African Union

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

World Health Organization

4th Biennial Scientific Conference on Medical Products Regulation in Africa

(SCoMRA IV)

SADC

MCAZ
Medicines Control Authority of Zimbabwe

PRIMARY HEALTH CARE · A HEALTHY NATION · MINISTRY OF HEALTH AND CHILD CARE · ZIMBABWE

AMRH
African Medicines Regulatory Harmonisation Programme

Theme: A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?

30 September – 01 October 2019
Victoria Falls, Zimbabwe

Conference Report

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

Office: +27 11 256 3600

@nepad.page

@nepad_agency

@auda_nepad

#TheAfricaWeWant

www.nepad.org

ISBN: 978-1-990962-93-6

November 2020

Recommended citation: African Union Development Agency - NEPAD, World Health Organization (WHO), Southern African Development Community (SADC), Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwean Ministry of Health and Child Care, African Medicines Regulatory Harmonisation Programme (AMRH) 2020, Innovative Finance for a Resilient Africa: Financing solutions for the continent, NPCA, Midrand, South Africa.

Table of CONTENTS

Message
from the Organisers

Every two years, the Scientific Conference on Medical Products Regulation in Africa (SCoMRA) brings together in an exciting and unique way the international regulatory community focused on improving public health outcomes in Africa.

We were thrilled to have organized this fourth SCoMRA – held in Victoria Falls, Zimbabwe in October 2019 - which marked a decade of regulatory harmonization in Africa and brought together the participants from all over Africa and across the globe to discuss the progress on the continent during this time.

The success of any conference depends on the active participation of the people who attended and we therefore thank each person who made the time to attend, present and discuss the content, whether as a delegate or as a sponsoring partner.

Regulation of medical products today requires, more than ever, a multi-disciplinary, multi-country, partnership-based approach. No single agency can work alone to cover the full range of regulatory functions that are needed to provide a comprehensive basket of essential medicines to a country and its people. At SCoMRA IV, by bringing together practitioners from all over Africa and beyond, we have continued to create and develop a platform for achieving our ultimate goal: equitable access to essential medicines. We are all members of an important cadre of professionals who care passionately about patients and the attainment of health and well-being for all. No matter which country we come from, our challenges are similar.

Through the multiple high quality presentations that were delivered and the social events, the conference always brings an optimism and confidence that lifts the spirits of those working hard to strengthen regulatory systems and focuses minds on the longer-term strategic opportunities that await the continent.

Among those opportunities are the development of a continent-wide regulatory body – an African Medicines Agency or AMA - to support and advance the regional efforts that have evolved within the African Medicines Regulatory Harmonization initiative (AMRH). This was set out in the AMA Treaty that was endorsed by all members of the African Union.

At SCoMRA IV, drawing on what we have learned over the last decade of regional regulatory harmonization in Africa, we endeavoured to bring that evolving vision of the AMA to its stakeholders, who will be its life-blood both on the demand and the supply sides. We aimed too to listen to feedback about this vision and about how the AMRH should evolve to support countries and regions in their efforts. More than ever before, we have been able to debate some of the solutions to ongoing challenges in medical products regulation, and how a continental agency could realistically address these.

Taking part in the event gave participants from thirty seven countries a truly unique opportunity to share ideas and lessons learned and improve the way in which they take forward regulatory systems strengthening.

Houda Langar (WHO AFRO) and Diadie Maiga (WHO EMRO) summarized the key recommendations coming out of the conference, as follows:

> NMRAs, RECs and Partners should facilitate collaboration between regulators, researchers, academia and the industry with a view to improve capacity for regulation of medical products and drug discovery on the continent.

> NMRAs and RECs should strengthen regional collaboration on pre-and post-marketing safety and quality surveillance (PMS) programs for promotion of patient safety and the fight against sub-standard and falsified (SF) medicines.

> NMRAs and RECs should improve regulatory review processes for marketing authorization and clinical trials by employing tools such as the eCTD/ harmonised CTD/ eCTD and measure the function of these in order to make ongoing improvements by using tools such as the WHO Global Benchmarking Tool (GBT), AMRH Indicators and Optimising Efficiency in Regulatory Science (OpERA) Program. These will support consistency, efficiency, transparency and predictability.

> NMRAs, RECs and Partners should develop business case and advocate for investment in regulatory systems strengthening, harmonization and convergence to sustain the AMRH efforts as a foundation of the African Medicines Agency.

> NMRAs and RECs should adopt and adapt the Global Curriculum and competency framework by learning from countries that are already utilizing it with a view to ensure production of credible and reliable regulatory workforce in Africa.

- Heads of NMRAs and Executive Secretaries of regional economic communities (RECs) should engage Ministers of Health, Ministers of Foreign Affairs and Parliamentarians to facilitate the signing and ratification of the Treaty for establishment of the African Medicines Agency (AMA).
- African Union Commission (AUC), AUDA-NEPAD and WHO should advocate for investment in regulatory science; facilitate adoption of regulatory tools and assist AU Member States in the signing and ratification of the AMA Treaty.

African Union Commission (AUC), AUDA-NEPAD and WHO should advocate for investment in regulatory science; facilitate adoption of regulatory tools and assist AU Member States in the signing and ratification of the AMA Treaty.

The major outcomes from SCoMRA IV were presented to the 6th African Medicines Regulatory Conference (AMRC), which operated as the AMRH Assembly for the first time following the review of the AMRH Governance Structure in 2017. This was a momentous opportunity for all Heads of Agencies in Africa to discuss key strategic questions and reflect on feedback from SCoMRA IV, including surrounding the AMA.

On behalf of the SCoMRA Organizing Committee, we therefore thank everyone who came to SCoMRA IV for enabling this important learning and feedback to take place. We look forward to seeing you again in 2021.

Margareth Ndomondo-Sigonda
Head of health programs, AUDA-NEPAD
Chair of SCoMRA IV Organizing Committee

Mme Gugu Mahlangu
DG-MCAZ
Co-Chair & Host

Members of **SCoMRA IV** Conference Organizing Committee

Scientific Committee

1.	David Mukanga (Bill and Melinda Gates Foundation – Chair)
2.	Tariro Sithole (Medicines Control Authority of Zimbabwe – Member)
3.	Dexter Tagwireyi (University of Zimbabwe – Member)
4.	Ossy Kasilo (WHO AFRO – Member)
5.	Sarah Adam (IFPMA)
6.	John Mwangi (IFPMA)
7.	Nevena Miletic (IFPMA)
8.	Paul Tanui (AUDA-NEPAD)

Continental Organizing Committee

1.	Margareth Ndomondo-Sigonda (Chair & AUDA-NEPAD)
2.	Nevena Milisavljevic (IFPMA)
3.	Ossy Kasilo (WHO AFRO)
4.	Samvel Azatyan (WHO)
5.	Mike Ward (WHO)
6.	Tariro Makamure (MCAZ)
7.	Brian Ngandu (AUDA-NEPAD)
8.	Chimwemwe Chamdimba (AUDA-NEPAD)
9.	Vanessa Msengezi (AUDA-NEPAD)
10.	Nancy Ngum (AUDA-NEPAD)
11.	Buhle Hlatshwayo (AUDA-NEPAD)
12.	Rachelle Harris (Bill and Melinda Gates Foundation)
13.	Ann Fortin (WHO AFRO)
14.	Diadie Maiga (WHO AFRO)
15.	Kim Eun Mi (WHO AFRO)

Local Organizing Committee

1.	Gugu Mahlangu (Chair & Medicines Control Authority of Zimbabwe - MCAZ)
2.	Shingai Gwatidzo (MCAZ)
3.	Fundo Tembo (MCAZ)
4.	Stanley Sanyanga (MCAZ)
5.	Joshua Govere (MCAZ)
6.	Lerato Makhurane (MCAZ)
7.	Maria Mudzudzu (MCAZ)
8.	Pauline Takawira (MCAZ)
9.	Malvern Gabaza (MCAZ)
10.	Charity Mutsata (MCAZ)
11.	Rosemary Hare (MCAZ)

List of **Acronyms**

ABRF	African Blood Regulators Forum
ADR	Adverse Drug Reaction
AMA	African Medicines Agency
AMA/UMU	Arab Maghreb Union
AMDF	African Medical Devices Forum
AMQF	African Medicines Quality Forum
AMRC	African Medicines Regulators Conference
AMRH	African Medicines Regulatory Harmonization
ARV	Anti-retrovirals
ACFTA	African Continental Free Trade Area
API	Active Pharmaceutical Ingredient
AU	African Union
AUC	African Union Commission
AUDA-NEPAD	African Union Development Agency - New Partnership for Africa's Development
AVAREF	African Vaccine Regulatory Forum
BMGF	Bill & Melinda Gates Foundation
BoMRA	Botswana Medicines Regulatory Authority
BPharm	German Federal Institute for Drugs and Medical Devices
CENSAD	Community of Sahel-Saharan States
CHMP	Committee for Medicinal Products for Human Use (EMA)
CIRS	Centre for Innovation in Regulatory Science
CMC	Chemistry, Manufacturing and Controls
COMESA	Common Market for Eastern and Southern Africa
CTA	Clinical Trials Application
CTD	Common Technical Document
DfID	UK Department for International Development
EAC	East African Community
ECCAS	Economic Community of Central African States
ECOWAS	Economic Community of West African States
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
GBT	WHO Global Benchmarking Tool
GMP	WHO Good Manufacturing Practice
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IGAD	Intergovernmental Authority on Development
IND	Innovative New Drug
ISO	International Organization for Standardization
LMHRA	Liberia Medicines and Health Products Regulatory Authority
MCAZ	Medicines Control Authority of Zimbabwe
NAFDAC	National Agency for Food and Drug Administration and Control
NCQACL	National Condom Quality Assurance Control Laboratories
NDA	New drug application
NMQCL	National Medicines Quality Control Laboratories
OTC	Over the Counter
PANDRH	Pan American Network for Drug Regulatory Harmonization
PAP	Pan African Parliament
PATH	Program For Appropriate Technologies in Health
PEI	Paul Ehrlich Institute
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PMS	Post Marketing Surveillance
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RCORE	Regional Centre of Regulatory Excellence
REC	Regional Economic Community
RSL	Remaining product Shelf-Life
SADC	Southern African Development Community
SF	Sub-standard and Falsified medical products
TB	Tuberculosis
TMDA	Tanzania Medicines and Medical Devices Authority
TWG	Technical Working Group of the AMRH
USAID	United States Agency for International Development
US FDA	US Food and Drug Administration
USP	United States Pharmacopeia
WHO	World Health Organization
WHO AFRO	WHO Africa Regional Office
WHO EMRO	WHO Eastern Mediterranean Regional Office
WHO PQ	WHO prequalification
WHO PQP	WHO Prequalification of Medicines Program

SCoMRA IV
Conference Sessions

1. Introduction

African countries made a bold decision in 2009 to harmonize regulation of medical products with an overall goal of strengthening regulatory systems on the continent. Following this decision, the African Medicines Regulatory Harmonization (AMRH) initiative was launched to facilitate the creation of an enabling regulatory environment for pharmaceutical sector development in Africa through harmonization and alignment of regulation in the Regional Economic Communities (RECs). The ultimate vision is for African populations to access quality, safe and efficacious essential medical products and technologies as enshrined in the African Union Policy Framework on Pharmaceutical Manufacturing Plan for Africa (PMPA). Through harmonization, the regulatory capacity challenges that the continent is facing that impede access to quality medical products and technologies will be surmounted.

The AMRH has over the last ten years (2009-2019) made a significant difference in strengthening regulatory systems in Africa. The initiative focuses on addressing gaps in regulatory capacity at national and regional levels, including weak or non-coherent legislative frameworks, sluggish medicine registration processes and subsequent delayed approval decision, inefficiency and limited technical capacity, inconsistent regulatory processes, and variable technical standards and guidelines that do not meet international standards among others.

The work of AMRH is guided by three focus areas: (a) policy alignment (b) regional integration and harmonization (c) and human and institutional capacity development. AMRH achieves these through implementation of Medicines Regulatory Harmonization (MRH) projects at regional level through the RECs and Regional Health Organizations (RHOs) across the continent of Africa. The approach benefits AU Member States by providing guidance to National Medicines Regulatory Agencies (NMRAs) to determine priority areas of action for medicines regulatory strengthening and harmonization in Africa.

In order to promote effective medicines regulation, ensure quality, safety and efficacy of medicines and facilitate information exchange between medicines regulators in Africa, the World Health Organization (WHO) organized the first African Medicines Regulators Conference (AMRC) in Addis Ababa, Ethiopia in 2005 covering the 46 Sub-Saharan countries. The second AMRC was jointly organized by WHO, the NEPAD Agency and the Ministry of Health of Mozambique from 24 to 26 November 2009. In recognition of the need to bring together all the AU Member States NMRAs (including those in the WHO-EMRO region), the WHO, NEPAD Agency and the Republic of South Africa, convened the third AMRC in December 2013.

The Biennial Scientific Conference on Medicines Regulation in Africa (SCoMRA) has been held every two years since 2013 as a means for stakeholders' to input into the AMRC deliberations and decision-making process. While the former brings together policy makers, regulators, industry, academia, research organizations and scientists to network and exchange information on innovative approaches for pharmaceutical sector development in Africa, the latter is solely dedicated to African Regulators and their respective RECs. It is against this background, that the African Union Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) held in Addis Ababa, Ethiopia in April 2015, in recognition of the need of convening all the AU Member States, adopted a decision to 'institutionalize the biennial AMRC as a platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision making processes'.

The AMRC has been institutionalized in the AU Structures and brings together all AU Member States NMRAs to deliberate on issues of common interest and concern. SCoMRA also makes recommendations to the AMRC as a technical organ of the AU to discuss, approve and endorse recommendations emanating from SCoMRA for further consideration by the Policy Organs of the AU. There is equally feedback from AMRC to SCoMRA on progress and challenges in regulatory systems strengthening in Africa.

The third SCoMRA held in Ghana in 2017 was convened under the theme: "Sustaining the Momentum for Regulatory Harmonization in Africa". As a follow-up, the fourth SCoMRA (IV) was held in Victoria Falls, Zimbabwe from 30th September - 1st October 2019 with the theme: "A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?"

The overall goal of SCoMRA IV was to stimulate discussion on progress made over the last decade of regulatory harmonization and alignment of regulatory networks, identify regulatory challenges facing Africa and lessons learnt, and propose to the AMRC the path forward for the next decade with a special focus on the new African Medicines Agency (AMA). The following were the objectives of SCoMRA IV:

> To review progress, identify challenges and lessons learnt in the implementation of AMRH, and the alignment of various regulatory networks and forums within AMRH.

> To serve as a platform for African Regulators to share results on regulatory practice operational research with a view to provide evidence-based policy and decision making.

> To review methods and new approaches for measuring regulatory outcomes and progress of harmonization, and regulation through reliance.

>

- To facilitate discussions on the role of NMRAs, RECs, the AMRH Partnership Platform, and other stakeholders in advancing regional and continental harmonization agenda.
- To discuss AMA's value proposition and operating model.

The conference was attended by over 230 participants including policy makers from ministries of health, finance, trade and industry and others; regulators from NMRAs in Africa; regulators from other NMRAs partnering with Africa; members of Ethics Committees/Institutional Review Boards (IRB); Clinical Trials sponsors; industry representatives; WHO and other AMRH partners and other non-AMRH partners involved in regulatory work in Africa; stakeholders involved in other aspects of medical products regulations including control of food and cosmetics and control of narcotics and psychotropic substances; representatives from RECs; researchers; academia; development partners involved in the health and pharmaceutical sectors in Africa; legislatures including national parliaments, regional parliaments and the Pan African Parliament; patient organizations; and other relevant stakeholders.

2. Opening Session

Margareth Ndomondo-Sigonda, AUDA-NEPAD and Ann Fortin, WHO Regional Office for Africa, welcomed participants and thanked the host country, the Republic of Zimbabwe and as well as the partners including but not limited to WB, IFPMA, BMGF, WHO for their valuable contribution to the organization and conduct of the conference. The organizing committee was recognized for the hard work done for the preparation of the conference. In her introductory remarks, Margareth Ndomondo-Sigonda reflected on the three preceding SCoMRA conferences held respectively in 2013 in South Africa, in 2015 in Ethiopia, and in 2017 in Ghana and introduced the theme of the fourth conference: "A Decade of Regulatory Harmonization in Africa: Where Are We? Where Do We Go from Here?"

Outlining SCoMRA's place and its role in the continental efforts for regulatory harmonization in Africa, Ndomondo-Sigonda emphasized that it feeds into the African Medicine Regulators Conference (AMRC) to be held on 2 - 4 October 2019, which will review the conference recommendations. Participants were invited to share their experiences, views and ideas contributing to the fruitful discussions in the plenary and parallel sessions.

2.1. Welcome Remarks - Alex Ntale Gasasira, WHO Representative to Republic of Zimbabwe

In the welcome remarks WHO Representative and Head of Country office welcomed participants and thanked the host country emphasizing on the importance of health systems strengthening for attaining of the Universal Health Coverage (UHC) and evoking Zimbabwe's commitment including its recent confirmation at the 2019 United Nations General Assembly.

Stanley Midair delivered welcome remarks on behalf of Alex Gasasira, WHO Representative and Head of the Country Office. He touched on the participation of Zimbabwe in the United Nations General Assembly and called for strengthening health systems towards achievement of the Universal Health Coverage. The performance of the pharmaceutical sector, as a contributor to UHC, would be measured against two sets of indicators, including 1) the level of access to essential medical products by patients in Africa and 2) the quality, safety and efficacy of the products that are supplied.

2.2. Official opening - H.E. Dr. Obadiah Moyo, Minister of Health and Child Care, Republic of Zimbabwe

Dr. Obadiah Moyo, Honorable Minister of Health & Childcare, Republic of Zimbabwe outlined the priority for primary healthcare strengthening on the road toward the Universal Health Coverage. Dr. Moyo highlighted the important role of learning, adaptation and reliance. With a long-standing commitment to medicines regulation dating back to 1969 he highlighted that Zimbabwe can share its experience with other countries, including through SCoMRA and the establishment of the African Medicines Agency (AMA).

Dr. Moyo discussed a case of efficient healthcare delivery, evoking Chitungwiza Central Hospital as a health institution where access to and affordability of care was institutionally supported with a quality system to ensure health outcomes, being certified in accordance with ISO standards. The key to the success of this hospital has been the collaboration between the public and the private sectors and the Honorable Minister recommended this model as an efficient example of healthcare organization, particularly at the primary level.

Dr. Moyo emphasized the critical role of pharmaceuticals in assuring good health outcomes and contributing to the effectiveness of health systems, which in turn helps to retain staff in the country. Recalling the theme of SCoMRA IV, Dr. Moyo emphasized the importance of reliance on regulatory review outcomes as a means of reducing barriers to access and facilitating quicker access to life-saving essential medical products. He urged the audience to leverage technologies for the fast-track registration of medical products to strengthen primary healthcare systems and support attainment of UHC, the two priorities of the Ministry.

Reflecting on previous Scientific Conferences, the Minister underlined the importance of the local pharmaceutical manufacturing sector and the need for capacity, resources and bold action from the health sector, including the regulatory authorities and the AMRH program initiated 10 years ago. He emphasized that it was critical to plan the next steps towards the establishment of the AMA and, cited Zimbabwe's ISO certification, WHO Pre-Qualification status and its leading role in Zazibona and the AMRH. Dr. Moyo offered Zimbabwe's support in creation of the AMA.

Benchmarking, replication and adjustment to own needs is a creative process, and the Hon. Minister encouraged this process for all engaged in regulatory harmonization.

2.3. Kelly Chibale, University of Cape Town: Viewing medicine discovery, development and approval as a continuum: the role of regulatory harmonization in Africa for better outcomes

Professor Kelly Chibale from the University of Cape Town delivered the keynote address.

As host to 15% of the world's population and a substantial burden of communicable and non-communicable diseases, Africa lags behind in the global health research and development (R&D) effort. This translates into economic losses, increased costs, low affordability and availability of essential medicines and ultimately, poor health outcomes.

Barriers such as long, unaligned and unpredictable regulatory procedures and requirements need to be addressed. Regulatory harmonization and convergence have a significant role to play to improve the situation, bringing together regulators, academics and the private sector to create opportunities to train specialists and increase capacity. Harmonization also supports the conduct of pre-clinical and clinical trials, simultaneously improving the attractiveness of Africa for R&D investment and addressing the health needs specific to the region.

A great many lives are at stake if the continent does not harmonize medical product regulatory systems. Lack of harmonization leads to (i) poor health outcomes for patients; (ii) high cost of medicines; and (iii) economic losses due to limited investment in pharmaceuticals on the continent. Regulatory success in Africa, in turn, is highly dependent on harmonization and convergence.

There are multiple challenges along the R&D value chain (Figure 1) and it takes a long time to discover and develop medicines that end up with the patient (Figure 2). Each step from discovery to marketing takes time and enhanced regulatory capacity is needed - including in clinical trials approvals, product registrations and marketing authorizations and post-marketing surveillance - to ensure that timelines are reduced so that African patients have fewer delays in accessing essential, high quality medical products.

Figure 1: *The R&D Value Chain*

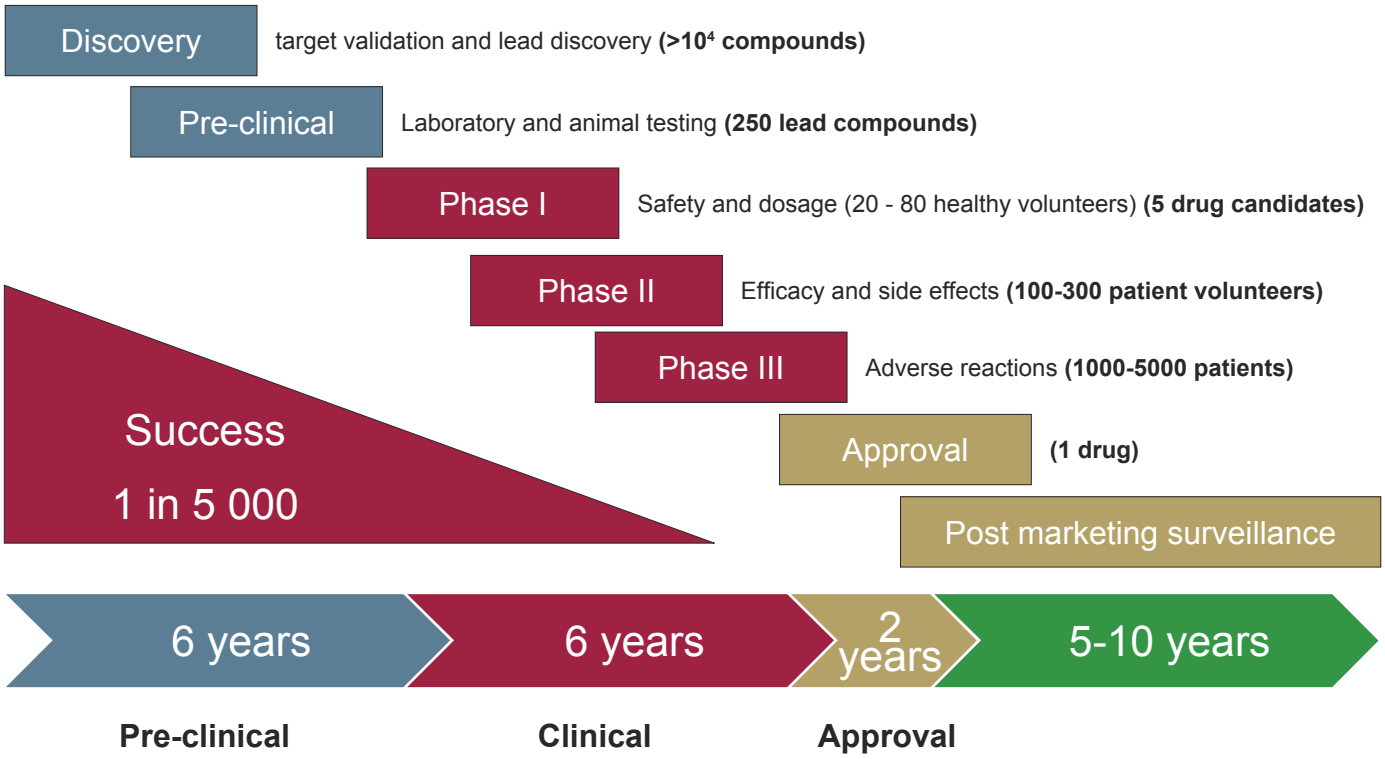


Figure 2: *The drug discovery & development process*

More effective and coordinated regulation across the whole value R&D chain could enable Africa to become more independent in addressing its people's health challenges. To-date, African countries have not yet become an attractive pharmaceutical R&D destination and this is partly due to long timelines for review clinical trial applications, unpredictable processes and lack of capacity. Conducting multi-country clinical trials in Africa is challenging, mainly due to a high level of variation in regulatory requirements in the different countries. The lack of local demand for local clinical trial data before market approval has reduced incentives for originator companies to conduct trials on the continent and, consequently, less than 2% of global clinical trials take place in Africa. This has undermined the strength of the African perspective on medicines entering the market, including intrinsic factors such as genetics, and extrinsic factors such as the practice of medicine on the continent. The low volume of clinical trials on the continent also means that there is no pre-clinical discovery tool for prioritizing African patients as medicines are studied based on other populations. .

The following recommendations are pertinent:

> Learn from each other to identify, adapt and adopt efficient models.

> Build partnerships and ecosystems among the key stakeholders for improved efficiency of health systems in general and medical product regulation in particular.

> Use and mobilize resources efficiently and effectively to build an environment conducive to professional excellence.

> Capitalize primary care in order to attain commitments on the UHC.

> Improve the environment for the conduct of preclinical and clinical trials, adopting science-based and data driven approaches to the research and development of medical products.

> Increase collaboration between regulators, researchers, academia and industry to improve capacity for regulation and drug discovery on the continent. Focus on the next generation in order to achieve long-term sustainable benefits.

- Re-think the review process, which needs to be underpinned by science and data for regulators to make evidence-based decisions.
- Acquire the necessary skills to leapfrog and take advantage of innovations in medicines discovery and development.
- Shorten time lines and bring efficiencies into the R&D and delivery system to make the African market attractive to pharmaceutical development investment.
- Foster harmonization and coordinated efforts in order to ensure efficiency and timely launch of products that respond to the needs of the African population.
- Rely on the outcomes of other regulators and leverage their technologies & innovation.

2.4. High-Level Plenary: A Decade of Regulatory Harmonization in Africa: Where are we? Where do we go from here?

Aggrey Ambali, Director for Technical Cooperation and Program Funding, Africa Union Development Agency (AUDA-NEPAD) indicated that as an initial step in the regulatory harmonization process, WHO and AUDA-NEPAD, conducted a number of studies that have provided the initial landscape of prevailing capacity gaps in Africa. At that point, the continent faced a high degree of variation in regulatory capacities. The launch of the AMRH Initiative in 2009, a partnership between AUDA-NEPAD and the Pan African Parliament (PAP), WHO, Bill and Melinda Gates Foundation (BMGF), UK Department for International Development (DFID), RECs and NMRAs, marked an intention to map and agree on the way forward.

Through RECs regional treaties, the NMRAs have started taking initial steps towards, and reinforced the need for medical products regulatory harmonization. There has been wide agreement across the continent that collaboration is needed to harness these initial efforts to push the harmonization agenda, starting with medicines registration and marketing authorization and later expanding to other regulatory functions and products. Specific milestones to-date have included the adoption and implementation of harmonized guidelines at the regional level, adoption and domestication of instruments such as the AU Model Law on Medical Product Regulation and institutional governance frameworks such as the treaty for the establishment of the AMA. Prof. Aggrey acknowledged the importance of these instruments for sustaining the harmonization effort in Africa.

Medical product regulatory harmonization efforts directly contribute to the AU development agenda set out in Agenda 2063. The First ten-year implementation plan of the Agenda 2063 identifies the establishment of AMA and the adoption of the African Continental Free Trade Area (AfCFTA) in 2017 as contributors to Agenda 2063: AMRH and AMA are key enablers for creating essential regional standards that will facilitate trade in medical products under the AfCFTA framework. Building the capacity of African regulators is thus essential for ensuring proper regulation of the African market for medical products and health technologies and AUDA-NEPAD plays a key role in supporting and enabling these efforts.

Dan Hartman, Director, Integrated Development, Global Health, Bill and Melinda Gates Foundation (BMGF) discussed the journey of harmonization in Africa to-date and the notable progress made in the last decade.

The global regulatory community has realized that no agency can undertake all regulatory functions on their own, making a collaborative, network-based, reliance model essential for all. Convergence is becoming a global practice.

The BMGF focuses on improving lives and the health and well-being of people in most need. Studies commissioned by the BMGF in 2009 and 2013 highlighted long registration timelines for approval. This prompted investment in the AMRH as an intervention to address the issue through a reliance and work-sharing process.

The AMRH is on the front line of the effort on the continent. AMRH progress has included technical alignment in the RECs, the successful certification of the Tanzanian Medicines and Medical Devices Authority (TMDA) at Maturity Level 3, and the AU endorsement of the treaty of AMA, which has the potential to transform the regulatory landscape and human health on the continent. AMRH has also achieved 50% reduction in registration timelines in some cases. With respect to clinical trials, the African Vaccines Regulatory Forum (AVAREF) has achieved timeline reductions for trials approvals from 3.5 years to 60 days.

We need to ensure continued leadership, local ownership and momentum at all levels in order to sustain progress. To have really improved access to quality essential medicines by Africans, we need to focus on translating regional registration efficiencies into benefits at national level. Technical harmonization is only of value if regional activities lead to beneficial national outcomes.

AMA is an exciting part of the future. It is founded on the AMRH and will only be as strong as the RECs are, highlighting the ongoing need to strengthen regional harmonization. Conference participants are urged to continue building the case, getting feedback and improving and offered BMGF partnership in moving forward.

Mike Ward, World Health Organization emphasized that functioning health care systems are underpinned by good regulatory systems. Regulatory system strengthening in Africa has seen the following progress:

> AVAREF's has provided guidance and reduced clinical trial application review timelines

> Countries are now exercising some form of reliance

> Regional joint assessments are underway

> A growing pool of regulatory expertise exists in Africa

> A Monitoring & Evaluation (M&E) framework has been developed to measure success

> AMRH Technical Working Groups (TWGs) are being evolved

> AMRH's new governance structure will see AMRC as a strategic policy platform informed by TWGs

Regulatory harmonization is a journey that has had many successes. Looking forward, the review processes that have so far been developed need to be optimized to progress towards AMA. TMDA's ability to reach Maturity Level 3 has played an important role in improving regional performance. Regional joint activities are now translating into national decisions and AMRH is extending to cover a wider range of medical products beyond generic essential medicines. The intention is for the AMRH and the AMA to support all 55 AU member states and this will require the concerted efforts of key stakeholders, including regulators, academia, industry and RECs.

Christianah Mojisola Adeyeye, Director General NAFDAC & Chairperson AMRH Steering Committee outlined NAFDAC's progress to-date. NAFDAC's success depends heavily on reliance, joint inspections and assessment at the regional level. She noted that there was a backlog of 6,000 applications when she joined NAFDAC, and that this presented an urgent need for change.

NAFDAC became involved in seven Technical Working Groups in the West African Medicines Regulatory Harmonization project. She noted that the West Africa Harmonization program is getting stronger and this is aided by investments in internal NMRA capacity. In this regard, NADFAC's investment into Quality Management System ISO certification, a WHO-guided internal benchmarking exercise and a structured approach to staff training and capacity development for GMP inspection, supported by WHO and UNIDO and leading to industry inspections in 165 companies and an ability to rank firms and plan for capacity building. Clear benefits of AMRH for NAFDAC have also included improvement to clinical trials approval timelines and improved collaboration between NAFDAC and ethics committees as well as strengthening of Post Marketing Surveillance (PMS).

Several milestones have been achieved including the implementation of seven expert working groups to develop guidelines; NMRAs converging; clear registration pathways; an agreed list of product eligible for harmonized review; call sent out, joint dossier assessment and joint inspections; and establishment of legal and policy frameworks, but there is still a distance to go.

AMRH is a precursor for the AMA, whose success would increase access to quality medicines through harmonization, reduced registration times and improved capacity. Partnerships with the private sector are getting stronger and AMA will support Africa to become a hub for quality medicines. Fundamentally the regions (RECs) are the basis for the AMA. AMA's implementation will take careful planning.

Emer Cooke, Director Regulation of Medicines and other Health Technologies, World Health Organization underlined that WHO is supporting AMRH as it transitions to AMA in a variety of ways, including developing and refining the governance and organizational arrangements of the AMRH. WHO has also helped to create a number of continental Technical Working Groups (TWGs) that will ensure consistency and develop the necessary expertise. Technical support is also being offered in the areas of benchmarking, joint assessment and inspection activities; development of the TWGs and the AMRH Partnership Platform as a means of coordinating resources and expertise.

Looking forward, the following actions for AMRH and AMA are proposed:

> Align AU development agenda, including Agenda 2063

> Ensure NMRAs take leadership in sustaining the harmonization process as we move towards AMA

> Build strategic partnerships to ensure successful realization of the harmonization agenda

3. Plenary Session I: AMRH Implementation – progress, lessons, challenges

Session Co-Chairs: Dan Hartman & Dexter Tagwireyi

The main objective of Plenary Session I was to review implementation of the AMRH by highlighting the major areas of progress, lessons learnt and challenges faced including mitigating actions, and the alignment of various regulatory networks and forums within AMRH to-date. The four speakers agreed that there have been tremendous changes in harmonizing medical product regulations and regulatory system strengthening in recent years.

Global context of harmonization and innovative models: Mike Ward, WHO

Building regulatory capacity in Member States, consistent with good regulatory practices, continues to be essential. Strategies in improving regulatory systems and practices through regulatory cooperation, convergence and transparency are all evolving. These will be enabled through networking, work-sharing and reliance on competent NMRAs for decision-making. All these areas are continued priorities for WHO.

AMRH Program: Continental Progress Update: Margareth Ndomondo-Sigonda, AUDA-NEPAD

The major achievements of the AMRH to-date have been 1) the establishment of the AMRH governance framework; 2) regulatory capacity building (11 designated Regional Centers of Regulatory Excellence (RCOREs), guidance and training in Marketing Authorization, Good Manufacturing Process (GMP) inspection & Clinical trial oversight); 3) adoption by 17 AU Member states of the African Model Law on medical products and regulations; 4) increased number of NMRAs with ISO 9001,2015 certification; 5) shorter approval timelines for product assured through RECs. The AMRH Governance Structure has been updated, to improve the way in which the various elements relate, including the AMRC, AMRH Steering Committee, Continental Technical Working Groups, AUC-NEPAD Joint Secretariat, and AMRH Partnership Platform. National regulatory capacities, frameworks and guidelines are still insufficient in some NMRAs, so building technical capacity and resources for sustainability will be essential in the development of the AMA.

More political and financial support is needed for these activities, requiring the development of solid business cases that can be presented to politicians with access to influence and resources. This will rely on advocacy for regulatory systems strengthening and harmonization to the generate political needed to sustain the AMRH effort.

WHO benchmarking of regulatory systems – Updates and implications for Africa: Hiiti Sillo, WHO

WHO works with partners to address regulatory capacity gaps and WHO also provides technical capacity building training support to countries. Progress has included the roll-out of the WHO Global Benchmarking Tool (GBT), the WHO Five Step Capacity Building Model for NMRAs used to respond to the recommendations coming from the WHO GBT, and the self-assessment process undertaken prior to the WHO country visit for the GBT assessment.

More than seventy (70) countries have gone through the GBT process. Thirteen (13) SADC countries have conducted the GBT self-benchmarking. An important component is the need for regional platforms such as the RECs or RHOs to follow-up with the implementation plan that follows the assessments to address issues regionally.

Some of the key achievements to-date include two formal GBT assessments in 2018, three in 2019, with three or four countries to be assessed in 2020); and the graduation of TMDA to Maturity Level 3 making it eligible to become a WHO-Listed Authority (WLA).

Building the Medicines Quality Control Capacities in Africa: Where are we? Karim Smine (United States Pharmacopoeia, USP)

Work by USP to support Quality Control (QC) systems strengthening support in Africa has emphasized improving national quality control laboratories. There has been an increase in internationally recognized laboratories since 2009 and state ownership and strong commitment have been important for success. Laboratory collaboration and inter-laboratory training have been significant in this effort. The African Medicines Quality Forum (AMQF), has become a platform for member states to share information that can help improve national quality control labs and overcoming challenges such as i) unclear mandate of QC labs within health systems, ii) limited human & financial resources to support NMQCLs systems strengthening, iii) lack of financial and management autonomy of NMQCLs rendering maintenance of quality systems unsustainable, iv) traditionally weak role of the NMQCL in market surveillance of medicines and v) fragmentation of regulatory functions within different government institutions.

Looking ahead, NMRAs should help determine which model will suit the country such that it can support product registration, market surveillance and testing to support public health. WHO confirmed that Quality Management System is integral to the WHO GBT and that QC laboratories are inherent within this.

Recommendations from Plenary I

> Culture should not be a barrier to harmonization and convergence. It is important to focus on common issues that go beyond the cultural differences because quality medicines are needed by everyone and are a priority for public health and well-being.

> To progress harmonization and convergence and adoption of the AU the Model Law, it is important to develop business cases that make the case and that can persuade policy makers and decision makers.

> Political will, ongoing feedback and lesson learning are all important for the harmonization effort.

4. Plenary Session II: AMRH Implementation – progress, lessons, challenges

Session Co-Chairs: Vincent Ahonkhai & Sarah Adam

This Plenary session aimed to review progress, identify challenges and lessons learnt in the implementation of AMRH from regional, country and individual presenters' perspectives.

East Africa: The East African Community Joint Assessment Procedure - Achievements, Challenges and Way Forward: Shani Maboko (Tanzania Medicines and Medical Devices Authority, TMDA)

The EAC joint assessment procedure was initiated in 2017 with seven NMRAs (represented by six countries). The TMDA (formerly the Tanzanian Food and Drug Authority or TFDA) has been the designated lead for the joint assessment procedure and remains so until the dossier is accepted. As part of the AMRH, the EAC joint assessment procedure aims to build on five specific objectives, as follows: (i) harmonize technical requirements; (ii) promote collaboration convergence and reliance; (iii) provide a platform for sharing regulatory information; (iv) strengthen regulatory systems of EAC partner states; and (v) promote capacity building and training.

The program's progress so far has included the implementation of the Common Technical Document (CTD) in all NMRAs, and adoption of a set of supporting guidelines; regular joint assessment meetings have been held, with the thirteenth meeting having recently been held in August. All NMRAs now have a functional Management Information System (MIS) and a regional MIS is being developed. A number of successful training events have been conducted, covering subject matters such QMS, Medicines Evaluation and Registration (MER), exports and safety and efficacy testing.

Challenges still remain as the process evolves, and these are both technical and administrative. For example, technical bottlenecks have slowed down the assessment procedure; poor quality submissions and delays in submission of query applications have been noted; there have been a relatively limited number of applications; applicants have not been willing to pay in all partner states; human resources still remain constrained; and financial sustainability is not yet assured.

Metrics to support Monitoring and Evaluation (M&E) efforts have been developed to monitor regulator and manufacturers' timelines. Efforts have also been made to increase applications and reduce regulator-processing times from 372 to 202 days and manufacturers' time processing time to 170 days. There have been improvements in joint acceptance and registration (made within 30 days) as well as total assessment timelines for only 240 days (150 days for regulators and 90 days for manufacturers), a marked improvement from the original

timelines. Industry has become more responsive to NMRA requests. With all the progress achieved so far and the continuous efforts being made within the region, further improvements in the timelines are expected in the next year.

Southern Africa: ZAZIBONA GMP inspections – Upward momentum, impact & Kaizen: Washington Dengu (Medicines Control Authority of Zimbabwe, MCAZ)

The Zazibona initiative was initially comprised of 4 countries: Zambia, Zimbabwe, Botswana and Namibia. It aims to assure quality, efficacy of products marketed in SADC region, and to improve work sharing among regional regulators, promote mutual confidence (through long-term reliance), and build regulatory capacity in the region.

As of August 2019, 13 of the region's 16 countries have participated in the scheme (with the exception of Angola, Seychelles, Eswatini and Madagascar). Since 2013, bi-annual meetings have been held, with 258 products assessed and 181 products finalized (with 59% products receiving a positive response and 16% negative response). Four joint inspections have been conducted each year, since 2014, with 19 desk reviews conducted as of October 2019. Annual managers' policy meetings are also being held, as well as quarterly meetings, and annual inspectors training.

Inspections are geared towards Good Manufacturing Practices (GMP) compliance to ensure that quality medicines enter the region. There have been 38 GMP inspections conducted since September 2019. Progress in harmonizing efforts has resulted in: 1) member states participating on inspections on a rotational basis; 2) final reports submitted using an agreed format; 3) collaborative peer review and corrective and preventive actions (CAPAs); 4) further reliance on outcome of collaborative process; and 5) a full adoption of WHO GMP. One biological product has been registered, in a case where a member state could not do it alone.

ZAZIBONA is a work-sharing initiative, and not yet in a mutual recognition state. It does not therefore issue a GMP compliance certificate. Despite low uptake by local manufacturers, the process has helped improve planning and coordination in the region. The initiative has also created good networking platforms, built capacity, paved a better pathway for manufacturers, and widened the market base with many registered products. Nonetheless, there is still the need to further develop QMS, increase the scope of inspections in the future, and advance trainings for inspectors.

Complexity of Life Cycle Management and the challenges for African countries – an Industry perspective: Bunmi Femi-Oyekan (IFPMA)

Post-approval changes or variations are often made to improve manufacturing processes, including to new facilities, administrative changes, labeling or safety updates, or any unplanned changes. One change or variation of this sort can require a number of submitted dossiers, to be updated, often due to complex or heterogeneous guidelines or varying requirements. Sample requirements have also often lengthened the procedure for submission, where a variation that requires a sample leads to a lengthy approval process (12 - 23 months) in contrast to one that requires an artwork (7 - 15 months).

Harmonized guidelines would help improve or fast track approvals, speeding up availability of medicines for patients. Reliance could benefit NMRAs by reducing any duplication of effort, optimizing their allocation of resources and reducing timelines. More efficient allocation of resources could also help NMRAs prioritize areas of work with more added-value (e.g. capacity building, tackling falsification of medicines).

For industry, harmonized requirements for variations would help improve regulatory compliance, ensure continuous supply of quality medicines, and reduce regulatory burden to optimize the development of new therapies and technologies. This can be achieved by recognizing WHO as reference, adopting risk-based categorization of changes, simplifying requirements (samples vs. artworks), and adopting digital tools (electronic formats for submissions). ZAZIBONA has begun working on variations, now having a working group to address the issue. EAC has developed guidelines for variations for vaccines.

An Urgent and Strong Need for Harmonized Regulation of Biologics Including Vaccines in East African Community and Africa at large: Grant Munkwase (NDA)

There is an urgent need to harmonize regulatory requirements for complex biological products in the region, which often require a multidisciplinary approach that can be challenging for individual NMRAs, given their limited capacity and resources. This is particularly important for life threatening or rare diseases, where there are no alternative effective treatment options. Within the EAC, there are only a limited number of NMRAs with standards for acceptance criteria for biologics, given that the manufacturing processes need to be robust and highly controlled. Reflecting the challenges inherent to assessing biologics, even stringent regulatory authorities such as EMA have centralized the registration process.

Reflecting on the above, Africa should take the following actions: 1) establish a regulatory system for biologics (legal and regulatory framework, available guidelines, and experts); 2) share experiences from other RECs to accelerate harmonization of registration and variation for biologics;

3) develop a system for centralized post authorization monitoring of biologics; and 4) establish a control laboratory for testing biologics especially for vaccines for lot release. ZAZIBONA has begun working on development of a central registration process for biologics, now having a working group to address the issue. EAC has developed guidelines for biotherapeutics and vaccines.

Recommendations from Plenary II

> Identify regulatory challenges and implement solutions; and ensure that there is consistent monitoring and evaluation effort across all the regions in the continent.

> Move towards a more realistic whole lifecycle management approach (including post-approval changes and post marketing surveillance) and ensure that this encompasses all product categories (e.g. biologics and vaccines).

5. Parallel session I: The role of harmonization in pharmacovigilance and post-market surveillance

Session Co-Chairs: Karim Smine

Parallel session I aimed to enable experiences, development and innovative approaches to be shared in the areas of pharmacovigilance and Post-Marketing Surveillance (PV and PMS).

Establishing the Electronic Adverse Reporting Tool - Tanzanian Perspective: Ambele Mwafula (TMDA)

The Management Information System (MIS) is one of the powerful tools for tracking, storing, manipulating and distributing information to internal and external customers. It helps Regulatory Authorities in decision-making process. MIS solutions improve customer service delivery.

The current MIS has been in use by TMDA for the past five years. The new enhancement allows customers to submit dossier applications online. It improves the administration of the business by bringing a discipline to daily operations, as everybody is required to follow and use systems and procedures. This process brings a high degree of professionalism in the business operations. With the system TMDA can keep track of all registered products. The availability of customers and products data has also helped TMDA to align its business processes according to the needs of its customers.

TMDA, in partnership with College of Informatics and Virtual Education (CIVE) of the University of Dodoma (UDOM), has developed an Adverse Reactions electronic reporting system. This e-platform (including web-based, mobile App and USSD tools) has led to a marked improvement in adverse drug reaction (ADR) reporting. The e-ADR reporting system has generated a notable public response and a tremendous improvement in the quality of reports. Data entry timelines into the Vigiflow (the WHO system for reporting adverse reactions) have been remarkably shortened.

Impact of Structured Stimulated PV in Tertiary Hospitals - A review of Individual Case Safety Reports received at the TMDA: Kissa Mwamwitwa (Tanzania Medicines and Medical Devices Authority, TMDA)

TMDA has taken a stepwise approach to achieving transformative change in a decade. It has moved from active surveillance (2009) to patient reporting (2013), to e-ADR reporting system (2016), to developing PV regulations and PV curriculum in undergraduates (2018) and now the launch of a structured stimulated PV program (2019) at Muhimbili Tertiary hospital.

A retrospective comparative study was undertaken to investigate structured stimulated PV on ADR reporting. The impact was an increase in ADR reports, greater ability to identify and prevent medication errors, signal detection, improved healthcare service and strengthening of Muhimbili National Hospital (MNH) PV Centre. As a next step, it is recommended that a structured PV program is instituted at all tertiary hospitals inclusive of all health care workers.

MEDISAFE presentation on Falsified Medicines: Helene Degui

MEDISAFE is a voluntary initiative to check on the status of falsified anti-retrovirals (ARVs), anti-Tuberculosis and Anti-malaria medicines in 11 countries in Africa. It is in its initial stage. The website contains information on progress and next steps.

Regulatory Reliance in Reacting to Global Quality and Safety issues related to Medicines - 'The Sartan Experience in S. Africa and ZAZIBONA countries': Patience Phuti Shabangu (SAHPRA)

The objectives of this study were to identify and quantify Sartan products in South Africa and ZAZIBONA, generating a risk matrix on identified products of Sartan and ensuring that they are dealt with efficiently. The work highlights the importance of PV in ensuring product quality.

The approach was to assess all Sartan products in the countries' registries to assess the levels of unwanted N-nitrosamine impurities. N- Nitrosamine impurities were detected in Sartan products. The potential sources of impurities were reactions during manufacture or contaminated active pharmaceutical ingredients (APIs), reagents and equipment. The recommendations coming from the study are for ongoing research and assessments on possible occurrence of mutagenic, carcinogenic and genotoxic materials. Regulators should establish collaborative PV and PMS programs in the region as well as to ensure registration of APIs.

Parallel session I Recommendations:

> Reporting of ADRs by professional health workers is central for effective PV.

> All countries need to create tailor-made tools for reporting ADRs electronically, including by cellphones.

> NMRAs should initiate API registration especially for generics as this area is neglected.

6. Parallel Session II: Regulation of medical devices, blood/blood products & clinical trials – where are we

Session Co-Chairs: Samvel Azatyan (WHO/HQ) and Ann Fortin (WHO/AFRO)

The objective of Parallel session II was to explore developments in the regulation of blood and blood products, vaccines and medical devices, which are critical to the achievement of the Sustainable Development Goals (SDGs) and UHC.

Regulation of Blood and Blood Products in Tanzania: The Current Progress and the Way Forward - Elirehema H. Mfinanga Person, Tanzania Medicines and Medical Devices Authority (TMDA)

The current regulatory framework including the new Tanzania Medicines and Medical Devices Authority (TMDA) sets out roles and the responsibilities of the National Blood Transfusion Services (NBTS) in the regulation of blood and blood products. Considering the challenges being faced and ambition for the future, the following steps are recommended:

> Review legislative framework for provision of blood regulatory oversight.

> Strengthen collaboration between stakeholders (NMRA and NBTS).

> Build capacity of stakeholders.

> Establish a partnership with the African Blood Regulator Forum (ABRF) to assist countries to close existing gaps.

Complexities around the Clinical Development of Novel Vaccines – an Industry perspective: Lorenz Scheppler (IFPMA)

Challenges for the clinical development of novel vaccines include (i) the sequential versus parallel review, which needs bioethics and NRAs approvals; (ii) the multiple review bodies; (iii) clinical trials approval time lines, with large differences, for example, between Europe and Africa. These challenges have an impact on the organization of clinical studies and often include a non-transparent process. It is essential to address the complexities associated with vaccine development, manufacturing processes and complex study designs. This should involve convergence, close harmonization and joint review with specialised and experienced NMRAs. AVAREF's experience in supporting approvals of the Ebola vaccine highlights the need for a call to action to develop a common global set of requirements for clinical trial applications (CTAs).

The VaccTrain/RegTrain Project: Achievements from the perspective of a partner country presented by Juwe D. Kercula (LMHRA)

Liberia faced significant challenges during the 2014-2015 Ebola outbreak, which included a lack of regulation and clinical trials. The 2017 WHO GBT self-benchmarking conducted by LMHRA with support from PEI's GHPP VaccTrain project led to the development of a strategy for regulatory capacity building, a legal framework and operational guidelines. After four country visits, the main achievements have been the establishment of a baseline, completion of an operational manual and implementation of new learning. The next phase of work will involve working towards achievement of the sub-indicators of maturity level M1 and M2.

Harmonization of Clinical Trials Regulation in Africa through African Vaccine Regulatory Network (AVAREF) - The NAFDAC Experience: Christiana Mojisola Adeyeye, NAFDAC

Clinical trials-related challenges centre on inadequate capacity and a lack of clear process. NAFDAC's collaboration with AVAREF has led to the creation of a framework for clinical trials authorization; the expedited review and registration in 2012 of inactivated polio vaccine; joint development of guidelines; joint reviews and general capacity development. It has been a good example of the benefits of collaboration and reliance.

Regulation of Medical Devices In Tanzania - What Has Been Achieved? Sunday Kisoma (TMDA)

A chronology of TMDA's regulation of medical devices was given, showing the progress of the agency between its establishment in 2009 and 2019. TMDA's medical devices unit currently performs: (i) market authorization based on a four-level risk assessment; (ii) formal registration; (iii) import and export control; (iv) post marketing surveillance (citing a collaborative local program regarding malaria rapid diagnostic test); (v) vigilance through sensitization on the need to report and a public awareness campaign; (vi) inspections through manufacturers audit; and (vii) a medical devices testing laboratory for physical and sterility testing. In terms of progress in the past decade, the number of import permits issued by TMDA has increased significantly since its establishment. 80 manufacturing sites have also been inspected, predominantly in China and India, leaving to at least six suspensions of marketing authorization and recalls. In some cases certifications had been issued without meeting minimum requirements. Kisoma observed that audit was a new concept to most manufacturers, who had place more emphasis on documentation than on GMPs. So far 142 medical device vigilance reports have been received and are available on android, leading to product recall, withdrawal of marketing authorization status and disposal where necessary.

Since 2017, TMDA's PMS activities have benefited from use of its Medical Devices Laboratory, which conducts PMS samples testing, pre-distribution testing (lot to lot) and performance evaluation on condoms, malaria rapid diagnostic tests (mRDTs), HIV kits, gloves, sutures, syringes, sanitary towels, and cannula. The agency is currently looking to expand its product scope.

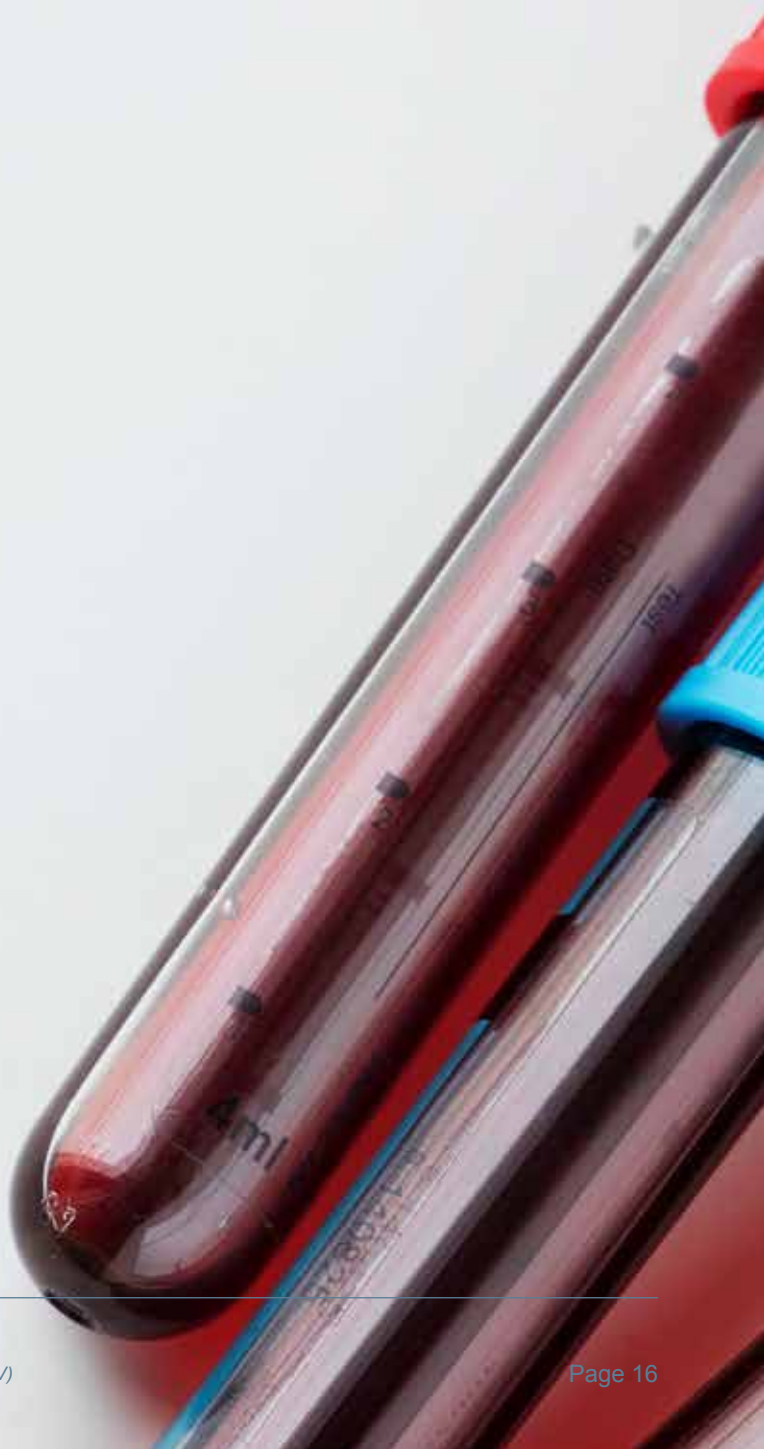
Concluding the presentation, Kisoma noted that regulation of medical devices needs investment in tools and resources as well as flexibility in adopting the tools to facilitate effective regulation. He also stated that work sharing and information exchange have been an important catalyst for developing more advanced systems. Discussions centered around the timelines for vaccine approval, the use of WHO guidelines to regulate blood and medical devices and the regulatory oversight for Clinical Trial Applications (CTAs) to ensure timely approvals on the African continent.

Parallel session II Recommendations

> Convergence, close harmonization and joint review with specialised and experienced NMRAs are essential to overcome regulatory complexities associated with vaccine development, manufacturing processes and complex study designs.

> There is a need for a call to action to develop a common global set of requirements for clinical trial applications (CTAs).

> Regulation of medical devices needs investment in tools and resources as well as flexibility in adopting the tools to facilitate effective regulation.



7. Plenary Session III: African Medicines Agency and Sustainable Financing Models

Session Co-Chairs: Gugu Mahlangu (MCAZ) & Murray Lumpkin (BMGF)

The objective of this session was to update participants on progress made in the establishment of AMA and share experiences from other regions outside Africa.

The proposed value proposition and operating model for the African Medicines Agency: Margareth Sigonda-Ndomondo, (AUDA-NEPAD)

Margareth Sigonda-Ndomondo spoke about the proposed value proposition and operating model for the AMA, presenting a theoretical framework for operating models for AMA and regional institutions. As background, the AMA Treaty was adopted by Heads of State on 11th February 2019 and should have been circulated to heads of governments for discussion and ratification by at least fifteen Member States. At the current time, five Member States have signed, but more engagement with countries is needed to encourage ratification.

Stakeholders are encouraged to speak to Ministers of Health and to be aware that there are multiple steps involved in the ratification process, including engaging Cabinets and preparing legislative tools. Given the steps required and the need for country engagement, it could be around two years to secure the fifteen ratifications.

There is a need to build consensus around the AMA operating model, its value proposition, and the roles and responsibilities of various actors, including but not limited to the AMRH stakeholders.

Key considerations and the AMA operating environment:

> An international treaty underpins continental and regional integration, but political will is essential. Countries will retain the legal power and sovereignty to adopt laws and conventions.

> The law needs to underpin integration but strong institutions and efficient enforcement must underpin supra-national integration. The EU model is interesting here as once a regional decision is adopted countries have two years to adopt these at national level.

> The basis of any model should create benefits for participants and the major stakeholders.

Some points to note when comparing regional entities such as the AU, SADC and the EAC as well as the EU:

> The regional entities of the SADC and the EAC are based on treaties. They have some limited legislative powers and are supported by a secretariat.

> Majority voting drives AU and EU decision-making, whereas consensus drives the SADC and EAC.

> In SADC, EAC and EU there is a requirement for Member States to conform to REC laws, whereas in the AU this is implied rather than mandatory.

Other examples of continental and regional arrangements were presented to draw comparisons with AMA, including the SADC Development Finance Resource Centre, a sub-regional Centre of Excellence that strengthens the SADC Development Finance Institutions, and the African Regional IP Office (ARIPO). The Harare Protocol was discussed, which enables the ARIPO office to receive and process patent and industrial design applications on behalf of the signatory States. Fees accrue to ARIPO and they split the revenues with the Member States. ARIPO complements the national IP system of the member states, with State sovereignty preserved. Flexibility and cost-saving are the main benefits for applications.

The cases highlight practical considerations and underlying principles for AMA, including:

> Benefits have to be clear to stakeholders and measurable (SMART: Specific, Measurable, Achievable, Realistic and Timebound).

> The distribution of benefits has to be carefully enumerated and split equitably.

> There may be a degree of sovereignty that would need to be surrendered.

> The system would need to be complementary to the regulatory system of the Member States.

> Users should be offered flexibility in terms of which system they use, national, regional or continental.

> Cost saving and efficiency must underpin the model, including for users.

> Membership will be voluntary and benefits can be used even if not a formal member.

> Alignment of domestic laws with the Treaty is important, using the AU Model Law as the basis.

> Clarity of roles and responsibilities and clear decision-making processes will ensure clarity of purpose and avoid power conflicts.

> Non-binding decisions at national level – binding decisions would be the exception.

> Dispute resolution mechanism within the Treaty that is easy to interpret and action.

> Capacity of the national systems is important.

> Financing will be through user fees, provision of services such as GMP inspections and innovative financing models such as taxation (e.g. tourism levies), social impact bonds or endowment funds.

> NMRAs transitioning into regulatory networks provides the basis for the AMA model.

Lessons from the EMA, and its Network of National Regulatory Authorities: Ian Hudson, former CEO of MHRA, and now consultant to BMGF on Regulatory Systems Strengthening

Europe is the continent with the greatest experience of regulatory harmonization and this may shed lessons learned for the AMA. The European Medicines Agency (EMA) (only 25 years old) is a model of shared responsibility, with each player having clear responsibilities, as follows:

> **CE:** Directives are translated at national level and support negotiation of international agreements.

> **EMA :**

- Run the procedures for the centrally authorized products (which are selected products), while most products go through the national level.
- Coordinate decisions for some activities, such as pharmacovigilance.
- Support arbitration for any dispute through the scientific committee, the CHMP, for a decision that will apply across the community.
- Coordinate inspections for the Community through an inspections service, application only for selected products.
- Issue most guidance.
- Is overseen by a Management Board that meets four times a year.

> **HMA** (Heads of Medicines Agencies):

- Coordinate the procedures that don't go through the Committee for Medicinal Products for Human Use (CHMP) / EMA committees.
- Enable discussion on policies.
- Support coordination of non-EMA procedures.

> **Member States:** Role has grown over the years.

- Provide all the scientific resource and advice for all EMA procedures.
- Enforce the rules .
- Host the inspectors and the experts for pharmacovigilance, providing to the EMA on request.
- Provide scientific advice.
- Provide legal status and classification.

Shared responsibility underpins the European model. An overarching five-year strategy for the whole network, underpinned by work plans for different components, has been developed. Standards are held consistent through a system of peer review and processes of joint inspections, review and benchmarking of each other to ensure everyone is operating to a similar standard across the network. Regular meetings across the network are very beneficial.

EMA authorization procedures are as follows:

> **Centralized Procedure:**

- Run by EMA, and focused on Innovative New Drugs (IND) – biotech products, biosimilars, new substances, and generics .
- Product is submitted and then assigned by EMA to countries.
- Rapporteur and co-rapporteur are assigned to assess from the Member States.
- Case discussed at CHMP.
- Scientific opinion produced and then transmitted to the EC as the licensing authority.

> **Decentralized Procedure:**

- Most products go through this procedure, which covers older medicines, mostly generics.
- Products submitted to a Member State with a preference expressed for an additional five countries selected to assess the product.
- National authority reviews, gives opinions, and sends consolidated list of questions to the applicant.
- Other Member States agree and a common license is issued.
- Otherwise, if there were points that can't be agreed, the case would go to arbitration.

> **Mutual Recognition:** This allows for an abbreviated procedure for national review and approval when a license has already been granted in one country.

What works well for the EMA?

> Generally, EMA is a very successful model of networking, with a good balance between the various players, and without dominance of any party. Close collaboration is key.

> Many opportunities exist for experts to work together across Working Parties (for guidance and common standards) and Committees. Technical groups reflect on issues such as big data, pharmacovigilance etc., and advise the network on how to prepare for or adapt to certain changes that are coming.

> Helps with being able to tap into resource and scientific expertise across the EU.

> Member States play a key role, which is increasing. They provide communications with national populations on safety issues, and resource to support the network. This varies according to capacity and capability. Five or six countries do the bulk of the work.

> Adherence to defined timings for all processes ensures predictability for users and participants and this enables good planning of resources.

> Fee-based system rewards the scale of contributions by Member States.

Areas to improve

> Speed – could be faster and should evolve to try to get smarter and faster.

> Changing legislation across the Member States is time-consuming.

> More flexibility would be beneficial.

> More regulatory tools for the future are needed to deal with the increasing complexity of products that are going to be available – this reflects the whole regulatory field, not just Europe.

> Need for more streamlining across different products and combination products.

> Healthcare provision varies across Member States, so some types of procedures and legal status changes can be challenging (e.g. the complexity of the health system and roles of pharmacists, needs for prescriptions etc.).

> Fees and funding.

> Member State contributions could be broadened to support the network.

Maximizing the regulatory efficiency and effectiveness of the AMA - Learning from the experience of others: Lawrence Liberti, Centre for Innovation in Regulatory Science (CIRS)

The AMA's potential role could be summarized as follows:

> Coordinating and facilitating initiatives to harmonize.

> Documenting and promoting best practice.

> Providing systems to monitor, evaluate and assess the comprehensives of systems used by NMRAs and RECs to improve efficiency and effectiveness.

NMRAs need to develop and maintain well-structured interactions to strengthen regulatory functions and promote cooperation. The Pan American Network for Drug Regulatory Harmonization (PANDRH) and EMA's objectives have some overlap and can provide important lessons for AMRH and AMA. PANDRH helps develop core competencies to support development of good regulatory practices, as a means of bringing standardization and good quality to these organizations.

Decision-making processes are usually not good at the organizational level. CIRS collects information to help NMRA's to improve these processes. The CIRS Optimising Efficiency in Regulatory Science (OpERa) system supports more detailed understanding of NMRA processes and then measures how these work.

Good starting points for AMA to support consistency across the Member States include:

> Good Review Practices (GRevP): Detail on regulatory review process.

> Highlights of results: standard operating procedures (SOPs) for guidance of assessors in place, assessment templates, internal quality audits, internal tracking systems to track consistency and timeliness of the process.

The EMA can provide lessons for the AMA

EU started with narrow scope of EMA activities in terms of Centralized Procedure: the Decentralized Procedure came along later. Mutual Recognition started off as optional and then became mandatory. Success was based on an evolution of trust and competence across the network. Working to common standards but giving all Member States the opportunity to express views and comment has been important. A strong desire to work share and agreement that it is in everyone's best interests to do so have driven this. Twinning and bringing new people in to build competence has been important. Training has also been central to address capacity gaps.

In summary:

> Implementing SOPs is important and could include, for example, guidance of assessors; using assessment templates and encouraging their active use; promoting use of quality audits; establishing tracking systems for timeliness; supporting industry interactions and supporting training.

> A fixed timetable for review processing, decision-making and adoption is essential.

Plenary Session III Recommendations

> Language and cultural challenges were overcome in EU and this should be an inspiration for the AMA.

> AMA's proposed operating model needs further interrogation to clearly define:

  - the roles and responsibilities of the National Medicines Regulatory Authorities (NMRAs), regional economic communities (RECs), planned regional medicines agency and AMA and working relationships;
  - financing models and fee structures;
  - obligations of the Conference of the Parties to the Treaty and
  - how non State Parties will benefit from AMA.

> Experience from existing agencies such as European Medicines Agency and its network can be leveraged in setting up AMA. Commitment and convening of Heads of Agencies (HOAs) is a key success factor.

> The established governance structures and tools under the African Medicines Regulatory Harmonization (AMRH) initiative serve as a good foundation for AMA.

> Existing tools for maximizing efficiency ("doing the thing right") and effectiveness ("doing the right thing") of regulatory processes such as OpERA, can be employed to ensure effective delivery at national, regional and continental levels.

> AU Ministers of Health and Ministers need reminding that they decided to take forward the creation of the continental regulatory agency and that they now have a role to play to ensure their governments ratify its creation. WHO will also help to advocate for this.

> Heads of NMRAs must engage Ministers of Health, Ministers of Foreign Affairs and Parliamentarians to facilitate the signing and ratification process.

> RECs have a critical role to play in convening Ministers of Health and Foreign Affairs and in advocating for signing and ratification of the AMA Treaty.

> A value-based user-fee model that factors in benefits and contributions needs to be explored.

8. Parallel Session III: Harmonization of regulation of medical products – Innovative approaches to measuring regulatory outcomes, reliance and harmonization: what have been the access gains at country level?

Session Co-Chairs: Lawrence Liberti (CIRS) & Jane Mashingia (EAC)

This session aimed to share innovative technologies in regulation, reliance models and country experiences in establishing autonomous agencies.

CTD, Electronic CTD and eCTD - Providing the Right Guidance: Kent Briggs (VECTOR Life Sciences)

The current situation relating to the Common Technical Document (CTD) is that acceptance is High, CTD guidance is available for many countries/regions and electronic CTDs are requested/required. However the "CTD" has not always been in line with the ICH guideline. South Africa is the only country with guidance on electronic submissions although the e-Submission Guidance is incomplete. In general, e-Submission/eCTD guidance is scarce or insufficient. Policies tend not to be clear and there are some conflicts between Regional and National guidance and mixed signals from evaluators vs. authorities.

It is important to understand the differences between CTD, Unstructured Electronic CTD, Structured Electronic CTD and eCTD. Africa is far enough along to take advantage of eCTD. The establishment of validation criteria will increase the Quality of Applications, increase the efficiency & consistency of evaluation and reduce the number of screening iteration, leading to faster approval times. Having harmonized structure & guidance offers a number of benefits, including reducing the costs for industry and making markets more attractive; increasing consistency and quality across regions; making joint-review activities easier while avoiding any reduction in autonomy over country required content.

Validation criteria need to be included in the CTD to increase efficiency and consistency in evaluation. The African continent should adopt and domesticate eCTD/ harmonized CTD/ eCTD, which will increase industry efficiency, reduce cost (both) and increase consistency of evaluation by experts across the continent.

Transition from a regulatory unit within a Ministry to a fully functional semi-autonomous regulatory authority: A case study of Botswana Medicines Regulatory Authority: Stephen Ghanie (BOMRA)

A model for transforming a regulatory unit was presented, using the case of Botswana. The underlying principles for the transition included client focus – the driving spirit, source of passion; efficiency – smart working, deadlines, being proactive, simplicity, effectiveness; team-work – communication, synergies, common goal; and integrity – confidentiality, demonstrating leadership, trustworthy.

Key elements within the transformation included:

> Governance Structure

> Resources

> Mandate and Business Model (QMS)

> Leadership and Talent Growth

> Stakeholders Engagement

> Publicity

> Strategy and Execution

> Value Proposition

> Evaluation of Industry Trends

> Monitoring and Evaluation

Lessons learned from the process were that managing key enabling relationships is vital including the Minister, Permanent Secretary Board Chairperson. Setting the Organizational Normal and Pace is key. Integrity and image are important. Asking for "outside" help is recommended, making sure the management team are involved and surveys of management and employees are done so that change can be effectively managed. Finally, personal drive and initiative are key success factors.

Over-the-Counter (OTC) Health Products Regulatory Framework in Africa - Securing AMRH's role to facilitate Wider Consumer Access to Non-prescription Medical Products: Caroline Mendy (Global Self-Care Federation)

Over-the-counter (OTC) medicines can be used for self-treatable and some chronic conditions and therefore enable healthcare systems to re-purpose resources on more important healthcare priorities.

Regulatory issues for OTC products do not differ to a large extent from those experienced for priority medicines at the inception of AMRH. Despite many unprecedented successes achieved through AMRH, regulatory fragmentation, hurdles for registration and life-cycle management remain major obstacles to timely access to non-prescription or OTCs.

Currently, harmonized medicines registration procedures (i.e. East and Southern Africa) are restricted to essential medicines (HIV, TB, malaria etc.). Despite observed longer lead times to market for OTCs, there are no examples of OTC medicines authorized for the harmonized registration process. It is up to individual countries Health Authorities to address the fragmentation and regulatory complexities for OTCs by adopting a reliance approach (e.g. SAHPRA adopting EMA variation guidelines). However, the implementation of these can be challenging.

Developed mobile digital platforms in Africa could already be an advantage to deliver greater self-care access. Yet, to meet increasing demand, the African continent needs to develop and implement an over-the-counter (OTC) regulatory framework, which will recognize OTCs contribution to the health care systems. There is also a need to introduce natural classification systems of OTC / OTC scheduling which will positively impact the accessibility of OTC products to consumers. A risk-based evaluation process for OTC should be adopted and promoted, with long safety profiles to address long registration timelines, harmonize requirements for renewal and continuous regulator and industry consultations. Terminologies for OTC/prescription/ non-prescription need to be clarified.

Effective mechanisms for regulatory reliance systems – an Industry perspective: Nevena Miletic (IFPMA)

With over 7,000 medicines in development, the exciting new wave of medical innovation will play a key role in addressing the challenges faced by patients and healthcare systems. Regulatory reliance supports building regulatory capacity and trust between stakeholders and could provide faster access to these innovations to patients in Africa.

In 2019, IFPMA conducted a survey to collect industry knowledge and experiences of regulation in Africa, in order to support improvements and give appropriate recommendations. There were a total of 78 responders, covering 39 countries and the topics they gave feedback on were:

1. Policy/Legal and Regulatory Reforms/ Regulatory System
2. Registration and Market Authorization
3. Reliance and Collaboration – general, and region-specific

Companies show high interest in the regional harmonization procedures, but face obstacles such as limited information and awareness about existing joint regulatory assessment procedures (JAPs), challenges around management of post-approval changes for the products approved via JAPs, and limited eligibility of products to participate in JAPs, due to limited scope of some procedures.

> NRAs and industry need to work together to ensure alignment related to regulatory frameworks.

> When establishing and implementing effective regulatory reliance mechanisms, NRAs should consider following key elements:

- Guidance on Documentation (i.e. what documents are required, how they will be used, who should provide what etc.)
- Clear Procedural Guidance (i.e. Predictable and transparent timelines, simple, straightforward and pragmatic procedures, publicly available list of accepted reference NRAs).
- Reduction in regulatory burden (i.e. reliance needs to offer clear benefit reflected in faster approval, reduced workload for all the parties and applicability through the entire product lifecycle).
- Other stakeholders should continue promotion of work on collaboration and understanding of the different reliance pathways in place as a first step to improve and fully benefit from regulatory reliance mechanisms.

9. Parallel Session IV: Alignment of regulatory networks and forums, and role of partnerships

Session Co-Chairs: Mike Ward (WHO) & Fatuma Adan (IGAD)

This session aimed to provide participants with lessons learned working through regulatory forums, networks and partnership frameworks.

Supply chain shelf-life regulations for health commodities: Christine Malati, (USAID)

Many countries require a minimum percentage of the Remaining Product Shelf-life (RSL) at the time of importation, having the effect of unnecessarily hindering importation of and patient access to life-saving medical products.

USAID is collaborating with WHO to develop a recommendation on importation requirements based on 'months remaining' rather than 'minimum percentage remaining'.

The WHO Expert Committee on Specifications will likely review the WHO Policy on Remaining Shelf-life of Medical Products and Recommendations for Pharmaceutical Preparations in October 2019. This will be informed by information on actual consumption patterns in countries, improvements in forecasting and supply chain management and manufacturer incentives to establish longer product shelf-life.

In summary, countries should adopt an importation requirement for shelf life based on months remaining rather than minimum percentage remaining, consistent with anticipated WHO Policy.

Harmonizing Research Ethics Review Frameworks in the East African Community: Ethel Makila (International AIDS Vaccine Initiative, IAVI)

Expedited ethics review of clinical trials is central to ensuring quicker access to new health technologies and stimulating research in Africa. IAVI's mission is to partner with policymakers and regulatory institutions to translate research findings to policies and practice to address public health needs.

Research is no longer a 'local' issue. The East African Health Research Commission (EAHRC) and IAVI are working with the EAC partner states to facilitate timely and efficient clinical trials reviews, particularly multi-site, multi country clinical trials.

Critical next steps include development and implementation of national roadmaps; harmonization of ethics review processes at country level; and the establishment of a review board with representation from all EAC member states under the leadership of EAHRC, supported by online systems.

Due to the high disease burden in African and less research in ethics, the complexity of interdisciplinarity in research, and the global nature of research harmonized ethic review is the way to go to ensure safety for better public health needs. Partnerships are playing a key role in establishing a framework for harmonization, capacity and collaboration related to research ethics review that will in turn contribute to stimulating research and access to new health technologies in Africa. Policy tools, guidelines and capacity building create an expanded pool of human, infrastructures and financial resources for regional ethic reviews and harmonization.

Proficiency Testing Scheme for Pharmaceutical Laboratories: East African Regional Experience: Eliangiringa Kaale (Muhimbili University of Health and Allied Sciences, MUHAS)

Proficiency testing (PT) schemes allow participant laboratories to evaluate and improve performance through pre-established criteria, test protocols and root cause analysis. This external quality assurance tool provides a competence assessment opportunity for the participant towards quality system improvement. Five locally organized PT schemes have been conducted in EAC with participant testing laboratories, indicating overall improvement in performance but inconsistence participation. AfroCondomNet is a platform for condom regulation, which can be used to enforce country capacity in technical assessment.

Participation of laboratories in proficiency testing schemes is encouraged as a means of measuring performance towards quality system improvement. Experience gained is useful for the further preparation towards ISO/IEC 17043 accreditation. Proficiency testing schemes and inter-laboratory comparisons for evaluation of quality control laboratories serve to improve the performance of laboratory and an onward upgrade to international accreditation.

EMA Reliance Model: Magdalena Pajewska, (European Regulatory Agency)

The EMA offers a number of regulatory pathways and initiatives to support reliance and facilitate international collaboration, the most prominent of which is the Article 58 - 'EU Medicines4all' procedure.

Article 58 was designed to facilitate registration and access to important medicines of high public health value that are destined for non-EU countries. A collaborative process that engages experts and regulators from target countries through WHO, Article 58 procedure has resulted in 138 approvals worldwide, 62 in Africa. Other pathways and mechanisms available to applicants as well as regulators from target countries include PRIME, Scientific Advice and new, future parallel procedure of the Article 58 and the normal EU Central Authorisation procedure. The joint WHO-EMA Collaborative Registration Procedure (CRP) pilot, which contributed to the development of the WHO Stringent Regulatory Authority/WHO-Listed Authority (SRA/WLA) CRP, offers an additional mechanism to accelerate country registration for non-prequalified (PQ) products.

A range of EU/EMA pathways and services are available to product applicants and non-EU regulatory authorities to facilitate access to important new public health medicines. In particular, Article 58 is a reliance approach that enhances information sharing, reduces registration times and prevents duplication of efforts.

AfroCondomNet: Stronger partnerships for effective condom regulation: Frank Loban (Unite Nations Population Fund, UNFPA)

Condom regulation in Africa tends to be overseen by agencies responsible for public health, through the national regulatory authorities, and trade and industry, through the bureaus that monitor standards. AfroCondomNet was established in 2017 after a series of regional technical and laboratory training events held since 2011 and a meeting of Heads of NMRAs in 2016 which agreed to "establish a forum where quality complaints can be shared and National Labs can also contribute. Hands-on training for condom testing has been taking place among National Condom Quality Assurance Control Laboratories (NCQACL) since 2014, including Ethiopia, Tanzania, Zambia, Ghana and Nigeria.

AfroCondomNet's purpose is to develop partnerships to strengthen regulation for condoms. During their annual meetings, UNFPA – which manages the UN Prequalification of condoms and Intrauterine devices (IUDs) - has worked with NMRAs to develop a more collaborative and inclusive approach, including better communication and collaboration on condom testing results, separation of the procurement function from the PQ function within UNFPA and increasing NMRA participation in the WHO/UNFPA prequalification inspections. Building on this, an inter-laboratory proficiency study is under development, led by AfroCondomNet. Sharing of information and intelligence among members has grown and training on technical file assessment has been carried out. WHO/UNICEF/UNFPA have also delivered training to manufacturers of condoms to ensure they are aware of ongoing regulatory concerns and that their technical knowledge is current.

10. Parallel Session V: Human resources - Models for capacity building and skills retention

Session Co-Chairs: Moji C Adeyeye (NAFDAC) & SF Malan (UWC)

This session aimed to take stock of various models for capacity building that have been piloted and rolled out in Africa in recent times.

RegTrain-Project: Widening the scope of regulatory capacity building based on the VaccTrain I Pilot Project: Regine Lehnert (BPharm)

RegTrain is the first joint partnership between the German Federal Institute for Drugs and Medical Devices (BPharm), The Paul Ehrlich Institute (PEI) within the Global Health Protection Programme (GHPP). It involves NMRAs of Gambia, Ghana, Liberia, Sierra Leone and Zimbabwe and other partners (SADC, ECOWAS, AUDA-NEPAD and WHO).

The program works on strengthening structures of NMRAs, supporting RCOREs train the trainers and strengthening collaboration, harmonization and networks. Using a train the trainer approach, curricula are tailored in line with feedback received from partner NMRAs on their the needs and priorities in the short and long term. To encourage sustainability, materials are prepared by the fellows for their colleagues in the NMRA and in RCORE trainings and the impact of training is followed up on by the GHPP. Training areas include pharmacovigilance of vaccines and biomedical therapeutics, quality assessment of biomedical therapeutics, which includes the regulation of biologicals, quality assessment of clinical trial applications and models of regulatory reliance. Training is also given on clinical evaluation, which involves medicinal product lifecycle, regulation of pharmaceuticals (including biosimilars), models of regulatory reliance, clinical aspects of bioequivalence studies, efficacy and safety studies and product information.

A Systematic Approach to Human Development - Botswana Medicines Regulatory Authority (BoMRA) Case Study: Padmine Rammidi (BoMRA)

BoMRA's vision is to reach Maturity Level 3 by 2024 and to collaborate & participate in harmonization initiatives. To achieve this, it undertook a WHO Global Benchmark Tool self-assessment to assess whether it had the right skills, tools, resources, mandates to reach Maturity Level 3. This revealed that it had a lack of objective tools to assess gaps in existing competence, staff development initiatives were not informed by evidence-based gaps and that it needed coordinated learning & effectiveness measures. As part of the BOMRA institutional development plan (IDP) to address gaps identified through self-benchmarking exercise, BoMRA requested WHO support in developing a systematic human resources development plan. The outcome will also input to the finalization of the global competency framework.

Aiming to take a systematic approach to human capital development, BoMRA has worked to determine the current & future needs of the Authority, assess the current workforce, identify gaps between existing and required and perform a causal analysis. It then developed strategic solutions, a Human Capital Development Plan, and implementation plan and then methods to assess improvement and improve learning effectiveness. The competence framework and assessment process were clearly documented and communicated during the process, with a clear distinction made between competency and performance assessment.

Fellowship in Regulatory Science for African Medicine Reviewers: Tariro Makamure – Sithole (MCAZ)

MCAZ has provided training to regulators on the continent for years, in areas such as Medicines registration, laboratory analysis, pharmacovigilance and GMP inspections. In 2014, MCAZ was designated by NEPAD-AUDA as a RCORE for medicines evaluation and registration, laboratory Quality Assurance / Quality Control and clinical trials oversight, with the goal to increase human and institutional capacity for the regulation of medical products and other health technologies on the African continent. To-date MCAZ, in its role as an RCORE, has provided technical training in bioequivalence, biosimilars and special dosage forms as well as GMP considerations for assessors. EDCTP has provided EUR 270 019 over a 36-month period starting 1 November 2018 to build capacity of African medicines reviewers to assess new medicines and conduct research in regulatory science by offering fellowships to assessors working in NMRAs.

In addition, MCAZ will develop modules and train 100 assessors working in NMRAs and regulatory science professionals working in Industry on a cost recovery basis through short courses. The 2-year part time fellowship in regulatory science is offered to 8 – 10 assessors working in Medicines Regulatory Authorities (MRA) in the SADC region. Fellows are admitted in two groups, the first in 2019 and the second group in 2020.

The goal is to develop between eight and ten competent medicines reviewers (WHO level II and III) who in turn train personnel in their agencies. These will be RAPS certified regulatory affairs professionals from African MRAs. Additionally, between eight and ten publications in regulatory science will be developed, alongside new modules for the MCAZ RCORE enabling approximately 100 regulators and industry personnel to be trained on a cost recovery basis. So far, four fellows have been selected for 2019 Cohort (two Zimbabwe, one South Africa, one Botswana) and four regulatory mentors from WLAs and four academic mentors from Universities have been selected. Two new modules have been developed for the RCORE (special dosage forms and GMP considerations for assessors). Surplus has been made from the first training, which has been used to offer scholarships to regulators for the second training. 60 regulators and industry personnel have been trained to-date.

11. Parallel Session VI: Optimizing regulatory outcomes, harmonization and experiences in Africa and beyond

Session Co-chairs: Sybil Ossei-Agyeman Yeboah & John Mwangi

The objective of this session was to share experiences in optimizing and measuring regulatory processes, outcomes, and experiences in harmonization and reliance. Harmonization of regulatory processes across the African continent is the best way to increase access to quality, safe and efficacious medicines for the population. This has already begun at national and regional levels, but the question that still remains is how do we identify effective implementation strategies to drive the harmonization agenda and sustain the processes for best regulatory outcomes?

Importance of Medicine Quality in Achieving Universal Health Coverage in Africa - what it means for patients: Kgothatso Motumi (Roche)

Adequate access to therapeutic options is essential for patients and industry should support the harmonization journey being spearheaded by various regional economic communities for the sake of the patient. Roche's participation in the Zazibona regulatory harmonization process using a biotechnology product, Hemlibra™ (Emicizumab) used for Heamohila A was a good experience.

Key drivers for harmonization initiatives success in Africa are high standard of science with regulatory efficiency, sustainability, predictable timelines and processes, predictable decision-making processes and a high level of engagement with regulatory bodies by industry, which ultimately benefits the patient.

Promoting risk-based approach to inspections and assessments: WHO collaborative registration procedure as a case study: Samvel Azatyan (WHO)

Regulation in countries is important and regulatory authorities make decisions through a range of normal or standard processes, reliance, work sharing, joint review and mutual recognition mechanisms, based on World Health Assembly (WHA) resolutions (WHA 67.20 of 2014, WHA 67.21 of 2014 and WHA 63.12). Reliance and recognition are distinct and defined concepts.

The WHO pre-qualification of medicines program has enabled about 65% of children under five years of age to be immunized and has addressed management of HIV/AIDs and other priority communicable diseases. WHO offers several regulatory pathways to facilitate accelerate approvals in Member States through the use of a risk-based approach to inspection and assessment that include Collaborative Registration Procedure (CRP), Stringent Regulatory Approval Collaborative Registration Procedure (SRA-CRP).

Regional networks like AMRH facilitate registration based on reliance. These pathways offer advantages to procurement agencies, NMRAs and industry.

In summary:

> Patients/consumers – wherever they are – deserve access to quality assured medical products with positive benefit-risk characteristics in order to achieve UHC.

> Regulators globally must collaborate and take into consideration the information available from other regulatory authorities in order to generate quality decisions.

> Not using the outputs and outcomes from other regulatory authorities can mean lost opportunity, duplication of efforts, increased regulatory burden and waste of scarce resources.

> The CRP provides a unique opportunity to regulators to accelerate and improve the quality of their regulatory decisions, based on the information available from trusted regulatory authorities. This can help to save the scarce resources and use them for other important activities.

Harmonization of Regulation of Medical Products - Innovative Approach to Measuring Regulatory Outcomes, Reliance and Harmonization: Monica Hemben Eimunjeze (NAFDAC)

Regional collaborative regulatory activities, global initiatives and capacity building are important in improving regulatory outcomes, reliance and harmonization. The objectives of harmonization include regulatory efficiency, access to quality medicines, availability of medicines and development of the knowledge and skills required to support harmonization.

ECOWAS has started joint assessments and inspections. There are now harmonized guidelines and procedures and QMS of key regulatory processes to improve regulatory outcomes. The WHO-GBT benchmarking exercise has helped Member States in the region improve their core regulatory functions to identify gaps and develop Institutional Development Plans (IDPs) and has promoted regulatory reliance. Capacity building has improved local capacity throughout the regulatory authorities. In summary, regional initiatives for regulatory strengthening are important for improving access to medicines.

Optimising Regulatory agencies review processes and performance through standardised systematic measures: Prisha Patel (Centre for Innovation in Regulatory Science)

Africa would benefit from an optimized, standardized system for measurement of regulatory processes and outcomes. The two core aspects to measure are the qualitative and quantitative aspects of regulatory processes.

Identification of relevant metrics for regulation is key for improvement of regulatory outcomes because they facilitate healthy competition and enable regulators to see what they do well and what others are doing better. Analysis of regulatory times can identify where time is spent in the regulatory review process, for internal benchmarking and external comparisons, to increase internal and external transparency and to monitor change initiatives that assist NMRAs prioritize areas for decision making with increased efficiency and quality of regulatory processes. Citing one case as an example, CIRS worked with the Saudi Arabian FDA to develop risk stratification approach that led to elimination of backlogs in the Agency. It is also important for sponsors to submit good quality dossiers to allow for a consistent and transparent review process and process predictability.

Embedding a culture of performance measurements allows agencies to continue to grow and improve. NMRAs should institutionalize a culture of systematic measurement of regulatory processes and outcomes. CIRS' methodology can help provide a consistent approach for NMRAs to assess their performance in comparison to other NMRAs. It can measure the impact of regulatory process changes and help improve processes for better planning, decision-making, continuous improvement and staff retention through professional development. Gaps may be identified following an audit of good review practices in an NMRA.

Recommendations from Parallel Session VI

> Quality of review processes should not be compromised over speed. Fast review processes do not equate to high quality processes.

> Reliance, mutual recognition and information sharing is important to bridge the ever-increasing regulatory resource needs and effective access and reduce duplication of efforts, increased regulatory burden and waste of scarce resources.

> Analysis of regulatory times can identify where time is spent in the regulatory review process and will allow internal benchmarking and external comparisons with increased transparency that assist will NMRAs prioritize areas, increased efficiency and quality of regulatory processes.

> Self-monitoring initiatives that can help optimize review processes, identify NMRAs resource limitations and or industry submission deficiencies. This can help key decision-making, adjustments and optimization through digitalization.

> Key drivers for harmonization initiatives success in Africa are high standard of science with regulatory efficiency, sustainability, predictable timelines and processes, predictable decision-making processes and a high level of engagement with regulatory bodies by industry, which ultimately benefits the patient.

12. Plenary Session IV: Shaping the future of medical products regulation in Africa including digital and innovative tools used in health regulation

Session Co-Chairs: Andreas Seiter (World Bank) & Houda Langar (WHO-EMRO)

The aim of this session was to highlight future of medical products regulation in Africa within the broader scope of new tools and technologies and broader context of universal health coverage.

Regulatory harmonization of medical products as a key driver to achievement of Universal health coverage in Africa: Sibusiso Hlatjwako (PATH)

The purpose of this study was to model the potential health impact of increasing regulatory harmonization across two regional economic communities in sub-Saharan Africa – EAC and SADC. In this context, it was assumed that regulatory harmonization can involve sharing of information, such as inspection findings between regulatory authorities; aligning safety and efficacy standards and processes used to assess and monitor research and products; conducting joint reviews of research protocols and product dossiers and inspections of research and manufacturing sites and mutual recognition of assessments and inspections conducted and decisions made by other regulatory authorities. While efficient registration is important for increasing product availability and access, it is recognized that registration is only one necessary component in launching a product and that registration alone does not guarantee these medicines will become available.

The medicines studied included heat-stable carbetocin and dispersible amoxicillin and the Johns Hopkins 'Lives Saved Tool' was used, analyzing results from 2018–2023. These two products alone were not intended to represent the total impact of regulatory harmonization. Rather, they can be used as case studies to highlight what is possible for select emerging medicines.

The study calculated the total annual lives saved from launching amoxicillin dispersible tablets and heat-stable carbetocin in the EAC and ZAZIBONA from 2018-2023. The results showed that accelerating access to two products through more efficient regulatory harmonization could have significant impacts: 11,778 incremental lives could be saved in Eastern and Southern Africa from products reaching patients one year faster, and 23,391 incremental lives could be saved in the same regions from products reaching patients two years faster. Regulatory harmonization efforts have improved since the modelling exercise occurred, thus the baseline model scenario may underestimate the recent progress.

In order to fully realize this potential health impact across Africa, sustained commitments both political, financial, and technical are required from policymakers and donors alike. The key priorities are to invest in regulatory harmonisation domestically and across Africa to enable scale-up, ensure all regulatory phases and functions are harmonized across products and domesticate the AU Model Law in all AU Member States.

Using collaborative cloud-based solutions for seamless collaboration and harmonization in Africa: Winona Rei Bolislis (Sanofi)

The collaborative cloud is a new platform that redefines the way pharmaceutical companies share data with regulators. It aims to facilitate collaboration across agencies using artificial intelligence, machine learning, and predictive analytic techniques in a modern cloud-based architecture.

The current process for regulatory filings is cumbersome. For example, there are multiple databases and global registration requires multiple (often repetitive) filings. Multiple sponsors may provide relevant information, but data silos can create a barrier to sharing internally. Regulators can share lessons learned and (some) information through designated programs.

An alternative, preferred submission route would be one secured by Blockchain, whereby data is captured and stored directly from the source to the cloud, it is then screened and evaluated by technology according to pre-agreed criteria with the Agency (i.e., design space). Depending on whether the data were in line with the predicted path, the sponsor would then re-engage with the Agency.

A cloud-based solution for regulatory filings would have many advantages, including that it would operate in real time, with the regulatory authority receiving data access as soon as the regulatory dossier is submitted. It can take place remotely at any period on data-housing platform, making it available at all times. The approach supports collaboration by permitting simultaneous review by multiple regulatory authorities and allowing input from multiple other sources to guide regulatory decision-making. It also allows regulators to draw insight from related submissions (with proper permissions). Finally, it enhances the ability of sponsors and regulators to use and integrate new sources of data, e.g. Real World Data.

In summary, in the context of the AMA, adopting a cloud-based solution can "leapfrog" towards a seamless regulatory future. It can help achieve regulatory alignment in terms of framework and methods – given the shared platform. It can also reduce country-specific requirements, while sharing information and good practice on lifecycle management of medical products.

Plenary Session IV Recommendations

> Key priorities are to invest in regulatory harmonisation domestically and across Africa to enable scale-up, ensure all regulatory phases and functions are harmonized across products and domesticate the AU Model Law in all AU Member States.Adopting a cloud-based solution can "leapfrog" towards a seamless regulatory future and help achieve regulatory alignment in terms of framework and methods and also reduce country-specific requirements.

> Cloud-based solutions should be used to support collaboration by permitting simultaneous review by multiple regulatory authorities and allowing input from multiple sources to guide regulatory decision-making, helping achieve regulatory alignment in terms of framework and methods, reducing country-specific requirements and sharing good practice on lifecycle management of medical products.

13. Award Ceremony for Best Oral and Poster Presentations

As part of cultivating excellence in abstracts presentations for oral and poster papers the SCOMRA Scientific Committee established a panel to review and evaluate the performance of presenters and select the best oral and poster presentation. The panel used the following criteria to evaluate the presenters:

1. Originality and Creativity
2. Organization (logical presentation of ideas)
3. Time Management
4. Presentation (Oral presentation and delivery)
5. Knowledge of Material (Familiarity with subject matter)
6. Neatness
7. Discussion / Response to Questions

The panel found that the quality of presentations at SCoMRA IV was much overall higher than in previous years. The scores for the oral presentation were extremely close, with a number of excellent presentations being delivered. The winning prize for the oral presentations was awarded to Frank Loban, presenting on AfroCondomNet, and the second prize to Magdalena Pajewska Lewandowska, presenting on the various European regulatory schemes aiming to promote access to medicines.

The quality of the poster presentations was also high, with the panel awarding first prize to Lynette Mutisi and the second prize to Sunday Kisoma.

14. Closing Remarks

Ann Fortin from WHO AFRO and Margareth Ndomondo-Sigonda from AUDA – NEPAD closed the conference giving enormous thanks to all partners, including the Organizing Committee and Scientific Committee as well as the host agency, MCAZ, and their successful execution of the logistics. The AUDA-NEPAD and WHO teams were acknowledge for their huge efforts and also the Bill and Melinda Gates Foundation for their tireless support.

The tremendous progress of SCoMRA, both in terms of logistical progress but most notably in terms of the science of regulation, is significant. The quality of the presentations has risen to a new level, raising the bar for future meetings. The new SCoMRA Scientific Committee added huge value to the event. David Mukanga from the Gates Foundation was noted in particular for his efforts in supporting, motivating and developing the work of SCoMRA IV.

Emer Cooke, Director Regulation of Medicines and other Health Technologies, World Health Organization

WHO continues to commit in the multiple areas of its engagements, including the Global Benchmarking Tool (GBT), development of Institutional Development Plans (IDPs), training with NMRAs, work with RECs and other relevant work that enhances access to medicines, which is the fundamental purpose of WHO's engagement in this area. Access to medicines is a human right not a luxury, and access to safe medicines is a key part of that access, with regulation an essential facilitator of that safety and quality assurance mission.

Nevena Milisavljevic, African Regulatory Network co-chair, International Federation of Manufacturers and Associations Africa

The IFPMA acknowledged its own large role in SCoMRA and the growth of its role during the life of AMRH. IFPMA colleagues have attended SCoMRA IV and given generously to the initiative. Continued development of measurement is essential as AMRH is implemented.

IFPMA looks forward to the developments in regulatory harmonization that AMA can bring. Expansion of activities towards broader product scope and regulatory functions is welcome, to enable regulatory system strengthening and increased access for products.

Dan Hartman, Director, Integrated Development, Global Health, Bill and Melinda Gates Foundation

The former BMGF program lead, Vincent Ahonkai, was the one of the founders of the AMRH and his work is continued in the Foundation: Mac Lumpkin and David Mukanga bring ongoing thought leadership and Ian Hudson is a welcome new addition to the team.

The calls and support for increased measurement of outcomes are welcome as a means of improvement and tracking progress. Tools such as OpERA, the GBT and Quality Control laboratories are important contributors for this. The exciting challenge is to move towards effective implementation of transformation, which is at the heart of what we are doing.

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

The journey of AMRH since its inception has been exciting and the Bank has had to work in new modalities in partnership in a way that it is not used to. It has aimed to be catalytic and enable partners to deliver on their own so that it can then move out of the space. The Bank's AMRH team has been essential to delivering AMRH. The private sector's role in this effort and has grown in the AMRH in an appropriate way.

Gugu Mahlangu, Director General, Medicines Control Authority of Zimbabwe (MCAZ)

The last ten years have yielded great progress for regulatory harmonization on the continent through the AMRH and the next decade will ideally enable the AMA to become fully operational. Partnerships are core to the AMRH and it is essential to continue to engage partners. Consensus is needed among all partners that reliance is not optional: it is a prerequisite to good regulatory practice. The variety and quality of the presentations and the role and value of the Scientific Committee has been notable at SCoMRA IV. Thanks is offered to all partners, the Ministry of Health of Zimbabwe, AUDA-NEPAD, World Bank, WHO, BMGF, IFPMA, all the presenters, rapporteurs and moderators, the organizing committee, interpreters, and media.

Annexe 1:
Conference Program

Monday, 30 September 2019		
Time	**Topic**	**Responsible**
07h00 - 09h00	Registration	Secretariat
09h00 - 11h00	**Master of Ceremony:** Margareth Ndomondo-Sigonda (AUDA-NEPAD) and Ann Fortin (WHO-AFRO) **Rapporteurs:** Chimwemwe Chamdimba (AUDA-NEPAD) & Stanislav Kniazkov (WHO-AFRO)	
09h15 - 09h25	Welcome Remarks	Dr. Willy Amisi, SADC Secretariat
09h25 - 10h30	**Plenary Session I (Part 1):** **AMRH Implementation – progress, lessons, challenges** **Session objectives:** To review progress, identify challenges and lessons learnt in the implementation of AMRH, and the alignment of various regulatory networks and forums within AMRH **Session Co-Chairs:** Dan Hartman & Dexter Tagwireyi **Rapporteurs:** Brian Ng'andu (AUDA-NEPAD) and Eun Mi Kim (WHO)	
09h25 - 09h45	Global context of harmonization and innovative models	Mike Ward (WHO)
09h45 - 10h05	AMRH Program: Continental Progress Update	Margareth Ndomondo-Sigonda (AUDA-NEPAD)
10h05 - 10h30	Panel Discussion including Q&A	AUDA-NEPAD and RECs Representatives
10h30 - 11h00	**Keynote speaker:** Viewing medicine discovery, development and approval as a continuum: the role of regulatory harmonization in Africa for better outcomes	Prof Kelly Chibale - University of Cape Town
11h00 - 11h30	Tea/Coffee Break	
11h00 - 12h00	**High-Level Plenary:** A Decade of Regulatory Harmonization in Africa: Where are we? Where do we go from here? **Moderator:** Gugu Mahlangu, DG MCAZ 5mins elevated speed talk from each panelist followed by a facilitated discussion	> Aggrey Ambali, Director, Technical Cooperation, Program Funding and Strategic Initiatives, AUDA-NEPAD > 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) > Mike Ward, [Title], Regulation of Medicines and other Health Technologies, World Health Organization Christianah Mojisola Adeyeye, Director General NAFDAC & Chairperson AMRH Steering Committee
12h00 - 12h10	**Remarks**	Alex Ntale Gasarira, WHO Representative to Republic of Zimbabwe
12h10 - 12h30	**Official Opening**	H.E. Mr Obadiah Moyo, Minister of Health and Child Care, Republic of Zimbabwe
12h30 - 13h30	**Group Photo, Media Briefing, Lunch**	

Time	Topic	Responsible
13h30 - 14h15	**Plenary Session I (Part 2):** **AMRH Implementation – progress, lessons, challenges** **Session objectives:** To review progress, identify challenges and lessons learnt in the implementation of AMRH, and the alignment of various regulatory networks and forums within AMRH **Session Co-Chairs:** Dan Hartman & Dexter Tagwireyi **Rapporteurs:** Brian Ng'andu (AUDA-NEPAD) and Eun Mi Kim (WHO)	
13h30 - 13h40	WHO benchmarking of regulatory systems – Updates and implications for Africa	Hiiti Sillo (WHO)
13h40 - 13h50	Building the Medicines Quality Control Capacities in Africa: Where are we?	Abdelkrim Smine (USP)
13h50 - 14h00	Discussion	All
14h00 - 12h15	Session Summary and Wrap up	Co-Chairs
Program now continues as planned		
14h15 - 15h30	**Plenary Session II:** **AMRH Implementation – progress, lessons, challenges** **Session objectives:** To review progress, identify challenges and lessons learnt in the implementation of AMRH from a regional, country and individual presenters' perspectives **Session Co-Chairs:** Vincent Ahonkhai & Sarah Adam **Rapporteurs:** MCAZ and IFPMA	
14h15 - 14h30	The East African Community Joint Assessment Procedure: Achievements, Challenges and Way Forward	Shani Maboko (TMDA)
14h30 - 14h45	ZAZIBONA GMP inspections – Upward momentum, impact & kaizen	Washington Dengu (MCAZ)
14h45 - 15h00	Complexity of Life Cycle Management and the challenges for African countries – an Industry perspective	Sarah Adam (IFPMA)
15h00 - 15h15	An Urgent and Strong Need for Harmonized Regulation of Biologics Including Vaccines in East African Community and Africa at large	Grant Munkwase (NDA)
15h15 - 15h25	Discussion	All
15h25 - 15h30	Session Summary and Wrap up	Co-Chairs
15h30 - 16h00	Tea/Coffee Break	
16h00 - 16h30	2nd Poster Session	All

Time	Topic	Responsible
16h30 – 18h00	**Parallel Session I:** **The role of harmonization in pharmacovigilance and post-market surveillance** **Session objectives:** To share experiences and developments in PV and PMS including innovative approaches **Session Co-Chairs:** Karim Smine & Raj Long **Rapporteurs:** Paul Tanui (AUDA-NEPAD), Bridget Dube (MCAZ) What health workers and patients know about adverse drug events/reactions reporting, why they do not report and what regulators can do to improve reporting: Dan Kajungu Establishing The Electronic Adverse Reaction Reporting Tool: The Tanzanian Perspective: Ambele Mwafula Impact Of Structured Stimulated Pharmacovigilance In Tertiary Hospitals: A Review Of Individual Case Safety Received At The Tanzania Medicines And Medical Devices Authority: Kissa Mwamwitwa MEDISAFE: a regional project to fight against falsified medicines in Africa: Helene Degui Regulatory reliance in reacting to global quality and safety issues related to medicines: The "Sartans" experience in South Africa and ZAZIBONA countries: Patience Phuti Shabangu	**Parallel Session II:** **Regulation of medical devices, blood/blood products & clinical trials – where are we?** **Session objectives:** To share regional and country experiences in regulation of medical devices, blood and blood products and other regulatory functions **Session Co-Chairs:** Samvel Azatyan & Jean-Baptiste Nikiema **Rapporteurs:** WHO Regulation of Blood and Blood Products In Tanzania: The Current Progress and the Way Forward: Elirehema Mfinanga Complexities around the Clinical Development of Novel Vaccines – an Industry perspective: Lorenz Scheppler The VaccTrain/RegTrain Project: Achievements from the perspective of a partner country: Juwe D. Kercula Harmonization of Clinical Trials Regulation in Africa through African Vaccine Regulatory Network (AVAREF): The NAFDAC Experience: Christiana Mojisola Adeyeye Regulation of Medical Devices In Tanzania: What Has Been Achieved?: Sunday Kisoma
19h00 - 21h00	Welcome Reception Cocktail	

Tuesday, 01 October 2019		
Time	**Topic**	**Responsible**
08h00 - 08h30	Day 1 Recap, Chimwemwe Chamdimba (AUDA-NEPAD) & Diadie Maiga (WHO AFRO)	
08h30 - 10h00	**Plenary Session III:** **African Medicines Agency and Sustainable Financing Models** **Session objectives:** To update participants on progress made in the establishment of AMA and share experiences from other regions outside Africa **Session Co-Chairs:** Gugu Mahlangu & Murray Lumpkin **Rapporteurs:** AUDA-NEPAD	
08h30 - 08h50	The proposed value proposition and operating model for the African Medicines Agency	Margareth Ndomondo-Sigonda (AUDA-NEPAD); Gugu Mahlangu (MCAZ/Former Chair AMA Task Team)
08h50 - 09h10	A Theoretical Framework for Operating Models for African Medicines Agency and Regional Institutions	Luther Gwaza (WHO)
09h10 - 09h25	Lessons from the EMA, and its Network of National Regulatory Authorities	Thomas Senderovitz (Danish Medicines Agency)
09h25 - 09h35	Maximizing the regulatory efficiency and effectiveness of the AMA: Learning from the experience of others	Lawrence Liberti (CIRS)
09h35 - 09h55	Discussion	All
09h55 - 10h00	Session Summary and Wrap up	Co-Chairs
10h00 - 10h30	Tea/Coffee Break	

Time	Topic	Responsible
10h30 - 11h45	**Parallel Session III:** **Harmonization of regulation of medical products – Innovative approaches to measuring regulatory outcomes, reliance and harmonization; What have been the access gains at country level?** **Session objectives:** To share innovative technologies in regulation, reliance models and country experiences in establishing autonomous agencies. **Session Co-Chairs:** Lawrence Liberti & Jane Mashingia **Rapporteurs:** EAC MRH CTD, Electronic CTD and eCTD: Providing the Right Guidance: Kent Briggs Transition from a regulatory unit within a Ministry to a fully functional semi-autonomous regulatory authority: A case study of Botswana Medicines Regulatory Authority: Stephen Ghanie Over-the-Counter (OTC) Health Products Regulatory Framework in Africa - Securing AMRH's Role to Facilitate Wider Consumer Access to Nonprescription Medical Products: Caroline Mendy Effective mechanisms for regulatory reliance systems – an Industry perspective: IFPMA	**Parallel Session IV:** **Alignment of regulatory networks and forums, and role of partnerships** **Session objectives:** To provide participants with lessons learned working through regulatory forums, networks and partnership frameworks **Session Co-Chairs:** Mike Ward & Fatuma Adan **Rapporteurs:** WAHO MRH Shelf-life Recommendations for Importation of Medical Products: Adrian Barojas Harmonizing Research Ethics Review Frameworks in the East African Community: Ethel Makila Proficiency Testing Scheme for Pharmaceutical Laboratories: East African Regional Experience: Eliangiringa Kaale AfroCondomNet: Stronger Partnerships for Effective Condom Regulation: Frank Loban The Impact Of Management Information System In Improving Customer Service Delivery And Decision Making: Experience From Tanzania Medicines And Medical Devices Authority: Ambele Mwafula

Time	Topic	Responsible
11h45 - 13h00	**Parallel Session V:** **Human resources - Models for capacity building and skills retention.** **Session objectives:** To take stock of various models for capacity building that have been piloted and rolled out in Africa in recent times. **Session Co-Chairs:** Moji C Adeyeye & SF Malan **Rapporteurs:** WHO & AUDA-NEPAD Human Capacity Building in Africa: The BIRS Model: Kari Clase Systematic human capital development for national medicines regulatory authorities: A case study of Botswana Medicines Regulatory Authority: Tendayi Roy Chihaka The RegTrain Project: Widening the scope of regulatory capacity building based on the VaccTrain I pilot project: Regine Lehnert Fellowship in Regulatory Science for African medicine reviewers: Tariro Makamure-Sithole	**Parallel Session VI:** **Optimizing regulatory outcomes, harmonization and experiences in Africa and beyond.** **Session objectives:** Share experiences in optimizing and measuring regulatory processes, outcomes, and experiences in harmonization and reliance. **Session Co-Chairs:** Sybil Ossei-Agyeman Yeboah & John Mwangi **Rapporteurs:** IGAD MRH Promoting risk-based approach to inspections and assessments: WHO collaborative registration procedure as a case study: Luther Gwaza Importance of Medicine Quality in Achieving Universal Health Coverage in Africa: Tatenda Yemeke Setting Dissolution Specifications for Generic Products to Ensure equivalence and Product Quality: Ethel Sebua Harmonization Of Regulation Of Medical Products-Innovative Approach To Measuring Regulatory Outcomes, Reliance And Harmonization: Monica Eimunjeze Optimizing Regulatory agencies processes and performance through standardized systematic measures: Prisha Patel
13h00 - 14h00	Lunch	
14h00 - 14h30	3rd Poster Session	All
14h30 - 15h30	**Plenary Session IV:** **Shaping the future of medical products regulation in Africa including digital and innovative tools used in health regulation** **Session objectives:** To highlight future of medical products regulation in Africa within the broader scope of new tools and technologies and broader context of universal health coverage **Session Co-Chairs:** Andreas Seiter & Houda Langar **Rapporteurs:** SADC MRH	
14h30 - 14h45	The need for improving reliability, currency and accessibility of product information using e-tools: the case for the QR code	Rutendo Kuwana (WHO)

Time	Topic	Responsible
14h45 - 15h00	Regulatory harmonization of medical products as a key driver to achievement of Universal health coverage in Africa	Johnpaul Omollo (PATH)
15h00 - 15h15	Using collaborative cloud-based solutions for seamless collaboration and harmonization in Africa	Winona Rei Bolislis (SANOFI)
15h15 - 15h30	Discussion and Summary	Co-Chairs
15h30 - 15h45	SCoMRA IV recommendations	Diadie Maiga (WHO AFRO) & Houda Langar (WHO EMRO)
15h45 - 16h00	Discussion on recommendations	All
16h00 - 16h30	Tea/Coffee Break	
16h30 - 16h45	Award Ceremony for best oral and poster presentations – Scientific Committee	
16h45 - 17h30	**Closing Ceremony** **Master of Ceremony:** WHO **Speakers:** Prof Aggrey Ambali, AUDA-NEPAD, WHO, IFPMA, BMGF, WB SADC, MCAZ **Rapporteurs:** AUDA-NEPAD	

Annexe 2:
List of participants

1. Clinton Rambanapasi
2. Abraham Kahsay
3. Adam Fimbo
4. Adrian Barojas
5. Aggrey Ambali
6. Ahamada Said Fazul
7. Aimé Bernard Djitafo Fah
8. Aisseta Touré
9. Alex GISAGARA
10. Dix Alexander E. George
11. Alexandre De la Volpilière
12. Alexis Kapanga
13. Ambele Mwafula
14. Aminata NACOULMA
15. Amira Younès
16. Amélie Robine
17. André Loua
18. Andriette Ferreira
19. Ann Fortin
20. Anna Thomas
21. Annette Ssenkindu Bukirwa
22. Anthony Toroitich
23. Apollo Edson Muhairwe
24. Ashish Kumar Das
25. Azwimpheleli Langalanga
26. Bakani M. Ncube
27. Benjamin Botwe
28. Bernad Kasekete
29. Bernadette Miraso
30. Bernice Mwale
31. Bonaventure Chilinde
32. Bordan Mapfumo
33. Brian Mutale Ngandu
34. Brighton Sibanda
35. Samunda brillant
36. Buhle Hlatshwayo
37. Bunmi Femi-oyekan
38. Carol Ruffell
39. Caroline DAMOUR
40. Caroline Mendy
41. Caroline Samatanga
42. Cassiano Joao
43. Cecilia Oh
44. Mutsata de charité
45. Charle Leibbrandt
46. Chawapuwa Mabvoro
47. Chika Umenyiora
48. Chimwemwe Chamdimba
49. Christine Malati
50. Dan Hartman
51. David Jefferys
52. David Mukanga
53. David Springer
54. David Sumo
55. Denver Phiri
56. Dexter Tagwireyi
57. Diadie Maiga
58. Diana Wanyonyi
59. Diogo Ribeiro
60. Dorah Diale
61. Dr Ivana Skrnjug
62. Dre Kristina Heinrich
63. Électeur Chikomo
64. Eliangiringa Kaale
65. Eliot Hunkgia
66. Elirehema Mfinanga
67. Elishiba Mwangi
68. Emer Cooke
69. Emmanuel Bamenyekanye
70. Emmanuelle Mbemba
71. Ernest Afesey
72. Ester Witi
73. Ethel Makila
74. Ethel Sebua
75. Eun Mi Kim
76. Evah Amwayi
77. Fatima Bulla
78. Fatuma Adan
79. Felistas Chepwogen
80. Florence Erb
81. Bhembe chanceux
82. François Aboagye-Nyame
83. François Karanja
84. Fundo Tembo

85. Gertrude Ngqabutho
86. Don T. Chareka
87. Godfil Langa
88. Grace Mushowo
89. Gugu Nolwandle Mahlangu
90. Guy NJAMBONG
91. Habsatou Mindadou
92. Hanna Flamme
93. Hashim Ubale Yusufu
94. Hiiti Sillo
95. Houda Langar
96. Hounnou Carmelle
97. Ian Hudson
98. Ignatia Stephens
99. James Sisise
100. Jane Mashingia
101. Jane Mwangi (R.Ph., Ph.D)
102. Jérémie Nyamundanda
103. Johaniu Ternandes
104. Johannes Gaeseb
105. John Mwangi
106. Joshua Govere
107. Julie Hofer
108. Juwe D. Kercula
109. Classe Kari
110. Karim Smine
111. Kate Kikule
112. Kent Briggs
113. Kgothatso Motumi
114. Kissa Mwamwitwa
115. Kudakwashe Chikomwe
116. Kudzaishe Wisikoti
117. Kwasi Boateng
118. Laban Nkonde Frank
119. Lawrence Liberti
120. Leonard Ncube
121. Lerato T Makhurane
122. Linda Mudyiwenyama
123. Liniah Mumbengegwi
124. Lorenz Scheppler
125. Lucile De Comarmond
126. Luckmore Safull
127. Lynette Mutisi
128. Magdalena Pajewska Lewandowska
129. Malick Sakho
130. Manana Mashologu
131. Margareth Ndomondo Sigonda
132. Maria Mudzudzu
133. Marie Mclellan
134. Marion Laumonier
135. Markieu Janneh-Kaira
136. Marlven Gabaza
137. Mawien Arik
138. Moi'Sheri Adams
139. Mercedes Leburu
140. Mike Ward
141. Moji Adeyeye
142. Monica Hemben Eimunjeze
143. Mouhoudine YERIMA
144. Muchaneta Mwonzora
145. Murray Lumpkin
146. Nadia Fenina
147. Nancy Ngum
148. Neimatu Adjabui
149. Nevena Miletic
150. Ngono Mballa Epse Abondo
151. Niya Bowers
152. Nkaelang Modutlwa
153. Nthabiseng Moiloa
154. Ntsiki Moek
155. Olanyo Joseph
156. Oussama Badary
157. Osaretin Jaiyeola
158. Padmine Rammidi
159. Paidamoyo Chipunza
160. Parthasarathi Gurumurthy
161. Patience Phuti Shabangu
162. Paul Njaria
163. Pauline Takawira
164. Portia Kampota-Munhuweyi
165. Portia Nkambule
166. Chida précieux
167. Priscilla Nyambayo
168. Prisha Patel

169. Pr Kelly Chibale
170. Prudence Manzunzu
171. Rachelle Harris
172. Rachelle Sarah Kyeyune
173. Régine Lehnert
174. Réjouis-toi Shumba
175. Rhonda Clymer
176. Richard Mihigo
177. Richard Rukwata
178. Robin Razakarivelo
179. Ronald Inyangala
180. Lièvre Rose
181. Lièvre Romarin
182. Roy Tendayi Chihaka
183. Safiatou Simpore
184. Sakhile Dube-Mwedzi
185. Samuel Asante-Boateng
186. Samvel Azatyan
187. Sarah Adam
188. Sarah Muthuri
189. Sateesh Jami
190. Saziso Dlamini
191. Seima Dijeng
192. Sevreina Smith
193. Shamar Juru
194. Shawn Dolley
195. Shingai Gwatidzo
196. Shungu Munyati
197. Shyam Bhaskaran
198. Sibusiso Hlatjwako
199. Stanislav Kniazkov
200. Stanley Midzi
201. Stanley Mkuluchi
202. Stanley Sanyanga
203. Stephen Ghanie
204. Dimanche Kisoma
205. Susan Wanjiru
206. Svein Rune Andersen
207. Sybil Ossei Agyeman Yeboah
208. Tafadzwa Tirivangani
209. Tandazani Zimbwa
210. Tariro Makamure - Semelle
211. Tendai Maunga
212. Thea Norman
213. Thomas Nyirenda
214. Thuli Makhene
215. Vanessa Gamuchirai Gonye
216. Vicky Manyanga
217. Victor Abiola
218. Vincent Ahonkhai
219. Wairi Paula
220. Wallada Im-Amornphong
221. Washington Dengu
222. Washington Samukange
223. Wilberto Robles
224. William Wekwete
225. Winnie Nganga
226. Winona Rei Bolislis
227. Yaya Coulibaly
228. Yetunde Alli
229. Yolanda Moyo
230. Yousuf Vawda
231. Yvonne Adu-Boahen

Annexe 3:
Image Gallery


NEPAD
AMRH


NEPAD
AMRH


NEPAD
AMRH


NEPAD
AMRH


NEPAD
AMRH


NEPAD
AMRH


AMRH
NEPAD


AMRH
NEPAD


AMRH
NEPAD


AMRH


AMRH
NEPAD


AMRH
NEPAD


AMRH
NEPAD


AMRH
NEPAD


AMRH
NEPAD


AMRH
NEPAD


MCAZ
Strategic Foundation
Mission
Vision
Values


AMRH
MCAZ
Strategic Foundation
Mission
Vision
Values


AMRH


AMRH


NEPAD
AFRICAN UNION DEVELOPMENT AGENCY


SPEAKER


AMRH
AMRH
AMRH


SCoMRA IV


SCoMRA IV


WHO


WHO
WHO


AUDA
NEPAD


WHO


PEI


ASSEMBLY


MCAZ


TOGO


AUDA
NEPAD


AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY