisions of the Common Market Protocol have significant implications for pooled procurement. Article 35 of the Common Market Protocol specifies that Partner States shall not discriminate against suppliers, products or services originating from other Partner States, for purposes of achieving the benefits of free competition in the field of public procurement.<sup>44</sup> Partner States are also required to implement programmes to prevent and manage HIV/AIDS, malaria and TB, as well as outbreak of epidemics and other diseases.<sup>45</sup> The Protocol also requires Partner States to cooperate to ensure the availability of relevant, timely and reliable statistical data for sound decision-making and effective service delivery in the Common Market, and develop and adopt harmonized statistical methods.<sup>46</sup> Harmonized statistical data quality and data collection methods will immensely facilitate information

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<sup>43</sup> Comment on the presentation of this research in a training course for patent officers, Members of Parliament, and civil society organizations on the harmonisation of the East African Community TRIPS Policy, national IP laws in the EAC and the Harare Protocol of ARIPO, organized by the South Centre, 30-31 July 2014, Arusha, Tanzania.

<sup>44</sup> Protocol on the Establishment of the East African Community Common Market, Article 35.

<sup>45</sup> *Ibid.*, Article 39.

<sup>46</sup> *Ibid.*, Article 41.

sharing on medicine stock and needs in order to undertake efficient regional pooled procurement.

## **V.2 The EAC Customs Union**

The EAC Customs Union has been in force since 2004. With Rwanda and Burundi joining the Customs Union in 2008, it is currently applicable to all EAC Partner States. The EAC Customs Union operates under the framework of the Protocol on the Establishment of the East African Customs Union. The Customs Protocol has established a common external tariff (CET) comprising three tariff bands across all tariff lines. A 10 per cent tariff was applicable on import of pharmaceutical products in the EAC countries but this was withdrawn in 2005 as this escalated the cost of pharmaceutical imports. The Customs Protocol has also established an internal tariff regime, which has made all trade between EAC Partner States duty free.

In the context of procurement of medicines, the internal tariff regime currently is of limited consequence as most of the pharmaceutical products in the EAC countries are imported from outside the EAC. However, in the context of the initiatives being undertaken in the EAC for promoting local production of medicines, the internal tariff regime can significantly facilitate procurement of cheaper locally produced generic medicines. The CET regime could also be a useful tool in supporting the growth of the local pharmaceutical industry if it is appropriately revised in relation to the level of development of the local pharmaceutical industry. For some simple formulations and active pharmaceutical ingredients (APIs) like paracetamol which can be manufactured locally an appropriate CET on imports of such pharmaceutical products along with a duty free regime for local manufacturers could enable local manufacturers to supply these medicines at affordable rates.

## **V.3 The EAC Regional Pharmaceutical Manufacturing Plan of Action, 2012-2016**

One of the critical factors for a pooled procurement mechanism for medicines is the source of medicines. Most of the local pharmaceutical firms in the EAC region have very limited manufacturing capacity and only produce some simple formulations. Most of the essential medicines purchased by national medical stores of EAC Partner States are imported from outside Africa, particularly from generic drug suppliers from India and China. The dependence on imports for supply of essential medicines may not be sustainable in the long run, particularly for some of the second and third line antiretroviral medicines where generic production would be constrained due to the existence of product patents. In this context, it will be important to support the development of local pharmaceutical manufacturing capacity to provide a sustainable source of cheap quality medicines in the EAC. In this context, the adoption of the EAC Regional Pharmaceutical Manufacturing Plan of Action 2012-16 (RPMPOA) is of utmost significance.

The EAC adopted the RPMPOA in 2012 and established a Regional Steering Committee on implementation of the RPMPOA. The meeting of the Sectoral Council on health directed the EAC Secretariat to expedite the implementation of the RPMPOA, particularly the promotion of intra-regional trade on pharmaceutical products.<sup>47</sup>

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<sup>47</sup> EAC Secretariat (2014), *supra* note 40, p. 33.

The RPMPOA has set out the following strategic objectives – promotion of competitive and efficient pharmaceutical production regionally, facilitating increased investment in regional pharmaceutical production, strengthening pharmaceutical regulatory capacity, development of appropriate skills and knowledge of pharmaceutical production, utilization of TRIPS flexibilities towards improved local pharmaceutical production in the region, and mainstreaming innovation, research and development within the regional pharmaceutical industry.<sup>48</sup> The establishment of a regional pooled procurement mechanism is an integral component of the EAC Regional Pharmaceutical Manufacturing Plan of Action, 2012-2016.<sup>49</sup> The EAC has started the process of implementation of the RPMPOA, which is being coordinated by a project steering committee comprising representatives from health, industrialization and EAC ministries of EAC Partner States, NMRAs, national pharmaceutical manufacturers associations and the Federation of East African Pharmaceutical Manufacturers (FEAPM).<sup>50</sup> The draft ToRs for the steering committee was considered by the EAC Sectoral Council of Ministers of Trade, Industry, Finance and Investment which recommended that the EAC Secretariat should establish a joint working group between health and industry to address issues of development of a pharmaceutical industry in the region. The ToRs were referred to the Sectoral Council on Health for further consideration and approval. The 9<sup>th</sup> meeting of the Sectoral Council on health approved the ToRs and directed the EAC Secretariat to expedite implementation of the RPMPOA.

#### **V.4 EAC Regional IP Policy on the Utilization of Public Health-Related WTO TRIPS Flexibilities**

In recognition of the need to promote access to essential medicines, the EAC has developed a regional policy on the use of Public Health-Related WTO-TRIPS flexibilities and the Approximation of National Intellectual Property Legislation, and the Regional Protocol on Public Health-Related TRIPS Flexibilities. Currently, many EAC Partner States do not make full use of the public health-related TRIPS flexibilities in their national patent or IP laws. This can have an adverse impact on the procurement of medicines, which are under patent protection. This is particularly significant for the EAC, where four out of the five Partner States are LDCs who are exempted from providing patent protection at least till 2021. However, some of these countries have only recently amended their patent laws to exclude pharmaceutical products from patent protection during the transition period.

#### **V.5 EAC Medicines Regulatory Harmonization Project**

The launch of the EAC Medicines Regulatory Harmonization (EAC-MRH) programme in 2012 has been one of the most significant developments in relation to the possible establishment of a regional pooled procurement mechanism. The EAC-MRH programme seeks to establish a harmonized and functioning medicines regulatory system in accordance with national and internationally recognized policies and standards, in order to increase access

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<sup>48</sup> EAC (2011), *supra* note 13, p. 11.

<sup>49</sup> *Ibid.*, p. 31.

<sup>50</sup> EAC Secretariat (2013), *Implementation of EAC Regional Pharmaceutical Manufacturing Plan of Action 2012-2016 Starts in Earnest*, available at [http://www.eac.int/index.php?option=com\\_content&view=article&id=1269:implementation-of-eac-regional-pharmaceutical-manufacturing-plan-of-action-2012-2016-starts-in-earnest&catid=146:press-releases&Itemid=194](http://www.eac.int/index.php?option=com_content&view=article&id=1269:implementation-of-eac-regional-pharmaceutical-manufacturing-plan-of-action-2012-2016-starts-in-earnest&catid=146:press-releases&Itemid=194) (last visited 17 June 2014).

to safe, efficacious and good quality essential medicines for the treatment of conditions of public health importance. It is designed as a five-year programme with the following specific milestones: 1) establishment of a common technical document format for submitting applications for medicines registration; 2) establishment of a common integrated information management system linked with all EAC Partner States and the EAC Secretariat, and building regional and national capacity to implement the harmonized medicines regulatory system. It also seeks to establish semi-autonomous NMRAs in Rwanda and Burundi by the end of the third year of the project. It also seeks to establish an EAC legal framework for mutual recognition of regulatory decisions by the end of the five-year programme.<sup>51</sup>

Further work is expected towards reviewing, updating and establishing a harmonized regional policy and legal framework, establishment of the East African Community Medicines Food and Safety Commission by 2016, and review of existing pharmaceutical policies and legislations of EAC Partner States. The 9th meeting of the EAC Sectoral Council of Ministers of Health held in April 2014 adopted the EAC harmonized guidelines, standards and requirements for Medicines Evaluation and Registration, GMP and quality management systems for NMRAs and recommended the EAC Council of Ministers to consider and approve these guidelines.<sup>52</sup>

Though establishing appropriate drug regulatory systems and regional cooperation on drug registration is necessary, the EAC MRH project should adopt regulatory standards that are appropriate to the needs of the region. The countries of the EAC region will have to rely on imported generic medicines or on locally manufactured medicines to ensure access to affordable medicines for the prevention and treatment of diseases that are endemic to the EAC Partner States. It should be noted that the Thirty-first report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations had stated that the approach to drug regulations must be attuned to available resources. The report also states that often problems in establishing regulatory control have resulted from trying to implement complex standards successful elsewhere but inappropriate to the requirements in the country adopting the standards. Therefore, the EAC Partner States have to ensure that common drug regulatory standards that are adopted for the region are appropriate to the resources and needs of the region and do not create unnecessary barriers for the entry of locally manufactured or imported generic medicines.

However, the EAC MRH Programme while mentioning internationally recognized regulatory standards refers to the standards, procedures and guidelines recognized by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use and states that the proposed common technical document for application and registration of medicines in all EAC Partner States is to be based on the WHO/ICH format. The influence of the ICH in the framing of standards, procedures and guidelines for drug registration in the EAC region through the MRH project is a matter of concern because the ICH guidelines are heavily influenced by multinational pharmaceutical companies and regulatory agencies from developed countries.<sup>53</sup> The ICH guidelines are not

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<sup>51</sup> Paul K. Tanui (2014), *Lessons and experiences: EAC Medicines Regulatory Harmonization (MRH) Project*, presentation at the Parliamentary Roundtable, Midrand, South Africa, 25-27 March 2014, available at <http://www.aidswatchafrica.org/sites/default/files/EAC%20MRH%20Project.pptx> (last visited 17 June 2014).

<sup>52</sup> EAC Secretariat (2014), *supra* note 40, p. 32.

<sup>53</sup> The ICH is a forum of regulatory authorities and the pharmaceutical industry of Europe, Japan and US that was established in 1990 to discuss scientific and technical aspects of drug registration. Though it is not a part of the WHO, the ICH effectively facilitates the pharmaceutical industry from developed countries to influence drug registration standards, which could restrict generic competition from developing countries.



approved by the WHO member States and hence they do not constitute the definitive international standard on drug regulation though some of the ICH guidelines have influenced the WHO guidelines. In the recently held World Health Assembly of 2014, member States of the WHO approved a resolution on regulatory systems strengthening only after removal of references to the ICH guidelines in the resolution.<sup>54</sup> It should be noted that a 2002 report of the WHO on the impact of ICH Guidelines on non-ICH countries states that

“In many countries, essential drugs required for the prevention and treatment of locally endemic conditions are not supplied by the major multinationals, but by local industry or by generic manufacturers. If these suppliers are unable to meet what may be unsubstantiated quality standards (set by the ICH), the adverse impact of the withdrawal of these drugs on the health of the population might well be far more dramatic than that of any hypothetical risk posed by failing to achieve the ICH standards.”<sup>55</sup>

The report stated further that though the ICH guidelines are being promoted and increasingly perceived as the “best” possible standard for international harmonization, many countries are led to believe that the adoption of the ICH guidelines is necessary to gain access to the pharmaceutical markets of the ICH countries. The report concluded that “The “spontaneous” dissemination of ICH products is not necessarily consistent with national priorities and represents a pressure that may lead to diverting limited national resources to unnecessary expenses entailed by the adoption of more costly regulatory requirements.”<sup>56</sup>

It is also significant to note that donor funded procurement programmes for HIV/AIDS, malaria or TB drugs require suppliers to comply with regulatory standards set by ICH. For example, the Global Fund’s quality assurance policy for pharmaceutical products, 2010, states that Global Fund grants may be used to procure antiretrovirals, anti-tuberculosis and anti-malarial drugs that are WHO prequalified or authorized for use by a Stringent Drug Regulatory Authority (SRA). An SRA is defined by the Global Fund as a regulatory authority which is a member or observer of the ICH, or a regulatory authority associated with an ICH member.<sup>57</sup>

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<sup>54</sup> K.M. Gopakumar (2014), *WHO: Governmental pushback on industry role in medical product regulation*, TWN Info Service on Intellectual Property Issues, 30 May 2014, available at [http://www.twinside.org.sg/title2/intellectual\\_property/info.service/2014/ip140513.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/2014/ip140513.htm) (last visited 14 July 2014).

<sup>55</sup> WHO (2002), *The Impact of Implementation of ICH Guidelines in non-ICH Countries*, Report of a WHO meeting, Geneva, 13-15 September 2001, Regulatory Support Series No.9, p.16, available at <http://apps.who.int/medicinedocs/pdf/h2993e/h2993e.pdf> (last visited 13 July 2014).

<sup>56</sup> *Ibid.*, p. 17.

<sup>57</sup> The Global Fund (2010), *Global Fund Quality Assurance Policy For Pharmaceutical Products* (as amended and restated on 14 December 2010), available online at [https://www.google.ch/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CB0QFjAA&url=http%3A%2F%2Fwww.theglobalfund.org%2Fdocuments%2Fpsm%2Fpsm\\_QAPharm\\_Policy\\_en%2F&ei=kOQGVKveE4S\\_ygOczILYDQ&usg=AFQjCNFjQz1IJ-XnFnXxtGKiiykaEhAETg&sig2=ONXZuMR1eTDbxNba3AV0yw&bvm=bv.74115972,d.d2s](https://www.google.ch/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CB0QFjAA&url=http%3A%2F%2Fwww.theglobalfund.org%2Fdocuments%2Fpsm%2Fpsm_QAPharm_Policy_en%2F&ei=kOQGVKveE4S_ygOczILYDQ&usg=AFQjCNFjQz1IJ-XnFnXxtGKiiykaEhAETg&sig2=ONXZuMR1eTDbxNba3AV0yw&bvm=bv.74115972,d.d2s) (last visited 3 September 2014).

## V.6 EAC Anti-Counterfeit Law

The EAC Secretariat has adopted an anti-counterfeit policy in 2011 and is currently engaged in the process of developing an anti-counterfeit law. The anti-counterfeit policy and the draft anti-counterfeit law seeks to prohibit trade in counterfeit goods, including counterfeit medicines. Policy makers in the EAC Secretariat seem to believe that the anti-counterfeit policy and law is required to stop the availability of fake medicines in the market which can be fatal or harmful for unsuspecting patients.<sup>58</sup> However, an anti-counterfeit law or policy will not resolve this problem of availability of poor quality medicines in the EAC region. On the contrary, public health groups are concerned that such an anti-counterfeit policy and law could undermine access to legitimate and safe generic medicines.<sup>59</sup>

This is because the word “counterfeiting” has a particular legal connotation that is unrelated to the quality of a product. In the TRIPS Agreement, “counterfeiting” is referred to in connection with wilful trademark infringement.<sup>60</sup> Some developed countries have expanded the definition of counterfeiting to include other forms of IP infringement as well. Thus, an anti-counterfeit law is essentially about enforcement of IP rights, particularly trademarks, and it has nothing to do with the quality of the product. A trademark for a product, including medicines, is registered based on the novelty of the brand name, rather than the quality of the product. Even a patent on a medicine is not granted on the basis of its quality.

Though consumers over time tend to associate a brand identity with the quality of the product so branded, in the field of medicines the patient buys medicines which are prescribed by the doctor. Indeed, pharmaceutical companies are known to promote their brands with the doctors in order to encourage them to prescribe the same to the patients. Moreover, the generic name or the International Nonproprietary Name (INN) of the medicine is an important identifier of the drug prescribed. Many patients have experienced situations where the pharmacy would offer the patient an alternative to the prescribed brand which may not be in stock. For example, a prescribed brand of paracetamol (INN) may not be in stock and the pharmacist could offer the patient a different brand of paracetamol. If this alternative brand name is very similar to the brand name of another paracetamol, it could be a case of wilful trademark counterfeiting but that in itself would not make the alternative paracetamol unsafe. Indeed, if the definition of counterfeiting is broad enough, it may be possible to challenge many generic brands of counterfeiting because in the drug industry generics naturally tend to develop their brand names that can be related to the originator brand. In fact, most brand names try to use some parts of the INNs. For example, Pfizer marketed the antibiotic azithromycin under the brand Zithromax, where “zithro” was derived from the generic name. What would make it unsafe is if the medicine is fake or of substandard quality, but that cannot be determined by a customs or police officer.

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<sup>58</sup> EAC, *Anti-Counterfeit Policy will provide "Proper" Generics*, Interview with Ambassador Juma Mwapachu, former Secretary-General of the EAC, available online at [http://www.eac.int/sg/index.php?option=com\\_content&view=article&id=87:ips-interview-may-2010&catid=40:sgs-blog&Itemid=1](http://www.eac.int/sg/index.php?option=com_content&view=article&id=87:ips-interview-may-2010&catid=40:sgs-blog&Itemid=1) (last visited 3 September 2014).

<sup>59</sup> East African Health Platform, *Draft Position Paper on the Impact of the Draft EAC Anti-Counterfeit Bill 2013 on Access to Essential Medicines in East Africa*, available online at [http://www.eahp.or.tz/uploads/EAHP\\_POSITION\\_PAPER\\_ON\\_THE\\_IMPACT\\_OF\\_THE\\_DRAFT\\_EAC\\_ANTI\\_COUNTERFEIT\\_BILL\\_2013\\_ON\\_ACCESS\\_TO\\_MEDICINES.pdf](http://www.eahp.or.tz/uploads/EAHP_POSITION_PAPER_ON_THE_IMPACT_OF_THE_DRAFT_EAC_ANTI_COUNTERFEIT_BILL_2013_ON_ACCESS_TO_MEDICINES.pdf) (last visited 3 September 2014).

<sup>60</sup> See TRIPS Agreement, Article 51.

Indeed, the WHO has conducted studies in Africa which suggests that the major problem with regard to quality and safety of medicines is the availability of substandard medicines. Even a legitimate medicine can become substantive over time if stored improperly.<sup>61</sup> The presence of medicines with reduced potency in the region actually suggests that this is a major problem in EAC as well. However, this will not be addressed through an anti-counterfeit legislation.

In this context, the proposed EAC Anti-Counterfeit Bill 2013 can become problematic. The Bill proposes to create criminal offences, procedures for prosecution and criminal sanctions against IP infringements. The definition of counterfeiting in the proposed Bill encompasses any IP right, including patents. This is an expansion from the limited definition of counterfeiting in TRIPS to certain acts of wilful trademark infringement. Thus, effectively, any generic medicine could be implicated under the proposed Bill as a counterfeit if there is suspicion of patent infringement. Therefore, the proposed anti-counterfeit Bill would effectively undermine the use of TRIPS flexibilities for ensuring access to medicines that the EAC seeks to achieve, as well as undermine the availability of generic medicines that could be procured through the pooled procurement mechanism. The constrained environment for generics would weaken the bargaining power of the EAC against multinational pharmaceutical companies in any price negotiation under the pooled procurement mechanism.

## **VI. LEGAL FRAMEWORK ON PROCUREMENT OF MEDICINES IN THE EAC PARTNER STATES**

The national laws and regulations governing public procurement also govern the procurement of medicines. The establishment of a common legal framework for a regional pooled procurement mechanism for essential medicines would require bringing about convergence among national laws and regulations by establishing a common legal framework.

All the EAC Partner States have enacted new public procurement legislations to introduce greater transparency and efficiency in the procurement process and have established independent regulatory bodies to exercise oversight on the procurement process. These new legislations are based on the UNCITRAL model law on procurement.<sup>62</sup> All of the EAC Partner States base their procurements on an essential medicines list (EML) drawn from the treatment protocols in the standard treatment guidelines (STG) which are updated from time to time.

All EAC Partner States have national or central medical stores constituted as statutory bodies to act as the principal procurement agency for medicines for the public health facilities in the country. However, the central or national medical stores are not the only agencies involved in procurement of medicines, but also includes procurement units of ministries of health which engage in procurement under vertical programmes that are supported by external funding agencies. Typically, these involve procurement of medicines for HIV/AIDS, TB and

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<sup>61</sup> J.M. Caudron, *et. al.* (2008), "Substandard Medicines in Resource-poor Settings: A Problem that Can no Longer be Ignored", *Tropical Medicine and International Health*, vol.13, no.8, pp. 1062-1072.

<sup>62</sup> WHO (2007), *supra* note 31, p. 38.

malaria. The increased reliance on external support for medicines financing could lead to complexities in coordinating funding sources as different donors could have specific requirements governing disbursements. In addition, there are faith based procurement agencies which provide 20-30 per cent of health care in the EAC. The prominent faith based procurement agencies from the EAC Partner States are Mission for Essential Drugs and Supplies (MEDS) in Kenya, Mission for Essential Medical Supplies & Services (MEMS) in Tanzania, Bureau des Formations Medicales Agréées du Rwanda (BUFMAR) in Rwanda and Joint Medical Stores (JMS) in Uganda.

## VI.1 Burundi

Burundi acceded to the EAC in 2007. Burundi has one of the highest population densities in Africa. Malaria and HIV/AIDS are among the leading diseases that affect most of population. Stock-out of medicines in the national medical stores is a major problem that impacts the availability of medicines in the health care facilities. Burundi predominantly relies on importation of medicines to meet its healthcare needs. There is only one local pharmaceutical manufacturer in the private sector – SIPHAR – which only produces a narrow range of medicines. In the public sector, the national pharmaceutical office (ONAPHA) manufactures 50 essential medicines. Article 17 of the industrial property law of Burundi (2009) excludes pharmaceutical products from patentability till 2016.

The procurement process in Burundi is regulated by the Director-General of Public Markets. In 2008, Burundi adopted a new Public Procurement Code, which established a Public Procurement Regulatory Authority (ARMP) and the National Procurement Monitoring Directorate (DNCMP). The DNCMP is responsible for advising the government on all dossiers above certain defined thresholds and exercises *ex-post* control on contracts below these thresholds. ARMP has to carry out regular audits of procurement contracts along with an independent review mechanism. However, these institutions lack financial autonomy and report to the ministry of finance. There is also no public procurement journal or website to ensure wider dissemination of information on procurement.<sup>63</sup> The ARMP is currently undertaking consultations to review the Public Procurement Code for further improvement.<sup>64</sup>

With regard to medicines, the national medical stores (CAMEBU) is responsible for the procurement of medicines. A quality control laboratory was established under the national institute of public health in 2009. The CAMEBU imports, stores and distributes medicines to pharmacies of health districts, which re-distributes the medicines to pharmacies of district hospitals and health centres. However, the storage capacity of CAMEBU is very limited and the Director General of CAMEBU has pointed to the need to significantly expand its storage capacity.<sup>65</sup> In the event of interruptions of inventory at CAMEBU, the district hospitals or healthcare facilities can use the services of private pharmaceutical wholesalers as a special

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<sup>63</sup> African Development Bank (2011), *Burundi: Country Strategy Paper 2012-2016*, p. 6, available at <http://www.afdb.org/fileadmin/uploads/afdb/Documents/Project-and-Operations/Burundi%20-%20CSP%202012-16.pdf> (last visited 17 June 2014).

<sup>64</sup> East African Business Week, “Burundi to Review Procurement”, 17 February 2014, available at <http://www.busiweek.com/index1.php?Ctp=2&pI=606&pLv=3&srI=77&spI=289&cl=10> (last visited 17 June 2014).

<sup>65</sup> Radio Isangiro, “La CAMEBU incapable de stocker les médicaments”, 3 February 2012, available from <http://www.isanganiro.org/spip.php?article881> (last visited 17 June 2014).

case, with the authorization of the Directorate of Pharmacies, Medications and Laboratories (DPML).

The funding for procurement of essential medicines is primarily available from government budgets and external financing by donors. Procurement of medicines for HIV/AIDS, TB and malaria are funded by external donors like GFATM and the World Bank.

The DPML was established in 2002 to regulate pharmaceutical products and ensure the quality of medicines. However, the DPML does not have the capacity to conduct quality control tests and relies on tests by external laboratories. As the pharmaceutical regulations systems are being standardized with other EAC Partner States, the DPML could be transformed to a National Pharmaceutical Governing Authority (NARP).<sup>66</sup> It will be necessary in this context to strengthen the internal quality control test capabilities of the DPML to transform it into a full-fledged regulator of the pharmaceutical sector.

The first essential drugs list was developed in 1977. The latest revised essential medicines list was published in 2012.<sup>67</sup> Since 2000 all medicines to be introduced in the market are required to be registered with the ministry of health.<sup>68</sup> The essential medicines list is based on treatment protocols in the standard treatment guidelines (STG).

According to the second National Health Development Plan 2011-2015 (NHDP II) availability of medications is identified as a strategic priority area. Activities that have been identified in furtherance of this strategic objective include implementation of an integrated supply and distribution chain, and preparation of an enabling legislation laying down the framework for the functioning of the pharmaceutical sector including approval, inspection, pharmaceutical oversight, quality assurance, price regulation, etc. It also seeks to pursue adoption of new bye-laws for CAMEBU and enhance its capacity. Moreover, NHDP II also seeks to promote inter-sectoral cooperation for regulation of medicines prices and improving quality control of medicines.

## VI.2 Kenya

Kenya is a founder member of the EAC and the only developing country Partner State of the Community. It has a high burden of communicable diseases, particularly HIV/AIDS, TB and malaria. According to the National Health Accounts 2010, 29.3 per cent of the health expenditure is from the government, 31 per cent is contributed by donors and 35.9 percent is generated from households. Foreign development assistance is a significant financing source for the health sector in Kenya. There has been a steady increase of import of pharmaceuticals, and though Kenya has considerable local manufacturing capacity in the region, local industry

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<sup>66</sup>Republic of Burundi, Ministry of Public Health and Fighting AIDS, *National Health Development Plan 2011-2015*, p. 40, available at [http://www.nationalplanningcycles.org/sites/default/files/country\\_docs/Burundi/burundi\\_pnds\\_2011\\_-\\_2015-en.pdf](http://www.nationalplanningcycles.org/sites/default/files/country_docs/Burundi/burundi_pnds_2011_-_2015-en.pdf) (last visited 17 June 2014).

<sup>67</sup> National Essential Medicines List of Burundi, available at [http://www.who.int/selection\\_medicines/country\\_lists/Burundi\\_LNME\\_2012.pdf?ua=1](http://www.who.int/selection_medicines/country_lists/Burundi_LNME_2012.pdf?ua=1) (last visited 18 June 2014).

<sup>68</sup> Réseau Médicaments et Développement, "Politique pharmaceutique du Burundi", available at [http://www.remed.org/html/politique\\_pharmaceutique\\_burun.html](http://www.remed.org/html/politique_pharmaceutique_burun.html) (last visited 18 June 2014).

has less than 10 per cent of the market share.<sup>69</sup> There are 41 companies listed as local pharmaceutical manufacturers in Kenya excluding GSK which makes Kenya an important centre for pharmaceutical manufacturing in the EAC region. About half of the pharmaceutical exports from Kenya are to Uganda and Tanzania.

The receipt, warehousing and distribution of medical equipment and supplies procured by the Ministry of Health for all hospitals and clinics in the country is conducted by the Kenya Medical Supplies Agency (KEMSA). The National Health Sector Strategic Plan envisioned KEMSA to be “a secure source of essential medicines for all public health facilities”, one of the four key pillars in reducing disease burden and move closer to achieving one of the millennium development goals – to reduce child and maternal morbidity. The other pillars are rational drug use, affordable cost/price and sustainable financing for drugs.<sup>70</sup>

KEMSA is also mandated to establish a network of storage, packaging and distribution facilities for provision of drugs and medical supplies to health institutions, entering into partnerships and establishing frameworks with county governments for services in procurement, warehousing and distribution of drugs and medical supplies, collecting information and reporting to the national and county governments on the status and cost effectiveness of procurement, the distribution and value of prescribed essential medical supplies delivered to health facilities, stock status, etc., and to support county governments in establishing and maintaining appropriate supply chain systems.<sup>71</sup>

KEMSA procures medicines on the essential medicines list upon request from the Ministry of Health. While procurement is generally done through an open bidding process, other methods of procurement are permitted under special circumstances. If quotes for specific products are not received, KEMSA seeks to procure alternative medicines in consultation with the Ministry of Health. Most of the procured medicines are delivered by vendors in the last quarter of the fiscal year in anticipation of speedy payments, which stresses the storage capacities of KEMSA.

In parallel with procurement by KEMSA, the Ministry of Health also conducts procurement of medicines through its own procurement unit. The lack of communication between KEMSA and the Ministry of Health on these procurement and delivery schedules complicates planning for warehouse space and distribution.

KEMSA procures nearly 30 per cent of all prescription drugs in Kenya and also procures for some donor partners. However, KEMSA cannot purchase all the medicines on the essential medicines list due to funding constraints. In addition to KEMSA, some donor-funded programmes also procure medicines in bulk. For example, PEPFAR procures and distributes ARVs through a faith-based organization called the Mission for Essential Drugs and Supplies (MEDS). The Clinton HIV Initiative carries out direct international procurement of second-line paediatric formulations which are then distributed by KEMSA and MEDS. Purchases from Global Fund are undertaken by the Procurement and Supply Chain

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<sup>69</sup> UNIDO (2010), *Pharmaceutical Sector Profile: Kenya*, available at [http://www.unido.org/fileadmin/user\\_media/Services/PSD/BEP/Kenya\\_Pharma%20Sector%20profile\\_TEGLO05015\\_Ebook.pdf](http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Kenya_Pharma%20Sector%20profile_TEGLO05015_Ebook.pdf) (last visited 18 June 2014).

<sup>70</sup> Republic of Kenya, *Public Expenditure Review 2007*, p. 22.

<sup>71</sup> Website of KEMSA, available at [http://www.kemsa.co.ke/index.php?option=com\\_content&view=article&id=19&Itemid=20](http://www.kemsa.co.ke/index.php?option=com_content&view=article&id=19&Itemid=20) (last visited 18 June 2014).

Management Consortium comprising KEMSA, Crown Agents, GTZ and John Snow Inc. However, KEMSA has contended that the Consortium acts as a parallel procurement system without any interaction with KEMSA.

Medicines for the public sector in Kenya are required to be purchased according to Good Pharmaceutical Procurement Practices which includes the following key elements – 1) drugs will be procured according to generic name and the product must be registered in Kenya, 2) procurement priority will be given to drugs on the Kenya Essential Drugs List (KEDL). Drugs that are not in the KEDL will be procured only if the drugs are for diseases not covered by the KEDL, or the drugs are for use in institutions with specialized medical personnel. Pharmaceutical requirements are to be calculated annually and periodically updated, and an annual procurement plan has to be developed. Procurement is to be done through competitive bidding. Quality of procured products is to be tested by the National Drug Quality Control Laboratory.<sup>72</sup> The National Drug Policy of 1994 has been replaced by a new National Pharmaceutical Policy in 2008 which seeks to improve the procurement of essential medicines by establishing KEMSA as the primary public medicines procurement agency.<sup>73</sup>

Public procurement in Kenya is regulated by the Kenya Public Procurement and Disposal Act, 2005. The Act established a regulatory agency for exercising oversight over public procurement known as the Public Procurement Oversight Authority (PPOA). The PPOA also clearly establishes the procurement methods to be applied, advertising rule and time limits, the content of tender documents and technical specifications, tender evaluation and award criteria, procedures for submission, receipt and opening of tender, and the complaints system structure and sequence.<sup>74</sup>

According to the Public Procurement and Disposal Regulation under this Act, the procuring entity may grant a margin of preference of up to 15 per cent in the evaluation of bids to candidates offering goods manufactured, mined, grown and extracted in Kenya. However, local pharmaceutical manufacturers have complained of a lack of implementation of preferential treatment with regard to local pharmaceutical manufacturers.<sup>75</sup> According to KEMSA, this is due to the lack of guidelines for implementation of the local preference scheme from the finance ministry.<sup>76</sup> Local pharmaceutical manufacturers are locked out of most donor funded procurement schemes of KEMSA and there is no incentive from KEMSA to procure pandemic drugs from local manufacturers to ensure sustainable sources of supply.<sup>77</sup>

The Pharmacy and Poisons Board (PPB) is the medicines regulatory authority of Kenya established under the Pharmacy and Poisons Act. It is responsible for ensuring that medicines and health products comply with standards of quality, safety and efficacy of medicines and medical products. The PPB is empowered to issue licenses for parallel importation of medicines that are patented, or registered in Kenya. The National Quality

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<sup>72</sup> Republic of Kenya, Ministry of Health, The Kenya National Drug Policy, 1994, p. 4, available at <http://apps.who.int/medicinedocs/documents/s16443e/s16443e.pdf> (last visited 18 June 2014).

<sup>73</sup> Republic of Kenya, Ministry of Medical Services, Kenya National Pharmaceutical Policy, 2008, p. 15, available at <http://apps.who.int/medicinedocs/documents/s18078en/s18078en.pdf> (last visited 18 June 2014).

<sup>74</sup> Public Procurement Oversight Authority of Kenya (2007), *Assessment of the Procurement System in Kenya*, available at <http://www.oecd.org/development/effectiveness/41583965.pdf> (last visited 18 June 2014).

<sup>75</sup> UNIDO (2010), *supra* note 69, p. 7.

<sup>76</sup> *Ibid.*, p. 9

<sup>77</sup> *Ibid.*

Control Laboratory (NQCL) is a WHO pre-qualified quality control laboratory (the first such laboratory in East Africa) and is mandated to undertake quality testing of medicines in circulation in Kenya. The results of quality testing by NQCL is transmitted to the government through the PPB. The PPB and KEMSA coordinate with NQCL to ensure procurement of quality assured and registered medicines.<sup>78</sup>

A 2008 assessment report of KEMSA by USAID states that the biggest challenge before KEMSA's operational success is inadequate funding and lack of timely allocation of approved procurement and operational budget. KEMSA relies heavily on procurement of medicines by the Ministry of Health, which often withholds a major portion of the procurement of medical supplies from KEMSA. Though there have been agreements to transfer all medical commodities procurement activities and funding to KEMSA, the Ministry of Health continues to control a large portion of the annual medical supplies procurement contracts.<sup>79</sup> The USAID review found that KEMSA does not have an internal strategic policy for its procurement department to facilitate internal procurement planning and processes. Although the procurement unit operates under the PPDA, it lacks access to reliable and accurate management information to ensure transparency in the procurement process or procurement planning. Therefore, it was recommended that KEMSA should formulate an internal policy framework for procurement, conduct forecasting and quantification in collaboration with the Ministry of Health, develop an integrated automated procurement module for reporting, monitoring and evaluation of vendor proposals, and undertake training in e-procurement methods and modules.<sup>80</sup>

Kenya has been following a national medicines policy known as the Kenya National Drug Policy since 1994. The policy was reviewed and replaced by a new Kenya National Pharmaceutical Policy in 2010 to pursue the overall objective of ensuring equitable access to essential medicines through the public, faith based, NGO and private providers.<sup>81</sup> The KNPP points to the following key challenges with regard to procurement of medicines – inadequate financial allocation for procurement and supply of essential medicines, bureaucratic delays in disbursement of public funds for pharmaceuticals, parallel procurement by numerous health sector players, lack of adherence to best practices such as Good Pharmaceutical Procurement (GPP) and Good Distribution Practices (GDP), lack of policy guidelines and control mechanisms on the prioritization and utilization of public medicines budget in line with public health priorities, inadequate mechanisms for ensuring access to essential medicines through non-public providers including alternative sourcing by facilities in the event of stock-outs in KEMSA, inadequate human resources capacity for procurement, inadequate mechanisms for procurement in case of emergencies, inadequate distribution of pharmaceutical outlets, price manipulation due to lack of segregation between wholesale and retail outlets, proliferation of unlicensed outlets for medicines, lack of a clear legal framework

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<sup>78</sup> H.K. Chepkwony (2009), "Quality Control of Medicines and Organization of Market Surveillance in Kenya", presentation by the Director of the National Quality Control Laboratory of Kenya at the Interregional Seminar for Quality Control Laboratories involved in WHO Prequalification Programme and /or participating in respective sampling and testing projects, Nairobi, Kenya, 23-25 September 2009, available at [http://apps.who.int/prequal/trainingresources/pq\\_pres/Workshop\\_KenyaSeptember2009/Day3/3-5a\\_Market\\_Surveillance.ppt](http://apps.who.int/prequal/trainingresources/pq_pres/Workshop_KenyaSeptember2009/Day3/3-5a_Market_Surveillance.ppt) (last visited 18 June 2013).

<sup>79</sup> Michael G. Johnson *et al.* (2008), *Assessment of Kenya Medical Supplies Agency (KEMSA)*, p. 7, available at [http://pdf.usaid.gov/pdf\\_docs/Pnadm474.pdf](http://pdf.usaid.gov/pdf_docs/Pnadm474.pdf) (last visited 18 June 2014).

<sup>80</sup> *Ibid.*, pp. 23-24.

<sup>81</sup> Republic of Kenya, Ministry of Medical Services & Ministry of Public Health and Sanitation (2010), *Sessional Paper on National Pharmaceutical Policy*, available at <http://apps.who.int/medicinedocs/documents/s18697en/s18697en.pdf> (last visited 18 June 2014).



for KEMSA, and lack of coordination between various procuring entities.<sup>82</sup> In this context, the policy seeks to centralize core functions relating to procurement of medicines such as supplier selection and monitoring, pricing and quality assurance in the KEMSA as the primary public procurement agency. It also seeks to promote adherence to the GPP and the PPDA, as well as adherence to the KEML. Further, the policy seeks to prioritize budgetary allocations for pharmaceuticals in accordance with public health priorities, develop mechanisms of alternative sourcing of medicines to be procured, delineate pharmaceutical wholesale from retail prices, and establish and enforce zoning regulations for private sector providers.<sup>83</sup>

Significantly, under the Constitution of Kenya, health is a concurrent function where the national government's role is limited to developing health policy, and the county governments (provinces) are responsible for managing health services, particularly county health facilities and pharmacies. Therefore, administrative and operational functions such as procurement and delivery of medicines which is conducted by KEMSA would squarely fall within the ambit of county governments.<sup>84</sup>

In this context, the government of Kenya has sought to introduce devolution of health services to the counties and has introduced a draft Health Bill. The draft Health Bill states that the national government will be responsible for enacting regulations on the procurement of medicines, and that the KEMSA will be the primary agency for undertaking procurement of medicines. The draft Bill also states that KEMSA may be the first call for procurement at the county level, but counties shall have the right to procure medicines from other sources if KEMSA is unable to supply them in good time or at competitive prices. National referral hospitals too shall have the right to purchase medicines from other accredited sources.<sup>85</sup> Therefore, not only can counties ignore KEMSA if they have a better alternative, national referral hospitals are given the right to completely ignore KEMSA even from consideration.

The devolution of health services to the counties has enabled counties to procure medicines from independent firms in the search for cheaper medicines. According to media reports, there is a perception among some counties that the prices charged by KEMSA are high and more than 10 counties are reported to have placed medicines procurement orders with MEDS – a regional faith based organization. There is a concern that devolution of medicines procurement to the counties who may not have strict procurement and monitoring mechanisms could lead to massive inflows of medicines of compromised quality. In this context, the House departmental committee on health of the Kenyan parliament has recommended the establishment of a task force to coordinate and supervise the reversal of all devolved health services. According to Rachel Nyamai, the committee would like the ministry of health to develop a policy to guide the procurement and supply of medicines through the state agency (KEMSA).<sup>86</sup>

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<sup>82</sup> Ibid., pp. 28-29.

<sup>83</sup> Ibid., p. 30.

<sup>84</sup> Obuya Bagaka (2014), "Align KEMSA's role in procuring medical supplies to the objectives of devolution", *Daily Nation*, 28 April 2014, available at <http://mobile.nation.co.ke/blogs/-/1949942/2296420/-/format/xhtml/-/5bims5/-/index.html> (last visited 18 June 2014).

<sup>85</sup> Onesimus Kipchumba Murkomen (2012), *Devolution and the Health System in Kenya*, presentation given at the Devolution and Health Consultative Meeting, Health Policy Project, USAID, 24 October 2012, available at [http://www.healthpolicyproject.com/ns/docs/Kenya\\_Kipchumba\\_Presentation.pdf](http://www.healthpolicyproject.com/ns/docs/Kenya_Kipchumba_Presentation.pdf) (last visited 18 June 2014).

<sup>86</sup> Angela Oketch (2014), "Why devolved health care is a bitter pill to swallow for some counties", 10 April 2014, available at <http://mobile.nation.co.ke/lifestyle/bitter-pill-to-swallow/-/1950774/2274290/-/format/xhtml/-/2i48pd/-/index.html> (last visited 18 June 2014).

### VI.3 Rwanda

Rwanda has been a member of the EAC since 2007. Rwanda has a high burden of communicable diseases, with the most common communicable diseases being HIV/AIDS, acute respiratory infections, diarrhoeal diseases and TB. Rwanda is experiencing a generalized AIDS epidemic and malaria is the primary cause of morbidity and mortality.<sup>87</sup> In this context, the government has committed to strive to achieve universal access to healthcare. Therefore, improving the availability of quality drugs, particularly essential drugs, is a major objective of Rwanda's health sector policy. Currently there is no company that manufactures pharmaceutical drugs locally on a big scale. A public sector company called LABOPHAR manufactures in a small scale some non-sterile drugs such as tablets, capsules, syrups, ointments, suppositories and infusions.<sup>88</sup> This means that Rwanda relies almost completely upon imported medicines to meet its healthcare needs. In this context, the Ministry of Health has adopted the Third Health Sector Strategic Plan (HSSP III) 2012-18 which seeks to increase local production of medicines and enhance good manufacturing practices. A National Pharmaceutical Policy has been developed by the Ministry of Health and is awaiting final approval. This is a key policy document that is integral to HSSP III. The Industrial Property Act of Rwanda excludes pharmaceutical products from patentability.

Rwanda has a very fledgling procurement and quality assurance system for essential medicines. Till 2011 the Central Medicines Store (CAMERWA) had been the procurement arm of the Ministry of Health. CAMERWA procured about 60 per cent of the public health facility medicines in Rwanda and it was the only supplier in Rwanda that was authorized to import ARV drugs. Though the CAMERWA was expected to provide pharmaceutical products to public and private referral hospitals, in reality referral hospitals relied heavily on private suppliers to procure medicines.<sup>89</sup>

In 2011, the Rwanda Biomedical Centre (RBC) was established as a statutory organization merging fourteen Rwandan health agencies including the CAMERWA, the National Medical Referral Laboratory (NMRL), and the Pharmaceutical Laboratory of Rwanda (LABOPHAR). Thus, procurement, quality testing and local production of medicines were brought under a single entity. In this framework, the Medical Procurement and Production Division of RBC (of which CAMERWA is a part) seeks to ensure access to quality, cost effective drugs for the people of Rwanda.<sup>90</sup>

Rwanda also did not have a national regulatory authority for quality control of medicines. Quality control of procured medicines was also done by CAMERWA based on documentary submissions rather than actual laboratory testing. In addition to document review, CAMERWA used to send limited samples to laboratories in Europe and South Africa for testing, but the process proved expensive and led to delays.

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<sup>87</sup> WHO Regional Office for Africa (2009), *WHO Country Cooperation Strategy 2009-2013: Rwanda*, available at [http://www.who.int/countryfocus/cooperation\\_strategy/ccs\\_rwa\\_en.pdf?ua=1](http://www.who.int/countryfocus/cooperation_strategy/ccs_rwa_en.pdf?ua=1) (last visited 18 June 2014).

<sup>88</sup> Rwanda Development Board, *Pharmaceutical Drugs Sector in Rwanda*, available at [http://www.rdb.rw/fileadmin/user\\_upload/Documents/Manufacturing/Pharmaceuticals\\_Profile.pdf](http://www.rdb.rw/fileadmin/user_upload/Documents/Manufacturing/Pharmaceuticals_Profile.pdf) (last visited 21 April 2014).

<sup>89</sup> USAID (2010), *Rwanda Health Governance Assessment*, p. 33, available at <http://apps.who.int/medicinedocs/documents/s18413en/s18413en.pdf> (last visited 18 June 2014).

<sup>90</sup> Rwanda Biomedical Center (2013), *Rwanda Biomedical Center Annual Report: July 2011 – June 2012*, p. 1, available at [http://www.rbc.gov.rw/IMG/pdf/rbc\\_annual\\_report\\_final\\_march2013.pdf](http://www.rbc.gov.rw/IMG/pdf/rbc_annual_report_final_march2013.pdf) (last visited 18 June 2014).

A Pharmacy Task Force (PTF) under the ministry of health performed the functions of registration of drugs, licensing of providers and quality inspection. It also monitored the import of medicines by CAMERWA. In 2013 Rwanda adopted a law to establish the Rwanda Food and Medicines Authority (RFMA). The RFMA is responsible for regulating importing, manufacturing, labelling and marking of medicines and also for regulating clinical trials on medicines. CAMERWA and other procurement agencies will also be regulated by RFPMA to ensure that they import only registered and quality drugs.<sup>91</sup>

Selection of medicines for procurement are required to be guided by the essential medicines list which was last revised in 2010, taking into account the Standard Treatment Guidelines of 2007.<sup>92</sup>

The legal framework for public procurement in Rwanda is under Law No. 12/2007 on public procurement. The Rwanda Public Procurement Authority (RPPA) was established by this law to exercise regulatory oversight on procurement activities. Before the establishment of the RPPA, all procurement operations and policy making and oversight functions were centralized in the National Tender Board (NTB). With the establishment of the RPPA the government sought to decentralize the operational activities relating to procurement.<sup>93</sup> The Procurement Act regards all government agencies including public institutions are considered as procurement entities. Under Article 23 of the Act, open bidding is to be the preferred method of procurement. Significantly, the law also makes provision for local preference to companies registered in Rwanda or to nationals and bidders in regional integration bodies of which Rwanda is a party in the tendering process, and such entities or persons are given a margin of 10 per cent in bid prices by other competitors. The Rwandan law is unique in the sense that it contains a specific provision which can accommodate the future establishment of a regional pooled procurement mechanism for medicines in the EAC.

#### VI.4 Uganda

Uganda is a founder member of the EAC. Similar to other countries in the EAC, Uganda also has a very high burden of communicable diseases and rising burden of non-communicable diseases. Malaria and HIV/AIDS are the leading causes of mortality and morbidity.<sup>94</sup> Uganda also has a very high incidence of TB. In this context, ensuring the consistent availability, accessibility and affordability of essential medicines of appropriate quality, safety and efficacy became the central aim of the National Drug Policy (2001) of Uganda. Ensuring access to essential medicines is also critical for the delivery of the Uganda National Minimum

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<sup>91</sup> Maria Kaitesi (2013), "Pharmacists back proposal for drugs regulatory body", *The New Times*, 9 May 2013, available at <http://www.newtimes.co.rw/news/index.php?i=15352&a=66735> (last visited 18 June 2014).

<sup>92</sup> Republic of Rwanda, Ministry of Health (2010), *The National Essential Medicines List* (5th edn.), available from <http://www.moh.gov.rw/fileadmin/templates/Clinical/MEDICAMENTS-ESSENTIELS.pdf> (last visited 18 June 2014).

<sup>93</sup> Ivan Rugema (2013), "The Regulatory Framework for Public Procurement in Rwanda", in Geo Quinot and Sue Arrowsmith (eds.), *PUBLIC PROCUREMENT AND REGULATION IN AFRICA* (Cambridge University Press), p. 165, available at <http://books.google.ch/books?id=gNCBwIAHjDkC&pg=PA164&lpq=PA164&dq=rwanda+public+procurement+local+preference&source=bl&ots=OZFdS60ulK&sig=tOs1iOmEeDzk1UXDdWZaJ3H-gRE&hl=en&sa=X&ei=t32XU7rdDoOM7Abj0IGADQ&ved=0CBwQ6AEwAA#v=onepage&q=rwanda%20public%20procurement%20local%20preference&f=false> (last visited 18 June 2013).

<sup>94</sup> USAID (2011), *Uganda Health Systems Assessment 2011*, p. 3, available at <http://health.go.ug/docs/hsa.pdf> (last visited 18 June 2014).

Healthcare Package (UNMHCP).<sup>95</sup> Strategies to implement the UNMHCP were laid out in the Health Sector Strategic Plan (HSSP). However, the effectiveness of the UNMHCP has been undermined due to funding constraints in the health sector.<sup>96</sup>

The National Medical Stores (NMS) is the government agency charged with procuring, storing and distributing medicines to the public health sector facilities. Faith based health service providers procure their medicines through the Joint Medical Stores (JMS). The public sector health facilities can procure medicines from elsewhere only if the medicines are out of stock in the NMS. More than 90 per cent of the medicines in Uganda are imported and less than 10 per cent of the medicines are produced locally.<sup>97</sup> The government is very keen to promote the local production of medicines to reduce the overwhelming reliance on imports, and in this context the industrial property law has also been amended to exclude pharmaceutical products from patentability in accordance with the transition period available under the TRIPS Agreement.

Procurement of medicines is guided by a national Essential Medicines List (EML).<sup>98</sup> In 2012, the government adopted the revised Essential Medicines and Health Supplies List (EMHL) which were harmonized with the Uganda Clinical Guidelines (UCG) to ensure that all essential medicines needed to treat medical conditions according to the UCG are included in the EMHL.<sup>99</sup> The National Drug Authority (NDA) is responsible for regulating the pharmaceutical market, including quality assurance, drug information, import permissions and disposal of expired medicines. However, the NDA has limited capacity with insufficient outreach.<sup>100</sup>

Nevertheless, only 30 per cent of the essential medicines required for the UNMHCP are supported by the national budget. For diseases like malaria, HIV/AIDS and TB, the bulk of the procurement is supported by international donor funded programmes. Thus, the procurement of these medicines is done by the Ministry of Health using the third party procurement process.

The public procurement of medicines by the NMS is regulated under the Public Procurement and Disposal of Assets Act of 2003. Under this Act, the public sector health facilities that procure medicines from the NMS operate as user departments which are responsible for initiating procurement and disposal requirements and forwarding them to the procurement and disposal unit of the NMS. In this context, user departments are required to prepare a procurement plan based on their approved budget and submit it for implementation to the procurement and disposal unit of the NMS. The Act has also established a regulatory authority for public procurement – the Public Procurement and Disposal of Assets Authority (PPDA).

<sup>95</sup> UN Millennium Project, *supra* note 3, p. 129.

<sup>96</sup> Uganda Health Equity Network (2010), *Right to Health: A Civil Society perspective on the 12th Annual Report of the Uganda Human Rights Commission*, p.v, available from [http://www.heps.or.ug/index.php/publications/doc\\_download/21-civil-society-perspective-on-the-12th-annual-report-of-the-uganda-human-rights-commission](http://www.heps.or.ug/index.php/publications/doc_download/21-civil-society-perspective-on-the-12th-annual-report-of-the-uganda-human-rights-commission) (last visited 18 June 2014).

<sup>97</sup> UN Millennium Project, *supra* note 3.

<sup>98</sup> Uganda Health Equity Network (2010), *supra* note 96, p. 1.

<sup>99</sup> Republic of Uganda, Ministry of Health (2012), *Essential Medicines and Health Supplies List for Uganda (EMHSLU)*, available at [http://childmed.ku.dk/uploads/media/Ministry\\_of\\_Health\\_-\\_Essential\\_Medicines\\_and\\_Health\\_Supplies\\_List\\_for\\_Uganda\\_2012\\_01.pdf](http://childmed.ku.dk/uploads/media/Ministry_of_Health_-_Essential_Medicines_and_Health_Supplies_List_for_Uganda_2012_01.pdf) (last visited 18 June 2014).

<sup>100</sup> Government of Uganda, Ministry of Health, *Health Sector Strategic Plan III 2010-11 – 2014-15*, p. 22, available at [http://www.health.go.ug/docs/HSSP\\_III\\_2010.pdf](http://www.health.go.ug/docs/HSSP_III_2010.pdf) (last visited 18 June 2014).

One of the most critical challenges confronting access to medicines in Uganda are stock outs of essential medicines. Volumes of essential medicines have been reported to have expired in the NMS as well as district and hospital stores. Neglect of stock monitoring and inefficient procurement planning are among the contributing factors to the problem of stock outs.<sup>101</sup> Therefore, an efficient procurement mechanism would be critical to address this problem.

In this context, the Public Procurement and Disposal of Public Assets Act was amended this year to introduce, among other things, efficiency in the process of public procurement of essential medicines and also introduce preference and reservation schemes to support procurement from local manufacturers. The Act allows a procurement and disposal entity to choose any of the following methods of procurement – open domestic bidding, open international bidding, restricted domestic bidding, restricted international bidding, quotation method, direct procurement or micro procurement. Unless specifically provided for in the Act or Regulations, the procurement and disposal entity is required to use the open domestic bidding method. It should be noted that foreign providers can also participate in the open domestic bidding process.

Section 40A of the Act states that if a procuring and disposing entity is unable to comply with a particular method of procurement required under the Act, it may apply to the PPDA for accreditation of an alternative system of procurement. Pursuant to this, the Public Procurement and Disposal of Public Assets (Procurement of Medicines and Medical Supplies) Regulations were made in 2014. The Regulations states that open domestic bidding shall be the preferred method of procuring medicines. However, if competition cannot be effected without foreign bidders or if foreign bidder increases the value for money, open international bidding may be used. If the number of providers is limited, the NMS can use the restrictive bidding method if the value of the procurement is less than 2 billion shillings. Other procuring and disposing entities can adopt restrictive bidding if the value of the procurement is 500 million shillings. The short list of bidders must have at least five providers unless the required medicine is available from less than five providers. A justification has to be provided if the short list has less than five providers.

If the value of the procurement is less than 1 billion shillings, the NMS may procure medicines using the request for quotations method. Other procuring and disposing entities can use this method if the value of the procurement is less than 100 million shillings. However, the request for quotations method can be used only if the time is not sufficient for restricted bidding or the restricted bidding does not receive responsive bids. The NMS may also use the micro procurement approach if the value of the procurement is less than 100 million shillings. Other procuring and disposing entities may do so if the value of the procurement is less than 5 million shillings. The short list for both the quotations method as well as the micro procurement method must have at least three providers except where the medicines are only available from less than three providers.

Where only a single provider or a sole source provider is available, the procuring and disposing entity shall adopt the direct procurement method. A single provider shall be used where a limited number of providers are able to supply the medicine, such as in an emergency

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<sup>101</sup> Josephine Katabaazi Nakyanzi *et al.* (2010), “Expiry of medicines in supply outlets in Uganda”, *Bulletin of the World Health Organization*, vol. 88, pp. 154-158, available at <http://www.who.int/bulletin/volumes/88/2/08-057471/en/> (last visited 18 June 2014).

situation. A sole source provider shall be used if only one provider is able to supply the medicines, or where there is need for continuity in the delivery of medicines.

The demand for health supplies and medicines in Uganda has been increasing steadily over the last two decades.<sup>102</sup> A study by UNCTAD points out that though the pharmaceutical sector in Uganda is small and nascent, it has been working towards expanding its local production capacity in recent years. The national drug policy of Uganda seeks to maximize procurement of locally produced essential medicines, encourages local pharmaceutical manufacturers to produce essential drugs at competitive prices and also encourages procurement agencies to source available essential drugs locally to support the local industry. The local firms in Uganda are only producing formulations rather than manufacturing APIs, which are predominantly imported for producing formulations.<sup>103</sup>

The increasing burden of HIV/AIDS and the inability of the government to meet the local demand for drugs have been the principal motivations behind the government's efforts to promote local production of medicines. Out of the 11 local pharmaceutical companies only 2 companies (Kampala Pharmaceutical Industries and Quality Chemicals Industries Ltd.) currently produce antimalarial formulations and only 1 company (Quality Chemicals Industries Ltd.) produces ARVs.

The primary constraint for local manufacturers is the difficulty in marketing their products in the face of stiff price competition from imported generic medicines. 90 per cent of medicines in Uganda's pharmaceutical market are imported, predominantly from India and increasingly from China. Price is the determining factor in the generic market of Uganda where the local industry faces overwhelming competition from generic manufacturers from India and China who can reduce their export prices and still receive good margins. This has encouraged the registration of low cost generic products at the expense of advancing pharmaceutical manufacturing in Uganda. As the government is the biggest buyer of medicines, the low price of imported generics leaves out local companies in government tenders. The Uganda Pharmaceutical Manufacturer's Association (UPMA) has been advocating for price differential between international bidders and the local industry.

Section 50 of the Act states that preference shall be given to domestically manufactured goods by giving them a competitive advantage over foreign goods when bidding for public procurement contracts, subject to economic and social policies and international obligations of the government. The law also allows the introduction of reservation schemes for specific public procurement contracts to promote particular sectors within specified geographical areas.

Section 59A of the amended Public Procurement and Disposal of Public Assets Act provides for the application of preference schemes in the procurement process. Accordingly, in respect of goods, preference schemes can be applied where open domestic or open international bidding methods are used, by adding a 15 per cent margin of preference to the

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<sup>102</sup> UNIDO (2007), *Pharmaceutical Sector Profile: Uganda*, United Nations Industrial Development Organization, Vienna, 2010, p. 7, available at [https://www.unido.org/fileadmin/user\\_media/Services/PSD/BEP/Uganda%20Pharma%20Sector%20Profile\\_TE\\_GLO05015\\_Ebook\\_.pdf](https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Uganda%20Pharma%20Sector%20Profile_TE_GLO05015_Ebook_.pdf) (last visited 21 April 2014).

<sup>103</sup> UNCTAD (2011), *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies by the UNCTAD Secretariat*, United Nations, New York and Geneva, 2011, p. 267, available at [http://unctad.org/en/PublicationsLibrary/diaepcb2011d7\\_en.pdf](http://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf) (last visited 21 April 2014).

bid that is not eligible for the preference. The margin of preference shall be based only on the evaluated price of the bid which does not qualify for the preference or the evaluated bid price of the foreign proposal. For domestically manufactured products, the preference shall be based on the percentage of labour, raw materials and components of the goods that originate in Uganda. Such domestically manufactured goods would be eligible for the preference scheme if the labour or value addition to the good is more than 30 per cent ex-works of the goods and the production facility is in Uganda.

This is particularly significant in respect of preference schemes for locally manufactured pharmaceutical products. Since most of the local manufacturers of medicines import the active pharmaceutical ingredients (API) which constitute the raw material for the production of formulations, the local cost component upon which the margin of preference would be based will be substantially lower than the actual value of the final product. Moreover, in the context of regional pooled procurement, since the law bases preference schemes on goods that originate in Uganda, goods originating in other East African countries may not be eligible for preference schemes.

Section 59B of the amended Public Procurement and Disposal of Public Assets Act provides for the application of reservation schemes. Thus, the PPDA in consultation with the competent authority and relevant stakeholders can specify the public procurement contracts to be subject to a reservation scheme and specify the particular sectors within a geographical area that can participate in the reservation scheme. The law does not lay down any condition regarding the origin of the product or the manufacturer to be eligible for a reservation scheme. Therefore, the competent authority in consultation with the PPDA may identify local firms in the EAC region as eligible for reservation to promote pharmaceutical manufacturing within the specified regional geographical area.

## VI.5 United Republic of Tanzania and Zanzibar

The United Republic of Tanzania and Zanzibar<sup>104</sup> is also a founding member of the EAC. Tanzania faces high prevalence of HIV/AIDS, TB and malaria in both mainland Tanzania and Zanzibar.

The Third Health Sector Strategic Plan (HSSP III) 2009-2015 of mainland Tanzania being currently implemented emphasizes the medical supply chain and drug access as critical health system components in need of strengthening in order to respond to key national health challenges. In this context, the Ministry of Health and Social Welfare of mainland Tanzania has committed to making available constant and adequate pharmaceuticals supplies of good quality for public health facilities and accredited private facilities.<sup>105</sup> However, mainland Tanzania still imports almost 80 per cent of its medicines requirement.

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<sup>104</sup> The United Republic of Tanzania is composed of mainland Tanzania and the semi-autonomous island of Zanzibar.

<sup>105</sup> James White *et. al.* (2013), PRIVATE HEALTH SECTOR ASSESSMENT IN TANZANIA (The World Bank, Washington, D.C.), p. 107, available at [http://books.google.ch/books?id=1eNVAQAAQBAJ&pg=PA118&lpg=PA118&dq=high+import+of+medicines+in+tanzania&source=bl&ots=9jv-vqdhCH&sig=cBTisZ9EOZpKVp3uvBRD\\_clw0bE&hl=en&sa=X&ei=UxybU\\_6kHMPY7Ab28oG4BQ&ved=0CFQQ6AEwBg#v=onepage&q=high%20import%20of%20medicines%20in%20tanzania&f=false](http://books.google.ch/books?id=1eNVAQAAQBAJ&pg=PA118&lpg=PA118&dq=high+import+of+medicines+in+tanzania&source=bl&ots=9jv-vqdhCH&sig=cBTisZ9EOZpKVp3uvBRD_clw0bE&hl=en&sa=X&ei=UxybU_6kHMPY7Ab28oG4BQ&ved=0CFQQ6AEwBg#v=onepage&q=high%20import%20of%20medicines%20in%20tanzania&f=false) (last visited 18 June 2014).

The patent law of mainland Tanzania does not utilize the transition period granted to LDCs under TRIPS and does not exclude pharmaceutical products from patentability, though the patent law of Zanzibar excludes pharmaceutical products from the scope of patent protection until 2016. The pharmaceutical sector comprises eight manufacturing industries, all of which import APIs mostly from India and China, and produce formulations.<sup>106</sup> The reliance on imports of APIs is a significant factor for local formulations producers because the time lag between purchasing APIs and starting production (about 6 months) adds to the working capital costs of the pharmaceutical manufacturer.<sup>107</sup> Most of the local pharmaceutical production is concentrated on less sophisticated medicines such as simple antibiotics, cough and cold preparations, etc. and generally local firms do not have the capacity to produce sophisticated pharmaceutical products.

In this context, access to medicines in Tanzania is affected by insufficient availability of medicines, particularly in the public sector. Deficiencies in procurement, forecasting, financing as well as quality assurance are contributing factors to this situation. Some recent reviews of the pharmaceutical sector in Uganda have identified inadequate access to medicines, particularly stock outs of medicines in public health facilities as the main problem in Tanzania. However, sustainability of procurement operations is dependent on contributions from development partners.<sup>108</sup>

There are two primary channels of supply of medicines in mainland Tanzania – public procurement by the Medical Stores Department (MSD) and procurement of medicines by vertical programmes for specific diseases such as HIV/AIDS, TB and malaria, which are supported by external donors. However, there is need for better coordination and information sharing between MSD, the ministry of health, donors, third party providers in vertical procurement programmes to avoid duplication by including the same medicines in both procurement programmes.

Mainland Tanzania's National Medicines Policy was adopted in 1991 and is currently undergoing revision. The Pharmaceutical Services Section (PSS II) under the Division of Health Quality Assurance in the ministry of health is mandated to oversee the implementation of the National Medicines Policy. Zanzibar follows the Zanzibar National Medicines Policy adopted in 2008.

The MSD is the leading agency for procuring medicines for mainland Tanzania's public health facilities.<sup>109</sup> The MSD operates as an autonomous department under the Ministry of Health and Social Welfare. The MSD Tender Board acts as the legal entity responsible for conducting the procurement process under the Tanzania Public Procurement Act. The MSD is comprised of the Central Medical Store (CMS) and nine Zonal Medical

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<sup>106</sup> Robert M. Mhamba and Shukrani Mbirigenda (2010), *The Pharmaceutical Industry and Access to Essential Medicines in Tanzania*, EQUINET Discussion Paper 83, p. 9, available at <http://equinet africa.org/bibl/docs/DIS83TZN%20medicines%20mhamba.pdf> (last visited 21 April 2014).

<sup>107</sup> African Union (2012), *Pharmaceutical Manufacturing Plan for Africa: Business Plan*, AU Secretariat, Addis Ababa, p. 31, available at <http://apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf> (last visited 21 April 2014).

<sup>108</sup> United Republic of Tanzania, Ministry of Health and Social Welfare (2014), *Draft Pharmaceutical Sector Action Plan 2020: 2014-2020*, p. 3, available at [file:///Users/nirmalyasyam/Downloads/PSAP%20draft%20v12%20-%202031%20Apr%2014%20\(1\).pdf](file:///Users/nirmalyasyam/Downloads/PSAP%20draft%20v12%20-%202031%20Apr%2014%20(1).pdf) (last visited 18 June 2014).

<sup>109</sup> Yale Global Health Leadership Institute, *An Innovative Public-Private Partnership: Medical Supply Solutions in Tanzania*, available at <http://nexus.som.yale.edu/ph-tanzania/?q=node/111> (last visited 18 June 2014).



Stores, which supply medicines to the regional and district hospitals, health centres and dispensaries. The MSD also provides supplies to private facilities and large international donor programmes. In Zanzibar, the ministry of health of Zanzibar has the legal mandate of procuring all medicines through its procurement unit and the medicines are distributed by the Central Medical Store (CMS).

The Tanzania Food and Drugs Authority was established in 2003 to ensure quality, safety and efficacy of distributed drugs in mainland Tanzania. The pharmaceutical supplies unit at the Ministry of Health and Social Welfare of mainland Tanzania has published and updated the National Essential Medicines List and the Standard Treatment Guidelines since 1991. The latest revision of the essential medicines list and the standard treatment guidelines was done in 2007.<sup>110</sup> However, the essential medicines list is not available with many public health facilities. Moreover, it is reported that some of the medicines on the essential medicines list are not routinely kept in stock in the MSD, and this leads to special procurements and delays in availability. Consequently, there is lack of adequate adherence to the essential medicines list and the standard treatment guidelines.<sup>111</sup>

The greatest percentage of expenditure for procurement by the CMS is for products purchased from international suppliers. However, the procurement by MSD is impacted by funding constraints. There is an unsustainable level of debt owed to the MSD on account of procurement by MSD for health facilities in the past years which is estimated at 76.5 billion Tanzanian shillings. This significantly impacts capital and operational expenditures of the MSD.<sup>112</sup> For example, replenishment orders cannot be placed unless funds are at hand. Hence, there is a need to recapitalize MSD.

The framework for public procurement in Tanzania that also applies to procurement of medicines is provided under the Public Procurement Act of 2011 and regulations under that law. The Act established a Public Procurement Regulatory Authority to set standards for public procurement in Tanzania, monitor compliance with such standards on the part of procuring agencies and also build procurement capacity. The Act requires each public body to establish a tender board like the MSD Tender Board for procurement of goods to approve procurement tender proposals and procurement contracts. Each public body is also required to develop a procurement management unit for the management of procurement operations. Every procuring entity is required to establish an annual procurement plan and the budget for the same has to be approved by the appropriate budget approving authority.

Under Section 54 (1) of the Act, a procuring entity may limit participation in procurement proceedings on the basis of nationality. This provision is distinct from local preference provisions in the procurement laws of other countries in the EAC region in the sense that it is broader in scope than a preference scheme that is restricted only to local or domestic providers. Thus, it may be possible, subject to the regulations under the Act, to limit participation in medicines procurement proceedings to providers that are nationals of EAC Partner States as Section 54 refers to restrictions based on nationality only.

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<sup>110</sup> United Republic of Tanzania, Ministry of Health and Social Welfare (2007), *Standard Treatment Guidelines (STG) and the National Essential Medicines List (NEMLIT) for Mainland Tanzania*, available at <http://apps.who.int/medicinedocs/documents/s16199e/s16199e.pdf> (last visited 18 June 2014).

<sup>111</sup> United Republic of Tanzania, Ministry of Health and Social Welfare (2014), *supra* note 108, p. 8.

<sup>112</sup> *Ibid.*, p. 11.

While Section 54 (1) states that a procuring entity “may” limit participation in procurement proceedings based on nationality, Section 54 (2) of the Act states that a procuring entity “shall” grant a margin of preference for goods manufactured in Tanzania. Thus, it would seem that while Section 54 (1) allows participation on procurement bids to be restricted based on nationality, Section 54 (2) makes it mandatory to provide a margin of preference to local manufacturers. This would mean that even if participation in the tendering process is restricted to nationals of EAC Partner States, the margin of preference for Tanzanian manufacturers will have to be provided. However, if an EAC wide law is adopted to the contrary, then the obligation to provide a margin of preference to local manufacturers would defer to the international obligation as specified in Section 4 of the Act. This would also apply to Section 55 which requires that where the procurement is funded exclusively by a Tanzanian public body, each procurement below a certain value has to be reserved exclusively for local providers.

Specific rules on procurement of medicines are provided under the Public Procurement Regulations 2013. Under Rule 140 of the Regulations, the MSD has to maintain a catalogue list of medicines stocked by it and has to publish it annually. The procuring entities are required to provide to the MSD by the end of January each year the provisional annual estimates of required catalogue medicines. The MSD is obligated to arrange for the procurement of catalogued medicines that are continuously in demand and are common to more than one procuring entity. If the requested catalogued medicines are not available, the MSD has to notify the same to the procuring entity within one day, and the procuring entity can pursue an alternative procurement method. A similar approach has to be followed for the procurement of non-catalogued medicines.

## **VII. CONCLUSIONS AND RECOMMENDATIONS**

The challenges relating to ensuring access to affordable medicines are similar among all the EAC Partner States. All the countries in the region have a very high burden of communicable diseases, and very high prevalence of HIV/AIDS, TB and malaria. All of the EAC Partner States rely overwhelmingly on imports of essential medicines and have very limited local manufacturing capacity for these medicines. In this context, the establishment of a regional pooled procurement mechanism for essential medicines has to be expedited in order to facilitate the realization of the common objective of ensuring access to affordable and quality essential medicines to all patients in the EAC Partner States. However, there has been very limited progress on the implementation of a regional pooled procurement mechanism since the decision of the EAC Council of Ministers in 2008 to establish a regional pooled procurement mechanism through group contracting.

The EAC Partner States have been invested on considering the establishment of a regional pooled procurement mechanism for medicines in furtherance of the cooperation among EAC Partner States in the health sector under Article 118 of the EAC for nearly a decade. Though the deliberations have led to a decision to establish a regional pooled procurement mechanism based on the Group Contracting Model as recommended in a feasibility study by the WHO, there has been a noticeable lack of momentum on this issue since then over the past few years. The lack of any progress towards implementation of the

regional pooled procurement mechanism despite its approval by the Council of Ministers is puzzling. The delay in implementation of the regional pooled procurement mechanism may be due to a desire by the EAC to first address other issues related to the functioning of a pooled procurement mechanism, such as a harmonized system of medicines registration among the EAC Partner States.

The issue of establishment of a regional pooled procurement mechanism for essential medicines has been largely discussed within the EAC Sectoral Council on Health. In stark contrast to the continued deliberations on this issue in the EAC Sectoral Council on Health and the Council of Ministers for nearly a decade, discussions on a regional pooled procurement mechanism has not featured in the records of the East African Legislative Assembly's (EALA) proceedings or resolutions. The issue of implementation of a regional pooled procurement mechanism must be given prominence in the discussions of EALA as it is necessary to develop an EAC wide legal framework for pooled procurement of medicines in order to effectively implement such a mechanism. Efforts to develop an EAC legal framework for pooled procurement of medicines should be pursued in the EALA. It is important to note that a community law on pooled procurement enacted by EALA would take precedence over national laws of EAC Partner States.

It will be imperative for EAC Partner States to accelerate the process of devising a plan of action for implementing the pooled procurement Group Contracting mechanism in order to address the problem of access to medicines in the EAC Partner States holistically. In terms of Article 8 of the EAC Treaty, Partner States have an obligation to plan and direct their policies and resources for creating conditions favourable for the development and achievement of the objectives of the EAC and implementation of the provisions of the Treaty. Therefore, Partner States should coordinate their policies on pooled procurement of medicines through the institutions of the EAC specifically established to facilitate such cooperation i.e., the establishment of an Expert Working Group (EWG) on EAC regional pooled bulk procurement initiative.

The 2007 situational analysis and feasibility study by the WHO found that procurement legislations and institutional framework in the EAC Partner States are relatively homogenous and provides the basis of establishment of Good Pharmaceutical Procurement practice for the adoption of regional pooled procurement. Indeed, the laws and regulations on public procurement in all the EAC Partner States other than Burundi have been modelled on the UNCITRAL model law on procurement. However, due to the lack of any specific law for regional pooled procurement, diverse interpretations of national and international legal obligations might give rise to potential conflicts.

Though the EAC is yet to discuss a plan of action of implementation of the regional pooled procurement mechanism as approved by the EAC Council of Ministers in 2008, there has been some progress with regard to related issues that can facilitate the pooled procurement mechanism. These are the implementation of the EAC Customs Union and the EAC Common Market Protocol, the adoption of the EAC Regional Manufacturing Plan of Action for pharmaceutical products, the adoption of the EAC regional protocol on public health-related TRIPS flexibilities, and the launch of the EAC Medicines Registration Harmonization (EAC-MRH) project. However, regulatory standards under the EAC-MRH project seems to be influenced by standards and guidelines made by the ICH which can be inappropriate to the local circumstances and cause unnecessary financial burden on the EAC Partner States. Particularly, the ICH standards may create obstacles for generic companies to

get regulatory approvals for putting their products in the market. It will be important to ensure that the regional pooled procurement mechanism requires suppliers to follow quality standards that are appropriate to the circumstances of the region and do not create disguised barriers for local pharmaceutical manufacturers to participate in the bidding process for procurement of medicines under the regional pooled procurement mechanism.

While the EAC has been exploring full utilization of the TRIPS flexibilities for access to medicines, and has developed a Regional Pharmaceutical Manufacturing Plan of Action, the EAC Secretariat is also in the process of developing an anti-counterfeit law that erroneously seeks to use IP enforcement to stop the availability of medicines of compromised quality. However, the anti-counterfeit law could render generic medicines of legitimate quality as counterfeits on the suspicion of IP infringement. This will undermine initiatives being pursued in the EAC to create a facilitative environment for access to medicines, including the implementation of a regional pooled procurement mechanism.

Most of the procurement of medicines for the treatment of HIV/AIDS, TB and malaria are conducted by the ministries of health under vertical procurement programmes supported by external donors such as the Global Fund, PEPFAR, etc. As these donors require products and suppliers to be compliant with WHO prequalification standards and also adhere to ICH influenced regulatory standards or guidelines most of the local pharmaceutical firms from the region are ineligible to bid in these procurement programmes as they do not have WHO prequalification or comply with quality standards recommended by ICH. The existence of parallel systems of procurement through donor funded programmes with different requirements adds to the complexity of the implementation of a regional pooled procurement mechanism. It will be desirable for the regional pooled procurement mechanism to have sole sourcing of procurements through the suppliers selected by the pooled procurement mechanism.<sup>113</sup> It is also necessary to ensure that all procurement under the regional pooled procurement mechanism is conducted under a common set of rules and quality standards that should also apply to donor funded procurement activities.

An overview of medicines procurement systems and legal framework for the same in the EAC Partner States suggests that not only is there a lot of commonality in the legal framework on procurement of medicines, all the EAC Partner States also face similar challenges with regard to procurement of medicines. Some of these challenges are unavailability of essential medicines due to stock outs of medicines, the predominant reliance on procuring medicines from foreign providers, and lack of mutual recognition of medicines registrations.

Significant developments have taken place with regard to procurement in the EAC Partner States since the WHO study of 2007. All EAC Partner States have adopted laws and regulations that provide the framework for public procurement and have established regulatory institutions to ensure all procuring entities conduct procurement operations in accordance with the law. However, all EAC Partner States should have specific regulations in respect of procurement of pharmaceutical products to address the specific challenges confronting procurement of medicines. Only a few EAC Partner States like Uganda and Tanzania have specific regulations on procurement of medical products under the procurement law. A community law on procurement of medicines can fill up gaps in existing national legislations on procurement of medicines.

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<sup>113</sup> WHO (2007), *supra* note 31, p. 63.

An important issue in this context is whether provisions of national legislations on procurement would defer to a regional legal framework on pooled procurement of medicines? The national legislations of some of the EAC Partner States contain such a provision. For example, the public procurement law of Rwanda, Uganda, Tanzania states that in the event of a conflict between their domestic public procurement law and any treaty or other agreement with other States to which those countries are parties, the provisions of the treaty or agreement shall prevail. However, the Public Procurement and Disposal Act, 2005 of Kenya states that in the event of a conflict between an international Treaty or agreement with the provisions of the domestic procurement law, the domestic legislation shall prevail. This can create difficulties in implementing a regional pooled procurement mechanism by the EAC. Hence, there is a need to ensure that national laws of all EAC Partner States create space for inclusion of the regional pooled procurement mechanism.

An EAC legal framework on regional pooled procurement should also reconcile differences between national laws on the application of preference and reservation schemes for local pharmaceutical manufacturers. Currently, the national procurement laws of most EAC Partner States restrict the scope of preference or reservation schemes to national manufacturers or providers. This would exclude pharmaceutical manufacturers from other EAC Partner States from the preference or reservation schemes and would impede sole sourcing of procurement of medicines wherein the EAC regional procurement mechanism could negotiate with a specific provider. Hence, there is a need to establish an EAC regional preference and reservation scheme where local pharmaceutical manufacturers from the EAC Partner States could participate exclusively. National procurement laws would have to be approximated to such an EAC law and special provisions preference and reservation schemes for pharmaceutical products would have to be developed in the national procurement laws.

For example, Section 54 (1) of the Tanzanian procurement law states that participation in the procurement process may be restricted on the basis of nationality. It could be possible under an EAC law to restrict participation to nationals of EAC Partner States only under a preference scheme in accordance with this provision.

The implementation of a regional pooled procurement mechanism could also complement national and regional initiatives being pursued by EAC Partner States to promote the growth of a strong local pharmaceutical industry to supply the essential medicines needed in the public health system at an affordable cost. In this context, the establishment of the EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) and the adoption of the EAC Protocol on TRIPS and Public Health as well as the implementation of the EAC Common Market Protocol are very positive developments that can create a facilitative environment for the growth of local manufacturing capacity in essential medicines. These developments at the EAC level also complement national policies being pursued by all EAC Partner States to strengthen local manufacturing capacity in order to reduce the overwhelming reliance on importation of essential medicines.

The implementation of a regional pooled procurement mechanism would also be impacted by the quality of medicines that are to be procured. As observed in this paper, most of the medicines procured for diseases like HIV/AIDS, TB and malaria are obtained from foreign companies who provide medicines. The procurement of these medicines are funded by international donor agencies like the Global Fund, etc. where local manufacturers are not able to participate as they do not satisfy quality standards such as WHO prequalification or ICH guidelines. Moreover, in situations of stock outs of medicines in public health facilities,

sometimes medicines of substandard quality may be procured by the health facilities from other suppliers. For a regional pooled procurement mechanism, there is a necessity to ensure that the movement of medicines within the region are in compliance with a regionally common and appropriate set of quality standards. There has been some notable development in this regard with launch of the EAC Medicines Registration Harmonization project. However, the EAC MRH project should ensure that common quality standards adopted are appropriate for enabling generic manufacturers to supply medicines for treating diseases endemic to the region and that such manufacturers are not constrained by unsubstantiated quality standards such as the ICH guidelines adopted and promoted internationally by multinational pharmaceutical companies and regulatory authorities of developed countries.

Though all the EAC Partner States do not have established drug regulatory bodies, efforts are being undertaken to establish and strengthen drug regulatory authorities in these countries. Among the EAC Partner States, only Burundi is yet to establish a specific drug regulatory authority but it seeks to establish a National Pharmaceutical Governing Authority (NARP) in course of standardization of quality assurance systems in the EAC. In 2013, Rwanda had established a drug regulatory authority – the Rwanda Food and Medicines Authority (RFMA) – which is responsible for medicines regulation including regulation of quality of medicines procured by the central medical stores (CAMERWA) and other procurement entities.

The capacity of national medicines regulatory authorities in the EAC Partner States to regulate the movement of quality assured medicines varies. For example, in Burundi, the Directorate of Pharmacies, Medications and Laboratories (DPML), which is responsible for regulation and quality assurance of pharmaceutical products, does not have the capacity to conduct quality control tests and relies on tests by external laboratories. Conversely, in Kenya the drug regulator – the Pharmacy and Poisons Board (PPB) and KEMSA - coordinate with NQCL to ensure procurement of quality assured and registered medicines. Though there is scope for effective cooperation where quality assurance trials by a national regulator with the capacity to do so is recognized by other national regulators with limited capacity, the national laws for quality control and registration of medicines are not recognized under the laws of other Partner States. At the EAC level there is need to promote mutual recognition of decisions of national drug regulators of the EAC Partner States.

## **VII.1 Recommendations**

In view of the discussions in this paper, the following recommendations can be made:

1. Discussions on a plan of action for implementing the EAC regional pooled procurement mechanism as recommended by the EAC Council of Ministers in 2008 must be expedited pursuant to the decision of the EAC Sectoral Council on health in its last session in 2014. The EAC Secretariat should identify the reasons why discussions the plan of action for establishing a regional pooled procurement mechanism has not progressed since 2008?
2. EAC Partner States should coordinate their policies on pooled procurement of medicines through the institutions of the EAC specifically established to facilitate such cooperation i.e., the Expert Working Group (EWG) on EAC regional pooled bulk

procurement initiative, as mandated by the EAC Sectoral Council on Health, as well as the East African Legislative Assembly (EALA).

3. The EAC Partner States should consider the development of a common EAC legal framework for implementing the regional pooled procurement mechanism. Such a legal framework should build on the common elements in the national procurement legislations of EAC Partner States and also address issues such as the scope of preference and reservation schemes, mutual recognition of medicines registration and quality assurance, and sustainable financing of the pooled procurement mechanism.
4. The East African Legislative Assembly should be increasingly engaged on the issue of implementation of a regional pooled procurement mechanism. The EALA should initiate discussions among national legislative bodies about the establishment of a regional pooled procurement mechanism and encourage national legislative bodies to provide inputs on the framing of an EAC wide legal framework for a pooled procurement mechanism.
5. The existence of parallel systems of procurement in the form of public procurement by the central medical stores as well as procurement by ministries of health under donor funded programmes with different requirements adds to the complexity of the implementation of a regional pooled procurement mechanism. It will be desirable for the regional pooled procurement mechanism to have sole sourcing of procurements through the suppliers selected by the pooled procurement mechanism. All procurement activities should be subjected to the same set of rules and quality standards.
6. While national public procurement laws in all the EAC Partner States based on UNCTRAL model procurement laws have brought about greater transparency in the procurement process, it may be desirable to have specific regulations in respect of procurement of pharmaceutical products to address the specific challenges relating to procurement of medicines. These should be guided by an EAC legal framework.
7. An EAC-wide legal framework on procurement of medicines must be developed by the EALA. The national procurement laws of all EAC Partner States should exist harmoniously with an EAC legal framework on procurement of medicines. The laws of all Partner States should ensure that in the event of a conflict between the domestic law and the regional law, the regional law shall prevail. Currently, the public procurement law of Kenya states that in the event of such a conflict the national law shall prevail. The potential for a possible exception to this clause for a regional procurement mechanism may be considered.
8. The implementation of the EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) must be expedited as directed by the 9<sup>th</sup> session of the EAC Sectoral Council on Health, and the implementation of the regional pooled procurement mechanism should be considered in the deliberations on RPMPOA.
9. The EAC regional policy on the use of Public Health-Related WTO-TRIPS flexibilities and the Approximation of National Intellectual Property Legislation, and the EAC Regional Protocol on Public Health-Related TRIPS Flexibilities must be expeditiously implemented in order to fully utilize the TRIPS flexibilities for

facilitating local manufacturing of medicines and also to facilitate the procurement of affordable generic medicines.

10. Current national procurement laws of EAC Partner States restrict the application of preference and reservation schemes to their nationals only. In the context of a pooled procurement mechanism for the region, it will be necessary to ease these restrictions on preference and reservation schemes and expand their scope to include nationals of any EAC Partner States.
11. Discussions on adoption of a common set of standards for medicines registration in the region under the EAC Medicines Registration Harmonization project should be cautious in following regulatory standards that are adopted and promoted by multinational pharmaceutical companies and drug regulators from developed countries through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, as such guidelines may create unnecessary barriers for local manufacturers and generic producers and restrict them from participating in procurement bids under the regional pooled procurement mechanism.
12. The EAC Secretariat should not present the current draft EAC anti-counterfeit bill before the EALA. Instead, the EAC Secretariat should review the implications of the draft law for public health and access to medicines and amend the draft legislation appropriately.



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