AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

World Health Organization

6th BIENNIAL SCIENTIFIC CONFERENCE ON MEDICAL PRODUCTS REGULATION IN AFRICA

Theme: Strengthening regulatory systems for the advancement of local production and increased access to medical products and technologies for Africans

EGYPT , CAIRO

05-07 DECEMBER

#SCoMRA2023

Monday, 04 December 2023		
15:00–18:00	Registration	AMRH Secretariat
Tuesday, 05 December 2023		
07:30–9:00	Registration	AMRH Secretariat
9:00-09:35	**Opening Ceremony**	
Session Co-Chairs: *Chimwemwe Chamdimba, AUDA-NEPAD and Houda Langar, WHO-EMRO*		
Welcome Remarks		▪ Dr David Mukanga, Chairperson of the AMRH Partnership Platform ▪ Dr Boitumelo Semete-Makokotlela, Chairperson of the AMRH Steering Committee ▪ WHO EMRO Representative ▪ Mr Symerre Grey-Johnson, Director of Human Capital and Institutional Development, AUDA NEPAD ▪ Prof Julio Rakotonirina, Director for Health & Humanitarian Affairs, AUC
Official Opening		▪ Dr Tamer Essam, Chairman, Egyptian Drug Authority
09:35-10:30	**Plenary Session I**	
Strengthening regulatory systems for the advancement of local production and increased access to quality medical products and technologies in Africa **Session Co-Chairs:** *Chimwemwe Chamdimba, AUDA-NEPAD and Houda Langar, WHO-EMRO* Panellists will discuss key challenges and opportunities in regulatory systems, including local manufacturing, quality assurance, and access to medical products in Africa. Special focus on ▪ Global Perspective on regulatory strengthening: **Hiiti Sillo, WHO** ▪ Regional initiatives and partnerships to strengthen regulatory systems: **Sybil Ossei- Agyeman-Yeboah, WAHO** ▪ National Regulatory Authority perspective: **Felistas Chepwogen, Kenya Pharmacy and Poisons Board** ▪ Industry's perspective on collaborating with regulatory agencies: **Emmanuel Mujuru, FAPMA** ▪ Procurement, Supply Chain and Distribution insights: **Peter Mbwiiri, UNICEF**		
10:30-11:00	**Group Photo and Tea/Coffee Break**	
11:00-13:00	**Plenary Session II**	
Advancing Regulatory Reliance in Africa: Progress, Challenges, and the Path Forward **Session Chair:** *David Mukanga, BMGF and Chairperson of the AMRH Partnership Platform* *Lead presentations:* ▪ Reliance at the Continental Level: Recent Developments under the AMRH Program: **Alex Juma Ismail, AUDA NEPAD** ▪ Abridged Medical Product Evaluation of Regional Applications: A Case Study of East Africa Community: **Diana Njiu, EAC Lead Agency on Registration and MA** ▪ Towards establishing a continental laboratory network to ensure the quality of medical products in Africa: **Bonaventure Chilinde, Chair of the AMQF** ▪ The African Vaccine Regulatory Forum (AVAREF): Experiences and Lessons Learned in Reliance for Clinical Trial Oversight: **Kwasi Nyarko, WHO AFRO**		

Panel Discussion (60min): What are the most significant obstacles that still need to be overcome to further strengthen regulatory reliance, and how can these obstacles be effectively addressed at both the national and continental levels. How do we scale up the key tools and learning for adoption across African continent

- **Panellists**: Boitumelo Semete-Makokotlela – SAHPRA; Karim Wanga – IGAD; Emmanuel Mujuru - FAPMA, Anthony Humphreys EMA and Marie Valentin – WHO

13:00–14:00	**Lunch & Poster Session**
14:00-15:30	**Plenary Session III**

Advancing access to quality-assured medical products by leveraging existing work on AMA operationalisation

Session Chair: *Boitumelo Semete-Makokotlela, CEO of SAHPRA and AMRH Steering Committee*

Lead Presentations:

- Progress on regulatory systems strengthening efforts, challenges opportunities: the contribution to Africa regulatory system strengthening: **Andrea Keyter, WHO**
- Leveraging on regulatory harmonisation to advance the AMA agenda: **Chimwemwe Chamdimba, AUDA-NEPAD**
- Sustainability and innovative mechanism for regulatory financing: **Anthony Humphreys, EMA**

Panel Discussion: The changing regulatory landscape in AMA era: what to expect?

Panellists

- Inas Mubarak, African Union Commission
- Adechina Rhanda, Agence Béninoise de Régulation Pharmaceutique
- Elsharif Amany, African Medicines Agency Treaty Alliance
- Sarah Adams, International Federation of Pharmaceutical Manufacturers & Associations
- David Mukanga, Bill and Melinda Gates Foundation

15:30-17:30	**Parallel sessions**

Parallel Session I: Substandard & falsified medicines: what is Africa doing to combat the scourge? ***Session Chair:*** *Oumy Ndiaye Ndao, Agence Sénégalaise de Réglementation Pharmaceutique*	***Parallel Session II: The future of medical products regulation and harmonization in the AMA era*** ***Session Chair:*** *Ahamada Said Fazul, Head of Agency Comoros and Chair of AMRC*
Understanding, readiness and response of healthcare professionals in combating falsified medical products in Eritrea: a population-based survey: **Azania Andemichael**	A Comparison of the Regional Medicines Regulatory Harmonisation Projects in East, West and Southern Africa: **Tariro Sithole**

Prioritizing Patient Safety: Focus on Raw Material and Excipient Quality to Combat Substandard and Falsified Medicines: **Chaitanya Koduri**	Strengthening Global Healthcare: Collaboration between the European Medicines Agency and African Medicines Agencies: **Victoria Palmi**
Modeling the Burden of Substandard and Falsified Oxytocin in Kenya: Pilot Experience: **Edward Abwao**	Strengthening pharmaceutical regulatory systems in Central and West Africa: common gaps in critical pillars: **Guy N'Jambong**
WHO response to over-the-counter syrups for children with confirmed or suspected contamination with high levels of diethylene glycol and ethylene glycol: **Leticia Megias Lastra**	Evolution of the Africa regulatory ecosystem for efficient National Approvals: **Nevena Miletic**
The Pilot Substandard and Falsified Medical Product University Curriculum: Sharing the Best Practices on FIP-WHO Collaboration: **Eliangiringa Kaale**	Maximizing the impact of Regional Regulatory Initiatives in Africa: An analysis of process characteristics of pathways on the FRPath® database: **Bakani Ncube**
	Evaluation of Risk-Based Approaches to the Registration of Medicines: Current Status Among African Regulatory Authorities: **Stuart Walker**
Q&A	Q&A
17:30-18:00	**Tea/Coffee Break & Poster Session**

Wednesday, 06 December 2023	
9:00 – 9:10	**Day 1 Recap**
9:10 – 11:00	**Plenary Session IV**

Current Innovations in fighting Substandard & Falsified medicines

Session Chair: *Sakhile Dube, SADC MRH Project*

Presentations :

- Country level experience in embracing innovations in the fight against SF- The case of Nigeria: **Oluwaseun Adesanya, NAFDAC**
- Regional approaches to post-market surveillance – IGAD experience: **Karim Wanga, IGAD**
- Continental plan to fight SF: **Anthony Kapeta, AUDA-NEPAD**
- United Nations Office on Drugs and Crime actions against SF in Africa: **Dina Faya, UNODC**
- Barriers to Reporting Substandard and Falsified (SF) Medical Products to the Global Surveillance and Monitoring System (GSMS) and (Possible/Key) Solutions to Bridge the Gaps Identified: **Leticia Megias Lastra**
- Strengthening Quality Control Laboratories in Fighting SF: **Timothy Nwogu, USP**

Q&A

11:00 – 11:30	**Tea/Coffee Break & Poster Session**
11:30 – 13:00	**Plenary Session V**

Digitalization for advancing regulation of medical products in Africa

Session Chair: *Adam Fimbo, TMDA and Vice Chairperson of the AMRH SC*

Presentations:

- Embracing digitalisation in the African the continental regulatory ecosystem - *The emerging continental data systems* focusing on Regulatory Information Management in Regulatory Performance and Decision Making-AMRH RIMS Technical Committee, eCRES and Continental API Database: **Chimwemwe Chamdimba, AUDA-NEPAD**
- One ECOWAS, One eCTD, One Harmonised Region: The digitalized way to accelerate assessment reviews: **Sybil Ossei- Agyeman-Yeboah, WAHO**
- Experiences, best practices and success stories from National Regulatory Authorities on implementation of Regulatory Information Management System: **Kereng Baleki, BoMRA**
- Artificial Intelligence and Cybersecurity in Medical Devices: Potential Risk and Regulations: **Samuel Egieyeh**

Q&A

13:00-14:00	**Lunch & Poster Session**
14:00-16:00	**Parallel sessions**

Parallel Session III: **The future of medical products regulation and harmonization in the AMA era** ***Session Chair:*** *Dalia Abouhussein, Egyptian Drug Authority*	***Parallel Session IV:*** **Digitalization for advancing regulation of medical products in Africa** ***Session Chair:*** *Eliangiringa Kaale, Muhimbili University of Health and Allied Sciences*
Evaluation of the Regulatory Review Process of FDA Ghana: Challenges and Opportunities for Improvement: **Mercy Owusu-Asante**	African Union Smart Safety Surveillance Joint Signal Management: African-Owned Safety Data Integration and Signal Detection for Covid-19 Vaccines: **Modupe Adeyemo**
Evaluation of New Medicines in SAHPRA's Backlog Clearance Project: The Impact of Reliance on Regulatory Performance: **Lorraine Danks**	Strategies for introducing VigiMobile for reporting of Adverse Events Following Immunization in Tanzania: Best Practices and lessons learned: **Elireheme Mfinanga**
Readiness of a sample of LMICs to expedite authorization of COVID-19 vaccines, and case study of Burkina Faso: **Souly Phanouvong**	Trends in adverse event reporting before and after the introduction of the med safety app in Nigeria: **Uchenna Elemuwa**
A need for post marketing surveillance of medical equipment: a case study in Tanzania: **Kissa Mwamwitwa**	Impact of digitalization of Market Authorization procedures for Medical Devices and Invitro diagnostics in Tanzania: **Christian Kapinga**
The role of medical device regulation harmonization in the feasibility of an internationally recognized African CE mark equivalent: **Samuel Egieyeh**	Digitalization to enable regulatory convergence - how can technology be used to improve communication, regulatory process efficiency, transparency and governance? **Angelika Joos**
IFPMA ARN Perspectives on Implementation of Quality Overall Summary-Product Dossier (QOS-PD) and Quality Information Summary (QIS) for Innovative Medicinal Products: **Zainab Aziz**	
Q&A	Q&A
16:00 – 17:00	**Tea/Coffee Break & Poster Session**

Thursday, 07 December 2023	
9:00 – 9:10	**Day 2 Recap**
9:10 – 11:10	**Plenary Session VI**

Linking regulation to local manufacturing and procurement

Session Chair: *Emmanuel Mujuru, Chairperson of FAPMA*

Presentations:

- Improving Access to Medical Products in the ECOWAS region in a Coordinated Approach: The Regulators, Procurers and Manufacturers Role: **Sybil Ossei- Agyeman-Yeboah**
- Identifying Potential African Manufacturers of Amoxicillin DT and Beta-Lactam Products to Expand Access to Quality-Assured Products: **Eliangiringa Kaale**
- The WHO GMP Compendium (10th edition): A Catalyst for Enabling Production of Pharmaceuticals on the African Continent: **Luther Gwaza**
- The WHO International Comparator Product List: An Essential Tool for Advancing Local Production of Quality, Affordable Generic Products in Africa: **Luther Gwaza**
- Striking a Balance: Challenges and Strategies for Local Pharmaceutical Manufacturing and Regulation: **Ian Warthin**
- Neglected Tropical Diseases (NTD) Medical Products in Sub-Saharan Africa: Survey of Manufacturers and Bulk Procurement Sources: **Vicky Manyanga**
- Assessment of in-use Shelf-Life and Labelling Requirement Compliance for liquid preparations in Tanzania: **Mbonea Mbwambo**

Q&A

11:10 – 11:30	**Tea/Coffee Break and Poster Session**
11:30 – 13:30	**Plenary Session VII**

Considerations of an Emerging Vaccines Ecosystem on Realization of AMA

Session Co-Chairs: *WHO AFRO & AUDA-NEPAD*

Discussion Segment 1: Strengthening Vaccine Manufacturing in Africa

- The Partnership for African Vaccine Manufacturing (PAVM) and Africa CDC's role in promoting vaccine manufacturing in Africa: **Sukyoung Kim, Africa CDC**
- Insights into WHO's support for local vaccine production in Africa: **David Woo, WHO**
- Regulatory support to local manufacturing of vaccines: **Portia Nkambule, SAHPRA**

Discussion Segment 2: Regulatory Considerations

- Private sector perspective on regulatory readiness to support local vaccine production: **Egypt**
- A role for AVAREF in Emerging Ecosystem for Vaccines: Potential Impacts on Realization of AMA: **Kwasi Nyarko, AVAREF**

Facilitated Session – Pragmatic approaches to create an enabling vaccine manufacturing ecosystem

13:30 – 14:00	**Closing Ceremony**

Master of Ceremony: Chimwemwe Chamdimba, AUDA-NEPAD and Houda Langar, WHO-EMRO

- Closing Remarks – Egyptian Drug Authority, AUDA-NEPAD and WHO
- SCoMRA VI recommendations

14 :00 – 16 :00	**Lunch & Poster Session**

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