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**The 4th Biennial Scientific Conference on Medical Products Regulation in Africa**

**(SCoMRA 2019)**

*Theme: A Decade of Regulatory Harmonization in Africa:*

*Where are we? Where do we go from here?*

30 September – 01 October 2019

Elephant Hills Hotel and Resort

Victoria Falls, Zimbabwe

**Provisional Programme**

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| **Time** | **Topic**  | **Responsible** |
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| **Sunday, 29 September 2019** |
| 12:00-19:00 | Registration  | Secretariat |
| **Monday, 30 September 2019** |
| 07:00-08:30 | Registration  | Secretariat |
| **08:30 – 10:00: Opening Ceremony****Master of Ceremony:** AUDA-NEPAD and WHO-AFRO**Rapporteurs:** *AUDA-NEPAD & WHO* |
| 08:30 – 08:45 | Welcome Remarks  | * Dr Stergomena Lawrence Tax, Executive Secretary, SADC
* WHO Representative to Republic of Zimbabwe
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| **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, DG MCAZ5 mins elevated speed talk from each panellist | * 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
* Christina Moji, Director General NAFDAC & Chairperson AMRH Steering Committee
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| 09:45 – 10:00 | Official Opening  | H.E. Mr Obadiah Moyo, Minister of Health and Child Care, Republic of Zimbabwe |
| 10:00 – 10:30 | **Group Photo and Tea/Coffee Break**  | **All** |
| 10:30 - 11:00 | **Keynote Speaker** | **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:** Paul Tanui (AUDA-NEPAD) and WHO |
| 11:00 – 11:15 | Global context of harmonization and innovative models | Emer Cooke, 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 GBT experience | 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** | **All** |

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| **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:** *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 | Sarah Adam (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**  | **All** |
| 16:00 – 16.30 | 2nd Poster Session | All  |

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| 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 & 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* |
| **19:00 - 21:00** | Welcome Reception Cocktail | All |

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| **Tuesday, 01 October 2019** |
| 8:00 – 8:30 | Day 1 Recap, Chimwemwe Chamdimba (AUDA-NEPAD) & Diadie Maiga (WHO AFRO)  |
| **8:30 – 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 & Murray Lumpkin****Rapporteurs:*** *AUDA-NEPAD* |
| 8:30 – 8:50 | 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) |
| 8:50 – 9:10 | A Theoretical Framework for Operating Models for African Medicines Agency and Regional Institutions | Luther Gwaza (WHO) |
| 9:10 – 9:25 | Lessons from the EMA, and its Network of National Regulatory Authorities | Thomas Senderovitz (Danish Medicines Agency) |
| 9:25 – 9:35 | Maximising the regulatory efficiency and effectiveness of the AMA: Learning from the experience of others | Lawrence Liberti (CIRS) |
| 9:35 – 9:55 | Discussion | All |
| 9:55 – 10:00 | Session Summary and Wrap up  | Co-Chairs |
| **10:00 – 10:30** | **Tea/Coffee Break**  | **ALL** |

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| 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 & 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: *Seloi Mogatle*The Impact Of Management Information System In Improving Customer Service Delivery And Decision Making: Experience From Tanzania Medicines And Medical Devices Authority: *Ambele Mwafula* |
| 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 & 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 harmonisation 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*Optimising Regulatory agencies processes and performance through standardised systematic measures: *Prisha Patel* |
| **13:00 – 14:00** | **Lunch** | **All** |
| 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 & Houda Langar* ***Rapporteurs:*** *SADC MRH* |
| 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) |
| 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:** Prof Aggrey Ambali, AUDA-NEPAD, WHO, IFPMA, BMGF, WB SADC, MCAZ **Rapporteurs:** *AUDA-NEPAD* |