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

FINAL REPORT

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A SITUATIONAL ANALYSIS AND FEASIBILITY STUDY ON REGIONAL POOLED BULK PROCUREMENT OF ESSENTIAL OF MEDICINES AND OTHER HEALTH SUPPLIES IN THE EAST AFRICAN COMMUNITY PARTNER STATES

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TABLE OF CONTENTS

ACRONYMS

ACAME	Association of Central Medical Stores for Generic Essential Medicines
AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral
CMS	Central Medical Stores
CRHC	Commonwealth Regional Health Community
DANIDA	Danish International Development Agency
EAC	East African Community
ECSA	East Central & Southern Africa
GFATM	Global Fund to fight against AIDS, TB & Malaria
HIV	Human Immunodeficiency Virus
IPR	Intellectual Property Rights
JSI	John Snow Inc.
MSH	Management Sciences for Health
NEML	National Essential Medicines List
NM(D)RA	National Medicines (Drugs) Regulatory Authority
OECS	Organisation of Eastern Caribbean States
PAHO	Pan American Health Organization
PEPFAR	President's Emergency Plan For AIDS Relief
SADC	South African Development Community
SCMS	Supply Chain Management System
SIDA	Swedish International Development Agency
STG	Standard Treatment Guidelines

SWOT	Strength, Weaknesses, Opportunities and Threats
TB	Tuberculosis
TRIPS	Trade Related Aspects on Intellectual Property Rights
UNDP	United Nations Development Funds
UNICEF	United Nations Children's Fund
UNFPA	United Nations Population Fund
WHO	World Health Organization

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EXECUTIVE SUMMARY

I. BACKGROUND

The East African Community (EAC), in January 2007, requested the assistance of the WHO Department of Technical Cooperation for Essential Medicines (TCM) to conduct a situational analysis and feasibility study for implementing Regional Pooled Procurement of Medicines as part of their efforts to address issues of accessibility and availability of essential medicines in the region.

Pooled procurement, otherwise known as joint purchasing, is increasingly being regarded globally as an efficient strategy to resolve challenges as high medicines prices, poor quality and other bottlenecks generally associated with Procurement and Supply Chains of Essential Medicines. A number of sub-regional and regional blocs as well as global initiatives have adopted the pooled procurement mechanisms with success stories to share. The Gulf States, who have carrying out pooled procurement for over twenty five years reported that it had reduced costs and made millions of dollars in savings, whilst the East Caribbean Islands reported an average cost savings of 37% for 25 selected items over a five year period. Other successful pooled procurement initiatives includes the WHO Pan American Health Organization (PAHO) Strategic Funds and the WHO Global Drug Facility for TB medicines, have shown significant achievements in lowering medicines prices, improving procurement process and quality of medicines.

The two models of pooled procurement, under review in this study are the Group Contracting and the Central Contracting. These models are similar as they both involve bulk purchasing of medicines on behalf of a group or countries, with the main difference being the level of collaboration and integration, the administrative infrastructure required to implement the pooled procurement and therefore the technical and financial resources needed. Thus in Group Contracting countries jointly negotiate prices and agree to purchase through the selected suppliers, but the various member countries conduct the purchasing individually. With Central Contracting, Member countries jointly conduct tenders and award contracts through a centralized procurement unit, which pools the financial resources from the member countries. Apart from reducing cost of medicines and contributing to a more cost efficient and transparent procurement system, pooled procurement also facilitates harmonization of standard treatment guidelines, medicines registrations and essential medicines lists.

The main objectives of this study are:

- To analyse the legal and regulatory framework on procurement and delivery of pharmaceutical products and other essential medical supplies in the public sector of the EAC Partner States;
- To determine the feasibility of pooled procurement of medicines
- To recommend a specific model of pooled procurement and identify a potential target commodity list for bulk purchasing;

- To develop guidelines and recommendations for the implementation of the recommended model.

II. METHODOLOGY

The situational analysis and feasibility study is based on an assessment of procurement laws, regulations, policies, practices and prices in Uganda, Kenya, Tanzania Mainland & Zanzibar, Rwanda and Burundi. It builds on existing studies and surveys already conducted in the EAC partner states on issues related to procurement and supply management.

The analytical framework for the situational analysis study focuses on the six components essential for the effective and sustainable implementation of pooled procurement to assess if it is feasible for the EAC region, and if so, which model can be successfully applied as per requirements of Group Contracting and Central Contracting:

- ✓ **Political commitment** supported by the implementation of required policies and reforms at the operational level;
- ✓ Appropriate **procurement legislation** and transparent purchasing mechanisms;
- ✓ Robust **supply systems** to deliver products to the end user;
- ✓ **Harmonized regulatory procedures**, including common Essential Medicines Lists, Standard Treatment Guidelines and medicines registration procedures;
- ✓ Adequate and predictable **financial resources** for the regular and timely allocation of funds and manage payments;
- ✓ Opportunities to achieve **greater pricing efficiencies** through bulk purchasing.

The study process included the following:

- Development of Inception Report (presented in Arusha 11-13th April, 2007)
- Revision and finalisation of methodology and tools (including survey translation and series of technical meetings with WHO/JSI/MSH in Geneva, June and July, 2007).
- In-country visits / survey using questionnaire conducted in all EAC countries (July).
- Data analysis and report writing
- Review of the findings and recommendations by the EAC Medicines Expert meeting held in Nairobi, Kenya, 17th -19th September 2007
- Finalization of the report

The main activities of the study involved a) desktop review on data and documents collated; b) country visits conducting survey utilizing the questionnaire developed, analysing and presenting the data in various formats e.g. feasibility matrix; a modified SWOT table and readiness assessment, c) presentation of preliminary findings to EAC Medicines Experts for consensus building.

III. FINDINGS / ASSESSMENT

The situational analysis report identified the similarities in legislative and regulatory framework as well as policies and practices, which were later translated into assets and strengths of the community, which are therefore regarded as supportive to regional pooled procurement but needs to be maintained through the development and implementation of the system. Similarly the disparities identified were translated as constraints and challenges which in their current states are not consistent or wholly supportive of regional pooled procurement. However these challenges further provides opportunities to address them either through improvement or harmonization efforts. The findings were further quantified to assess the feasibility of adopting a pooled procurement model, and also identify the appropriate model.

A. Political will and organizational commitment

The political will and commitment for a harmonized regional economic bloc is strongly evident, and further supported by the existing hierarchical structure of the EAC Policy Organ. The inherent asset for the EAC therefore is that it guarantees political commitment and support from the highest level of government for its approved programmes. The EAC member states are currently involved in a number of pooled procurement related activities, thus confirming the active participation of partner states. The main issues to address is the limited capacity of the EAC Secretariat to implement either of the two pooled procurement models, but even more so with the Central Buying Model. The level of awareness on pooled procurement at national level is still limited thus emphasizing the need for more advocacy and further consultations.

B. Procurement legislations and policies

The current procurement legislations and institutional framework in the EAC member states is relatively homogenous, providing the basis for Good Pharmaceutical Procurement Practice for the adoption of regional pooled procurement. However as no specific legislation currently exists for regional pooled procurement, the various interpretations on national laws and international obligations might give rise to potential conflicts and needs to be addressed. The main issue to address is potential role of local manufacturers in regional pooled procurement of medicines, with the current disparity in the utilization and support of national medicines industry. Two of the EAC member states with the largest number of local manufacturers are strongly supporting the national industry through the local preference clause in their respective legislations, which might be perceived as ‘non-competitive’ and therefore a challenge at regional level. On the other hand, local production could be dealt with as a potential area for harmonization through improvement of quality and the pooling of local capacity to meet regional needs that will benefit not only the specific countries that produce the medicines but the sub-region as an economic bloc.

C. Medicines regulation

The regulatory legislations, institutional framework and capacities to regulate the movement of quality assured medicines within the member countries are relatively diverse. Likewise the varying capacity of the National Medicines Regulatory Authorities (NMRAs) in the region

makes it necessary to establish a regional Quality Assurance system to support either model of pooled procurement. It is important to note that the NMRAs are meeting regularly and working towards harmonization of standards and practices for Quality Assurance. As part of the quality assurance system at national level, medicines registration is one of the key criteria for the tendering and importation of medicines in most of the EAC partner states. It therefore poses a challenge towards the implementation of regional pooled procurement, as there is no system of mutual recognition of EAC member states National Medicines Regulatory Authorities (NMRA) decisions on registration of medicines. The harmonization of medicines registration procedures and process needs to be prioritized for regional pooled procurement.

D. Medicines supply chain

The set up and mode of operation of the National Medical Stores varies considerably, but with most of them operating as semi/ autonomous institutions. Apart from the national medical stores, the procurement of medicines for the public sector involves other stakeholders such as development partners and procurement agents with various procurement regulations and methods. This diverse number of players in the procurement arena might either negatively impact regional pooled procurement or offer opportunities for negotiation for pooled procurement. The inadequate Logistics Management Information System, which impacts on the accuracy and availability of information, has a substantial negative impact of quantification of needs and further limits information sharing.

Although Essential Medicines Lists and Standard Treatment Guidelines are not fully harmonised, each of the countries procure similar essential medicines and HIV/AIDS products with which to initiate pooled procurement. However, the lack of harmonisation of these essential documents therefore limits the selection of the products that can be successfully pooled together for bulk purchasing.

E. Financing

The medicines financing environment among EAC member-states is complex as each potential category of target commodities for pooled procurement involves multi-source financing that will require negotiation and revision to the current financing structure for medicines. Political commitment however exists to increase internal resources for medicine procurement. Furthermore all the EAC countries have access to and use convertible currency for international procurement, with 80% of the national medical stores identifying Letter of Credit as the most prevalent method used for procurement which is also the preferred method by international suppliers. The EAC regional financial institution, i.e. the East African Development Bank can be utilized to facilitate payment processing for pooled procurement. Other opportunities or potential sources of funding for regional pooled procurement of medicines include household financing of medicines which presents opportunity to capture additional funds, if concerted efforts are made to channel fund for purchases. Likewise, the pool of donors and bilateral agencies providing funds for medicines within the sub-regions provides the EAC with the opportunity to mobilize technical and financial support for joint procurement for their sub-region.

F. Pricing

The primary monetary advantage of pooled procurement is that unit prices can be reduced by purchasing higher volumes. As a sub-regional bloc, the opportunity to negotiate for lower prices does exist, with monetary savings identified as one of the potential benefits of pooled procurement, and from the simulation of savings conducted for the region it was found that significant savings could be made at a regional level up to 22% for common essential medicines.

The amount of financing necessary to support the procurement of the range of essential medicines to treat HIV in the EAC region is quite substantial in comparison to other essential medicines purchases. There is no question that the support of international donors in partnership and ministries of health will be a vital component in ensuring adequate quantities of medicines can be procured. This scale, however, also provides opportunities for significant savings over current prices both for the 12 products examined in this section and, assumably, for the several dozen, perhaps hundreds of other products not examined in this analysis. Figure 3.9 compares the procurement costs under four pricing scenarios. The volume is derived by adding the most recent procurement for each of the 12 products found in the GPRM database. As can be seen, if all the products were procured at the LTP, the total cost would equal $ 9,956,998, compared with $20,047,217 if procured at the HTP – which amounts to over a $US 10 million difference for based on only one procurement for each product for each country. Even comparing the LTP to the median price obtained by the EAC member-states amounts to a difference of over $3 million U.S...(Annex 6 contains the cost variations for each price).

IV. CONCLUSIONS AND RECOMMENDATIONS

This study confirms the feasibility of the EAC region to adopt and embark on regional pooled procurement of medicines, with an initial limited list of essential medicines. The feasibility analysis and readiness assessment of the study suggested that Group Contracting was more feasible for the EAC than the central contracting model. However as part of the consensus process, it was recommended that both models be proposed for consideration by the EAC and its development partners. The EAC Medicines Expert meeting in September 2007 selected the Group Contracting model for the EAC pooled procurement programme. Thus the recommended and endorsed regional pooled procurement model for the East African Community is Group Contracting.

The rationale for the selection of Group Contracting model included the following:

- The Pooled Procurement feasibility study concluded on a technical basis that Group Contracting is a feasible, beneficial alternative for regional procurement for select medicines in the EAC.
- With adequate technical and financial assistance, the existent capacity in the EAC member states will be able to implement regional pooled procurement of medicines.
- Individual partner states have resources and the technical capacity to assist in conducting tenders and negotiating prices.

- It allows member states to retain a degree of autonomy in the procurement process.
- The current degree of harmonization of essential medicines lists and medicines regulations is adequate to initiate the Group Contracting.
- Group contracting requires less investment, financial and human resources for efficient management and coordination of the process and requires less cumbersome payment mechanisms.

The study identified a recommended initial list of eleven (11) essential medicines common to at least three or more countries to initiate the EAC regional pooled procurement.

Recommended List of Essential Medicines
Acetylsalicylic Acid 300 mg tab
Metronidazole 200 mg tab
Chloramphenicol 1G Injection Vial
Amoxicillin 250 mg caps
Erythromycin 250 mg tab
Amoxicillin Granules 125mg/5ml 100 ml
Cotrimoxazole 400+80mg Scored
Paracetamol 500 mg tab
Quinine Sulphate 300 mg tab Coated
Chloramphenicol caps 250 mg
Oral Rehydration Salts For 1Lt, 27.9G (Packet)

The EAC Medicines Expert meeting of September 17-19th 2007 recommended that the regional pooled procurement of medicines be initiated on a pilot basis and the initial list of essential medicines will be further identified. The study further recommended that selection of additional items should be based on the following criteria:

1. Commonly procured by majority of member states
2. The current prices at national level is higher than reference prices
3. Wide disparity between Highest Transaction Prices and Lowest Transaction Prices

4. Essential medicines with high treatment value
5. Potential policy support and flexible financing

The report further noted that due to the current multi-source funding for ARV medicines, TB and ACTs, it recommends that EAC can initiate negotiation with the various development partners to utilize earmarked fund s at the national level for regional pooled procurement.

Apart from assessing the feasibility of adopting and selecting a model for regional pooled procurement, this study has also reiterated the fact that "pooled procurement" of pharmaceutical products goes beyond the mere activity of the acquisition or purchasing of products. It relies on the efficiencies of the various supporting structures and systems to provide the enabling environment for a successful, efficient and sustainable multi-country joint procurement programme. This therefore requires an integrated approach towards systems support for the regional pooled procurement programme, with key recommendations outlined below:

1. The EAC to adopt Group Contracting pooled procurement model for the joint purchasing of medicines.
2. Strengthen the capacity of the EAC Secretariat to coordinate the regional pooled procurement of medicines.
3. The EAC to establish a Regional Pooled Procurement Taskforce that will be responsible to develop, implement and monitor regional operational plan and coordinate activities within countries and other stakeholders.
4. Develop with the support of partners, the budgeted regional operational plan for the implementation of the pooled procurement programme, including timeframe.
5. Mobilise resources for initial capital expenditures and on-going external financing for medicine procurement.
6. The EAC to design the pilot phase of the pooled procurement and defined the initial list of medicines to be used.
7. Identify relevant structures at country level for coordinating pooled procurement activities (e.g., forecasting/quantification, financing, and price monitoring)
8. The EAC should prioritize key technical activities from the operational plan to be implemented in the first phase of the project and plan for their implementation.

9. The EAC should ensure that all member states are actively involved and take **ownership** of the regional pooled procurement programme.

10. A contractual, binding, and funded agreement should be signed among the EAC member states for the implementation of pooled procurement.

On the basis of the recommendation made above, the EAC medicines experts made the following recommendations to the EAC Council of ministers to be held in Arusha, 24th-25th September 2007.

1. To adopt the findings in the EAC Pooled Procurement Situational Analysis and Feasibility Study;
2. To adopt the Group Contracting pooled procurement model as per draft report of the EAC Situational Analysis and Feasibility Study;
3. To establish an EAC Health Secretariat Task force on Pooled Procurement to be responsible for:
    a. The development of an EAC operational plan for the implementation of regional pooled procurement including budget and timeframe.
    b. Identify relevant structures at country and regional levels for coordinating pooled procurement activities (e.g. forecasting/quantification, financing and price monitoring).
    c. Develop initial Group Contracting pilot program for the purchase of a select number of essential medicines

CHAPTER I: INTRODUCTION

1. RATIONALE FOR POOLED PROCUREMENT

1.1 Rationale for Pooled Procurement of Medicines

In recent years, a number of sub-regional groups of countries have expressed their interest in adopting or have established pooled procurement to improve availability, quality and affordability of essential medicines in the respective countries concerned. Pooled procurement is increasingly seen globally as an efficient strategy to resolve some of the challenges associated with high prices of medicines, poor quality and bottlenecks in the procurement and supply chains of pharmaceuticals. The harmonisation of procurement, quality and supply policies and procedures within these groups of countries is key to achieving the objectives stated above. There are currently a number of sub-regional, regional and global pooled procurement initiatives with success stories to share.

The Organization of East Caribbean States (OECS) Pharmaceutical Procurement Services and the Gulf Cooperation Council (GCC) Group Purchasing Programme have carried out pooled procurement based on the central contracting model for more than twenty years. OECS reported an average cost savings of 37% for 25 selected items over a five-year period (1998-2002) (OECS, 2007). After 27 years of using a centralized tendering system, the GCC has successfully demonstrated that its pooled procurement services, based on a collective decision-making policy, has reduced costs, saved millions of dollars over the years and enhanced the efficiency of health services for its member states.

The Pan American Health Organization (PAHO) Strategic Fund, under the auspices of the World Health Organization, (WHO) is an another group operating a Group Contracting service, which exemplifies how negotiated group contracts has resulted in favourable pricing (PAHO, 2007) The WHO Global Drug Facility for TB exemplifies pooled procurement at global level. All these initiatives have shown significant achievements in lowering medicine prices as well as in improving information sharing, procurement processes, medicine supply systems and quality of pharmaceutical goods within sub regional groups of countries.

In addition to the examples above, a number of institutions and group of countries have initiated process or are exploring feasibility for pooled procurement. In Africa, the Association of Central Medical Stores for Generic Essential Medicines (ACAME) identified Group Contracting as their mode of pooled procurement, whereas the East, Central and Southern Africa health community (ECSA) has established a Coordinated Informed Buying (CIB) system for its member countries.

As part of its efforts to facilitate improved availability of medicines and other medical supply, the Global Fund to fight against AIDS, TB and Malaria (GFATM) conducted a feasibility study on voluntary pooled procurement for its recipient countries, and has consequently decided to move forward with pooled procurement for a number of medicines where it has

been suggested that bulk purchasing can reduce prices and improve distribution. The Pacific Islands also recently concluded a feasibility study on pooled procurement to improve on availability and accessibility of medicines in those islands. The East African Community (EAC) and South African Development Community (SADC) member states are in the process of identifying feasible models for adoption.

With these benefits in mind, the EAC Secretariat expressed a desire to conduct a situational analysis and feasibility study of regional pooled procurement of medicines, to evaluate if pooled it would be a suitable purchasing arrangement for the region and identify the appropriate model for it.

1.2 Models of pooled procurement

This section provides a brief overview on the various pooled procurement models. It describes the requirements, benefits and challenges of each model.

Four models of pooled procurement have been identified that may be appropriate for a region depending on a) the level of collaboration and integration within the member countries, b) the degree of complexity of the administrative and operational set-up and c) the human and financial resources required to establish the system. The first two models, *informed buying* and *coordinated informed buying*, are modes of information sharing while *group contracting* and *central contracting* are models for actual pooled procurement for which the purchasing or negotiations is carried out jointly or coordinated by one procurement office on behalf of a group of facilities, health systems, or countries, with group members agreeing to purchase certain drugs exclusively through the group' (MSH, 2000).

It is generally envisaged that the more integrated the pooled procurement model is, the higher the administrative costs and complexity of the model, but the greater the benefits. Accordingly, informed buying is expected to be the least costly and complex option, but the potential benefits are also fewer. In comparison, Central Contracting using pooled financing is more costly and complex, but provides the greatest benefits. A summary description of the main models highlighting their advantages and risks are outlined in Table 1.1 (Adopted from: Onyango C et al, 2003; Abdallah H. et al, 2004).

During the WHO Expert meeting on multi-country pooled procurement of medicines held in Geneva, January 2007, several expected price and non-price benefits were identified, key among these being:

Price benefits:

- Lower prices / reduced costs achieved through greater negotiating and purchasing power, benefits of bulk purchasing and economies of scale
- A more cost efficient and transparent system of purchasing
- Improved efficiency in administrative costs with reduction in market research costs due to information sharing.

Non-price benefits:

- Harmonization of standard treatment guidelines, medicines registration, Essential Medicine Lists or National Medicines Formularies;
- Encourage or facilitate technical collaboration and exchange of information;
- Rationalization of the procurement process & monitoring financial accountability;
- Improving the reliability of suppliers and ensuring the quality of medicines through the prequalification of suppliers;
- Addressing specialized health and medicines needs of a region;
- Improving technical and human capacity through the pooling of resources and expertise;
- Facilitating exchange of pharmaceutical goods and services within the regional bloc;
- Providing a good entry point for political integration.

Model	Description	Advantages & Disadvantages
Informed Buying	• Member countries share information on prices and suppliers • Procurement is conducted individually	• Low administrative costs • Limited management capacity on procurement or finances required • May not achieve significant volume savings
Coordinated Informed Buying	• Member countries conduct joint market research, share information on supplier performance and prices • Procurement is conducted individually	• Similar advantages & disadvantages as Informed Buying • Greater coordination is required to manage shared information • Can assist in quality assurance and reliability of supply through information sharing
Group Contracting	• Member countries jointly negotiate prices and select suppliers • Member countries agree to purchase from selected suppliers • Procurement is conducted individually	• Requires central capacity to negotiate prices and select suppliers • Requires commitment from member countries to purchase from selected suppliers • Can achieve volume savings through negotiations • Pre-qualification of suppliers may improve quality and reliability of suppliers • Allows countries to retain autonomy for purchasing and does not require transfer of funds to central procurement organization • Requires some degree of harmonization of essential medicines list and in medicines registration.
Central	• Member countries jointly	• Greatest potential for volume

	behalf of member countries	• Can achieve efficiency savings in administrative costs through central procurement • Requires significant capacity in tendering, contracting and financial management in central buying unit • Requires commitment for prompt payment and sole source purchasing from member countries • Requires harmonized essential medicines list and medicines registration procedures • Model can be utilized to pool financial resources, e.g. donor funding.

Table 1.1: Pooled procurement models

2. BACKGROUND INFORMATION

The East African Community (EAC) is a regional inter-governmental organization comprising five member countries, the Republics of Kenya, Uganda, Tanzania, Rwanda and Burundi representing over 115 million population. It was established in 1999 under a signed treaty, with its headquarters located in Arusha, Tanzania. The two newer partner states, Burundi and Rwanda, were admitted in 2006 and became full members on July 1st 2007.

According to the 1999 Treaty, the vision of EAC is to have a prosperous, competitive, secure and politically united East Africa. In 2005, a new EAC Development Strategy (2006-2010) was formulated to ensure the systematic implementation of the Treaty and it focuses on economic cooperation and regional development in priority areas such as health, education, customs & trade, agriculture, transport and monetary & fiscal affairs with the ultimate objective of moving towards an East African Political Federation by 2013. In the health sector, the EAC has committed itself to strengthen and accelerate regional collaboration to address the deepening health crisis in the region by outlining a series of health activities to enhance efficiency of health services in an integrated and harmonized fashion.

Figure 1.1: Map of the EAC member countries

Preventable communicable diseases especially HIV/AIDS, malaria, tuberculosis, respiratory infections, and diarrhoea are responsible for the highest morbidity and mortality among both

the general population and the under five children in the EAC Partner States[1]. Despite declining rates of prevalence, the HIV/AIDS epidemic continues to pose a serious threat to the socio-economic development of the sub-region. Of the estimated 25.5 million people living with HIV/AIDS in sub-Saharan Africa, 17 million live in Eastern and Southern Africa[2]. The present overall national HIV prevalence rates in partner states are 6.1% in Kenya, 6.7% in Uganda and 6.5% in Tanzania including Zanzibar, 3.1% in Rwanda and 3.3% in Burundi (see table I for EAC Health Indicators).

Essential medicines for the treatment of these preventable diseases remain however out of reach for many, and the high price of medicines is a key factor in their inaccessibility. In Sub Saharan Africa, half of the population lacks reliable access to needed medicines, and out-of-pocket expenditures constitute a heavy burden for the poorest and most vulnerable. WHO estimates that in Sub Saharan Africa, approximately 34% of health expenditures are paid for out-of-pocket by patients (WHO, 2002). Efforts to scale up access to affordable and good quality essential medicines are therefore needed to save lives, reduce suffering and improve health in the East African Community.

As part of achieving increased availability and affordability to essential medicines, the EAC has become increasingly interested in regional pooled procurement. Further, pooled procurement may serve as a means of facilitating harmonization of national policies and regulatory frameworks for the pharmaceutical sector through increased collaboration and integration, thereby enhancing its efficiency. Thus, the EAC Secretariat requested WHO to conduct in coordination with its partners e.g. MSH, JSI, UNDP etc. this *Situational Analysis and Feasibility Study* to assess and analyse the potential for regional pooled procurement of essential medicines among its member states. The situational analysis study focused on the five partner states of EAC, i.e. Uganda, Kenya, Tanzania, Rwanda and Burundi. The key elements identified as essential for the various models of pooled procurement will be used as indicators to assess the feasibility to adopt pooled procurement strategy.

[1] EAC Report of Meeting, 24-27 May 2005, Arusha. Regional Workshop for East African Community (EAC) Partner States Legal, Trade and Pharmaceutical Experts and Manufacturers of Essential Medicines on the Review of National Patent Laws and WHO TRIPs Flexibilities. Ref: EAC/TF/35/2005.

[2] These figures are taken from (i) UNAIDS Epidemic Update, November 2005 (ii) UNAIDS at the Country Level: Progress Report. September 2004 (both documents are available online at: www.unaids.org).

Table 1.2: Health Indicators in the EAC countries (Source: WHOSIS)

	Health indicators	Tanzania	Kenya	Uganda	Rwanda	Burundi
Basic demographic and socio- economic indicators	Total population	38.328 m	34.255m	28.816m	9.038m	7.548m
	% of population in urban areas	37.5	41.6	12.4	21.8	10.6
	Crude birth rate (births per 1,000 pop)	36.7	39.5	50.7	41.2	45.5
	Crude death rate (deaths per 1,000 pop)	16.6	15	14.8	17.7	18.4
	Gross national income per capita	$290	$390	$240	$220	$100
	Total expenditure on health as % of GDP	5	5	7	5	3
	Per capita expenditure on health (US$)	31	70	77	48	16
	Total fertility rate	5.6	5	7	6	5
	Child mortality total (2003)	165	123	140	203	190
	Maternal mortality rate per 100,000 live birth	1,500	1,000	880	1,400	1,000
	Neonatal mortality	43	29	32	45	41
	Life expectancy at birth m/f (years)	44/46	50/49	47/50	43/46	40/45

3. PURPOSE AND OBJECTIVES OF THE STUDY

A previous study was conducted by the Rational Pharmaceutical Management Plus (RPM Plus), Management Sciences for Health (MSH) in 2002 to assess the readiness of the Commonwealth Health Regional Community (CHRC) of which Kenya, Uganda and Tanzania participated (Onyango et al, 2002). The study reported that while Tanzania demonstrated readiness, Uganda and Kenya were not yet ready to adopt any of the four pooled procurement models. It was therefore recommended that the Regional Drug Forum (RDF) of the CHRC could start with the Coordinated Informed Buying Model, which later resulted to the establishment of East Central South African (ECSA) Medicines Website. As member countries, Uganda, Tanzania and Kenya are supposed to provide and access the information available on this website.

Since the MSH study, there have been numerous changes in the health and pharmaceutical sectors of the EAC member states, which justify the need for a new feasibility study for pooled procurement in the region. The indication is that the EAC Secretariat is interested in establishing a pooled (joint) procurement program irrespective of the plans and activities of ECSA. The preliminary assessment of the harmonization activities currently being embarked on within the framework of medicines regulation, procurement and policies by the partner states underscores the desire of the EAC for a more integrated model of bulk purchasing. The stakeholders meeting on pooled procurement of ARVs and Essential Medicines in the EAC held in Zanzibar, 13th – 15th November 2006 further re-iterated the interest of the community to adopt a comprehensive bulk procurement model.

A preliminary review of the Terms of Reference was made and found to be quite broad, encompassing a number of areas within the pharmaceutical sector, with some of the issues not directly linked to the study on pooled procurement. The Inception Report for the situational analysis study, including the revised Terms of Reference, was presented and subsequently approved during the EAC Medicines Experts Meeting of 11th to 13th April 2007 in Arusha (annex 1). Also, after considerable discussion and review of the model options, the two models proposed for the situational analysis and feasibility study were. **Group Contracting** and **Central Contracting.**

Both models have similar requirements, with the key differences for Group Contracting being negotiated contracts and individual purchases in the absence of a central purchasing mechanism and pooled financing associated with the Central Contracting model. Nonetheless, both models require: a) Political and organizational commitment, b) technical capacity at the central level, c) contractual agreement from participating countries, d) reliable financial systems and resources, and e) harmonization of key procurement and regulatory procedures.

The main objectives of this situational analysis and feasibility study were:

1) To analyse the policy and regulatory frameworks, capacity and systems in the public sector with regards to procurement and delivery of pharmaceutical products and other essential medical supplies within each of the EAC Partner States, in view of a proposed regional pooled procurement mechanism based on either the group or central contracting models;

2) To determine if pooled procurement of medicines is feasible;

3) If feasible, to recommend a specific model of pooled procurement that is consistent with the political will, capacities, and objectives of the EAC member-states;

4) To develop guidelines for the adoption of the selected regional pooled procurement model and recommendations for the harmonization of medicines policies, procurement legislation and policies and regulatory frameworks necessary to develop and implement the recommended model.

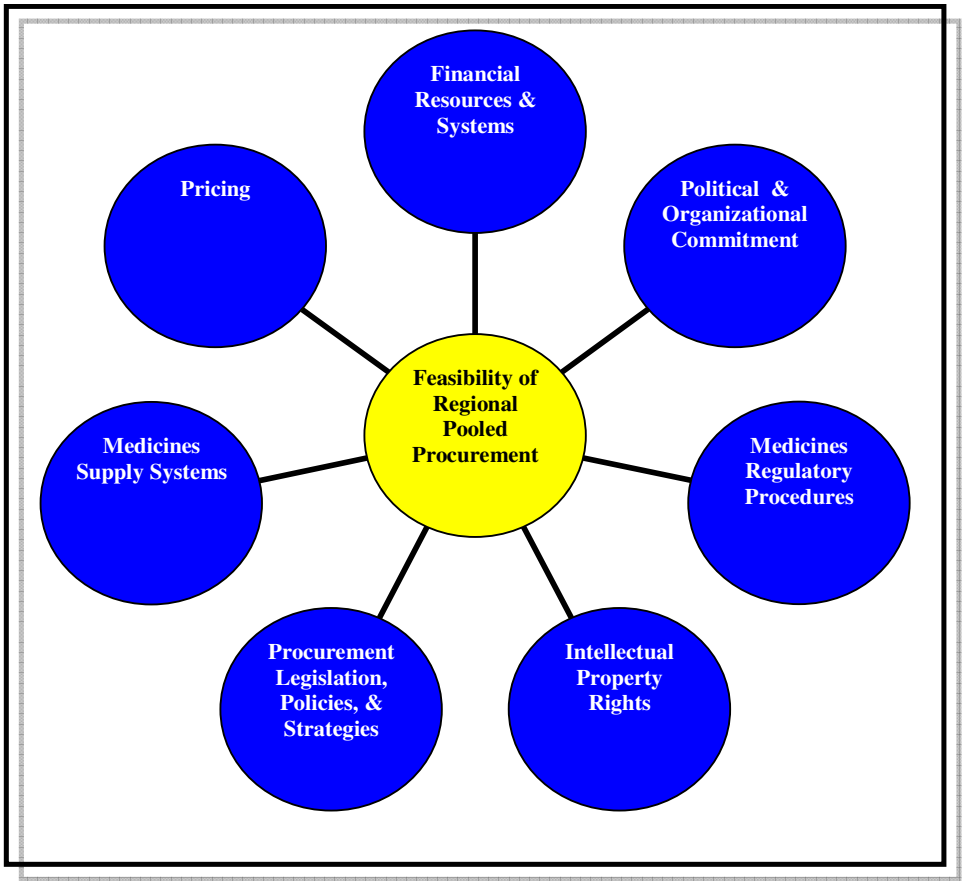
CHAPTER II: METHODOLOGY

1. ANALYTICAL FRAMEWORK

The situational analysis and feasibility study is based on an assessment of procurement practices, prices, policies, laws and regulations in Uganda, Kenya, Tanzania (Mainland & Zanzibar), Rwanda and Burundi. It builds on studies and surveys already conducted in the partner states on issues related to procurement and supply management by WHO, MSH, JSI and others. The analytical framework (Figure 2.1) consists of seven components that are examined in this study to determine if pooled procurement in the EAC region is feasible, and if so, which model can be successfully applied as per requirements of Group Contracting and Central Contracting:

- ✓ **Political commitment** that is backed by implementation of required policies and reforms and filters down to the operational level;
- ✓ Adequate and predictable **financial resources** that can routinely allocate funds and manage payments;
- ✓ **Harmonized regulatory procedures**, including common EMLs, STGs, and medicines registration procedures;
- ✓ Common **intellectual property legislation** necessary to make joint product selection decisions consistent with global intellectual property agreements and flexibilities;
- ✓ Appropriate **procurement legislation** and transparent purchasing mechanisms;
- ✓ Robust **supply systems** to deliver products to the end user;
- ✓ Opportunities to achieve **greater pricing efficiencies** through bulk purchasing.

Figure 2.1: Pooled Procurement Analytical Framework



The Study Process involved the following phases:

1) Development of an Inception report outlining methodology, tools, work plan and time frame, and presented in Arusha, April 2007;

2. Revision and finalization of the methodology and tools developed, including a two day meeting of WHO/JSI/MSH in Geneva, June 2007. This included the development of a questionnaire for the country survey, which was subsequently translated for use in the two francophone countries.

3) Collation of data / information and In-country visits for the survey conducted in July 2007;

4) Data analysis and report writing, including a one week WHO & Partners meeting in Geneva, August 2007.

5) Dissemination of findings (EAC Medicines Experts meeting, Nairobi, Kenya, 17th -19th September 2007.

6) Incorporation of comments and recommendation from the stakeholders and finalization of the report.

2. ACTIVITIES / STEPS

A comprehensive outline on methodology, tools for data collection from the structured questionnaire and documents plus the detailed work plan are in the Inception Report. Additional details on methodology used for the pricing section is provided on the relevant section. This study included the following activities;

i. Desktop review on data and documents collated on national policies and regulation related to pooled procurement such as legislation/policies/ procedures/practices; financial management/ systems/ procedures; pricing, medicines regulations; and logistics management.

ii. Country visits for In-depth interview and discussions (based on the questionnaire developed) with key stakeholders to supplement information on collated data and also assess their knowledge on and political willingness and readiness to adopt regional pooled procurement. These included the Ministries of Health, Central or National Medical Stores, National Medicines Regulatory Authorities and any other relevant national or international institution or partner identified.

iii. Data presentation findings are made utilizing a) a modified SWOT analysis and b) feasibility matrix. These will feature the various elements identified as essential for the pooled procurement activity, highlighting the readiness of the member states in adopting pooled procurement and identifying their strengths and also the disparities or conflicting areas that might impede or become constraining factors towards pooled procurement.

iv. Draft Report - will highlight the preliminary findings and recommendations of the study, also indicating a roadmap (step wise approach) to implementing regional pooled procurement.

v. Stakeholders meetings - the preliminary findings will be shared during various stakeholders meeting, with the initial meeting of EAC health experts scheduled for 17th -19th September 2007 in Nairobi, Kenya. The recommendations will be incorporated into a revised report which will subsequently be submitted to the relevant policy organs of the EAC.

The main limitation of the study is the time available to conduct a study of this magnitude involving five countries (Kenya, Uganda, Tanzania, Rwanda and Burundi) representing six institutional structures (Tanzania Mainland and Zanzibar Islands) with two official languages (English & French). The study team had a limited time to collect and analyze the data and draft the findings. Therefore only a limited number of stakeholders could be interviewed during the country visits. However, it is envisaged that during the planned EAC Medicines Expert Meeting to present the findings, additional input and comments will be captured.

CHAPTER III: FINDINGS

A. POLITICAL AND ORGANISATIONAL COMMITMENT

INTRODUCTION

The level of political will and organizational commitment is critical to the success of multi-country pooled procurement. Four main ingredients are identified for the success of regional pooled procurement efforts:

- Political commitment from the highest level of Government
- Formal signed agreement
- Cohesion of the regional bloc
- Active participation of the member countries

1. REGIONAL LEVEL

As a regional economic bloc, the East African Community is established by the highest level of Government based on signed treaty. According to the EAC, the foundation for the EAC regional cooperation and integration is linked to their shared history, language, culture and infrastructure, and therefore is relatively cohesive.

The institutional framework of the EAC which is well-defined constitutes of i) The Summit comprising the heads of government of partner states which give general directions towards the goal and objectives of the Community; ii) The Council of Ministers, which is made up of ministers from the partner states responsible for regional cooperation and is the main decision-making institution; iii) The Coordinating Committee consisting of permanent secretaries is responsible for regional cooperation and coordinating of sectoral committees activities; iv) Sectoral Committees who conceptualise programmes and monitor their implementation; and v) The Secretariat which is the executive organ of the community. The indication therefore is that any regional programme endorsed by the various policy organs of the Community is assured of political commitment at the highest level.

In 2006, the EAC Development Strategy was reviewed to facilitate implementation and strengthen the areas of the decision-making process, roadmaps for implementation, enforcement and follow-up mechanisms, capacity-building and information-sharing and budgetary issues in the region.

1.1 Health strategy

The EAC Secretariat is currently focused on strengthening and expanding regional collaboration in the health sector, based on the mandate and scope of cooperation as outlined in Chapter 21, Article 118, and which identifies the following priority health activities:

- Take joint action towards the prevention and control of communicable and non-communicable diseases and to control pandemics and epidemics of communicable and vector-borne diseases such as HIV-AIDS, cholera, malaria, hepatitis and yellow fever that might endanger the health and welfare of the residents of the Partner States, and to co-operate in facilitating mass immunization and other public health community campaigns;
- Promote the management of health delivery systems and better planning mechanisms to enhance efficiency of health care services within the Partner States;
- Develop a common drug policy which would include establishing quality control capacities and good procurement practices;
- Harmonize drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the Community;
- Harmonize national health policies and regulations and promote the exchange of information on health issues in order to achieve quality health within the Community;

1.2 EAC activities in the health and pharmaceutical sectors

In stating their intention to adopt pooled procurement of essential medicines and medical supplies, the EAC Secretariat have demonstrated organizational commitment by identifying and /or initiating a number of activities that can be categorized broadly into the following areas:

✓ Harmonization of the National Medicines Regulations

- Development of draft protocol on the establishment of an EAC Food and Drugs Authority and also EAC Health Professional Authority
- Meetings of National Medicines Regulatory Authorities (NMRAs) on the Harmonization of Medicines Regulatory Activities, December 2005; August 2006, April 2007 and July 2007.
- The establishment of an EAC Pharmaceutical Program Office (2007)

✓ Harmonization of National Medicines Procurement systems and legislations

- Establishment of the EAC Regional Pooled Bulk Procurement Steering Committee.
- EAC Partner states and stakeholders meeting on pooled bulk procurement of HIV/AIDS medicines, November 2006; and submission of the recommendations on the HIV/AIDS meetings to the EAC Council of Ministers of Health in May 2007.
- Presentation of the EAC planned regional pooled procurement activities during the WHO Meeting on Multi-country Regional Pooled Procurement of Medicines, January 2007.

- ✓ Harmonization of National Health Services Delivery Systems
    - EAC Partner states and stakeholders meeting to review the 1st Draft of EAC HIV/AIDS Strategic Plan, 2006-2010, December 2006 and the approved Common EAC 1st line HIV/AIDS & TB treatment protocol/regimen (2005).

The EAC Secretariat is presently the driving force in putting the issue of pooled procurement on the agenda of the community. However, its major challenge is institutional capacity as its health desk is limited to one person, i.e. the health coordinator. Plans are underway to improve the capacity through the addition of a pharmaceutical officer to assist with the ongoing harmonization activities.

2. NATIONAL LEVEL

The five partner states are currently actively involved in the EAC programmes on harmonization of regulatory activities and pooled procurement issues, which underscores their active participation in the preliminary stages of regional pooled procurement. From the activities and initiatives being undertaken by the EAC in collaboration with several development partners, the indications are that the EAC member states are committed in theory to enter into negotiations and find a suitable model for pooled procurement. The harmonization efforts on national medicines regulations, national medicines procurement systems and legislation, and national health services delivery systems which are reported to be ongoing in the EAC, underscores the organizational commitment presently at regional and national level. These issues will be assessed in depth in subsequent sections.

The concept of pooled procurement is relatively well understood by the various stakeholders interviewed in all EAC countries. From the survey collected, the key informants interviewed at the Ministry of Health (MOH) stated that commitment at both national and regional levels would be critical and that additional efforts should be focused on building capacity and reinforcing information exchange systems, thus increased training is identified to be essential. It was also mentioned that heavy bureaucracy and weak institutional capacity would be among the challenges the EAC would have to face. All the countries believed the Ministries of Health should take up an advisory role, provide technical capacity, facilitate harmonisation steps and assist in resource mobilisation. The commitment of the MOH of all EAC member states will therefore be critical in ensuring the successful implementation of pooled procurement in the region.

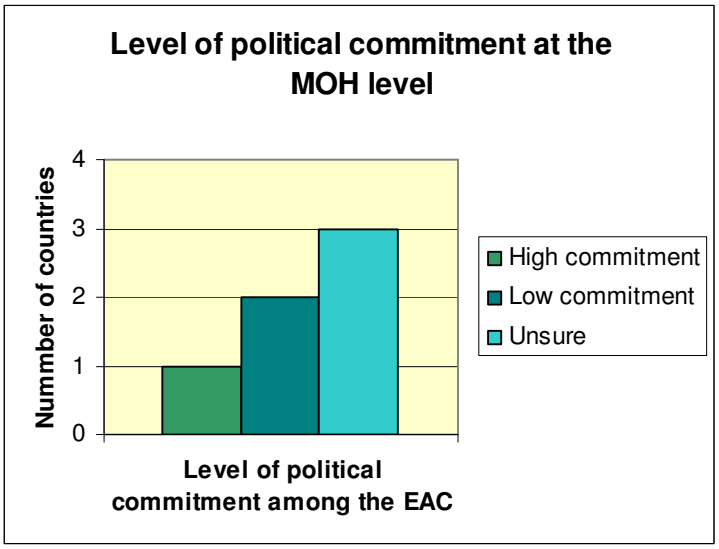
3. READINESS OF MEMBER STATES TO IMPLEMENT POOLED PROCUREMENT

To further assess the perception and / or readiness of key stakeholders on regional pooled procurement, the responses to specific questions asked as part of the country survey, are highlighted in Figure 16. Respondents were from the Ministries of Health; National Medical Stores and National Medicines Regulatory Authorities.

A. The question 'Is there a visible MOH level of **political commitment**?' resulted to only 17% (one country) responding yes, while the rest answered either no (33%) or not

sure. This underlines the need for advocacy and consultations to increase level of awareness in member states, which is essential for organizational commitment.

Figure 4.1: Indication of "Visible" Level of Political Commitment at MOH Level



B. The request to indicate the **potential benefits** expected from regional pooled procurement showed a high degree of similarities, with the following commonly identified

a) Price (increased negotiation power, economies of scale).
b) Quality of products through improved regional Quality Assurance system
c) Enhancement of Regional Cooperation through sharing of information / medicines: professional interaction, increased capacity)
d) Increased Affordability / Accessibility through better prices and strengthening of capacity in countries.
e) Harmonization / rationalization on treatment guidelines, use of medicines – facilitate selection and procurement within the sub-region.
f) More efficient and transparent procurement system through capacity building.

C. Likewise respondents shared their concerns by identifying **potential disadvantages** or problems envisaged with regional pooled procurement:

a) Problems related to harmonization of Procurement laws; Essential Medicines List; Taxes & tariffs;
b) Financing concerns with regards to budgets (limited amounts, disbursement problems); Individual / national agreements with donors & development partners;
c) Implementation issues linked to a centralized bureaucratic set-up; inadequate capacity at central level; problems of quantifications; level of commitment at national level, political influence.
d) Loss of power and authority for procuring agencies (medical stores); Loss of potential revenue (registration fees & import fees) for regulatory agencies

D. Respondents were asked to indicate the **pooled procurement model preferred** for adoption, and all selected the Group Contracting model. The rationale behind this choice, according to respondents, was that public sector procurement organizations perceive a lesser degree of loss of autonomy, budget authority, and decision-making because the procurement and, largely the financing function, is maintained at the national level.

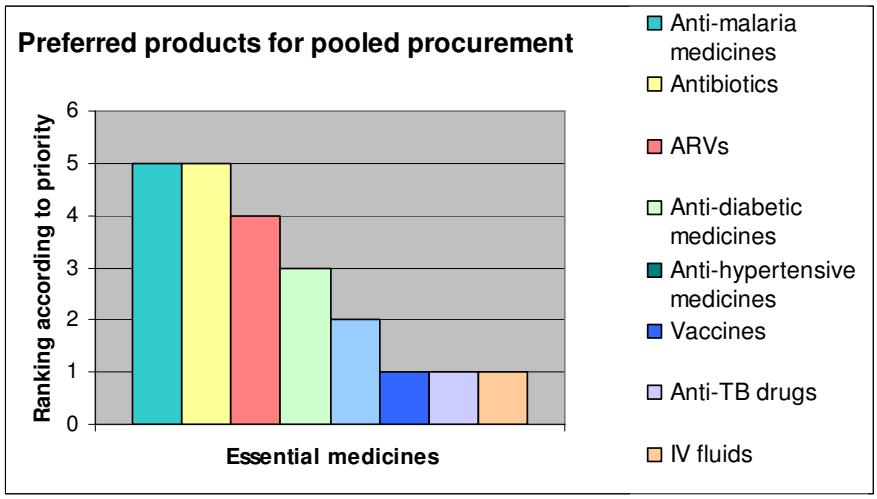
E. Respondents identified three main criteria that should be utilized for the **selection of pooled procurement products:**
i. Purchase valuation

ii. Common use in EAC partner states

iii. Health impact

F. Respondents further identified anti-malaria medicines (ACTs), antibiotics (including medicines for Opportunistic Infections) and anti-Retroviral (ARV) medicines as the **key products for bulk purchasing.**

Figure 4.3: Preferred products for Pooled Procurement



CHAPTER III: FINDINGS

B. PROCUREMENT LEGISLATION AND POLICIES

INTRODUCTION

Public procurement of pharmaceuticals and other medical supplies are generally governed by national laws and regulations. The basis for Good Pharmaceutical Procurement Practice is well-defined in procurement legislation, regulations and procedures. National procurement legislations might therefore impact regional pooled procurement activities, especially with Group Contracting, where the actual purchasing is done at country level. The review of the procurement legislations and policies in the partner states focuses on two main areas:

- An overview of the procurement legislative framework and institutional organization in the member countries
- A comparative assessment of these legislations and how they might impact on regional pooled procurement.

1. OVERVIEW OF PUBLIC PROCUREMENT LEGISLATIONS AND REGULATIONS

1.1 Public Procurement Laws

Four of the five EAC member states, i.e. Uganda, Tanzania, Kenya and Rwanda, have during the last five years enacted new procurement legislations. Burundi is the only country without current procurement legislation.

i. Uganda - The Procurement and Disposal of Public Assets Act, 2003

The Public Procurement and Disposal of Public Assets Act of 2003 was officially published on 17th January 2003 on The Uganda Gazette No. 3, Volume XCVII. It is in eight sections arraigned in 99 articles outlining the application of the act; the institutional arrangements; the devolvement of responsibilities to procuring and disposing entities; the basic principles of procurement and disposal; rules and regulations of public procurement; the various methods of procurement; administrative review; code of conduct, penalties and offences. This Act repealed the Public Finance Procurement Regulations.

ii. United Republic of Tanzania

a. Mainland Tanzania - The Public Procurement Act, 2004

In mainland Tanzania, the Public Procurement Act of 2004 was officially published on 11th February 2005 on The Tanzania Gazette No. 6, Volume 86. The eight sections are arranged in 91 articles outlining the application of the act; the institutional arrangements; the devolvement of responsibilities to the tender boards; the basic principles of procurement; the methods of procurement; unacceptable actions in procurement proceedings and measures for action: dispute settlement; code of conduct, offences and penalties. The Public Procurement Act of 2001 was repealed.

b. Zanzibar - The Public Procurement and Disposal of Assets Act, 2005

The Zanzibar Public Procurement and Disposal of Public Assets Act, which was enacted in 2005, is arranged in six sections comprising 53 articles. It deals with the application of the act; the institutional framework; the basic rules of procurement and disposal; methods of procurement; unacceptable conducts in procurement proceedings, penalties and code of conducts; the establishment of evaluation committee, arbitration and judicial review in disputes. The Central Tender Board Act No 5 of 2002 was repealed.

iii. Kenya - The Public Procurement and Disposal Act, 2005

The Kenya Public Procurement and Disposal Act of 2005 is arraigned in eleven sections of 141 articles. The procurement legislation outlined the purpose of the act; the institutional arrangements; the devolvement of responsibilities; general procurement rules; the method of open tender; alternative procurement procedures; right to review and judicial review; powers of the Authority; disposal of stores and equipment; offences and penalties.

iv. Rwanda - Law on Public Procurement, 2007

The Law on Public Procurement of Rwanda was officially gazetted on 15th April 2007 on the Rwanda Gazette, Year 46, No 8 arranged in 6 chapters of 181 articles. It outlined the general provision of the law; institutional arrangements; procurement methods; the right to review; procedures and guidelines for contract review; and penalties for offences and breach of public
procurement rules. The Royal Decree of February 25th 1959 on tenders is repealed.

v. Burundi

There is currently no public procurement legislation in existence in Burundi. However, the National Medical Store (CAMEBU) is obligated to procure medicines and other medical supplies using the International competitive Bidding (ICB) method. The procurement process is regulated by the Director General of Public Markets, and a sub-committee is established for the technical evaluation of bids.

1.2 Public Procurement Authorities

The enactment of the procurement legislations in the various member states resulted in the establishment of regulatory bodies assigned with the responsibility of ensuring that the public procurement laws are adhered to. These regulatory bodies had generally replaced the central or national tender boards of their respective countries.

i. **Uganda** - The Public Procurement and Disposal of Assets Authority (PPDA) was established as a body corporate in 2003. Its main functions are reported to be a) advisory - providing the various tools for conducting public procurement and compliance with the law; b) data management - developing a system of managing data on all public procurement; c) capacity building - developing procurement capacity through training and support; and d) audit - auditing the bidding process, award and execution of contracts. The PPDA currently has six departments, 1) Executive Director and Corporate Office, 2) Finance and Administration Department, 3) Internal Audit Department, 4) Legal and Compliance Department, 5) Training and Capacity building and 6) Audit and Investigations department.

ii. **The United Republic of Tanzania**

a. Mainland Tanzania - The Public Procurement Regulatory Authority (PPRA) was established under the Public Procurement Act of 2004 to regulate public procurement in Tanzania. Their vision statement is "to become a model Procurement Oversight Body with highly trained, competent and dedicated personnel working in unison towards improving and promoting procurement practices which offers value for money to the Public". Apart from the office of the Chief Executive Officer, internal audit unit, procurement management unit and legal unit, the PPRA has the following divisions: 1) Finance and Administration, 2) Capacity Building and Advisory Services, 3) Monitoring and Compliance and 4) Information Technology.

b. Zanzibar - The Revolutionary Government of Zanzibar established a Department of Stock Verification and Procurement Services under the Ministry of Finance, assigned with the responsibility of regulating public procurement.

iii. **Kenya** - The Public Procurement Oversight Authority (PPOA) is a public body established under the 2005 Public Procurement law. It is mandated with the following responsibilities: i. ensuring that procurement procedures established under the Act are complied with; ii. monitoring the procurement system and reporting on its overall functioning; iii. assisting in the implementation and operation of the public procurement system by preparing and distributing manuals and standard tender documents, providing advice and assistance to procuring entities, and to develop, promote and support training and professional development of staff involved in procurement; and iv. initiate public procurement policy.

iv. **Rwanda** is currently in the process of establishing its regulatory body. The Rwanda Bill on functions and responsibilities of the Rwanda Public Procurement Authority (RPPA) was reportedly passed by the Chamber of Deputies in July 2007 (ref. allAfrica.com). The duties of the RPPA are expected to include the collection and dissemination of procurement information, preparation of standard tender documents for use by procuring entities and organize public awareness campaigns on matters related to public procurement. In addition, it is reported that the PPRA will be empowered to suspend any procurement proceedings or award of tenders, if suspected or reported of misconduct.

v. **Burundi**'s procurement system is regulated by the Director General of Public Markets. However, its mandate and responsibilities are not clearly defined.

2. COMPARATIVE ASSESSMENT OF PUBLIC PROCUREMENT LEGISLATIONS

The procurement legislations of Uganda, Kenya, Tanzania and Rwanda were all enacted during the past five years. The rationale behind the new public procurement legislations were basically to fight corruption, increase transparency and efficiency in procurement procedures and award of contracts, and accordingly build on public confidence. The development and implementation of these acts were partly donor driven with support from development partners and international organizations.

The procurement legislations of the respective member states can be described as generic versions of an international procurement law model, namely the United Nations Commission on International Trade Law (UNCITRAL). The procurement legislation generally provides guidelines and procedures for an efficient and transparent procurement system based on a decentralized purchasing mechanism and regulated by a central authority. It further provides detailed guidelines on how to conduct public procurement using standardized bidding documents. The pre-requisite checks and balances is assured through the delineation of functions and responsibilities for conducting public procurement. The institutional framework for the enforcement of the procurement legislation is well-defined through the establishment of regulatory bodies functioning on a system of auditing and reporting of activities. The legislation also provides a procedural system of dealing with complaints and disputes, as well as measures for disciplinary actions or penalties.

A comparative analysis of the procurement laws mainly focuses on all the countries with the exception of Burundi, unless otherwise specified. The analysis further focuses on the elements that could impact pooled procurement of pharmaceuticals and other medical supplies. The legal implications and ramifications for harmonization are not considered in this section and are expected to be dealt with by EAC legal experts in due course.

Similarities and Differences

1. Objectives and Principles for Public Procurement

The objectives and principles of the various procurement laws are similarly related to:

- Ensuring transparency & accountability
- Ensuring fairness and competition
- Achieving economy & efficiency
- Getting value for money

2. Institutional Framework

The various legislations made provision for the establishment of a regulatory or oversight body assigned with the overall mandate of ensuring adherence and compliance to the public procurement legislation. The institutional arrangements are similar with the establishment of the main regulatory institution either as body corporate or department, with an oversight board or ministry.

The functions of the regulatory bodies, i.e. Uganda Public Procurement and Disposal of Assets Authority (PPDA), Tanzania Public Procurement Regulatory Authority (PPRA), Kenya Public Procurement Oversight Authority (PPOA) and Rwanda Public Procurement Authority (RPPA) and Zanzibar Department of Stock Verification and Public Procurement are similar and are related to ensuring adherence and compliance to the public procurement laws. These oversight bodies are responsible to standardize bidding documents, monitor the procurement processes, audit the procurement procedures and execution of contract, collate the data and information on public procurement activities and assist in procurement capacity building.

The devolvement of public procurement responsibilities and activities in a decentralized manner is also similar in all these countries. This has resulted to the establishment of procuring entities or tender committees / board, which in most case include a procurement unit, an evaluation and /or contracts committee, and an accounting or chief executive officer assigned with distinct functions and responsibilities of conducting public procurement within a User Department.

3. Procurement methods & procedures

The basic principles and procedures of procurement and the various procurement methods are similarly defined in the procurement legislations. All the countries, including Burundi, identified open competitive bidding (domestic or international) as the main choice of public procurement. The other methods of procurement such as restricted tender, quotation or direct procurement are also identified as alternative methods based on specified conditions and requirements, and in some cases linked to financial thresholds.

4. Language

There is a common language as English is selected as an acceptable language for use in international bidding / tendering process for the four of the five EAC countries. Rwanda identifies both French and English for bidding whereas Burundi indicates French only for their bidding documents. However with the expansion of the EAC membership, the Community now has two official languages, English and French, and thus will be able to harmonize the issue of languages in official documents.

5. Currency

In all the five EAC countries, foreign currencies are acceptable as the means of financial transactions.

6. Transparency

The need for transparency is further emphasized throughout procurement procedures outlined in the respective procurement laws and regulations. The establishment of bodies to deal with complaints and settle disputes further provides the bidder with the opportunity and the right to call for review any procurement procedure or award of contract. Data and information on procurement activities collated by the various oversight agencies are to be made available to the public.

7. Accountability

In the bid to ensure accountability in public procurement, the countries identified similar actions such as fraud, corruption and other unacceptable conducts influencing public officers etc. as prohibitions and offences, with subsequent penalties. Code of conduct for officers and agents are also defined.

Similarly, providers / suppliers / bidders can be suspended / blacklisted / debarred from engaging in public procurement activities for a period of time according to the legislations of Uganda, Tanzania, Kenya and Rwanda.

8. National / Local preferences

The four countries, i.e. Uganda, Tanzania, Kenya and Rwanda, identified the need to provide certain concessions or a margin of preference to local or national bidding entities. For Tanzania and Kenya, the legislation further specifies goods manufactured, mined, extracted or grown in the country which can therefore be related to local production of pharmaceuticals. Rwanda, on the other hand, extends the local preference clause to companies registered in Rwanda or to Rwandan nationals or bidders in regional economic integration bodies or member states. Uganda procurement regulation, which linked the use of a preference scheme with the main objective of developing local business, allows its application in all competitive procurement methods.

9. Pre-qualification of suppliers

The four countries made similar provisions in their legislations for the application of the pre-qualification of suppliers in their procurement proceedings. Zanzibar procurement legislation made no mention of this.

10. International obligations

In cognizance of the fact that there might be potential conflicts between national laws and international obligations, there are differences in the procurement legislations on how to deal with such conflicts.

a. For Uganda and Tanzania, International obligation prevails over the national legislation.

- Uganda procurement law states "where this Act conflicts with an obligation of the Republic of Uganda arising out of an agreement with one or more states, or with an international organization, the provisions of the agreement shall prevail over this Act".
- Tanzania procurement law states " To the extent that this Act conflicts with an obligation of the United Republic under or arising out of any treaty or other form of agreement to which the United Republic is a party with one or more other states or political sub-divisions of such states, the requirement of such treaty or agreement

shall prevail, but in all other respects, the procurement shall be governed by this Act".

b. For Kenya, the national law prevails as stated "Where any provisions of this Act conflicts with any obligations of the Republic of Kenya arising from a treaty or other agreement to which Kenya is a party, this Act shall prevail, except in instances of negotiated grants or loans".

c. Rwanda and Zanzibar – their respective legislation is silent on this issue.

11. Third party procurement or procuring agents

Kenya, Uganda and Tanzania made provisions for the engagement or appointment of third party procurement services, especially in situations where there is lack of technical capacity. The selection of such agents must be in accordance to the guidelines of their respective authorities. Rwanda & Zanzibar made no mention of this issue in their respective legislations.

3. PROCUREMENT HARMONIZATION ISSUES

As the current procurement legislations in the EAC member countries are all based on international procurement guidelines, they share a common procurement legislation, policy and institutional framework as reflected on the comparative analysis table. There are certain areas that might be of relevance in regional pooled procurement and would require harmonization. So far, the indications are that the proposed plan for harmonization of procurement policies and the establishment of a regional pooled bulk procurement steering committee has not yet taken off the ground.

In the survey conducted, respondents confirmed their awareness of the existence of procurement legislation and the role of the public procurement agencies to regulate the procurement of pharmaceuticals and other medical supplies in the respective countries. Four of the six respondents (Tanzania including Zanzibar, Kenya and Burundi) felt that their countries procurement legislations could not limit pooled procurement, whiles Uganda felt that problems of harmonizing the policies might pose a problem.

Additionally, it was reported that Rwanda Central Medical Stores (CAMERWA) enjoys special provisions for procurement of medicines as it is exempted from the public procurement regulations. Uganda reported that existing public sector procurement laws and/or regulations would have to be revised to allow the flow of funds for pooled procurement. These considerations are mainly related to existing procurement guidelines that call for strict adherence to competitive bidding in purchases exceeding certain minimal levels. As competitive bidding will no doubt be the method used by any proposed pooled procurement mechanism, any regional purchasing system would therefore be consistent with existing country procurement guidelines. Further, these considerations may actually indicate strong regulatory environment governing public sector procurement and should not necessarily be viewed as potential barriers to a regional purchasing system.

Harmonizing the respective procurement laws and regulations and creating awareness were the main recommendations given on resolving legislative and regulatory problems. Certain areas that might require harmonization includes the following:

ELEMENTS OF PROCUREMENT SYSTEM	Uganda	Kenya	United Republic of Tanzania Mainland Tanzania	United Republic of Tanzania Zanzibar	Rwanda	Burundi

- The issue of national procurement laws and the partner countries international obligations to regional pooled procurement as there is currently no EAC regional procurement legislation.

- Regional pooled procurement which can be regarded as third party procurement is not recognized by all partner states.

- It is reported from the survey that even though local or national preferences is indicated in the various laws and regulations, it is currently being mainly practiced in two member states, i.e. Kenya and Tanzania, with a 15% margin being provided. It is presently not applicable in Rwanda and Zanzibar, while Uganda reported that the main challenge to implementation is the limited availability of products from local manufacturers. The issue of national preference can be considered either as a challenge / constraint to pooled procurement or a potential area for harmonization and pooling of resources and capacity.

Customs and Tariffs Policies

Custom duties and taxes are not levied on pharmaceuticals procured by the public sector in Uganda, Tanzania, Zanzibar, Kenya and Rwanda and thus does not have any impact of national procurement or potential regional pooled procurement. Burundi on the hand reported that a 5.5% tax is levied on essential medicines, medical supplies and laboratory supplies while vaccines, contraceptives and condoms are exempted. Furthermore, the tax is exempted when procured with external funds. With the establishment of an EAC Customs Union in 2005, it is envisaged that all customs and tariff issues would be resolved as part of the harmonization process.

Legislative Framework	The Public Procurement and Disposal of Public Assets Act, 2003	The Public Procurement and Disposal Act, 2005	The Public Procurement Act, 2004	The Public Procurement and Disposal of Assets Act, 2005	The Public Procurement and Disposal Act, 2005	Not applicable
Institutional Framework	- Public Procurement and Disposal of Assets Authority	Public Procurement Oversight Authority	Public Procurement Regulatory Authority	Department of Stock Verification & Procurement	Rwanda Public Procurement Authority (RPPA)	Director General of Public Markets

	(PPDA) -	(PPOA)	(PPRA)	Services		
Procurement Entities	Procurement & Disposal Unit	Procurement Unit	Tender Board	Tender Board	Procurement Unit	CAMEBRU
Preferred Procurement methods	Open bidding	Open tender	Open Competitive bidding	Open tender	Open domestic / international bidding	International Competitive Bidding
Language for bidding	English	English	English	English	English /French	French
International Obligations	International Obligation prevails	National Legislation prevails	International Obligation prevails	Not Applicable	Not Applicable	
Pre-Qualification of Suppliers / bidders	Acceptable	Acceptable	Acceptable	Not Applicable	Accepted	
Preferential Treatment for Local / National Bidders	Acceptable – not being implemented	Acceptable, and being implemented	Acceptable, and being implemented	Not Applicable	Acceptable, not being implemented	
Third Party Procurement	Acceptable	Acceptable	Acceptable	Not Applicable	Not Applicable	
Administrative Review (Settlement of complaints & disputes)	Yes	Yes	Yes	Yes	Yes	
Penalties for Offences	Yes	Yes	Yes	Yes	Yes	

CHAPTER III: FINDINGS

C. MEDICINES REGULATORY PROCEDURES

INTRODUCTION

Ensuring the safety, efficacy and quality of medicines is based on an effective regulatory control on the manufacture, export, import and distribution of medicines by National Medicines Regulatory Authorities (NMRAs). With the increasing need to coordinate medicines regulations in order to facilitate the movement of pharmaceutical goods within the EAC bloc, the regulatory procedures for the import and registration of medicines are identified as important factors to regional pooled procurement. Harmonization of these activities, which are essential for development of a standard list of medicines and the free movement of these products within the region are the focus of this section.

1. LEGISLATIVE FRAMEWORK & INSTITUTIONAL ORGANIZATION

Medicines legislations in various partner states provide the institutional framework for the National Medicines Regulatory Authorities (NMRAs) and regulatory mechanism for the control of medicines.

- The Tanzania Food and Drugs Authority (TFDA) was established as a semi-autonomous institution under the Ministry of Health by the Tanzania Food, Drugs and Cosmetics Act, No 1, 2003. Its main function is to regulate the quality, safety and effectiveness of food, medicines, herbal medicines, cosmetics and medical devices. The TFDA activities include product evaluation & registration and the control on import and export of products. The Zanzibar Food and Drugs Act No.2 of 2006 established the Food and Drugs Board in 2007 for the registration of medicines and ensuring the quality control of products.

- The Drug Regulatory Authority of Kenya, which is the Pharmacy and Poisons Board (PPB), was established under the Pharmacy & Poisons Act, 1957, Chapter 244 of the Law of Kenya. After a number of legislative amendments, the PPB was established as a body corporate with responsibilities including the registration of products and the control of the import, export and manufacture of medicines.

- The National Drug Authority (NDA) of Uganda was established by the Uganda Government Statute No 13 of 1993 for regulation on manufacture, import and export of medicines including product registration.

- The current pharmaceutical legislation in Rwanda was enacted in 1999, with the Medicines Regulatory Authority as part of the Ministry of Health. In January 2006, Rwanda started the transformation process for an autonomous Medicines Agency, to be responsible for inspection of pharmacies, medicines registration, quality control laboratory etc.

- Burundi's 1980 legislations on regulating the pharmaceutical sector is reported to be outdated and is currently being revised. The Department of Pharmacy, Medication and Laboratories (DPML) was established in 2002 to regulate the pharmaceutical practice and ensure the quality of medicines etc.

2. COMPARATIVE ANALYSIS OF REGULATORY SYSTEM AND PROCEDURES

Uganda and Tanzania share similar institutional framework with the establishment of independent National Medicines Regulatory Agencies. Quality Assurance of medicines is an inherent responsibility of NMRA. The National Drug Quality Control Laboratories are part of the Uganda and Tanzania NMRA. The Kenya NMRA is supposed be a body corporate, but is still a department under the Ministry of Health. Furthermore, the National Drug Quality Control Laboratory is established as a separate institution operating independently of the Kenya Pharmacy and Poisons Board. Zanzibar Food and Drugs Board is established as a semi-autonomous structure under the Ministry of Health, and depends on a separate government laboratory facility for drug quality control. Rwanda and Burundi are in the process of organizing their regulatory systems and processes.

Kenya, Uganda and Tanzania share a similar regulatory system, whereby registration of medicines for both manufactured and imported products is mandatory. Currently, there is no registration of medicines in Rwanda, whereas Burundi is still in the process of re-structuring its registration procedures to cover all products.

The survey conducted identified certain similarities but also differences on registration processes and procedures:

1. Special registration (fast tracking) procedures are in place for: a) ARV medicines in Uganda; b) HIV/AIDS, TB, Malaria, products for public health concern, local manufacturers and orphan drugs in Tanzania mainland; c) HIV / AIDS in Zanzibar; and d) HIV/AIDS, malaria & TB in Kenya.

2. The registration status of products in other EAC member countries is not factored in the registration process of individual country's NMRA. Zanzibar on the other hand, automatically registers medicines already approved by its counterpart in mainland Tanzania.

3. Sharing of information on quality of products with other NMRA within the sub-region is limited. Uganda cites the WHO hosted web-based shared point for the EAC as means of sharing information. Tanzania indicates that there is no formal way of sharing information, and Kenya only shares information upon request or following complaints. Rwanda and Burundi reported that there is no sharing of information.

4. Apart from Rwanda and Burundi whose medicines registration process are not yet fully operational, the current registration systems and Standard Operating Procedures in Tanzania, Uganda and Kenya might be limiting factors on regional pooled procurement of medicines.

3. CURRENT HARMONIZATION ACTIVITIES

One of the priority health activities identified within the scope and mandate of the EAC cooperation is the harmonization of medicines registration to attain good control of pharmaceutical standards within the community. The formation of an EAC Custom Union in 2005 provided the impetus for the harmonization of medicines regulatory systems in the then three EAC partner states. A series of activities were accordingly implemented and the EAC Secretariat also held a series of meetings to assess the progress made on the harmonization of medicines regulations in the partner states as outline below. It is important to note that prior to their formal accession to the EAC, Rwanda and Burundi participated in some of these meeting with Observer status.

- 12th -15th December 2005, Kampala, Uganda - A situational analysis conducted on the regulatory status in Uganda, Tanzania and Kenya was submitted and reviewed. A three year plan of action and budget for harmonization was developed and subsequently submitted for funding. This meeting also facilitated the establishment of the Technical Working Groups (TWGs) on a) Administrative aspects, b) Quality, Safety & Efficiency, c) Good Manufacturing Practices and d) Veterinary medicines, each of which would be responsible for a number of harmonization activities according to a specific time frame.
- 14th -16th August 2006, Nairobi, Kenya - This meeting was to further discuss the developed harmonization plan, the draft Terms of Reference for the Technical Working Groups, modalities of establishment and working procedures for the TWGs. Zanzibar, Rwanda and Burundi also presented country reports on the situation analysis of medicines regulations.
- 11th -13th April 2007, Arusha, Tanzania - Progress on the Technical Working Groups (TWGs) harmonization activities were reported, assessment report on the Zanzibar Food and Drugs Board submitted and the Plan of Action for the 2007 EC/ WHO funded activities discussed and adopted. The Inception report of EAC situational analysis and feasibility study on pooled procurement was presented, discussed and endorsed. One key issue that was discussed was the linking of pooled procurement to medicines policies and regulations. The operationalization of the EAC Pharmaceutical Programme Office was finalized with the priority areas of work for the 2008 -2009 biennium identified.

The EAC 2007 Plan of Action, which is currently being implemented with technical assistance from WHO and financial support from the European Community includes:

1. Capacity building:

- Regional training of EAC National Medicines Regulatory Authorities on WHO prequalification guidelines and assessment dossiers.

- Training of local pharmaceutical manufacturers and NMRA/GMP inspectors on WHO GMP guidelines.

2. Regulatory Harmonization

- Support Technical Working Groups to review existing guidelines on medicines regulatory activities, i.e. GMP, registration of medicines and medicines schedules.

3. Regional training centres

- Regional training to develop pre- & in-service curriculum for medicines regulations and quality control
- Finalization and printing of regional pharmacy curriculum

4. Rational Use of Medicines

- Regional workshop to develop communication strategy to guide social mobilization and advocacy for effective use of medicines.

The National Medicines Regulatory Authorities has identified their similarities, differences and gaps, defined the areas of harmonization and initiated the process. Activities at this stage included for instance developing a medicine schedule, a code of conduct for the staff; registering veterinary medicines; conducting clinical trials; pharmaco-vigilance; monitoring counterfeit medicines and developing a website to facilitate information exchange, which are reported to be in the process of being either reviewed or implemented.

Despite the progress reported in the harmonization process, the critical regulatory elements of medicines registration for product importation are yet to be finalized and therefore still remain as a barrier to regional pooled procurement.

Table 3.2: Comparative analysis of medicines regulation

ELEMENTS OF MEDICINES REGULATION	Uganda	Kenya	United Republic of Tanzania Mainland	United Republic of Tanzania Zanzibar	Rwanda	Burundi
Medicines Legislation	National Drug Policy & Authority, 2003	Pharmacy & Poisons Act, 1957 & amendments	Tanzania Food, drugs & Cosmetic Act, 2003	Zanzibar Food & Drugs Act, 2006	Pharmaceutical Legislation, 1999	Pharmacists Legislation, 1980 (under revision)
Medicines Regulatory Authority	National Drug Authority (NDA) 1993	Pharmacy & Poisons Board (PBB) 1957	Tanzania Food & Drugs Board (TFDA) 2003	Zanzibar Food & Drugs Board (ZFDA) 2007	Ministry of Health	Department of Pharmacy, Medication and Laboratories (DPML), 2002
Main activities	1.Medicines Assessment & Registration 2. Inspection 3. Medicines Information 4. Quality Control & Assurance	1.Medicines Registration 2. Pharmaceutical Inspection 3. Medicines Information 4. Training and Assessment	1. Product Evaluation and Registration 2. Inspection and Surveillance 3. Laboratory Services 4. Licensing	1. Medicines Registration 2. Inspection and Licensing 3. Quality Control	1. Licensing 2. Inspection 3. Pharmaceutical Information	1. regulate pharmaceutical practice and laboratories 2.Ensure the respect of quality norms of medicines

Sources of funding	a. Registration & licensing fees - major source b. Govt. subvention - minimal c. Donor support or loan form financial institutions	a. Registration and licensing fees - main source b. Govt. pays salaries	a. Revenue from registration and licensing fees - major source b. Govt. subvention	a. Govt. pays salaries b. Revenue from licensing, penalties & importation fees c. Donor support	a. Govt. funding	a. Govt. funding b. Registration & import authorization fees c. Donor support
ELEMENTS OF MEDICINES REGULATION	**Uganda**	**Kenya**	**United Republic of Tanzania** **Mainland**	**United Republic of Tanzania** **Zanzibar**	**Rwanda**	**Burundi**
Are all categories of medicines required to be registered?	Yes	Yes	Yes	Yes, but accepted if already registered by TFDA.	n/a	Yes, but registration process being re-structured to cover all products
Quality control tests	Yes	Yes	Yes	Yes (TFDA)	No - Uses external	No - uses external

by NMRA laboratory					laboratories	laboratories
Sharing of information quality of products within other NMRAs within sub-region	Yes - through EAC web-based shared point for regulators (WHO)	No - not formally	Yes	Yes, but only on request or following complaints	No	No
Registration requirement for importation of product including pooled procurement	Yes, Current registration process, SOPs on importation and GMP inspection	Yes, registration requirement for tendering	Yes, Current registration requirement for floating of tender	No	n/a	n/a
EAC harmonization activities on medicines registration	Yes -	Yes	Yes	Yes	No	No

CHAPTER III: FINDINGS

D. MEDICINES SUPPLY CHAIN SYSTEM

INTRODUCTION

The medicine supply chain deals with the components of pharmaceutical management, (e.g., selection, procurement, storage, distribution, and use of medicines and supplies). The current status of these systems will be a defining factor in the selection of an appropriate model of pooled procurement and the speed of implementation. The current status of this system will be a defining factor in the selection of an appropriate model of pooled procurement and the speed of implementation. Supply chain efficiency is a major determinant of availability and affordability of quality medicines and supplies.

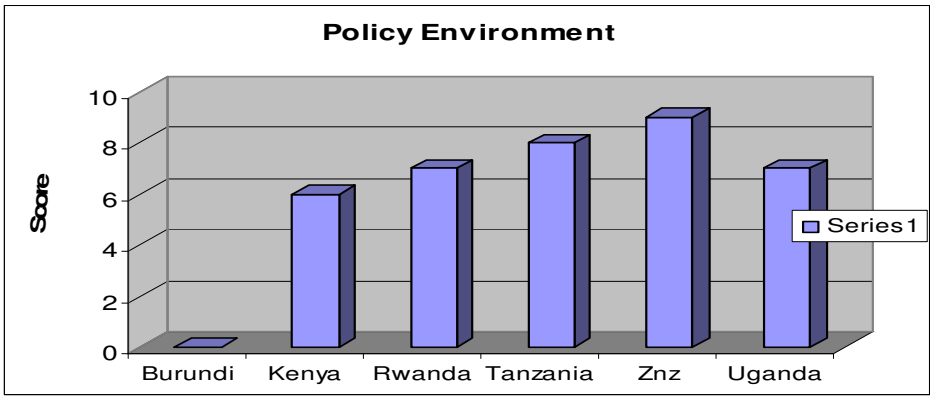
1. NATIONAL MEDICINES POLICIES (NMP)

National Medicines Policies determine the strategic and operational environment of the pharmaceutical sector by providing a guiding framework for the attainment of goals set for an effective and efficient pharmaceutical sector. Essentially, the overarching goal is to ensure that good quality, safe and efficacious essential medicines are available to and affordable by the population. The policy therefore outlines how activities will be coordinated by government and other stakeholders (i.e. public, non-governmental, private and funding partners).

Kenya, Uganda and Tanzania developed their first National Medicines Policies in the early 90's. Uganda reviewed its NMP in 2002, but is currently reported to be outdated, while Kenya and Tanzania are currently reviewing with the new documents expected by end of 2007. Both Rwanda (2005) and Burundi have a draft document at different stages of readiness towards cabinet ratification and adoption. Thus all the countries except Zanzibar, 2006, currently have an older and/or a draft policy document.

The main components of the NMP were selected as the following: 1) legislative/regulatory, 2) supply chain (selection, procurement, distribution, appropriate use), 3) financing and resource mobilization, 4) medicines pricing policy, 5) local production, 6) traditional medicines, 7) research development, 8) monitoring and evaluation, 9) local and regional collaboration and 10) international trade/WTO agreements/patents. These elements each scored 1 point to indicate the inclusiveness of the various country's medicines policies with regards to the essential components of a medicine policy (Figure 3 below). This may serve as a proxy indicator of how enabling the policy environment is. The rating allotted one point each for inclusion of "international trade" and regional/international collaboration.

Figure 3.1: The policy environment in the EAC



The principle elements of the policies are comparable, with the main difference arising out of the disparity in the implementation capacity of the pharmaceutical sector of each country. Implementation of the NMP is the responsibility of the Division/Department of Pharmacy through the office of the principal/chief pharmacist at the Ministry of Health. Strategic or master plans for the effective implementation and Monitoring and Evaluation plans for these revised policies will be developed immediately after the policies are ratified.

2. NATIONAL ESSENTIAL MEDICINES LISTS

All the five countries in the survey have national Essential Medicines List (EML), although Burundi's is not fully implemented. The EML are primarily derived from National Standard Treatment Guidelines (STG) and/or the disease-specific treatment protocols for the major health conditions. All the EML were developed or revised between 2001 and 2007. Because they are based on the treatment guidelines, a change in treatment protocols may not be immediately reflected on the EML, but the products will nevertheless be treated as Essential Medicines (e.g. Arthemisinin-based Combination Therapies (ACTs) do not currently feature on many of the EML, but are essential medicines in each of the countries (See Table 3.3). The Essential Medicines List, by legislation and procurement regulation, is the basis for procurement and therefore products selected for pooled procurement would be drawn from the active Essential Medicines List.

Table 3.3: Essential Medicines List (EML) & Standard Treatment Guidelines (STGs)

Country	EML	Year Pub.	HIV/AIDS STGs	Year Pub.	TB STGs	Year Pub.	Malaria STGs	Year Pub.
Burundi	√	2005	√	2007	√	2005	√	2007
Kenya	√	2003	√	2006	√	2006	√	2006
Rwanda	√	2005	√	2007	√	2007	√	2007
Tanzania	√	2007	√	2006	√	2003	√	2006
Zanzibar	√	2007	√	2006	√	2006	√	2006
Uganda	√	2001	√	2005	√	2005	√	2006

In the five EAC countries reviewed, the revision of the EML is conducted on an ad hoc basis by a committee appointed by the MOH, with the exception of Tanzania, which have an active National Pharmacy and Therapeutics Committee to undertake the task. The vertical programs are generally included in the selection committee. At the time of the survey, two countries, Uganda and Kenya were at different stages of reviewing the national STG and EML.

To date, there has been no attempt to harmonize the Essential Medicines List of the partner states of the EAC. From the survey, only eleven (11) essential medicines drawn from the 50 highest value products procured by the public sector, (other than ARV, Anti-TB and anti-malarials) are on the EML in the same formulation and strength in at least 3 countries (60%), including Zanzibar.

Table 3.4: Procured by EAC member-states and on national EMLs

Product	Formulation and Strength
Acetylsalicylic Acid	300mg Caps
Amoxicillin	250mg Caps
Amoxicillin	125mg/5ml Syrup
Chloramphenicol	250 mg Caps
Chloramphenicol	1 g injection vial
Co-Trimoxazole	480mg Tablets
Erythromycin	250mg Tablets
Metronidazole	200mg Tablets
Oral Rehydration Salts	27.9 g (Sachet) for 1Lt
Paracetamol	500mg Tablets
Quinine Sulphate	300 mg Tablets

3. STANDARD TREATMENT GUIDELINES (Malaria, HIV/AIDS, TB).

Before the accession of Rwanda and Burundi into the EAC, the countries of Kenya, Uganda and Tanzania approved a common 1st and 2nd line HIV/AIDS&TB treatment protocol, which is an important step towards harmonizing standard treatment guidelines.

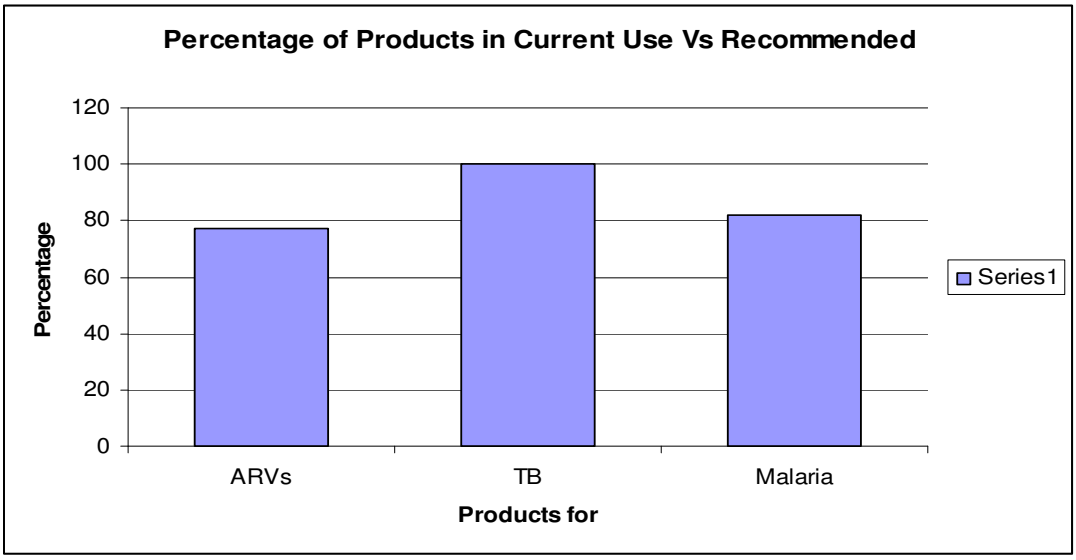
A comparative analysis and subsequent recommendations on harmonization of Standard Treatment Guidelines for HIV/AIDS, TB and malaria was carried out in 2006 and updated in 2007 for East Central and Southern Africa (ECSA) countries[3] (NB: in the study, Burundi was included only in the analysis for the treatment of Malaria).

The harmonized guideline reflects the similarity of treatment protocols for the three major disease conditions in the five EAC partner states as all the products in current use are on the recommended list. For example,

[3] Guideline for the Management of HIV&AIDS, TB and Malaria for ECSA; 2007: *Siika A.M., Wangai M.;Kirika R.; Thuo M.*

- 1st Line treatment of HIV/AIDS in adults and adolescents, for children, for the Prevention of Mother To Child Transmission (PMTCT) and for Post- Exposure Prophylaxis (PEP) comprises five products (Stavudine -D4T, Lamivudine -3TC, Nevirapine-NVP, Efavirenz-EFV and Zidovudine-AZT) in different combinations and strengths. The recommendations from the harmonized guideline include the above plus an additional four products, mainly for substitution of single items. i.e. ten chemical entities are in use and thirteen are recommended for the harmonized protocol.
- For TB, five products are in use currently (Streptomycin, Rifampicin, Isoniazid, Pyrazinamide and Ethambutol [S, R,H,Z,E]).and the same are recommended in the harmonized guideline.
- For Malaria, five products are in use for treatment of uncomplicated, severe/treatment failure and intermittent preventive therapy, namely, ACTs, (principally Artemether & Lumefantrine combination), Quinine, Amodiaquine, Sulfadixine / Pyrimethamine for P Falciparum, and, Chloroquine for P.Vivax.

Figure 3.2: Percentage of Products in Current Use vs Recommended



4. NATIONAL (CENTRAL) MEDICAL STORES / DEPARTMENT/ AGENCY

All the EAC countries have national or central medical stores, i.e. Burundi **-** Central Medical Stores (**CAMEBU)**; Kenya **-** Kenya Medical Supplies Agency (**KEMSA)**; Tanzania **-** Medical Stores Department (**MSD)**; Uganda **-** National Medical Stores (**NMS)**; Rwanda **-** Central Medical Stores (**CAMERWA)**; Zanzibar **-** Central Medical Stores (**CMS).**

Currently there is a strong drive at national level towards making the medical stores autonomous, which may reflect Governments' desire to increase the efficiency of the stores. There are also plans to integrate and have a more coordinated procurement for all medicines and health supplies under one body/organization (i.e. the medical stores). It is noteworthy that in the four countries, except Tanzania, there is a competing source of medicines and medical supplies through the faith-based (private not for profit) stores.

Organizational & management structure

All the six national procurement agencies (referred to as medical stores) are established by the national Governments through Acts of Parliament or statutes. Therefore, the Ministries of Health has ultimate oversight of these bodies. In all the medical stores, the technical capacity is said to be inadequate, but there is an obvious effort to improve the situation. Professionals (pharmacists and procurement officers) have been deployed to manage key departments of the medical stores, while the Chief Executive Officers of the organizations are usually employed from the market.

Staff Establishment	Burundi	Kenya	Rwanda	URT		Uganda
				Mainland	Zanzibar	
Pharmacists/Technicians	3	19	7	30	3	12
Total Staff	16	220	69	320	14	120

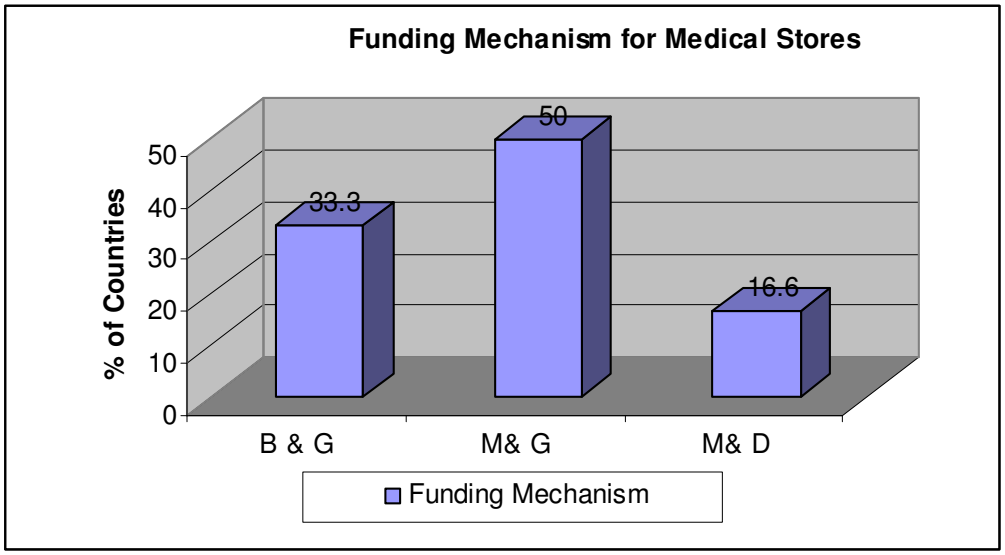
4.2 Sources of funding

Funding for the medical stores varies with:

- Budgetary allocations and grants from Government (B&G) in Kenya and Zanzibar;
- Sales mark-up and grants from the Government for Tanzania, Burundi and Uganda (M&G);
- Rwanda's CAMERWA, is an autonomous body and gets funds largely from mark up on sales, but also receives donor support (M&D).

Grants are donor financing channelled through budgetary support to governments.

Figure 3.3: Funding Mechanism for Medical Stores



4.3 Procurement Planning (selection, forecasting, budget & financing)

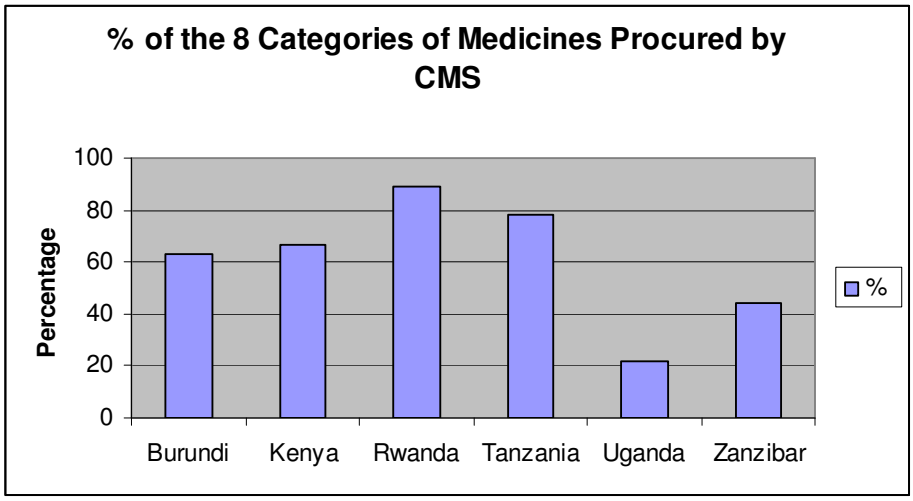
All the Medical stores participate in procurement planning, though the degree of involvement differs appreciably in each country. Medical Stores have little involvement in product selection ((see section on National Essential Medicines List).

i. Procurement

Several groups are involved in procurement of medicines and medical supplies. The key ones are the medical stores, Ministry of Health -procurements units / vertical programs and funding agencies. It should be noted that most of the countries are moving towards an integrated procurement plan where the medical stores will take the lead role. EAC countries import over 70% of health commodities products, except in Kenya where 80% of essential medicines (barring ARVs, Anti-TB and ACTs) are procured locally. Procurement procedures are the same for products except in instances where there is a sole source or pre-qualified suppliers.

To ease analysis and presentation, products were categorized into eight groups, i.e. Essential Medicines; HIV/AIDS (ARVs & medicines for OIs); Anti-TB; Anti-malarials; Vaccines, Reproductive Health; Medical supplies and Laboratory & diagnostics, which also reflect to a large extent on the funding streams. Figure 6 below indicates the percentage of categories that CMS procures.

Figure 3.4 Percentage of the 8 categories of medicines procured by CMS



In all the countries, estimation of needs is undertaken through a combination of methods, the fundamental component being the issues data. For TB, HIV/AIDS and Malaria, morbidity or/and target populations methods are also used. For vaccines and contraceptives, demographic and historical data are used in estimating needs. In all these methods, accuracy is compromised by the inefficient/ incomplete flow of consumption/issues data from the different levels of care and the programme units to the medical stores. To a large extent, timely data is unavailable for quantification/forecasting purposes. All the medical stores cited quantification / forecasting of needs as a likely major challenge to pooled procurement.

For budget and financing, the medical stores play only a contributory role. In Tanzania the office of the chief pharmacist and by extension the Medical Stores Department (MSD), is involved in budget discussions up to Ministerial level.

ii. Tendering process & Contract Management

The medical stores are fully involved in the tendering process and monitoring for those products it procures. The medical stores award the contracts, monitor the order status and receive the products. Zanzibar is the exception since its tendering process is carried out either by their Procurement Management Unit (PMU),Tanzania Medical Stores Department (MSD) or DANIDA.

iii. Quality Assurance system

In all the countries, the medical stores have an in-house quality assurance program through supplier selection and standard operating procedures for receiving medicines & supplies and inventory control. Countries observe, within resource constraints, selection of products

whose stability in storage is suited to the country set-ups. However, the larger role in quality assurance is undertaken by the Medicines Regulatory Authorities of each country. The NMRA inspect manufacturing plants, license suppliers, registers products, and observes recommendations of international bodies (WHO) on products as part of Quality Assurance. Also, NMRA carry out Quality control tests, through the national quality control laboratories though to a limited extent. Quality Control is usually undertaken on products with questionable quality. Samples are obtained during market surveillance activities or in response to complaints. The regulatory bodies are meeting regularly towards regional harmonization of regulations and standards as discussed in the previous sections.

iv. Logistics Management

The major role of all the medical stores is storage and delivery as most products, except for vaccines, are stored and distributed by the medical stores. There is substantial level of automation of medical stores activities at the central level. Uganda and Kenya have similar software, *Navision,* though the level of integration is very different; Tanzania mainland and Zanzibar use *Orion*, for receiving, storage, inventory control and distribution, accounting and human resource management. Although Zanzibar has the software, its storage and distribution operations still are largely manual. Tanzania Medical Store Department (MSD) and Kenya Medical Supplies Agency, KEMSA have regional stores; while Uganda National Medical Store does not have branches but has one commercial outlet whose customer base is the private sector.

Most of the countries have shifted or are transiting from a "push" to a "pull" distribution system. Delivery is generally undertaken by a fleet of vehicles owned by the medical stores with limited outsourcing when the need arises.

CHAPTER III: FINDINGS

E. FINANCIAL RESOURCES AND SYSTEMS

INTRODUCTION

The financing environment associated with pharmaceutical procurement includes the amount and sources of financing; funding policies of members states and their development partners; and financial management system and procedures. Reliable and sustainable financing and timely payment systems are major requirements for pooled procurement. This section describes and assesses the major financing components necessary for regional pooled procurement of pharmaceuticals.

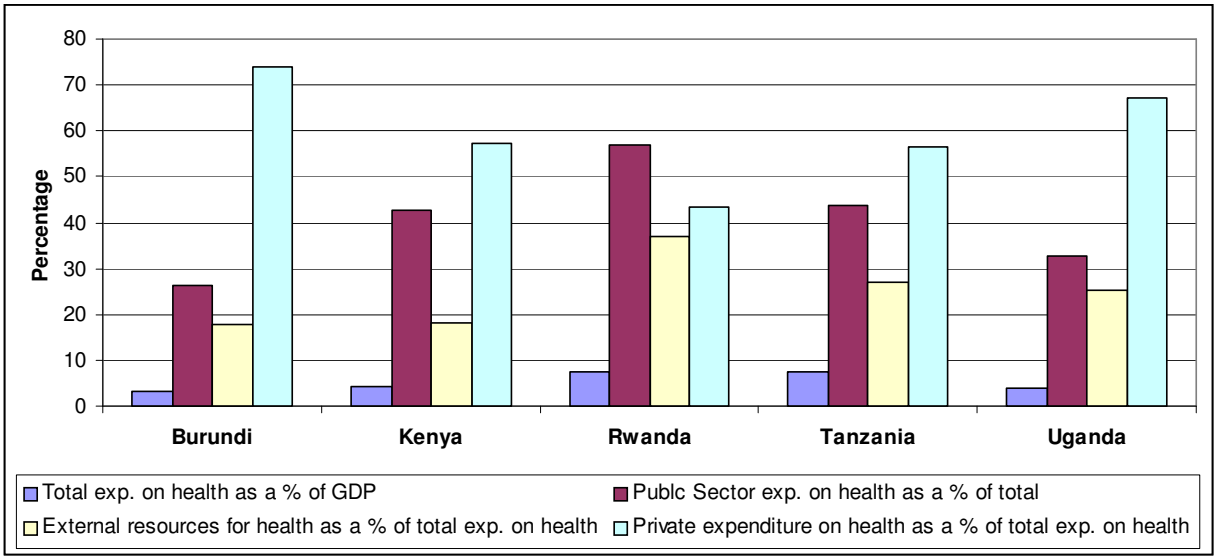
1. FINANCING SOURCES

Funding for medicines among the EAC partner states comes from a variety of sources, including government budgets, health basket funding associated with Sector Wide Approaches (SWAp), bilateral donors, and international organizations such as the Global Fund. Private households offset some of the costs through enrolment in national health insurance schemes and, more directly through user fees at point-of-service.

Figure 3.5 lists broad health expenditure data of the member countries shows that Rwanda and Tanzania have the highest total expenditure on health as a percentage of Gross Domestic Product (GDP) at over 7 percent.[4] These two countries also receive the highest amount of external resources for health as a percentage of total expenditures on health when compared to the other member-states. Both these indicators are useful proxies to measure the financing environment for pharmaceutical procurement as a significant component of total health expenditure. In addition, the private sector expenditure on health as a percentage of total spending averages nearly 60 percent in the five countries.

[4] http://www.who.int/whosis/database/core/core_select_process.cfm. 2007. All data is from 2004.

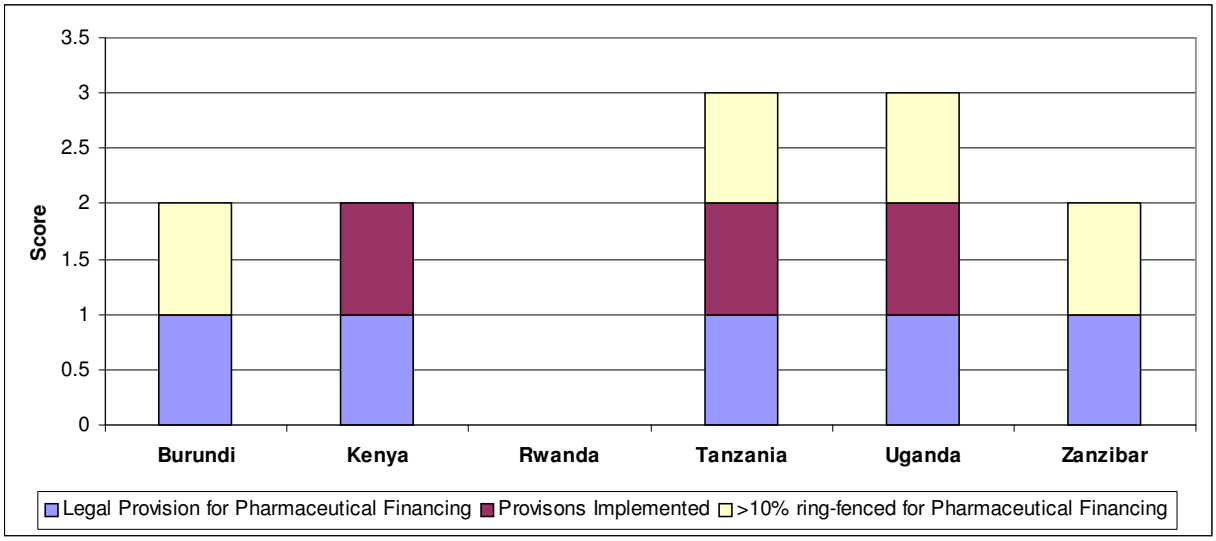
Figure 3.5: Health Expenditure in EAC Member States



1.1 Financing for pharmaceutical procurement

Many countries have recently strengthened their legal and regulatory statutes to ensure that governments adequately finance the purchase of medicines. These legal provisions often take the form of a) **mandated budget lines** or b) **specific allocations "ring-fenced**" or c) **protected for medicines procurement**. The extent to which these legal provisions exist and are implemented will be important when determining the feasibility of pooled procurement. The findings from the country surveys indicate that the three defined key legal provisions for effective public sector pharmaceutical financing exist in Tanzania and Uganda. In both countries, the surveys reported that legal provisions exists, the provisions are generally implemented, and there is a mechanism for ring-fencing at least 10 percent of the health sector budget for medicine procurement. It is noted that these conditions also exist in Kenya, but the medicine procurement budget is less than 10 percent of the broader health sector budget. Zanzibar reported lack of implementation of the legal provisions as a major challenge. There was no data was available from Rwanda.

Figure 3.6: Legal Provisions for Pharmaceutical Financing



2. FINANCING FLEXIBILITIES

As shown on Table 3.5, there are multiple sources of financing for the five broad categories of potential target commodities for pooled procurement in each of the EAC countries. Different sources provide procurement financing or in some cases, direct procurement for each of the medicines category. The Global Fund provides much of the directly through user fees at point-of-service funding for the three major public health diseases (HIV/AIDS, TB and Malaria) through different procurement sources. The United States President's Emergency Plan For AIDS Relief (PEPFAR) program provide financing and direct procurement sources for a number of medicines and consumables for HIV/AIDS, with the majority of those funds spent on ARV medicines. The WHO Global Drug Facility (GDF) is involved in and supports the procurement of drugs for TB. The essential drugs budget for other health problems, i.e. both communicable and non-communicable diseases is supported by government revenue and development partner allocations through direct budget support.

Table 3.5: Funding Sources for Priority Medicines

Category	Burundi	Kenya	Rwanda	Tanzania	Uganda	Zanzibar
HIV/AIDS	GFATM, World Bank	GFATM, SIDA, DANIDA,USG	PEPFAR, GFATM, WB, CTP	GFATM, PEPFAR	GFATM, PEPFAR	GFATM
Malaria	GFATM	GoK; GFATM,PMI	GFATM, Belgian Coop	GFATM	GFATM, PMI (USG)	GFATM
Tuberculosis	Belgian Technical Cooperation, GDF	GTZ, USG	DAMIEN, GF, GoR	GDF	GDF, GFATM	GFATM
Family Planning	UNFPA	USAID	UNFPA, USAID	GoT; USAID	USAID	UNFPA, USAID
Essential Medicines	GoB, donors	GoK, World Bank	GoR, UNFPA	GoT	GoU, DANIDA	DANIDA

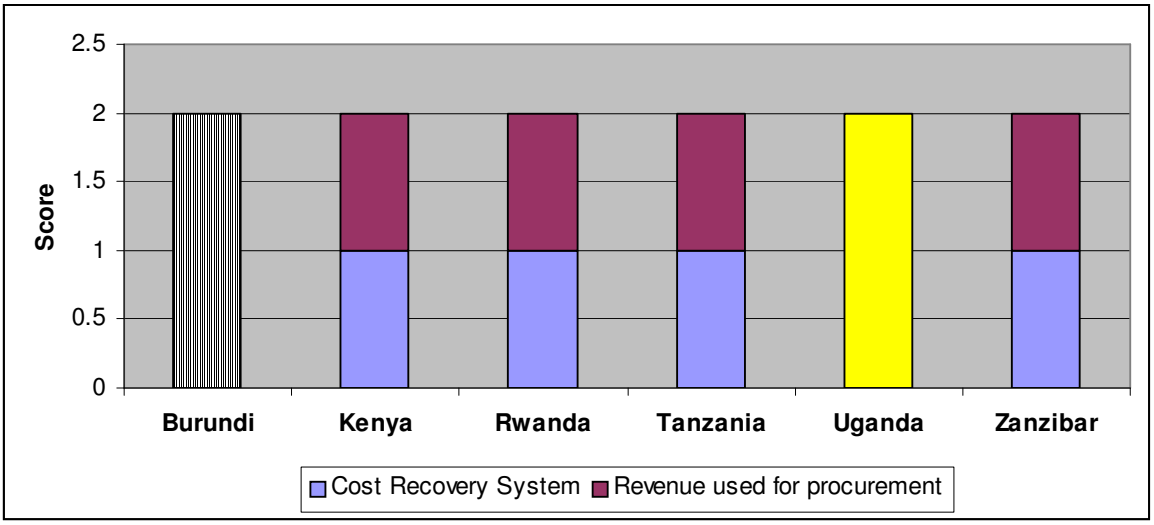
The Group Contracting and Central Contracting models require commitments to sole source procurements through the supplier(s) selected by the regional purchasing mechanism. Thus countries must demonstrate the willingness to sole source part of their pharmaceutical needs to the pooled procurement mechanism as defined by the regional bloc. This guarantees the demand and the financial basis for fully leveraging the volume advantage inherent to pooled procurement. However, with increased reliance on external support for health sector financing, and by extension medicines financing, the coordination of funding sources becomes more complex as many donors have specific requirements governing disbursements. The initial step therefore is to identify the donors with financing and procurement flexibilities as these will likely require revisions and specific changes in agreements and regulations by the funding organizations currently providing bilateral procurement financing to each of the EAC member-states and approvals to re-channel funding through national governments to a regional entity charged with pooled procurement.

2.1 Household Financing

A substantial component of pharmaceutical financing is being absorbed by households through purcha[NO DATA] medicines in the private and NGO sectors, and through cost-recovery mechanisms i[NO DATA]public sector. Public sector cost recovery mechanisms in general, and among the EA[NO DATA]mber-states specifically, are not designed to capture the full price of the medicines and [NO DATA]associated distribution costs. Rather, they offset the total cost of the medicine and [NO DATA]istribution system by charging either for dispensing services or a set, subsidized cos[NO DATA]e medicine, e.g. a flat fee to cover consultation and treatment. . At the same time, ma[NO DATA]tegories of patients, disease conditions, and medicines are often exempt from the cost-recovery program, decreasing the total amount of recouped funds. For example, the indigent, aged over 62 or under fives are reported as exempt from payment by many countries in the East African region. Likewise, are most medicines for Malaria, Anti-retroviral therapy (ART), vaccines, and contraceptives.

More significantly, the utilization of the recovered funds varies from situations where it is used to finance Revolving Drug Funds (RDF) to support subsequent procurements or used to supplement local capital improvements such as building renovations and maintenance. As shown on Figure 3.7, a cost recovery system is in place in four of the five programs where data was available. The survey from Uganda indicated that the majority of medicines are provided free of charge. In Kenya, Tanzania, Zanzibar, and Rwanda revenue from the cost recovery mechanism is also used to capitalize local Revolving Drug Fund or is redistributed back to the central level for subsequent procurements.

Figure 3.7: Medicines Cost Recovery in EAC Member-States



3. PAYMENT PROCEDURES

Group Contracting and Central Contracting models require a predictable flow of funds. In East Africa, Ministries of Health are dependent on different procedures for obtaining funding from Ministries of Finance. Funds are sometimes disbursed late in the fiscal year, not disbursed or are less than what was originally budgeted. The release of funds in "tranches" throughout the year can also deprive procurement agencies of required funding to make annual purchases. In Tanzania, for example, annual allocations are required to be expended on procurement within the same fiscal year. As funds are released quarterly, and procurement lead times are often 12 months or greater, the efficiency of the process is affected because the budget and procurement cycles are not synchronized. In Kenya, payment processing can also be challenging because Government of Kenya financial disbursement systems are occasionally not aligned with supplier payment schedules established by the medical stores, KEMSA.

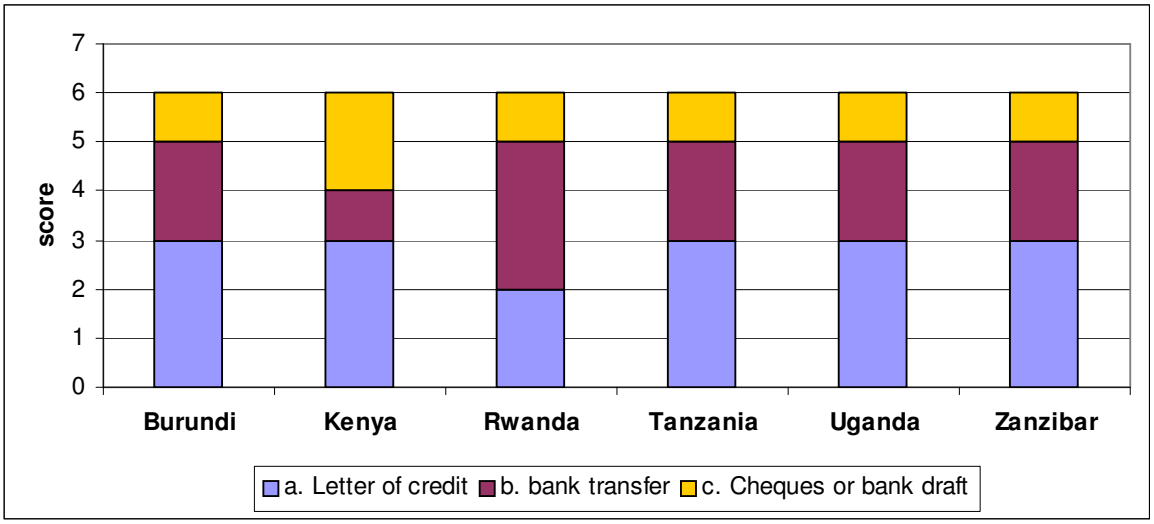
3.1 Payment Method

The payment method used can affect actions of suppliers. Survey respondents reported that international suppliers frequently insist on using Letters of Credit when doing business with developing countries. Eighty percent of procurement agencies (Kenya, Tanzania, Uganda, Zanzibar and Burundi) reported that a Letter of Credit was the most prevalent method used for procurement. This finding is consistent with the previous study conducted where 55% of the countries identified the use of letters of credit as the main method of payment (Onyango, et al, 2003).

- In Tanzania, Uganda, Zanzibar and Burundi, this was followed by Bank Transfer as the next most widely used method.
- Rwanda reported Bank Transfer as its preferred method of payment.
- Cheques/Bank drafts were reported as the least frequent method of payment reserved for small, local purchases or for emergency procurements.

The findings therefore confirms that the majority of EAC member-states are already using the method of payment preferred by suppliers and which are likely to attract the most favourable payment terms and prices for a potential pooled procurement mechanism. Many of the survey respondents also indicated that the options for managing payments for pooled procurement should include the East African Development Bank (EADB), or similar multilateral institution, where negotiations between the EAC and such an entity may result in a reduction of waiver of a surcharge, making the Letter of Credit an attractive option.

Figure 3.8: Payment Method for Pharmaceutical Procurement



3.2 Use of local and convertible currency

Countries implementing the most integrated form of pooled procurement (e.g., Central Contracting) noted that having a currency that is convertible on the international market greatly facilitates payment of invoices. If the buyer's currency is not freely convertible, or if the currency's value is subject to major fluctuation, the country may face problems with meeting its financial obligations to suppliers. In practice, many international suppliers do not accept payment in local currency, requiring the country instead to obtain convertible currency (such as U.S. dollars or Euros) for payment of invoices.

Use of a Letter of Credit as payment method addresses the issue of the need for convertible currency in conducting procurement transactions. Surveys responses from the EAC member states indicated that in the majority of countries, procurement from local suppliers, notably local manufacturers, were made in local currency. Larger medicine procurements conducted through the public sector were routinely made to suppliers in U.S. dollars, with exchanges made by either through commercial banks or the national central banks to facilitate the convertible currency.

Table 3.6: Comparative Analysis of financing systems in the EAC

ELEMENTS OF FINANCING SYSTEMS	Burundi	Kenya	Rwanda	Tanzania	Uganda	Zanzibar
Health expenditures (% of GDP)	5%	5%	6%	5.6%	7%	---
Per capita expenditure on health (US$)	16	70	48	31	77	---
Legal provisions for pharmaceutical financing	Yes	Yes, through the Public Health Act	n/a	Yes- Modus Operandi of the MOH	Yes- through the HSSP framework & the Poverty Eradication Action Plan (PEAP)	Yes
Main sources of funding for the public sector procurement						
Essential medicines	MOH, Cost recovery, Donors	MOH	Cost recovery	n/a	MOH, donors	n/a
Medical supplies	MOH, Cost recovery, Donors	MOH	Cost recovery	n/a	MOH, donors	n/a
Vaccines	GAVI, UNICEF, MOH	UNICEF	GOR & GAVI	UNICEF	MOH, donors	UNICEF
Cost recovery system in the public health facilities	Yes	Yes	Yes	Yes	No	No
What is the revenue used for?	Purchase of medicines	Primary health care activities	Replenishment of supplies	Replenishment of supplies	n/a	Move towards a revolving Drug Fund
Payment method	1) Letter of credit	1) Letter of credit 2) Cheque or bank transfer	1) Bank transfer	1) Letter of credit 2) Bank transfer	1) Letter of credit	1) Letter of credit
Currency	Local: 33% Foreign: 67%	Local: 95% Foreign: 5%	Local: 15% Foreign: 85%	n/a	n/a	n/a

Legal constraints to using MOH funds for regional pooled procurement	No	----	-----	Yes, need harmonisation with the PPDA Act	---	No
Main donors for:						
a. HIV/AIDS	GFATM, World Bank	GFATM, SIDA, DANIDA, GTZ	PEPFAR, GFATM	GFATM PEPFAR	GFATM/PEPFAR	GFATM
b. Malaria	GFATM	GOK, GFATM	GFATM, Belgian Cooperation	GFATM	GFATM/PMI	GFATM
c. TB	Belgian Cooperation, GDF	GFATM	DAMIEN, GFATM, GOR	GDF	GDF/GFATM	GFATM
d. Contraceptives	KFW, UNFPA	USG	UNFPA, USAID	GFATM /GOT/USG	USG	UNFPA/USG
e. Condoms	KFW, UNFPA	USG	GoR, UNFPA	GF/GOT	USG/GF	UNFPA/USG

CHAPTER III: FINDINGS

F. MEDICINE PRICING

INTRODUCTION

A number of benefits to pooled procurement have been identified throughout this study, including improved quality, greater accessibility and availability through a consistent supply chain, improved rational use, and greater efficiencies in the acquisition process. Broader benefits mainly linked to increased regional collaboration, technical cooperation and harmonisation can also be gained from the adoption and implementation of pooled procurement of medicines.

What also cannot be underestimated is the advantage of pooling procurement volume to achieve lower prices. The scale of savings that can be achieved by buying in larger volumes is an important tool in improving efficiencies in drug management, and therefore remains a central focus and objective of policymakers as they seek to gain efficiencies in public health programs. Higher volume purchases enable manufacturers to reduce their margin on health commodities, thus allowing savings, which could then be used to purchase additional medicines thus increasing the available supply for patients – the ultimate beneficiary. This has been documented in the recent study conducted on the potential cost savings through the pooled procurement of contraceptives for 15 Economic Community of West African States (ECOWAS) countries.

The OECS Pharmaceutical Procurement Service (PPS) has saved over 30 percent on unit prices over individual country procurements in the region.[5] The GCC's Group Purchasing Program (GPP) has also demonstrated unit prices savings through bulk purchasing. And in 2005 – 2006, PAHO's Strategic Fund, through diligent negotiations and the aggregation of product volume, obtained prices significantly lower than other reference prices in the region.[6]

[5] A presentation given by the Organization for Eastern Caribbean States (OECS) Pharmaceutical Purchasing Service (PPS) at the WHO Expert Committee Meeting on Pooled Procurement. January, 2007.

[6] A presentation given by the PAHO Strategic Fund, *Linking Technical Cooperation in PSM with Acquisition of Strategic Public Health Supplies.* January, 2007.

1. METHODOLOGY

A brief overview on the specific methodology used in this section is given to supplement the general section of methodology in chapter 2. Public sector procurement agencies, i.e. national medical stores, in the five EAC member-states provided the study team with a list of their 50 highest value individual procurements during the last 12 months. Fifty products were requested in order to help ensure that the study team could identify a list of commonly procured medicines across the region. Medicines procured by three or more countries indicate potential multi-country demand for a specific product and, were included on the initial procurement target commodity list. In addition, survey respondents were asked to identify the source of financing for the procurements, so that products procured by partners and third party agents may also be considered for the establishment of the final list of target commodities. Finally, the pharmaceuticals and consumables to treat HIV, Malaria and TB were identified as potential pooled procurement commodities. The analysis on HIV/AIDS products includes non-public sector procurement agencies.

1.1 Comparing Prices

The unit prices of the fifty products for each EAC country are compared with the Lowest International Reference Price (LIRP) listed in the *Management Sciences for Health (MSH) Price Indicator Guide, 2006*. Median International Reference Prices (MIRPs) were not used as many of the MIRPs were composed of purchases from middle-income countries at higher prices than most Sub-Saharan African countries resulting in distorted MIRPs. The variance of the transaction prices with the LIRP are expressed as percentages as a measure to determine purchasing efficiency. Negative percentages indicate that a country is obtaining prices lower than the LIRP, while positive percentages indicate that transaction prices are higher than the LIRP. Where reference data was available, median "buyer" prices were used in place of median "supplier" prices. The median price variance for all commodities reported by the countries is established, and then an inter-country comparison is made to draw conclusions about the current purchasing efficiencies. Where there were outliers or insufficient data on reference prices, adjustments, including the use of alternate references prices or data exclusion were made. All unit prices obtained from the countries, unless noted otherwise, are quoted in Cost, insurance, and freight (CIF) and Carriage and insurance paid (CIP).

1.2 Commonly Purchased Products

As mentioned in previous section, a medicine is identified as “common” if at least three countries, i.e. 60% of member states, have purchased it, which was the basis for establishing a list of potential pooled products. A comparison on the median transaction price (MTP), highest transaction price (HTP) and lowest transaction price (LTP) with the Lowest International Reference Price for each commonly procured products were made to determine the potential scope for price improvements. The analysis also highlighted the wide-range of prices paid for the identical product across EAC countries.

1.2 Monetary Impact

Establishing the potential monetary savings that could be realized from pooled procurement was derived from multiplying the unit prices for the LIRP, MTP, HTP, and LTP by the reported and estimated transaction volume. This established aggregated total costs for each product on the common list for EAC member-states, which was then compared against the separate transaction prices to identify the potential savings by countries. This was finally added to determine regional savings if the LTP were obtained. Further, those amounts were subsequently divided by the LTP unit prices to determine how many additional units of each product could be procured if the purchases were done at the lower prices. In instances where commonly procured products were not found for all five countries (which was in all cases, as the highest number of identical products procured across countries were four), the MTP was used and population based estimates were developed to determine volume.

2. COMMONLY PROCURED PRODUCTS

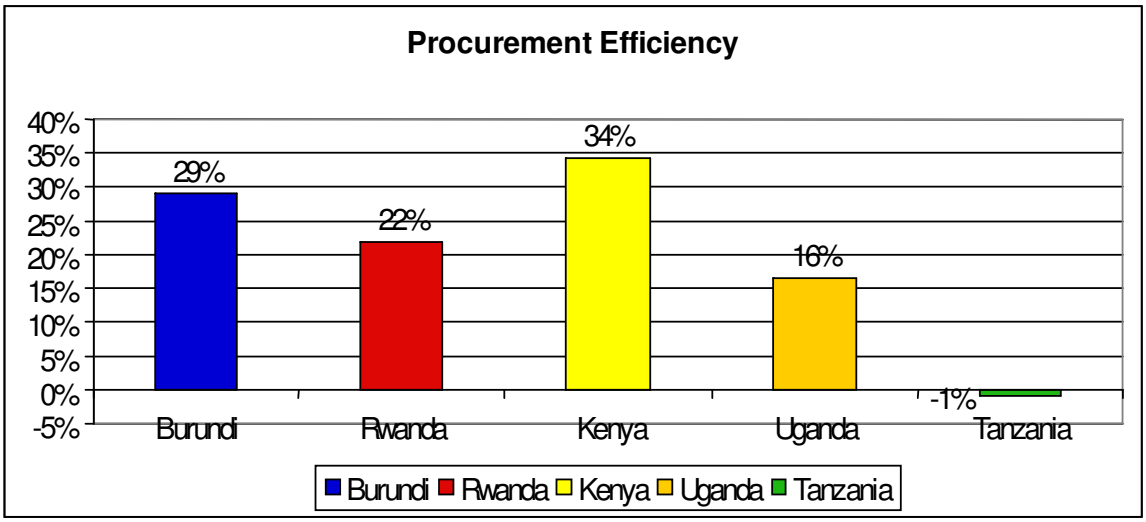
The data presented is drawn from the quantitative component of surveys administered in Burundi, Kenya, Rwanda, Tanzania, and Uganda. Public sector procurement for Zanzibar is done through the Medical Stores Department (MSD) in Tanzania, thus the data for Tanzania includes purchases for both the mainland and Zanzibar. The survey primarily focused on pharmaceuticals, excluding medical supplies and other health products. Anti-retroviral medicines were not reported among the products procured by public sector agencies of Kenya, Tanzania and Burundi as these are mainly done through third party procurement agents / suppliers, NGOs and bilateral and multilateral donors (e.g., PEPFAR, GFATM, UNICEF).

a. Country Pricing Efficiencies

The purchasing efficiency of the five EAC countries in comparison to the Lowest International Reference price is illustrated in Figure 3.9. As can be seen, the 50 highest-value procurements in four of the five countries (Burundi, Rwanda, Kenya, and Uganda), are purchased substantially above the LIRP, with only Tanzania procuring at lower prices than the reference price. This does not however mean that the procurement of an individual country or a region is “inefficient” as the comparison is with the “lowest available prices” that many countries, because of low volume, geographical context and high logistics costs or poor supplier performance, do not have access to. However, Figure 11 indicates that there is margin to improve efficiencies (prices) for the essential medicines that are currently procured

among EAC member-states. Further, when looking at individual products, the data indicates that each of the five countries is achieving value for money for a number of pharmaceuticals, with 33% of all the products being purchased below the LIRP.

Figure 3.9: Comparing Pricing Efficiency in the EAC



Despite these efficiencies, 67 percent of the 153 medicines examined were procured above the Lowest International Reference Prices (LIRP) – indicating a potential for improved pricing performance. Burundi and Rwanda, the two Francophone countries in the EAC, purchase pharmaceuticals at similarly higher prices compared to the LIRP and also with Tanzania and Uganda. Cotrimoxazole 480mg, purchased by four countries in the EAC, Burundi, Kenya, Rwanda, and Uganda, is an example of this disparity, with Burundi and Rwanda purchasing this product at the highest price -respectively 91% and 66% greater than the LIRP- compared with a 17% and 4% variance for Kenya and Uganda respectively.

Additionally, a comparison can be made between countries with easier access to sea ports (Kenya and Tanzania) and land-locked countries (Burundi, Rwanda and Uganda). *Erythromycin* 250mg,[7] which is purchased by all five countries of the EAC, varies widely in price between Kenya/Tanzania and the other three countries. Kenya and Tanzania purchase Erythromycin 250mg/caps at very similar prices – 0.0189 and 0.0187 USD$ respectively, while Uganda, Burundi and Rwanda procure them at 1.3, 1.4 and 2.0 times

[7] *Note: The MSH LIRP for **Erythromycin** was found to be 0.0053 US$ and was acquired by the Pharmaceutical Supply and Logistics Provisional Department of Ethiopia (ETHIOPIA) which conducts an annual, international open tender. This price was found to be greatly lower than the MIRP of 0.0337 US$, and 14 times smaller than the highest IRP. Lower prices can indicate better procurement but may also be reflective of lower quality standards. The team therefore decided that this value was an outlier and did not reflect prices usually obtained for erythromycin. The IRP directly above the LIRP of 0.0222 US$ was chosen.*

greater than those prices. Access to ports and overall reduced transportation costs stemming from improved roads may be factors associated with the price differences.

b. Identifying a common set of products across the region

This part of the analysis examines the identical pharmaceuticals procured by EAC member states. Products currently purchased by all or a majority of countries would naturally provide a logical basis for initial regional procurement list because they indicate the products are in demand and almost all of the medicines examined are on the WHO model Essential Medicines List and that of the respective country.

Of the 153 total products assessed, 11 were found to be common to three or more countries, with equivalent strengths and dosages (Table 3.6). The three main therapeutic categories found are 1) Antibacterials, 2) Anti-inflammatory medicines, 3) Anti-malarials, with the anti-bacterials accounting for over 60% of the products. All these drugs are multi-source pharmaceutical products, i.e. they are widely found as generics and are available from a range of manufacturers around the world, with information on quality standards readily available.

Table 3.6: Common products within the EAC by therapeutic categories

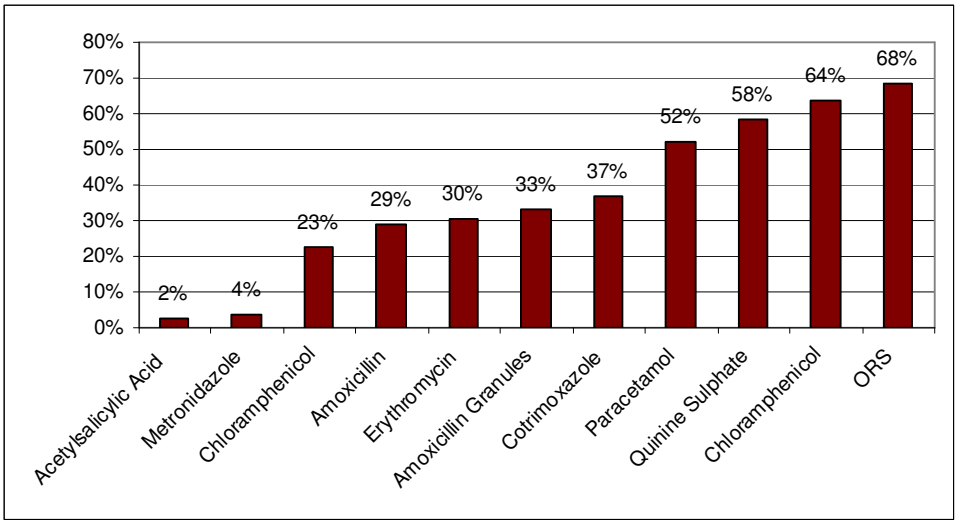
Products	Therapeutic category	Comments	WHO Essential Medicines List
1. Acetylsalicylic Acid 300 mg tab	Non-opiods and non-steroidal anti-inflammatory medicines (NSAIMs)	For the treatment of acute migraine attack; medicines used in palliative care	√
2. Amoxicillin 250 mg caps	Antibacterials (Beta Lactam medicines)		√
3. Amoxicillin Granules 125mg/5ml 100 ml	Antibacterials (Beta Lactam medicines)		√
4. Chloramphenicol caps 250 mg	Antibacterials		√
5. Chloramphenicol 1G Injection Vial	Antibacterials		√
6. Cotrimoxazole 400+80 mg Scored (or Sulfamethoxazole 400mg + Trimethoprim 80mg)	Antibacterials	For prophylactic treatment (action against common bacteria, parasites including toxoplasmosis and those causing chronic diarrhea); effective to combat both HIV and TB infections (Cochrane Collaboration, 2007). Used for pneumonia caused by Pneumocystis carinii.	√

7. Erythromycin 250 mg tab	Antibacterials		√
8. Metronidazole 200 mg tab	Antibacterials		√
9. Oral Rehydration Salts For 1Lt, 27.9G (Sachet)			√
10. Paracetamol 500 mg tab	Non-opiods and non-steroidal anti-inflammatory medicines (NSAIMs)		√
11. Quinine Sulphate 300 mg tab Coated	Anti-malarial	For use only in the management of severe malaria, and used in combination with doxycycline	√

Source: WHO Model List of Essential Medicines (15th list, March 2007)

An additional analysis (Figure 3.10) between the Median Transaction Prices (MTP) and the Lowest Transaction Prices (LTP) reveals wide difference in procurement price between the median and lowest price paid for the same pharmaceutical. The range is most pronounced for ORS at 68 percent and chloramphenicol capsules at 64 percent. The gap between the median prices paid and the lowest prices obtained represents a signficant amount of lost efficiency but also an opportunity to lower prices for a number of pharmacetuicals commonly procured by member-states.

Figure 3.10: Percentage Difference between MTP and LTP in EAC Countries



3. MONETARY SAVINGS

In this section we look at potential monetary savings that could be obtained in the region through lower priced procurements of the eleven commonly purchased products in the EAC. The comparison is made by quantifying the difference between current MTPs in the EAC, and the LTP and the LIRP. Two potential pooled prices were identified to determine

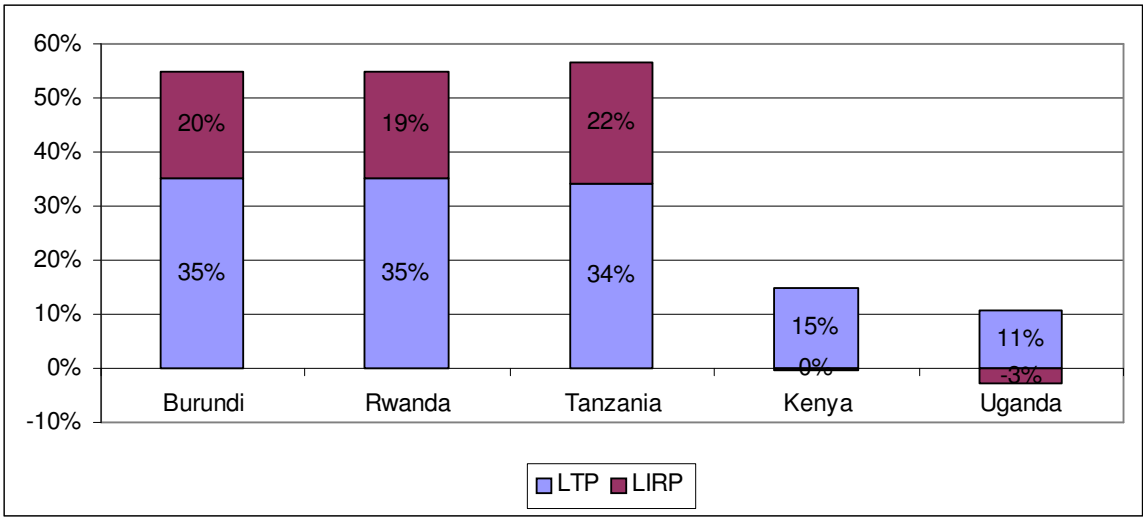
monetary savings: (1) the lowest transaction price and the actual transaction prices; and (2) the difference between the transaction prices and the lowest international reference price.

a. Savings by Country

A comparison of the transaction prices for the commonly procured products indicates that the potential for price reductions is greater between transaction prices and the LTP than between transaction prices and the LIRP. The findings suggest that substantial price reductions are achieved when using the lowest unit price currently obtained by one of the EAC members. The countries that would most benefit from pooled procurement according to our estimation of quantities purchased are the following in a decreasing order: Burundi, Rwanda, Tanzania, Kenya and Uganda. As discussed previously, because both Burundi and Rwanda were obtaining comparatively higher prices, these two countries will therefore achieve most important savings through pooled procurement.

It must be cautioned, however, that low prices alone do not adequately reflect the potential benefits of pooled procurement. In fact, reduced prices do not necessarily ensure that the quality of the products has been maintained. In certain cases, supplier performance – includidng GMP and adherence to strigent qualtiy control – may be at risk when focusing exclusively on achivieing the lowest price to achieve efficienices and cost savings.

Figure 3.11: Identifying the Lowest Price



Moreover, if for example, Tanzania purchased all products on the list at the LTP, it could achieve up to 34% savings above the current prices it pays compared to Uganda, which would achieve 11%. Of course, these results are based upon estimations and low prices would depend on the effectiveness of all EAC countries to jointly manage a competitive bidding process and (potentially) conduct negotiations with the suppliers.

b. Regional Savings

Aggregating all the purchase transaction data among the commonly procured products suggests that the EAC as a region could achieve considerable savings, if prices were negotiated at the LTP rather than the LIRP. With the LTP, the region could achieve total savings of 22 percent while 9 percent savings could be obtained with the LIRP. If all the members of the EAC participated in regional pooled procurement (and purchased the basket of common products), then US $2.4 million could be saved and almost 238,000,000 additional units of the 11 medicines selected for the study could be purchased.

Table 3.7: Regional Savings by Product Compared against LTP and LIRP

		LTP			LIRP		
Common products	**Current costs (US$)**	**Costs (US$)**	**Savings (US$)**	**% Savings**	**Costs (US$)**	**Savings (US$)**	**% Savings**
Acetylsalicylic Acid 300 mg tab	309,094	303,291	5,803	2%	369,726	- 60,632	-20%
Amoxicillin 250 mg caps	2,647,413	1,804,322	843,091	32%	1,929,294	718,119	27%
Amoxicillin Granules 125mg/5ml 100 ml	25,346	5,772	19,574	77%	8,217	17,128	68%
Chloramphenicol caps 250 mg	676,776	472,594	204,182	30%	453,428	223,348	33%
Chloramphenicol 1G Injection Vial	724,153	625,866	98,287	14%	632,459	91,695	13%
Cotrimoxazole 400+80mg Scored	1,936,576	1,803,064	133,513	7%	1,741,782	194,794	10%
Erythromycin 250 mg tab	1,357,004	1,151,615	205,389	15%	1,363,568	- 6,564	0%
Metronidazole 200 mg tab	391,892	380,317	11,575	3%	525,142	-133,249	-34%
Oral Rehydration Salts For 1Lt, 27.9G (Sachet)	624,442	378,927	245,515	39%	633,527	- 9,085	-1%
Paracetamol 500 mg tab	520,597	439,659	80,938	16%	623,933	-103,337	-20%
Quinine Sulphate 300 mg tab Coated	1,507,842	948,639	559,202	37%	1,477,373	30,469	2%
Total	**10,721,135**	**8,314,065**	**2,407,071**	**22%**	**9,758,449**	**962,686**	**9%**

Table 3.8: Additional Medicines Unit Procured if Purchased at LTP

Number of products	Common products	LTP Savings (US$)	Additional units
3	Acetylsalicylic Acid 300 mg tab	5,803	4,831,545
5	Amoxicillin 250 mg caps	843,091	79,077,682
4	Amoxicillin Granules 125mg/5ml 100 ml	19,574	8,196,598
3	Chloramphenicol caps 250 mg	204,182	25,776,541
3	Chloramphenicol 1G Injection Vial	98,287	501,376
3	Cotrimoxazole 400+80mg Scored	133,513	25,289,202
5	Erythromycin 250 mg tab	205,389	10,954,560
3	Metronidazole 200 mg tab	11,575	5,327,555
3	Oral Rehydration Salts For 1Lt, 27.9G (Sachet)	245,515	8,112,189
4	Paracetamol 500 mg tab	80,938	41,022,027
4	Quinine Sulphate 300 mg tab Coated	559,202	28,741,884
	Total	**2,407,071**	**237,831,160**

Again, these results are based on numerous assumptions but remain indicative of the extent to which prices may go down with increased procurement volumes. In fact, higher volumes may lead to even lower prices but these will be highly dependent upon the effectiveness of the procurement process, the level of harmonisation of national medicines policies in the region, and the willingness of the member countries (and suppliers) to commit to such a purchasing arrangement.

4. HIV / AIDS PRODUCTS

This section contains an analysis of the prices paid for a basket of commonly procured HIV/AIDS commodities among all five member-states. Many, but not all, of the procurements described in this section were financed by multilateral and bilateral donors (e.g., PEPFAR and GFATM) and procured/supplied by third party agents including UNICEF, CHAI, and others. The source data was obtained through a search of GFATM's Global Price Reporting Mechanism (GRPRM) publicly available on the Internet. The products in this section were included in the analysis as the products were procured recently by each of the five countries and therefore confirm the finding on Essential Medicines List and Standard Treatment Guidelines that treatments for HIV (1st and 2nd line) are standardized. The prices used are those taken from the highest volume single procurement over the last 24 months.

Table 3.9: Twelve HIV/AIDS Commodities Commonly Procured in the EAC

Determine HIV-1/2 w/b test (Rapid Test)
Didanosine (ddI) 200mg cap/tab
Efavirenz (EFV) 600mg cap/tab
Lamivudine (3TC) 150mg cap/tabs
Nevirapine (NVP) 10mg/ml oral liquid
Nevirapine 200mg cap/tab
Stavudine (d4T) 30mg cap/tab
Stavudine (d4T) 40mg cap/tab
Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) 40/150/200
Zidovudine (ZDV) 100mg cap/tab
Zidovudine (ZDV) 300mg cap/tab
Zidovudine (ZDV) + Lamivudine (3TC) 300/150mg cap/tab

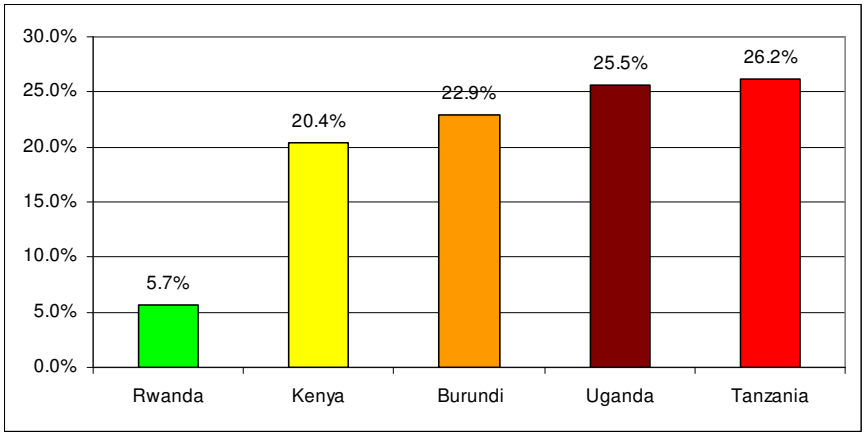
*source : GPRM Database 2005 - 2007

4.1 Pricing Environment

A wide range of prices were found amongst the 12 common products identified in the GPRM database, with the more recent purchases and those involving generic equivalents showing the lowest prices. In 2005, for example, Kenya purchased approximately 400,000 units of the innovator Viramune (Nevirapine) 200mg tablets for US$0.60 per tablet. A year later, Rwanda received over 2.7 million units of Nevirapine from a generic manufacturer in India for US$0.066/tablets – over 800 percent lower. Similar differences were seen for several other products. Burundi paid US$0.724 per tablet for Efavirenz 600 mg tablets, while procurement agents in Rwanda and Uganda procured it for US$0.51 and US$0.58 U.S. cents per tablet respectively.

As a group of countries, the median purchase price for the 12 commodities was 20 percent greater than the LIRP. Among the five countries, procurement of HIV/AIDS commodities was the most efficient in Rwanda at only 5.7 percent above LIRP, followed by Kenya, Burundi, Uganda, and Tanzania – where median procurement prices were over 26 percent higher than Lowest International Reference Prices.

Figure 3.12: Pricing Environment for Select HIV/AIDS Commodities in the EAC



4.2 Relationship between Volume and Price

An analysis of procurement quantities among the LTP and HTP for each of the 12 commonly procured products (Table 3.10) reveals that the relationship between volume and price is not, by any means, perfect as only 50 percent of the LTPs recorded in the GPRM database were obtained with higher purchase volumes than the HTPs. For example, 15,000 units of Stavudine 30mg cap/tabs were procured by Uganda in February, 2007 at a price of .028 U.S. per unit, while a quantity of nearly ten fold was procured by agents in Burundi in July, 2005 for .046 U.S. per unit. Similarly, the LTP for Stavudine 40 mg cap/tabs was obtained by Rwanda with significantly lower volume than procurement agents for Burundi who obtained a price 46 percent higher. Nonetheless, one-half of the purchases examined showed an inverse relationship between price and volume – a key benefit of pooled procurement. Those include Efavirenz 600mg (Rwanda), Nevirapine 200mg cap/tabs (also Rwanda), and several others (marked in yellow).

Factors, apart from volume that appear to be associated with lower prices, include HIV/AIDS commodities that have been procured within the last 6 – 12 months and the purchase of generic products through large-scale generic-equivalent suppliers. It has been well documented that the cost for 1st line ARVs, for example, and some second line regimens have dramatically fallen in price over the past several years and price negotiations and the use of established, high-volume generic manufacturers have contributed to this. These are both factors that should be considered in designing a pooled procurement system for HIV/AIDS commodities – notably ARVs.

Table 3.10 Relationship Between Volume and Price

	Volume		
	LTP	HTP	
Determine HIV-1/2 w/b test (Rapid Test)			
Didanosine (ddI) 200mg cap/tab	107,940	150,900	
Efavirenz (EFV) 600mg cap/tab	2,147,310	622,800	✓
Lamivudine (3TC) 150mg cap/tabs	76,020	54,000	✓
Nevirapine (NVP) 10mg/ml oral liquid	107,760	280,608	
Nevirapine 200mg cap/tab	2,721,960	436,080	✓
Stavudine (d4T) 30mg cap/tab	15,480	150,000	
Stavudine (d4T) 40mg cap/tab	18,360	150,000	
Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) 40/150/200	5,184,360	300,000	✓
Zidovudine (ZDV) 100mg cap/tab	397,020	935,400	
Zidovudine (ZDV) 300mg cap/tab	1,159,200	588,000	✓
Zidovudine (ZDV) + Lamivudine (3TC) 300/150mg cap/tab	1,200,000	109,080	✓

4.3 Scope for Savings: Comparing Prices and Quantifying Savings

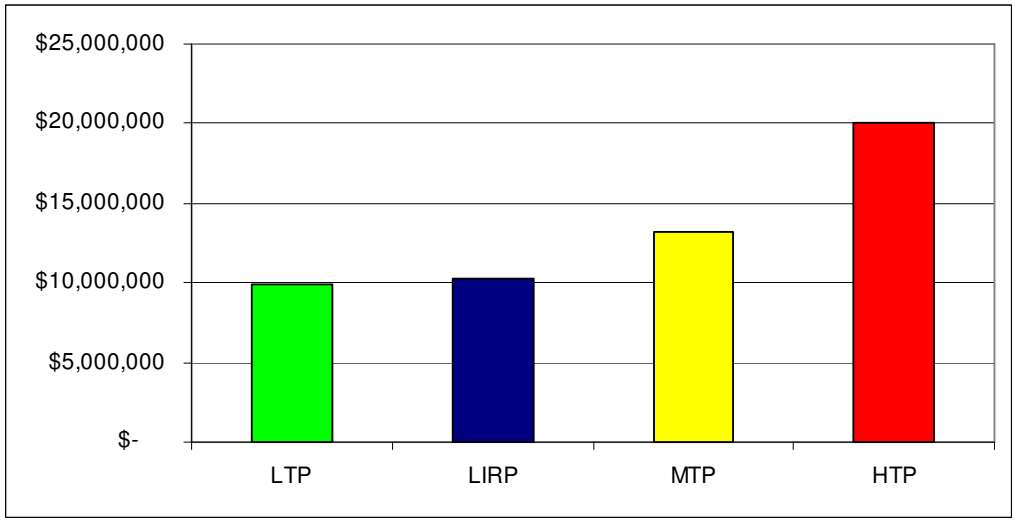
A comparison of unit prices for the 12 selected products indicates that there is a wide-range of different prices paid for the same product. According to data derived from the GPRM database, Rwanda, for example, has 7 of the 12 Lowest Transaction Prices. In comparison to the previous analysis of the procurement price of essential medicines, Rwanda is achieving remarkable pricing efficiencies for many ARVs. What must be considered, of course, is that a number of these products were procured and financed by third parties who are also able to achieve lower prices through aggregating orders at the global level (e.g., PEPFAR). By contrast, Burundi has 4 of the 12 Highest Transaction Prices, Uganda 3, and Kenya and Tanzania one each.

Overall, the median price variation between the Lowest and Highest Transaction Prices for the 12 products is 90 percent. The inordinate purchase price of Nevirapine by procurement agents in Kenya was included in the calculation to underscore the remaining fact that innovator brands (in this case Viramune) do indeed still cost multiple times that of generic equivalents. The reasons for other observed differences include data of purchase, volume, and supplier.

4.4 Quantifying Pricing Scenarios

The amount of financing necessary to support the procurement of the range of essential medicines to treat HIV in the EAC region is quite substantial in comparison to other essential medicines purchases. There is no question that the support of international donors in partnership and ministries of health will be a vital component in ensuring adequate quantities of medicines can be procured. This scale, however, also provides opportunities for significant savings over current prices both for the 12 products examined in this section, and presumably, for the several dozen, perhaps of hundreds of other products not examined in this analysis.

Figure 3.13: Cost of 12 Commonly Procured HIV/AIDS Commodities



The amount of financing necessary to support the procurement of the range of essential medicines to treat HIV in the EAC region is quite substantial in comparison to other essential medicines purchases. There is no question that the support of international donors in partnership and ministries of health will be a vital component in ensuring adequate quantities of medicines can be procured. This scale, however, also provides opportunities for significant savings over current prices both for the 12 products examined in this section and, assumably, for the several dozen, perhaps hundreds of other products not examined in this analysis. Figure 3.9 compares the procurement costs under four pricing scenarios. The volume is derived by adding the most recent procurement for each of the 12 products found in the GPRM database. As can be seen, if all the products were procured at the LTP, the total cost would equal $ 9,956,998, compared with $20,047,217 if procured at the HTP – which amounts to over a $US 10 million difference for based on only one procurement for each product for each country. Even comparing the LTP to the median price obtained by the EAC member-states amounts to a difference of over $3 million U.S...(Annex 6 contains the cost variations for each price).

CHAPTER IV: FEASIBILITY ANALYSIS

1. ANALYZING THE FINDINGS

This section analyzes the main findings from the report and compares them to the requirements for the Group Contracting and Central Contracting models to determine if pooled procurement is feasible for the EAC region, and if so, which model should be developed.

a. Table 4.0 is a feasibility matrix which highlights the main findings for each country to assess the readiness of each country to adopt regional pooled procurement of medicines. It further illustrates the similarities and the disparities within the member countries which would require the development of a regional operational plan for pooled procurement to further harmonize and improve systems.

b. Table 4.1 Summarizes the findings for each of the variables used in the study as an *Asset/ Strength* or *constraints/challenges.* Each of the variables are categorized within the major assessment components. Asset/Strength is defined as a variable that currently is supportive of either model of pooled procurement, while Constraints/Challenges indicate that are opportunities that are in fact necessary to address variables (e.g., systems, policies, and organizational harmonization) *not* consistent or supportive of pooled procurement. This table, along with Table 4.0, provide further basis to inform a regional operational plan for pooled procurement.

c. Table 4.2 (a) compares the findings of the situational analysis with the criteria that needs to be in place to successfully operate the Group Contracting pooled procurement model. Table 4.2 (b) compares the findings against additional Criteria necessary to operate the Central Contracting model. Based on the findings, each criteria is given a score from 1 – 4, then an overall rating to determine the feasibility of each model. The scores are defined and opportunities/potential actions are identified that would form the basis of a regional operational plan addressing gaps regarding the operation of either model.

The findings in the tables suggest that further organizational, capacity, and system improvements will be required before either model of pooled procurement can be operated successfully. Opportunities for making these improvements are detailed in Chapter 5.

Table 4.0: Pooled Procurement Feasibility Matrix

	BURUNDI	KENYA	RWANDA	UGANDA	TANZANIA	ZANZIBAR
Political commitment						
Political commitment among the highest level of government	Yes	Yes	Yes	Yes	Yes	Yes
Formal signed agreement on pooled procurement of medicines	No	No	No	No	No	No
Active participation of member countries on harmonization activities	Yes since 2006	Yes	Yes	Yes since 2006	Yes	Yes
Preferred model of pooled procurement	Group contracting	Group contracting	Group contracting	Group contracting	Group contracting	N/A
Good Pharmaceutical Procurement Practices						
Procurement legislations	No	Yes	Yes	Yes	Yes	Yes
ICB as preferred procurement method	Yes	Yes	Yes	Yes	Yes	Yes
International currency acceptable	Yes	Yes	Yes	Yes	Yes	Yes

Language	French	English	English/French	English	English	English
Preference to local manufacturers						
a. Legally	No	Yes	Yes	Yes	Yes	N/A
b. In practice	No	Yes	No	No	Yes	N/A

	BURUNDI	**KENYA**	**RWANDA**	**UGANDA**	**TANZANIA**	**ZANZIBAR**
Regulatory procedures						
Medicines regulation	No	Yes	No	Yes	Yes	Yes
Adequate in-country quality assurance	No	Yes	No	Yes	Yes	No
Mutual system for the harmonization of medicines registration	No	No	No	No	No	Yes, as part of the United Republic of Tanzania
Formalized system for information sharing	No	No	No	Yes	No	No
Medicines supply chain						
National medicines policies	Yes	Yes	Yes	Yes	Yes	Yes

Essential medicines list	Yes	Yes	Yes	Yes	Yes	Yes
Standard treatment guidelines	Yes	Yes	Yes	Yes	Yes	Yes
National medical stores	Yes	Yes	Yes	Yes	Yes	Yes
Financing of medicines						
Sources of funding	Govt. & Donors	Govt. & Donors	Govt. & Donors	Govt. & Donors	Govt. & Donors	Govt. & Donors
Preferable payment method	Letter of credit	Letter of credit	Bank transfer	Letter of credit	Letter of credit	n/a
Access to foreign and convertible currency	Yes	Yes	Yes	Yes	Yes	Yes
Pricing						
Presence of 11 essential medicines and 13 HIV/AIDS common products	Yes	Yes	Yes	Yes	Yes	n/a

Table 4.1: Summary Findings of Pooled Procurement Variables

A. Political & Organizational Commitment	Assets / Strengths	Constraints/ Challenges	Summary Findings
Political Commitment from the highest level of Government	☑		- Existing EAC Policy body, which involves heads of Government, ratified support for pooled procurement - Political/organizational support among country stakeholders recorded in survey.
Formal signed agreement	☑		The EAC Treaty which is a formal signed agreement is the basis for all joint activities
Cohesion of regional bloc	☑	☑	- The original three partner states had a shared history, language, culture and infrastructure as basis of their regional cohesion. - The two newer partners may reduce the degree of cohesion (language & infrastructure), which can be a challenge, though evidence of this has not been found.
Active participation of member countries	☑		- The member countries are actively participating in some pooled procurement related activities (e.g., harmonization of medicines regulatory activities, standardization of STGs for ART). -The level of awareness on pooled procurement at national level is still limited and organizational commitment to implement the pooled procurement will be a challenge without active political leadership
B. Procurement Legislation / Policies	**Assets/ Strengths**	**Constraints / Challenges**	**Summary Findings**

Legislative Framework	☑		Procurement Legislation and Institutional framework is similar in the countries and can be adapted, as necessary to support both PP models
International Obligations		☑	-Various interpretations on international obligations might give rise to conflict of interest -Countries will need to gain policy support for PP from international partners
National Preference	☑	☑	-The issue of giving preference to local manufacturers might be perceived as "non-competitive" by countries with low local manufacturing capacity and by international partners -National preference can also be viewed as “regional preference” which can support development of the EAC region
C. Medicines Regulations	**Assets/ Strengths**	**Constraints / Challenges**	**Summary Findings**
Legislative Framework		☑	There are disparities in legislative or regulatory framework that are hurdles to clear within the organizational structures of NMRAs .
Quality Assurance	☑	☑	The varying capacity of the National Medicines Regulatory Authorities in the region makes a regional QA system more necessary to support either model of PP. -NMRAs are meeting regularly and working towards harmonization of standards and practices for Quality Assurance. PP provides an opportunity to enhance regional QA activities.

Medicines Registration		☑	-National drug registration procedures vary across the region. This is recognized as a barrier to pooled procurement of medicines. Registration procedures should be harmonized and mutual recognition among countries considered inorder to speed up registration within the sub-region.
D. Supply Chain Systems	**Assets/ Strengths**	**Constraints/ Challenges**	**Summary Findings**
Medicines Policies	☑		-Policies well developed and international/regional collaboration is a common component of the policies
Essential Medicines Lists	☑		Not formally harmonized but each of the countries procure similar essential medicines and HIV/AIDS products with which to initiate PP
Standard Treatment Guidelines	☑		A degree of harmonization for ART, TB, and Malaria treatment has taken place providing a limited list of standard treatments and common products.
National Medical Stores	☑		-NMS in all countries are seeking greater efficiency and performance through increased autonomy in management and financing. .
Organization		☑	The structure and mode of operation varies considerably.
Procurement	☑	☑	At country level, there are several stakeholders / partners with various procurement policies that lead to inconsistencies whose impact may become magnified at the regional level. At the same time, the players may offer opportunities to negotiate for more efficient and sustainable procurement in EAC.

Logistics Management		☑	Incomplete computerization limits accuracy, availability and sharing of information and has a substantial negative impact on quantification.
E. Financing Components	**Assets/ Strengths**	**Constraints/ Challenges**	**Summary Findings**
Health Expenditures		☑	On average, a 25% reliance on external sources for health expenditure makes financing of medicines more complex and challenging
Legal Provisions	☑		Each country recognizes the role of medicines in health and development strategies in formal legislation.
Implementation of Provisions		☑	Implementation of legislative mandates to fund medicines is uneven across member-states
Funding Amount		☑	Existing legislation and MOH mandates to fund medicines are unclear and consequently are sometimes ignored.
Household financing	☑		Household financing of medicines presents opportunity to capture additional funds for procurement if concerted efforts are made to channel fund for purchases.
Payment Methods	☑		All countries use Letter of Credit as a major form of payment, leading to a more efficient payment environment, and in cases, lower prices.
Payment Efficiency	No data	No data	No data
Use and Access to Convertible Currency	☑		All countries have access to and use convertible currency for major international procurements.

Political Commitment to the Financing Environment	☑		Political commitment by senior-level decisions makers to implement necessary changes in the financing environment to support pooled procurement is high. However, organizational-level commitment in countries to a regional purchasing mechanism is not overwhelming, but is a pre-requisite for PP and thus may pose a challenge.
E. Pricing Components	**Assets/ Strengths**	**Constraints/ Challenges**	**Summary Findings**
Pricing Efficiency	☑		-Country pricing efficiency against median reference prices very good; procurement efficiencies compared to lowest reference prices indicates more than 20% paid in the public sector
Common Products	☑		-Several common essential medicines procured by the public sector -STGs and EMLs for HIV/AIDS consistent resulting to a number of commonly procured ARVs
Opportunities for Reduced Prices	☑		-Substantial opportunities exist for achieving reduced prices for essential medicines and ARVs.
Monetary Savings	☑		Potential monetary savings from PP can be made annually for products examined.
Suppliers	☑	☑	-Use of local suppliers results in lower unit prices -Quality and potential political issues must be addressed to integrate local manufacturers in PP mechanism.
Volume and Price	☑	☑	-Correlation between higher volume and lower prices imperfect, but evidence indicates it exists.

READINESS ASSESSMENT FOR POOLED PROCUREMENT

1. COMPARING PROCUREMENT MODEL REQUIREMENTS WITH FINDINGS

Table 4.2 (A and B) lists requirements (criteria) necessary for the feasible implementation of the Group Contracting and Central Contracting Models. The requirements are based on and reflect the study variables listed in Table 4.1. These variables represent a comprehensive group of indicators that aim to demonstrate if and to what extent each pooled procurement model may be feasible for the EAC region.

The scores assigned for criteria were subsequently reviewed and revised by the panel of EAC Health Experts when meeting in Nairobi 17 – 19 September. The Health Experts, in group work and plenary discussions, revised the scores for several criteria, including the level of readiness regarding STGs, national supplier preference, and the pricing environment. They also provided data the study team was unable to obtain for payment efficiency and scored it accordingly.

A score of 1 – 4 has been assigned to each requirement. These scores are based on the current situation for each subject as found in the situational analysis and interpreted by the study authors. The scores are also a composite of the findings in each of the five EAC countries and Zanzibar, so they represent regional readiness for pooled procurement and are not reflective of any particular country.

Each study variable can receive maximum score of 4.

- A score of “4” indicates that, at present, the particular criteria for pooled procurement has, for the most part, been largely been achieved, though, would, of course, need to be maintained through the development and implementation of any system.

- A score of “3” indicates that significant capacity, progress, or development has occurred, but additional opportunities to strengthen these areas must be taken advantage of to improve feasibility.

- A score of “2” indicate that significant challenges exist in these areas that will need to be strengthened before the related model can be implemented.

- A score of “1” indicates that either the policy, system, funding or other criteria does not exist at all, or would require a special focus in any pooled procurement action plan.

The scores are subjective, as they are open to wide variety of interpretation. They are also intended for further revision during and following a series of meetings in September, 2007 with EAC health experts and policymakers when deciding which, if any, model to pursue.

The third column in the tables, "Opportunities/Action Areas," goes beyond a summary or interpretation of the findings to provide a critical first look at potential activities that must be undertaken as part of a EAC managed regional operational plan for pooled procurement. Depending on the model selected, the areas receiving scores of "1" and "2" should receive priority, as they effort will need to be directed towards these areas to improve the feasibility of the proposed system.

As noted in Table 4.2, both Group Contracting and Central Contracting models require similar criteria from countries to be effective. Political and organizational commitment, harmonized EMLs, STGs, and other regulations; reliable payment systems; and other variables discussed at length in this study are a few, among many requirements that need to be in place.

Table 4.2(a): Requirements for Group Contracting

GROUP CONTRACTING		
Model Requirement (Criteria)	**Aggregate Score EAC Countries (1 – 4)**	**Opportunities/Action Areas**
Political and Organizational Commitment		
• Commitment from the highest level of Government	4	-Maintain this support with efficient analysis and implementation of the system -Policymakers must be willing to: • take ownership of PP • fund operational requirements • communicate, and enforce requirements with related personnel at national level and regional levels

• Organizational Support from senior operational staff	2	-Increase organizational support by underscoring that pooled procurement will be limited to a target set of commodities. Therefore, national purchasing systems are still vital and necessary
• Formal signed agreement	2	-Formal EAC treaty in place, but formal agreement among member-states should be signed after model type is selected. This agreement can serve as the political and legal basis to implement mechanism.
• Cohesion of regional bloc	3	-Continue to integrate new members using regional mechanisms. -Pooled procurement represents opportunities to improve regional cohesion
• Active participation of member countries	2	-Increase awareness of pooled procurement among national-level stakeholders
Procurement Legislation & Policies		
• Legislative Framework	3	-Revise legislative framework in countries to enable regional purchasing
• International Obligations	2	-Negotiate with partners to allow external support for regional purchasing
• National Preference	1	-Develop and ratify clear policy on national manufacturing preference as it relates to regional purchasing to ensure expectations are aligned
Medicines Legislation		
• Medicines Registration	2	-Ensure harmonized registration procedures in each country that are responsive to regional purchasing requirements and synchronized to ensure regionally purchased products are registered in all countries in advance of delivery.
Supply Chain Systems		
• Essential Medicines Lists	2	-Ensure that EMLs become increasingly harmonized to: • Expand the list of potential target commodities for pooled procurement • Avoid legal and clinical challenges to products that are purchased through regional pooled procurement

• Standard Treatment Guidelines	2	-Ensure STGs are harmonized (for the same reasons above)
• Forecasting/Quantification	2	Improve forecasting and quantification capacity to: • ensure that regional pooled procurement planning is consistent with need, • avoid surplus or shortage in the contract volumes, • and create efficient ordering within any framework contract that is negotiated.
Financing		
• Political Commitment to the Financing Environment	2	-Political commitment to drug financing stated by policymakers need to routinely be translated to increasing government budgetary amounts
• Legal Provisions for[8] medicines financing	n/a	-Legislation supporting medicines financing should be amended to include language on the use of regional structures for bulk procurement
• Implementation of Guidelines for medicine Financing	2	-Improve the implementation of legislation for medicine financing by providing policymakers, partners, and senior drug management staff with data on need, costs, and benefits of full supply of essential medicines
• Funding Amount	2	-Increase total funding amount for essential medicines and associated systems through the use of data demonstrating needs and benefits
• Payment Methods	4	-Maintain capacity to use preferred payment methods such as letter of credit
• Payment Efficiency	2	-Ensure that public sector procurement agencies, donors, banks, and others that may be involved in financing regional purchases possess payment systems consistent with contractual requirements.
• Use and Access to Convertible Currency	4	-Maintain current systems providing access to convertible currency and look for new mechanisms to access CC for purchases, such as regional and national banks in the EAC.
Pricing Environment		

[8] The EAC Health experts recommended that the study variable related to the "Legal Provision of Financing" should be removed from the table because it was not directly related to the issue.

• Pricing Efficiency	3	-Transfer and use existing national procurement management skills to support a potential regional purchasing mechanism
• Opportunities for Reduced Prices for target commodities	3	-Though current price is efficiency is good, there is opportunity to obtain lower prices for target commodities through higher volume purchasing
• Monetary Savings *(to be reformulated)*	2	-Develop system to recapitalize regional procurement fund with savings obtained from bulk purchasing
• Suppliers (local production)	2	-Develop and implement quality control program on all local suppliers consistent with regional and international standards to widen the scope of potential funding channels for regional purchasing mechanism.
Highest Possible Score	**88**	
Total Score	**53**	
Percentage	**60%**	

Group Contracting

The highest possible score among the 22 indicators used to measure the feasibility of Group Contracting was 88. Of this total, the analysis of the findings resulted in a total score of 53, or 60%. As Table 4.2 (A) indicates, there is strong political commitment, regional "cohesion," and high degree of capacity in procurement. However, certain legislative requirements and implementation of policies, and supply chain management, for example, are areas that need to be substantially strengthened.

The findings from the survey regarding the readiness and commitment to implement pooled procurement as presented in Section I of the findings (Political will and organizational commitment) indicates that there is a strong preference for Group Contracting over the Central Contracting model among the senior-level drug management staff in-country which is consistent with the readiness scores illustrated in Table 4.2.

Central Contracting

Additional requirements are necessary to implement the Central Contracting model. These requirements include:

- A centralized revolving drug fund capable of collecting payments from countries
- A centralized payment processing and financial management system that can make timely payments to suppliers
- Initial capitalization for secretariat operations and sustainable financing for these operations until self-sufficiency can be achieved
- Technical capacity to manage and review order quantities, demand forecasts from member-states, and participate in tender management and contract negotiations for a wide-range of target commodities

Table 4.2 (B) illustrates these additional requirements for Central Contracting, the associated scores (current state of readiness), and Opportunities/Action areas. The scores of 1 and 2 for this model reflect the current situation and the fact that the systems and financing for these operations do not yet exist. These scores, however, do not indicate that these requirements cannot be met, but would require a deeper commitment by the EAC and partners to take advantage of the opportunities that have been identified.

The increased complexity and cost of the Central Contracting model results in six additional criteria included in the analysis of this model. These criteria are then combined with the base criteria for the Group Contracting model in Table 4.2 a. As a result 24 points are added to the highest possible score for total of 112 points. The scoring for Central Contracting, following a review by the EAC Health Experts remained unchanged from those proposed by the study team – 7 of 24 possible points. When added to the base score, the analysis indicates a 54% feasibility score. This score however may not reflect fully the substantial investment, human and financial resources required to implement a central contracting model.

Table 4.2 (b): Additional Requirements for Central Contracting

CENTRAL CONTRACTING		
Model Requirement (Criteria)	**Aggregate Score EAC Countries (1 – 4)**	**Opportunities/Action Areas**
Regional Pooled Procurement Secretariat		
• Technical capacity to review demand forecasts	2	-Identification and development of personnel and acquisition of hardware and software at the regional level to interface with national counterparts to develop forecasts for target commodities as the basis for tendering and ordering

• Identification of procurement, legal, and supply chain staff	1	-Identify, hire, retain, and train small cadre staff to manage the functions of the regional procurement service
• Quality Assurance System	1	-Develop regional product quality assurance system to ensure high-level of quality for member-states (clients)
• Regional financial management and payment system	1	-Develop financial management systems and payment procedures internally within the secretariat and with member-state counterparts
Financing		
• Funding EAC Pooled procurement Secretariat	1	-Identify funding sustainable funding for operations from EAC and partners
• Regional medicines procurement fund	1	-Ensure the RDF for regional purchases is capitalized to avoid borrowing or default on payments
Highest Possible Score	**112**	
Total Score	**60**	
Percentage	**54%**	

2. RECOMMENDED MODEL

The findings and the scores from the readiness assessment tables suggest that Group Contracting is, at present, marginally more feasible for the EAC than the Central Contracting model. The criteria accounting for the difference, as illustrated in Table 4.2 (B), are the score of the additional requirements necessary to implement Central Contracting.

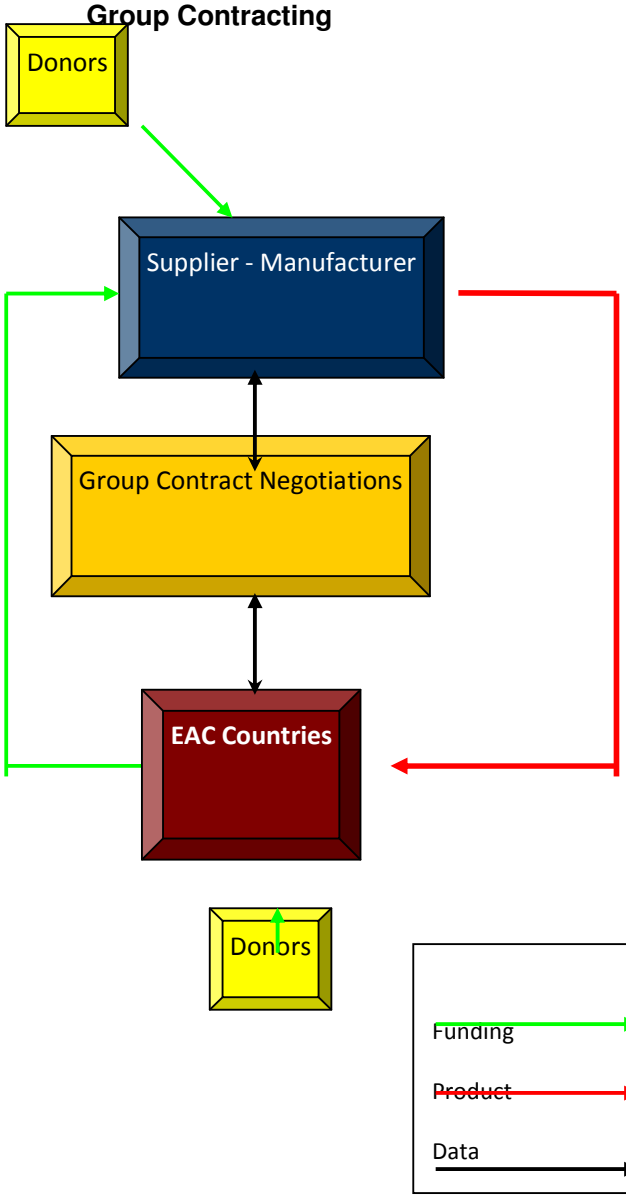
A total feasibility score of 100% for either model would of course indicate that all requirements have been met, and the region exceedingly well positioned to begin development of a pooled procurement mechanism. The consensus of the study team and the EAC Health Experts further suggested that a score of 50% or below for either model would indicate that pooled procurement should not be developed at this point. Rather all efforts should focus on addressing existing gaps. However, the 60% feasibility score for Group Contracting suggest that the EAC and partners should proceed cautiously and deliberately, focusing on addressing the gaps identified in the analysis, while beginning the necessary planning and developing the structure for the Group Contracting model.

Both models were proposed for consideration by the EAC health experts at the EAC Medicines Experts meeting (Nairobi, 17th-19th September 2007), with the recommendation that region first pursue the development of Group Contracting. For the model chosen, the EAC will need to lead the development and implementation of regional operational plan for

pooled procurement, which will address the gaps identified in this report. Further, it is suggested that the model may require "donor funding" element for certain categories of product such as ARVs, ACTs and TB medicines.

3. DESCRIPTION OF THE RECOMMENDED POOLED PROCUREMENT MODEL

Group Contracting



Group Contracting

- Member countries jointly negotiate prices and select suppliers.
- Member countries agree to purchase from selected suppliers.
- Countries conduct purchasing individually.
- *Optional*: Donor funding for products is channelled through countries or directly to supplier

Requirements

- Requires central capacity to collect information on countries medicines volumes required, negotiate prices, and commitment from countries to use selected suppliers
- Can achieve volume cost savings through negotiation
- Pre-qualification of suppliers may improve quality and reliability of supply
- Allows countries to retain autonomy for purchasing
- Does not require transfer of funds to a central procurement organization
- Requires contractual commitment from participants
- Requires some degree of harmonization of essential medicines lists and in drug registration procedures

CHAPTER V: CONCLUSIONS AND RECOMMENDATIONS

1. SUMMARY OF FINDINGs AND RECOMMENDATIONS

This study has assessed the five EAC member countries with regards to the feasibility and their readiness to embark on joint procurement of selected medicines as a regional bloc. Accordingly, the assessment focused on the essential components of pooled procurement for the two models identified in this study, i.e. Group Contracting and Central Contracting. The report further indicated that given the current situation, Group Contracting is marginally more feasible for the EAC than the Central Contracting Model. In addition, this study has highlighted and confirmed the fact that "pooled procurement" of pharmaceutical products goes beyond the mere activity of the acquisition or purchasing of products. It relies on the efficiencies of the various supporting structures and systems for a successful and sustainable multi-country joint procurement system. These systems and structures provide the enabling environment for a smooth adoption and an effective and sustainable implementation process.

A Regional Operational Plan for Pooled Procurement: Moving the Process Forward

The tables in Chapter 4.0 suggest that – despite recent improvements in supply systems, strengthened regional policies and harmonization, and a high-level of procurement efficiency, the development and implementation of either procurement model will be dependent on the ability of the EAC, its Health Secretariat, and member-states to organize and develop a regional operational plan for pooled procurement which addresses the requirements detailed in this report. It is critical that this planning process is lead by the region for the region, and that it is adequately funded and supported at all levels (e.g., politically and organizationally).

The fact that gaps regarding the development of the pooled procurement models have been identified should not dissuade the EAC and its partners from embarking on the development of the recommended model. The regional operational plan could and should also include activities directly related to building a regional procurement mechanism, while simultaneously addressing the gaps. For example, the benefits derived from strengthened regional policies and legislation and implementation of existing policies regarding medicines (Table 4.2 a) go beyond procurement by serving to strengthen health systems, and thereby health outcomes, more broadly.

The following recommendations are premised on a regionally lead approach that is cognizant of the steps that need to be taken to improve the feasibility of either model. An integrated approach, lead by the EAC and supported by partners, is therefore required for the support of the systems that are the building blocks for the proposed joint procurement programme for the EAC member countries. This section, informed in part by the “opportunities/action areas” in Tables 4.2 a and b, further detail and recommend the potential areas for a regional operational plan for pooled procurement.

a. Political will and organizational commitment

The political will and commitment for a harmonized regional economic bloc is strongly evident from the various actions being implemented by the East African Community. With the existing hierarchical structure of the EAC Policy Organ, there is guarantee for political support from the highest level of government for EAC approved programmes. Even though, the issue of regional pooled procurement of medicines is still at an exploratory stage, thus this feasibility study, with the implication that policy- and decision makers are yet to make a commitment on regional pooled procurement, it confirms the current political interest on pooled procurement. Maintaining the political commitment for regional pooled procurement of medicines is essential as it can provide the basis for a harmonized and integrated EAC health care delivery system.

The EAC Secretariat is presently the driving force behind the ongoing pooled procurement related activities, however, its biggest constraint is the lack of institutional capacity to implement either of the two pooled procurement models, but even more so with the Central Buying Model. There is a need for the coordination and implementation of pooled procurement at the Secretariat level, and the minimum human and technical capacity required should be identified.

At national level, the various stakeholders are aware of the benefits and challenges of pooled procurement of medicines, but in varying degrees, thus emphasizing the need for more advocacy and further consultations. The indications are that they are willing to give it a trial, with their main concern being the level of commitment required from policy makers for a successful and efficient regional pooled procurement programme. However, the member countries must take ownership of the pooled procurement programme, not only of the successful implementation but also to maintain and increase the political and organizational commitment in regional pooled procurement.

Recommendations:

1. The EAC should ensure that all member states are actively involved in the process of adopting and implementing pooled procurement and take ownership of the regional pooled procurement programme.
2. The capacity of the EAC Secretariat must be strengthened and the existing capacities at national levels maximally utilized to support to the EAC Secretariat to coordinate the regional pooled procurement programme.
3. A contractual and binding agreement should be signed among the EAC member states specifically for the implementation of pooled procurement to strengthen the organizational commitment.

b. Procurement legislations

The current procurement legislative environment in the EAC member states is relatively homogenous, thus providing the basis for Good Pharmaceutical Procurement Practice for

regional pooled procurement. Even though the similarities in the procurement legislations and policies far outweigh the disparities, there are certain issues that need to be resolved. One major challenge that could also be a potential barrier is the role of local manufacturers in regional pooled procurement of medicines. Kenya and Tanzania with the largest number of local manufacturers are also the countries heavily supporting the national industry through the local preference clause in their respective legislations, which makes it legally binding nationally. It is also a complex issue with both political and socio-economic implications but also dealing with issues and concerns related to capacity of local manufacturers to meet the selection of needed medicines, pooled quantities, Good Manufacturing Practices, quality of products and WHO pre-qualification scheme requirements, especially where donor funding is involved. This area is also an opportunity for the EAC to deal with the issue of local production as a potential area for harmonization through improvement of quality and the pooling of local capacity to meet regional needs that will benefit the not only the specific countries that produce medicines but the sub-region as an economic bloc.

Recommendations:

4. A detailed study should be conducted assessing the current capacity of national manufacturers to address needs for pooled procurement in EAC in terms of medicines selection, volumes and quality and also identifying their potential role in regional pooled procurement of medicines and mapping the way forward.

5. Develop and ratify clear policy on national manufacturing preference as it relates to regional purchasing to ensure expectations are aligned.

c. Medicines Regulations

The regulatory legislations, institutional framework and capacities to regulate the movement of quality assured medicines within the member countries are relatively diverse. This group, in recognizing their strengths and weaknesses, is currently the most active in working towards a harmonized Medicines Regulatory System which would be the basis for an EAC Food and Drugs Authority. The medicines registration procedures is the main stumbling block towards the implementation of regional pooled procurement as three of the countries (Tanzania, Kenya and Uganda) do not allow tender and import of medicines without product registration. Since there is no system of mutual recognition of EAC member states National Medicines Regulatory Authorities (NMRA) decisions on registration of medicines, the harmonization of this activity needs to be prioritized. This is therefore an opportunity for the NMRAs to strengthen their capacities and harmonized their regulatory procedures especially on medicines registration to ensure the purchase of quality assured medicines as part of the pooled procurement process in their sub-region.

Recommendations:

6. Technical and financial support should be provided to strengthen the capacities of the NMRAs of the five EAC member states with the ultimate objective of facilitating

the harmonisation of quality assurance procedures.

7. The Harmonization of medicines registration procedures should be prioritized as part of regional pooled procurement activities.

d. Medicines Supply Chain

The set up and mode of operation of the National Medical Stores varies considerably, but with most of them operating as semi/ autonomous institutions. The inadequate Logistics Management Information System, which impacts on the accuracy and availability of information, has a substantial negative impact of quantification of needs and limits information sharing. The procurement process involves development partners and procurement agents with various procurement regulations and methods, several players, which might either negatively impact regional pooled procurement or offer opportunities for negotiation for pooled procurement. Essential Medicines Lists are not harmonized, whilst Standard Treatment Guidelines are not fully harmonised either, however, there are some medicines that are common to all the EAC countries. The lack of harmonisation of these essential documents therefore limits the selection of the products that can be successfully pooled together for bulk purchasing.

Recommendations:

8. Harmonize the Essential Medicines Lists and Standard Treatment Guidelines to attain a wider range of products to select for regional pooled procurement.

9. Strengthen the capacity of the National medical Stores for quantification of needs, assessment of supplier performance and increased collaboration and information sharing.

10. Improve forecasting and quantification of needs at national level to create an efficient ordering system within the negotiated framework contract for regional pooled procurement.

e. Financing systems

The medicines financing environment among EAC member-states is complex. Each potential category of target commodities for pooled procurement involves multi-source financing that will require negotiation and revision to the current financing structure for medicines. Likewise, similar structural changes may also need to take place between member-states and bilateral donors involved in funding for other commodity categories. Financing policies with regards to EAC member-states themselves do not appear to pose a major challenge because there is significant political support and nascent organizational support to move forward with pooled procurement. Furthermore, the pool of donor and bilateral agencies providing funds for medicines within the sub-regions provides the EAC with the opportunity to mobilize technical and financial support for joint procurement for their sub-region.

Recommendations

11. Determine financing sources for pooled procurement of target commodities and negotiate revisions to existing mechanisms for the utilization of funds.
12. Ensure legislative support for regional pooled procurement financing (specify amounts, financing channels, and commodity categories) in member countries.
13. Work with the East African Development Bank (EADB) or other regional financial institution to manage procurement payments, including currency exchange services of a potential regional purchasing mechanism

f. Pricing

The scale of savings that can be achieved by buying in larger volumes is an important tool in improving efficiencies in medicines management, and remains a central focus and objective of policymakers as they seek to gain efficiencies in public health programs. The primary monetary advantage of pooled procurement is that unit prices can be reduced by purchasing in higher volume.

As a sub-regional bloc, the opportunity to negotiate for lower prices does exist, with monetary savings identified as one of the potential benefits of pooled procurement. The use of existing national procurement management capacity and skills can be transferred and build upon to support purchasing mechanisms at regional level and also improve purchasing at national level.

Recommendations:

14. Review initial target commodities list to determine other products that could potentially meet the criteria for pooled procurement and will increase costs benefits.
15. Use pricing data to conduct additional advocacy with national stakeholders to increase awareness of monetary/pricing benefits to pooled procurement.
16. Improve the purchasing mechanisms and negotiation skills at national level and utilize them for regional pooled procurement.

2. PROPOSED TARGET COMMODITIES

A list of target commodities has been identified from which it is suggested that EAC countries may choose to begin purchasing under a pooled procurement mechanism. The initial list is based on both price and non-price criteria used to identify medicines that are currently purchased at comparatively high prices but also provide a significant health impact in each of the five EAC countries. The first criteria – common medicines being procured in at least three member-states – have been established as this list is drawn from the 50 "highest value" procurements in the public sector. The second criteria is also fulfilled as the products are part of the standard treatment in the majority of countries in the EAC. The additional criteria are:

- **Commonly Procured Products > Lowest International Reporting Prices (LIRP):** Products that at least three EAC member countries have procured at prices higher than the LIRP. This indicates that procurement efficiency for these products (in these countries) is low and there is subsequently scope for pricing improvement. A score of "1" indicates the procurement price was greater than the LIRP; a "0" means it was lower.

- **Commonly Procured Products > Lowest Transaction Price (LTP):** The analysis in the previous section indicates that in at least 50 percent of the procurements the LTP was associated with higher volume purchases – supporting the "economies of scale" theory described in this study. The relationship is not perfect, not all low transaction procurement prices were obtained through high volume purchases. Nonetheless, products procured by other countries in the region at prices greater than the LTP indicates that there is scope for lower prices and bulk volume purchases are often associated with those prices. A benchmark of 10 percent variance between the highest transaction price (HTP) and LTP was established to determine if a product should be included on the target commodity list.

Table 5.1: Initial Target Commodity List for Pooled Procurement

		Criteria					
		Price		Non-Price			
# Countries Common	Common Products	>10% variance b/w MTP &LIRP	>10% variance b/w HTP & LTP	Health Impact	Policy Support	Financing Flexibility	% Criteria
3	Acetylsalicylic Acid 300 mg tab	0	1	1	1	1	80%
3	Metronidazole 200 mg tab	0	1	1	1	1	80%
3	Chloramphenicol 1G Injection Vial	1	1	1	1	1	100%

4	Amoxicillin 250 mg caps	1	1	1	1	1	100%
5	Erythromycin 250 mg tab	1	1	1	1	1	100%
4	Amoxicillin Granules 125mg/5ml 100 ml	0	1	1	1	1	80%
4	Cotrimoxazole 400+80mg Scored	1	1	1	1	1	100%
4	Paracetamol 500 mg tab	1	1	1	1	1	100%
4	Quinine Sulphate 300 mg tab Coated	1	1	1	1	1	100%
3	Chloramphenicol caps 250 mg	1	1	1	1	1	100%
3	Oral Rehydration Salts For 1Lt, 27.9G (Packet)	1	1	1	1	1	100%
	HIV/AIDS Products						
5	Determine HIV-1/2 w/b test (Rapid Test)	1	0	1	1	0.5	70%
5	Didanosine (ddI) 200mg cap/tab	1	1	1	1	0.5	90%
5	Efavirenz (EFV) 600mg cap/tab	1	1	1	1	0.5	90%
5	Lamivudine (3TC) 150mg cap/tabs	1	1	1	1	0.5	90%
5	Nevirapine (NVP) 10mg/ml oral liquid	1	1	1	1	0.5	90%
5	Nevirapine 200mg cap/tab	1	1	1	1	0.5	90%
5	Stavudine (d4T) 30mg cap/tab	1	1	1	1	0.5	90%
5	Stavudine (d4T) 40mg cap/tab	1	1	1	1	0.5	90%
5	Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) 40/150/200	1	1	1	1	0.5	90%
5	Zidovudine (ZDV) 100mg cap/tab	1	1	1	1	0.5	90%
5	Zidovudine (ZDV) 300mg cap/tab	1	1	1	1	0.5	90%
5	Zidovudine (ZDV) + Lamivudine (3TC) 300/150mg cap/tab	1	1	1	1	0.5	90%
Median		**1**	**1**	**1**	**1**	**1**	**90%**

Other criteria should also be evaluated in developing the initial set of target commodities for pooled procurement. While potential low prices, and products already commonly procured by member-states should be used, consideration must also be given to non-price criteria.

These include:

- **Health Impact:** the set of products that will have the greatest health impact on the

major communicable and non-communicable diseases in the region. A review was conducted to determine if each selected product was on the WHO Model EML, which serves as proxy for potential health impact. While the EAC should give more consideration to this criteria to ensure the broadest impact for regional health concerns, this simple indicator ensures that the target list contains medicines *that satisfy the priority health care needs of the population*.[9] Each of the products, formulation and strength or an alternate, is on the WHO model list, except the *Determine* rapid HIV test kit. As HIV test kits are a vital component to prevention and treatment programs, it is also given a score of "1."

- **Policies:** Invariably, policy considerations such as the potential preference of one or a group of countries to buy high-quality products from a certain manufacturer located in the region may also need to be considered. An assumption – based upon the results from the country surveys and public discussion and statements made by the EAC – is made that policy support exists to jointly purchase all products included in the analysis. Therefore, a score of "1" is assigned to each product in the Table.

- **Financing Flexibility:** The source of financing may either support or hinder the efforts of the EAC to include certain products, or even entire categories of products, on an initial target list for pooled procurement. Donors, lending institutions, and EAC national governments, for example, may stipulate that the procurement financing they provide for drugs can only be used by the national public sector agency, and not as a part of combined "pooled financing" supporting a regional purchasing secretariat.[10] Further, many of the ARVs examined in this section are financed and procured by third parties, resulting in greater complexity in efforts to "re-channel" support for those products to a regional procurement mechanism. A score of "1" was given for each product in Table15 if the product was procured and majority financed by the public sector in each country. A score of .5 was assigned to the HIV/AIDS products because the majority of ARV supply is financed, and in many cases procured by third party agents. However, in at least three countries, significant public sector funding and procurement support has been provided to secure these commodities.

3. STEPS TO OPERATIONALIZE THE MODEL

This report recommends the selection of Group Contracting Model as the more feasible model for adoption by the EAC, taking into account the current situation in member countries as highlighted in this report. It also focused on the feasibility of addressing the gaps and requirement identified to adopt the pooled procurement model.

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[9] http://www.who.int/medicines/services/essmedicines_def/en/index.html

[10] The discussion on policy and financial considerations are included in Chapters 2 and 3, and are important components in identifying readiness for pooled procurement broadly.

The steps to be taken for the establishment of the pooled procurement programme will therefore depend on developing a comprehensive operational plan including a budget and timeframe for implementation. This will therefore considered to be the next phase of the EAC Regional Pooled Procurement of Medicines process. Certain key operational steps essential for establishing the procurement model are outlined below:

9. The EAC to adopt Group Contracting pooled procurement model for the joint purchasing of medicines.
10. Strengthen the capacity of the EAC Secretariat to coordinate the regional pooled procurement of medicines.
11. The EAC to establish a Regional Pooled Procurement Taskforce that will be responsible to develop, implement and monitor regional operational plan and coordinate activities within countries and other stakeholders.
12. Develop with the support of partners, the budgeted regional operational plan for the implementation of the pooled procurement programme, including timeframe.
13. Mobilise resources for initial capital expenditures and on-going external financing for medicine procurement.
14. The EAC to design the pilot phase of the pooled procurement and defined the initial list of medicines to be used.
15. Identify relevant structures at country level for coordinating pooled procurement activities (e.g., forecasting/quantification, financing, and price monitoring)
16. The EAC should prioritize key technical activities from the operational plan to be implemented in the first phase of the project and plan for their implementation.

9. The EAC should ensure that all member states are actively involved and take **ownership** of the regional pooled procurement programme.

10. A contractual, binding, and funded agreement should be signed among the EAC member states for the implementation of pooled procurement.

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