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 Live interactive streaming  
 from Cairo, Egypt

## Day 1: November 3rd 2024

08:30 - 09:15 Coffee and Registration		
09:15 - 09:45 Opening Ceremony		
AfriSummit Welcome Address AfriSummit Official Opening Welcome Remarks - Titanium Sponsor	Dr. Mona Al Moussli EDA - Speaker TBC Mr. Ramez Sawiris	Co-founder and Managing Director - PRA Consultancy Egyptian Drug Authority - EDA Senior Director R&D Lead - Haleon
09:45 - 10:45 Session 1: Current Landscape of Pharmaceutical Regulations in Africa - Challenges and Opportunities		
AMRH support to the Operationalisation of AMA <b>Panel Discussion: Regulatory Pathways: Harmonization, Industry Shifts, and Strengthening Public-Private Collaboration</b> Panelists: ECOWAS/WAHO SADC MRH - ZAZIBONA IGAD IFPMA	Moderated by: Mrs. Bunmi Femi-Oyekan Dr. Nancy Ngum Mrs Sybil Nana Ama Ossei-Agyeman-Yeboah Mrs. Sakhile Dube-Mwedzi Dr. Karim Wang Mrs. Zainab Aziz	Regulatory Lead (Snr Director) Accord and Access, Emerging Market - Pfizer Programme Officer - Public Health - AUDA-NEPAD Regulatory Consultant & CEO of SNAAP Access Programme Coordinator - SADC MRH - ZAZIBONA Pharmaceutical Expert - IGAD Associate Director- RA Policy and Strategic Operations SSA, Novartis (IFPMA representative)
10:45 - 11:30 Session 2: Egypt National Regulatory Updates		
Egypt Regulatory Updates Unified Procurement Authority (UPA) Q&A	Moderated by: Dr. Inas Chehimi Dr. Yasmine Mohamed Hisham Mohamed Al-Saeed Dr. Hisham Stait	Exécutive Director, Regulatory and Policy Head Middle East & Africa, Pharma and Oncology Divisions - Novartis Manager of evaluation unit for registration file of imported human pharmaceutical - Egyptian Drug Authority (EDA) Vice Chairman Of The Board - Unified Procurement Authority (UPA)
11:30 - 12:00 Coffee and Networking Break		
12:00 - 13:00 Session 3: Harnessing Potential: Africa's Journey to Pharmaceutical Reliance: Panel Discussion		
Presenter Presenter Panelist Panelist - Industry perspective	Moderated by: Dr. Eman Wahdan Dr. Heba Ibrahim Dr. Sonia Sebai Ben Amor Dr. Karim Wang Dr. Naglaa Fathy	Head of Regulatory Affairs, Egypt - Opella General Manager of GA of Biological products - Egyptian Drug Authority (EDA) Head of National Drug Control Laboratory - Tunisian National Regulatory Authority Chief Principal Regulatory Officer - Pharmacy and Poisons Board, Kenya (PPB) Regulatory Affaires Head GDD - Novartis

13:00 - 14:00	Session 4: Innovation and Accessibility: Shaping the OTC Landscape in Africa	Moderated by: 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	Senior Director R&D Lead - Haleon
	Regulatory Pathways in Self-Care: Mastering the Switch	Dr. Marwa Souei	Regulatory Affairs Head Africa Middle East & Turkey - Sanofi CHC
	Panelist	Dr. Shereen Abdel Gawad	Head of the Central Administration of Pharmaceutical care - Egyptian Drug Authority (EDA)
	Panelist	Dr. Sonia Sebai Ben Amor	Head of National Drug Control Laboratory - Tunisian National Regulatory Authority
	Panelist	Dr. Haidy Morsy	Regulatory Affairs Director North Africa - Haleon
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	Director Regulatory Affairs, Quality Assurance & Strategic Projects - Abbott EPD-GEM & Levant
	Presenter	Prof. Saleh Bawazir	CEO - Prof. Bawazir Pharma Consulting Center
	Panelist	Dr. Ivan E Mwikarago	Diagnostic and Medical Device Assessment and Registration Analyst - Rwanda FDA
	Panelist	Dr. Zivanai A. Makoni	Head of Evaluation and Registration Division - Medicines Control Authority of Zimbabwe (MCAZ)
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. Zakiya Al-Kurdi	Public Policy and Regulatory Affairs Director, EMEA - USP
	Panelist	Dr. Claudy Raymond Tarazy	Chairman & Managing Director - One Pharma Medics
	<b>Panel Discussion : Collaborating for Sustainable and Efficient Nearshoring of Generics and Biosimilars</b>		
	Panel Moderated by:	Mr. Mohamed Larbi Jelassi	Head of Market Access International - SPIMACO
	Panelists	Dr. Zineb Housni	Head of Medical Supplies Unit - Directorate of Medicine and Pharmacy (DMP), Morocco
		Dr. Heba Ibrahim	General Manager of GA of Biological products - Egyptian Drug Authority (EDA)
		Dr. Ahmed El-Iekawy	Innovative Products' Registration Manager - Egyptian Drug Authority (EDA)
		Dr. Karim Wanga	Chief Principal Regulatory Officer - Pharmacy and Poisons Board, Kenya (PPB)
		Dr. Eric Konan	Director of the Regulatory Affairs Department - ETHICA
16:45 - 17:15	Coffee and Networking		
17:15 - 18:00	Session 7: Southern Africa National Regulatory Updates	Moderated by: Mrs. Simone Rudolph-Shortt	Chairperson - Medical Device Manufacturers of South Africa (MDMSA)
	Botswana Regulatory Updates	Ms. Ntsetselele Kago	Manager Human Medicines - Botswana Medicines Regulatory Authority (BoMRA)
	Zambia Regulatory Updates	Mr. Lyoko Nyambe	Assistant Director-Marketing Authorisation - Zambia Medicines Regulatory Authority (ZAMRA)
	Zimbabwe Regulatory Updates	Dr. Zivanai A. Makoni	Head of Evaluation and Registration Division - Medicines Control Authority of Zimbabwe (MCAZ)
	Namibia Regulatory Updates	Ms. Fransina Nambahu	Registrar of Medicines - Namibia Medicines Regulatory Council (NMRC)
	Q&A		
18:00	End of Day 1		



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## Day 2: November 4th

09:00 - 09:30 Coffee and Networking		
09:30 - 09:45	Opening Remarks Day 2	Dr. Ahmed El Kamhawy Country Head, Egypt - Opella
09:45 - 10:45	<p>Session 1: Unlocking the Future: Regulatory Pathways and Innovations in Biosimilars &amp; Biologics</p> <p>Overview of Biosimilars in MENA: Comparative Assessment of Biosimilars PAC Guidelines in MENA</p> <p>Innovating with AI in Biologics: Ethical and Regulatory Frontiers in Africa</p> <p>Panel Discussion: EDA</p> <p>EDA</p> <p>DMP Tunisia</p>	<p>Moderated by: Dr. Yara Hussien</p> <p>Dr. Safa' H. Abu Gharbiah</p> <p>Dr. Fatima Zaid Abu Zanat</p> <p>Dr. Ahmed El-iekawy</p> <p>Dr. Asmaa Ahmed</p> <p>Dr. Sonia Sebai Ben Amor</p> <p>Director, Regional Regulatory Hub Team Lead-MERAST - Pfizer</p> <p>Regulatory Affairs Sr. Director - MENA at Hikma Pharmaceuticals</p> <p>Regional Director of Regulatory Affairs &amp; Scientific Office Middle East, Turkey &amp; Africa - Ipsen Pharma</p> <p>Innovative Products' Registration Manager - Egyptian Drug Authority (EDA)</p> <p>Researcher and Head of Biotechnology Laboratory - Egyptian Drug Authority (EDA)</p> <p>Head of National Drug Control Laboratory - Tunisian National Regulatory Authority</p>
10:45 - 11:30	<p>Session 2: National Regulatory Updates EAC</p> <p>Kenya Regulatory Updates</p> <p>Rwanda Regulatory Updates</p> <p>Ethiopia Regulatory Updates</p> <p>Uganda Regulatory Updates</p> <p>Q&amp;A</p>	<p>Moderated by: Dr. Daniella Munene</p> <p>Dr. Karim Wanga</p> <p>Dr. Ivan E Mwikarago</p> <p>Mr. Abebe Alamneh</p> <p>Dr. Rachel Juliet Mujawimana</p> <p>Dr. Pamela Ajwang</p> <p>Head of External Affairs - Africa Health Business (AHB)</p> <p>Chief Principal Regulatory Officer - Pharmacy and Poisons Board, Kenya (PPB)</p> <p>Diagnostic and Medical Device Assessment and Registration Analyst - Rwanda FDA</p> <p>Vice Chairman - East Africa Regulatory Affairs Professionals Association (EARAPA), Medicine registration expert- Ethiopia Food and Drug Authority (EFDA)</p> <p>Inspector of Drugs - National Drug Authority, Uganda (NDA)</p> <p>Regulatory Officer - National Drug Authority, Uganda (NDA)</p>
11:30 - 12:00 Coffee and Networking Break		
12:00 - 13:00	<p>Session 3: Vaccine Regulations in Africa: Harmonization and Access for Public Health Impact</p> <p>Harmonizing Vaccine Regulatory Pathways in Africa : Enhancing Preparedness for Future Health Emergencies</p> <p>National Network for the African Reliance Laboratories Status and Its Impact</p> <p>Strengthening Vaccine Manufacturing Capabilities in Africa: A Strategic Approach to Ensuring Self-Sufficiency and Resilience</p> <p>Panel Discussion</p>	<p>Moderated by: Dr. Mariham Gergis</p> <p>Dr. Jacqueline Acquah</p> <p>Dr. Doaa Rady</p> <p>Dr. Mariam Ghobrial</p> <p>Submission Excellence Lead - Emerging Market EMEA RMC - Johnson and Johnson</p> <p>Senior Regulatory Strategy Lead Africa &amp; Middle East - CEPI (Coalition for Epidemic Preparedness Innovations)</p> <p>Lot Release Administration Manager - Egyptian Drug Authority (EDA)</p> <p>Technical Specialist (LifeSciences) - Access Health International (AHI)</p>

13:00 - 14:00	Session 4: Ensuring Safety and Compliance: Regulatory Perspectives in Track & Trace & Serialization	Moderated by: Mr. Chris Oduor	Senior Regulatory Affairs Manager Middle East, Africa - Novo Nordisk
	Complete Control: How End-to-End Traceability Creates Benefits	Mr. Görkem Aydin Ms. Tutku Naz Kazan	International Marketing Manager - VISIOTT Traceability Solutions Director of Marketing - VISIOTT Traceability Solutions Chief Executive Officer - Evoteg
	Fireside chat	Mr. Jihad Tayara	
	<b>Panel Discussion: Securing Africa's Supply Chain: Advances in Track &amp; Trace &amp; Serialization Technologies</b>		
	Panelists:	Mr. Mete Karaca Mr. Lyoko Nyambe  Dr. Aliou Ndiaye Ms. Nuran Idris	Executive Board Member - Tiga Healthcare Technologies Director Marketing Authorisation - Zambia Medicines Regulatory Authority (ZAMRA) Drug Serialization Department Directorate of Drug Approval and Serialization of Drugs and Other Health Products - Senegalese Regulatory Agency Manager, Healthcare Africa - GSI Global
14:00 - 15:00	Lunch and Networking		
15:00 - 15:30	Session 5: NRA Pharma Regulatory Updates - North Africa	Moderated by: Dr. Fazila Laras	Regulatory Affairs Manager French Speaking Africa Cluster - Abbott
	Tunisia Regulatory Updates	Dr. Mariam Aounallah	Pharmacist - Directorate of Medicine and Pharmacy (DMP), Tunisia
	Morocco Regulatory Updates	Dr. Zineb Housni	Head of Medical Supplies Unit - Directorate of Medicine and Pharmacy (DMP), Morocco
	Q&A		
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 Regulatory Affairs - MSD Egypt Cluster (Egypt, Libya Sudan & Yemen)
	Harmonisation: Africa becomes One through one eCTD specification	Dr. Madelein Terblanche Dr. Mariam Aounallah	Senior Operations Consultant - VECTOR Life Sciences Pharmacist - Directorate of Medicine and Pharmacy (DMP), Tunisia
	E-Labeling Presentation	Dr. Rehab Mehrez	Manager of the General Administration of Pharmaceutical References and 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		
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, Magreb Countries, Developing Africa Markets) - Merck
	Enhancing Regulatory Preparedness through Digital Collaboration: CEPI's Framework for Accelerated Access during Public Health Emergencies	Mr. Alessandro Lazdins	Regulatory Policy and Intelligence Manager - Coalition for Epidemic Preparedness and Innovations (CEPI)
	Q&A		
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	Drug Serialization Department Directorate of Drug Approval and Serialization of Drugs and Other Health Products - Senegalese Regulatory Agency
	Ivory Coast Regulatory Updates	Dr. Chantale Affoue	Director of Approval of Drugs and Other Pharmaceutical Products - Pharmaceutical Regulatory Authority (AIRP), Ivory Coast
	Q&A		
18:00	NRA Break Out Round Table Discussions		