12-15 SEPTEMBER

VIRTUAL CONFERENCE

TOGETHER FOR PATIENTS

Transforming the regulatory ecosystem in Africa

ORGANIZED BY IFPMA

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CONFERENCE PROGRAMME OVERVIEW

On **12-15 September, from 13h00 – 16h00 CET**, join us for a 4-day virtual conference that brings together key stakeholders, including national regulatory authorities and pharmaceutical manufacturers, who are active in the regulatory field in Africa. The conference will focus on exploring future directions as the continent progresses towards the operationalization of the African Medicines Agency. Two satellite sessions will be organized on **18** September, **from 10h00 – 13h00 CET** and on **23 October, from 14h00 – 15h30 CET.**

Emphasizing the need for collaboration among stakeholders to advance regulatory science, reliance, and convergence, the conference aims to contribute towards building a robust regulatory ecosystem that ensures the availability of safe, effective, and quality medicines and vaccines for the people of Africa, ultimately leading to improved health outcomes and better access to healthcare for all.

Objectives: The aim of this **virtual conference is to offer a platform for:**

- Examining where we stand on the continent regarding regulatory harmonisation and convergence towards improving the quality, safety, and efficacy of medicines and vaccines globally.
- Gathering regulatory, access, pharmaceutical, academic, civil society, international organisations, non-governmental organisations, and policy experts from the African region and beyond.
- Informing on recent regulatory policies, share experiences and best practice and other success factors that have facilitated and accelerated delivery of medicines and vaccines to patients.
- Tackling regulatory challenges and identify solutions to help strengthen regulatory processes and systems in the region.

Please find below the working conference programme. For more details and registrations, please go to https://www.africaregulatoryconference.ifpma.org/.

Day 1: 12 September – How can the regulatory ecosystem in Africa be strengthened?

13h00 CET	**Conference opening remarks**
13h10 CET	**Keynote speech** • **Margareth Ndomondo-Sigonda,** AMRH/AMA Advisor to AUDA-NEPAD & AUC
13h30 – 14h40 CET	**Track 1: Navigating the maze: simplifying the path to efficient national registration of medicinal products** **Objectives**: • Identify common and distinct elements in WHO SRA CRP and JAP • Evaluate through case studies which are working best and how to fill gaps • Discuss governance, funding, IT infrastructure and technical needs • Discuss how to efficiently translate the outcome of CRP & JAP into a national registration **Speakers**: • **Sybil Nana Ama Ossei-Agyeman-Yeboah**, West African Health Organisation • **Christelna Reynecke**, Chief Operating Officer of South African Health Products Regulatory Authority (SAHPRA) • **Sakhile Dube,** Southern African Development Community (SADC) • **John Mwangi,** Head, Regulatory Affairs -East & West Central Africa, Bayer • **Mariana Roldao Santos**, Technical Officer, Facilitated Product Introduction, (WHO) • **Prof. Stuart Walker,** Founder, Centre for Innovation in Regulatory Science (CIRS) • **Nevena Miletic** (moderator), Regulatory Policy Head Eastern Europe, Middle East & Africa (EEMEA) Global Regulatory Policy (F. Hoffmann-La Roche)
14h40-14h45 CET	**Break 5 min**

14h45 – 16h00 CET	**Track 2: Clinical trials & research ecosystem in Africa: optimization for the future** **Objectives:** • Explore what the endorsement of the WHA 75.8 resolution on *Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination* means for Africa. How can implementation of the resolution help facilitate efficient clinical research? • Iterate the continued importance of convergence/harmonization and system strengthening for clinical research in Africa. Ideally, focus on identifying an outcome that can lead to a tangible activity on 'how do we get to a point where countries look holistically at the clinical research ecosystem in terms of harmonization, list of pre-requisites, ethics considerations, etc.'? • Provide understanding on the roles and responsibilities, activities of stakeholders **Speakers**: • **Vasee Moorthy**, Senior Advisor, R&D, WHO • **Jacqueline Rodgers**, AVAREF Secretariat • **Shingai Grace Machingaidze,** Ag. Chief Science Officer, Africa CDC • **Thomas Nyirenda**, Strategic Partnerships and Capacity Development Manager & Head of Africa Office, EDCTP • **Dirk Gillé**, Vice President, Head Capacity Development, J&J Global Public Health R&D • **Kelly Chibale**, Neville Isdell Chair in African-centric Drug Discovery & Development, University of Cape Town, South Africa (moderator)

Day 2: 13 September – How can regulatory collaboration help achieve patient-centric impact?

13h00 – 13h05 CET	**Welcome**
13h05 – 14h25 CET	**Track 3: Reaching regulatory maturity through reliance: lessons learned in the African continent** **Objectives**: • Provide an overview of best practices and practical considerations on how to implement reliance • Highlight international and regional initiatives that provide opportunities for training and capacity building • Explore how reliance has been implemented in the region, discuss challenges and lessons learned and opportunities for further advancements **Speakers:** • **Marie Valentin**, Facilitated Product Introduction Team Lead (WHO) • **Isabelle Colmagne-Poulard,** Head of International Global Regulatory Affairs & Scientific Policy, Merck KGaA • **Dr. Anthony Hotton**, Asst. Director/GBT-Coordinator, National Agency for Food & Drug Administration & Control (NAFDAC) • **Angelika Joos,** Executive Director Global Regulatory Policy, MSD (moderator)
14h25 – 14h35 CET	**Break 10 min**

14h35 – 16h00 CET	**Track 4: Optimizing regulatory frameworks for management of post-approval changes to benefit patients**
	
	Objectives:
	• Provide an overview of the complexity of the current PACs frameworks around the world and how this can have a direct impact on supply.
	• Explain how the following recommendations can be applied usefully to address the issue:
	  ○ Reduction in the number of PACs to be reported
	  ○ Streamlined approval timelines
	  ○ Implementation of PACs reporting as defined by ICH Q9, Q10, Q12 reliance principles
	• Describe how reliance can be applied to handling of post approval changes and share best practices

	Speakers: • **Dianliang Lei,** Scientist, WHO • **Francesca Mangia,** International Operations, Regulatory Manager, Roche/IFPMA • **Farida El Maouhab,** Director of Registration of Pharmaceutical Products, ANPP

Day 3: 14 September: How can Africa pioneer regulatory system innovation and digitalization?

13h00 – 13h05 CET	**Welcome**
13h05 – 14h25 CET	**Track 5: Regulatory digitalisation – New trends for a modern Agency** **Objectives:** • Highlight the importance of digitalization to establish a strong AMA • Raise awareness on what is happening at continental and regional levels • Work together towards establishing a roadmap for the Africa continent **Speakers:** • **Kristiina Puusaari,** European Medicines Agency (EMA) • **Christelna Reynecke**, Chief Operating Officer of South African Health Products Regulatory Authority (SAHPRA) • **Emmanuel Owusu Adasi**, ICT Officer, (FDA Ghana) • **Tim Powell,** chair of eCTD group, European Federation of Pharmaceutical Manufacturers and Associations (EFPIA) • **Karim Kacimi**, Regulatory Affairs Manager, Algeria, Merck KGaA • **Teresa Eastwood-Kiefer,** Chapter Leader, Regulatory Data and Content, Roche, Switzerland (moderator)
14h25 – 14h35 CET	**Break 10 min**
14h35-16h00 CET	**Track 6: Ability of regulatory systems to incorporate innovation and change** **Objectives**: • Share perspectives from key stakeholders on the future of regulatory systems in Africa and identify the most important steps required to integrate best practices from the pandemic and increase cutting-edge regulatory science **Speakers:** • **Jacqueline Acquah,** Associate Director, Global Public Health Vaccines Regulatory Affairs (EMEA), J&J • **Edwin Nkansah,** Director, Vaccine, Vigilance and Clinical Trials Directorate, Ghana Food & Drugs Authority • **Wilberforce Winyanga**, FAPMA Board Member • **Nick Cappuccino**, Chair, IGBA Science Committee • **Ginny Beakes-Read**, Vice President, Global Regulatory Policy and Intelligence, Janssen Inc. (moderator)

Day 4: 15 September:

13h00 – 13h05 CET	**Welcome**
13h05 – 13h35 CET	**Fire side chat with patients: Why are strong regulatory systems important for patients and how are African patients engaging in regulatory activities?** **Objectives**: • Highlight why it's important that patients are aware and engaged throughout the lifecycle of medicines and vaccines, which includes regulatory processes. • Share knowledge and experiences of patients in regulatory processes • Understand barriers to patient involvement in regulatory processes • Create awareness amongst the African patient community about the importance of strengthening regulatory systems in Africa to facilitate timely access to timely safe, quality, effective medical products. Use the African Medicines Agency as an example of pharmaceutical regulatory strengthening. **Speakers:** • **Alex Adusei**, Executive Director, Women's Hope Foundation, Ghana • **Ruth Nankanja Mukiibi,** Executive Director, Sickle Cell Association, Uganda • **Flavia Kyomukama**, Executive Director, Action Group for Health, Human Rights and HIV/AIDS (AGHA) Uganda • **Paloma Tejada**, Associate Director, Alliance Building, IFPMA (moderator)
13h35 – 13h40	**Break 5 min**
13h40-14h50 CET	**Track 7: The Africa New Public Health Order: creating a sustainable ecosystem for the biopharmaceutical industry** **Objectives**: • The Importance of Regulatory structures to promote a sustainable business environment for the biopharmaceutical industry • To review recent developments and challenges enhancing sustainable business environment for the biopharmaceutical industry on the Africa Continent • To highlight the important role of the Regional Economic Communities, and connect the dots with the establishment of AMA, its operationalisation and the development of capacity building efforts • To understand the link between local/regional production, market authorisation and local/regional procurement for the continent

	• To provide a platform for engagement and dialog between key stakeholders involved in a sustainable business environment for the biopharmaceutical industry. **Speakers:** • **John Mwangi**, Head, Regulatory Affairs – East & West Central Africa, Bayer Pharmaceuticals • **Susan Winks,** Head of Research Operations and Business Development, H3D • **Sylvia Vito**, Africa Head, EVA Pharma International • **Akhona Tshangela,** Programme Coordinator for Partnerships for African Vaccine Manufacturing (PAVM) • **Patrick Tippoo**, Chief Science and Innovation Officer (BIOVAC) and Executive Director (AVMI) • **Khadijah Ade-Abolade**, Deputy Director, Drug Evaluation & Research (NAFDAC) • **Zainab Aziz,** Associate Director- RA SSA Policy and Strategic Operations, Novartis (moderator) • **Greg Perry,** Assistant Director General, IFPMA (moderator)
14h50– 16h00 CET	**Track 8: Powering up: uniting stakeholders for a successful AMA operationalisation** **Objectives**: • Share AMRH progress and workplan at continental technical committee level • Share the latest development regarding the operationalisation of AMA • Discuss the establishment of a network of experts to support AMA and how countries and regions are preparing to integrate efficiently the new regulatory ecosystem **Speakers:** • **Sakhile Dube,** Southern African Development Community (SADC) • **Mohamed Ismail,** WHO Regional Adviser for AFRO • **Victoria Palmi Reig,** International Affairs officer EMA • **Samuel Asante-Boateng,** Director of Drugs and Herbal medicine Registration Directorate, Ghana FDA • **Gabriela Zenhausern,** Deputy Head of Stakeholder Engagement, Swissmedic • **Uchenna Adesugba**, Head, Regulatory Affairs Policy & Strategic Operations SSA, Novartis • **Chimwemwe Chamdimba,** Head of the African Medicines Regulatory Harmonisation, African Union Development Agency (AUDA-NEPAD) (moderator) • **Jo Ann De Crescenzo**, Johnson & Johnson (moderator)

18 September: Satellite session - Pharmacovigilance expertise; the importance of collaboration and learning

10h00 – 13h00 CET	**Track: Pharmacovigilance expertise** **Objectives**: • Develop a good understanding of current thinking about collaboration in the field of pharmacovigilance and reliance based on lessons from COVID-19 • Share information about pharmacovigilance activities in several countries **Speakers:** • **Florah Mafora Matlala**, Pharmacovigilance Manager, South African Health Products Regulatory Authority (SAHPRA) • **Raj Long**, Bill and Melinda Gates Foundation • **Helen Ndagije**, National Drug Authority, Uganda • **Martha Mandale**, Pharmacy and Poisons Board, Kenya • **Felix Mochache**, Country Patient Safety Head, Novartis • **Adela Ashie**, Principal Regulatory Officer, Ghana FDA • **Jayesh Manharlal Pandit**, PVCH and QPPV, East and North-West Africa countries, Bayer (moderator) • **Benita Morar,** PV Partnership Lead, AbbVie (moderator) • **Pat Harding**, Senior Advisor, Medicines Quality Organisation International, Lilly (moderator) • **Sean Burke**, Regional Lead - International Pharmacovigilance, MSD (moderator) • **Willemijn (Wim) Van Der Spuij**, Executive Director Europe, Worldwide Patient Safety, Bristol Myers Squibb & Chair of EFPIA International PV Group

23 October: Satellite session - How can the regulatory landscape on biosimilars be navigated?

14h00-15h30 CET	**Track: Biosimilars** **Objectives**: • Overview of biotherapeutic regulatory landscape including the revision of WHO GLs for Biosimilars and mAbs and their implementation. • Understanding the changing landscape of biosimilar regulations including topics such as traceability and interchangeability. **Speakers:** • **Dr Hyena Kang**, Access to Medicines and Health Products (MHP) division, World Health Organization (WHO) • **Dr Virginia Acha,** Associate Vice President – Global Lead, Global Regulatory Policy, MSD