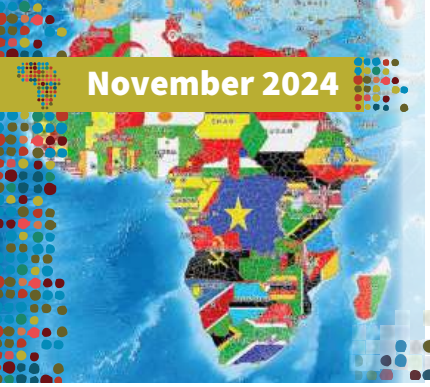


November 2024

AFRiSUMMIT

Grand Nile Tower, Cairo - Egypt

AGENDA

DAY 1: 3 November 2024

08:30 - 09:15

COFFEE AND REGISTRATION

09:15 - 09:45

Opening Ceremony

AfriSummit Welcome Address

Dr. Mona Al Moussli
Chairman of
AfriSummit

AfriSummit Welcome Address

Dr. Ahmed Ashour
Chair of the Organizing
Committee for AfriSummit
Egypt

AfriSummit Official Opening

Dr. Rasha Ziada
Chairman Assistant for Professional
Development and Capacity Building Affairs
Egyptian Drug Authority (EDA)

AfriSummit Opening Remarks

Dr. Hisham Stait
Vice Chairman, Unified Procurement
Authority - Egypt

Welcome Remarks - Titanium Sponsor

Mr. Ramez Sawiris
R&D Lead - Haleon
MEA

09:45 - 10:45

Session 1: Current Landscape of Pharmaceutical Regulations in Africa - Challengesand Opportunities

Moderated by

Mrs. Bunmi Femi-Oyekan
Regulatory Lead, Accord &
Access (Snr. Director)
Pfizer

AMRH support to the Operationalisation of AMA

Dr.Nancy Ngum
Public Health Officer- AUDA
NEPAD

Q & A Panel Discussion: **Regulatory Pathways: Harmonization, Industry Shifts, and Strengthening Public-Private Collaboration**

ECOWAS/WAHO

Pharm. Mrs. Sybil Nana Ama
Ossei Agyeman Yeboah
Regulatory Consultant & CEO of
SNAAP Access

SADC MRH - ZAZIBONA

Mrs. Sakhile Dube-Mwedzi
Program Coordinator -
SADC MRH
ZAZIBONA

IGAD

Mr. Karim Wanga (M Pharm)
Senior Principal Regulatory Officer
Pharmacy & Poisons Board (PPB
Kenya

IFPMA

MS. Zainab Aziz
Associate Director RA Policy &
Strategic Operations, SSA
Novartis

10:45 - 11:30

Session 2: Egypt National Regulatory Updates

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

Egypt Regulatory Updates

Dr. Yasmine Mohamed Hisham
Manager of The Evaluation Unit For Registration Files of Imported Human Pharmaceuticals in Central Administration of Pharmaceutical Products
Egyptian Drug Authority
(EDA)

Unified Procurement Authority (UPA)

Dr. Hisham Stait
Vice Chairman, Unified Procurement Authority - Egypt

Q & A Panel Discussion

11:30 - 12:00

Coffee and Networking Break

12:00 - 13:00

Session 3: Harnessing Potential: Africa's Journey to Pharmaceutical Reliance: Panel Discussion

Moderated by
Dr. Eman Wahdan
Egypt regulatory Head for
Opella

Presenter

Dr. Hebatallah Ibrahim Abdel-Salam
General Manager of Biological Products General Administration & Head of Biological Products Marketing Authorization Administration
Egyptian Drug Authority
(EDA)

Presenter

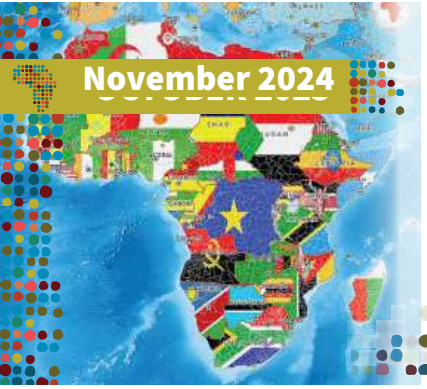
Sonia Sebai Ben Amor. MD
Head of National Control Laboratory
National Regulatory Authority
Tunisia

Panelist

Mr. Karim Wanga (M Pharm)
Senior Principal Regulatory Officer
Pharmacy & Poisons Board (PPB)
Kenya

Panelist - Industry perspective

Dr. Najlaa Fathy
Regulatory Affairs Head, GDD
Novartis



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13:00 - 14:00

Session 4: Innovation and Accessibility: Shaping the OTC Landscape in Africa

Moderated by
Pharm. Mrs. Sybil Nana Ama
Ossei Agyeman Yeboah
Regulatory Consultant & CEO of
SNAAP Access

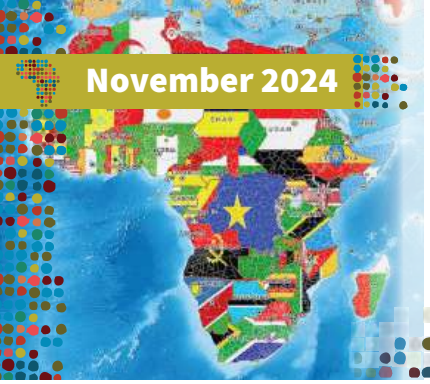
Empowering Access: Strategic Insights into Self-Care Products in Pharma
Mr. Ramez Sawiris
R&D Lead - Haleon
MEA

Regulatory Pathways in Self-Care: Mastering the Switch
Dr. Marwa Souei
Head of Regulatory Affairs across Africa
Middle East & Turkey
Opella

Panelist
Dr. Shereen Abdelgawad
Head of the Central Administration of
Pharmaceutical Care
Egyptian Drug Authority
(EDA)

Panelist
Sonia Sebai Ben Amor. MD
Head of National Control Laboratory
National Regulatory Authority
Tunisia

Panelist
Dr. Haidy Ahmed
Director Regulatory Affairs
North Africa
Haleon



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14:00 - 15:00 Group Photo, Lunch and Networking

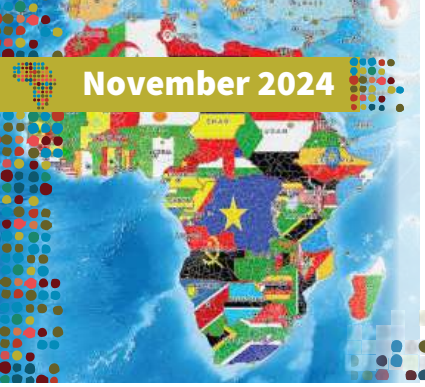
15:00 - 15:45 Session 5: Attaining WHO Maturity Level and Collaboration Opportunities

Moderated by
Dr. Yousra Farid
Regulatory Affairs | Quality Assurance Director &
Strategic Project Lead - Gulf
Levant & Emerging Markets
Abbott

Presenter
Prof. Saleh A. Bawazir
Prof. of Clinical Pharmacy & CEO
of Bawazir Pharma Consulting Center

Panelist
Dr. Emil Ivan Mwikarago
Technical Analyst, Assessment
of Medical Devices, In Vitro
Diagnostics (IVDs), Vaccines,
& Biologicals Rwanda Food & Drugs
Authority (Rwanda FDA)

Panelist
Dr. Zivanai Makoni
Head of Division Evaluation &
Registration – Medicines Control
Authority of Zimbabwe (MCAZ)



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15:45 - 16:45

Session 6: Empowering Local Production: Advancing Pharmaceutical Manufacturing and Localization in Africa

Moderated by
Dr. Alaa Attia
Business Development Director
EIPICO

Building a Sustainable Pharma Ecosystem: Regulatory Perspectives on Localization in Africa
Dr. Zakieh Ibrahim Al-Kurdi
Regulatory Affairs & Public Policy Director for EMEA Region - U.S. Pharmacopeia (USP)

Panelist
Dr. Claudy Raymond Tarazy
Chairman & Managing Director
One Pharma Medics

Q & A Panel Discussion :Collaborating for Sustainable and Efficient Nearshoring of Generics and Biosimilars

Moderated by
Dr. Mohamed Larbi Jelassi
Head of Market Access International
SPIMACO

Panelists
Dr. Zineb Housni
Pharmacist Inspector, Evaluator of Marketing Authorization Files For Medicinal Products for Human - Directorate of Medicines and Pharmacy
Morocco

Panelists
Dr. Hebatallah Ibrahim Abdel-Salam
General Manager of Biological Products General Administration & Head of Biological Products Marketing Authorization Administration
Egyptian Drug Authority (EDA)

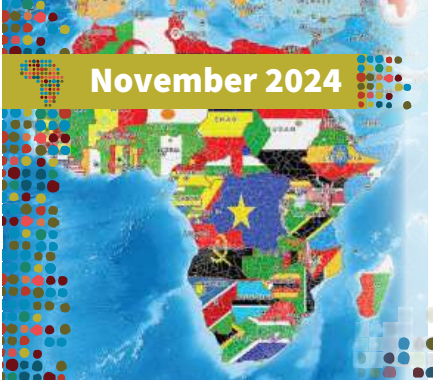
Panelists
Dr. Ahmed El-lekawy
Innovative Products' Registration Manager
Egyptian Drug Authority
(EDA)

Panelists
Mr. Karim Wanga (M Pharm)
Senior Principal Regulatory Officer
Pharmacy & Poisons Board (PPB)
Kenya

Panelists
Dr. Eric Konan
Director of the Regulatory Affairs Department
ETHICA

16:45 - 17:15

Coffee & Networking



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17:15 - 18:00

Session 7: Southern Africa National Regulatory Updates

Moderated by
Mrs. Simone Rudolph-Shortt
Chairperson
MDMSA

Botswana Regulatory Updates
Ms. Ntsetselele Kago
Manager, Human Medicines Unit
Botswana Medicines Regulatory Authority
(BoMRA)

Zambia Regulatory Updates
Mr. Lyoko Nyambe
Director Marketing Authorisation
Zambia Medicines Regulatory Authority
(ZAMRA)

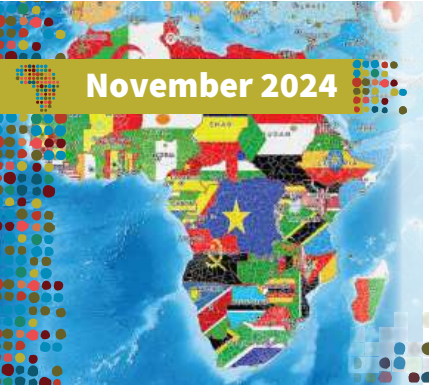
Zimbabwe Regulatory Updates
Dr. Zivanai Makoni
Head of Division Evaluation and Registration
Medicines Control Authority of Zimbabwe
(MCAZ)

Namibia Regulatory Updates
Ms. Fransina Nambahu
Registrar of Medicines at Namibia Medicines Regulatory Council (NMRC) of the Ministry of Health and Social Services
(MoHSS)

Q & A Panel Discussion

18:00

End of Day 1



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AGENDA

DAY 2: 4 November 2024

09:00 - 09:30

COFFEE AND NETWORKING

09:30 - 09:45

Opening Remarks Day 2

Dr. Ahmed El-Kamhawy
Country Head
Opella

09:45 - 10:45

Session 1: Unlocking the Future: Regulatory Pathways & Innovations in Biosimilars & Biologics

Moderated by
Dr. Yara Hussein
Director, Regional Regulatory Hub Team lead – MERAST
Specialty Care Business Unit Lead
Pfizer Biopharmaceutical
GRS IRSP

Overview of Biosimilars in MENA: Comparative Assessment of Biosimilars PAC Guidelines in MENA

Safa' Abu Gharbiah, PhD.
Senior Director Regulatory Affairs, MENA
Hikma Pharmaceuticals

Innovating with AI in Biologics: Ethical & Regulatory Frontiers in Africa

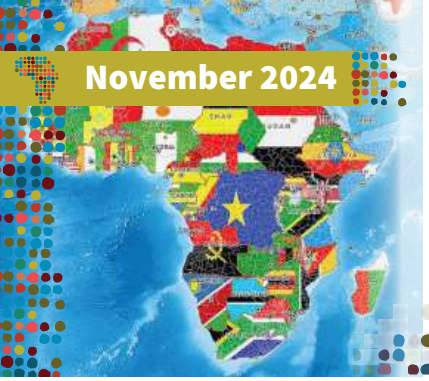
Dr. Fatima Zaid Abu Zanat
Regional Director of Regulatory Affairs & Scientific Office – Middle East
Turkey & Africa
Ipsen

Q & A Panel Discussion

EDA
Dr. Ahmed El-lekawy
Innovative Products' Registration Manager – Egyptian Drug Authority (EDA)

EDA
Dr. Asmaa Ahmed Abdel-Ghaffar Mohammed
Researcher and Head of Biotechnology Lab
Egyptian Drug Authority (EDA)

DMP Tunisia
Sonia Sebai Ben Amor. MD
Head of National Control Laboratory
National Regulatory Authority
Tunisia



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10:45 - 11:30

Session 2: National Regulatory Updates EAC

Moderated by
Dr. Daniella Munene
Head of External Affairs
Africa Health Business

Kenya Regulatory Updates
Mr. Karim Wanga (M Pharm)
Senior Principal Regulatory Officer
Pharmacy & Poisons Board (PPB)
Kenya

Ethiopia Regulatory Updates
Mr. Abebe Alamneh
Vice Chairman of East African Regulatory Affairs Professionals Association (EARAPA) & Medicine Registration Expert
Ethiopia Food and Drug Authority (EFDA)

Rwanda Regulatory Updates
Dr. Emil Ivan Mwikarago
Technical Analyst, Assessment of Medical Devices, In Vitro Diagnostics (IVDs), Vaccines, & Biologicals Rwanda Food & Drugs Authority (Rwanda FDA)

Uganda Regulatory Updates
Dr. Rachel Juliet Mujawimana
Inspector of Drugs
National Drug Authority (NDA)
Uganda

Ms. Pamela Ajwang
Regulatory Officer
National Drug Authority (NDA)
Uganda

Q & A Panel Discussion

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11:30 - 12:00

COFFEE AND NETWORKING BREAK

12:00 - 13:00

Session 3: Vaccine Regulations in Africa: Harmonization & Access for Public Health Impact

Moderated by
Dr. Mariham Gergis
Submission Excellence Lead – Emerging Market
EMEA Regulatory Center
Johnson and Johnson Innovative Medicine

Harmonizing Vaccine Regulatory Pathways in Africa : Enhancing Preparedness for Future Health Emergencies

Pharm. Jacqueline Acquah
Senior Regulatory Affairs Strategy Lead
MEA - Coalition for Epidemic Preparedness Innovations
(CEPI)

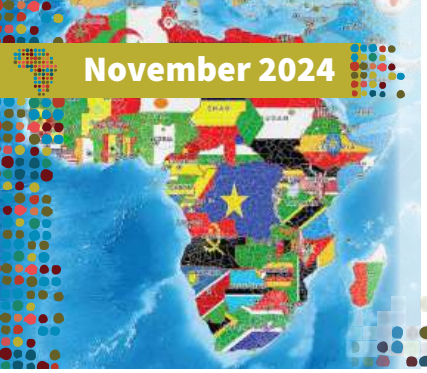
National Network for the African Reliance Laboratories Status and Its Impact

Dr. Doaa Rady
Lot Release Administration Manager
Egyptian Drug Authority (EDA) &
Chairperson for AMQF Vaccine Subcommittee

Strengthening Vaccine Manufacturing Capabilities in Africa: A Strategic Approach to Ensuring Self-Sufficiency and Resilience

Dr. Mariam Raouf Wefky Ghobrial
Technical Specialist (Life Sciences)
Access Health International
(AHI)

Q & A Panel Discussion



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13:00 - 14:00

Session 4: Ensuring Safety and Compliance: Regulatory Perspectives in Track &Trace & Serialization

Moderated by
Mr. Christopher Oduor
Senior Regulatory Affairs Manager
Middle East, Africa and CIS
Novo Nordisk

Complete Control: How End-to-End Traceability Creates Benefits
Mr. Görkem Aydın
International Marketing Manager
VISIOTT

Ms. Tutku Kazan
Marketing Director
VISIOTT

Fireside chat
Mr. Jihad Tayara
Chief Executive Officer of
EVOTEQ

Q & A Panel Discussion: Securing Africa's Supply Chain: Advances in Track & Trace & Serialization Technologies

Panelists
Mr. Mete Karaca
Executive Board Member
Tiga Healthcare Technologies

Panelists
Mr. Lyoko Nyambe
Director Marketing Authorisation
Zambia Medicines Regulatory Authority
(ZAMRA)

Panelists
Dr. Aliou Ndiaye
Pharmacist in Drug Serialization Department
Senegalese Pharmaceutical Regulatory Agency
(ARP)

Panelists
Ms. Nuran Idris
Manager Healthcare Africa
GS1 Global Office

14:00 - 15:00

LUNCH AND NETWORKING

15:00 - 15:30

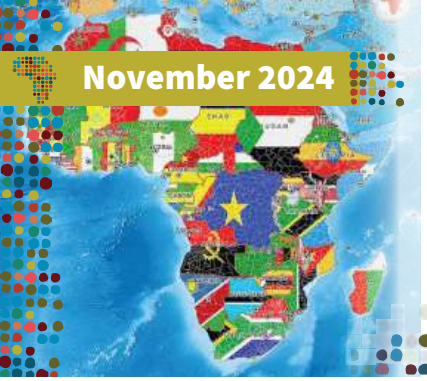
Session 5: NRA Pharma Regulatory Updates - North Africa

Moderated by
Dr. Amina Fazila Laras
Regulatory Affairs Manager
French Speaking Africa Cluster
Abbott

Tunisia Regulatory Updates
Dr. Mariam Aounallah
Project Manager
National Agency of Medicines &
Health Products in Tunisia
(ANMPS)

Morocco Regulatory Updates
Mr. Michael Faust
RCC Business Consultant
EXTEDO

Q & A Panel Discussion



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15:30 - 16:30

Session 6: Digital Transformation in Pharma: Navigating e-Labeling & eCTD in Africa's Regulatory Landscape

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

Harmonisation: Africa becomes One through one eCTD specification
Dr. Madelein Terblanche
Senior Operations Consultant
VECTOR Life Sciences

Dr. Mariam Aounallah
Project Manager
National Agency of Medicines & Health Products in Tunisia
(ANMPS)

E-Labeling Presentation
Dr. Rehab Mehrez
Manager of the General Administration of Pharmaceutical References & Leaflets
Central Administration of Pharmaceutical Care
Egyptian Drug Authority
(EDA)

Data Consistency through Production, Supply Chain & Regulatory Business Processes
Mr. Michael Faust
RCC Business Consultant
EXTEDO

Q & A Panel Discussion




16:30 - 17:00

COFFEE AND NETWORKING

17:00 - 17:30

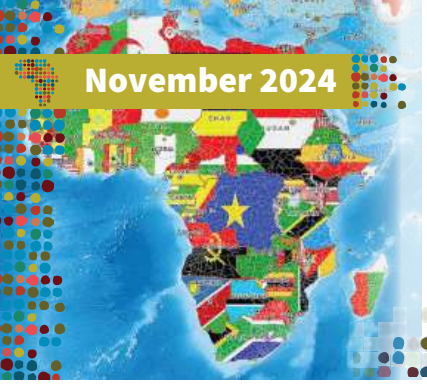
Session 7: AI Revolution: Shaping the Future of Pharmaceutical Innovations

Moderated by
Dr. John M. Mwangi
Regulatory Policy & Science Lead
Bayer Pharmaceuticals

AI & R&D in Pharmaceutical Industry
Dr. Neveen Kamel
Director of Regulatory Affairs
(Egypt, Maghreb Countries, Developing Africa Markets)
Merck

Enhancing Regulatory Preparedness through Digital Collaboration: CEPI's Framework for Accelerated Access during Public Health Emergencies
Dr. Alessandro Lazdins
Regulatory Policy and Intelligence Manager
Coalition for Epidemic Preparedness and Innovations
(CEPI)

Q & A Panel Discussion

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17:30 - 18:00

Session 8: West African NRA Pharma Regulatory Updates

Moderated by
Dr. Eric Konan
Director of the Regulatory Affairs Department
ETHICA

Senegal Regulatory Updates

Dr. Aliou Ndiaye
Pharmacist in Drug Serialization Department
Senegalese Pharmaceutical Regulatory Agency (ARP)

Ivory Coast Regulatory Updates

Dr. Chantalle Affoue
Director of Approval of Drugs and Other Pharmaceutical Products
Ivorian Pharmaceutical Regulation Authority (AIRP)

Q & A Panel Discussion

17:30 - 18:00

NRA Break Out Round Table Discussions