3RD BIENNIAL SCIENTIFIC CONFERENCE

ON MEDICAL PRODUCTS REGULATION IN AFRICA

Sustaining the Momentum for Regulatory Harmonization in Africa

CONFERENCE REPORT

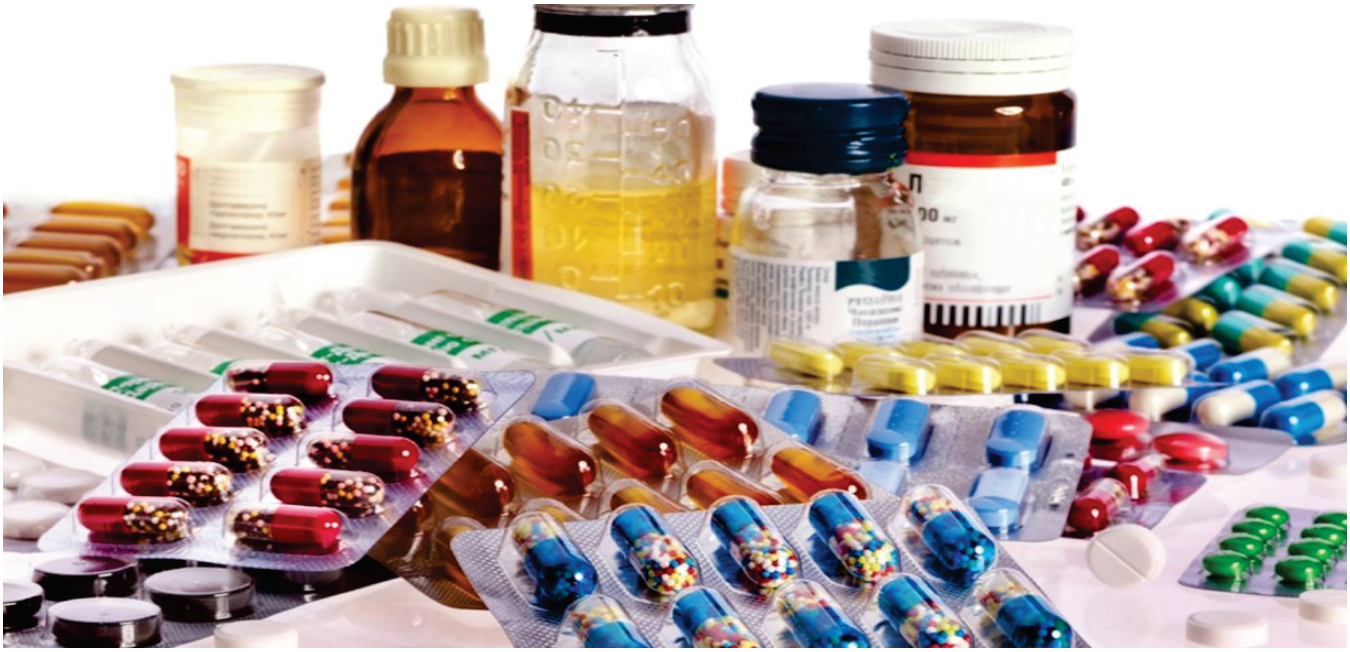


Table of Contents

Executive Summary

Executive Summary

Since 2016, access to medicine in Low and Middle Income Countries (LMICs) has shown a steady improvement according to the global Access to Medicines Index. Scientific predictions for the future outlook of access to medicine, especially in Africa, indicate that the continent will make positive strides by the year 2030. This will pull Africa closer to meeting the health targets set in both the United Nations (UN) Sustainable Development Goal (SDG) and African Union (AU) Agenda 2063 and deliver on the promise of *The Africa We Want*. The establishment of the African Medicines Regulatory Harmonization (AMRH) Initiative in 2009 has contributed to improved access to medicines in Africa by reducing medicine registration timelines to get products on the market faster, built expertise in key regulatory functions, and harmonized varying medicines regulatory frameworks using a regional approach. Hence, current efforts in medicines regulatory strengthening and harmonization in Africa such as the AMRH Initiative need to be sustained to retain the momentum and build on its achievements to raise the bar even higher to continue improving the health of the African people.

Imagine an Africa where safe, efficacious and quality medicines and vaccines covering all of the continent's ailments are available, affordable and easily accessible for use by the patients and medical fraternity. An Africa where pharmaceutical products are manufactured locally for the benefit of indigenous people and contributing to the socio-economic development of the continent. Engagement of key stakeholders in the development of the pharmaceutical sector on the continent is critical. The 3rd Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA) brought together various partners and stakeholders to brainstorm, exchange innovative ideas, share lessons learnt and best practices with the view of turning the above imagination of Africa into a reality. SCoMRA provided a platform for stakeholders to review progress achieved under the AMRH Initiative, and other similar Pan-African Initiatives, over the past decade and map the trajectory moving forward in a consultative manner.

Sustaining the medicines regulatory strengthening and harmonization work requires not only political will, but also technical, social and financial commitment to accelerate local ownership, as well as the involvement of public and private stakeholders with a common agenda. During the SCoMRA, different partners and stakeholders participated in reviewing progress made in this line of work by taking stock of what each Regional Economic Community (RECs) was doing in working with African Union Member States belonging to their respective regions. East Africa Community (EAC), Southern African Development Community (SADC), Inter-Governmental Authority on Development (IGAD), Organization of Coordination for the Fight against Endemic Diseases (OCEAC) and in West Africa under the West African Health Organization (WAHO) provided updates on what they are doing at regional level to advance medicines regulatory strengthening and harmonization work. In addition to the RECs, World Health Organization (WHO) presented an overview of the African Vaccines Regulatory Forum (AVAREF), and Civil Society Organizations (CSOs) voices were also heard in recognition of their important role in strengthening regulatory systems in Africa. A Monitoring and Evaluation (M&E) model of how this work can be tracked in Africa was also discussed.

SCoMRA is also an opportunity to share knowledge and best practices so that participants can learn from one another. Participants at SCoMRA benefitted from the approach to broaden the scope of the work in Africa by learning from proven best practices within and outside the continent. As the technical lead, WHO presented their collaborative registration procedures with a view to finding opportunities that could benefit Africa. Other best practices from the Life Cycle Management (LCM) and Marketing Authorization for Global Health Products (MAGHP) were presented and discussed. In addition, Africa has also made some progress in medicines registration through the Joint Assessments procedure pioneered by the EAC and later adopted in the SADC region through the Zazibona scheme. This approach to approval of medicines registration applications was highlighted as one of the success stories and added value in Africa that could be replicated in other regional platforms. The whole purpose of sharing lessons learnt and best practices within Africa and other continents is to ensure that the current state of affairs is reviewed and planning for the future takes into account emerging innovative ideas.

The work for medicines regulatory strengthening and harmonization has been in existence in Africa now for at least a decade. SCoMRA provided a platform to reflect on the past decade, as well as to strategically plan for the way this work will be shaped in the coming decade. The role of the AMRH Partnership Platform as the Africa chapter of the WHO Coalition of Interested Parties (CIP) were both presented and discussed to ensure effective coordination of various partners and stakeholder involved in regulatory work in Africa. In addition, other specific regulatory platforms and their roles were discussed such as the Pan African Harmonization Working Party (PAHWP) focused on regulation of medical devices, the Network of Official Medicines Control Laboratories (NoMCoL) focused on improving laboratory capacity and the quality of medicines. New stream of work on strengthening regulatory capacity for Blood and Blood Products that is being led by the Paul Ehrlich Instut (PEI), were also discussed.

How these platforms and specific regulatory streams of work will fit into the proposed African Medicines Agency (AMA) is something that remains to be seen. Participants at SCoMRA exchanged ideas on how AMA can position itself on the continent and fill a leadership void. This is critical in reaping the results quickly and in a coordinated fashion and will ensure that partners and stakeholders working in Africa avoid duplication of work, and ensure resources (both human and financial) are effectively coordinated and used optimally. It is clear that the proposed establishment of AMA is an opportunity to work towards a strong continental institution that can provide oversight in the various medicines regulatory functions and platforms without compromising national sovereignty.

A trajectory on how the future of medicines regulatory strengthening and harmonization work in Africa was developed, defining the scope of regulatory work and the need to expand it to include other equally important regulatory functions and ensure end to end impact was also a highlight. SCoMRA participants emphasized the importance of building on the success of registration or Marketing Authorization (MA), of generic medicines in Africa by expanding the scope to include Clinical Trials Authorization (CTA), and Pharmacovigilance (PV). Incorporating these functions will lead to faster approval of medicines, improved pharmacovigilance systems and infrastructure and guide the clinical development and oversight of new therapies and vaccines for prevention and treatment of diseases that disproportionately affect the African population.

Improving access to medicines, rolling back Substandard and Falsified (SF) medical products and technologies, promoting partnerships and establishing strong institutions, improving investment in Africa's local pharmaceutical industry all represent one side of the first decade of the implementation of the AMRH spectrum of activities. In the coming years, it is important to sustain these gains and sustain the momentum for regulatory harmonization in Africa.

1.0 Background

The 3rd Biennial Scientific Conference for Medical products regulation in Africa (SCoMRA) organized by NEPAD Agency, the African Union Commission (AUC), the World Health Organization (WHO), National Medicines Regulatory Authorities (NMRAs), Regional Economic Communities (RECs) and Regional Health Organizations (RHOs) and hosted by the Government of Ghana was held at Alisa Hotel from 27 to 28 November 2017 under the theme: *"Sustaining the Momentum for Regulatory Harmonization in Africa"*.

This theme enabled participants to contribute towards the future of medical products' regulation and harmonization in Africa. It provided a platform for stakeholders to brainstorm on role of ethical and regulatory approval of clinical trials in bridging the gap between research and development given the existing vacuum in advancing clinical trials that are relevant for diseases affecting African countries.

At the end of the Conference it was expected that there would be:

- ✓ Increased commitment from key stakeholders on regulatory systems strengthening and harmonisation as exemplified by the number of participants who funded their participation and diligently listened to the discussions throughout the two conference days;
- ✓ Actions for sustaining the momentum on regulatory harmonisation in Africa identified and agreed as part of conference recommendations;
- ✓ Increased knowledge on regulation of medical products and harmonisation efforts in Africa;
- ✓ Stakeholder awareness on the progress made in medical products regulatory systems in Africa through the various presentations made;
- ✓ Agreed framework for collaboration and networking among regulators, researchers and industry in advancing research and development and subsequent commercialization of products for diseases disproportionately affecting Africa;

The Conference was attended by two hundred ninety five (295) participants representing AU Member States, RECs, UN, Development Agencies, Civil society Organizations, Academia, Private sector, and NGO's, (List of participants is attached to this report)

2.0 Opening Session

Mrs. Margareth Ndomondo-Sigonda, NEPAD Agency and Professor Jean-Baptiste Nikiema, WHO-AFRO co-moderated the opening ceremony. They recalled the two previous conferences and extended appreciation to all the partners for supporting these series of conferences and to participants for taking time off their busy schedules to attend the 3rd Biennial Scientific Conference for Medical Product Regulation in Africa.

2.1 Welcome Remarks by Dr Kofi Busia on behalf of Dr. Xavier Crespin, Director General of the West African Health Organization (WAHO)

On behalf of Dr. Crespin, Dr Kofi Busia, underlined the importance of collaborative efforts as the prerequisite for efficiency of the regulatory processes hailing all the achievements made in the continent. He applauded the timeliness and choice of the region to host the 3rd Biennial Scientific Conference for Medical Product Regulation which coincided with the launch of the ECOWAS MRH Projects. He noted that achievements such as the joint GMP inspection programme and the streamlined registration procedures made within the ECOWAS region were as a result of the growing collaboration between WAHO and UEMOA. He expressed his gratitude to NEPAD, WHO, and other Partners as well as national medicines regulatory authorities for their support to WAHO's programs

2.2 Opening Statement by Dr. Owen Laws Kaluwa WHO Country Representative for Ghana

Dr. Kaluwa emphasized the role of medicines regulators and efficient regulatory systems in the attainment of the Sustainable Development Goals (SDGs) and Universal Health Coverage (UHC). He reminded participants of the WHO's Regional Strategy for Regulation of Medical Products in Africa (2016-2025) which was adopted in 2016 and is underpinned by four (4) guiding principles namely: Governance, Regulatory Systems Strengthening, and Fight against Substandard and Falsified (S&F) medicines.

He ended his statement by reiterating WHO's support for regulatory harmonization initiatives such as the AMRH and the ultimate establishment of the African Medicines Agency (AMA).

2.3 Official Opening by Honorable Kwaku Agyeman-Manu, Minister of Health of the Republic of Ghana

Before declaring the 3rd Biennial Scientific Conference officially open, the Minister of Health of Ghana, Mr. Agymen- Manu welcomed the distinguished guests and participants to Accra appreciating the organizers for having selected Ghana among all African countries to host the important conference. He emphasized the importance of regulatory harmonization in ensuring access to medicines in the African Countries especially in the face of scarce financial and human resources. Harmonization he said, harnesses the collaborative efforts of stakeholders to curb duplication and shorten timelines required to make quality assured products on the market and accessible to all who need them. He acknowledged three barriers to the harmonization process namely culture, language and currency but said these like many other challenges were not insurmountable.

He appreciated WHO's technical input, NEPAD's advocacy, World Bank, BMGF and other partners' financial and advisory support to the regulatory harmonization agenda on the continent but most importantly the RECs and NMRAs for the successes registered in the EAC region, SADC through the ZAZIBONA initiative, and current efforts in ECOWAS region. Harmonized GMP guidelines, joint

inspections, joint reviews are now being conducted and have resulted in improved efficiency and effectiveness of the regulatory system.

Specifically in ECOWAS, the Minister reported that besides the harmonization projects currently underway, implementation of the ECOWAS Regional Pharmaceutical Manufacturing Plan – a plan inspired by the AU PMPA Business plan. The strategy promotes the development of and manufacture of priority medicines for the region. So far, he said, incentives for local manufacturers were included in when the Common External Tariff was being negotiated and adopted. Other achievements include a Committee on S&F and illegitimate medicines has been set up, and approval by the ECOWAS Council of Ministers of legislation against S&F medicines.

Minister of Health of Ghana (2nd from left), WAHO Representative of the Director General (2nd from right) and WHO Ghana Country Representative (left) sharing a light moment during the opening session

3.0 Setting the Scene

As part of the opening and setting the scene for the two days deliberations, two high level panel sessions were conducted. Moderated by Mr. Richard Jones, an editor at DEVEX Partnerships, the first panel consisted of one high level dignitaries representing five (5) organizations namely: AUC, NEPAD, WHO, Word Bank and GMGF. The second panel session entitled *Accelerating access to medicines – perspectives of industry, Civil Society and Patient Organizations* was moderated by Mrs. Margareth Ndomondo-Sigonda. It comprised of high level representatives from various private sector and civil society organizations within the continent and beyond including: The Federation of African Pharmaceutical Manufacturers Associations (FAPMA), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), PATH, and International Alliance of Patients' Organizations (IAPO).

3.1 First High-Level Panel: Putting patients first – reforming access to medicines in Africa

High-Level Panelists seated from (L-R): Prof. Aggrey Ambali, Dr Margaret Agama-Anyatei, Dr Samvel Azatyan, Andreas Seiter and Dr Dan Hartmann. Moderated by Richard Jones (standing)

3.1.1 ***Professor Aggrey Ambali, Head, Industrialization, Science,***

Technology and Innovation (ISTI), NEPAD Agency

In responding to the moderator's questions, Prof. Ambali provided a detailed historical overview and milestones of the AMRH initiative. He said that NEPAD acting on the mandate issued by the Pan-African Parliament has since 2009 spearheaded the strengthening and harmonization of regulatory systems through

the Regional Economic Communities (RECs) to remove barriers for access to quality-assured medicine. He appreciated the technical support of WHO in guiding all the technical aspects of the initiative. One important tangible result he pointed out was the fact that as a result of the harmonization EAC was enjoying reduction of up to 40-60% reduction of the review and approval timelines for medical products.

The initiative also became a potent incentive for the countries to develop national regulatory frameworks. Adoption of the Model AU Law on Medical Product Regulation was a landmark milestone whose impact has been felt in thirteen (13) African countries , eight (8) of which have amended their national legislation and 5 more countries currently reviewing their laws in alignment with the Model Law. Moreover was noted the impact of the Model Law transcended the continent offering its benefits to countries of other regions. Professor Ambali emphasized the importance of prioritization and capitalizing on the systemic impact of medicines regulation. To this end, such areas as pharmacovigilance and market surveillance were to be prioritized to ensure value chain integrity. Harmonization among the Regional Economic Communities and the prospective launch of the African Medicines Agency were signaled as the way forward. He urged participants to expand these benefits beyond the sector to other sectors such as the mining sector.

3.1.2 Dr. Margaret Agama-Anyetei, Head of Health and Social Affairs, African Union Commission (AUC)

Dr. Agama-Anyetei acknowledged political commitment as a critical element for the success of the AMRH initiative, which leveraged the AU Agenda 2063 which aspires for high standards of living, good health and well-being. In this context good quality medicines manufactured gain particular importance. Establishment of the African Medicines Agency (AMA) is the next important milestone envisaged in the harmonization process.

Beyond the strengthening of regulatory systems, the Commission she said continues to pursue the strengthening of local manufacturing capabilities including through a recommendation by the Specialized Technical Committee on Health, Population and Drug Control issued in March 2017 to set up a Fund for Africa's Pharmaceutical sector Development (FAP-D). The objective of this fund is to support/complement local manufacturers' efforts to achieve international standards of production. The fund comes as a guarantees of durability and sustainability of the AMRH gains as it would lead to the increased production capacity of high quality medical products. The fund management of would draw on the experience of the African Development Bank and other institutions with expertise in managing specialized funds she reported.

3.1.3 Dr. Samvel Azatyan, WHO HQ

Dr. Samvel elaborated on the remaining bottlenecks for patients' access to medicines in Africa. As the WHO's goal is to guarantee the highest attainable level of health and well-being for any human being, medicines came into prominence as one of the important instruments for that. One third (1/3) of the world population still does not have access to the essential medicines they need. "Despite the fact that medical products are being developed and manufactured, they do not reach many patients in the low- and middle-income countries. Medicines regulators have a role to play in addressing this situation and improving access but also have to serve as a safe harbor to guarantee their quality" – said Dr Azatyan. A number of challenges including funding, human resources and expertise were said to prevent making access to medicines for all

a reality. Training, reducing duplication, building trust being instrumental to boosting regulatory capacity Dr Azatyan acknowledged the AMRH contribution in this area. He also highlighted remarkable AMRH achievements, and advised that this momentum needed to continue in order to reach the Sustainable Development Goals and the Universal Health Coverage.

3.1.4 Mr. Andreas Seiter, Global Lead – Private Sector, Health, Nutrition and Population, World Bank

Mr. Seiter in his remarks welcomed MRH initiative in the West African Region expressing hopes and aspirations of the World Bank to play its role in addressing the funding gaps. “Hundreds of thousands of lives can be saved on the continent if access to medicines is improved” – he stated. Africa is confronted with the unfinished agenda of the infectious diseases and the emerging burden of the non-communicable diseases. Compounded by the fragmentation of pharmaceutical markets resulting from state and non-state players creating their own supply chains with myriad of retail shops dispensing medicines creates a huge challenge for regulators. This calls for a viable local pharmaceutical industry well-regulated to ensure quality. To achieve this goal for a the private sector needs to be incentivized to adopt a commitment of bringing quality-assured products to patients with regulators playing a key role in ensuring maintenance of and compliance with quality standards.

3.1.5 Dr. Dan Hartman, Director, Integrated Development, Global Health, Bill and Melinda Gates Foundation (BMGF)

Mr. Hartman shared the Foundation’s perspective on the AMRH initiative stating that the foundation has been supporting the initiative since 2009. Beyond addressing the issue of quality medicines another reason which prompted BMGF support, was a significant layback for introduction of medicines into the health systems in Africa. A study commissioned by the Foundation unveiled a delay of up to 4 years for introduction of medicines in countries of the continent; contrastingly, in the high income countries the market entry was a matter of a couple of months. Mr. Hartman said the lack of technical capacity and human resources, diversity of requirements, and duplication of efforts were the major drivers for such protracted timelines.

“We are pleased that by now the introduction time has been reduced by 50%. It was achieved through reliance on high-quality regulatory decisions, re-engineering regulatory systems, increasing technical capacity and expertise and the focus on the regions” – said Dan Hartman.

Expressing satisfaction in the substantial number of joint reviews which were taking place and recommending improved coordination as a key driver for success, Mr. Hartman said the Foundation was committed to continue working in the area of medicines regulatory strengthening and supporting the harmonization initiatives.

Take-away messages from the panelists

- Professor Ambali, NEPAD: *"Regional processes are usually seen as a challenge. Therefore, we should be proud of what AMRH has achieved. Let us support this project to move forward to further success".*
- Ms Agama-Anyetei, AUC: *"Support the establishment of the African Medicines Agency and the fund for manufacturers, continue support of the AMRH initiative!"*
- Dr Azatyan: *"Work-sharing, reliance, collaboration, using best practices and information available from elsewhere to work together in a collaborative manner!"*
- Mr Seiter, WB: "*Importance of dialogue in the region between regulators and industry."*
- Mr Hartman, BMGF: "*AMRH is a great initiative, which needs to continue implementing its activities. Its expertise is to be leveraged in the continent rather than starting regulatory collaborations from the scratch.*

3.2 Second High-Level Panel: Accelerating access to medicines – perspectives of industry, Civil Society and Patient Organizations

This session was moderated by Margareth Ndomondo-Sigonda, Head of Health Program's NEPAD Agency. It consisted of four (4) speakers two from industry and two from civil society.

3.2.1 Emmanuel Mujuru, Chairman, Federation of African Pharmaceutical Manufacturers Associations (FAPMA)

Mr. Mujuru began his intervention by providing a background of the Federation of African Pharmaceutical Manufacturers Associations (FAPMA) which was officially launched in 2013 in Addis Ababa. It consists of pharmaceutical manufacturers associations from the Southern, Eastern, and Western regions of Africa. These regional federations in turn are composed of national pharma manufacturers associations. FAPMA is committed to working with relevant stakeholders including private companies, policy makers and donors representing the African private sector voices with the aim of addressing some of the challenges hampering the development and growth of the pharmaceutical industry on the African continent. It envisions a vibrant and self-sustaining pharmaceutical manufacturing industry in Africa by providing quality and affordable medicines so as to contribute to the reduction of disease burden and promote economic development of the continent.

Mr. Mujuru urged policy makers to improve the business environment for manufacturing in Africa including through expanding markets, providing time-limited incentives and access to affordable capital. Currently the raw materials which in most cases are imported are liable to duty, whereas finished medical products are exempt, he lamented. Moreover, the issue of weak regulatory systems on the continent continue to give an impression that the quality of products from Africa cannot be relied on and can't access the donor-funded markets. He reported that with the increased efforts to strengthen and harmonize regulatory systems including GMP, a number of companies continue to invest in acquiring GMP and for some companies' acquiring WHO PQ for their products.

Furthermore since the collaboration between FAPMA and the Global Fund started a few years ago, a lot of progress has been made towards assisting African pharmaceutical manufacturers to work towards accessing the donor markets. A road map for procurement from African Manufacturers to the extent that compliant companies producing medicines for opportunistic infections will participate in GF procurement. This is expected to be expanded to include pandemic drugs. Other activities under the GF-FAPMA project include development and implementation of GMP Roadmaps to promote and accelerate the quality of medicines production in Africa.

3.2.2 *Thomas Cueni, Director General, International Pharmaceutical Manufacturers Associations (IFPMA*)

Mr. Thomas B. Cueni, Director General of IFPMA responded to the question paused by reiterating the need for strong medicines registration system in Africa and expressed their interest in being a part of the process of Achievement SDG 3 on health and target 17 which stresses the role of partnerships. She reported that according to WHO and UNICEF, more than 80% of reasons for shortages of vaccines are domestic. She also mentioned that Africa is becoming more attractive for local manufacturing. Therefore it is imperative that Africa engages in addressing the common challenges such as delays in decision making, non-transparency, duplication. She hailed the efforts that are being made to bring together experts from different countries as these would go a long way in reducing duplications and facilitating improvement of standards. She ended her remarks by announcing an initiative known as 'Access Accelerated' which IFPMA supported by the WB is undertaking. The initiative involves more than 20 biopharmaceutical companies and associations to help address the full spectrum of access barriers to NCD medicines in low-income and lower-middle income countries. '*The first African city benefitting from this programme is Kumasi – a town in Ghana'*, she said.

3.2.3 *Ms Pauline Irungu, PATH*

Ms Irungu highlighted what PATH has been doing to consolidate the voice of the civil society (CS) for the AMRH initiative. She said that while activists and advocates called for access to treatment they recognized the gap with regard to their role on the subject of medicines regulation. AMRH initiative was recognized a good entry point as African platform. Realizing that civil society was not well equipped to engage in this process, PATH undertook to build capacity of Civil Society Organizations (CSOs) starting with those based in Kenya and South Africa. The aim was to increase their understanding about medical products regulation and why regulation matters for access. The focus was on broad health as opposed to a disease or vertical programme.

Other areas of work that PATH reported having worked on are:

i) Translation of available documentation on medical products regulation in Africa into the language well understood by civil society. For instance a simplified version of the AU Model Law on medical products regulation was drafted in collaboration with NEPAD Agency and AUC.

ii) Helping civil society access areas they do not normally access, i.e. engage with academia; want to bring the voice of the African civil society to inform medicines regulation and harmonization. For example civil society is now involved in developing the research for health policy and Kenya medicines and food agency- CSOs are represented in the working group shaping these initiatives.

Therefore, '*We need to understand that civil society can be a critical partner to government and to regulators and we ask you to open space for civil society, make them understand and engage them to have their voice heard'* she said.

3.2.4 Theobald Owusu-Ansah, International Alliance of Patients' Organizations IAPO

On behalf of Mr. Theobald Owusu-Ansah, Mr. Richard expressed his gratitude to the NEPAD for engaging CSOs in such meetings as SCoMRA. The International Alliance of Patients' Organizations (IAPO) is a unique global alliance representing patients of all nations across all disease areas 'We are building the capacity of our members to reach out to patient organizations to help them better understand what AMRH is about'. He recalled the 'Entebbe statement' which was adopted to ensure patients are placed at the center of all decision making processes. He reiterated the commitment of IAPO to collaborate with NEPAD and other partners to ensure that African Medicines Agency (AMA) places patients are at the center of its operations and that patient and consumers provide their views in the harmonization process. In conclusion he urged the AU to consider creating a 'Patient and Consumer Working Party' just like it in the one that exists in EU to bridge the gap between manufacturers and patients.

Key take-away messages from the panelists

- Thomas Cueni, Director General IFPMA –... '*it is key that we bring expertise to the table, act as facilitators for capacity strengthening, ensure gender balance'*
- Mr. Emanuel Mujuru, Chair, FAPMA:'*Five (5) areas are critical to us: i) GMP upgrades to ensure that companies meet international GMP standards, ii) market access; iii) harmonization; iv) regulatory systems strengthening; iv) Engagement of and coordination with African pharma is key.*
- Ms Pauline Irungu, *Path: African patients are stakeholders in health sector, hence in AMRH. Power of the civil society to pave the way for change needs to be recognized and leveraged. SC has to be seen as a partner and it can help to accelerate the alignment process. SC can be a neutral convener to bring different stakeholders to a table*.
- Mr. Richard, IAPO-: "*No decision about me without me*". Decision making processes need to involve patients' and consumers organizations as early as possible.

4.0 Plenary Session I: Harmonization of Regulation of Medical Products in Africa, Where Are We?

Harmonization of medical product regulation in Africa was initiated with the aim to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional approach starting by harmonizing and streamlining technical requirements for product registration and eventually expanding the scope to other products categories and regulatory functions. The African Medicines Regulatory Harmonization (AMRH) was launched in 2009 to galvanize Regional Economic Communities' (RECs) efforts towards achieving regional harmonization. This session, therefore, aimed at reviewing the progress that has been made in regulatory systems strengthening and harmonization; and indicators for measuring impact at regional and continental levels. The session also reviewed opportunities, challenges and lessons learned with the aim of designing strategies for moving forward and sustaining the momentum that has been gained so far. The session was moderated by Mimi Darko, CEO of Ghana Food and Drug Authority.

4.1 AMRH Initiative: Continental Progress Update

An update on the progress of the AMRH initiative was presented by Ms. Chimwemwe Chamdimba, of NEPAD Agency. She provided a background on when the initiative started and that listed the frameworks within which the initiative is anchored namely: the 2005 AU decision 55 that requested for the Development of Pharmaceutical Manufacturing Plan for Africa (MPA) within the NEPAD Framework and subsequent endorsement by the assembly of the PMPA business plan in January 2012;The AU-Roadmap on shared responsibility and global solidary on AIDS, Tuberculosis and Malaria response in Africa; and the 2015 AU Executive Council Decision on AMRH to set the foundation for African Medicines Agency (AMA).

AMRH initiative has registered a number of achievements:

- ✓ Regional regulatory platforms have been set up, Harmonized technical requirements / guidelines, Joint regional dossier assessments, GMP inspections, Work sharing / pooling of resources, Streamlined decision-making processes and Reduced registration cycle time are some of the achievements. Others include but are not limited to:
- ✓ Developed the AU model law on medical products' regulations that has been domesticated by 8 countries used the model law and 5 are in the process of using it;
- ✓ Building of regulatory capacity through eleven (11) Regional Centers of Regulatory Excellence (RCOREs)
- ✓ A Monitoring and Evaluation framework for tracking progress has been developed and under discussion by a technical working group;
- ✓ Setting the foundation for the establishment of the AMA
- ✓ Adopting a new AMRH governance structure to reflect the expanded coverage beyond registration to other regulatory function areas and range of medical products;
- ✓ Establishment of the AMRH Partnership Platform supports activities under the different components of the AMRH governance framework.
- ✓ Alignment of Regulatory Systems Strengthening and Harmonization Efforts e.g.;

    - ➢ *Clinical Trials Oversight and Ethical Clearance:* African Vaccines regulatory Forum (AVAREF):
    - ➢ *Quality control and post market surveillance:* Network of Medicines Control Laboratories in Africa (NOMCoL-Africa) transformed into an African Medicines Quality Forum (AMQF)
    - ➢ *Medical devices & diagnostics:* Pan African Harmonization Working Party for medical devices and diagnostics (PAHWP)
    - ➢ *Pharmacovigilance:* Proposed Africa PV Advisory Group (APAG) to guide implementation of Continental Framework on PV
    - ➢ *Blood and Blood Products:* Forum for Blood Regulators in Africa

4.2 Progress on Regulatory Harmonization in EAC, Presented by Jane Mashingia, EAC Senior Health Officer

The EAC being the first REC to implement AMRH projects has made significant progress and has shared its lessons across other RECs on the continent. Ms Jane highlighted the following achievements:

- ✓ Six (6) NMRAs recognizing decisions made by others based on mutual recognition framework by end of year 2017.
- ✓ Rwanda and Burundi have plans to establish semi-autonomous NMRA;

- ✓ EAC Technical Cooperation Framework Agreement adopted by the 15th Ordinary Session of Permanent Secretaries awaiting approval by EAC Ministers of Health in March 2018
- ✓ In 2014 Rwanda enacted a Law to establish RFDA, Act 2014
- ✓ This year 2017 the United Republic of Tanzania (Zanzibar) enacted a Law to establish Zanzibar Food and Drug Authority;
- ✓ Burundi Drafted a bill to establish their national medicines regulatory authority known as 'Autorite Burundaise de la Regulation des Medicaments et des Aliments (ABReMA)
- ✓ EAC Medicines and Health Technologies Strategic Plan (2018-2022) adopted by Permanent Secretaries awaits approval by Ministers in March 2018

4.3 Progress on Regulatory Harmonization in SADC, presented by Mr. Joseph Mthetwa, Senior Program Officer

Mr. Mthetwa reported on key achievements related to strengthening regulatory systems and the harmonization process of the SADC region. Under the medicines regulatory harmonization project supported by the World Bank, SADC seeks to promote and protect public health by achieving rapid and sustainable access to safe, effective and affordable essential medicines of acceptable quality. Its goal is to increase access to quality, safe and effective medicines, vaccines, biologicals, and other health products in the Southern Africa Development Community by strengthening regulatory systems, increasing efficiency and enhancing transparency in the registration of these products. SADC is set to achieve the following objectives under its MRH project:

- ✓ To institutionalize use of medicine registration systems in SADC NMRAs;
- ✓ To strengthen and expand areas of technical cooperation among Member States NMRAs;
- ✓ To develop and implement a national and regional information management system (IMS) to facilitate decision making and sharing of knowledge among member states and stakeholders;
- ✓ To increase functionality and effectiveness in medicine regulation in SADC Member States;
- ✓ To facilitate capacity building of National Medicines Regulatory Agencies.

He enlisted some of the Phase I achievements under the World Bank supported Medicines Regulatory Harmonization Project

- ✓ Zazibona has now been adopted as an official SADC Initiative and South Africa and DRC have joined as active members.
- ✓ Implementation of SADC regulatory guidelines with technical assistance and guidance from WHO.
- ✓ So far the six member countries of the ZaZiBoNa initiative have jointly assessed more than 150 products and established an information-sharing platform supported by WHO.

- ✓ About 50 assessed products have already been registered and other registrations are imminent. Zazibona also represents a platform for training and regulatory networking.

He concluded his presentation by hailing the ZaZiBoNa initiative which he said could be used to expand collaboration to cover post-marketing quality control and pharmacovigilance.

4.4 Progress on Regulatory Harmonization in ECOWAS

Representing Ms. Sybil Nana Ossei Agyeman Yeboah from WAHO, the following were presented as main achievements of the medicines regulatory harmonization process in the ECOWAS region:

- ✓ Consensus Meeting between WAHO, UEMOA , Member States and Partners on the West African MRH;
- ✓ Establishment of a governance structure consisting of a Steering Committee & Experts Working Group;
- ✓ Development of Common Technical Document for MRH Harmonization
- ✓ Quality Management System (QMS) implementation for ISO 9001 and PICs ascension for 7 NMRAs conducted, roadmap implementation plan for each country developed; eight (8) more countries assessment to begin this October, 2017;
- ✓ SWEDD/ECOWAS MRH project supported by the World Bank underway to support Dossier evaluation, GMP and Inspection, Quality Management Systems, Information management Systems;
- ✓ A draft ECOWAS legislation and regulation in accordance with the AU Model Law on medical products regulation;
- ✓ Two WHO NRA Assisted Self-Benchmarking of ECOWAS MS Workshops
- ✓ Designing a strategic Direction to Strengthen Pharmacovigilance;
- ✓ Increased Status of Quality Control Laboratories (QCLs) with fifteen (15) QCLs in ECOWAS including Chad and Mauritania joining the Networks of Official Medicines Control Laboratories (NOMCoL) to ensure standards and international accreditation;
- ✓ Demonstrated efforts in the fight against counterfeit and illicit trade in medicine by drafting of the Legal Directive for Counterfeit and Illicit Trade in Medicines and adopted it since 2014;
- ✓ Four (4) companies within the region are WHO Good Manufacturing Practices GMP compliant;
- ✓ A Good Manufacturing Practices (GMP) Roadmap Initiative supported by WHO and UNIDO was launched and has led to progressive transformation of the West African Pharmaceutical Manufacturers Association (WAPMA).

The presenter shared the following as future perspectives:

ECOWAS is envisaging the creation of a centralized procedure that would allow marketing of medicines on the basis of a single West Africa-wide assessment and marketing authorization which is valid throughout the region.

The above is expected to be achieved through:

- ✓ Application of common technical documents and guidelines;
- ✓ Utilization of common legislation and regulation;
- ✓ Common safety monitoring of medicines circulating on the regional market;
- ✓ Common database of information on clinical trials, pharmacovigilance, and tracking of counterfeit and substandard medicines
- ✓ And a unified procurement, distribution and supply chain of medicines

4.5 Progress on Regulatory Harmonization, IGAD

The progress of the harmonization project in the IGAD region was presented by Mr. Anthony Toroitich *Consultant, IGAD Medicines Regulatory Harmonization.* He said that the objective of the 5 year IGAD MRH project was to increase access and provision of quality assured, effective and safe medicines through a harmonized regulatory system. Specifically the projects aims to:

- ✓ Achieve *Minimum maturity level III by at least three NMRAs and maturity II for the remaining NMRAs based on the WHO Global Benchmarking Tool Indicators in Regulatory System (RS), Marketing Authorisation (MA), Regulatory Inspection (RI), Post Market Surveillance and Pharmacovigilance. In addition to strengthening of Quality Management Systems (QMS) and Information Management Systems (IMS);*
- ✓ Develop and implement harmonized technical and operational guidelines for regulation of medicines.
- ✓ Collaborate and implement convergence of activities through communication, information and work sharing in the IGAD region.
- ✓ Build capacity of national pharmaceutical industries in the region for regulatory compliance.

He reported the following achievements:

- ✓ WHO/IGAD Rapid Benchmarking of Six IGAD-NMRAs (Djibouti and Eritrea not done)
- ✓ IGAD-MRH Initiative Proposal Development and Approval: April - August 2017 (World Bank and WHO)
- ✓ Establishment of Regional Expert and Project Steering Committee
- ✓ IGAD Regional Proposal endorsed by member states
- ✓ Donor Sensitization meeting August 2017
- ✓ Launch the IGAD MRH initiative
- ✓ Implementation of IGAD-MRH activities by NMRAs

4.6 Progress on Regulatory Harmonization in CEMAC

In line with the implementation of the regulatory system harmonisation initiative in the CEMAC region, Member States committed to elaborate, adopt and implement common technical guidelines. The region has established a technical commitee on harmonisation in each member. These efforts will create conducive environment for joint reviews and joint inspections with ultimate goal of mutual recognition. He acknowledged that the process of harmonisation of medicines regulatory systems will take long but that it was worth the undertaking and that the region is optimistic. He thanked all the Partners in particular EU, NEPAD and WHO for the technical and financial support.

4.7 'AMRH'; Are we making progress?

Mr. David Mukanga, BMGF presented a summary of the achievements of all MRH projects supported by the BMGF. '*The program set out to accelerate access to essential/lifesaving commodities in LMICs through regulatory systems optimization through 50% reduction in registration timelines against 2012 baseline'*, he said. The priority areas were to focus on value added activities through; improving manufacturer inputs and/or regulatory processes and decreasing complexity.

He then outlined the achievements and expected outcomes by end 2018 at continental level (AMRH), Regional level (EAC, ECOWAS and SADC) and finally mentioned the outcomes of the AVAREF clinical trial reviews as follows:

4.7.1 AMRH (at continental level)

- ✓ EAC joint assessment process has taken 9.8 months on average to recommend a product. First 4 products took < 4 months
- ✓ IGAD NMRA benchmarking completed, web-portal developed, exploring joint assessments
- ✓ EAC PV plan developed
- ✓ Endorsed a 60-day CTA approval timeline
- ✓ Times reported 12 countries
- ✓ Framework for R&D in emergencies in development starting with table top exercise
- ✓ 13 countries have/or in process of domestication of AU Model law

4.7.2 EAC

- ✓ 100% of applications submitted to most EAC NMRAs are done using the CTD format since 2015
- ✓ CTD, common guidelines and SOPs for registration of medicines defined and in use in all member countries since 2015;
- ✓ The set objective to have at least 75 medicines registered per NMRA under the common CTD by TFDA, NDA and PPB was far exceeded

- ✓ For the set target of At least 50 medicines registered per NMRA under the common CTD by ZFDB, Burundi and Rwanda; ZFDA has registered 42, and Burundi has registered 10.
- ✓ Out of 49 applications received 7 medicines approved at national level using the joint assessment
- ✓ Online application only available in Kenya
- ✓ For the target set to have at least 80% of medical products submitted to EAC NMRAs are registered within 6 months, has not yet been attained.

4.7.3 ECOWAS

- ✓ A Benchmarking of 1st six countries has been completed;
- ✓ A Mock dossier assessment using agreed CTD will be conducted in the last quarter of 2018
- ✓ By the second quarter of 2018, the 1st Joint dossier assessment is expected to take place.

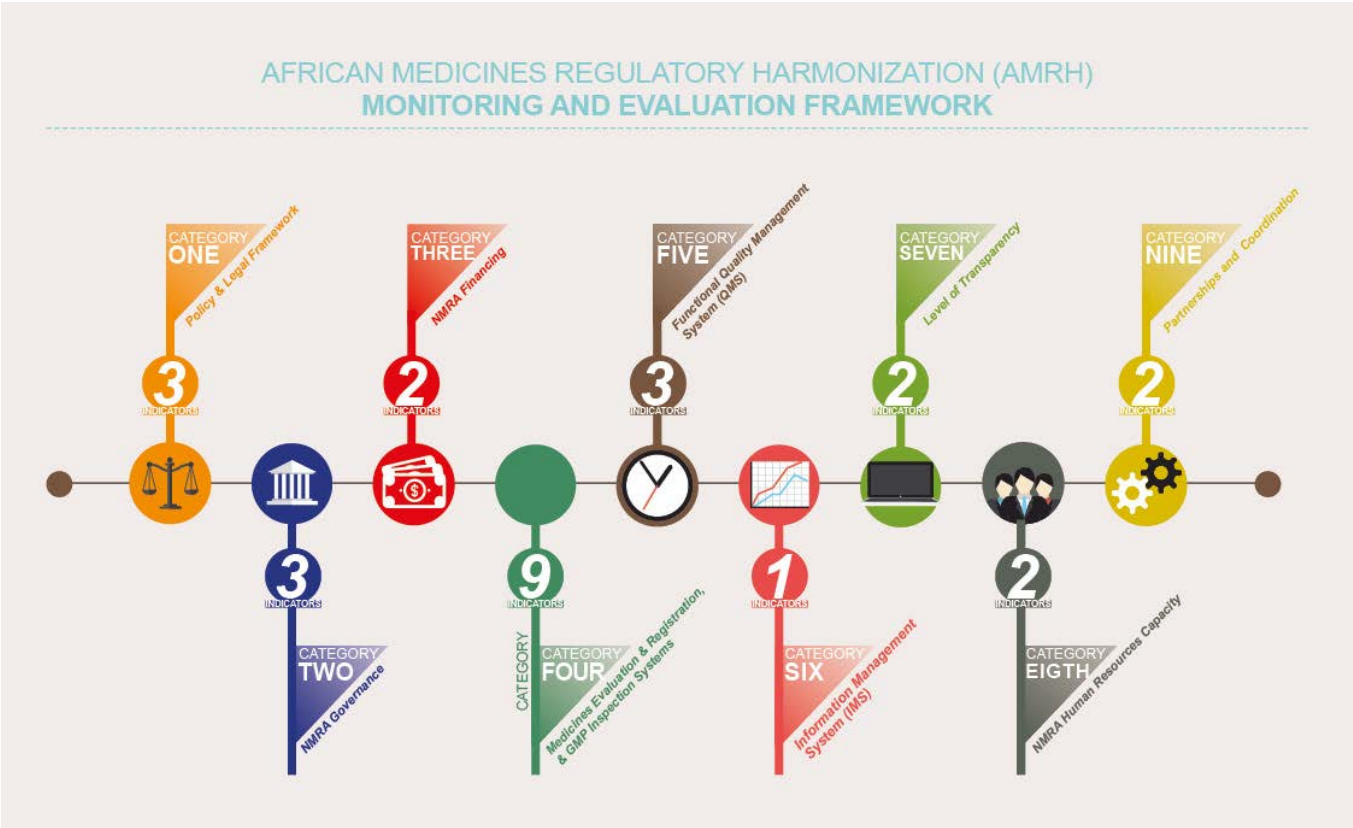
4.7.4 SADC

- ✓ Under the ZAZIBONA initiative, 193 products have been evaluated with final joint recommendation for 123 products
- ✓ The presented expressed the need to capture regional recommendation to national registration data.

4.7.5 AVAREF

- ✓ Currently parallel submissions are made to NRAs and to Ethics Committees;
- ✓ Average decision timelines have reduced from 160 days in 2016 to 140days in 2017;
- ✓ AVAREF target is to reduce decision timeline to 60 days;
- ✓ In 2016, 50% of Clinical Trial Applications were in South Africa and in the same year only South Africa out of the fourteen (14) reporting countries submitted applications;
- ✓ In 2017 three countries namely Ghana, Tanzania and Zimbabwe submitted applications.

4.8 Results Oriented Monitoring of Medicines Regulatory Systems and Harmonization Initiatives in Africa



The session comprised of two presentations followed by the questions and answers slot from the floor. The first presentation provided an account of the African Medicines Regulatory Harmonization Monitoring and Evaluation (AMRH M&E) mechanisms for the harmonization initiatives. The presenter remarked that without data you can't tell a comprehensive or compelling story. The overall aim of the AMRH M&E is to systematically track progress to assist partners to get a sense of achievements. Furthermore, the aim of AMRH M&E is establish whether there is alignment between the goals that has been set and the actual work that is being done. Progress to date includes the development of the AMRH M&E's guideline that was piloted in the East African Community (EAC). Secondly, a Technical Working Group (TWG) has been set up to agree terms with respect to the modalities of implementation and the work plan. The TWG comprise of national, regional and continental role players. Additionally, there are representatives of the World Health Organization (WHO), as well as experts on medicine registrations. The first meeting of the AMRH M&E's TWG he announced was to take place on 30 November 2017 in Accra, Ghana. Annual reports on the AMRH M&E will be generated going forward starting with the EAC.

4.9 Experience in aligning global submissions with regulatory reviews across mature and Developing NMRAs

A Non-Governmental Organization (NGO), CIRS that comprise of various stakeholders involved in improving patient's access to medicines using Regulatory Sciences appraised the meeting of the various approaches to the registration of medicines, facilitated regulatory pathways (FRPs). Two types of FRPs were discussed during the session. Primary FRPs entails the first review of the product by mature regulatory agencies such as the United States Food and Drug Administration (US FDA). Secondary FRPs involve regional initiatives that relies on the primary reviews with a view to make an effective use of scarce resources. Secondary FRPs lends credence to the work of the primary FRPs with minor adaptions where necessary to allow the regulatory authorities to maintain their sovereignty without duplication of efforts. Secondary FRPs involves Risk Stratification where the risks are balanced out against the benefits.

4.10 Sustaining the momentum: Recognising the role of civil society in strengthening regulatory systems in Africa[1]

During the session discussions, there was consensus that there is a great opportunity for CSOs to revitalize their working relationship with AU organs and institutions as well as the regional economic communities (RECs). The roles CSOs play in promoting the domestication of AU Model Law on medical products regulation (AU Model Law) provides a justification for their essential recognition nationally and regionally as important stakeholders in promoting and sustaining momentum for regulatory harmonization. Additionally, CSOs need to be capacity built on AU Model Law for them to effectively participate in drafting and reviewing of various national regulatory policies that require inclusion of AU Model Law recommendations. Generally, capacity building will greatly increase the capability of CSOs in addressing identified gaps in policy, legal, and regulatory reforms in the continent

It was acknowledged that a lot of strides have been made with regards to strengthening medical products regulation including through the domestication by Member States of the AU Model law. For instance Francophone countries in West Africa, encouraged by regional (UEMOA), continental (African Union) and international (WHO) are considering transforming the directorates of Pharmacy and Medicine, attached to the ministries of health, into autonomous drug agencies. In this perspective, the AU Model Law has emerged as an essential tool for assisting the process. Côte d'Ivoire reported having used the AU model law to reform the architecture of the Ivorian Authority for Pharmaceutical Regulation (AIRP), adopted by the government and supposed to regulate the pharmaceutical regulation in the country.

[1] **Presenters:** Pauline Irungu, PATH; Daniel Molokele, SAHTAC; Janet Byaruhanga, NEPAD; Richard Nii Yemoh Laryea, IAPO; Samia Saad, Bill & Melinda Gates Foundation

For such reforms to be accelerated and the continents vision for stronger more robust regulatory systems achieved, CSOs remain a critical should ally in driving this agenda. It is of importance to note that already there are platforms that are active in advocating for medicines regulation and harmonization on behalf the communities e.g. SAHTAC (South African Health Technologies Advocacy Coalition) and CoHRED (Coalition for Health Research and Development) in Kenya.

CSOs have key role to play in advocating for access to medicine and political support at country level. Their role in pushing for the adoption, approval, implementation and monitoring of harmonization directives on behalf of communities at country and regional level cannot be over emphasized as really important hence the motto “No decision about me without me”. CSOs invitation and involvement in medicines regulatory harmonization work is essential and their representation in key continental, regional, and national forum is vital as they play a representative role in promoting regulatory systems strengthening, accountability and interpreting key scientific information and recommendations to the larger nonscientific community.

CSOs can also participate in advocating for other new innovative ways of raising fees and funds for their National regulatory Agencies. Building sustainable cooperation and partnership between civil society groups, governments, RECs and NRAs is key in promoting regulatory harmonization. The session acknowledged that there is need for continued partnerships among RECs, NRAs and CSOs as this will promote collaboration and sharing of information. This will also promote mutual recognition among countries in different regions.

Various partners and stakeholders from multiple sectors were represented at the Scientific Conference

Partnerships for Regulatory Harmonization

This session aimed at learning from other regulatory harmonization and collaborative efforts within the African continent and beyond. Focus was made on regional efforts beyond Africa such as the WHO driven collaborative efforts. The session utilized these efforts and recommend how they can be adapted to contribute to the success of harmonization in Africa. In addition to learning from other regulatory harmonization and collaborative efforts, the session also looked at strategies for fostering collective impact

and mutual accountability through partnerships for regulatory systems strengthening and harmonization. The session finally considered product Life Cycle Management (LCM as it relates to regulatory systems and processes.

5.1 Marketing Authorization for Global Health Products (MAGHP)

Presented by Ms. Cordula Landgraf, Head of Networking, Swiss medic, Swiss Agency for Therapeutic Products. She started her presentation by emphasizing the advantage of involving of NMRAs as opposed to telling or teaching them is that they get to understand the process. Ms. Landgraf described the 330-days process undertaken to authorize markets for global health products under the MAGHP which involves NMRAS in all six stages namely prior notification90-180days), validation (30days), evaluation phase 1(120 days), evaluation phase 2(90days), labeling (90 days) and affirmation (90days). She reported that some NMRAs from African countries have been considered by applicants to participate actively or passively in MAGHP process during which experience will be gathered and process improved.

5.2 Medicines Regulation in Africa- Current state and future opportunities[2]

This paper revealed that the regulatory landscape in Africa has changed. Apart from the Sahrawi Republic, every country in Africa currently has a NMRA; albeit variations in functionalities and different levels of growth, maturity and expertise. At least 35 African countries (64%) are members of PIDM with South Africa, Morocco, Nigeria, Egypt and Kenya classified as the main ICSR reporting countries. Thirty-four counties in SSA (72%) have quality-control laboratories with different levels of development, and 21 of these (63%) are engaged in market surveillance.

There is need to benchmark African NMRAs in a more transparent and objective manner, based on agreed criteria, to identify the different levels of capacities and performance. Outcome of the benchmarking process should be used to support the ongoing harmonization efforts and facilitate capacity building among the agencies including twinning arrangements and sharing of best practices.

5.3 Protecting and promoting public health is a shared responsibility, where to for Africa? Lessons from WHO Collaborative registration procedure

Mr. Luther Gwaza reiterated the current national-centric set up as being consistently unable to deliver the desired outcomes due to resource and regulatory capacity constraints. For instance he reported that most NMRAs in Africa do not:

- ✓ Carry out inspection of API manufacturers;
- ✓ Routinely review the full DMF for APIs;
- ✓ Inspection of CROs performing BE studies; and
- ✓ Capacity to regulate complex therapies.

[2] Margareth Ndomondo-Sigonda, Jacqueline Miot, Shan Naidoo, Alexander Dodoo, Eliangiringa Kaale Open Access Publication, Pharmaceutical Medicines Journal, 03 November 2017

Current CRP Status by Product Stream (medicines, vaccines, in vitro, vector control products)

Participating NMRAs – 24/31 Africa. As at 19 September 2017, Africa accounts for 75% of total registrations (257) Media time to registration – 90 days. In 2013, when Zazibona collaborative registration started, implementation of BE standards was almost non-existing in nearly all of the participating countries, yet 4 years of collaboration has resulted in this being a routine requirement in those participating countries.

5.4 A review of the SADC Medicines registration collaboration (Zazibona) from 2013 to 2016[3]

There are eleven(11) participating SADC Member States namely: Botswana; Democratic Republic of Congo; Namibia; South Africa; Zambia; Zimbabwe; Mozambique; Angola, Seychelles, Malawi, and Swaziland. The approach used is such that one primary assessment is conducted for five (5) countries to produce one (1) consolidated report.

The study revealed that:

- ✓ 12% of the finalized products were withdrawn;
- ✓ The relatively high withdraws could point to applicants not being familiar with the requirements;
- ✓ 29% rejection rate points to a need for increased stakeholder engagement
- ✓ The Median time is about 8 months to finalization (approximately 240 days)

It was recommended that:

- ✓ Stakeholder engagements should be increased;
- ✓ New applicants should familiarise with relevant guidelines;
- ✓ Zazibona should continue to learn from other established initiatives

5.5 Role of Regulatory harmonization and collaboration in accelerating patient access to medicines-Industry experience with EAC Joint Assessment (JA) procedure

The following were presented as the procedural highlights;

- ✓ Timelines for new product registration were significantly shorter in the EAC JA procedure compared to the individual National Procedures (NP) with the EAC JA Procedure taking between 7-12 months while the NP took 13-24 months;
- ✓ All companies that submitted dossiers for registration evaluation received queries;

3

Farai B. Masekela (Presenter), Prof S. Byrn, Prof K. Clase, Dr P. Shivanand

- ✓ The time taken to receive the Assessment report from the EAC JA team varied between three (3) weeks to six (6)months from initial submission;
- ✓ Acceptance letter confirming approval of the dossier was received within 3 to 10 months;

The study concluded that:

- ✓ Collaboration among regulators and work sharing is highly appreciated, should be a model for other regions in Africa (and beyond). However, harmonization is work in progress and additional harmonized procedures and guidelines are needed for specific topics (e.g. LCM & PAC, PV, certain product categories, e.g. bio therapeutics)
- ✓ Single application for several countries (dossiers prepared only once), and single set of queries (Q&A correspondence harmonized and simplified) could result in significant saving in resources for documentation preparation compared to eventual national procedures;
- ✓ It is recommended to have "a one-stop-shop" for dossier submission, payments, etc. (instead of going to individual NMRAs);
- ✓ It should be *joint assessment* and therefore NMRAs are encouraged to build confidence among themselves and allow for reliance on reviews done by rapporteur/co-rapporteur NMRA;
- ✓ Although the timelines were significantly shorter than with NP, they were still not always in line with regulations;
- ✓ Clarification and improvement of the administrative process is needed (e.g. issuance of approval letters), as well as following procedural steps (e.g. meetings being scheduled and/or cancelled last minute);
- ✓ Clarification of the role of EAC, NMRAs, SRAs and
- ✓ Communication with the applicant should be improved.

The following were suggested as potential future considerations:

- ✓ A 'holistic' approach to regulation of medicines including vaccines, bio therapeutics (e.g. PV, PMS, PACs, CTs…);
- ✓ Transition from national to EAC licenses and procedures;
- ✓ Binding commitments from NMRAs to EAC activities;
- ✓ Adoption of WHO/other international guidelines and standards, but with local considerations - always put in the local context and assess what are the important issues for your healthcare system (e.g. capacities, IP protection).

5.6 Life cycle Management (LCM) variations[4]

LCM is when systematic collection of information on Product Safety, Product Quality based on risk factors is done for the purpose of analysis, planning, control and evaluation of marketed products. Lack of effective PMS represents a public health threat. The study revealed that up to 30% of medicines in developing countries are counterfeit; 36% of anti-malarial drugs in Southeast Asia are falsified; and 10% of the world medicines are counterfeit. Data helps increase awareness formedicines quality agenda, and has served as an effective tool for advocacy.

Recommendations

- Regulatory agencies should have legal mandate with the appropriate scope to perform PMS as a regulatory function;
- Agencies should put in place sound PMS governance structure, which is independent, accountable, transparent, responsive, and equitable. Should be guided by procedures;
- Financial resources and budget should be allocated to implement effective PMS program;
- Recruit/utilize personnel with requisite training and expertise to undertake PMS activities;
- NRA should plan and coordinate PMS activities with relevant stakeholders, and develop an implementation plan with clearly defined roles and responsibilities;
- PMS guidance, lessons, and results should be communicated within the NRA units (assessment, inspections, enforcement), and with relevant stakeholders and countries as appropriate.

6.0 Plenary Session III: Expanding the Scope for Regulatory Harmonization in Africa & Sustaining the Momentum after 10 Years of Harmonization Efforts – Opportunities & Challenges

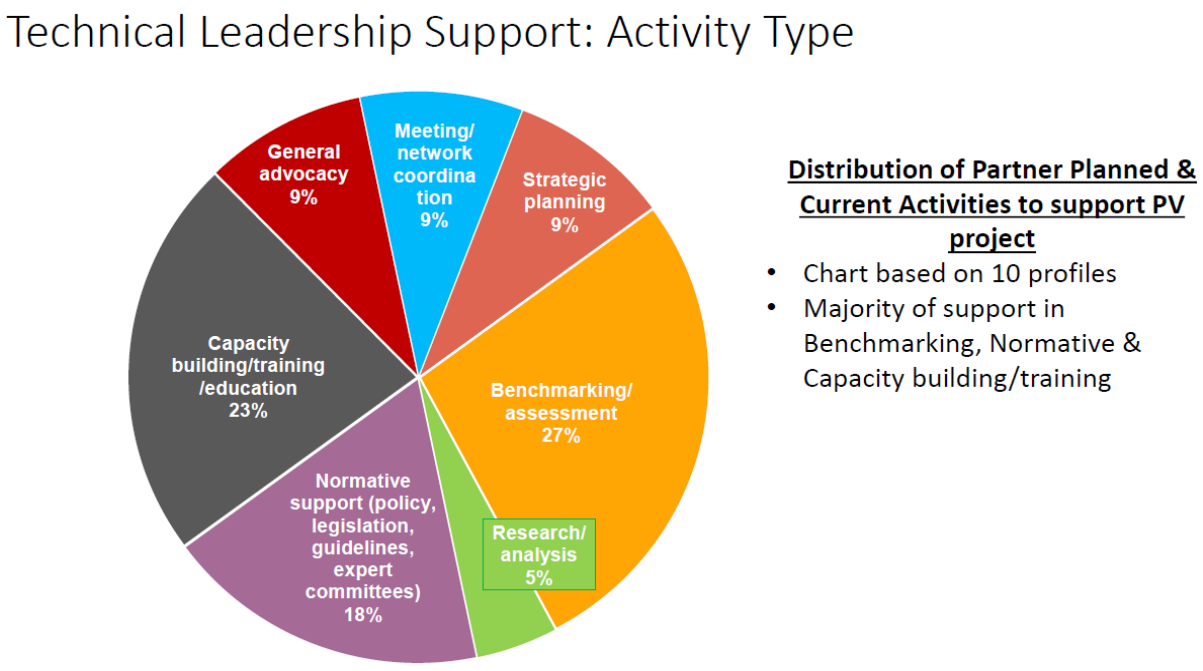
The initial focus on regulatory harmonization was on registration of generic medicines with the view to expand to other product ranges such as biologicals and vaccines and regulatory functions such as clinical trials oversight, pharmacovigilance and quality assurance/quality control amongst others. The primary focus on registration was meant to facilitate learning before expanding to other regulatory functions and other regulated products. This session therefore looked at the lessons that have been learned so far with the view to identify gaps, propose strategies to address them and discuss modalities for expansion to other products and regulatory functions while ensuring alignment. Thus the session provided direction on alignment of partners supporting regulatory systems strengthening and harmonization efforts and recommend actions to be undertaken at the national, regional and continental levels.

[4] Abdul-Karim Smine and Farouk Adams Umaru

6.1 The Coalition of Interested Parties (CIP)

The idea to establish a “Coalition of Interested Partners” or CIP framework to achieve better coordination, efficiency and outcomes in regulatory strengthening activities in the same target Member States (MS) or regions to achieve better public health outcomes. The CIP value proposition is that it provides for: More effective use of overall resources; Better outcomes and impact through coordinated action at regional/country level; Wealth of expertise available across the member organizations; Greater capacity and sustainability; Sharing and adoption of best practices; Branding and Potential for joint products.

A mapping of regulatory systems strengthening (RSS) support across the globe and although based on 10 CIP profiles it indicates that majority of support is in three categories: i) Benchmarking, ii) Normative e.g. policy, legislation, and guidelines iii) Capacity building and training.



6.2 The AMRH Partnership Platform (AMRH-PP)

The mandate to establish APP is drawn from AU PMPA Technical Committee meeting held in 28-29 November 2015. It was further noted by stakeholders of the AMRH that different institutions are currently working at the national, regional & continental, level supporting different aspects of the medicines regulation and harmonisation agenda. Although these efforts are seen as a positive step, the minimal effort for collaboration and coordination of the actions by different actors has led to duplication of effort; competition for resources and regulators time, lack of clarity on the steps and approaches to be followed by the Member States and RECs; and inefficient use of scarce resources.

The AMRH-PP aims to; increase collaboration among stakeholders supporting regulatory systems development in Africa; foster mutual responsibility, accountability and shared impact; and ultimately minimize duplication and coordinate efforts at all levels of implementation

It's expected that before the end of May 2018: the Framework document will be finalised; an electronic platform will be created and launched; the first Call for Expression of Interest made and the First Meeting of the AMRH-PP held.

6.3 The role of the Network of Official Medicines Control Laboratories (NoMCoL) – Africa in strengthening regulatory capacity in Africa (USP)

Quality Control Laboratories are crucial components of a comprehensive response to poor quality medicines. QC Laboratories can face a myriad of challenges in their operations to combat Poor Quality Medicines. USP-Global Public Health established networks of official medicines control laboratories across the globe including in Sub-Saharan Africa (SSA). They serve as a platform for knowledge sharing, south-south collaboration and for sharing best practices across the regions; Since its establishment more than five (5) years ago, NOMCoL has transformed regional laboratory capacity of thirty five (35) of participating member labs, trained over one hundred and fifty (150) staff, provided over $1M worth of Reference standards and convened approximately twelve (12) annual Meetings. NOMCoL provides tailored support to each region with its three (3) key programs to i) Train, ii) Evaluate & advice; and iii) Connect.

At a meeting to align the activities of NOMCoL-Africa with NEPAD-AMRH QC RCOREs and WAHO programs to support OMCoLs in the ECOWAS region, it was decided that NOMCoL-Africa be transformed to AMQF.The ultimate goal is to expand the focus and align with the AU, NEPAD-AMRH harmonization and medical products regulation initiatives. Therefore currently NOMCoL-Africa is working with NEPAD under the AMRH Programme on its transformation into African Medicines Quality Forum (AMQF). The AMQF will focus on: advocacy and communication; lab. Capacity building; Proficiency testing; QC analyst & lab certification scheme; Bioanalytical studies for BE studies; and Regional post marketing surveillance.

6.4 The African Vaccine Regulatory Forum efforts in Strengthening Capacity for clinical trials oversight and ethics clearance" by Diadié Maïga

Health is a fundamental right and access to medical products remains a centerpiece. To ensure access to products and to meet regional health priorities, product development will have to improve and the current slow pace of introduction of new products and poor access in Africa dealt with. Regulators and ethics committees have an important role to play in offering independent decisions which ensure this right to access is to products which meet quality, safety and efficacy requirements. Recognition of the challenges confronting ethics and regulatory authorities and the need to utilize a network approach to strengthening ethics and regulatory oversight of clinical trials as well as to improve harmonization of practices in support of product development and regulation of clinical trials; led to the establishment of AVAREF in 2006. The work of AVAREF is based on strengthening capacity through reliance and cooperation, while recognizing national ownership, leadership and transparency. AVAREF has since played a crucial role in the successful development of several vaccines, including the first vaccine developed in Africa for Africa.

Over the years AVAREF has played an unappalled role in addressing the needs of countries in clinical trial oversight, while evolving from an initial informal network to a formal one and later to a new AVAREF, with a renewed governance structure and modelled on the Regional Economic Communities (RECs) concept of the African Medicines Regulatory Harmonization (AMRH).

The new governance structure comprises a Steering Committee, a Technical Coordinating Committee, with Working Groups and an Assembly. As the strategic and policy decision-making body, the Steering Committee (SC) will develop through its Technical Coordinating Committee (TCC) and Working Groups, the key guidelines and documents required by AVAREF, review them and present them to the Assembly for endorsement and domestication.

AVAREF capacity building efforts have covered, among others, the following activities: Guidelines and templates for CTAs, reviews and Inspections; Joint review of clinical trials; Joint inspection of clinical trial; Expedited review procedure for registration of vaccines; Regulatory strategy development; Linkages with other programs and initiatives of WHO: GACVS and partner organizations; Inter and intra country collaboration; Proposal for development program; Training; Technical support and Table top exercise.

In conclusion, AVAREF has served as vectors of cooperation and harmonization mechanisms and procedures between countries, National Regulatory Authorities and Ethics Committees. Its activities have contributed to strengthen capacity of NRAs and ECs, regulation clinical trials, their approval and registration.

6.5 Pan African Harmonization Working Party (PAHWP) efforts for medical devices and diagnostics capacity strengthening

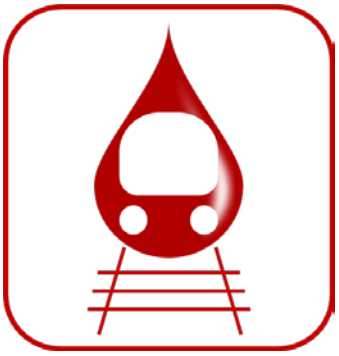
The Mission of PAHWP is to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa. This organization has been involved in various capacity strengthening efforts across the continent since 2013 to date. Training on various topics facilitated by a number of platform/institutions including: The African Regulatory Forum for Medical Diagnostics, Annecy, France LSHTM and Fondation Mérieux; US FDA, South African Medical Device Industry Association, WHO, PEPFAR, & TFDA among others has been conducted and benefitted many. PAHWP also provides a source of training materials and reference websites for learning purposes (www.pahwp.org). Currently PAHWP is working towards its transformation into a TWG of the AMRH Steering Committee to advance regulatory systems strengthening and harmonization.

6.6 Paul Ehrlich Institute (PEI)-Blood and Blood Products efforts to strengthen regulatory capacity in Africa

PEI Blood Train promotes the availability, safety, and quality of blood and blood products through supporting the development of a regulatory structure and its adaptation to crises in the partner countries.

PEI supports WHO in a number of areas including:

- ✓ Development of globally harmonized written and physical standards to advance development, authorization and use of safe and efficacious blood products, IVDs and vaccines;
- ✓ Assistance in implementing WHO guidelines into regulatory practice (e.g. workshops);
- ✓ Provision of technical assistance and scientific advice to reach global consensus on emerging issues;
- ✓ Support to the WHO pre-qualification program, to facilitate the access to safe and efficacious products for low and middle income countries.



PEI Vac-Train on the other hand provides regulatory training and advice in the area of vaccines and biomedical therapeutic products. PEI is currently creating a working relation with the NEPAD Agency on the AMRH program particularly to support the establishment of Forum for Blood Regulators in Africa (NEPAD-AMRH technical working group on Blood and Blood Products).

6.7 Emerging Health Technologies: A Case for Malaria Eradication

The global community especially Africa is burdened with diseases that are elusive to current interventions of disease management e.g. more than 2.5 billion people in over 100 countries are at risk of contracting dengue alone. Malaria causes more than 400 000 deaths every year globally, most of them children under 5 years of age. Other diseases such as Chagas disease and emerging diseases like Leishmaniasis, Rift Valley Fever, Oropuche virus, Mayaro (Trinidad 1954), Elizabethkingia and schistosomiasis that affect hundreds of millions of people worldwide are adding onto the burden.

Some of the hitherto effective interventions are facing resistance from diseases and vectors as well as problems of access and an increasing cost of sustaining the achievements so far. There are therefore calls from bodies such as the World Health Organization (WHO) and the African Union for new and innovative solutions to this threat to humanity. There are a plethora of emerging technologies some of which could be harnessed to fight and reduce the global disease burden and that of Africa in particular. Even though these technologies may have an impact on health, health regulators may not be familiar with them. The health sector may not have all the expertise required to regulate some emerging technologies. The novelty of these technologies would require a paradigm shift in the way health regulators usually operate. Health regulators and ethics committees must be open-minded and be ready to collaborate with other sectors and among themselves. An example is the potential use of gene drive technology as a complimentary tool to existing tools to eradicate Malaria in Africa. Agencies under health, environment and agriculture will have to work together to ensure a proper regulation of the technology.

6.8 The African Medicines Agency (AMA)

In 2014 in Luanda, Angola at meeting of African Health Ministers jointly organized by the African Union Commission and the WHO, the Ministers endorsed a set of milestones towards the establishment of the African Medicines Agency. They committed to:

- ✓ Prioritize investment for regulatory capacity development;
- ✓ Pursue the efforts towards convergence and harmonization of medical products regulation in RECs and
- ✓ Allocate adequate resources for AMA.

In 2016 The Executive council Decision made endorsed the milestones and requested the AUC and NEPAD in collaboration with WHO and relevant partners to work out the modalities of the AMA building on the AMRH as a foundation. The AMA will be established by treaty as a specialized technical Agency of the AU with the aim to improve access to quality, safe and efficacious medical products on the continent through:

- ✓ Coordination and strengthening of ongoing initiatives to harmonize medicines regulation, promote cooperation and mutual recognition of regulatory decisions;
- ✓ Carrying out regulatory oversight of selected medical products and providing technical guidance to Member States and RECs;
- ✓ Pooling expertise and capacities and strengthening networking for optimal use of the limited resources available.

In every strategic aim, objective or activity, the AMA will demonstrate how its initiative adds value to the medical products regulatory activities of States Parties and other partners. The remaining steps in the implementation of the milestones towards the launch of AMA in 2018/2019 were listed as follows:

- ✓ Ministers of consultations on the draft treaty for the establishment of AMA due to take place in May in 2018;
- ✓ Consideration of the draft Treaty for by the AU Specialized Technical Committee (STC) on Legal and Justice Affairs in 2018;
- ✓ Launch of AMA through a Decision/Endorsement by the Assembly of Heads of State and Governments.
- ✓ It is only when AMA has been launched by the Assembly of Heads of State and Government that the governing board, selection of host country and operationalization of its institutional framework would commence.

7.0 Plenary Session IV: Shaping the Future of Medical Products Regulation in Africa

This session builds a case for the future of regulatory systems strengthening and harmonization in Africa, building on global efforts in capacity building. It provided direction on key topics for regulators including developments in capacity building, rule of law, and medicine information and comparator products for bioequivalence studies.

7.1 Systematic capacity building through a global competence framework for regulators (WHO-Luther Gwaza)

Significant Progress has been made in harmonization, joint activities, and information and work sharing stream of work. Therefore having an internationally accepted set of competences will maximize the benefits of collaboration and cooperation in medical product regulation. WHO has established a well-recognized process for benchmarking and strengthening regulatory systems. The current approach in regulatory capacity development must include a common global competence framework if desired public health outcomes are to be achieved. As part of regulatory systems strengthening, the WHO is working with partners to develop a global competency framework and global curricula to support training and professional development of regulatory staff. The existing basic framework will be updated to:

- ✓ Includes the range of functions as defined in the global benchmarking tool (GBT)
- ✓ Account for the maturity levels of regulatory authorities and good regulatory practices and
- ✓ Ensure flexibility and adaptability by different users at different levels.

A globally accepted competence framework that is adaptable is essential to ensure standardized training approach and systematic development of competent regulatory professionals.

7.2 Conformity of package inserts (PIs) information to key medicines information parameters among selected innovator and generic essential medicines circulating on the East African Community (EAC) market (TFDA)[5]

A study on the Conformity of package inserts to key medicines information parameters among selected innovator and generic medicinal products circulating on the East African Market**.** The study revealed absence of much needed critical product information in essential medicinal products circulating in EAC Partner States. NMRAs in the EAC Partner States should enhance enforcement on ensuring adherence by the manufacturers on product information requirements prior to and after marketing authorization to ensure safe and appropriate use of medicines by patients.

[5] **Hiiti B. Sillo, Nelson Masota, Sunday Kisoma, Lembit Rago, Eliangiringa Kaale**

7.3 Rule of Law: A new frontier in medicines regulatory strengthening and harmonization (Fozley & Associates)

"Law" means any type of legal instrument, including parliament acts, regulations, orders and related regulatory instruments of SOPS, guidelines, forms and applications and others, depending on the country system. Good regulatory practices inform, draft, implement and operationalize law. Ms Fozley emphasized the need to for full implementation of the regulatory system which involves three things:

- ✓ Rule and standard-setting
- ✓ Gate-keeping procedures and
- ✓ Enforcement

7.4 Strengthening Medicine Regulatory System by Implementing Electronic Medicine Registration Data Management System (Pharmadex) in Mozambique

Mozambique like many countries in sub-Saharan Africa experience shortage of quality essential medicines exacerbated by the time it takes for medicine importers and distributors to get authorization for importing and selling medicines. The longest wait times are for antiretroviral, antimalarial, and new molecule medicines that require more complex documentation, such as World Health Organization (WHO) prequalification. To help close these gaps, Mozambique department of pharmacy with support of SIAPS developed PharmaDex - a web-based integrated solution that streamlines management, dissemination, and sharing of regulatory information around i) Registration ii) Inspection & iii) post market surveillance.

Three important benefits of PharmaDex have been: i) Effective communication ii) Good Review Practice & iii) Transparency and Accountability. Moving forward the ministry of health pharmaceutical department intends to stabilize and expand the model.

8.0 Workshops

8.1 Parallel Session I. Investing in Africa's Pharmaceutical Industry: The role of regulation

The African Union, through the adoption of the Pharmaceutical Manufacturing Plan for Africa demonstrated the commitment to improving local production of pharmaceuticals. To this end, a number of activities have been implemented. The session therefore reviewed progress that has been made and recommend actions that need to be taken to sustain progress.

8.8.2 Keynote Presentation: Regulatory Harmonization in Africa: The Journey and the Future outlook

The key note address was delivered by Mrs Precious Malebona Matsoso, Director General – South African Department of Health and AMRH Champion.

The African heads of State and Governments as well as the World Health Organization Regional Committee for Africa as part of the mandate resolved to establish the African Medicines Agency (AMA) in response to the lack of access to affordable, quality essential medicines. Moreover there is a growing complexity in medicinal products and their ingredients making managing the risks and benefits of these medicinal products much more difficult for the already constrained regulatory authorise. This growing landscape requires that regulators should consider regional, continental and international collaborative approaches to provide access to regulatory authorities' resources and the best available scientific and technical expertise.

Working together, the African Medicines Regulatory Harmonization initiative strives to apply the best scientific and regulatory standards to protect and promote health through;

- ✓ Providing independent, science-based recommendations on quality, safety and efficacy of medicines;
- ✓ Providing information on general issues relevant to public and animal health;
- ✓ Applying efficient, predictable, transparent evaluation procedures;
- ✓ Implement measures for continuously monitoring and supervising the quality, safety and efficacy of all medicines authorised in the African Union to ensure that their benefits outweigh their risks;
- ✓ Providing scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- ✓ Recommending safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the African Medicines Agency;
- ✓ Involving representatives of patients, healthcare professionals and other stakeholders in its work to facilitate dialogue on issues of common interest;
- ✓ Publishing impartial and comprehensible information about medicines and their use;
- ✓ Developing best practices for medicines evaluation and supervision in Africa, and contribute alongside the Member States and the African Union to the harmonization of regulatory standards at International Level.

Collaboration among National Medicines Regulatory Authorities in their strive towards regulatory Harmonization will result in:

- ✓ A region in which efficacious, safe and good-quality medicines are available to all those who need them;
- ✓ Reduction of time taken to grant marketing authorization (registration) in the individual countries;
- ✓ Efficient utilization of resources through work sharing;
- ✓ Being an enabler between science and healthcare systems

Through the establishment of AMA the Medicine Regulatory Authorities of Africa is striving for better regulation to allow for the development, access and marketing of safe and effective products and ensure effective patient protection but at the same time keep pace with innovation to support and provide innovative therapies to patients.

8.1.2 Local Manufacturing in Africa. Challenges and opportunities- FAPMA

Players in the manufacturing system in Africa continue to face a myriad of challenges mainly due to the capital, skills and technology intensive nature of the industry. High interest rates, taxes on raw materials small fragmented markets continue to hamper progress. Despite the challenges, FAPMA continues to play its advocacy role and has registered significant progress especially as it relates with engaging the Global Fund. Roadmaps have been developed to assist companies with the requisite minimum requirements to work towards accessing global fund market. FAPMA is also harnessing the opportunity to present through the current efforts of the AMRH to strengthen and harmonize regulatory systems and the recent effort to establish a fund for Africa's pharmaceutical development (FAP-D). FAPMA appreciates the efforts by policy makers and partners in creating an enabling environment for the local pharma to thrive. More incentives will be needed to ensure the achievement of the PMPA objectives and the AIDA framework.

8.1.3 ECOWAS Experience on regional and national efforts to promote local l production and the role of regulatory harmonization – WAHO

The ECOWAS Assembly endorsed the ECOWAS Regional Pharmaceutical Manufacturing Plan which envisions 'A strong regional pharmaceutical sector, incorporating a vibrant manufacturing industry and a robust regulatory system that is enduring, sustainable, competitive and managed in an integrated manner to be able to provide quality, affordable, safe and efficacious essential medicines that meet the needs of the ECOWAS region and for exports of medicines by 2025'.

Role of regulators

- ✓ Regulators and manufacturers have had joint training programs together to build trust and confidence;
- ✓ The MRH Steering Committee have involved manufacturers as observers in the decision of ensuring access to quality, safe and efficacious medicines on the market;
- ✓ WAPMA, local manufacturers associations and the NMRAs at country level have strongly worked together to ensure the smooth development of the national and regional GMP roadmaps.

Perspectives

- ✓ Regulators and manufacturers have had joint training programs together to build trust and confidence;
- ✓ The MRH Steering Committee have involved manufacturers as observers in the decision of ensuring access to quality, safe and efficacious medicines on the market;
- ✓ WAPMA, local manufacturers associations and the NMRAs at country level have strongly worked together to ensure the smooth development of the national and regional GMP roadmaps.

8.1.4 Country experience in the implementation of national strategies for local production- Ethiopia

In 2015. Ethiopia launched its National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025) as a visionary programme of action. Implementation is expected to follow value chain approach (from packaging of finished producing through to Research and development and discovery of new drugs. The government has manifested its commitment to developing its local pharmaceutical industry by putting in place a wide range of incentives including land, taxes and FDI. The government has engaged in fostering strategic partnerships with universities, big pharmaceutical companies and other players.

It is hoped that with contribute to improving access of the Ethiopian people and the region at large to locally produced, good quality essential medicines, and result in the creation of a research and development-based industry that would effectively contribute to skilled human resource development and to the growing knowledge economy. Because the sector is built on the 'industrial parks' model, the government of Ethiopian pharmaceutical sector has the potential to spur economic activities across various other sectors.

8.2 Parallel Session II: Post marketing and Pharmacovigilance Initiatives

This session aimed to provide a platform for learning and sharing experience on Pharmacovigilance (PV) and Post Marketing Surveillance (PMS) activities and their contribution in addressing patient safety and the problem of sub-standard and falsified medicines. The role of QC laboratories and Regional Centers of Regulatory Excellence (RCOREs) in QC was explored.

8.2.1 Proficiency Testing (PT) Schemes for Pharmaceutical Laboratories: East African regional experience – MUHAS

This presentation was made by Mr. Eliangiringa Kaale. Reliability and credibility is a key component parameter which provides confidence and ensures laboratory result performance. Pharma testing laboratories demonstrate test competence by participating in a proficiency scheme as a requirement of ISO/IEC 17025 accreditation.

The study aimed to develop a quality assurance tool to laboratories and to provide them an opportunity to compare performance and take remedial action when preparing for ISO/IEC 17025 accreditation status. It also builds regional capacity for providing PT services in the pharmaceutical sector within the EAC. He highlighted the limitations of the study as being low participation of stakeholders, consideration as extra work to participants, extra cost incurred by participants. Despite the mentioned challenges, the exercise provided an opportunity for improvement to both the provider and participants through lessons learned and experience sharing which forms the ground for Continuous Quality improvements towards ISO/IEC 17043 accreditation. The presenter urged African pharma testing labs to consider actively participate in future exercises such as these as way to improve and demonstrate testing competences.

8.2.3 Risk-based Approaches to Post Marketing Surveillance (PMS) in Africa – USP

This topic was presented by Mr. Abdul Karim Smine. Lack of effective PMS represents a public health threat to poor quality medicines which may cause undesired effects to patients. Risk base approach in regulatory services of Post marketing surveillance which is a systematic collection of product safety, product quality based on risk factors require analysis of data, planning, control and evaluation of marketed products. NMRAs should develop guidelines which will provide a practical reference to assist LMICs design and implement technically sound, cost-effective and sustainable national PMS programs, increase the effectiveness of PMS, while reducing overall cost.

In order to have a PMS in place within the NMRAs a lot of key considerations should be putting made for example NMRAs should obtain a legal mandate with the appropriate scope to perform PMS as a regulatory function also should put in place sound PMS governance structure, which is independent, accountable, transparent, responsive, and equitable and also should be guided by procedures. Additional requirements for success included:

- ✓ Human resources with requisite training and expertise to undertake PMS activities;
- ✓ Financial resources and budget allocation for effective PMS program implementation;
- ✓ Good strategic plan which will enable environment for coordinating activities with relevant stakeholders with clearly defined roles and responsibilities;
- ✓ Communication to the various stakeholders.

He emphasizes to regulators and other stakeholders to implement PMS as a key regulatory function and also to link it to PV and public health programme for producing desired outcome.

"Dying from a disease is sometimes unavoidable, dying from a medicine is unacceptable'. He said. Therefore building capacity in Quality control lab is paramount.

8.2.4 Continental Framework on Pharmacovigilance - NEPAD Agency

Presentation was made by Paul TANUI from NEPAD Agency.PV capacity in low and middle income countries (LMIC) is weak hence reducing the ability of these countries to monitor the safety of products in their countries after product registration and widespread use. Additionally, underreporting of Adverse Drug Reactions (ADRs) in low income countries, very few Individual Case Safety Reports (ICSRs) are received from Africa rendering the reports unreliable for real-world assessment of products in Africa. Absence of strong verifiable PV systems in Africa delays the early roll out of interventions and access to products for unmet needs are among challenges facing PV in Africa

The AMRH initiatives which involve partnership with African countries (regulatory authorities) and regional blocs, NEPAD, AUC, PAP, WHO, BMGF, DFID, PEPFAR/USG, GAVI, World Bank aims to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional and simplified one. Stepwise approach started by harmonizing and streamlining technical requirements for product registration, leading to increased and timely product access also creates a platform to build African regulatory capacity by region by reduced registration cycle time starting with generics extending to other product categories and other regulatory functions such as

Pharmacovigilance. Harmonizing working tools for collection, analysis and use of adverse reaction information; designation of PV RCOREs to improve the human resources for PV in Africa by offering formal short term and postgraduate training in PV; and establishment of the Africa PV Advisory Group (APAG) under the AMRH Framework indicate the commitment to strengthen PV in Africa.

8.2.5 Pharmacovigilance in emerging markets: an industry initiative to strengthen global engagement and support – Johnson & Johnson

This presentation was made by Mr. Derek Addy. Pharmacovigilance is an industry led initiative although it should be everyone's responsibility. All medicines have the potential to cause adverse reactions. Therefore bbuilding effective PV systems globally is the ultimate goal. This allows for ongoing and robust monitoring of medicines ensuring patients receive safe and efficacious treatments.

The industry's objectives are to:

- ✓ Support robust global understanding within companies
- ✓ Support staff regionally & nationally in compliance
- ✓ Advocate for change when needed
- ✓ Encourage alignment/ harmonisation of PV practices when appropriate
- ✓ Advocate for development effective PV systems

Some countries in Africa (Algeria, DR Congo, Eritrea, Ethiopia, Ghana, Kenya, Mauritius, Morocco, Nigeria, Rwanda, South Africa & Tunisia and Egypt) have participated in the Africa & Middle East Legislation review resulting in the review of requirements of the local safety representative and PSMF PV System Sub File (PSSF). There is need to address challenges facing the PV industry such as unavailability of PV System Master File (PSMF), Accepted PSMF, and Local Safety Responsible Person (LSR).

Recommendations from the parallel session on PV

- Countries should work together with the Regional Economic Community (RECs) to develop strategic plans which will provide direction on the road map for strengthening the existing PV work using EAC PV strategic plan as model.
- AMRH Partners should extend support to on ongoing PV activities within the RECs and at continental level for strengthening of PV harmonization.
- NMRAs should improve capacity and infrastructure of the NMRAs for strengthening of PV for achieving intended result.
- Countries should harmonize PV policies, laws, regulation, guidelines, requirements and working tools on PV in order to have efficient signal detection, assessment, understanding and prevention.

- Countries to consider implementing risk based approach on Post Marketing Surveillance to ensure efficiency on utilizing regulatory resources.
- Countries to enhance and improve technical collaboration and networking regionally and continentally on proficiency testing (PT)/inter-laboratory testing (ILT).
- Need for countries to focus on improving quality infrastructure to ensure quality medicines and reducing of counterfeiting.

9.0 Closing

9.1 Conference recommendations

The conference recommendations were categorized into three sections namely: i) sustaining momentum for harmonization, ii) NMRAs strengthening and iii) Local production of pharmaceuticals.

9.1.1 Sustaining Momentum for Regulatory Harmonization

1) Africa Union Commission, NEPAD Agency and WHO with the support of countries, RECs and Partners to deploy a transparent tracking mechanism with clear performance indicators for achieving the milestones on setting up the Africa Medicines Agency- an important instrument for sustainability of current regional efforts and initiatives(e.g. ZaZiBoNa) for regulatory capacity strengthening and harmonization in Africa;
2) RECs and partners to ensure that harmonization creates a platform for strengthening capacity for regulators to capture and use data, and embrace information communication technologies (ICTs), science and technology;
3) AMRH partners to ensure that the AMRH monitoring and evaluation indicators which focus on the regional harmonization are in alignment with the WHO benchmarking tool for NMRAs in order to ensure comprehensive evaluations that inform policy and practice;
4) AMRH partners should put deliberate effort to work with North African countries through the Arab Maghreb Union (AMU) including Libya and Egypt in order to facilitate regional harmonization towards the establishment of the African Medicines Agency;
5) NMRAs, RECs and partners to align existing regulatory systems strengthening and harmonization initiatives and expand to other regulatory functions & products such as vaccines, medical devices, diagnostics, QC, PV, clinical trials oversight, blood and blood products, sub-standard & falsified products (SF) etc.;
6) NMRA to ensure regulatory interventions are patient centred responding to health systems challenges and the disease burden disproportionately affecting the African continent.
7) Partners working on medical products regulatory systems strengthening and harmonization in Africa to align with the AMRH Partnership Platform as a Chapter of Global Coalition of Interested Partners (CIP) in order to ensure coordinated effort and collective impact;

8) African Union Commission and NEPAD Agency to explore and advocate for NMRAs and regional harmonization sustainable financing mechanisms/models.

9.1.2 NMRA Strengthening

9) Countries advised to use the African Union Model law on Medical Products Regulation as a reference guide for reviewing medicines laws and setting up of autonomous NMRA that will be technically and financially sustainable to carry out key regulatory functions;

10) NMRAs to explore and institute mechanisms for collaboration, reliance, and recognition of decisions made by other regulators at the regional and international levels in order to leverage on capacities existing elsewhere and reduced registration lead times.

9.1.3 Local Pharmaceutical Production

11) African Union Commission, NEPAD Agency and RECs to facilitate multi-sectorial efforts for improving local production that will address gaps in financing, human resource capacity, regulation, policy coherence, market fragmentation in order to provide a conducive investment environment;

12) The AMRH GMP expert working group should support REC and country efforts to strengthen capacity on GMP for both NMRAs (assessment) and manufacturers (compliance) in order to facilitate quality local production that will meet international standards; which could be done through membership in relevant international organizations (PIC/s). Appropriate international standards should be implemented also to other related GxP activities (e.g. storage, transport and distribution of the medicines).

13) AMRH capacity building should go beyond NMRAs to also build capacities for manufacturers in order to improve the quality of applications that will expedite the evaluation process.

9.2 Closing Remarks

Representatives from FAPMA, IFPMA ARN, BMGF, WHO and NEPAD delivered closing remarks.They all thanked the government of Ghana for the hospitality and the organizers for a successful conference. They congratulated the participants for the valuable interactions and contributions and wished everybody safe journey to their respective countries. The 3rd Biennial Scientific Conference on Medical Products Regulation in Africa: *Sustaining the Momentum for Regulatory harmonization in Africa'* was declared officially closed by Professor Aggrey Ambali, Head of Industrialization, Science, Technology and Innovation at NEPAD Agency.

10.0 Annexes

a) Annex: Conference Programme

Time	Topic	Presenter
Monday, 27 November 2017		
07:00-08:20	Registration	Secretariat
08:30 – 10:00: Opening Ceremony **Master of Ceremony:** Margareth Ndomondo-Sigonda, NEPAD Agency and Thomas Lapnet-Moustapha, World Health Organization (WHO) **Rapporteurs:** Janet Byaruhanga (NEPAD Agency) & Jean Baptiste Nikiema (WHO)		
08:30 – 08:40	Welcome Remarks	• Dr. Xavier Crespin, Director General, West African Health Organization (WAHO) • WHO Representative, Ghana
First High-Level Plenary: Putting patients first – reforming access to medicines in Africa		
08:40 – 09:15	Moderator – Richard Jones, Devex 5mins elevated speed talk from each panel participant	• Aggrey Ambali, Head: Industrialization, Science, Technology and Innovation (ISTI); NEPAD Agency • Dr Margaret Agama-Anyetei, Head of Health at Social Affairs, African Union Commission (AUC) • Andreas Seiter, Global Lead – Private Sector, Health, Nutrition and Population, World Bank • Dan Hartman, Director, Integrated Development, Global Health, Bill and Melinda Gates Foundation (BMGF) • Samvel Azatyan, WHO
Second High-Level Plenary: Accelerating access to medicines – perspectives of industry, Civil Society and Patient Organizations		
09:15 – 09:40	Moderator – Margareth Ndomondo-Sigonda, NEPAD Agency	• Emmanuel Mujuru, Chairman, Federation of African Pharmaceutical

Time	Topic	Presenter
	5mins elevated speed talk from each panel participant	Manufacturers Associations (FAPMA) • Thomas Cueni, Director General, International Pharmaceutical Manufacturers Associations (IFPMA) • Representative from IAPO - TBC • Representative from PATH - TBC
09:40 – 09:45	**Choreography on Conference theme organized by Local Committee**	
09:45 – 10:00	Official Opening	Hon. Kwaku Agyeman-Manu, Minister for Health, Republic of Ghana
10:00 – 10:30	**Group Photo and Tea/Coffee Break**	

10:30 – 12:30: Plenary Session I: Harmonisation of regulation of medical products in Africa, where are we?

Session objectives: *Harmonisation of medical product regulation in Africa was initiated with the aim to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional approach starting by harmonizing and streamlining technical requirements for product registration and eventually expanding the scope to other products categories and regulatory functions.*

The African Medicines Regulatory Harmonization (AMRH) was launched in 2009 to galvanise Regional Economic Communities' (RECs) efforts towards achieving regional harmonisation.

This session, therefore, aims at reviewing the progress that has been made in regulatory systems strengthening and harmonisation; and indicators for measuring impact at regional and continental levels. The session will also review opportunities, challenges and lessons learned with the aim of designing strategies for moving forward and sustaining the momentum that has been gained so far.

Session Co-Chairs: Delese Mimi Darko, CEO – Ghana FDA & Samvel Azatyan, WHO

Rapporteurs: Ossy Kasilo (WHO) & Paul Tanui (NEPAD Agency)

10:30 – 10:45	AMRH Programme: Continental Progress Update	Margareth Ndomondo-Sigonda, NEPAD Agency
10:45 – 10:55	Progress on Regulatory Harmonisation in East African Community (EAC)	Jane Mashingia, EAC Secretariat
10:55 – 11:10	Progress on Regulatory Harmonisation in Southern African Development Community (SADC)	Joseph Mthetwa, SADC Secretariat

Time	Topic	Presenter
11:10 – 11:20	Progress on Regulatory Harmonisation in the Economic Community of West African States (ECOWAS)	Sybil Nana Ama Ossei-Agyeman-Yeboah, WAHO
11:20 – 11:30	Progress on Regulatory Harmonisation in the Intergovernmental Authority on Development (GAD)	Anthony Toroitich, IGAD Secretariat
11:30 – 11:40	Progress on Regulatory Harmonisation in the Central Africa Economic and Monetary Community of Central Africa (CEMAC)	Aime Djitafo Fah, The Organization for the Fight Against Endemic Diseases in Central Africa (OCEAC)
11:40 – 11:55	"AMRH", Are We Making Progress?	David Mukanga, BMGF
11:55 – 12:30	Discussions and recommendations	Moderated by Session Chairs
12:30 – 14:00	**Lunch**	**ALL**
14:00 – 15:30: Plenary Session I (Continued): Harmonisation of regulation of medical products in Africa, where are we? **Session Co-Chairs:** David Mukanga, BMGF& Chimwemwe Chamdimba, NEPAD Agency **Rapporteurs:** David Matle (TFDA) and Godfrey Keele (FAPMA)		
14:00 – 14:20	Result-Oriented Monitoring of Medicines Regulatory Systems and Harmonization Initiatives in Africa	Brian Ng'andu, NEPAD Agency
14:20 – 14:40	Experience in aligning global submissions with regulatory reviews across mature and developing NMRAs	Lawrence Liberti, Director, Centre for Innovation in Regulatory Science (CIRS) - TBC
14:40 – 15:30	**Discussions and recommendations**	**Moderated by Session Chairs**
15:30 – 16:00	**Tea/Coffee Break**	**ALL**
16:00 – 17:30: Plenary Session II: Learning from other harmonisation and collaborative efforts, and partnerships for regulatory harmonisation ***Session objectives:*** *This session aims at learning from other regulatory harmonisation and collaborative efforts within the African continent and beyond. Focus will be made on regional efforts beyond Africa such as the WHO driven collaborative efforts. The session will utilise these efforts and recommend how they can be adapted to contribute to the success of harmonisation in Africa. In addition to learning from other regulatory harmonisation and collaborative efforts, the session will also look at strategies for fostering collective impact and mutual accountability through partnerships for regulatory systems strengthening and harmonisation. The session will finally consider product Life Cycle Management (LCM as it relates to regulatory systems and processes.* **Session Co-Chairs:** Mike Ward, WHO & Hiiti Sillo, TFDA **Rapporteurs:** Paul Tanui & Apollo Angole		

Time	Topic	Presenter
16:00 – 17:00	Marketing Authorisation for Global Health Products (MAGHP) – Swissmedic, EAC, WHO and Concept Foundation working to increase access to quality assured medicines	Dr Cordula Landgraf - Swissmedic
	Medicines Regulation in Africa - Current state and future opportunities	Margareth Ndomondo-Sigonda, NEPAD Agency
	Protecting and promoting public health is a shared responsibility, whereto for Africa?: Lessons from WHO collaborative registration procedure	Luther Gwaza, WHO
	A review of the SADC Medicines Registration Collaboration (Zazibona) from 2013 to 2016	Farai Masekela, MCAZ
	Role of regulatory harmonization and collaboration in accelerating patient access to medicines – industry experience with EAC Joint Assessment procedure	Nevena Miletic- IFPMA-ARN
	Life Cycle Management (LCM)/Variations	Anders Vinther (Sanofi) on behalf of IFPMA Representative
17:00-17:30	**Discussion and recommendations**	**Moderated by Session Chairs**
17:30	**End of Day 1**	
Tuesday, 28 November 2017		
8:00 – 8:20	**Report of Day 1 and introduction to workshops; Jean Baptiste Nikiema & Ossy Kasilo, (WHO)**	
8:20 – 08:40	**Keynote Presentation**: Regulatory Harmonization in Africa: The Journey and the Future outlook	Precious Malebona Matsoso, Director General – South African Department of Health and AMRH Champion

Time	Topic	Presenter
8:40 – 10:00	***Parallel Session I: Investing in Africa's Pharmaceutical Industry: The role of regulation*** ***Session Objectives:*** *The African Union, through the adoption of the Pharmaceutical Manufacturing Plan for Africa demonstrated the commitment to improving local production of pharmaceuticals. To this end, a number of activities have been implemented. The session will therefore review progress that has been made and recommend actions that need to be taken to sustain progress.* ***Session Co-Chairs:*** *Dr Margaret Agama-Anyetei (AUC) & Paul Lartey (Lagrey Co)* ***Rapporteurs:*** *Janet Byaruhanga (NEPAD Agency) and Godfrey Keele (FAPMA)* 1. Local Manufacturing in Africa, challenges and opportunities – Mr Emmanuel Mujuru (FAPMA) 2. EAC Experience on regional and national efforts to promote local production and the role of regulatory harmonization - Eng. Jennifer Gache, (EAC) 3. ECOWAS Experience on regional and national efforts to promote local production and the role of regulatory harmonization; Sybil Nana Ossei Agyeman Yeboah, (WAHO) 4. Country experience in the implementation of national strategies for local production – Ethiopia	***Parallel Session II: Post Marketing Surveillance and Pharmacovigilance Initiatives*** ***Session Objectives:*** *The session aims to provide a platform for learning and sharing experience on Pharmacovigilance (PV) and Post Marketing Surveillance (PMS) activities and their contribution in addressing patient safety and the problem of sub-standard and falsified medicines. The role of QC laboratories and Regional Centres of Regulatory Excellence (RCOREs) in QC will also be explored.* ***Session Co-Chairs:*** *Fred Siyoi (Kenya Pharmacy and Poisons Board) and Prof Alex Dodoo, (WHO-CC on PV, Ghana)* ***Rapporteurs:*** *Paul Tanui (NEPAD) and Hidaya Juma Hamad (ZFDB)* 1. African Vision and contribution to global efforts in curbing SF medical products – *WHO-AFRO* 2. Proficiency Testing Scheme for Pharmaceutical Laboratories: East African Regional Experience - Eliangiringa Kaale, MUHAS 3. Risk Based Approaches to PMS in Africa – Karim Smine, USP 4. Continental Framework on PV – Paul Tanui, NEPAD Agency

Time	Topic	Presenter
	5. **30 Minutes Discussion** & **Recommendations**	5. Pharmacovigilance in emerging markets: An industry initiative to strengthen global engagement and support – Derek Addy, Johnson & Johnson 6. **30 Minutes Discussion & Recommendations**
10:00 – 10:30	**Tea Break**	**ALL**

10:30 – 13:30: Plenary Session III: Expanding the scope for regulatory harmonisation in Africa & sustaining the momentum after 10 years of harmonisation efforts – opportunities and challenges

Session objectives: *The initial focus on regulatory harmonisation was on registration of generic medicines with the view to expand to other product ranges such as biologicals and vaccines and regulatory functions such as clinical trials oversight, pharmacovigilance and quality assurance/quality control amongst others. The primary focus on registration was meant to facilitate learning before expanding to other regulatory functions and other regulated products. This session will therefore look at the lessons that have been learned so far with the view to identify gaps, propose strategies to address them and discuss modalities for expansion to other products and regulatory functions while ensuring alignment. Thus the session will provide direction on alignment of partners supporting regulatory systems strengthening and harmonization efforts and recommend actions to be undertaken at the national, regional and continental levels.*

Session Co-Chairs: Precious Matsoso, Director General, Department of Health, Republic of South Africa & Dan Hartman, Director, Integrated Development, Global Health, BMGF
Rapporteurs: Godfrey Keele (FAPMA) and Nancy Ngum (NEPAD Agency)

Plenary Session III: A		
10:30-11:30	WHO update on the Global Coalition of Interested Partners (CIP)	Mike Ward, WHO
	The AMRH Partnership Platform (APP)	Nancy Ngum, NEPAD Agency

Time	Topic	Presenter
	The role of Network of Official Medicines Control Laboratories–Africa in strengthening regulatory capacity in Africa	**Kwasi Boateng, USP**
	The African Vaccines Regulatory Forum (AVAREF) Efforts in Strengthening Capacity for Clinical Trials Oversight and Ethics Clearance	Dicky Akanmori, WHO
	Discussion and recommendations (20 min)	**Moderated by Session Chairs**
Plenary session III: B		
11:30-13:00	Pan African Harmonization Working Party (PAHWP) efforts for medical devices and diagnostics capacity strengthening	Hiiti Sillo, DG-TFDA
	Paul Ehrlich Institute (PEI)-Blood and Blood Products efforts to strengthen regulatory capacity in Africa	Washington Samukange, Paul-Ehrlich-Institut Global Health Programme
	Emerging Health Technologies: A Case for Malaria Eradication	Hudu Mogtari, for NEPAD Agency
	The African Medicines Agency	Janet Byaruhanga, NEPAD Agency
	Discussion and recommendations (30 min)	**Moderated by Session Chairs**
13:30 – 15:00	**Working Lunch:** ***Sustaining the momentum: Recognising the role of civil society in strengthening regulatory systems in Africa***	
15:00 – 16:30: Plenary Session IV: Shaping the future of medical products regulation in Africa **Session objectives:** *This session will build a case for the future of regulatory systems strengthening and harmonization in Africa, building on global efforts in capacity building. It will provide direction on key topics for regulators including developments in capacity building, rule of law, medicine information and comparator products for bioequivalence studies.* **Session Chair: Jean Baptiste Nikiema (WHO)** **Rapporteurs: Paul Tanui, NEPAD Agency and Hidaya Juma Hamad (ZFDB)**		
15:00 – 16:15	Systematic capacity building through a global competence framework for regulators	Luther Gwaza, WHO
	Conformity of package inserts (PIs) information to key medicines information parameters among	Hiiti Sillo, DG- TFDA

Time	Topic	Presenter
	selected innovator and generic essential medicines circulating on the East African Community (EAC) market	
	Rule of Law: A new frontier in medicines regulatory strengthening and harmonization	Michelle Forzley, Forzley & Associates
	Strengthening Medicine Regulatory System by Implementing Electronic Medicine Registration Data Management System (Pharmadex) in Mozambique	Nazalia Macuvele, PD Mozambique
	Application of global comparator products for bioequivalence studies in Southern African Development Community (SADC) collaborative registration (Zazibona)	Clariator Mvurume, MCAZ
16:15 – 16:30	**Discussion and recommendations**	**Moderated by Session Chair**
16:30 – 17:00	**Tea/Coffee Break**	
17:00 – 18:30: Closing Ceremony **Master of Ceremony:** Margareth Ndomondo-Sigonda, NEPAD and Thomas Lapnet Moustapha, WHO **Rapporteurs:** Chimwemwe Chamdimba & Janet Byaruhanga		
17:00 – 17:20	Presentation of conference recommendations	Chimwemwe Chamdimba
17:20 – 17:40	Discussion on conference recommendations	All
17:40 – 18:00	Partners Remarks	• Emmanuel Mujuru, Chairman, FAPMA • John Mwangi (Bayer), Co-Chair of IFPMA ARN • BMGF Representative
18:00 – 18:15	Remarks from WHO	WHO Representative, Ghana
18:15 – 18:30	Closing Remarks, NEPAD Agency	Prof Aggrey Ambali, NEPAD Agency
18:30	**End of Conference**	

b) Annex: List of Participants

Full Name	Email	Company (optional)
Mai Abdalla	maie@africa-union.org	African Union Commission (AUC)
Francis Aboagye-Nyame	kofinyame@franeva.com	MSH
Angela A Ackon	angiackon@yahoo.com	NDIRC - MOH
Danjuma Adda	danadda02@yahoo.com	Center for Initiative & Development (CFID)
Lucia Addae	pmagsecretariat@yahoo.com	WAPMA
Derek Addy	daddy1@its.jnj.com	Johnson & Johnson
Ajibade Adesiyun	ajibadeadesiyun@gmail.com	University of Lagos.
Uchenna Adesugba	uchenna.adesugba@novartis.com	Novartis Nigeria Limited
Adebukola Adeyemo	adebukola.t.adeyemo@gsk.com	GlaxoSmithKline Pharmaceutical Nigeria
Dr Obi Peter Adigwe	o.p.adigwe@gmail.com	PMG-MAN
Maame Amakyewaa Adu	maame.adu@roche.com	Roche Products Ghana Limited
Priscilla Aduse-Poku	priscilla.adusei@sanofi.com	SANOFI
Margaret Agama-Anyatei	agama-anyeteim@africa-union.org	African Union Commission(AUC)
Césaire Damien AHANHANZO	cahanhanzo@prj.wahooas.org	WAHO
Morgane AHMAR	morgane.ahmar@gmail.com	Association de Lutte Contre le Sida (ALCS)
Habib Ahmed	nhabahmed@gmail.com	All African Leprosy & TB rehabilitation and trainig center(ALERT CENTER)
DJITAFO FAH Bernard AimÃ©		OCEAC
Dicky Bartholomew Akanmori	akanmorib@who.int	World Health Organization (WHO)
Dr Simon Okechukwu Akpa	okeyakpa@gmail.com	MD/CEO , SKG Pharma Ltd,
Mukundane Bamwonjobora Albert	mukundanealbertb@gmail.com	follow the star/nogamu
Thed Albert	thedyalbert@hotmail.com	Ministry of Health
Martin Harvey Allchurch	martin.harvey@ema.europa.eu	European Medicines Agency
Yetunde Alli	yetunde.alli@bayer.com	BAYER MIDDLE AFRICA LIMITED
Shanaaz Allie	shanaaz@biovac.co.za	The Biovac Institute
Akua Amartey	akuamart@yahoo.com	
Uzoamaka Amatokwu	uzo.amatokwu@sanofi.com	SANOFI
Aggrey Ambali	aggreya@nepad.org	NEPAD Agency
Thomas Amedzro	tom62kk@yahoo.com.au	
David Ameko	david.ameko@sandoz.com	Sandoz dd, Ghana
Edward Amporful	amporful221065@yahoo.com	COCOA CLINIC, GHANA COCOA BOARD
Apollo Angole	aangole@nda.or.ug	National Drug Authority (NDA)
Edith Annan	andrewse@who.int	WHO
Vincent Ansong	vincent.ansong@merck.com	MSD
Kwadwo Odei Antwi-Agyei Antwi-Agyei	kodeiantwiagyei@gmail.com	FACULTY OF PUBLIC HEALTH, GHANA COLLEGE OF PHYSICIANS AND SURGEONS
Adobea Anyinam-Boateng	adobea.anyinam-boateng@roche.com	ROCHE PRODUCTS GHANA LTD

Mengistab Aregay	mengtgm@yahoo.com	
Albert Wiredu Arkoh	awarkoh@yahoo.com	Pharmacy Council of Ghana
Njambong Armelle	anjamb@santaconsulting.com	S.ANTA CONSULTING
Geoffrey V. Arthur	geoffreyarthur@rocketmail.com	
Theodora Asa-Eck	theaasaeck@gmail.com	KNUST
Ayenew Ashenef	ayenew.ashenef@aau.edu.et	Addis Ababa University
Constance Assohou	constance.assohou@gmail.com	University of Abidjan and IRD-benin
Eyobed Atakilt	eyobed_atakilt@yahoo.com	Ethiopian food medicine and health care administration and control authority
Mawien Atem	m.mawienarik@gmail.com	South Sudan Drug and Food Control Authority
Bwana Awetse	awetse20@gmail.com	
Denis Awuni	denisazabra.awuni@navrongo-hrc.org	Navrongo Health Research Centre
Richard Ayah	ayah@uonbi.ac.ke	University of Nairobi Science and Technology Park (FabLab)
Samvel Azatyan	azatyans@who.int	WHO HQ
Fall Abdou Aziz	ziza4540@gmail.com	ASBEF, SWAA
Therese Ehounoud Ba-Gomis	therese.ba-gomis@bayer.com	BAYER WEST& CENTRAL AFRICA
Marieme Ba	marieme.ba@pharmalys.com	Pharmalys
Amethyst Babael	amethystjane.babael@abbott.com	Abbott
Binta Bah	bintabah708@yahoo.fr	Universite De Conakry
Dennisila Baidoo	denisilla101@yahoo.com	
Wilbert Bannenberg	wilbert@hera.eu	hera
Joseph Y. Bernie Bennie	eskabus@yahoo.com	
Edward Bentil	edybentil@gmail.com	Aspee pharmaceuticals Ltd
Dr ASSI ASSI Bernard	bassi@prj.wahooas.org	WAHO
Janis Bernat	j.bernat@ifpma.org	IFPMA
Avanthi Govender Bester	avanthi.bester@bd.com	BD
Shyam Bhaskaran	shyam.bhaskaran@gatesfoundation.org	Bill & Melinda Gates Foundation
Fortunate Bhembe	fortunatebhembe@gmail.com	Ministry of Health Kingdom of Swaziland
Immaculele Bigirimana	bigimma2006@yahoo.fr	
Sophie BIPOLO	bipsophie@yahoo.fr	
Fabio Bisordi	fabio.bisordi@roche.com	F. Hoffmann-La Roche
Yvonne Adu Boahen	vonei2000@yahoo.com	Food and Drugs Authority
Kwasi Poku Boateng		USP Ghana
Mr. Kwasi Poku Boateng	kpb@usp.org	USP
Olivia Boateng	nanayaa1970@gmail.com	Food and Drugs Authority
Samuel Asante Boateng	dekompi2005@yahoo.com	
Nyabenda Bonaventure		
Anthony Boni	aboni@usaid.gov	USAID
Jennifer Bonnah	jennifer.bonnah@fdaghana.gov.gh	
Benjamin Kwame Botwe	benbotwe@gmail.com	AMRH/ EOWAS MRH
Omar Bouazza		
Kent Briggs	kent@vectorls.co.za	VECTOR Life Sciences Ltd. (Pty)
Dr Carlos Brito	cbrito@wahooas.org	WAHO

Carinne Bruneton	carinne.bruneton@hotmail.fr	Pharmacienne
Johnson Bukola	bukola.johnson@merck.com	MSD IDEA Pharm. Nigeria Ltd.
Priscilla Buliga	priscilla.buliga@novartis.com	Novartis Pharma Services
Christian Burri	cbsnub@gmx.ch	Swiss TPH
Janet Byaruhanga	jessiegaju@gmail.com	NEPAD Agency
Aida Cancel	acancel@fhi360.org	FHI 360
Hounnou Carmelle	hounnoucnk@yahoo.fr	Dr
Dino Celeste	dino@clientelis.com	Clientelis
Joseph Chabi	joc@vestergaard.com	Vestergaard / Noguchi Memorial Institute for Medical Research
Chimwemwe Chamdimba	chimwemwec@nepad.org	NEPAD Agency
Ceciliah Chigwada	ceciliachigwada70@hotmail.com	Women Today Worldwide
Edwin Chipala	cchipala2@gmail.com	Pharmacy Medicines and Poisons Board
Keith Chirgwin	keith.chirgwin@gatesfoundation.org	BMGF
Liberty Chirinda	lchirinda@mcaz.co.zw	Medicines Control Authority of Zimbabwe
Conrad Christoph	christoph.conrad@pei.de	Paul-Ehrlich-Institut
Chrissy Chulu	chrissychulu@gmail.com	Pharmacy Medicines and Poisons Board
Clarisse Kaul Clamoungou	clarisse.k.clamoungou@gsk.com	GlaxoSmithKline
Judy Coates	judy@ipasa.co.za	IPASA
Lucile de Comarmond	lucile.decomarmond@health.gov.sc	Ministry of Health Seychelles
Ondo Efua Mangue Consuelo	docconsuelo@yahoo.com	MINISTRY OF THE HEALTH OF EQUATORIAL GUINEA
James Cordahi	james.cordahi@abbott.com	Abbott
Marcellina José da Costa	marcelina.costa11@yahoo.com.br	
Yaya Coulibaly	couliyaya2003@yahoo.fr	Autorité de Réglementation
Dr Xavier Crespin	xcrespin@wahooas.org	WAHO
Thomas Cueni	t.cueni@ifpma.org	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
Patience Dabula	patience.dabula@nhls.ac.za	The National Health Laboratory Service (NHLS)
Robyn Daniel	robyn@mra-regulatory.com	MRA Regulatory Consultants (Pty) Ltd
Jacqueline Darfoor	jacqui.darfoor@gmail.com	Pfizer
Delese Afia Amoakoa Darko		FOOD AND DRUGS AUTHORITY
Mimi Darko	mimidarko66@yahoo.co.uk	Ghana Food and Drugs Authority (FDA)
Elisha Olatunji David	au.ecosoc@gmail.com	African Union Economic, Social and Social Cultural Council
Dr Aissatou Diack	adiack@worldbank.org	World Bank
Maitre Ely Noel Diallo	ediallo@wahooas.org	WAHO
Collen Dikobo	collen.dikobo@novartis.com	Novartis South Africa
Hien Dinh	hdinh@fhi360.org	FHI 360
Krakou Emmanuel Esaie Djigbenou	emmanuel.djigbenou@pfizer.com	PFIZER
Amadou Moctar DIEYE	ctdieye@yahoo.fr	

Alex Dodoo	alexanderdodoo@gmail.com	African Collaborating Centre for Pharmacovigilance
Hanneke Dominicus	hanneke.dominicus@gmail.com	Consortium for African Regulatory Expertise Development CARED
Jicui DONG	dongj@who.int	World Health Organization
Rachelle Duncan	rachdunc2002@yahoo.fr	
Michael Durowaiye	mstand2000@yahoo.com	University of Ibadan
CHOUGOUO KENGNE spouse NKUITCHOU Rosine DÃ©sirÃ©e	nrosinedesiree12@yahoo.fr	UniversitÃ© des Montagnes
Assefa Ejamo	asebegeta@gmail.com	Expert
Abigail Ekeigwe	abigail.a.ekeigwe@gmail.com	NAFDAC (Purdue University PhD Student on Harmonisation)
Dzahini Kwakutse Elagbe	dzakoszy@yahoo.fr	Association YOUTHLEAD
Elemide oyebola adebola ELEMIDE	bolafebi@gmail.com	FEDERAL COLLEGE OF AGRICULTURE AKURE ONDO STATE NIGERIA
Imam Mohamed Elhassan	imam@nmpb.gov.sd	
Bamenyekanye Emmanuel	bamenyekanye@hotmail.com	Department of Pharmacy, Medicines and Laboratory
Yvonne Y. Esseku	yesseku@yahoo.com	
N'Dri N'Dah Ezechiel	ezec_ndri@yahoo.fr	PFIZER WEST AFRICA
Nwamaka Ezurum	amakaezurum@outlook.com	Abbott Laboratories
Hamoud FADEL	directionpharmacie@yahoo.fr	
Aime Djitafo Fah	aimedjitafofah@yahoo.fr	Organization for Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC)
Fortunate Ntombi Fakudze	fortunate.fakudze@yahoo.com	
Ahamada Said Fazul	sfazul@yahoo.fr	Ministere de la santÃ©
Bunmi Femi-oyekan	bunmi.femi-oyekan@pfizer.com	Pfizer
Prof. Nadia FENINA	nadia.fenina@rns.tn	
Andriette Ferreira	andriettef@nepad.org	
Dr Julio Ferreira	julioferreira60@yahoo.com.br	de Farmácia, Laboratório e Medicamento -Direcção-Geral de Estabelecimentos de Cuidados de Saúde
Charles Agyemang Fordjour	charles.fordjour@roche.com	Hoffman La Roche
Michele Forzley	michele@micheleforzley.com	Forzley & Associates
Mick Foy	mick.foy@mhra.gov.uk	MHRA
Naana Frempong	afraks77@yahoo.co.uk	
Eng. Jennifer Nyambala Gache	jennygache777@yahoo.com	East Africa Community Secretariat
Jennifer Gache	gache@eachq.org	East Africa Community Secretariat
Stephen Awudi Gadri	tafi.ghana@gmail.com	Trokosi Abolition Fellowship International
Johannes Gaeseb	gaesebj@gmail.com	Ministry of Health and Social Services / Namibia Medicines Regulatory Council
Daouda Lawa Garandji	deouth35@gmail.com	DGPL

Prof. Fernand GBAGUIDI	ahokannou@yahoo.fr	Pharmacy of Medicines and Diagnostiques (DPMED)
Stephen Gbedema	sgbedema@yahoo.com	KNUST
messay Getu	messay1979@gmail.com	Ethiopian biotechnology institute
Mona Ghobashi	dppc_egypt@hotmail.com	
Victoria Gilbert	victoria@iapo.org.uk	IAPO
Magalie GOMBE	mgombe@exphar.be	Exphar
Odile Goya	o.goya@medicaments-export.fr	MEDICAMENTS EXPORT
Dr. Alexandra Graham	alexandra.graham@lagray.org	USAID
Simeon Gray	graysimeon@gmail.com	PATIENT AND COMMUNITY WELFARE FOUNDATION(MALAWI)-PAWEM
Habtamu Beyene Guluma	skeennaa@gmail.com	Ethiopia Food Medicine and Healthcare Admi.istration and control Authority
Luther Gwaza	gwazal@who.int	World Health Organization (WHO)
Adela Gwira	a_uora@yahoo.com	Food And Drugs Authority, Ghana
Daniel Gyan	gyan.daniel@gmail.com	ministry of health
Martha Gyansa-Lutterodt	maglutt@hotmail.com	Ministry of Health
Dr Desire Habonimana	habonimanadesirefr@gmail.com	University of Burundi, Faculty of Medicine
Kidu Hailu	kiduhailu@yahoo.com	Ethiopian Pharmaceutical Association
Hidaya Hamad	hiddayya@gmail.com	Zanzibar Food and Drugs Agency
Hidaya Juma Hamadi	hiddayya@gmail.com	Zanzibar Food and Drugs Board (ZFDB)
Dan Hartman	dan.hartman@gatesfoundation.org	Bill and Melinda Gates Foundation
Dr Hassan Moussa Hassan	libahsakatabte@yahoo.fr	Ministry of Health /Republic of djibouti
Moussa Bogore HASSAN	hassanbogore@yahoo.fr	
Katherine Hencher	hencherk@who.int	Unitaid
Daniel Henneh	daniel.henneh@quintiles.com	Quintiles West Africa Ltd
Marcela JuÃ¡rez HernÃ¡ndez	marcela.juarez-hernandez@pei.de	Paul-Ehrlich-Institut
Abiola Idowu	abiola.idowa@roche.com	Roche Products Limited, Nigeria
Jacqueline Idusso	jidusso@gmail.com	Elizabeth Glaser Pediatric AIDS Foundation
Vivian Ihechu	vago_uk@yahoo.co.uk	News Agency Of Nigeria (NAN)
Charity Ilonze		NATIONAL AGENCY FOR FOOD AND DRUG ADMNINISTRATION AND CONTROL
Chi Chi Ilonze	chyplusiyke@yahoo.com	National Agency For Food and Drug Administration and Control (NAFDAC)
Ikechukwu Ilonze	iilonze@yahoo.com	SpringForth HealthCare Ltd
Wallada Im-amornphong	wallada@conceptfoundation.org	CONCEPT FOUNDATION
Pauline Irungu	pirungu@path.org	PATH
Colmagne-Poulard Isabelle	isabelle.colmagne-poulard@merckgroup.com	Merck Serono
Abdul-Samad Issah	samad_72@yahoo.co.uk	FOOD & DRUGS BOARD
Johnson Iyiola	iyiolajohnson@gmail.com	Federal Ministry of Finance
Osaretin Jaiyeola	osaretin.jaiyeola@fensyl.com	FENSYL MHP CONSULTING LIMITED

Mariatou Tala Jallow	mariatou.jallow@theglobalfund.org	The Global Fund to fight AIDS, TB & Malaria
Alice Jamieson	a.jamieson@wellcome.ac.uk	Wellcome Trust
Roy Jamieson	roy.jamieson@btinternet.com	AstraZeneca
Sheesha JANKEE	sjankee@mail.gov.mu	
Salah Eldin Abdel Rahman Abdel Aziz Jawher	gohersalaheldin@yahoo.com	Federal Ministry of Health -SUDAN
David Jefferys	david_jefferys@eisai.net	Eisai Europe Limited
Margarita Monserrat Jimenez	monserratt18.jim@gmail.com	LABORATORIOS SILANES, S.A. DE C.V.
DOUA Yorokpa Joachim	y.j.doua@gmail.com	CARED (Consortium for African Regulatory Expertise Development
Wiltshire Johnson	infopharm_pbsl@yahoo.com	Pharmacy Board of Sierra Leone
Tandong Calistus Jong	tandongcalistus@yahoo.com	AMYOFACIG
DÃ¶rrbecker Juliane	juliane.doerrbecker@pei.de	Paul-Ehrlich-Institut
Eliangiringa Kaale	elia.kaale@muhas.ac.tz	Muhimbili University of Health and Allied sciences
Joseph Kabatende	joska24@yahoo.com	
Godfrey Kadewele	gkadewele@pmpb.mw	
Sadia KAENZIG	s.kaenzig@ifpma.org	IFPMA
Harvey De Hardt Kaffils	hkaffils@prj.wahooas.org	WAHO
Abraham Kahsay	gebregiorgisa@who.int	Mr.
Markieu Janneh Kaira	markieu@yahoo.co.uk	Medicines Control Agency
Felix Kalevera	felix.kalevera@merckgroup.com	Merck Healthcare & Life Science Limited - Kenya
Daniel Kalibbala	dkalibbala@nda.or.ug	NATIONAL DRUG AUTHORITY - UGANDA
Dalilah Kalla	dalilah0710@gmail.com	Lupus Alert
Mhenga Kanena	1696031670416763@facebook.com	Muhimbili university
Francis Karanja	francis.m.karanja@gsk.com	GlaxoSmithKline
David Karenye	david.karenye@bbraun.com	B.Braun AG
Amina Kashoro	aminakashoro@rocketmail.com	Zanzibar Cllimate Change Alliance
Ossy Muganga Julius Kasilo	kasiloo@who.int	World Health Organization (WHO)
Richard Kasonogo	kasonogo@gmail.com	Tanzania Food and Drugs Authority
Mothobi Godfrey Keele	godfreyk@moteli.co.za	United Nations Industrial Development Organization
Eby Cheikh Khou	eckhou@unicef.org	UNICEF Western & Central Africa Regional Office
Damaris Kihianyu	wangari21@yahoo.com	Sandoz, Kenya
Agnes Kijo	agnes.kijo@tfda.go.tz	Tanzania Food and Drugs Authority (TFDA)
Kate Kikule	katkikul@nda.or.ug	Management Sciences for Health/SIAPS Program
Kate S. Kikule	katkikul@yahoo.com	Management Sciences for Health/SIAPS Program
Stephanie Josephine Kimou	stephaniekimou@yahoo.fr	DIRECTION DE LA PHARMACIE, DU MEDICAMENT ET DES LABORATOIRES
Verena Kluempers	verena.kluempers@pei.de	Paul-Ehrlich Institut, Federal Institute for Vaccines and Biomedicines

Stanislav Kniazkov	kniazkovs@who.int	WHO
Francis Kazungu Kombe	kombe@cohred.org	COHRED Africa
Juliet Konje	jkonje002@gmail.com	Pharmaceutical Society of Kenya
Kipkerich Koskei	koskei07@yahoo.com	
Amadou KOUMARE	akoumare2002@yahoo.fr	PRSDHU/Banque Mondiale
Joseph Senyo Kwashie	bossbig24@gmail.com	COMMUNITY AND FAMILY AID FOUNDATION
Robina Kyamuhangire	rkyamuhangire@gmail.com	rwakafuzi and co advocates
Cordula Landgraf	cordula.landgraf@swissmedic.ch	Swissmedic
Thomas Lapnet-Moustapha	lapnett@who.int	World Health Organization (WHO)
Paul Lartey	paul.lartey@lagray.org	American Association for the Advancement of Science
Richard Laryea	richardlaryea@yahoo.com	Hepatitis Foundation of Ghana
Agustin Martin Lasanta	agustin.martin@dsw.org	Deutsche Stiftung Weltbevoelkerung (DSW)
Zina Lazea	zina.lazea@amringpharma.com	AMRING FARMA
Lawrence Liberti	larryliberti@verizon.net	CIRS- Centre for Innovation in Regulatory Science, Ltd
Bora Mposanje Lichanda	babawatatu@gmail.com	Zanzibar Food and Drugs Board
Susan des Ligneris	sue.desligneris@astrazeneca.com	AstraZeneca Pharmaceuticals
Raj Long	raj.long@gatesfoundation.org	Bill and Melinda Gates Foundation
Dr Eugene Lottering	elottering@specpharm.co.za	SPECPHARM
BAHAKOULA MABIDI Louis	ong.ajedcg@gmail.com	Action Jeunesse pour le DÃ©veloppement (AJED)
Patrick Lukulay	plukulay@hitmail.com	In Transition
Murray Lumpkin	murray.lumpkin@gatesfoundation.org	BMGF
Mukisa Davis M	mukisadevis@gmail.com	Right Here Right Now Uganda
Nazalia Leonardo Macuvele	nasaliamacuvele47@gmail.com	Phamaceutical Department - Ministry of Health
Noxolo Magubane	nmagubane@womancareglobal.org	WCG
Gugu N. Mahlangu	gnmahlangu@gmail.com	Medicines Control Authority of Zimbabwe (MCAZ)
Gugu Nolwandle Mahlangu	gnmahlangu@mcaz.co.zw	Regulatory
Margaret Mahlomuza	margaretr@nepad.org	NEPAD Agency
Ambassador Dr Olawale Maiyegun	maiyeguno@africa-union.org	African Union Commission (AUC)
Rajesh Makanwal	rajesh.makanwal@rediffmail.com	Pharmanova Malawi Limited
Diran Makinde	diranm@nepad.org	NEPAD Agency
Tanya Malpica-Llanos	tmalpica-llanos@msh.org	Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program/Management Sciences for Health
Mohamed benslimane MANSOURI	lncpp@hotmail.com	
Daniel Marfo	bladido91@gmail.com	The Janssen Pharmaceutical Companies of Johnson & Johnson
Rehema Mariki	rehmariki@gmail.com	TANZANIA FOOD AND DRUGS AUTHORITY
Farai B. Masekela	fmasekela@gmail.com	Medicines Control Authority of Zimbabwe (MCAZ)

Jane Mashingia	jmashingia@eachq.org	East African Community Secretariat
Danielle Matia	dmatia@bvgh.org	BIO Ventures for Global Health
Robert Matiru	matirur@who.int	UNITAID
David Matle	drmatle@hotmail.com	Tanzania Food and Drugs Authority (TFDA)
Precious Malebona Matsoso	dg@health.gov.za	Department of Health of South Africa
Patricia Mayer	pmayer@ipmglobal.org	International Partnership for Microbicides
Regina Mbindyo	mbindyor@who.int	World Health Organization, Kenya Country Office
Edwin Mbugua	edwin.maina@concern.net	Concern Worldwide Kenya
Morris Mbulo	morris.mbulo@medtronic.com	MEDTRONIC
Gelise McCullough	mcculloughg@who.int	UNITAID WHO
Mpolo Melba	melmuzmariz@gmail.com	Journal Le Phare
Adjo Mfodwo	amfodwo@msh.org	MSH
Nevena Miletic	nevena.milisavljevic@roche.com	F. Hoffmann-La Roche Ltd. and IFPMA ARN (Africa Regulatory Network)
Hlazo Mkandawire	hlazom@nepad.org	NEPAD Agency
Seloi Mogatle	mogatle@unfpa.org	UNFPA
Ademola Mogbojuri	andyjuri@yahoo.com	National Agency for Food and Drug Administration and Control
Hudu Mogtari	h.mogtari@gmail.com	African Centre for Health Regulatory Consult
Makhlouf Djoubeir Mohamed	djoubeir.makhlouf@roche.com	Roche
Evelyn Mohanlall	evelyn.mohanlall@merckgroup.com	Merck Consumer Health
Nthabiseng Moiloa	nthabisengl@nepad.org	NEPAD
Boitumelo Mokgatla	boisa2002@yahoo.com	International AIDS Vaccine Initiative
M. Etienne MOKONDJI-MOBE	mmobet@yahoo.fr	
Greogorio Gori MOMOLU	ggorimomolu@yahoo.es	
Asgedom Mosazghi	asgedomm@moh.gov.er	
Gertrude Mothibe	gertiemothibe@gmail.com	National University of Lesotho
Yolanda Moyo	ymoyo@path.org	PATH
Germina Mphoso	gmphoso@yahoo.com	MINISTRY OF HEALTH
Vanessa Msengezi	vmsengezi@path.org	PATH
Joseph Mthetwa	jmthetwa@sadc.int	Southern African Development Community (SADC)
Apollo Muhairwe	amuhairwe@worldbank.org	World Bank
Emmanuel Mujuru	mujpfive@iwayafrica.co.zw	Federation of African Pharmaceutical Manufacturers Association (FAPMA)
David Mukanga	david.mukanga@gatesfoundation.org	Bill and Melinda Gates Foundation (BMGF)
Fatima Mukarmat	fatima@hotmail.com	
Tapiwa Mupereki	tmupereki@ghsc-psm.org	Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM)
Sarah Muthuri	sarah.muthuri@novartis.com	NOVARTIS PHARMA
Cristina ArnÃ©s MuÃ±oz	c.arnes@ifpma.org	IFPMA

Clariator Mvurume	clariatorm@gmail.com	Medicines Control Authority of Zimbabwe
Bernice Mwale	bcmwale@zamra.co.zm	#SCoMRA Attendee
Bernice Mwale		Zambia Medicines Regulatory Authority
Jane Mwangi	jamwangi@usaid.gov	USAID
John M. Mwangi	jmureithi58@gmail.com	Bayer HealthCare
John Patrick Mwesigye	jmwesigye@eachq.org	East African Community (EAC) Secretariat
Sophia Mziray	sophia.mziray@gmail.com	Tanzania Food and Drugs Authority
Jean-Rollin Bertrand N'DO	jeandorollin@gmail.com	
Ange Jocelyne Kebe N'Guessan	angenguessan76@yahoo.fr	DPML/MSHP
Dr Aminata P. NACOULMA	natanac5@gmail.com	Directeur général de la pharmacie, du médicament et des laboratoires
Rose Lule Nalukwago	rosielule@yahoo.com	Uganda Platform for Dibetics
STRUB WOURGAFT Nathalie	osushchenko@dndi.org	Drugs for Negleced Diseases initiative (DNDi)
Ildephonse Nduwayo	nduwayo35@yahoo.fr	DEPARTMENENT OF PHARMACY MEDICINE AND LABORATORIES/ DPML-BURUNDI
Annalene Nel	anel@ipmglobal.org.za	IPM
Bahizi Nestor	phcbjeannestor@gmail.com	DEAPARTEMNENT OF PHARMACY, MEDECINES AND LABOBORATORIES
Augusto Rosa M. Neto	augusrneto@hotmail.com	
Jacob Ngaba	jngaba2005@yahoo.fr	
Emily Njoki Ngamau	emng@novonordisk.com	Novo Nordisk
Brian Mutale Ngandu	briann@nepad.org	NEPAD Agency
Daniel Ngeleka	dangelemutolo@yahoo.fr	
Alice Ngotho	alice.ngotho@novartis.com	NVS Kenya Limited
Skhu Ngozwana	docskhu@gmail.com	FAPMA
Nancy Ngum	nancyn@nepad.org	NEPAD Agency
Jean Baptiste Nikiema	jbnikiema85@gmail.com	WHO
Déogratias NIYONZIMA	niyoga2007@yahoo.fr	
Guy NJAMBONG	guy@njambong.com	BioTechnica Pharma Africa
Mercy Njuguna	mercy7njuguna@gmail.com	BD
Wairimu Njuki	wairimu.njuki@roche.com	Roche Kenya
Portia Nkambule	nkambp@gmail.com	National Department of Health, Medicines Control Council
Edwin Nkansah	edwin.nkansah@yahoo.co0m	
Emmanuel Nkrumah	emmlnkrumah@hotmail.com	
Nathaniel Nkrumah	pharmnat@yahoo.com	FDA, Ghana
Barira Dan Nouhou	barira_dany@yahoo.fr	direction of pharmacy
Priscilla P.M. Nyambayo	pnyambayo@mcaz.co.zw	Medicines Control Authority of Zimbabwe
Gerald Nyamutamba	gnyamutamba@yahoo.com	University of Zimbabwe
Docteur Atany A.T. NYANSA	bnyansa@yahoo.fr	Directeur de la Pharmacie, du Médicament et des Laboratoires du Togo

Admire Nyika	anyika@mcaz.co.zw	Medicines Control Authority of Zimbabwe
Joseph Baah Obeng	jbobeng@gmail.com	Komfo Anokye Teaching Hospital
Kwame Obeng	kwame.obeng@bausch.com	Valeant Pharmaceuticals
Kwabena Offei	senatekw@gmail.com	Johnson & Johnson
Michael Oke	maof2020@gmail.com	Michael Adedotun Oke Foundation
Samuel Okunoye Okewoye	samok48@yahoo.com	COMMUNITY DEVELOPMENT ALLIANCE (CDA)
David Oladimeji	toluxeey@yahoo.com	university of lagos
Chief Olubunmi Olaopa	olaopa@evansmedicalplc.com	Evans Medical Plc
Oluwakemi Olawale	oluwakemi.olawale@sandoz.com	Novartis Nigeria Limited
Yayo Sagou Patrick Olivier	yayooli07@yahoo.fr	MinistÃ¨re de la SantÃ©- Programme National de DÃ©veloppement de l'ActivitÃ© Pharmaceutique (PNDAP)
SOPEIN-MANN Oluwafunmike	osopein-mann@prj.wahooas.org	WAHO
Abdillahi Omar	habiibo@hotmail.com	
Muhiddin Omar	muhiddin.omar@yahoo.com	ZANZIBAR FOOD AND DRUGS AGENCY
Louise Ongare	louiseakeyo.ongare@pfizer.com	Pfizer Laboratories Limited
Hesbon Simba Onyancha	hsimba@path.org	PATH
Yewande Oresanya	labowale2002@yahoo.com	Reals Pharm. Ltd
Ivy Osei	ivy.osei@ghsmail.org	Research and Development Division, Ghana Health service
Faiza Mohamed Osman Osman	projects006@inbox.com	university of khartoum
Sybil Nana Ama Ossei-Agyeman-Yeboah	sossei@wahooas.org	West African Health Organization (WAHO)
Nati Safiatou OUATTARA	natisafiatou.ouattara@sanofi.com	Sanofi
Charles O. Oviawe	coviawe@guosalifesciences.com	Guosa Life Sciences
Theobald Owusu-Ansah	theobald2003@yahoo.com	Hepatitis Foundation of Ghana
Mercy Owusu-Asante	mercyacquaye@yahoo.com	World Health Organization
Ama Owusu-Asare	akyampoma@yahoo.co.uk	
Olayinka Oyeneyin	olayinka.oyeneyin@pfizer.com	Pfizer Specialties Ltd
Abimbola Oyinlola	abimbola.oyinlola@pfizer.com	Pfizer
Gabriela Meza Parra	gmeza@silanes.com.mx	Laboratorios Silanes S.A. de C.V.
Shivani Patel	shivani.patel@abbott.com	Abbott Laboratories SA (Pty) Ltd
HELVENSTEIN Pierre	phelvenstein@exphar.be	Exphar s.a.
Manvi Porwal	manvi.porwal@pei.de	Paul Ehrlich Institut
Tilna Ingsala Poumne	tilnaingsala@yahoo.fr	
Solofomboahangy Harisoa RABENANDRIANINA	harisoa.agmed@gmail.com	
Dr. Clinton Rambanapasi	clinton.rambanapasi@roche.com	Roche South Africa
Mankele Antonin Ray	mankeler@who.int	World Heath Organization
Gopa Raychaudhuri	gopa.raychaudhuri@fda.hhs.gov	Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA)
Djamila Reis	djamila.reis@arfa.gov.cv	ARFA
N Retteh	nmacuvele@yahoo.com.br	

Portia Rodolo	n.ngutshane@unido.org	FAPMA
Adriana RodrÃguez	arodriguez@silanes.com.mx	Laboratorios Silanes S.A. de C.V.
Osman Omar Ron	omarr@africa-union.org	African Union Commission
Adriana Isabel Rodríguez de la Rosa	airdelarosa@hotmail.com	LABORATORIOS SILANES S.A. DE C.V.
Samia Saad	samia.saad@gatesfoundation.org	Bill and Melinda Gates Foundation
George Sabblah	gyorg1@yahoo.co.uk	
Daniel Sackey	daniel.sackey@denkpharmagh.com	Denk Pharma
Solomon Sackitey	kennsack@gmail.com	Northeastern University
Diop Saliou	saliou.x.diop@gsk.com	Gsk
Dr Adeniyi-Jones Samuel	samuel.adeniyi-jones@hhs.gov	U.S. Dept of Health and Human Services
Washington Samukange	washington.samukange@pei.de	Paul-Ehrlich-Institut (PEI)
Bruno SANTOS	bruno.santos@arfa.gov.cv	
ADAM Sarah	s.adam@ifpma.org	IFPMA
Eugene Saxon	gsaxon@path.org	PATH
Gene Saxon	genesaxon@gmail.com	PATH
Lorenz Scheppler	lscheppl@its.jnj.com	Janssen Vaccines & Prevention B.V
Seth Seaneke	seth.seneake@fdaghana.gov.gh	Food and Drugs Authority
Konji Sebati	konji@ipasa.co.za	IPASA
Myriam Sedrati	myriam_sedrati@merck.com	MSD
Andreas Seiter	a_seiter@hotmail.com	World Bank Group
Brian Sekayombya	bsekayombya@uhsc.ug	Euro Health Group
Patrick Seleka	patrick.g.seleka@gsk.com	Sefako Makgatho
Sinah Matlhodi SELELO	sselelo@gov.bw	
AMARI Antoine Serge	amariantoineserge@gmail.com	University Felix Huphouet Boigny
Seshni Sewlall	seshni.sewlall@merckgroup.com	Merck
Dhirendra Shah	dvshah@biodealkenya.com	Biodeal Laboratories Ltd
Bongani Sibeko	bsibeko@mphathiswa.com	Mphathiswa Pharma Services
Margareth Ndomondo Sigonda	margarets@nepad.org	NEPAD
Hiiti Sillo	sillohb@gmail.com	Tanzania Food and Drugs Authority (TFDA)
Burhani Simai	bsimai@yahoo.com	ZFDA
Githa Singh	githa.singh@abbvie.com	AbbVie
Tânia Vuyeya Sitoie	vuyeya78@yahoo.com	Ministry of Health, Mozambique
Fred Siyoi	fmsiyoi@gmail.com	Pharmacy and Poisons Board
Karim Smine	karimdqi@yahoo.com	US Pharmacopeia
Sevreina Smith	sevreina.smith@gatesfoundation.org	Bill & Melinda Gates Foundation
Dr Kabiné SOUARE	drsouare_kabine@yahoo.fr	National de la Pharmacie et des Laboratoires Ministère de la Santé
Cassandra de Souza	cdesouza@worldbank.org	World Bank
Fatoumata Jah Sowe	jahsowe@yahoo.com	The Gambia Medicines Control Agency
PADZYS Guy Stephane	padzys@gmail.com	UnivsersitÃ© des sciences et techniques de Masuku /Gabon
Ignatia Stephens	ies@usp.org	Centre for Pharmaceutical Advancement and Training- USP-Ghana

Live Storehagen	livs@fhi.no	Norwegian Institute of Public Health
David Sumo	d.sumo@yahoo.com	Liberia Medicines and Health Products Regulatory Authority (LMHRA)
Moses Talibita	mtalibita@unhco.or.ug	Uganda National Health User's/ Consumer's Organisation
Paul Tanui	paulk@nepad.org	NEPAD Agency
Eduardo Jorge Monteiro Tavares	eduardo.tavares@ms.gov.cv	
John Taylor	ekowtaylor@yahoo.com	Kwame Nkrumah University of science and Technology, Dept. of Biochemistry
Dr. Pierre K. TCHAMDJA	ptchamdja@prj.wahooas.org	WAHO
Lynette Terblanche	lynette.terblanch@merck.com	MSD (Pty) Ltd
Dr Edem Tette Tette	edemtette@hotmail.com	University of Ghana
Ralph Tettey-Amlalo	r.tetteyamlalo@gmail.com	Ashanti Atlantic
Fiona Theunissen	fiona.theunissen@conceptfoundation.org	Concept Foundation
Haytham EL Tigani	hithamtigani@gmail.com	House of Medicine & Investment
Nmaka Tijani	nmakatijani@fidson.com	Fidson Healthcare Plc
Anthony Toroitich	anthony.toroitich@igad.int	IGAD
Zerlealem Tsegaye	zerlealem8@hotmail.com	Medicine Registration And Licencing Expert
Andri A. Tsingi, MD	drflaquita@yahoo.com	Roche Products Ltd
Nana Adjoa Turkson	nturkson@phyto-riker.com.gh	PHYTO-RIKER (GIHOC) PHARMACEUTICALS LIMITED
Evans Tusubira	e2tusubira@gmail.com	National Drug Authority
Lucky Uzu Ubokor	regulatory@wwcvl.com	World Wide Commercial Ventures Ltd
Uwemedimo Udoma	uwemedimo.g.udoma@gsk.com	GlaxoSmithKline Pharmaceuticals
Ateba Ngoa Ulysse	ulysse.atebangoa@pei.de	Paul Ehrlich Institute
Farouk Umaru	fau@usp.org	US Pharmacopeia
Abiola Victor	abiola.v@nafdac.gov.ng	NAFDAC
Anders Vinther	anders.vinther@sanofi.com	Sanofi Pasteur
Chris Visser	chris.visser@ge.com	GE Healthcare
Ana Vladulescu	ana.vladulescu@amringpharma.com	AMRING FARMA
Edward Wachira	dwrdwachiran@gmail.com	Sandoz Kenya
MBECK Elie Walter	ewalterm@yahoo.fr	The University of YaoundÃ© 1
Joshua Wamboga	jwamboga@yahoo.com	Uganda Alliance of Patients'Organizations (UAPO)
Wilberforce Wanyanga	wow@pharmaqltd.com	FAPMA
Michael David WARD		World Health Organization
Mr Michael Ward	wardmi@who.int	World Health Organization
Josh Wells	drflames@yahoo.com	Novo Nordisk
Johanna Wilbard	johannawilbard@yahoo.com	Namibia Medicines Regulatory Council
Lucilo Williams	lwilliams@msh.org	Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program/Management Sciences for Health (MSH)
Claire Wingfield	cwingfield@path.org	PATH
Lorenzo WITHERSPOON	witherspoonl@who.int	UNITAID
David Woo	wood@who.int	World Health Organization

WÃ©tchirÃ© Fidelia-Rolande YAKPA	wetchirefidelia-rolande.yakpa@pfizer.com	Pfizer West Africa
Samira Yakubu	samira.yakubu64@gmail.com	Pharmacy
Mohammed Kofi Yasimo	yasimo2001@yahoo.com	Hepatitis Coalition of Ghana
Yeboah Paa Collins Yeboah	depart4christ@gmail.com	MALARIA RESEARCH CENTRE, AGOGO ASANTE AKIM
Hashim Yusufu	hashimyusufu@gmail.com	The Anaconda Consultants
Gomes da Costa Zeferina	zenhauserng@who.int	Ministerio de Saude
Gabriela ZenhÃ¤usern	zenhauserng@who.int	WHO
Dr Gabriela Zenhäusern	g.zenhaeusern@gmail.com	World Health Organization
Christine Årdal	chaa@fhi.no	Norwegian Institute of Public Health

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World Health Organization
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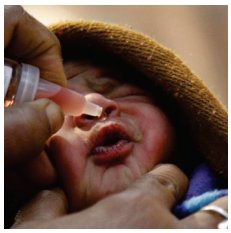

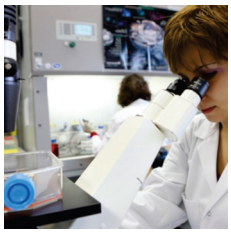

New Partnership for Africa's Development (NEPAD) Agency

230, 15th Road, Randjespark
1685, Midrand
Johannesburg,
South Africa

Email: info@nepad.org