

OCTOBER 2023

AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

An Initiative of **PRA** CONSULTANCY In Collaboration with **PIONEERS** Organized By **hubplus** events

AGENDA

DAY 1: 8 October 2023

TIME ZONE: GMT +3

8:00 - 9:00

BREAKFAST REGISTRATION

9:00 - 9:30

AfriSummit Opening



AfriSummit Welcome Address

Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy



AfriSummit Official Opening

Dr. Feirouz Ellouze
General Manager
Sanofi Consumer Health Care

9:30 - 10:30

Session 1: African Medicines Agency (AMA) - Towards strengthening regulatory framework in Africa



Moderated by

Dr. Hala Abu Ghazalah
Head of Regulatory Science, Africa & Middle East
Pfizer



Status of AMA operationalization and next steps towards regulatory strengthening in Africa

Ms. Vanessa Msengezi
Officer in charge of Regulatory Policy
Reforms African Union Development
Agency-NEPAD



Role of other stakeholders in support of AMA

Ms. Susan Lin
Senior Analyst - Public
Health Advisor, Advocacy and Public Policy
PATH

Q & A Panel discussion - NRA and Industry perspective on AMA



Ms. Marlene Moonsamy
Head of Regulatory Affairs for
the African Cluster
AstraZeneca



Dr. Karim Wanga
Chief Principal Regulatory Officer
Pharmacy and Poisons Board
Ministry of Health - Kenya



Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug
Administration and Control
NAFDAC



Ms. Silverani Padayachee
Senior Manager
Pharmaceutical Evaluation Management
SAHPRA



Mr. Samuel Asante-Boateng
Director
Drugs and Herbal Medicine Registration
Ghana FDA



Dr. Sybil Nana Ama Ossei Agyeman Yeboah
Ag. Principal Program Officer and
Head of Public Health Division
WAHO

10:30 - 11:15

Session 2: NRA Pharma Regulatory Updates North Africa



Moderated by
Dr. Neveen Kamal
Regulatory Affairs Director for Egypt
North Africa & Africa developing Markets
Merck



Post market Changes & Reliance approach for Small Molecules
Dr. Mariam Maged Moris
Manager of human pharmaceuticals
Variations Administration
Egyptian Drug Authority (EDA)

Q & A Panel discussion



Dr. Nabiha El Khaldia Boutarene
Director of Technical Monitoring
Inspection and Vigilance
The National Agency for Pharmaceutical
Products
ANPP



Ms. Naoual Assam
Technical-Regulatory Deputy Director
Registration Department
The National Agency for Pharmaceutical
Products
ANPP



Dr. Mariam Maged Moris
Manager of human pharmaceuticals
Variations Administration
Egyptian Drug Authority (EDA)



Dr. Samia Seleem
Scientific & Regulatory Affairs Director
AbbVie

11:15 - 11:45

Session 3: Regulatory Challenges



Moderated by
Dr. Amal Ibrahim
Regulatory Affairs and Pharmacovigilance Director
Egyptian International Pharmaceutical Industries
Co. EIPICO



Critical & comparative analysis of Marketing Authorization Procedures
Safa' Abu Gharbia, PhD
Senior Director
Regulatory Affairs MENA
Hikma Pharmaceuticals

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11:45 - 12:15

Coffee Break

12:15 - 13:30

Session 4: Southern African National Regulatory Updates



Moderated by
Dr. Inas Chehimi
Senior Director
Head of Regulatory Affairs
Middle East and Africa
Novartis



**South African Health Products
Regulatory Authority**
Ms. Silverani Padayachee
Senior Manager
Pharmaceutical Evaluation Management
SAHPRA



Botswana Medicines Regulatory Authority
Dr. Ropafadzai Hove
Chief Regulatory Officer
Botswana Medicines Regulatory Authority
BoMRA



Zambia Medicines Regulatory Authority
Mr. Lyoko Nyambe
Assistant Director
Marketing Authorization
Zambia Medicines Regulatory Authority
ZAMRA



Medicines Control Authority of Zimbabwe
Mr. Richard Tendayi Rukwata
Director General
Medicines Control Authority of Zimbabwe
MCAZ

Q & A Panel discussion



13:30 - 14:30

Conference Photo and Competition announcement Lunch and Networking

14:30 - 15:15

Session 5: Pharma Manufacturing



Moderated by
Dr. Winnie Ng'ang'a
Chairperson
Kenya Association of Pharmaceutical Industry
KAPI



**Pharmaceutical Industry Localization and
contract Manufacturing**
Dr. Mona Mousa
Regulatory Affairs
Associate Director
Hikma Pharmaceuticals



**Pharma Manufacturing in Egypt:
SCZone opportunities for growth**
Dr. Ibrahim Mustafa
Vice President
General Authority Economic
Zone of the Suez Canal





15:15 - 16:15

Session 6: How to strengthen Supply Chain in Africa



Moderated by
Dr. Donia Fady
Regulatory Affairs Head
Takeda



Parallel importation
Dr. Winnie Ng'ang'a
Chairperson
Kenya Association of Pharmaceutical Industry
KAPI



Ensuring Quality of Medicines: Role of USP
Dr. Zakieh Ibrahim Al-Kurdi
Regulatory Affairs & Public Policy Director
EMA Region
USP



Counterfeit Prevention
Mr. Franck Chauty
Security Head
Sanofi Consumer Health Care

Are you ready to comply with new regulatory requirements?



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We help companies get ready for Serialization

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2. Aggregation & full traceability adapted

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16:15 - 17:00

Session 7: The Evolution of Biosimilars in Africa



Moderated by
Dr. Yasmine Maher El-Shebiny
Director Regulatory Affairs
Egypt Cluster (Egypt, Libya Sudan & Yemen)
MSD



The regulatory updates of biosimilar products in Egypt
Dr. Hebatallah Ibrahim Abdel-salam
Head of biological Products Marketing
Authorization Administration
Egyptian Drug Authority
EDA



Biosimilars overview from the industry perspective
Dr. Ahmed Ghazala
Regulatory Affairs Manager
ELI countries
Amgen

17:00 - 18:00

Session 8: Landscape for Clinical Trials of Africa



Moderated by
Dr. Sahar Ebrahim
Regional Head of Clinical Operations
MENA
IQVIA



Optimizing the efficiency of the African Clinical Trials Ecosystem
Dr. Elvis Temfack
Senior Research Officer
Africa CDC



Review of latest resolutions and guidelines: ICH GCP R3 & WHO new draft guidance Q3
Ms. Bicky Nyeleti
Director
CRO AfriLeadTech Research (PTY) LTD
Chairperson
The South African Clinical Research Association
SACRA

Q & A Discussion Panel: Country specific capacity building and status



Dr. Rania Ibrahim Hassan
General Manager
General Administration of Clinical Trials
C.A. of Biological, Innovative Products &
Clinical Studies
Egyptian Drug Authority
EDA



Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug
Administration and Control
NAFDAC



Dr. Manal El-Sayed
Director of the Clinical Research Center
(MASRI-CRC)
Faculty of Medicine
Ain Shams University



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18:00

NRA Break Out Round Table Discussions



Egypt

Dr. Mariam Maged Moris
Manager of human pharmaceuticals
Variations Administration
Egyptian Drug Authority (EDA)



Botswana

Dr. Ropafadzai Hove
Chief Regulatory Officer
Botswana Medicines Regulatory Authority
BoMRA



Algeria

Dr. Nabiha El Khaldia Boutarene
Director of Technical Monitoring
Inspection and Vigilance
The National Agency for
Pharmaceutical Products
ANPP



Ms. Naoual Assam
Technical-Regulatory Deputy Director
Registration Department
The National Agency for
Pharmaceutical Products
ANPP



Zambia

Mr. Lyoko Nyambe
Assistant Director
Marketing Authorization
Zambia Medicines Regulatory Authority
ZAMRA



Mr. Arthur Sichivula
ICT Manager
Zambia Medicines Regulatory Authority
ZAMRA

18:00

End of day Coffee Break and Networking

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AGENDA

DAY 2: 9 October 2023

TIME ZONE: GMT +3

8:00 - 9:00

BREAKFAST REGISTRATION

9:00 - 9:15

Session 1: Opening Session



Opening and Welcoming
Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy



**The link between regulation and public health
Why medicines regulation must align with Africa's
New Public Health Order**

Dr. Amit N. Thakker
President of Africa Healthcare Federation &
Executive Chairman of Africa Health Business

9:15 - 10:15

Session 2: National Regulatory Updates East Africa



Moderated by
Dr. Mariham Gergis
Regulatory Affairs Lifecycle Manager
EMEA RMC
Janssen



Kenya
Mr. Karim Wanga (M Pharm)
Chief Principal Regulatory Officer
Pharmacy and Poisons Board Pharmacy
Poisons Board
Ministry of Health
Kenya



Uganda
Mr. Amos Mulera Atumanya
Senior Inspector of Drugs
National Drug Authority
Uganda



Ethiopia
Mr. Abebe Alamneh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals
Association (EARAPA)

Q & A Panel discussion



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10:15 - 11:00

Session 3: Vaccine production in Africa



Moderated by
Dr. Heba Adel
Senior Manager Regulatory Affairs
GlaxoSmithKline (GSK)



Lot release for vaccines in African countries

Dr. Doaa Rady
Lot Release administration manager
Egyptian Drug Authority
EDA



Vaccine Manufacturing and Regulatory Capacity

Ms. Silverani Padayachee
Senior Manager
Pharmaceutical Evaluation Management
SAHPRA

Q&A Panel discussion



11:00 - 11:30

Coffee Break

11:30 - 12:30

Session 4: Selfcare Regulations



Moderated by
Dr. Haidy Ahmed
Director Regulatory Affairs, North, East & West Africa
Consumer healthcare Egypt Limited
GSK (Now part of the Haleon group of companies)



Dr. Mohamed Larbi Jelassi
Africa Public Affairs Head
Sanofi Consumer Health Care



Mr. Lyoko Nyambe
Assistant Director
Marketing Authorization
Zambia Medicines Regulatory Authority
ZAMRA



Mr. Karim Wanga (M Pharm)
Chief Principal Regulatory Officer
Pharmacy & Poisons Board Pharmacy
Poisons Board
Ministry of Health
Kenya

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12:30 - 13:00

Session 5: West African NRA Pharma Regulatory Updates



Moderated by
Ms. Marlene Moonsamy
Head of Regulatory Affairs for
the African Cluster
AstraZeneca



Pharmaceutical Regulatory Strengthening in Nigeria Following GMP Roadmap Implementation
Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug
Administration and Control
NAFDAC



Ghana
Mr. Samuel Asante-Boateng
Director
Drugs and Herbal Medicine Registration
Ghana FDA

Q&A and Panel Discussion



13:00 - 14:00

Lunch and Networking

14:00 - 15:15

Session 6: Regulatory Digitization



Moderated by
Heba Nabil
Regulatory Affairs Senior Manager
Egypt & Sudan
Pfizer



Utilizing Digitization in support of Harmonization
Mr. Kent Briggs
Director
VECTOR Life Sciences



ECOWAS perspective in the utilization of eCTD
Dr. Sybil Nana Ama Ossei Agyeman Yeboah
Ag. Principal Program Officer and
Head of Public Health Division
WAHO



Digitizing labeling in Pharma: e-labeling in Egypt
Dr. Rehab Mehrez
Manager of the General Administration of
Pharmaceutical References and Leaflets
Egyptian Drug Authority
EDA

Q&A Panel discussion





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15:15 - 16:15

Session 7: Track & Trace



Moderated by
Mr. Konstantine Ivanov
Co-founder & CEO
Utrace



Traceability Revolution: Transforming pharmaceutical supply chain for a healthier world

Mr. Udit Singh
CEO
ACG Inspection



End-to-End Compliance: A Practical Roadmap to Serialization Success Track and Trace the Status in Africa Panel discussion

Mr. Arif Gadzhiev
Business Development Director
Utrace

Q&A and Panel Discussion



Nigeria

Ms. Folasade Osho
Chief Regulatory Officer
National Agency for Food &
Drug Administration
Control (NAFDAC)



Zambia

Mr. Arthur Sichivula
ICT Manager
Zambia Medicines Regulatory Authority
ZAMRA



Senegal

Dr. Aliou Ndiaye
Drug Serialization Department Directorate
of Drug Approval and Serialization of Drugs
Other Health Products
Senegalese Regulatory Agency

16:15 - 17:00

Session 8: Regulatory Intelligence



Moderated by
Dr. Amal Fathy
Africa Science Affairs Head
Sanofi Consumer Health Care



Regulatory Access and Market intelligence

Dr. Rima Nsheiwat
Regulatory Access and Market intelligence
Strategist and Consultant
B.V. Amsterdam Medical & Scientific Alliance



Regulatory Strategy and Vision

Dr. Marielouise Abi Hanna
Industry Leader in Corporate Strategy
Market Access & Founder
The Reg.Cloud



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17:00 - 18:00

Session 9: Orphan Drugs Regulation in Africa



Moderated by
Dr. Fatima Zaid Abu Zanat
Regional Director of Regulatory Affairs &
Scientific Office Middle East
Turkey & Africa
Ipsen Pharma



Fighting Rare Disease and Developing Orphan Drugs to support

Dr. George Kamal
Regional Regulatory Affairs Hub
Lead MEAR
Merck Group



Market insight and development of regulations

Dr. Reham Allassily
Associate Director Regulatory Affairs NEMEA
IQVIA

Q&A and Panel Discussion



18:00

Closing Remarks End of PharmaReg AfriSummit

18:00

NRA Break Out Round Table and Networking



Ethiopia
Mr. Abebe Alamneh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals
Association (EARAPA)



Nigeria
Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug
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NAFDAC



Uganda
Mr. Amos Mulera Atumanya
Senior Inspector of Drugs
National Drug Authority
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Ghana
Mr. Samuel Asante-Boateng
Director
Drugs and Herbal Medicine Registration
Ghana FDA

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