EAST CENTRAL AND SOUTHERN AFRICA HEALTH COMMUNITY

# REGIONAL PHARMACEUTICAL FORUM

## Technical Report of the 9th Meeting of the Regional Pharmaceutical Forum

**5th -6th May 2014 - Nairobi, Kenya**


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# East Central and Southern Africa Health Community

## 9th Regional Pharmaceutical Forum Meeting

## Safari Club Hotel, Nairobi, Kenya

## 5th and 6th May 2014

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**Report Summary**

The Regional Pharmaceutical Forum (RPF) is one of East, Central and Southern Africa Health Community (ECSA-HC) Experts' Committees. It was established in 2003 as a network to strengthen pharmaceutical management systems in member states, through provision of technical leadership and support to countries to enhance advocacy for and implementation of best practices in pharmaceutical management. The RPF meets annually, and the objective of the 9th meeting was to share the work that has been undertaken in the pharmaceutical sector in the member states and by the ECSA-HC secretariat. In addition, it was meant to share best practices that could be adopted in the region with regards to pharmaceutical management.

During the two day meeting, the ECSA-HC secretariat gave updates on the status of implementation of activities that were agreed upon during the 8th RPF meeting. It was noted that some of the activities have not been implemented due to lack of funding, and thin staffing at the secretariat that are coordinating the pharmaceutical activities. In particular, it was noted that the lack of a pharmaceutical expert at the secretariat was the most proximal cause of the slow progress in the implementation of the pharmaceutical activities. The high turnover of RPF members was also another challenge impacting of the work of the RPF.

The following recommendations were made to strengthen the work of RPF and accelerate the implementation of pharmaceutical activities.

- The ECSA-HC accelerates the process of recruiting a **pharmacist** to coordinate pharmaceutical activities in the ECSA region.
- ECSA-HC develops a pharmaceutical strategic or Business Plan in order to facilitate resource mobilization for the strategic plan.
- ECSA-HC secretariat writes to Principal/Permanent Secretaries requesting for permanent member representations in the experts' committee so that there is continuity in the work of the committees.
- Hasten the process of creating Coordinated Informed Buying platform, but consult Southern Africa Development Community (SADC) and East Africa Community (EAC) to avoid duplication.
- Member states to share pharmaceutical procurement documents with the ECSA-HC secretariat, once the documents become public.
- Develop and own and assessment tool on regional pharmaceutical management where the secretariat can independently administer instead of relying on partners.
- Support the pharmaceutical regulatory harmonization processes.
- Identify and implement strategies that will facilitate member states to appreciate the role of pharmaceutical experts in the health care system.

## List of Abbreviations

| | |
|---|---|
| AUC: | African Union Commission |
| CIB: | Coordinated Informed Buying |
| CMST: | Central Medical Store Trust of Malawi |
| DD: | Direct Delivery |
| ECSA-HC: | East, Central and Southern Africa Health Community |
| eLMIS: | Electronic Logistic Management System |
| EML: | Essential Medicine List |
| GCC: | Gulf Cooperation Council |
| GMP: | Good Manufacturing Practices |
| HPTs: | Health Products and Technologies |
| HSSD: | Health Systems and Services Development |
| HSSF: | Health Sector Services Fund |
| ICCM: | Integrated Community Case Management |
| JMS: | Joint medical Store |
| KEML: | Kenya Essential Medicine List |
| KEMSA: | Kenya Medicine Supply Agency |
| KNPP: | Kenya National Pharmaceuticals Policy |
| LMU: | Logistic Management Unit |
| MAUL: | Medical Access Uganda Limited |
| MOH: | Ministry of Health |
| MSD: | Medicine Store Department, Tanzania |
| NDA: | National Drug Authority, Uganda |
| NEMLIT: | National Essential Medicine List |
| NEPAD: | New Partnership for Africa's Development |
| NHTC: | National Health Training College |
| NMRAs: | National Medicine regulatory Authorities |
| NMS: | National Medical Store, Uganda |
| NMTC: | National Medicine Therapeutic Committee |
| NMTPAC: | National Medicine and Therapeutic Advisory Committee, Zimbabwe |
| OECS/PPS: | Organization of Eastern Caribbean States/Pharmaceutical Procurement Service |
| PAHO: | Pan American Health Organization |
| PBF: | Performance Based Financing |
| PHC: | Primary Health Care |
| QC: | Quality Control |
| QPPU: | Quantification, Procurement and Planning Unit |
| RAS: | Rapid Assessment System |
| RECs: | Regional Economic Communities |
| RPF: | Regional Pharmaceutical Forum |
| SADC: | Southern Africa Development Community |
| SANU: | Southern Africa Nazarene University |
| SCGs: | Standard Clinical Guidelines |
| *SCM:* | *Supply Chain Management* |
| SSFFC: | substandard, spurious, falsified, falsely label and counterfeit medical products |
| STG: | Standard Treatment Guideline |
| TFDA: | Tanzania Food and Drug Authority |
| USAID/EA: | U.S. Agency for International Development, East Africa bureau |
| WHO/AFRO: | World Health Organization, Regional office for Africa |
| ZAZIBONA: | Zambia, Botswana, Namibia and Zimbabwe coalition for fast tracking harmonization medicine registration |

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## 1.0 Introduction

Accessing high quality pharmaceuticals and other health commodities remain an enigma to most citizens of the ECSA-HC member states. This is due to a number of challenges, but the most proximal ones include inadequate financial allocation, inefficient supply chain systems, accelerated development of microbial resistance due to irrational medicine usage, absence of enabling medicine policy environments and strategic pharmaceutical and commodity management information. In addition, because of the sheer huge expenditures incurred by countries on health commodities, typically about 40% of health expenditure, the financial risks are also huge thus a call for robustically efficient and effective procurement processes and budget management. All the aforementioned challenges can be circumvented to a large extent, with resultant improvement in access to quality efficacious medicines through strengthening governance in the pharmaceutical sector including enforcing rational use of medicine, improving pharmaceutical management systems and financing mechanisms.

Pharmaceutical management system strengthening involves enhancing the capacities of the national supply chain systems so that they are able to accurately forecast and quantify the needed health commodities. In addition, innovative approaches such as bulk pooled procurement can tame inadequate financing through creating a monopsony scenario, where countries in the region bargain with pharmaceutical manufacturers and suppliers as a single entity. Countries implementing this approach have already demonstrated significant savings. Examples include the Organization of Eastern Caribbean States/Pharmaceutical Procurement Service (OECS/PPS), Gulf Cooperation Council (GCC) and Pan American Health Organization (PAHO).

Cognizant of the access problems to pharmaceuticals and aware of the underlying causes and how these causes can be solved, ECSA-HC with support from its partners established a regional forum of experts on pharmaceuticals in 2003 to act as a catalyst in solving the problem of access to pharmaceuticals in the ECSA-HC member states. Since its inception, the regional pharmaceutical forum (RPF), as a network to strengthen pharmaceutical management systems in member states has focused on improving and expanding access to high quality pharmaceuticals and other health commodities. The RPF works by providing technical leadership and support to countries to enhance advocacy for and implementation of best practices in pharmaceutical management.

The RPF has continued to identify critical activities that are implemented at the country level as well as regional level through the secretariat.

*Convening of the meeting*

The Regional Pharmaceutical Forum is one of ECSA-HC's expert committee. The ECSA-HC secretariat coordinates and facilitates the RPF meetings. The RPF meetings provide an avenue in which Regional Pharmaceutical Strategies are identified, developed or initiated; the working groups formed or re-constituted to align them to the Forum needs; key documents received and edited, working modalities and plans developed and specific topics addressed.

*Venue of the meeting*

This 9th RPF meeting was held in Nairobi Kenya on 5th and 6th May 2014.

**2.0 Purpose of the meeting**

The meeting aimed at providing a platform for sharing the work that have been undertaken in the pharmaceutical sector in the member states and also share best practices that could be adopted in the region.

*The Specific Objectives of the meeting were to:-*

- Review the status of implementation of the activities that were identified for implementation during the 8th RPF meeting held in Mombasa, Kenya in August 2012.
- Identify areas of capacity improvement in member states that ECSA-HC could organize and support.
- Get updates from the Regional Economic Commissions (EAC and SADC) on the ongoing and/or new initiatives being implemented by Regional Economic Commissions in the pharmaceutical sector and identify how the RPF could add value.
- Identify strategies for strengthening the RPF.

*Focus areas of the meeting*

The meeting focused on the following areas;

a) Strengthening RPF
b) Coordinated Informed Buying

## 3.0. Methodology of the meeting

The meeting had plenary presentations from the member states and the secretariat on progress made, challenges and future plans in strengthening Pharmaceutical Management Systems. This was followed by plenary Discussions.

## 4.0. Outcome of the meeting

Key recommendations on fast tracking the establishment of the Coordinated Informed Buying (CIB) platform and the strengthening the RPF were made.

## 5.0. Proceedings

### 5.1. Participants of the meeting

Participants of the meeting included the representatives from seven member states and the secretariat. The member state represented included; Kenya, Lesotho, Malawi, Swaziland, Tanzania, Uganda, Zimbabwe

### 5.2. Opening Remarks

***Mr. Edward Kataika, Director of Programs at ECSA- Health Community***

The meeting was officially called to order at 9.00 am by Mr. Edward Kataika, Director of Programs at ECSA-HC secretariat. He welcomed all Members of the Regional Pharmaceutical Forum to the 9th Meeting of the Regional Pharmaceutical Forum in Nairobi. He noted that some ECSA-HC member states were not present as well as Regional Economic Communities (RECs).

In his remarks he noted the following;

1. The importance of pharmaceutical sector in the universal healthcare coverage and in the healthcare systems in general
2. Four out of ten reasons of inefficiency in the health systems relates to pharmaceuticals.
3. ECSA efforts were meant to complement rather than duplicate the activities undertaken by member states and the RECs
4. Several regional bodies invited to the meeting but despite some confirming attendance they did not make it. These included SADC, EAC, New Partnership for Africa's Development (NEPAD) and African Union Commission (AUC)

Dr. Jackson Omondi officially opened the meeting. In his opening remarks, he welcomed the participants to Nairobi Kenya on behalf of the Ministry of Health (MOH), Kenya. He reiterated the importance of the pharmaceutical sector in health systems and highlighted the following expectations of the meeting;

1. Feedback from the 8th RPF meeting
2. Milestones achieved and any challenges encountered in the implementation of the 8th RPF meeting recommendations
3. Updates from the RECs

**5.3. Presentations**

**Overview of Regional Pharmaceutical Forum**
**Dr. Walter Odoch, Ag. Manager, Health Systems and Services Development (HSSD) - ECSA-Health Community**

This presentation outlined the RPF background, progress made and challenges experienced since the 8th RPF meeting.

**Background**

The presenter first gave and overview of The East, Central and Southern Africa Health Community (ECSA-HC) organizational structure and functioning. Due to high turnover of member state representatives, the presenter introduced ECSA-HC to the new RPF members. He noted that ECSA is a regional Inter-governmental organization. It currently has nine active member states comprising of; Kenya, Lesotho, Malawi, Mauritius, Swaziland, United Republic of Tanzania, Uganda, Zambia and Zimbabwe.

The presenter pointed out the fact that ECSA is the oldest inter-governmental body outside AU (formally OAU). It will be celebrating its 40th anniversary in 2014.

The presenter noted that the RPF Expert Committee is one of the Expert Committees in the ECSA-HC Governance Structure. It was established in 2003 as a network to strengthen pharmaceutical management systems in Member States. RPF's aim is to improve access to high quality pharmaceuticals and other health commodities.
Since its inception, the RPF has contributed measurably in the formulation of pharmaceutical generic policies and guidelines, and proposing initiatives for improving access to pharmaceutical products.

**Progress subsequent to 8th RPF meeting**

Dr. Odoch noted that the following issues were identified for implementation by the 8th RPF meeting:-

***Establishment of CIB platform***

Funding for this activity had been mobilized and a concept note on the process to be developed.

***Establishment of database of regional pharmaceutical experts***

The funding had been mobilized and the secretariat expected the 9th RPF to advice on the process to be followed and the criteria to use in determining pharmaceutical experts.

***Recruitment of a pharmacist at the secretariat to coordinate pharmaceutical activities***

It was reported that no progress had been made, as the secretariat could not secure funding for the position

***Documenting and sharing knowledge and best practices including on pool procurement, waste management and ware housing***

The secretariat had secured requisite funding and would undertake an assessment on Pooled Procurement. The other activities including warehousing best practices were to be led by member states

The secretariat was in the process of updating its website which could be used for effective information sharing. This would include the establishment of knowledge gateways for technical discussion forums.

***Regional/assessment on Supply Chain Management (SCM), pharmaceutical product prices and taxation of pharmaceutical products***

It was noted that this assessment would be conducted as part of the CIB establishment

***Revival of assessment tool on pharmaceutical management system***

No progress had been made in this area. The secretariat sought advice from the RPF on whether the tool was still relevant.

***Capacity building (short term training) and curriculum assessment***

It was reported that funding had been secured for short-term trainings and for assessment of pharmacy training curricula in the EAC member states. The RPF was

asked to advice on the areas of training and the cadres of pharmacy professionals to be trained.

***Harmonization; pharmaceutical laws policies and guidelines***

Harmonization would be led by individual countries in collaboration with RECs (SADC and EAC). The secretariat was to identify and recommend minimum requirements for National Medicine regulatory Authorities (NMRAs) as part of the processes to support member states that did not have such bodies. The secretariat was to provide technical assistance for the establishment of NMRAs from the member states without NMRAs. Such requests were yet to be received.

***Challenges of the RPF include the following;***

The presenter also noted some of the constraints that affected the implementation of the activities identified in the 8th RPF meeting including;

- Limited funding
- Insufficient staffing at the secretariat

**Discussion on progress following 8th RPF recommendations**

The discussions centered on:-

- Coordinated Informed Buying (CIB)
- Pharmaceutcal expert at the ECSA-HC secretariat
- Capacity Building in pharmaceutical management
- Knowledge and best practice sharing
- Harmonisation

***Coordinated informed buying***

The issue here was the need to avoid duplication of efforts, especially those already undertaken by RECs and the mechanisms of gathering CIB information. It was noted that SADC already had initiatives towards sharing of information on medicine prices. Under the initiatives member states had already submitted such information. However EAC member states did not have such initiatives.

The issue of reluctance by countries to share procurement information was noted. From the discussion, it was noted that in many member states, after the procurement process

the information is ideally supposed to be public. Countries were encouraged to share such information with the secretariat to aid information sharing.

In view of the above, it was proposed that ECSA-HC Secretariat undertakes an assessment of the information collected and initiatives by the RECs with a view of identifying any possible gaps. It would then develop a CIB platform to fill the gaps. In doing so it would use the information from the RECs, where such information exists.

***Pharmaceutical expert at ECSA and database of pharmaceutical experts***

It was noted that some of the slow progress in the implementation of the 8 RPF was due to absence of a dedicated staff who would handle pharmaceutical issues at the secretariat. It was recommended that the secretariat should find ways of recruiting a pharmacist as a matter of urgency. This officer could first be recruited as part of a project, with a view to institutionalize the position in the medium to long term.

After discussion on the database on pharmaceutical experts, it was noted the need to appreciate its rationale. It was agreed that, this should be mainly to support capacity strengthening in the region. It was not useful to just have a list of pharmacists in the region. It was agreed that the secretariat could develop the database, but should consult the World Health Organization, Regional office for Africa (WHO/AFRO) on issues of specialist areas in the pharmaceutical area since they had started a similar initiative.

***Capacity Building in pharmaceutical management***

After discussion it was agreed that RPF members consult when they go back and submit to the secretariat areas for possible short term training as well as the cadres to be trained by 16th May. The secretariat will then analyse and choose from the countries submissions. Given that the funding is meant to be used by September, the training should be held soon, before end of September 2014. Delegation from Malawi promised to share some of the short term courses offered by a WHO collaborating centre in South Africa.

***Knowledge and best practice sharing***

It was noted that this has been happening in the region for example Lesotho visited Tanzania to learn about their warehousing and Swaziland visited Zimbabwe's MACZ in a benchmarking exercise in preparation for establishing its NMRA. Tanzania has started a similar initiative of governance of medicine program that was being implemented in Malawi.

*Pharmaceutical legislations and Harmonisation*

It was noted that harmonization initiatives had been started, most of the member states are working closely with the RECs, where they fall (SADC and EAC). However there has been slow progress resulting in some member states forming coalition of those wanting to move faster, for example the "ZAZIBONA" comprising Zambia, Botswana and Namibia and Zimbabwe closely working together on issues to do with GMP inspections and medicine registrations. It was noted ECSA-HC secretariat should continue to contribute to these processes. The curriculum assessment that secretariat is to conduct is one of such contributions. It was noted that such assessment should be conducted for the whole ECSA-HC and not only East Africa.

Many of the member states have required legislation to guide the pharmaceutical sector. In some member states these legislations are being reviewed in light of new developments.

**Country Presentations**

**Countries progress in Strengthening Pharmaceutical Management**

The presentation by member states highlighted activities undertaken in their respective countries, milestones/achievement made, challenges, and emerging issues. They also mentioned areas requiring regional support or approach. The table below presents only highlights from the presentations, but the presentations are in annex 4.

| Country | Activities | Milestones/Achievements | Challenges | Emerging issues/issued for regional collaboration |
|---|---|---|---|---|
| **Kenya** | • Re-launch of the NMTC<br>• continued capitalization of the HPTs<br>• Finalisation of push to pull system of procurement<br>• Implementation of the 2010 constitution<br>• Devolution of health services provision to the county governments | • The merging of the two ministries responsible for Public health and for medical services<br>• The National HPTS agency converted to an Authority<br>• The KNPP sessional paper was tabled in Parliament and been adopted<br>• A functional pull system in place<br>• Abolition of user fees in PHC facilities<br>• Free maternity services in public health facilities | • Delay in reviewing the KEML and the SCGs<br>• Uncertainty in the operations of KEMSA in the decentralized system<br>• Taxation of pharmaceutical Raw Materials<br>• Slow enactment of health related legislations | • Support in setting up of health technologies assessment system<br>• Harmonisation of Medicines Registration<br>• Pooled procurement of Health Products Technologies |
| **Lesotho** | • Centralized procurement and distribution system<br>• Revitalization of PHC in collaboration with the ministry of local government | • Medicine bill submitted to ministry of health for minister to get cabinet approval for parliament discussion<br>• Training of pharmacy managers in SCM<br>• Improved supply chain system<br>• Pharmaceutical strategic plan in place<br>• Procurement of 70% of the ARVs and 100%o of first line anti TB done by the government | • No functional NMRA<br>• Difficulty in the last mile delivery of the pharmaceuticals<br>• Inadequate absorption of pharmacy personnel<br>• Poor quantification and forecasting at the periphery manned by nurses<br>• Poor reporting from health center to central through districts | • Advocacy<br>• Capacity building in regulatory affairs<br>Harmonization ( Registrations) |
| **Malawi** | • District based quantifications | • Increased training of pharmacy professionals | • High pharmaceutical staff turnover | |

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| | • Shift from paper based to eLMIS<br>• Good governance on medicines<br>• Review of National Medicines Policy underway<br>• Pharmaceutical strategic plan to be review | • STG to be revised<br>• Current GMP inspections now undertaken for local and foreign companies<br>• Plans underway to establish QC lab<br>• CMST now fully functional<br>• Commodity delivered to the last mile | • Low budgetary allocation to pharmaceuticals<br>• Lack of recapitalization of the CMST<br>• Financial constraints facing PMPB | |
| **Swaziland** | • Draft legislation on pharmacy and medicines in parliament<br>• Centralized procurement and distribution<br>• PULL system used<br>• Rx solution utilization at all levels of the supply chain<br>• QC equipment under procurement | • The 2011 National Pharmaceutical policy operationalized<br>• STG and EML operationalized<br>• PULL system in place<br>• NMRA implementation plan and proposed structure developed<br>• Medicines listing data base developed | • Delay in approving the appropriate legislations<br>• Low capacity in medicine regulation and QC control<br>• Lack of pharmacy professionals | • Capacity building in regulation and QC<br>• Capacity building through joint assessment of dossiers and inspections<br>• Mutual recognition in the region |
| **Tanzania** | • Revival of training of pharmacy assistant and technician training by the private sector<br>• Implementation of pharmaceutical basket funding<br>• Domestic resource mobilization at council level<br>• Implementation of RAS for SSFFC by TFDA<br>• Implementation of the last mile delivery (direct delivery)<br>• One more distribution center established | Several initiatives in place<br>• LMU for coordinating SC activities<br>• eLMIS for Logistics data availability and Visibility(rolled up to 117 councils),<br>• Tool kit for good medicine governance<br>• MSD-ERP bar coding for warehouse commodities,<br>• TFDA implementing Rapid Assessment System (RAS)<br>• Launching of the STG and NEMLIT<br>• NMTC in place | • Inadeqate Infrastructure and connectivity-to support eLMIS<br>• Change management handling difficulty<br>• Illegal importation of unregistered medicines<br>• Inadequate budgetary allocation for pharmaceuticals<br>• Inadequate local manufacturing capacity<br>• Lack of sufficient capacity in quantification and forecasting | • Sharing of experience and best practices<br>• Harmonization training and of curriculum<br>• Harmonization of medicines registration<br>• Tracking of pharmaceutical management - Counterfeit and Substandard drug<br>• Pharmaceutical Continuing Professional Development |

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| | | • Waste and medicine disposal policy in place and roll out to councils<br>• Strengthened Pharmacovigilance<br>• TFDA retains WHO prequalification status in Jan 2014 | | • Exchange of Technology<br>• Pharmaceutics Research and Development<br>• Pharmaceutical Pooled Procurement<br>• Strengthening Pharmaceutical Industries in ECSA Region |
| **Uganda** | | • Establishment of Quantification, Procurement and Planning Unit (QPPU)<br>• Rationalization of ARV/Lab supplies<br>• Integration of storage and distribution of vertically managed commodities<br>• Dispensing of dispensing guidelines for lower level units<br>• Accreditation of public sector outlets by NDA | • Dependence on seconded staff for most activities<br>• Inadequate budgetary allocation<br>• Lack of price control for pharmaceuticals | • Pooled procurement<br>• Harmonization of medicines registration<br>• Price control of pharmaceuticals |
| **Zimbabwe** | • Implementation of relevant legislation and policies on-going<br>• Centralised procurement and distribution<br>• Use of STG established<br>• Participating in the Pooled Procurement under SADC<br>• On-going in-service training on SCM for pharmacy professionals and nurses<br>• Pre-service training of pharmacists and pharmacy technicians on SCM | • Waste management guidelines disseminated | • Staff establishment not commensurate with workload<br>• Staff attrition – continuous training ground<br>• Low utilisation capacity of local manufacturers | • Staff retention strategies |

**Discussions of Country Presentations**
**Kenya - Dr Jackson Omondi Deputy Chief Pharmacist**

The key issues included mention of the implementation of the new constitution and several health related legislations which are all in different advance stages of development. There has been a merger in the ministries responsible for health in to one and this has facilitated the work in the health sector, other change management issues notwithstanding. One of the challenges relate to the fact some of these bill formulations did not anticipate devolution. For example the operation of KEMSA in the face of devolution, is challenging especially given the fact that the funds are sent to the County governments and there is no law requiring that they procure from KEMSA.

The delay in passing of the Kenya National Pharmaceutical Policy was a result of the fact that initially the thinking that the sessional papers need not pass through the parliament, but it was later noted that it still needed to pass through the parliament as well. This delayed the passing of the KNPP and its implementation plan development.

Members also sought more information regarding the capitalization of KEMSA and the capacity of KEMSA in fulfilling its roles. He noted that KEMESA was capitalized to a tune of USD 62million and it's the national supplier of essential medicines excluding the public health programs commodities. In the delivery of medicines it has contracted with private transporters except for the cold chain medicines. The board membership is being revised to take into account the county governments. As part of improving rational use of medicine, the national medicine therapeutic committee is being revived.

Another development is the removal of user fees at Primary health Care Centres, in addition all maternal health services are free at the point of care in public health facilities. The health facilities are reimbursed through the Health Sector Services Fund (HSSF). Attempts are being made to covert the HSSF to health facilities basing on performance (performance based financing-PBF) and pilots are ongoing in three counties with support from the World Bank and the Danish Government. The process of changing from the 'PUSH' to the 'PULL' system in the KEMSA supply chain management (SCM) has been finalized. The railway levy and the inclusion of pharmaceutical raw materials amongst items for VAT are likely to result in increased pharmaceuticals product prices. One area needing support is the setting up of Health Technologies Assessment System

**Kingdom of Lesotho - Mamojalefa Lirontso Matsoara-Pharmacist Ministry of Health**

The Discussion on the presentation by the Kingdom of Lesotho was around one of its 'best practices' in the ECSA-HC, where over 70% of the ARVs are procured by government funds and partners only support the 30%. Also all the first line anti-TB drugs are procured by the government. Members noted the need for governments in the region to learn from the Kingdom of Lesotho the way it is managing this. This is especially important given the unreliability of donor funding and also their effects at weakening the national health systems through their vertical nature.

Members also wanted to understand the delay in the passing of the Pharmacy (Medicines) Bill. The presenter noted that, the delay is also attributable to the change in government but the bill is now at Ministry of Health. This, the presenter noted has caused delay in the establishment of a National Medicine Regulator Authority. But there is a Pharmaceuticals Strategic Plan that is awaiting the PS approval and an implementation plan will be drawn.

The members also asked for information regarding local pharmaceutical manufacturer. The presenter noted that the factory was closed some years ago, but the government is planning to revive it, under a public-private partnership arrangement. There was consensus that there is need for a regulator, especially for quality control where there are local manufacturers of pharmaceutical control. The presenter also noted that the Diploma level training for the National Health Training College (NHTC) is being converted to be a competency based training and is affiliated to National University of Lesotho which is also producing pharmacists. The presenter also noted the lack of deployment of pharmacy technologists at the health center level, despite the need for them and this has contributed to challenges of quantification at the peripheral level. This triggered a prolonged discussion on the issue HRH, especially the pharmacy professionals. Some member noted the need to first have this post established within the public sector before training. This is because after the training, without such posts in the public sector, then the trainees cannot be absorbed into the system. In the case of Lesotho, they end up going to other countries. In addition, it was noted that our training does not emphasized the fact that after training one may be required to go and work in the rural areas. Most young people think that after training they have to work only in urban setting. Example were given of Cyprus, where even in the villages there are qualified doctors and pharmacists, this is because of the mind-set and the trainings emphasizes the need for them to offer services in all settings. Issues of working conditions, enabling facilities and remuneration were discussed. Lesotho noted that, in

the Kingdom there has been infrastructure improvements, but the impact on attracting and retaining health workers in the so called 'hard to reach' are yet to be felt.

Support would be required in establishing the NMRA.

**Kingdom of Swaziland – Ms Brenda Mhlanga, Quality Assurance Pharmacist-Ministry of Health**

The discussion of Swaziland's presentation also dwelled on the issue of human resources noted in the Lesotho discussion above. Pharmacy Assistants training has been introduced at Southern Africa Nazarene University (SANU) which will be followed by Pharmacy Technicians training.

The delay in passing of the Medicines and related substances Control Bill and Pharmacy Bill was a result of parliament dissolution. This was restarted; Bills have gone through Cabinet and have been approved. It is in the process of being gazetted then it will be send back to parliament.

Minilabs are being used to quality control test of pharmaceutical products but the procurement process for robust quality control equipment is underway. In the meantime a medicine listing database exists, where all the medicine imported, sold and used in the Kingdom are listed and there are a total of 5 major importers and the medicine database list has 4,970 medicines listed.

In addition, of the Kingdom good practice is that the government uses its funds to procure all the ARVs, TB medicines and the rest of the Essential Medicines.

Support in the area of strengthening medicine regulation and quality control is desired as well as sharing the work that has already been carried by other NMRAs. The Kingdom would also wish to participate in joint assessment of medicine dossiers and inspection as this will help improve its staff capacity.

**Tanzania- Mercy Mpatwa Masuki, Pharmacist – Head Logistics and Monitoring Component Ministry of Health and Social Welfare**

The Presenter succinctly noted some of the key progress that has been made since the last meeting. She also noted that following the 8th forum they received visit from Lesotho and Swaziland particularly to come and see their warehousing for the Medicine

Store Department (MSD). One of the key developments has been the establishment of the Logistics Management Unit (LMU). The discussion on the Tanzania presentation centered on the LMU. The presenter noted that LMU is very key in the planning and coordinating of logistics management in the country. And one of achievement has been the in the shift from paper based logistics management to electronic based logistic management through the eLMIS (electronic Logistic Management Information System). This system, she noted was developed in partnership with the Zambian Ministry of Health and it is now operational in 117 district council. In line with the objective of the RPF, following Malawi's presentation during the 8th RPF, Tanzania has introduced a toolkit for Medicine Management and good governance on medicine. She also noted the active participation of the TFDA in the harmonization process of medicine regulation being spearheaded by the EAC. The TFDA has maintained its status has a WHO prequalified lab following the 2014 audit. This has enable it to participate in the implementation of the rapid assessment system for substandard, spurious, falsified, falsely label and counterfeit (SSFFC) medical products. The MSD (central medical stores) now directly delivers medicine directly (Direct Delivery-DD) to the health facilities since July 2013. The effectiveness of this approach will be assessed in the coming months. It is likely that the DD (last mile delivery will be outsourced), about 50%.

Another notable achievement is the development of the disposal guideline for expired medicine; this is being enrolled to the council. Discussion around here centered on the generic disposal guideline of WHO. The RPF members noted the lack of process description in the WHO guideline and thus the need for approaches such as that done by Tanzania.

**Uganda – Mr Morries Seru Principal Pharmacist Ministry of Health**

The discussion on Uganda's presentation centered on the establishment of Quantification, Procurement and Planning Unit (QPPU), the price control pf pharmaceutical products and the involvement of pharmacist in the integrated community case management.

Clarification on the role of QPPU were sought, this was noted to be similar to the Tanzania's LMU. The challenge is that this unit is mainly manned by seconded staff from the development partners and if partners withdraw their support, the unit may fail to function, but current the unit support a bi-monthly national stock status report update. The supplies for lab reagents and ARVs have been rationalized, with the three

medicine supplies National Medical Store (NMS) supplying the Public Sector facilities, the Joint medical Store (JMS) supplying the private not for profit facilities and Medical Access Uganda Limited (MAUL) supplying the private for profit/not for profit health facilities.

The presenter noted that in Uganda there is no price control on the price of medicines; basically this is left to the market forces. Members noted that this was the same in their countries and it would be difficult to enforce where the government policy is that the market liberalized.

The issue of pharmaceutical profession getting interest on Integrated Community Case Management (ICCM) was discussed. It was noted that the issue of rational use of medicine tend to be more concentrated on prescription by health workers. But now the community health workers are dispensing a lot of medicines and irrational use of medicine is likely to occur. Pharmacists should advise the policy makers and programmers of ICCM on the rational use of medicine by community health workers.

**Zimbabwe – Mr. Misheck Ndhlovu Supply Chain Management Advisor Ministry of Health and Child Care Directorate of Pharmacy Services**

The Presenter noted that relevant policies and guidelines exists including STG (in the process of being revised), disposal guidelines (the challenge is the limited capacity of existing incinerators), National medicine policy various acts that guide the pharmaceutical other medical products handling in the country.

He noted that the selection of medicine is done by the National Medicine and Therapeutic Advisory Committee (NMTPAC). A lot of consideration is made by this committee in coming up with the medicine list, including possibility of supply by local manufacturers. The quantification is done centrally by the Directorate of Pharmacy services in the Ministry. It is the responsibility of the National Pharmaceutical Company of Zimbabwe to procure the medicines, store and distribute, but in recent time they have concentrated on the latter two roles. This is because most of the pharmaceutical products are being bought by development partners. The Medicine Control Authority of Zimbabwe has the regulatory role in the country. Its laboratory has achieved the ISO 17025 since 2010 and it is working towards WHO prequalification.

One of the key challenges as discussed under Lesotho presentation is that the Human Resources establishment is not commensurate with the workload. The other challenge is

the low capacity utilization by local manufacturers because most of the products are bought by partners from out and because most have not attained WHO pre-qualification they cannot export their products.

**Malawi - Albert R. Khuwi Deputy Director - Pharmaceutical Services Ministry of Health**

The discussion on Malawi presentation where similar to those discussed above, To note was that the National medicine policy is under review and it is expected to be completed by June 2014. Governance for Medicine is progressed well, but has recently slowed down due to high staff turnover. Also there is a process of transition from the paper based LMIS to eLMIS. Unlike in Zimbabwe, the quantification for pharmaceutical products is done at the district level. It was also noted that the number of pharmaceutical professional are growing, but still majority are taken up by the private sector. The presenter also noted that the capacity of the Pharmacy Board continues to grow, both in terms of human resource capacity and ability to conduct quality control. Plans are under way to build a quality control lab. The Central Medicine Store Trust has been functional since 2012. The Trust faces liquidity challenges due to low funding for medicine in the hospitals.

## 6.0. Cross-cutting issues and challenges

**Human Resources (Pharmacy Profession)**

All countries raised issues in relation to quality and quantity of pharmacy professional. Overall the number of pharmacy professional in the region is rising. But there is poor absorption into the public services and particularly in rural areas. The trainings need to be matched with the absorption capacity of the public services. Therefore training purse may not circumvent the problems; this has been noted with Pharmacy Technicians in Swaziland as well as in Zimbabwe. Due to lack and/or misdistribution of the right technical staff there are challenges in quantifications, forecasting and reporting needed for effective supply chain operation. Initiatives such as ADDO in Tanzania are important for improving access to and rational use of pharmaceuticals especially where formally trained pharmacy professionals are lacking.

The role of pharmacy professional in the region is not well appreciated and as a result at the ministries of health Pharmacy is usually only a unit with the exception of Zimbabwe where it is a directorate. Concerted effort is required to raise the profile of pharmacy professionals in the region. As a start, it was agreed that RPF members should be making key presentations at regional fora attended by national policy elites. The

presentations should illuminate the work of pharmacy professionals and best practices where pharmacist professionals are given major roles in a country's health sector.

**Resource Mobilization for Pharmacy activities at the secretariat and strengthening RPF**

There is need for the secretariat to develop a strategic/business plan for pharmaceutical activities. Without such documents it is very difficult to mobilized resources. The RPF members would be able to contribute to development of such a document once the secretariat come up with a draft.

It was also noted that the lack of continuity in the RPF is due to frequent changes in the membership. The need for stability in the RPF membership was noted as crucial, being a technical expert committee which is part of ECSA-HC governance structure. The secretariat should engage the Ministries of Health emphasizing the need for the same officers to attend the RPF meetings, unless such officers are no longer there. The secretariat was also advised to engage the Ministries of Health and have a focal point person who follows up ECSA issues in the countries where such focal persons are absent. Technical conversation amongst RPF members need not always to go through the PS offices.

In addition, the secretariat was asked to share reports of previous RPF meetings so that the new RPF members can appreciate the milestone of the RPF over the years. The RPF members were encouraged to share also the reports with relevant officers in the ministries and other agencies in the health sector

**Laws, Policies and Guidelines**

Most countries have relevant guiding documents such as health laws, pharmacy acts, Essential Medicine List, Standard Treatment Guidelines, etc. The process of harmonization has been slow. Also some laws are very old and require revision in light of recent developments, but given the political process, usually it takes long. Swaziland and Lesotho do not have enabling legislations and these have affected for example the establishments of regulatory authorities. Underutilized capacity of local pharmaceutical industries due to import of products from outside the region has stifled growth of local pharmaceutical manufacturers, this is acute in Zimbabwe.

**Supply Chain Management**

Majority of member states use the PULL system as opposed to the PUSH system in the supply of pharmaceutical and other medical products to the public health facilities. Uganda uses a combination, with the higher facilities using the PULL while the PUSH is for lower level health facilities. In Malawi, Uganda and Tanzania quantification is done

at the district level generally, while in Swaziland, Lesotho, Zimbabwe and Kenya there is centralized quantification.
All the member states have Centralized Medical Stores for the public sector. Combinations of last mile and district level delivery are used. In Uganda, Tanzania and Kenya the delivery is made up to the health facility level while in Malawi, Lesotho and Swaziland medicines are delivered to districts by the Central Medical Stores.

Tanzania is already implementing eLMIS and Malawi is also at advance stages in transitioning from paper based to electronic LMIS. But most member states although not having fully pledge eLMIS have some kind of e-reporting and/or e-monitoring of stock levels such as the M-track in Uganda and RxSolution in Swaziland.

**Sharing of Knowledge and Best Practices**
Sharing of Knowledge and Best Practices is one of the objectives of the RPF meetings. Because of these, initiatives for better pharmaceutical management has been adopted or adapted. These include amongst other:-

- Good governance on medicines
- Good warehousing practices
- National Essential Medicine List, Standard Treatment (Clinical) Guidelines publication
- Improved coordination of pharmaceutical management; LMUs, QPPU
- Reduced reliance on donor funding

**Areas of regional support**
The meeting noted that the secretariat should work closely with the member states particularly in:-

- Advocacy for enabling policy environment for the pharmaceutical managements in the region.
- Raise the issue of human resources for health including pharmacy professional high in regional and international agenda.
- Support strengthening of national capacities in the areas of pharmaceutical regulation and access

## 7.0. Way forward and Recommendations

On the way forward, the RPF members recommended that the meeting report be shared as soon as possible for their inputs. In addition two key recommendations were made:

1. The secretariat should engage the Permanent/Principal Secretaries on the need to have stable membership of the expert committees including the RPF.
2. Conduct a gap analysis on issue of pharmaceutical products information sharing as it establishes the coordinated informed buying so that it is not duplication with the RECs.

The secretariat was also requested to continue with the implementations of activities identified during the 8th RPF meetings. The table below summarizes the issues, recommendations, activities and proposed time frame.

| **Key Recommendations of the 9th RPF meeting** | **Time Frame/Responsible** |
|---|---|
| 1. Create CIB platform but consult RECs to avoid duplication | December 2014, Secretariat |
| 2. Engage the Permanent Secretaries with concise reasons on the need to have the same officer appointed to an expert committee to continue to participate in successive meetings of that particular committee and to appoint of a focal person to follow ESCA issues where such persons do not exist. | By August, Secretariat |
| **Other Recommendations** | |
| 1. Share the draft report of the RPF meeting as well as previous RPF meeting report for the benefit of new RPF members | Before 16th Of May 20114 |
| 2. Establish a database of pharmaceutical experts, but consult the WHO/AFRO for issues of specialization grouping | By July, Secretariat |
| 3. Short course training in the pharmaceutical area.<br>• RPF members to consult and submit to the secretariat areas of training and the cadres to be trained<br>• Secretariat to organize and/or facilitate the training | <br>By 16th May 2014<br>Before the end of September 2014 |
| 4. Develop strategic or business plan for the pharmaceuticals to aid resources mobilization<br>• Draft plan<br>• Input on the on draft by RPF | <br><br>By December, Secretariat<br>Member States, in December |
| 5. Recruit a Pharmacist to coordinate pharmaceutical activities. | Next Financial year beginning in July; will depend of successful proposal funding-Secretariat |
| 6. Key presentations in regional fora to raise the profile of pharmacy professional.<br>• Make a presentation on good practices a resulting from more involvement of the pharmacy professionals during the 8th BPF and the 24th DJCC | <br><br>Draft presentation by June for RPF members inputs; Malawi to lead |
| 7. Develop and own and assessment tool on regional pharmaceutical management where the secretariat can independently administer instead of relying on partners. | By December; secretariat |

## 8.0. Closing Remarks

In the closing the meeting, Dr. Odoch thanked RPF members for their active participation and particularly given their very busy schedule their presence in this meeting, the secretariat does not take it for granted. He underscored the importance of the RPF as one of the ECSA-HC expert's committees. Above all he highlighted the meeting objectives and alluded to the fact that these have been achieved during the course of the two days. He promised the secretariat will take the recommendations seriously and follow them through. On his part Dr. Omondi thanked the participants and reiterated the commitment of the MOH in participating in regional initiatives. He wished all a safe travel back home.

## Annexes

### Annex 1: Meeting Program

| **DAY 1: Monday, 5th May, 2014** | | |
|---|---|---|
| **Time** | **Session** | **Speaker/Facilitator** |
| 8:15-8:45 | **Registration** | |
| 8:45 – 9:15am | **Welcome and Opening** | *ECSA-HC* |
| 9:15 -10:00 am | • Purpose & Objectives of the Meeting<br>• Feedback on the 8th RPF meeting | *ECSA HC* |
| 10:00-10:30 am | ***TEA BREAK*** | |
| 10:30-12:45 am | Discussion | Session Chair: Kenya |
| 1:00-2:00 pm | ***LUNCH*** | |
| 2:00 – 5:00 pm | Initiatives and new developments in the pharmaceuticals in the member states<br>Country activities, milestones/ achievements, partners, challenges, support required from the regional bodies<br>• Kenya<br>• Lesotho<br>• Malawi<br>• Swaziland<br>• Tanzania<br>• Uganda<br>• Zambia<br>• Zimbabwe<br>• Mauritius<br>• Seychelles | Session Chair: Uganda |
| **DAY 2: Tuesday 6thMay, 2014** | | |
| 9:00 – 9.30 am | Recap of key issues from day 1 and discussions | Rapporteur<br>Session Chair: Lesotho |
| 9:30 – 10:00 am | Revitalization of the RPF and the Technical Working Groups (TWGs)<br>• Innovative approaches<br>• Resources<br>• Communication | Session Chair: Malawi |
| 10:00-10:30 am | ***TEA BREAK*** | |
| 10:30-11: 00 | Capacity building areas<br>What training areas can ECSA-HC support in the short term | Session Chair: Kenya |
| 11.00-11. 30am | Recap of Key Issues and Way forwards | Rapporteur |
| 11.30-12.00 | Closing Remarks | ECSA-HC |

**Annex 2: List of Participants**

| Country/Organization | Contact Details |
|---|---|
| Kenya | 1. Dr Jackson Omondi<br>Deputy Chief Pharmacist<br>Ministry of Health<br>P.O. Box 30016-00100<br>Nairobi, Kenya<br>Mob: +254720337925<br>Email: omondij2005@yahoo.com |
| | 2. Chamugei Sichiei Cheworei (Rapporteur during the meeting)<br>Pharmacy and Poisons Board, Kenya<br>P.O. Box 27663-00506<br>Nairobi, Kenya<br>Mob: +254722353784<br>csichey@yahoo.com |
| Lesotho | 3. Ms. Mamojalefa Lirontso Matsoara<br>Pharmacist<br>Ministry of Health<br>P.O. Box 514,<br>Maseru 100<br>Lesotho<br>Mob: +26662002517<br>Email: lirontsomatsoara@yahoo.com |
| Malawi | 4. Mr. Albert R. Khuwi<br>Deputy Director - Pharmaceutical Services<br>Ministry of Health, Malawi<br>P.O. Box 3077<br>Lilongwe, Malawi<br>Mob: +265999382447<br>Email: albertkhuwi@yahoo.co.za |
| | 5. Dr. Moses Chisale<br>Director of Pharmaceutical Operations<br>Central Medical Stores Trust<br>P/B 55, Mzimba Street<br>Lilongwe, Malawi<br>Mob: +265111756744<br>Email: mchisale@cmst.mw |
| | 6. Mr. Godfrey Kadewele<br>Registrar/CEO – of PMPB<br>Ministry of Health<br>PMPB, BOX 30241<br>Lilongwe 3, Malawi<br>Mob: +265999949161<br>Email: gkadewele@pmpb.mw |
| Swaziland | 7. Ms. Zinhle Matsebula – Myeni<br>Senior Pharmacist |

| Country/Organization | Contact Details |
|---|---|
| | Ministry of Health – RFMH<br>P.O. Box 14<br>Manzini, Swaziland<br>Mob: +268 76060429<br>Fax: +26825055077<br>Email: zmkholo@gmail.com |
| | 8. Ms. Brenda Mhlanga<br>QA Pharmacist<br>Ministry of Health – Central Medical Stores<br>P.O. Box 72, Kwaluseni, Swaziland<br>Mob: +26876112812<br>Fax: +268 25186279<br>Email: brendad@realnet.co.sz |
| Tanzania | 9. Ms. Mercy Mpatwa Masuki<br>Pharmacist – Head Logistics and Monitoring Component<br>Ministry of Health and Social Welfare<br>P.O. Box 9083<br>Dar es Salaam, Tanzani<br>Mob: +255784666043<br>Email: mercy.masuki@gmail.com and mmpatwa@moh.go.tz |
| Uganda | 10. Mr Morries Seru<br>Principal Pharmacist<br>Ministry of Health<br>P.O. Box 7272<br>Kampala, Uganda<br>Mob: +256772570869<br>Email: serumorries@gmail.com |
| Zimbabwe | 11. Mr. Misheck Ndhlovu<br>Supply Chain Management Advisor<br>Ministry of Health and Child Care<br>Directorate of Pharmacy Services<br>P.O. Box CY 1122 Causeway,<br>Harare, Zimbabwe<br>Mob: +263772945004<br>Email: mndhlovu@zol.co.zw and msndlovu@yahoo.com |
| ECSA Health Community | 12. Mr. Edward Kataika<br>Director of Programmes<br>East, Central and Southern Africa Health Community<br>P.O. Box 1009<br>Arusha, Tanzania<br>Tel: +2552725449365<br>Email: ekataika@ecsa.or.tz |
| | 13. Dr Walter Odoch<br>Acting Manager, HSSD<br>East, Central and Southern Africa Health Community |

| Country/Organization | Contact Details |
|---|---|
| | P.O. Box 1009<br>Arusha, Tanzania<br>Tel: +2552725449365<br>Email: wodoch@ecsa.or.tz |
| | 14. Ms. Devota Mawole<br>Programme Officer<br>East, Central and Southern Africa Health Community<br>P.O. Box 1009<br>Arusha, Tanzania<br>Tel: +2552725449365<br>Email: vnestory@ecsa.or.tz |
| | 15. Ms. Agnes Nyangi<br>Admin Assistant<br>East, Central and Southern Africa Health Community<br>P.O. Box 1009<br>Arusha, Tanzania<br>Tel: +2552725449365<br>Email: nutrition@ecsa.or.tz |

## Annex 3: Power Point Presentations by ECSA-HC secretariat

### 1. Meeting Objectives and RPF overview

East Central and Southern Africa Health Community

**9th REGIONAL PHARMACEUTICAL FORUM MEETING**

**Background to RPF**

Safari Club Hotel, Nairobi-Kenya

5th – 6th May 2014

ECSA Health Community | P.O Box 1009, Arusha, Tanzania | Plot No.157 Oloirien, Njiro Road
Tel: +255 272 549 362/5/6 | Fax: +255 272 549 392 | Web: www.ecsahc.org



## Outline

- Overview of ECSA-HC
- Overview of Regional Pharmaceutical Forum
- Meeting Objective



## Overview of ECSA-Health Community

Conference of Health Ministers

Advisory Committee

Secretariat
Seven Thematic Areas

Expert Committees

Directors Joint Consultative Committee (DJCC)

Member States: Kenya, Lesotho, Malawi, Mauritius, Seychelles, Swaziland, Uganda, Tanzania, Zambia, Zimbabwe

## Expert Committee Membership

- Experienced professionals, with relevant advanced qualifications in their technical field.
- Conversant with key technical and policy issues relating to the field.
- Senior decision making or advisory positions in Member States, advocate or move the regional agenda at country level.
- Technical representatives of key international and Regional institutions in Health



## Expert Committee TOR

- **Expert Committees play an advisory role to DJCC & Secretariat**
  - Synthesize information from Member States and other sources and provide an up to date regional picture of the state of affairs of particular health issues.
  - Provide technical inputs to the activities of Programmes
  - Review and advise on any Regional document developed by ECSA Secretariat on behalf of the Community
  - Analyze developments and trends of key policy and technical issues as they relate to the region and advise on their implementation options
  - Contribute to the setting of regional health priorities and strategic plans for addressing such priorities and monitoring and evaluation of regional strategic plans
  - Ensure active country representation and ownership, thereby ensuring an effective mechanism for responding to member country needs by the technical programmes



## Regional Pharmaceutical Forum Overview

- One of the Expert/Advisory committees of ECSA-HC
- One of the recommendations from a feasibility assessment for Pool Procurement
- The RPF was launched in August 2003.
  - To provide technical leadership and support for implementation of best practices in pharmaceutical management
  - Advise Secretariat and member states on issues of pharmaceutical management
  - To review strategies for improving access to medicines in the region

## Regional Pharmaceutical Forum Overview

- RPF is meant to work through Technical Working Groups (TWGs), namely:-
  - Policy, Legal Framework and Management Support;
  - Procurement, Distribution and Supplies Management (including HIV/AIDS-related Pharmaceuticals);
  - Rational Use of Medicines;
  - Medicines Registration and Quality Assurance.



## Regional Pharmaceutical Forum Overview

- Since its launch in August, 2003, the RPF has held several meetings
  - Key documents received and edited
  - Regional Pharmaceutical Strategies, policies and guidelines have been developed or ratified
    - A generic National Medicines Policy and Medicines Policy Implementation Plan
    - The Standard Treatment Guidelines for HIV/AIDS, TB and malaria and a complementary Regional Formulary
    - Curricula on Commodity management at District level
    - Performance assessment tool for pharmaceutical management systems.
  - Coordinated Informed Buying process initiated
  - Working modalities and annual rolling work plans developed and specific topics addressed



## 9th RPF Meeting Objectives

- **To share the work that has been undertaken in the pharmaceutical sector in the member states and best practices that can be adopted in the region.**
  - Review the status of implementation of the activities identified during the 8th RPF meeting.
  - Identify areas of capacity improvement for ECSA-HC to address in the short to medium term.
  - Updates from the Regional Economic Commissions on initiatives being implemented in the pharmaceutical sector and identify how the RPF can add value.
  - Identify strategies for strengthening the RPF.



## Outcomes

- How RPF and ECSA-HC secretariat can value to improving pharmaceutical management system in the region without duplication of activities with RECs identified.
- Capacity need area for ECSA-HC to support the member states identified.
- Strategies for strengthening RPF identified.

## 2. Implementation status of activities identified during the 8th RPF meeting

East Central and Southern Africa Health Community

### 9th REGIONAL PHARMACEUTICAL FORUM MEETING

Safari Club Hotel, Nairobi-Kenya

5th – 6th May 2014

### Implementation status of activities identified during the 8th RPF meeting

ECSA Health Community | P.O Box 1009, Arusha, Tanzania | Plot No.157 Oloirien, Njiro Road
Tel: +255 272 549 362/5/6 | Fax: +255 272 549 392 | Web: www.ecsahc.org

1

### Key issues from the 8th RPF meeting

| Issue/Activity | Status | Comments |
|---|---|---|
| **Coordinated informed Buying (CIB)** | • Process has been re-started<br>• Funding available for the initial phase | RPF to advise on:<br>• The type of information<br>• Who can access which information from the website<br>• Focal persons at country level for market research and sending information |
| **Regional database of pharmaceutical experts** | • The process is on<br>• Funding available | RPF to advise on<br>• Areas of specialization<br>• Who is considered a pharmaceutical expert (criteria) |
| **Institutional capacity (pharmaceutical Officer at ECSA)** | • Lack of funding<br>• Needs to be project based | ECSA-HC to engage a partner to support this position |



### Key issues from the 8th RPF meeting

| Issue/Activity | Status | Comments |
|---|---|---|
| **Best Practices**<br>Document/disseminate information on<br>• Centres of excellence in Pool procurement<br>• Waste mgt<br>• warehousing | • Process of engaging a consult to document current global practices on bulk pooled procurement of pharmaceutical has started. | RPF to advise on:<br>• The concept note, scope of work and relevance<br><br>Members of RPF were to identify and submit best practices to ECSA-HC secretariat |
| **Knowledge Management, Sharing Best Practices and South to South Collab**<br>• Repository for country & regional documents<br>• Identify Centres of excellence | • ECSA-HC is currently upgrading its website to be able to share regional information effectively<br>• Exchange learning visits | Members states through the RPF members were meant to submit relevant country documents to ECSA-HC secretariat |



### Key issues from the 8th RPF meeting

| Issue/Activity | Status | Comments |
|---|---|---|
| **Regional Studies/Assessment; -SCM, pricing of pharm pdts, taxation of pharm pdts** | • Will be done as part of the CIB establishment | |
| **Revive assessment tools which ECSA used to administer** | • No progress yet | 9th RPF to advise the ECSA-HC secretariat |
| **Human Resources**<br>• Undertake capacity building in identified<br>• Harmonize pharmacy professional training curriculum | • Some funds available for short training workshop<br>• RECs with initiative in this areas<br>• ECSA-HC will conduct assessment of the current situation | • 9th RPF to advise on the area for a training workshop and the cadre to participate<br>• Countries were to develop HR retention strategies |



### Key issues from the 8th RPF meeting

| Issue/Activity | Status | Comments |
|---|---|---|
| **Establish/strengthen regulatory bodies** | • Little progress, but RECs are supporting the NMRAs | ECSA-HC will focus of strengthening management aspects |
| **Laws, Policies and guidelines devt and harmonization**<br>• Identify and recommend minimum requirements for NMRA<br>• Implement harmonization of medicine registration, waste mgt, SCM and pooled procurement | • EAC in collab. With AU support the harmonization process for medicine registration in EAC. | These were to be member countries' led processes and ECSA-HC was meant to provide TA to those falling below minimum requirements and to support the M&E framework |



### Country Level Issues during the 8th RPF

- Cross-cutting
  - Human resources in the pharmaceutical sector
    - High of attrition (Zimbabwe, Lesotho
    - Low production (except Uganda)
      - Training of pharmacy assistants (Swaziland)
  - Quality Control
    - Lack of quality control lab
    - No regulation of medicine registration (Swaziland)
    - Regulation on local production of medical products
  - SCM
    - Quantification of national medicines requirements by health facilities
    - Pilferage
  - Pharmaceutical policies
    - Essential medicine list
    - Standard treatment guidelines (lack in TZ)
    - National Medicine polices

## Key issues from the 8th RPF meeting

- Others:
  - Domestic resources mobilization/hospital efficiency studies
  - Basket funding
  - Track expenditure on pharmaceuticals using NHA
  - Resource mobilization for program implementation



## Constraints to implementation

- Limited funding for implementation, resulting into
  - Inadequate interaction of RPF Members, including inability of TWG members to meet.
- Absence of dedicated staff at ECSA Secretariat to deal with pharmaceutical issues.

**Annex 4: Power Point Presentations by Member States**

**Kingdom of Lesotho:** Presentation on new developments in the pharmaceuticals management

## INITIATIVES AND NEW DEVELOPMENTS

LESOTHO

1

## COUNTRY PROFILE


2

## Conti.....

- The Kingdom of Lesotho is landlocked and surrounded by South Africa with a surface area of 30,3552 square kilometres.
- The population is estimated to be 1,876,633 people. Seventy-seven percent (77%) and 23% of the population live in rural and urban areas respectively.
- Fifty eight percent (58%) of the population is under 19 years of age. Women make up 51% of the total population.
- Fifty six percent (56.6%)of the population live below the national poverty line. 43.4% live on one dollar a day and are considered to live in vulnerable households often headed by a female. The intensity of deprivation is estimated at 44.1%.
- The male to female ratio is estimated to be 95:1006. The population growth rate has declined from 1.5% in 1996 to 0.08% in 2006. This is the lowest population growth rate in Southern Africa countries.
- Life expectancy at birth has improved from 45.97 in 2010 to 48.7 years in 2013.

3

## Country activities

- Maintain a centralised distribution system
- One Distributor - National Drug Service Organisation EST: 2007 by law as a trading account under Ministry of Finance
- Procures, Stores and Distribute and quality assurance of pharmaceuticals
- Central ordering system and payment system
- Of the total health budget pharmaceuticals financing = 13%

4

## Conti.....

- Currently Lesotho Government contribute 70% of the total budget for ARVs
- First line TB commodities supported 100% by Lesotho Government
- Revitalisation of PHC together with Ministry of Local Government

5

## Achievements

- Medicines Bill awaiting parliament discussion
- Pharmacy managers trained in supply chain management leadership and development programme (SIAPS)
- NHTC diploma programme is converted to competency based from content based training (undergoing approval by NUL Senate before august 2014)
- Degree and diploma programmes under going accreditation by Council of Higher Education

6

## Conti……

- Monthly stock situation reporting from health facilities to district and then central which also enables the central to know the total amount of holding stocks in facilities.
- Pharmaceuticals Strategic Plan in place and awaiting approval by PS health prior to implementation (Strategic Plan for Medicines and Health Products 2013/14 – 2015/16)
- Functional Supply Chain Technical Working Group chaired by pharmaceuticals directorate

7

## Partners

- Global fund (ARVs and second line TB commodities)
- UNFPA ( reproductive health commodities partially)
- SIAPS –
  - supply chain management Technical support and trainings including development of reporting tools
  - review of documents (STGs, EML, NMP, Legislation)

8

## Challenges

- Delivery of pharmaceuticals to the last mile
- High need for deployment of Pharmacy Technologists personnel at health centres.
- Poor quantification and forecasting at the periphery ( done by nurses)
- Poor reporting from the health centres to districts to central ( incomplete to no report)
- No functional Medicines Regulatory Authority

9

## Support required from regional bodies

- Advocacy
  - Enactment of the Medicines Bill and establishment of regulatory body
  - Deployment of PT at health centres
  - Hiring of pharmacists and pharmacy technologists
- Capacity building in regulatory affairs

10

**Republic of Zimbabwe:** Presentation on new developments in the pharmaceuticals management

## REGIONAL PHARMACEUTICAL FORUM

Nairobi, Kenya
5-6 May 2014

Misheck Ndhlovu
ZIMBABWE

DIRECTORATE OF PHARMACY SERVICES
MINISTRY OF HEALTH AND CHILD CARE

## Outline

- Zimbabwe
- National Medicines Policy
- Legal Framework
- Procurement and Supply Management (PSM)
- Quality Assurance
- National and Regional Cooperation
- Challenges


## Zimbabwe

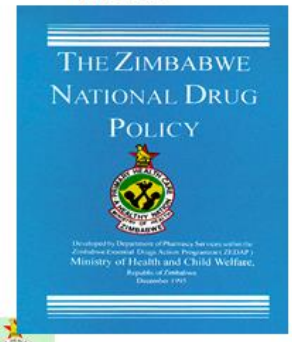
- Population – 13 million
- 8 rural and 2 urban provinces
- 1,560 public health facilities
- Privately run hospitals
- Large mines and agricultural estates health facilities
- Private pharmacies/surgeries
- Industrial clinics
- 15 local Pharmaceutical manufacturers

## National Medicines Policy

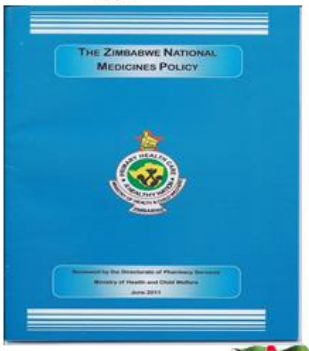
- Initial policy 1987
- National workshop 1994
- Linked to the national health policy
- Formalised in 1995
- Launched in 1998
- Revised in 2006 and 2010
- Approved in 2011

## National Medicines Policy

Previous




New



## OBJECTIVES OF THE NMP

SEQAAAR

**Health related:**

- availability, accessibility, affordability
- safe, efficacious, good quality
- rational medicines use

**Economic related:**

- increase local production
- self reliance
- develop sufficient human resources
- legislation/regulation
- avoid unregistered or counterfeit medicines

## Components

Drug availability

- Selection
- Financial resources
- Procurement/production
- Distribution
- Stock management/storage
- Quality assurance
- Drug regulation/legislation
- Monitoring and Evaluation

Rational drug use

- Training/Information
- Prescribing/dispensing
- Therapeutics committees
- Monitoring/evaluation
- Collaboration
- National cooperation
- International co-operation
- Human resource development

## Legal Frameworks (1)

- Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03] and Regulations
- Dangerous Drugs Act [Chapter 15:02] and Regulations
- Procurement Act [Chapter 22.14]
- The Government Medical Stores (GMS) Commercialisation Act (2000)
- Environment Management Act [Chapter 20:27]

## Legal Frameworks (2)

- Public Health Act [Chapter 15:09]
- Health Professions Act [Chapter 27:19]

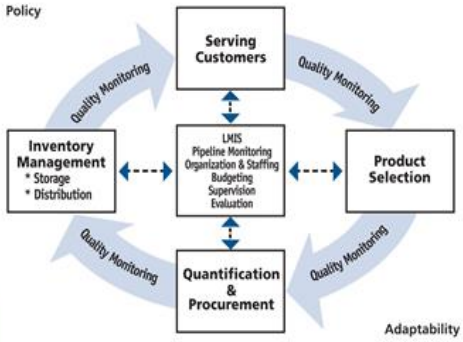
## NMP and Regional co-operation

- Aim is to improve medicines availability
- Promote efficient medicines management
- Promote rational medicines use
  - Government encourage technical cooperation within the region (ECSA, SADC, COMESA) health ministries
  - MOHCC encourages and facilitates cooperation offered through multilateral and bilateral agencies and organisations

## PROCUREMENT AND SUPPLY MANAGEMENT

## PROCUREMENT AND SUPPLY MANAGEMENT

## Logistics cycle




## SELECTION

- Selection done by the National Medicine and Therapeutics Policy Advisory Committee (NMTPAC)
- Medicines selected according to
  - Relevance to prevalent diseases
  - Proven efficacy and safety
  - Adequate scientific data in a variety of settings
  - Adequate quality
  - Favorable cost benefit ratio
  - Desirable pharmacokinetics
  - Possibility for local manufacture
  - Available as a single ingredient item

## Medicines Selection and NDTPAC

- National Drug and Therapeutics Policy Advisory Committee (NDTPAC)
- 16 members representing:-
  - Physicians
  - Obs & Gynae
  - Pharmacists
  - Clinical Pharmacologists
  - Paediatricians
  - National Medicines Regulator Agency (MCAZ)
  - National Procurement Agency (NatPharm)
  - Directorate of Pharmacy Services
  - Aids and TB Unit
  - Pharmaceutical Manufacturers' Association (PMA)
  - City Health Department
- Multidisciplinary group

## Procurement

- Quantification conducted by Ministry's Directorate of Pharmacy Services (DPS) in collaboration with Ministry departments, appropriate govt. agencies and partners
- National agency (National Pharmaceutical Company of Zimbabwe - NatPharm) mandated to procure, store and distribute
- Not carrying much procurement due to lack of funds
- Most procurement carried out by donors or partners

## Storage and Distribution

- NatPharm storing and distributing mainly for public sector
- NatPharm providing storage and distribution services for donors/ partners
- Private wholesalers mainly cater for the private sector
- All private sector facilities handling medicines licensed
- All person handling medicines in the private sector licensed.
- Plans are there to apply same in the public sector

## Procurement and Supply Management

- LMIS managed by Ministry in conjunction with NatPharm with support from partners
- Management of pharmaceuticals carried out by
  - pharmacists/pharm techs/Dispensary assistants at hospital level
  - nurses at primary care level
- Waste Management – Disposal guidelines printed
  - Challenge with capacity of current incinerators

## USE

- Standard Treatment Guidelines established
- Revised every 4 years
- Next edition due 2015
- Specific program guidelines revised more often
- Establishment of HMTCs


## Quality assurance (1)

- MCAZ is an autonomous statutory body since 1997 (previously an MOH department since 1969)
- Medicines to be distributed in the country must be registered with the NMRA - the Medicines Control Authority of Zimbabwe (MCAZ)
  - Exemptions given where item is not registered but of public health importance
- Medicines cleared by the regulatory authority at the designated ports of entry before delivery to the warehouse – authorised points of entry reduced to 5

## Quality assurance (2)

- Import permits required for all medicines brought into the country
- Random batch sampling and testing is done
- Post marketing surveillance carried out
- Country quality assurance plan developed
- Good storage practices maintained in approved warehouses
- Storage capacity and conditions being improved at selected health facilities.

## Quality assurance (3)

- The MCAZ Laboratory achieved ISO 17025 accreditation in mid -2010
- MCAZ laboratory working towards WHO prequalification
- Receiving support from donors in the form of equipment and reagents
- Capacity issues at regularity authority
- Risk management as opposed to risk elimination as a strategy to deal with registration backlog

## Quality assurance (4)

- MCAZ is the national pharmacovigilance center for monitoring adverse drug reactions
- Voluntary reporting of ADRs in place and the reports are assessed by a Committee of the Authority
- Targeted spontaneous reporting now in place for HIV, TB and malaria medicines

## NMP and National co-operation (1)

- Through cooperation and collaboration with all sectors (Private, civil society, industry, and others)
- MOHCC actively involves
  - Ministry of Finance
  - Ministry of Industry and Commerce
  - Ministry of Education
  - Local Government
  - Autonomous govt agencies under MOHCC – MCAZ, NatPharm, ZNFPC

## NMP and National co-operation (2)

- MOH&CC also consults:-
  - Pharmaceutical, medical and nursing professional associations
  - Faith Based Organisations
  - Medical Aid Societies
  - Consumer organisations
  - Academic Institutions
  - Uniformed Forces Medical Services
  - Pharmaceutical industry – *working to have a laboratory that will carry our bioequivalence studies for industry.*
  - Donors and technical partners operating in the country

## Regional and International Cooperation (1)

- Country part of efforts towards pooled procurement under SADC
  - Initiative starting with ARVs
  - Starting with information hub where issues like prices offered to countries by suppliers are shared and these can be used to negotiate favourable prices
  - Establishing TWG on pooled procurement whilst awaiting formation of SADC Pooled Procurement Services (SPPS)
  - Plans are there to have Group contracts where appropriate in future.
  - Registration harmonisation initiated in 2011

## Regional and International Cooperation (2)

- MCAZ collaborating with Zambia, Botswana and Namibia under the "ZAZIBONA" Initiative
- MCAZ working with WHO to have laboratory prequalified.
- Woking with international partners in strengthening SCM in the country

## Human Resources for Pharmacy (1)

As at December 2013:-

- 634 Pharmacists – *13% in public sector*
- 404 Pharmacy Technicians - *77% in public sector*
- Pre-service training
  - College of Health Sciences training for pharmacists
  - MOHCC training for pharmacy techs
  - Ministry of Higher and Tertiary Education – pharmacy technicians

## Human Resources for Pharmacy (2)

- In-service training:-
  - Supply chain management (SCM) - supported by donors for pharmacists, pharm techs and nurses
- SCM incorporated pre-service curricula for pharmacists and pharm techs
- Plan to incorporate SCM into pre-service training curriculum for nurses

## Co-ordination Mechanisms

- The Procurement and Logistics Subcommittee (PLS)
- Medicines and Medical Supplies Co-ordination Team (MMSCT)
  - Technical and Policy Committees
  - Delivery Team Topping Up (DTTU) Technical Committee
  - Delivery Team Topping Up (DTTU) Policy Committee

## Challenges

- HR establishment not commensurate with workload
- Staff attrition especially in public sector - *pharmacists*
- Manual systems in most facilities
- Funding for medicines mainly from donors
- Low capacity utilisation by local manufacturers
- Attaining WHO pre-qualification by local manufacturers
- Time taken to harmonise procedures

Thank you Siyabonga Tatenda

**Republic of Malawi:** Presentation on new developments in the pharmaceuticals management

East, Central and Southern Africa Health community 9th Regional Pharmaceutical Forum

5- 6th May 2014

Nairobi Safari Club

## Country Activities, milestones/achievements, etc

- Pharmaceutical Services Management.
- Annual quantification: district- based as opposed to central level.
- Logistics Management Information System (LMIS): transition to paper based to eLMIS. Mobilising resources.
- Good Governance on Medicines: Slow progress due to high staff turnover

2

## Country activities, milestones/achievements, etc

- Human Resources: Number of newly qualified pharmacists steadily growing, although most of them are being absorbed by the provate sector( greener pasture?)
- Review of the National Medicines Policy is under way, final document expected end of June 2014
- National Pharmaceutical Strategic Plan to be reviewed to reflect the new policy .

3

## Country activities, milestones/achievements, challenges, etc

- Revision of the Standard Treatment Guidelines will commence soon.

4

## Country activities, milestones/achievements, challenges

- Medicines Regulation
- ❖ Pharmacy Board continues to grow in terms of number of professional pharmacy staff
- ❖ cGMP inspections are being conducted both locally and international
- ❖ Plans to build a QC Laboratory to strengthen QA activities

5

## Country activities, achievements/ milestones, etc

- Medicine Supply and Distribution
- ➢ Central Medical Stores Trust fully functional since 2012.
- ➢ Deliveries of commodities up to health facility level
- ➢ Challenges in increasing liquidity due to low funding for medicines to hospitals
- ➢ Some key functions do not have staff with requisite competencies.

6

## Country activities, achievements/milestones, etc

- Challenges:
- ✓ High staff turnover which results in loss of momentum in implementation of planned activities
- ✓ Low budgetary allocation to pharmaceutical services
- ✓ Lack of appropriate incentives for health workers resulting in low retention of newly qualified pharmacists

7

## Country activities, achievements/milestones, etc

- Challenges:
- ✓ Some policy changes adversely affecting financial stability of PMPB- local producers have a framework agreements. Most of the international manufacturers are reluctant to retain products on register due to the framework agreement policy.
- ✓ Lack of recapitalization of the CMST so as to give a strong financial standing.

8

**Kingdom of Swaziland:** Presentation on new developments in the pharmaceuticals management

## KINGDOM OF SWAZILAND UPDATE

ECSA REGIONAL PHARMACEUTICAL FORUM

5TH – 6TH MAY 2014

NAIROBI, KENYA

## OUTLINE

- Introduction – Demography
- Overview of Health System
- Pharmaceutical Policy and Governance
- Purchasing and Supply Chain
- Achievements
- Challenges
- Issues requiring joint action

2

## INTRODUCTION


3

## INTRODUCTION Cont.

- ***National languages:*** SiSwati and English
- ***Expenditure of health per capita:*** $312, 6.3 % of GDP (2009)
- The Kingdom of Swaziland is a landlocked country covering 17,364 km2 sharing boarders with South Africa and Mozambique
- The population of Swaziland is 1, 018, 449, comprising of 53% women and 47% men (2007 Population Census)
- The country is divided into four administrative regions namely Hhohho, Manzini, Lubombo and Shiselweni Region, fifty-five (55) constituencies and three hundred and sixty (360) chiefdoms.

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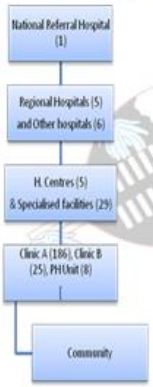
## OVER VIEW OF HEALTH SYSTEM




- **National Referral Hospital**: the country does not have a designated tertiary or national referral hospital currently. However, the MOH is in the process of transforming Mbabane government hospital into an autonomous national referral hospital.
- **Hospitals**: provide secondary health services
- **Health centers**: provide an intermediate range of promotive, preventive, and curative services
- **Clinics**: provide primary health care services
- **Community and outreach sites**: providing community based promotion, prevention and basic curative care

5

## OVER VIEW OF HEALTH SYSTEM Cont.

- ***Set up of health system management and organization:*** The public health system is decentralized from the MOH to the four Regional Health Offices.
- There are Regional Health Management Teams (senior medical doctors, nurses and regional pharmacists) headed by the Regional Health Administrators.
- The Swaziland pharmaceutical sector is decentralized with a Chief Pharmacist as the head of the cadre at the MOH.
- ***Private sector:*** 64 registered retail pharmacies and 6 wholesalers.

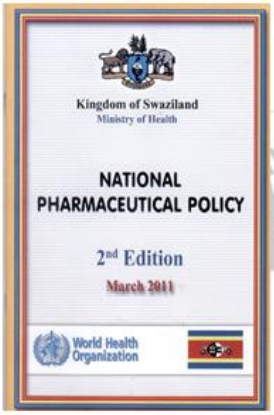
6

## Pharmaceutical Policy & Governance

- ***Laws governing pharmaceutical sector:*** Pharmacy Act, 1929 and the Opium and Habit Forming Act, 1922
  - Legislation has been reviewed into the Pharmacy Bill, 2014 and the Medicines and Related Substances Control Bill, 2014
- Pharmaceutical Policy was reviewed and the Swaziland National Pharmaceutical Policy, 2011 is in effect.
  - Swaziland Pharmaceutical Strategic Plan (implementation plan for NPP)
  - Swaziland Pharmaceutical Sector Baseline Assessment Report (to facilitate M&E of Strategic Plan implementation)

7

## The NPP and SPSP Documents





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## Standard Treatment Guidelines and Essential Medicines List


9

## Purchasing & Supply Chain

- Centralized system of procurement and distribution through Central Medical Stores
- All pharmaceuticals including ARVs are procured by government using state budget
- The country operates a pull system
- No quality control laboratory, but Minilabs have been procured for CMS by MSH/SPS.

***Management information systems***

- Same inventory management system used at CMS and facilities - RxSolution

10

## ACHEIVEMENTS

1. Pharmacy and Medicines Bill approved by Cabinet
2. Pharmaceutical management SOPs
3. Establishment of the Supply Chain Working Group(SCTWG)
4. MRA implementation plan and proposed structure developed.
5. Development of draft regulations for the Pharmacy and the Medicines Bills.

11

## ACHEIVEMENTS Cont.

6. A medicines listing database has been developed to register all medicines imported, sold and used in Swaziland.
   (i) Total of 5 major importers
   (ii) 4970 medicines listed
7. Procurement of Quality control equipment for quality control laboratory in the pipeline
8. Introduction of training of pharmacy Assistance at SANU to be followed by the introduction of the training of Pharmacy Technicians

12

## CHALLENGES

- Dissolution of Parliament before House of Senate could approve Bills (2013) – approval process has started afresh from Cabinet
- There is need for capacity building in the area of medicine regulation and quality control
- Human Resource challenges in the pharmaceutical cadre no pool of professionals

13

## Issues Requiring Joint Support

- Capacity building in medicine regulation and quality control
- Joint assessment of medicines dossiers and inspections for capacity building purposes
- Work sharing in terms of recognition of work already carried out by other regional MRAs

14

**THANK YOU**

**SIYABONGA**

15

**Republic of Uganda:** Presentations on new developments in the pharmaceuticals management

- **COUNTRY ACTIVITIES MILESTONES /ACHIEVEMENTS AND SUPPORT REQUIRED FROM REGIONAL BODIES**

Safari Club Hotel, Nairobi-Kenya

## Initiatives and new developments

- Rationalization of ARV/ Lab supplies
- Integrating storage and distribution of programmatic commodities (Ant TB and Vaccines in the main national supply system
- Establishments of QPPU unit in Pharmacy Division
- Development of dispensing guidelines for lower level units ( in form of a formulary )
- Accreditation of Public sector pharmaceutical out lets by National Drug Authority

2

## Emerging issues

- ICCM, Integrated community case management
- Decline by Development partners to pay handling fees for commodities they procure

3

## Challenges

- Dependence on seconded staffs to do most of the activities
- Inadequate funding to met the forecasted pharmaceutical requirements
- Price control of Pharmaceutical products

4

## Areas of Regional Collaboration

- Pooled procurement
- Harmonization of medicine registration
- Price control (need to learn from partner states on how they are handling this issue
- Harmonized tools for monitoring medicine availability

5

**Republic of Kenya:** Presentations on new developments in the pharmaceuticals management

## 9th ECSA-HC RPF MEETING

**Country Report – Republic of Kenya**

## Presentation Outline

- Introduction
- Country Activities
- Milestones / Achievements
- Partners
- Challenges
- Support Required from regional Bodies

2

## Introduction

**Ministry of Health**

**Vision** - A healthy and productive nation that is globally competitive.

**Mission** - To provide equitable, accessible, affordable, high quality and sustainable health care for all Kenyans.

3

## Country Activities

- Several Health related legislation at an advanced stage of development
- Re-launch of the NMTC
- Continued capitalisation of the national HPTs procurement authority
- Finalisation of process of moving facilities from the supply driven 'PUSH' to the demand driven 'PULL' system of distribution

4

## Country Activities

- Implementation of the constitution 2010

5

## Milestones /Achievements

- 3rd Bloodless transfer of political power
- Establishment of two levels of Governments
- Transfer of Health Functions to County Governments
- National HPTs agency converted to an authority
- Merger of the Ministries responsible for Health

6

## Milestones /Achievements

- Kenya National Health Policy 2012-2030 approved by cabinet
- KNPP presented to national assembly and adopted
- All health facilities now on a demand driven 'PULL' system of distribution
- Presidential Decree – Abolition of user fees atPHC faciltieis and 'free' Maternity Services at all public health facilities

7

## Milestones /Achievements

- Formation of several inter-governmental bodies – Summit, CoG, intergovernmental health committee
- Appointment of CS who are not politicians
- Consolidation of most procurements of HPTs to KEMSA

8

## Partners

- DANIDA
- WB
- USAID – HCSM Program
- GF
- CHAI
- WHO
- EU
- Gavi
- ADB
- GIZ

9

## Challenges

- KEML and SCGs 2010 overdue for review
- Future of KEMSA in a devolved system of Government
- Resistance by HWs to be transferred to counties
- Introduction of railway development levy on all imports and expansion of VAT to cover pharmaceutical raw materials

10

## Challenges

- Speed of enacting health legislation not fast enough

11

## Support Required from Regional Bodies

- Support in setting up Health Technologies Assessment system

12

**United Republic of Tanzania:** Presentations on new developments in the pharmaceuticals management

EAST, CENTRAL AND SOUTHERN AFRICAN REGIONAL PHARMACEUTICAL FORUM at SAFARI CLUB HOTEL NAIROBI

Ministry of Health and Social Welfare

TANZANIA

5-6th May, 2014

## Tanzania Map

2


## RESPONDING TO 8th RPF ACTION ITEMS

3

- Established Data Base of Experts
- Best Practices – Tapping on eLMIS and Establishment of LMU (GF and USAID/ JSI) to strengthen SCM
- Standard Treatment Guidelines and NEMLIT launched in 2013.
- NMTC Guidelines in place promoting RUM at all level.(RUM communication Strategy)
- Facilitated development of waste and medicine disposal policy

## RESPONDING TO 8th RPF ACTION ITEMS

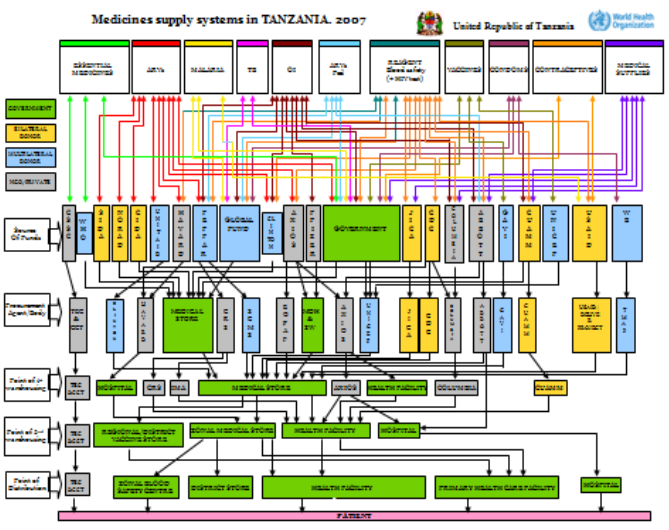
4

- Issue of HR in Pharmaceutical Sector – Revived and registered private sector to provide pharmacy assistants and pharm tech trainings
- Domestic resources mobilization for funding Pharmaceuticals at council level
- Basket Funding being implemented ( from Donors )

## Initiatives and new developments

5

- LMU- Purpose establishment and objectives
- eLMIS – vision, objectives
- Toolkit for Good Governance on Medicine
- MSD – ERP bar coding
- TFDA – Harmonization of Medicine Regulatory systems in EAC
- TFDA- Implementing Rapid Assessment System



## In-country Supply Chain Stakeholders

7

## Logistic Management Unit **LMU Objectives**

8

1. Coordinate logistics management activities of all commodity categories under one unit through harmonizing national health commodities supply chains.
2. Strengthen logistics data management and visibility
3. Link different organization levels and partners within supply chain to improve health commodities availability at the national level
4. Identify supply chain bottlenecks, brainstorm mitigation strategies and collaborate with key players involved to implement those interventions.

## LMU Functions

9

- Logistics Data Management
- Quantification Coordination
- Monitoring & Evaluation
- Coordination and Collaboration
- Supply Chain Intervention Planning
- Training & Capacity Building
- Supervision

## eLMIS

10

- (eLMIS) was developed through a partnership between the Ministry of Health and Social Welfare (MOHSW) in Tanzania and the Ministry of Health (MOH) in Zambia.
- eLMIS is a web-based application which computerizes existing paper-based logistics management information systems (LMIS)
- Currently the system is live operating in 117 district councils and some reports are now being received at MSD

## eLMIS Vision

11

*An effective and sustainable electronic logistics management information system (eLMIS) should be user friendly and* facilitate that adequate quality and quantities of health commodities* are always available at the point of service to meet patient demand. *The eLMIS must provide integrated access to:*

- *Accurate, timely and routine consumption data*
- *Real-time logistics management capabilities covering point of origin to point of consumption*
- *Demand forecasting, capacity planning & modeling based on consumption*

*(* vaccines, medicines, medical & diagnostic supplies, etc.)*

## Tool kit for Medicine Management & Good Governance on Medicine

12

- The toolkit aims at providing the LGA and HCW with practices and guidance on how best to manage and improve availability and accessibility of health commodities .
- Innovation in fund mobilization for Health commodities/Cost sharing/CHF

## Accomplishment

13

- System development from Aug 2012 and roll up to 117 councils by April 2014
- LMU Establishment in 2013
- Toolkit Development on Medicine Management and Good Governance on Medicine
- Launched STG and NEML
- RUM communication Strategy in Place
- Disposal Guidelines in place and training to HFs and Councils is ongoing.

## TFDA

14

- TFDA was first established in 2003 by the Tanzania Food ,Drugs and Cosmetic Act, cap 219
- Tanzania Food and Drugs Authority (TFDA) is a regulatory body under the Ministry of Health and Social Welfare which is responsible for regulating the quality and safety of food, drugs, cosmetics and medical devices.

## TFDA Mission

15

- The Mission of TFDA is to protect the health of consumers against hazards associated with food, drugs, herbal drugs, cosmetics and medical devices. This mission is achieved by performing the following core activities

## Achievements

16

- Harmonization of Medicine regulatory systems in EAC- April 2014 MoH Ministers endorsed harmonized technical requirements for regulations of Medicines in EAC and guidelines on GMP for approval by councils of Ministers
- This will facilitate quick access to good quality and safe medicines including TZ as beneficiary
- Pharmacovigilence Issues has been strengthened currently coordinated at TFDA

## Achievement

17

- TFDA Lab is WHO prequalified since 2011.
- It was Audited in Jan 2014 and managed to maintain WHO Prequalified Status.
- At Global Level – Implementation of Rapid Assessment System - substandard/spurious/falsified/falsely labeled counterfeit (SSFFC) medical products coordinated by WHO.

## Benefits & Opportunities

18

- To be replicated in SADC cross-fertilization
- Mutual recognition throughout EAC after Legal procedures have been finalized among member state.
- Opportunities to explore New cutting edge health technologies
- Strengthening Laboratory at TFDA

## Medical Stores Department

19

- Medical Stores Department (MSD) was enacted by Act of Parliament No.13 of 1993.
- It is an autonomous entity under Ministry of Health & Social Welfare. With independent Board of Trustees MSD uses commercial principles for financial sustainability.
- MSD has three main functions namely:
  a) Procurement
  b) Storage and
  c) Distribution of pharmaceuticals, medical supplies and laboratory reagents for public health.

## … Introduction

20

**Mission statement**

- To make available, at all times, medicines and medical supplies of acceptable quality at affordable prices to all Tanzanians

**Vision**

- Centre of excellence for health commodities supply chain in Africa

**Motto**

- "Dedicated to save your life - Stock out no more"

**Values**

- Respect, Integrity, Passion, Courtesy and Innovation

## 4.0 Accomplishments-

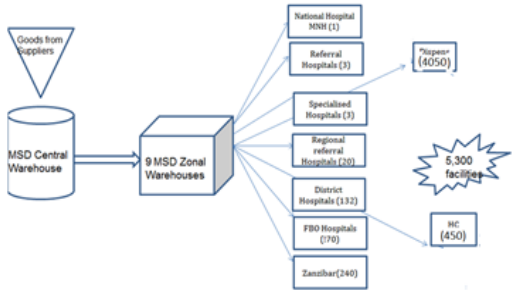
21

**DD (Direct Delivery)**

- DD to all health facilities in the country since July 1, 2013
- Quarterly delivery to Primary health facilities
- Bi-monthly delivery to hospitals
- Assessment of effectiveness of DD under way.
- 50% of transportation for last Mile Logistics to be outsourced on phased approach
- Started a new distribution centre at Muleba to serve Geita and Kagera regions

## Accomplishments

22




## Major Challenges

23

- Infrastructure and connectivity
- Readiness – Change management plan in place
- Substandard Medicines
- Illegal Importation of unregistered Medicines
- Changing Technology

## Major Challenges

24

- Increased needs for health commodities that does not match with budget allocations
- Lack of local capacity to manufacture medicines and related medical supplies
- Weak quantification of health commodities

## support required from the regional bodies

25

- Sharing of experiences and best practices
- Harmonize training curriculum for pharmacy professional in ECSA region

26

EAST CENTRAL AND SOUTHERN AFRICA HEALTH COMMUNITY

# Regional Pharmaceutical Forum

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