#SCOMRA2019

4th Biennial Scientific Conference on Medical Products Regulation in Africa

30 September - 1 October 2019

Conference Programme

Elephant Hills Hotel & Resort
Victoria Falls
Zimbabwe

A Decade of Regulatory Harmonization in Africa:
Where are we? Where do we go from here?

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KEY ISSUES TO BE DISCUSSED DURING SCOMRA IV
AMRH
African Medicines Regulatory Harmonisation Programme
8
REGIONS
AMA
African Medicines Agency
African Medicines Harmonization Initiative
Review progress in implementation, identify challenges and alignment of regulatory networks within AMRH
Harmonization in practice
Regulatory networks will have an opportunity to share updates on implementation of harmonisation
African Medicines Agency (AMA)
Progress made in the establishment of AMA, sustainability, as well as lessons learnt from similar initiatives outside Africa
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TIME	TOPIC	RESPONSIBLE
12:00-19:00	Registration	Secretariat
30 September 2019		
07:00-08:30	Registration	Secretariat
08:30 – 10:00: Opening Ceremony Master of Ceremony:Margareth Ndomondo-Sigonda (AUDA-NEPAD) and Ann Fortin (WHO-AFRO) Rapporteurs: Chimwemwe Chamdimba (AUDA-NEPAD) & Stanislav Kniazkov (WHO-AFRO)		
08:30 – 08:45	Welcome Remarks	• Stergomena Lawrence Tax, Executive Secretary, SADC • Alex Ntale Gasasira, WHO Representative to Republic of Zimbabwe
08:45 – 09:45	High-Level Plenary: A Decade of Regulatory Harmonization in Africa: Where are we? Where do we go from here? Moderator – Gugu Mahlangu, Director General, MCAZ 5 mins elevated speed talk from each panellist followed by a facilitated discussion	• Aggrey Ambali, Director, Technical Cooperation, Programme 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) • Emer Cooke, Director Regulation of Medicines and other Health Technologies, World Health Organization • Christianah Mojisola Adeyeye, Director, General NAFDAC & Chairperson AMRH Steering Committee
09:45 – 10:00	Official Opening	H.E. Dr Obadiah Moyo, Minister of Health and Child Care, Republic of Zimbabwe
10:00 – 10:30	**Group Photo and Tea/Coffee Break**	

TIME	TOPIC	RESPONSIBLE
10:30 - 11:00	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
11:00 – 12:30 Plenary Session I: 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)		
11:00 – 11:15	Global context of harmonization and innovative models	Mike Ward (WHO)
11:15 – 11:35	AMRH Programme: Continental Progress Update	Margareth Ndomondo-Sigonda (AUDA-NEPAD)
11:35 – 12:10	Panel discussion including Q&A	AUDA-NEPAD & RECs Representatives
12:10 – 12:20	WHO benchmarking of regulatory systems – Updates and implications for Africa	Hiiti Sillo (WHO)
12:20 – 12:30	Building the Medicines Quality Control Capacities in Africa: Where are we?	Abdelkrim Smine (USP)
12:30 –12:40	Discussion	All
12:40 – 12:50	Session Summary and Wrap up	Co-Chairs
12:50 – 13:15	1st Poster Session	All
13:15 – 14:15	**LUNCH**	

TIME	TOPIC	RESPONSIBLE
14:15 – 15:30: 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: William Wekwete (MCAZ) and IFPMA		
14:15 – 14:30	The East African Community Joint Assessment Procedure: Achievements, Challenges and Way Forward	Shani Maboko (TMDA)
14:30 – 14:45	ZAZIBONA GMP inspections – Upward momentum, impact & kaizen:	Washington Dengu (MCAZ)
14:45 – 15:00	Complexity of Life Cycle Management and the challenges for African countries – an Industry perspective	Bunmi Femi-Oyekan (IFPMA)
15:00 – 15:15	An Urgent and Strong Need for Harmonized Regulation of Biologics Including Vaccines in East African Community and Africa at large	Grant Munkwase (NDA)
15:15 – 15:25	Discussion	All
15:25 – 15:30	Session Summary and Wrap up	Co-Chairs
15:30 – 16:00	**Tea/Coffee Break**	
16:00 – 16.30	2nd Poster Session	All

TIME	TOPIC	RESPONSIBLE
16:30 – 18:00	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 (USP) & Francis Aboagye-Nyame (USAID-MTaPS) 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 (TMDA) 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 (TMDA) MEDISAFE: A regional project to fight against falsified medicines in Africa: Alexandre de la Volpilière (MEDISAFE) 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 (SAHPRA)	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 (WHO) & Jean-Baptiste Nikiema (WHO) Rapporteurs: Andre Loua (WHO) Regulation of Blood and Blood Products In Tanzania: The Current Progress and the Way Forward: Elirehema Mfinanga (TMDA) Complexities around the Clinical Development of Novel Vaccines – an Industry perspective: Lorenz Scheppler (IFPMA) The VaccTrain/RegTrain Project: Achievements from the perspective of a partner country: Juwe D. Kercula (LMHRA) Harmonization of Clinical Trials Regulation in Africa through African Vaccine Regulatory Network (AVAREF): The NAFDAC Experience: Christianah Mojisola Adeyeye (NAFDAC) Regulation Of Medical Devices In Tanzania: What Has Been Achieved?: Sunday Kisoma (TMDA)
19:00 - 21:00	**Welcome Reception Dinner**	**All**

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TIME	TOPIC	RESPONSIBLE
08:00 – 08:30	Day 1 Recap	Chimwemwe Chamdimba (AUDA-NEPAD) & Diadie Maiga (WHO AFRO)
08:30 – 10:00: 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 (MCAZ) & Murray Lumpkin (BMGF) Rapporteurs: Nancy Ngum (AUDA-NEPAD)		
08:30 – 08:50	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)
08:50 – 09:10	A Theoretical Framework for Operating Models for African Medicines Agency and Regional Institutions	Gugu Mahlangu - Director General, MCAZ & Former Chair AMA Task Team)
09:10 – 09:25	Lessons from the EMA, and its Network of National Regulatory Authorities	Thomas Senderovitz (Danish Medicines Agency)
09:25 – 09:35	Maximising the regulatory efficiency and effectiveness of the AMA: Learning from the experience of others	Lawrence Liberti (CIRS)
09:35 – 09:55	Discussion	All
09:55 – 10:00	Session Summary and Wrap up	Co-Chairs
10:00 – 10:30	**Tea/Coffee Break**	

TIME	TOPIC	RESPONSIBLE
10:30 – 11:45	Parallel Session III: Harmonisation 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 (CIRS) & Jane Mashingia (EAC) Rapporteurs: IGAD MRH CTD, Electronic CTD and eCTD: Providing the Right Guidance: Kent Briggs (VECTOR) 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) 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 (WSMI) Effective mechanisms for regulatory reliance systems – an Industry perspective: Nevena Miletic (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: Emer Cooke (WHO) & Fatuma Adan (IGAD) Rapporteurs: WAHO MRH Shelf-life Recommendations for Importation of Medical Products: Adrian Barojas (FHI 360) Harmonizing Research Ethics Review Frameworks in the East African Community: Ethel Makila (IAVI) Proficiency Testing Scheme for Pharmaceutical Laboratories: East African Regional Experience: Eliangiringa Kaale (MUHAS) Reliance and networking to facilitate access to medicines: Case studies from the European Medicines Agency: Magdalena Pajewska Lewandowska (EMA) AfroCondomNet: Stronger Partnerships for Effective Condom Regulation: Seloi Mogatle (UNFPA) The Impact Of Management Information System In Improving Customer Service Delivery And Decision Making: Experience From Tanzania Medicines And Medical Devices Authority: Ambele Mwafula (TMDA)

TIME	TOPIC	RESPONSIBLE
11:45 – 13:00	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 (NAFDAC) & Emer Cooke (WHO) Rapporteurs: WHO & Paul Tanui (AUDA-NEPAD) Human Capacity Building in Africa: The BIRS Model: Kari Clase (Purdue) Systematic human capital development for national medicines regulatory authorities: A case study of Botswana Medicines Regulatory Authority: Tendayi Roy Chihaka (BOMRA) The RegTrain Project: Widening the scope of regulatory capacity building based on the VaccTrain I pilot project: Regine Lehnert (BfArM) Fellowship in Regulatory Science for African medicine reviewers: Tariro Makamure-Sithole (MCAZ)	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 harmonisation and reliance Session Co-Chairs: Sybil Ossei-Agyeman Yeboah (WAHO) & John Mwangi (IFPMA) Rapporteurs: EAC MRH Promoting risk-based approach to inspections and assessments: WHO collaborative registration procedure as a case study: Samvel Azatyan (WHO) Importance of Medicine Quality in Achieving Universal Health Coverage in Africa: Tatenda Yemeke Hemlibra and Zazibona; what it means for patients: Clinton Rambanapasi (Roche) Harmonization Of Regulation Of Medical Products-Innovative Approach To Measuring Regulatory Outcomes, Reliance And Harmonization: Monica Eimunjeze (NAFDAC) Optimising Regulatory agencies processes and performance through standardised systematic measures: Prisha Patel (CIRS)
13:00 – 14:00	**LUNCH**	

TIME	TOPIC	RESPONSIBLE
14:00 – 14:30	3rd Poster Session	All
14:30 – 15:30: 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 (WB) & Houda Langar (WHO-EMRO) Rapporteurs: Sakhile Dube-Mwedzi (SADC MRH) and Washington Dengu (MCAZ)		
14:30 – 14:45	The need for improving reliability, currency and accessibility of product information using e-tools: the case for the QR code	Rutendo Kuwana (WHO)
14:45 – 15:00	Regulatory harmonization of medical products as a key driver to achievement of Universal health coverage in Africa:	Johnpaul Omollo (PATH)
15:00 – 15:15	Using collaborative cloud-based solutions for seamless collaboration and harmonisation in Africa	Winona Rei Bolislis (Sanofi-Pasteur)
15:15 – 15:30	Discussion and Summary	Co-Chairs
15:30 – 15:45	SCoMRA IV recommendations	Diadie Maiga (WHO AFRO) & Houda Langar (WHO EMRO)
15:45 – 16:00	Discussion on recommendations	All
16:00 – 16:30	**Tea/Coffee Break**	
16:30- 16:45	Award Ceremony for best oral and poster presentations	Scientific Committee
16:45 – 17:30	Closing Ceremony Master of Ceremony: WHO Speakers: AUDA-NEPAD, WHO, IFPMA, BMGF, WB, SADC, MCAZ Rapporteurs: AUDA-NEPAD	

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