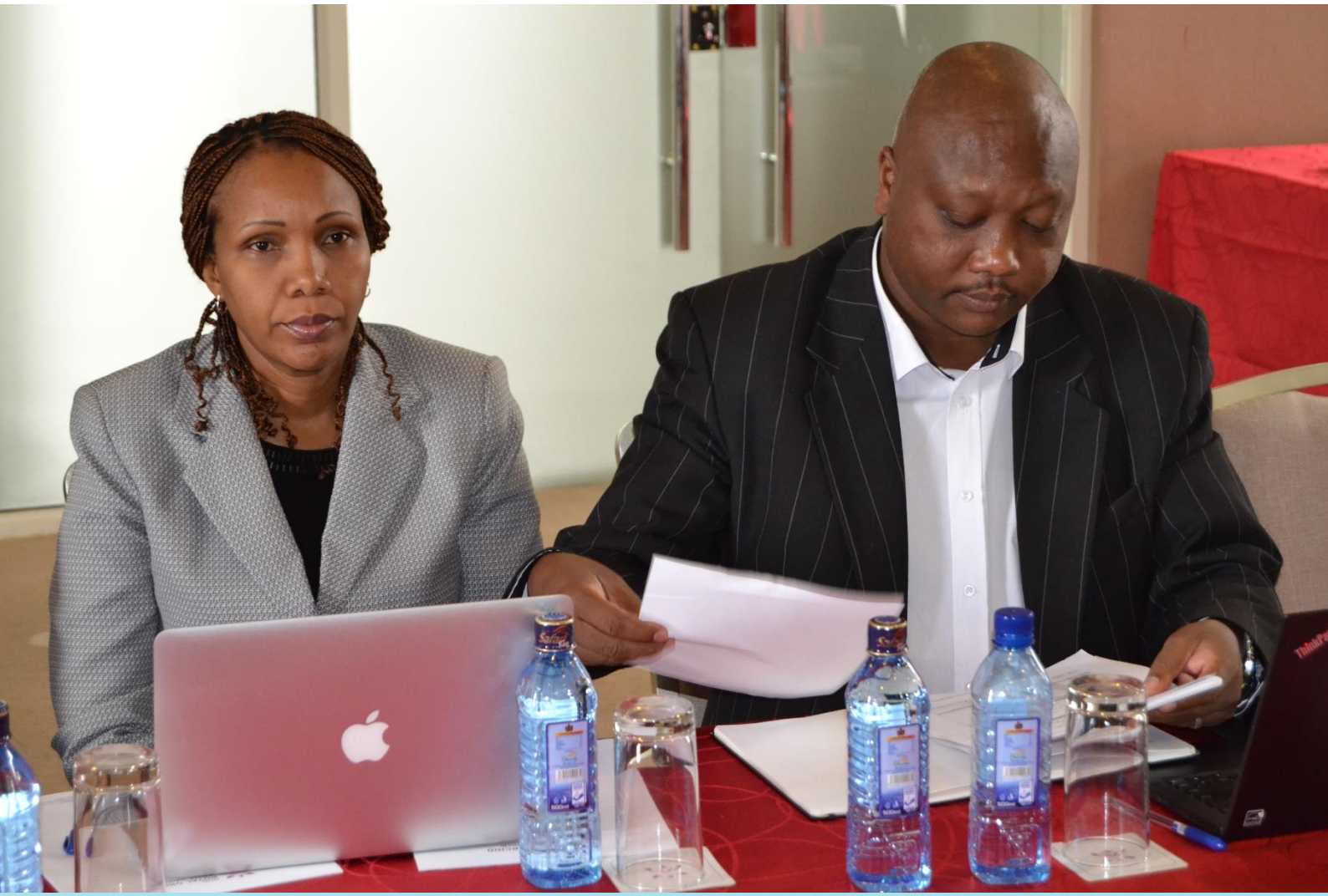
# AMRH Newsletter

July – September 2016

## African Medicines Regulatory Harmonization



# 27 applications assessed at EAC-MRH programme

# 3rd Joint Medical Dossier Evaluation

NEPAD TRANSFORMING AFRICA · World Health Organization · BILL & MELINDA GATES foundation · Department for International Development · THE WORLD BANK IBRD • IDA | WORLD BANK GROUP · AFRICAN UNION · UNDP · PEPFAR U.S. President's Emergency Plan for AIDS Relief · Gavi The Vaccine Alliance · swissmedic

# Editor's Note

Dear all,

As we approach the last quarter of the year 2016, African Medicines Regulatory Harmonization (AMRH) would like to share with you some of the success stories in the work that we do regarding medicines regulatory harmonization. The previous newsletter highlighted many achievements over a six month period, this one is packaged to showcase what we have been doing in the last 3 months covering July and September 2016.

AMRH has intensified its work on joint medical dossier evaluations especially in the East African Community and the Southern African Development Community (SADC) through the ZaZiBoNa initiative. This is in line with the medicines Regulatory harmonization agenda in Africa.

AMRH has also accelerated work on the implementation of the AU Model Law at regional and national level. In addition, AMRH has also provided support to the Organization for the Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC) which is the health organ of the Central African Economic and Monetary Community (CEMAC) to combat the use and sale of counterfeit medicines in Central Africa.

Lastly, AMRH has presented the preliminary results of the EAC pilot M&E and received feedback. This M&E approach will be rolled out to other regions and countries.

## Content - Highlights



# ABOUT AMRH

**African Medicines Regulatory Harmonization (AMRH) Programme**

The African Medicines Regulatory Harmonization (AMRH) initiative is a programme of the African Union (AU) implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Under the theme "Strengthening of Health Systems for Equity and Development in Africa", the AU Conference of Health Ministers (AUCHM) in April 2007 responded to the AU Assembly Decision 55 (Assembly/AU/Dec.55 (IV) taken during the Abuja Summit in January 2005 which mandated the African Union Commission (AUC) to develop the PMPA within the framework of the NEPAD. The programme started in 2009 as a response to addressing challenges faced by National Medicine Regulatory Authorities (NMRAs) in Africa. These challenges include; weak or non-coherent legislative frameworks, redundant/duplicative processes, sluggish medicine registration processes and subsequent delayed decision, inefficiency and limited technical capacity, among others. The work of AMRH is guided by three focus areas: policy alignment, regional integration and harmonization, and human and institutional capacity development.

The programme works in collaboration with the AUC, Pan-African Parliament (PAP), World Health Organization (WHO), Bill and Melinda Gates Foundation, World Bank (WB), UK Department for International Development (DFID) and US Government-PEPFAR and Global Alliance for Vaccines and Immunization (GAVI). The AMRH Strategic Plan defines the strategic direction for the medicines harmonization agenda in Africa and provides direction to advance the development of the pharmaceutical sector and provides guidance in monitoring and evaluation.

**Our Vision in Africa**

African people have access to essential medical products and technologies

**Our Mission in Africa**

Provide leadership in creating an enabling regulatory environment for pharmaceutical sector development in Africa

# EAC-MRH programme Third Joint Medical Dossier Evaluation assesses 27 applications

| Type of Procedure | Type | Received | Assessed | Queried | Registered | Refused | Planned for assessment |
|---|---|---|---|---|---|---|---|
| **EAC joint assessment** | New | 35 | 27 | 23 | 4 | 0 | 6 |

The East African Community (EAC) regional experts on medicines evaluation and registration, with technical experts from the World Health Organization (WHO) Prequalification and the Swiss Agency for Therapeutic Products, held a successful Third EAC Joint Dossier Assessment of medical products to review a total of 35 new applications. This is an initiative of the EAC Medicines Regulatory Harmonization (EAC-MRH) Programme and resulted in the assessment of 27 applications of which 23 were queried, 4 registered and 0 rejected and took place from 8th – 12th August 2016 in Entebbe, Uganda.

The meeting is a follow-up on the First and Second EAC-MRH Joint Dossier Assessment meetings held in October 2015 and May 2016 respectively. The main objectives of this Third Joint Dossier Assessment meeting was to assess 35 new applications for registration, as well as to share knowledge and practical skills in assessment quality, safety and efficacy data with the aim of ensuring consistency and harmonization in decision making among NMRAs. The workshop was also attended by expert observers from the Ethiopia Food, Medicines and Healthcare Administration and Control Authority, NEPAD Agency, World Bank (WB), Bill and Melinda Gates Foundation (BMGF), WHO and United States Pharmacopeia.

Overall, the main aim of Joint Dossier Assessments is to increase access to medicines, enhance capacity, work sharing and confidence building among National Medicines Regulatory Authorities (NMRAs). It also serves as a foundation for future mutual recognition of regulatory decisions among NMRAs of EAC Partner States.

During the workshop, Dr Dan Hartman, Director of Integrated Development at BMGF thanked all participants for their unique contributions in the implementation of the African Medicines Regulatory Harmonization (AMRH) agenda. He stated that regulatory affairs have been prioritized by BMGF, noting that Warren Buffett had also partnered with BMGF in supporting MRH programs.


**The EAC region continues to be a trendsetter in the medicines regulatory harmonization agenda in Africa**

He called on EAC to strive to be a blue print for medicines regulation implementation and to improve efficiency in regulatory activities through the elimination of ABCs (Arrogance, Bureaucracy and Complacency). Dr Hartman also informed the meeting that BMGF has plans to appoint a new Senior Regulatory Officer to be based in Africa, upon the retirement of Dr Vincent Ahonkhai at the end of 2016 who has been very instrumental in advocating AMRH initiatives.

NEPAD Agency Pharmaceutical Coordinator, Mrs. Margareth Ndomondo-Sigonda applauded EAC Partner States NMRAs for showing commitment to medicines regulatory harmonization since 2012. She stated that the role of NEPAD and the African Union (AU) was to facilitate implementation, coordination and advocacy in improving access to medicines in all Regional Economic Communities (RECs) in Africa.

In addition, Dr Samvel Azatyan, Group Lead - Capacity Building, Regulatory Systems Strengthening Team from WHO noted that the initial efforts of EAC NMRAs were yielding results and that WHO and Swissmedic would continue to provide technical support to EAC regional experts. Mr. Apollo Muhairwe, Senior Operations Officer at WB commended product development partners like TB Alliance, Foundation for Innovative New Diagnostics (FIND), DnDi, Medicines for Malaria Venture (MMV), PATH and International Aids Vaccine Initiative (IAVI) that have shown a willingness to interface with MRH Programs especially in the areas of clinical trials, marketing authorization, pharmacovigilance and post marketing surveillance.

Besides the assessment of dossiers, regional experts identified 11 sites that require Good Manufacturing Practices (GMP) inspection or assessment by document review. They also explored ways of improving predictability and efficiency of the joint evaluation process.

# NEPAD supporting Central Africa to combat use and sale of illicit, counterfeit medicines

The NEPAD Agency has reaffirmed its commitment to supporting the Central African region in the development and implementation of the Plan of Action against Counterfeit medicines through the African Medicines Regulatory Harmonization (AMRH) programme.

This commitment was emphasized during two separate but related meetings that took place in Douala, Cameroon from 21st – 23rd June 2016. The objective of the meetings was to put in place strategies for combatting the use and illicit sale of counterfeit medicines in the region.

**The African Union (AU) Model Law addresses licensing of manufacturers & prohibition of counterfeit medical products**

NEPAD Agency emphasized that its support will mainly focus on four (4) strategic areas which include:

(a) supporting the implementation of the Plan of Action
(b) Coordinating and advocacy of national and regional activities at continental level
(c) Streamlining the implementation of the Model Law on medical products regulation with the implementation of the Plan of Action and the Common Pharmaceutical Policy in Central Africa Region
(d) And monitor and evaluate the Plan of Action as contribution to improving access to safe, efficacious and affordable medical products.

## Central Africa Ministers of Health adopt Communique and endorse Plan of Action

During the meetings, a report of a situation analysis on counterfeit medicines in the Central African Member States was presented. The report showed that illicit trade in drugs account for 25% of the pharmaceutical market size in countries where it is poorly developed but goes up to 55% in countries where it is developed.

The Ministers of Health in the region adopted the Communique on the Plan of Action, and endorsed it for combatting the use and illicit sale of counterfeit medicines in the region.

In addition, the Ministers of Health also endorsed the declaration and commitments from the technical and technical partners to advance strengthening health systems to combat the use of counterfeit medicines and sale of illicit medicines in the regions.

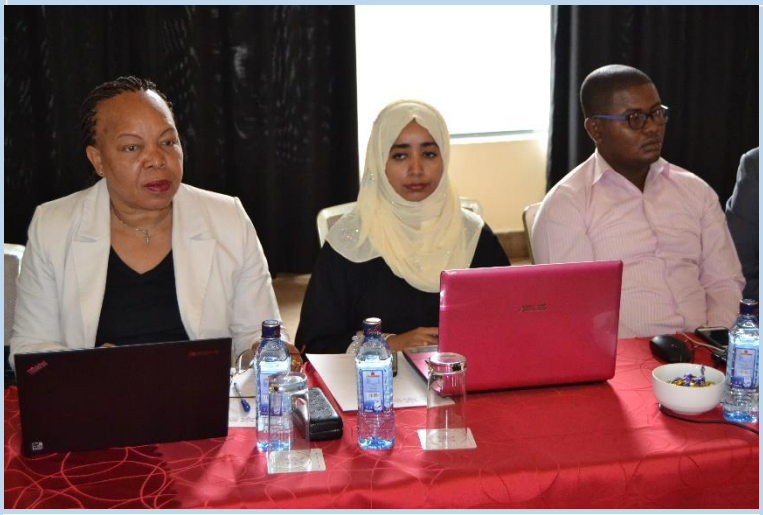
The two meetings were hosted by the Organization for the Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC) which is the health organ of the Central African Economic and Monetary Community (CEMAC). OCEAC is mandated to implement health programmes in the Central African region that is comprised of six member states (Gabon, Cameroon, Congo Republic, Equatorial Guinea and Tchad).

The first meeting concerned technical and financial partners and was specifically aimed at looking at partners' support in strengthening health systems at national and regional levels and reviewing the Plan of Action for combating

the use of counterfeit medicines and the illicit sale of counterfeit medicines in the region.

This meeting highlighted the importance of the role of technical and financial partners in supporting the implementation of the Plan of Action in the region. The second meeting focussed on Health Ministers in OCEAC and was organized under the theme "Coordinated Fight Against the use of Counterfeit medicines and illicit sale of Counterfeit medicines in the Central Africa Region". The meeting validated and endorsed the OCEAC Regional Plan of Action for combatting the use and sale of illicit medicines in the Central African Region.

# NEPAD receives feedback on compiled regional AMRH M&E preliminary results report

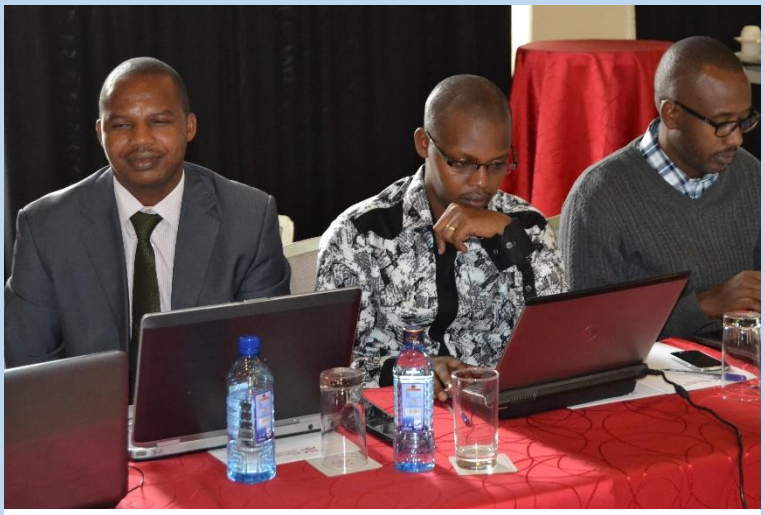


NEPAD Agency Head of Health, Margareth Ndomondo-Sigonda at the EAC M&E pilot preliminary results meeting in Nairobi, Kenya

On 18th August 2016, NEPAD Agency has successfully delivered preliminary results of the M&E pilot that was conducted in all six (6) East African Community (EAC) Partner States and received valuable feedback from participating stakeholders in Nairobi, Kenya. The feedback received shall be used to update the report before it is finalized and shared with the African Medicines Regulatory Harmonization (AMRH) Advisory Committee for validation.

> "There is need to have a designated personnel for M&E for the EAC-MRH Project at regional level and NMRA level with clear ToRs," Mr Mwesigye

The main objective of the meeting was to consult stakeholders on the EAC-MRH Project M&E pilot report, revise and update the Indicators Reference Manual and agree on mechanism of data collection in preparation for the expected expansion of this framework to other Regional Economic Communities (RECs). These objectives have been met and the reference documents will now be finalized to form part of the M&E roll out process to other RECs in Africa.

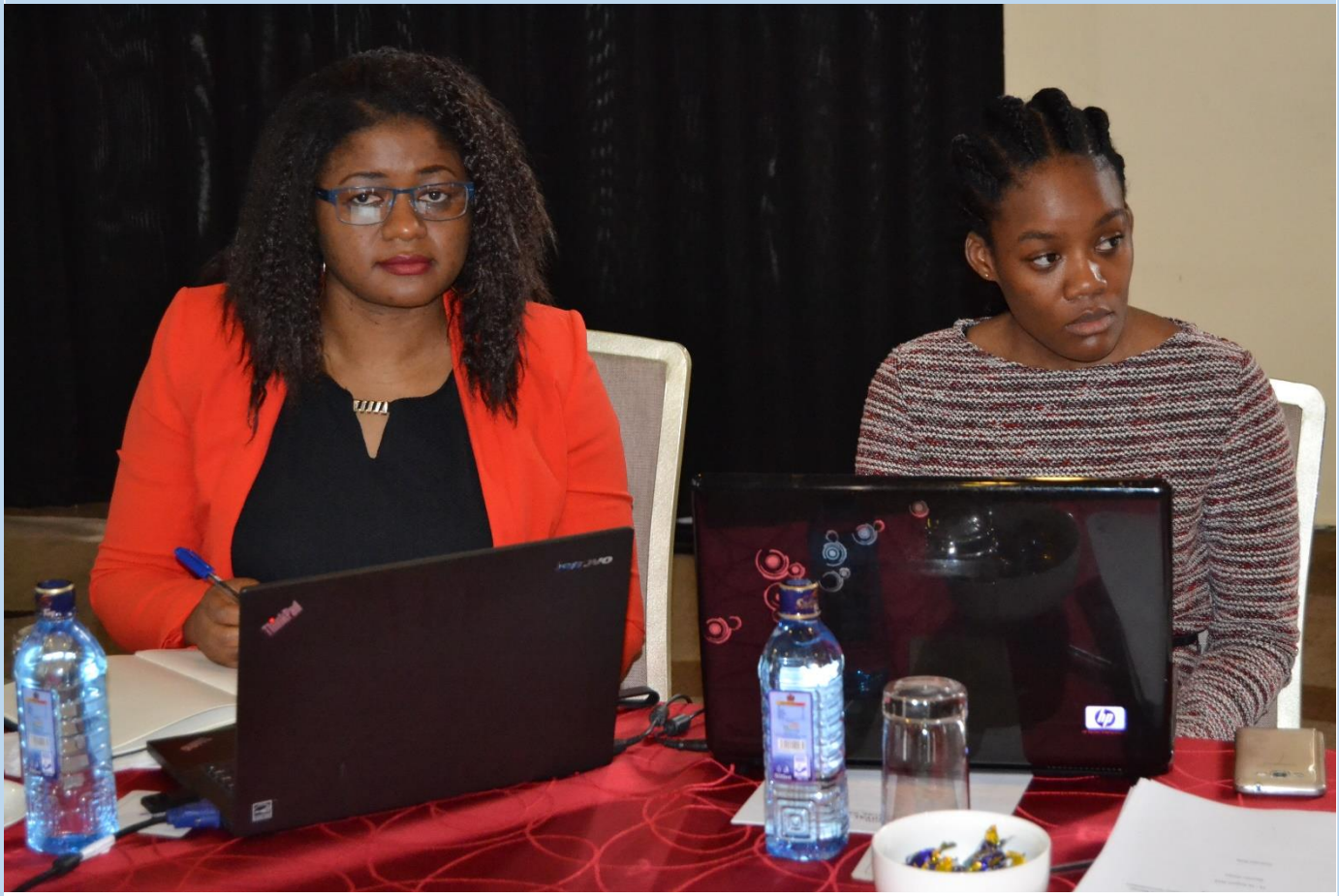


John Patrick Mwesigye from EAC Secretariat also made a presentation on behalf of the Secretariat during the AMRH M&E meeting in Kenya

During the meeting, EAC-MRH Project Senior Health Officer, John Patrick

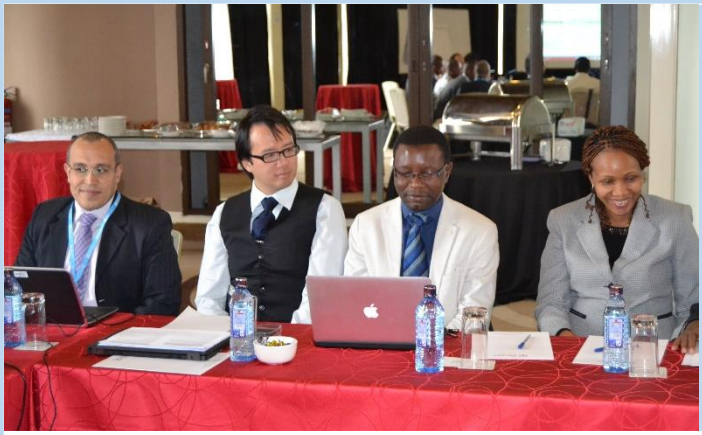
Mwesigye presented proposed interventions for strengthening the EAC-MRH Project M&E. He outlined how EAC conducts systematic M&E through quarterly, semi-annual and annual reports from Partner States, meeting reports, as well as reports of project implementation support missions from World Bank (WB), World Health Organization (WHO) and NEPAD Agency of the African Union (AU). Mr Mwesigye also highlighted the need to have streamlined data and information collection from sources and to establish an automated indicator tool that can collect national level information to feed in to a consolidated regional outlook. He also emphasized the importance of knowledge and information sharing at regular intervals and the need for dedicated M&E focal persons to accelerate the implementation of these activities.

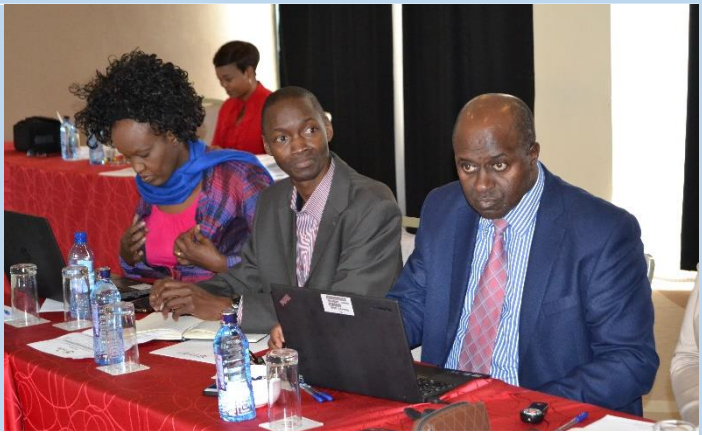
"There is need to have a designated personnel for M&E for the EAC-MRH Project at regional level and NMRA level with clear ToRs," Mr Mwesigye emphasised.



Nancy Ngum and Mercedes Leburu played a critical role in the success of the M&E meeting in Nairobi, Kenya

Following this report from the EAC Secretariat and findings from the AMRH M&E pilot report, it became clear that M&E focal persons were quite critical in delivering a robust and effective M&E system. As a result, the meeting identified dedicated M&E focal persons and proposed ToRs were developed for easy future collection of M&E data. Southern African Development Community (SADC) also made a presentation of their work plan that outlines the systematic steps towards implementing a version of





Participants representing different stakeholders within and outside EAC region were present during the M&E meeting in Nairobi, Kenya

the M&E system based on lessons learnt from the EAC region. SADC representative, Luther Gwaza highlighted the data protocols, quality assurance systems and evaluation processes that shall inform the SADC M&E roll out. The process is expected to kick start at the beginning of September, 2016 and a draft SADC MRH M&E framework has already been developed.

Fatuma Ibrahim Adan representing the InterGovernmental Authority on Development (IGAD) said that the NEPAD M&E system shall be inculcated to form part of the broader IGAD M&E plan and MRH Project assessment. She explained that IGAD already has a functional M&E coordinator on health and details of the M&E work will be streamlined under this unit to ensure coherence. Mrs Adan called on NEPAD Agency to expedite the roll out of the M&E framework to other IGAD Partner States not covered under the EAC region.

Chimwemwe Chamdimba presented the AMRH M&E approach

The M&E framework will help to accelerate AMRH project impact by identifying gaps in MRH Project implementation and crafting relevant interventions for improving medicines regulatory systems in Africa. The M&E framework is also critical in contributing towards enhancing knowledge management on regional MRH Projects and at national level, refining and guiding policy and regulatory reform interventions and shading light on regulatory capacity development. These three factors constitute the main areas of intervention of the AMRH programme. The presentation of preliminary results of the pilot M&E report was led by Nancy Ngum of NEPAD Agency who highlighted 9 categories and 31 indicators.

# NEPAD's AMRH M&E Framework vital for assessing impact, identifying gaps and designing interventions for strengthening medicines regulatory systems

Participants at the M&E consultation meeting in Nairobi Kenya posing for a group photograph before engaging in intense discussions

NEPAD Agency Pharmaceutical Coordinator, Margareth Ndomondo-Sigonda has hailed the importance of the African Medicines Regulatory Harmonization (AMRH) monitoring, evaluation and impact assessment framework in assessing Medicines Regulatory Harmonization (MRH) Project impact, identifying gaps and designing interventions that shall also benefit National Medicines Regulatory Authorities (NMRAs) and enhance the regulatory environment for pharmaceutical sector development in Africa.

Mrs Sigonda was speaking during the AMRH organized M&E consultation meeting in Nairobi, Kenya aimed at refining the AMRH Indicator Reference Manual and updating the Data Collection Tool. This meeting follows the successful piloting of the AMRH M&E Framework (indicators tracking table and data collection tool) in all the 6 NMRAs in the East African Community (EAC) Region. The meeting serves as a platform not only to present the results of the preliminary report on the EAC M&E pilot exercise, but also to get feedback and discuss proposed interventions that could improve the work of AMRH and MRH Projects in EAC and other regions.

"This exercise is an important NEPAD initiative and vital component of the AMRH programme as it will assist in generating data that shall inform programme implementation, policy and political advocacy," Mrs Sigonda clarified.

Mrs Sigonda further explained that the overall goal is to scale up the M&E Framework to other Regional Economic Communities (RECs) in Africa, starting with the SADC region.

All this has been done in recognition of the existence of a comprehensive WHO Assessment Tool for assessing medicines regulatory systems and the World Bank (WB) MRH Project Results Frameworks but focusing on the AMRH contribution and alignment to the African Union (AU) Policy Instruments, Frameworks and Health Programmes.

The meeting is taking place from 16 – 18th August 2016 and is attended by representatives from the Tanzania Food and Drugs Authority (TFDA), Zanzibar Food and Drugs Board (ZFDB), Pharmacy and Poisons Board of Kenya (PPB), National Drugs Authority (NDA) of Ugandan, Department of Pharmacy and Medicines Laboratory (DPML) of Burundi, NEPAD Agency, Southern African Development Community (SADC) and East African Community (EAC) Secretariat, Ministry of Health in Rwanda, Inter Governmental Authority on Development (IGAD), WB and World Health Organization (WHO).

**The goal is to scale up the M&E Framework from EAC to other RECs in Africa**

# SADC Medicines Regulators Forum review progress on Phase I of MRH activities, develops work plan for the implementation of phase II

The Southern African Development Community (SADC) Medicines Regulators Forum held a successful meeting in Victoria, Seychelles from 27th – 29th July 2016 to review progress on the completion of Phase I of the implementation of the Medicines Regulatory Harmonization (MRH) Project and develop a work plan for the implementation of Phase II of the project covering the period 2016 – 2017.

The meeting was attended by SADC Heads of National Medicines Regulatory Authorities (NMRAs) or their representatives, and representatives from partner organizations, NEPAD Agency, World Health Organization (WHO) and the World Bank (WB). The meeting was also graced by Seychelles Health Minister, Mitcy Larue. The purpose of the meeting was to review and plan for the SADC medicines regulatory activities.

During the meeting, a progress report on the implementation of the first year outputs on the MRH

Project was presented and a report on the status of medicines regulation in the SADC region was also shared and discussed. In addition, a work plan for the implementation of Phase II of the SADC-MRH Project activities was developed. Participants also took time for a visit and orientation to the Quality Control Lab in Seychelles as a learning process.

NEPAD Agency representative, Paul Tanui made a presentation on the overview of the African Medicines Regulatory Harmonization (AMRH), the AMRH M&E Framework and next steps for the implementation of the African Union (AU) Model Law on medical products regulation. The SADC Secretariat also presented the SADC MRH Project M&E Framework. It was agreed that a robust M&E system should be developed to track progress and performance, including baseline data and standard periodic monitoring in all 15 SADC Member States.

The SADC Medicines Regulators Forum provides technical advice and guidance on regulatory issues relating to medicines and health commodities in the SADC region. The Forum supports implementation of regulatory harmonisation initiatives and strengthening of the medicines regulatory capacity in the region in-line with the business plan. Further, under the medicines regulatory harmonization, the SADC Regulators' Forum also acts as the Project Steering Committee.

Participants during the SADC Medicines Regulators Forum pose for a photo in Victoria, Seychelles

# 13 new products assessed at 12th ZAZIBONA Assessors meeting, 6 recommended for approval

The recent ZAZIBONA 12th assessors meeting held in Windhoek, Namibia from the 4th – 9th September 2016 successfully assessed a total of 13 new products, provided responses to 11 previous requests for additional data. From the assessments, six products were recommended for approval (positive opinion), three products were recommended for rejection (negative opinion), and additional information was required for the remaining 15 products before a final recommendation could be made.

The Assessors meeting was attended by five (5) active ZAZIBONA Member States: Botswana, Namibia, South Africa, Zambia and Zimbabwe. In addition, seven Member States were in attendance including Angola, Lesotho, Madagascar, Malawi, Mozambique, Swaziland, and Tanzania. This is the 3rd planned ZAZIBONA Assessors meeting for 2016. The 4th meeting is slated to take place from 21 – 25 November 2016 in Botswana and the ZAZIBONA Heads of Agencies will also meet at the same time on the 24th and 25th November.

The assessors meeting started with a Good Clinical Practice (GCP) workshop facilitated by World Health Organization (WHO) from the 4th to the 6th of September 2016 and this was inclusive of assessors and inspectors.

Following this training, it was agreed for ZAZIBONA to initiate inspection of Contract Research Organizations (CRO) when triggers for inspections are identified during the assessment of documentation submitted to ZAZIBONA regulatory authorities. Consequently, the assessors focused on reviewing bioequivalence data with the aim of looking for triggers that were presented to inspectors. Three CROs were recommended for GCP / GLP inspection.

## ZAZIBONA GMP Inspectors review, finalize previous reports

ZAZIBONA inspectors also met parallel to the assessors meeting to review & finalise previous GMP inspection reports as well as to plan for the inspection activities. A list of SOPs that are required before, during and after conducting an inspection; including the following: preparation for a GMP inspection, conducting an inspection, preparing an inspection review, closing out an inspection, tracking inspection, risk classification of observation according to TRS 996 was prepared.

Three ZAZIBONA GMP inspection reports conducted in the last quarter were reviewed. The participants also discussed the 2017 work plan, which included coming up with a risk assessment for scheduling inspections, routine inspections and re-inspections as well as areas for further training of inspectors.

# Upcoming Events

- **WAHO High Level Engagement on West Africa MRH Project and AU Model Law implementation:** 02 – 03 October, Bobo Dioulasso, Burkina Faso
- **Central African Regional consultation on AMRH implementation:** 03 – 07 October, Gabon, Equatorial Guinea and Cameroon
- **EAC stakeholders meeting on regional pharmaceutical policy and mutual recognition mechanism:** 06 – 07 October, Kampala, Uganda
- **EAC stakeholders meeting on pharmacovigilance and post marketing surveillance programmes:** 18 – 20 October, Zanzibar, Tanzania
- **5th Meeting on the Global Vaccine Safety Initiative (GVSI):** 26 – 27 October, Addis Ababa, Ethiopia
- **Film Documentary on EAC-MRH Project implementation success stories:** 02 – 11 November, Kampala, Bujumbura, Arusha and Dar es Salaam
- **1st EAC Regional Pharmaceutical Manufacturing Promotion and Investment Forum:** 02 – 04 November, Nairobi, Kenya
- **1st EAC Regional Pharmaceutical Manufacturing Promotion and Investment Forum, EAC-MRH Project Appraisal Mission and the 5th EAC-MRH Project Steering Committee Meeting:** 01 – 04 November, Nairobi, Kenya: Arusha, Tanzania and Bujumbura, Burundi
- **EDCTP Forum 8th High Level meeting of African and European Policy Makers:** 07 – 08 November, Lusaka, Zambia
- **1st EAC Regional Pharmaceutical Manufacturing Promotion and Investment Forum:** 06 – 11 November, Kigali, Rwanda and Bujumbura, Burundi
- **Medicines Regulatory Harmonization (MRH) Project Steering Committee Meeting for Central Africa:** 15 – 16 November, Douala, Cameroon
- **ZAZIBONA 13th Assessors Workshop:** 21 – 25 November, Gaborone, Botswana
- **17th International Conference of Drug Regulatory Authorities:** 27 November – 02 December, Cape Town, South Africa
- **3rd African Medicines Agency (AMA) Task Team Meeting:** 03 December, Cape Town, South Africa
- **1st Meeting of the Technical Working Group on Pharmaceutical Manufacturing Plan for Africa (PMPA) Financing Mechanism:** 06 – 07 December, Midrand, South Africa

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