



**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

September 2007



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SEPTEMBER 2007

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REFERENCES

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

ACKNOWLEDGEMENTS

The Situational Analysis and Feasibility Study on Regional Pooled Bulk Procurement of Medicines and other Health Supplies was made possible with technical support from the department of Technical Cooperation for Essential and Traditional Medicines (TCM) at the World Health Organization (WHO), John Snow Incorporate (JSI), and the Rational Pharmaceutical Management Plus (RPM) Plus Project of Management Sciences for Health (MSH), with financial support through the WHO by the United Kingdom's (UK) Department for International Development (DFID) and the European Community's Office of EUROPEAID.

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 funds 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
-