12–15 SEPTEMBER | VIRTUAL CONFERENCE

TOGETHER FOR PATIENTS

Transforming the Regulatory ecosystem in Africa

DAY 4 | How do patients benefit from stronger regulatory systems?

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THANK YOU FOR JOINING!
Participant guide

- The 5th AfRC conference is held in English.
- All participants are muted. We encourage you to use the Q&A box to raise questions to the speakers. If a question you would like to ask has already been raised, you can also "like" that question.
- For some sessions, participants will have the opportunity to also engage with speakers through Mentimeter polls. To take part, a QR code will be displayed on screen and a link will be shared in the chat box.
- We encourage you to join all conference days.
- The 5th AfRC conference is recorded. All speaker presentations and videos will be made available on the africaregulatoryconference.ifpma.org website after the conference.

Présentations en anglais. Veuillez appuyer sur le globe pour avoir l'interprétation en français.
Apresentações em inglês. Clique no globo para interpretação em português.

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Fireside Chat Session with Patients

Moderator

Paloma Tejada
Associate Director, Alliance Building, IFPMA

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Fireside Chat with Patients

Paloma Tejada
Associate Director, Alliance Building, IFPMA

Ms. Flavia Kyomukama
Executive Director
Action Group for Health, Human Rights and HIV/AIDS (AGHA) Uganda

Mrs. Nankanja Ruth Mukiibi
Executive Director Sickle Cell Association of Uganda

Mr. Alex Adusei
Executive Director
Women's Hope Foundation and NGO advancing patient safety, women and girls human rights and gender equality

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Virtual coffee/tea break

We will be back at ***13h40*** **CEST**

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AfRC Track 07

Moderators:

Greg Perry – Assistant Director General - **IFPMA**

Zainab Aziz – Associate Director- RA SSA Policy and Strategic Operations – **Novartis**

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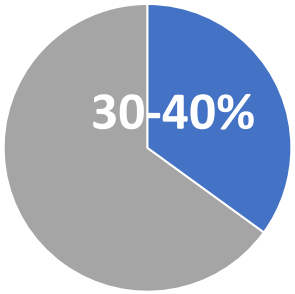
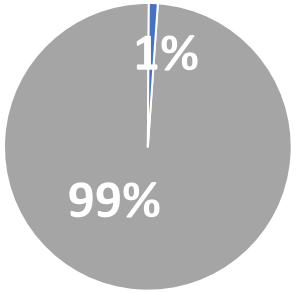
Setting the scene for local manufacturing of health products – Needs, challenges and solutions

– Akhona Tshangela, Africa CDC

Pharmaceutical manufacturing in Africa is still nascent

	Therapeutics		Vaccines	
Total demand volume produced locally		**Africa has limited manufacturing capacity, concentrated in a few countries that has a low level of integration along the value chain**		**The vaccines market is publicly driven and supply is concentrated to a small number of importers**
Supply	**8**	Countries contributing 80% of local production with over 600 manufacturers	**5**	Countries contributing 100% of local production with only 10 value chain players
	<20%	Manufacturers producing APIs operating in Africa	**>80%**	Manufacturers focus on fill and finish or packaging and labelling
	<2%	Worldwide R&D projects in Africa	**5**	Companies engage in drug substance manufacturing, however at a small scale
Financing and procurement	**~40%**	Financed through private sector	**~80%**	Vaccines publicly financed and supplied through Gavi for 40 countries
	~25%	manufacturers belong to Multinationals	**~70%**	Gavi supported volume and ~40% self-financed volumes originate from a few established players in India

Covid-19 challenge of vaccine national protectionism and delayed access in Africa highlighted need for Health security on the continent

Source: Fitch solutions (September 2020), IQVIA (September 2020) , OCHA(United Nations Office for the Coordination of Humanitarian Affairs)

Health product manufacturing and innovation provides a sizeable opportunity on the African continent

Large health product market in Africa provides an attractive business case

~30 bn USD market in 2022 in Africa across health products (vaccines, therapeutics, diagnostics, etc.)

Market has been growing 4% per annum (4bn USD increase) in the past 5 years

Additional ~7 bn USD growth expected in the next 5 years[2]

Additional benefits of localizing manufacturing and innovation

Improve health security and capacity for emergency response

Improves public health (DALY's)

Improves access and affordability

Accelerate ongoing regional harmonization initiatives to facilitate trade

Elevate technological expertise and capabilities

Facilitate economic growth

Africa CDC has set a goal to ensure 60% of health products required in Africa by 2040 are produced on the continent

Mission

To promote health security and self-reliance in Africa, by increasing its ability to develop, manufacture, and trade essential health products that help prevent, diagnose, alleviate, and cure local medical needs

Ambition

To increase manufacturing and innovation of health products (and raw material inputs) on African continent to meet 60% of demand by 2040

Strategic priorities

- **A** **Ensure healthy markets** for locally produced health products (incl., market design and intelligence)
- **B** **Strengthen the local R&D ecosystem** through facilitation of IP and tech transfer, increase of R&D capabilities and capacity
- **C** **Support capability building and talent development** to enable local manufacturing
- **D** **Incubate and scale capacity and infrastructure** of local manufacturing and supply chain

⊕ **Attract investments to drive delivery of above strategic priorities** through catalyzing strategic partnerships and resources

Our 5-year roadmap aims to realize the AU's public health order across health products, expanding from the current focus on vaccines

Objectives along 5-year roadmap

Gaps to close

2018 – 2022

PAVM set-up and start implementation

- **Set-up and mandated PAVM** to execute towards manufacturing 60% of local Vx demand
- **Develop continental strategy** and launch Framework for Action (FFA)
- **Install Secretariat** and launch implementation of priority bold program activities

2023-2028

Step-change towards self-reliant continent with local development and manufacturing

- **Expand into broader health products/raw material manufacturing strategy** and implementation, while scaling bold programs
- **Build organizational capacity** for PAVM and Harmonized Africa Health Manufacturing Platform
- **Define innovation ecosystem foundation required to address** priority medical unmet needs
- **Continue cultivate partnerships and incentivize funding** across the health ecosystem

1. Assessment of local Vx manufacturing raw material needs to enable manufacturing at scale

PAVM has enabled ecosystem shifts through its strategic priorities and bold programs

		Achievements	
Strategic priorities	**Bold programs**	**Ecosystem**	**23 H1 achievements**
Ensure healthy markets for locally produced health products	**Market design**	**2 continental market shaping instruments** in progress (i.e., Gavi AMC, Africa CDC PPM)	• **PPM politically approved** and design launched • **MOU signed** with Gavi on AMC
	Regulatory strengthening	**AMA treaty came into force and 5 NRAs with ML3 status** (2 in producing countries)	• **30mn USD dispersed and 5 NRA's supported** for capacity and capability building (incl., needs assessment; implementation plan) • **4 RCOREs endorsed** (SAHPRA, TMDA, Ghana FDA, Egypt FDA)
Strengthen the local R&D ecosystem through facilitation of IP, tech transfer, and R&D capabilities	**R&D**		*Fully operationalized in 2023 H2*
	Tech Transfer and IP	**For 10 vaccines 1+ suppliers** signed or started tech transfer (incl. YF, Hexa, PCV)	
Support capability building and talent development to enable local manufacturing	**Talent development**	**~3,000 FTEs active in local vaccine manufacturing and R&D** and continental strategy on training curriculum	• **Manufacturing needs assessment tool** launched • **MOU signed with IVI** for $200K sponsored training with 50+ manufacturing FTE's trained
Incubate and scale capacity and infrastructure of local manufacturing and supply chain	**Infrastructure development**		• **Vx value chain** diagnostic completed and aligned with 7+ manufacturers and other stakeholders • **Partnership established with CEPI** on stakeholder engagement and roadmap development (e.g., forum, publication)
Attract investments to drive delivery	**Access to Finance**	**Donors and DFI's committed >1.5 Bn USD investment** into continent	• **Common goal and set of initiatives** galvanized across African member states and stakeholders
	Agenda setting and coordination	**9 commercial scale facilities** and broader publicly announced ramp-up of manufacturer capacity (e.g., Aspen, Moderna, IPD)	• **MoH convened on a regular basis** on local vaccine manufacturing, 10+ meetings held

Short term (2023-2024) milestones need to be achieved across the ecosystem to work towards the 2040 ambition

2024 milestones for the vaccine manufacturing ecosystem …

237Mn doses p.a.
to be produced by local manufacturers (i.e., Biovac, IPD, Vacsera, Aspen)

AMC and PPM pilot set-up
with MoU signed for operationalization of pilot in 2024

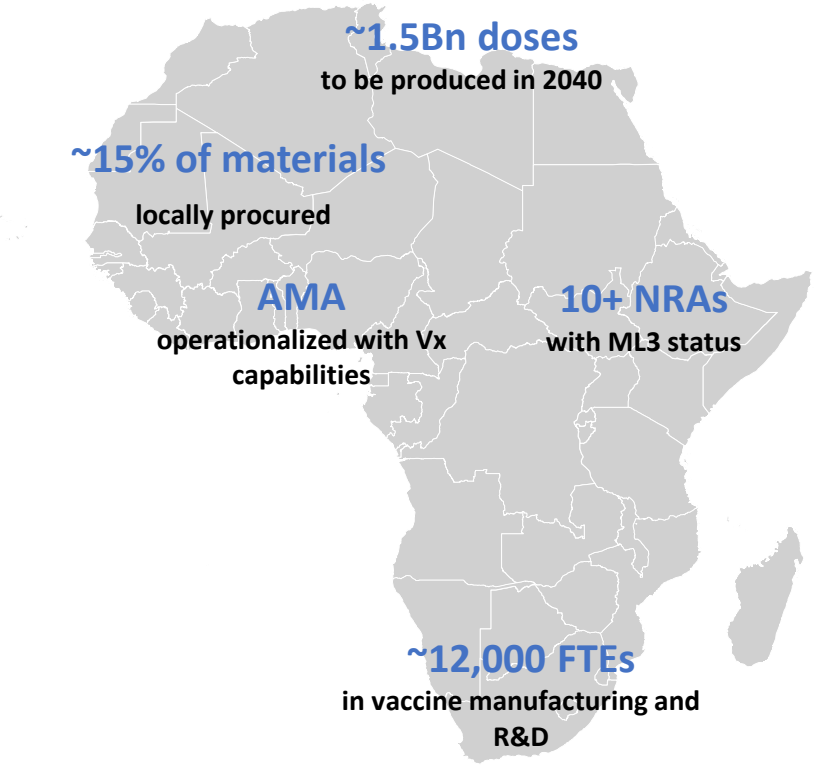
2+ RCOREs operationalized
for ML3 NRA(s) to provide know-how and capability building to other NRAs

Additional 5+ tech transfers
Initiated with increasing number of projects involving more upstream processes

>1k of people trained
through comprehensive training offering (e.g., short courses, internships, placements)

Further ~2Bn USD attracted
e.g., $25Mn for scholarship programs

… to support the 2040 ambition of 60% local vaccine production



Expanded scope to include broader health products (exact milestones tbd)

Source: CHAI/Path report, AUDAA-NEPAD announcement, news releases

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PANEL DISCUSSION

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Associate Director- RA SSA Policy and Strategic Operations
Novartis

Greg Perry
Assistant Director General
IFPMA

Akhona Tshangela
Program coordinator
PAVM

John Mwangi
Head, Regulatory Affairs – East & West Central Africa
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Khadijah Ade-Abolade
Deputy Director
Drug Evaluation & Research
NAFDAC

Sylvia Vito
Africa Head
Sub-Sahara Africa & Frontier Markets
EVA PHARMA INTERNATIONAL

Patrick Tippoo
Chief Science and Innovation Officer
BIOVAC
Executive Director
AVMI

Susan Winks
Head of Research Operations and Business Development
H3D

Kirti Narsai
Owner, HealthValue Consulting, Senior Researcher – Nelson Mandela School of Public Governance, Strategic Health Advisor – **Corporate Council on Africa**

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QUESTIONS AND ANSWERS

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KEY TAKEAWAYS – AfRC Track 07

- **Increased local production** would assist in ensuring more equitable access to medicines in Africa.

- Developing a **sustainable local manufacturing landscape** is key and drivers of this include:
  - Private and public sector partnerships;
  - Effective funding models;
  - Strengthening and harmonising regulatory activities across the continent;
  - Building capacity in a streamlined manner.

- **Securing the existing local supply chain routes** to prevent counterfeiting are also equally critical.

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AfRC Track 08

Session Moderators:

Chimwemwe Chamdimba

Head of the African Medicines Regulatory Harmonisation
AUDA NEPAD

Jo Ann De Crescenzo

Senior Director, Head of Regulatory Affairs, EMEA Emerging Markets & GPH
Jansen

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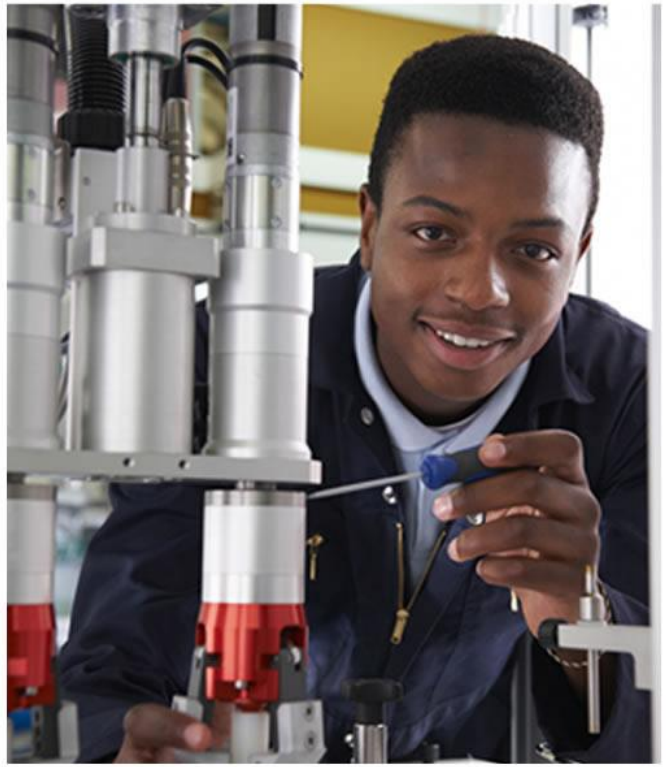

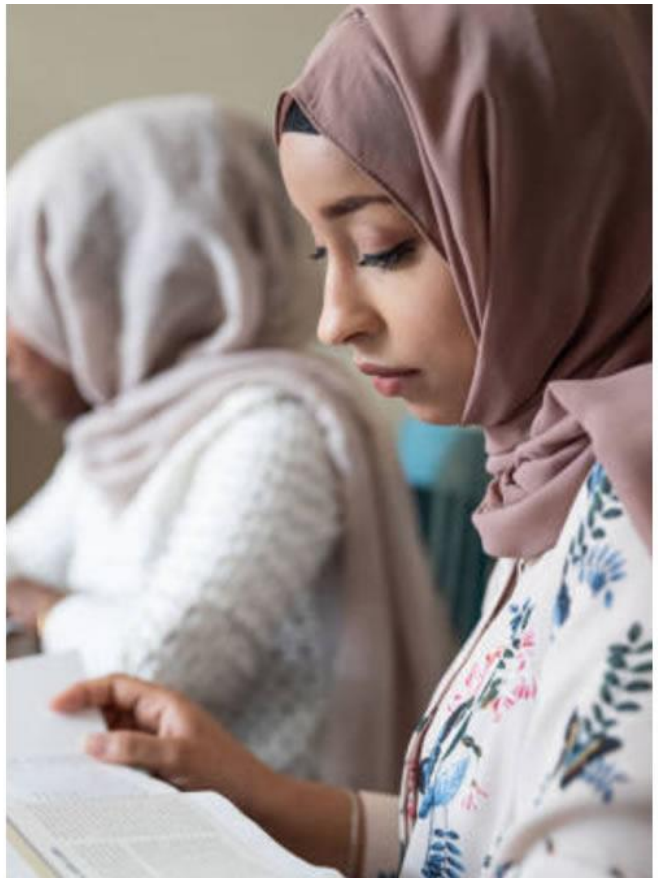

AMRH Initiative and latest developments on AMA

Where are we coming from?

- **2005:** AU Decision 55 on Development of the Pharmaceutical Manufacturing Plan for Africa (PMPA) within the NEPAD Framework
- **2009:** Initiation of the African Medicines Regulatory Harmonisation Programme (2011 – First regional project launched)
- **2012:** PMPA Business Plan developed
- **2015:** Executive Council Decision recognising the AMRH as the foundation of the AMA
- **2016:** Adoption of the AU Model Law on Medical products regulation (broaden the focus to all products
- **2019:** Adoption of the Treaty for the establishment of the AMA

The African Medicines Regulatory Harmonization Initiative Achievements

- **Coordinating Regional Regulatory Platforms EAC, SADC, ECOWAS, ECCAS, IGAD from 2009 (>85% of Sub-Saharan Africa)**

- **Reduction of registration timelines through joint review of dossier applications and inspection of manufacturing sites**
- **Domestication of the AU Model Law for Medical Products Regulation**
- **Adoption of the AMA Treaty by the AU Summit in February 2019**
- **Attainment of ISO-Certification and WHO Maturity Level 3 by some NMRAs**
- **Designation of 11 Regional Centres of Regulatory Excellence (RCOREs);**
- **Evolution of the AMRH Governance structure**
- **Support on COVID-19 response**

Partners: the African Union Commission (AUC), the Pan African Parliament (PAP), the World Health Organization (WHO), the World Bank, the Bill and Melinda Gates Foundation, the Foreign, Commonwealth & Development Office (FCDO)

1. AVAREF is a Continental Technical Committee under the AMRH Governance Framework

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The Africa Medicines Agency (AMA)

- Aimed at facilitating sustained continental-wide harmonization of technical standards and processes.
- Build on AMRH efforts to sustain ongoing regulatory harmonization initiatives.
- Will support countries to assess complex medical products.
- Will provide scientific and regulatory advice in support of local pharma industry development.

- Will lead to removal of unnecessary technical barriers to trade in pharmaceuticals in support of African Continental Free Trade Area (AfCFTA).

Highlights on AMA

- 26 Member Stated ratified the AMA Treaty
- AMA Treaty came into force on 5th November 2021
- Governance structures of the AMA established
    - CoSP
    - Bureau of the AMA
        - Ghana – Chair of Bureau
    - Governing Board (being established)
- CoSP constituted and Rules of Procedure adopted.
- Host country selected and host country agreement signed
    - Rwanda
- Ongoing process of recruiting the AMA DG

AMRH support to AMA operationalisation

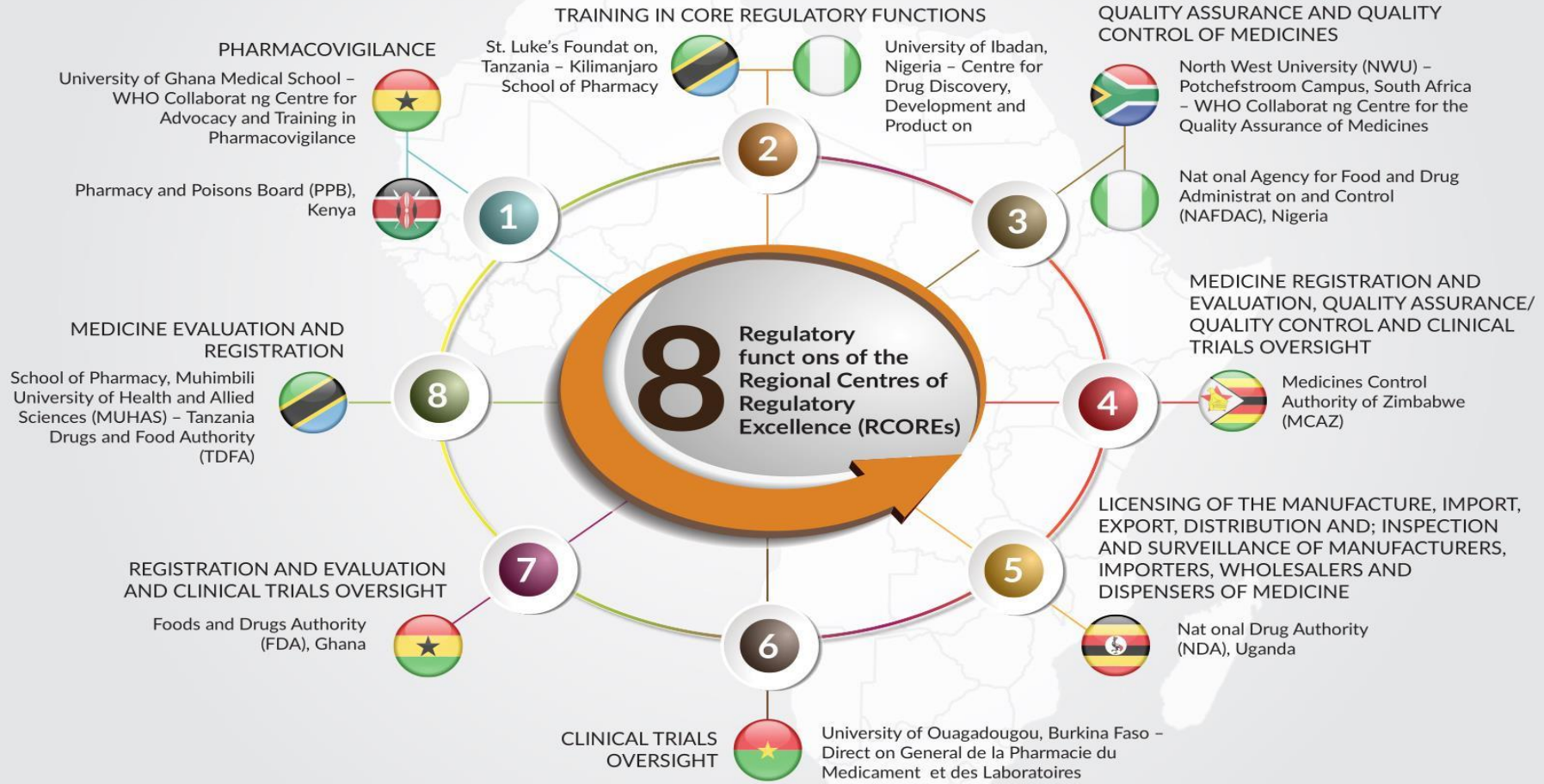
- Provide technical support building on AMRH technical assets (as per AU Executive Council Decision)
  - Setting up Technical Committees in specialized regulatory technical areas
  - Linking with RECs on the regulatory harmonization
  - Adoption of continental technical guidelines and approval processes in key regulatory areas
  - Piloting continental EMP and GMP
  - Supporting regulatory systems strengthening in Member States including the domestication of Model Law
  - Research and capacity building of regulator through RCORES
  - Leading regulatory work required for the PAVM
  - Building regulatory infrastructure e.g., IT Systems
  - Reliance framework development
  - Laboratory systems strengthening
  - Developing a continental plan on SF linked with RECs and MS
- Supporting participation of countries yet to ratify AMA Treaty
- Advocacy for ratification

AMRH Support to AMA

1	**The African Vaccines Regulatory Forum (AVAREF)**	• Regulatory oversight on clinical trials and joint reviews of complex products including vaccines
2	**The African Medicines Quality Forum (AMQF)**	• Quality controls and market surveillance
3	**The African Blood Regulatory Forum (ABRF)**	• Technical oversight on blood and blood products regulation
4	**The African Medical Devices Forum (AMDF)**	• Technical oversight on medical devices and invitro diagnostics regulation
5	**Pharmacovigilance / Safety Surveillance**	• Safety monitoring of medical products
6	**Good Manufacturing Practice (GMP)**	• Inspection of manufacturing sites
7	**Regulatory Capacity Development (RCD)**	• Coordination of regional centers of regulatory excellence (RCOREs)*
8	**Medicines Policy and Regulatory Reforms (MPRR)**	• Domestication of the AU Model Law on Medical Products Regulation
9	**Information Management Systems (IMS)**	• Support the operationalization of regulatory information management systems (RIMS)
10	**Product Evaluation & Registration (PE&R)**	• Support joint reviews and marketing authorization

Regional Centres of Regulatory Excellence (RCOREs)

As part of its mandate to strengthen regulatory capacity development in Africa, the NEPAD Agency through its AMRH programme has designated **11 Regional Centres of Regulatory Excellence (RCOREs)** in **eight diff erent regulatory funct ons**



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Regional Centers of Regulatory Excellence (RCOREs) on Vaccines Regulatory Oversight

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WHO GBT function/ area of designation:

- RS — National Regulatory Systems
- MA — Registration & Market Authorization
- VI — Vigilance
- LT — Laboratory Access & Testing
- CT — Clinical Trials
- RI — Regulatory Inspections
- MC — Registration & Market Authorization
- LI — Licensing of Premises
- LR — Lot Release

RS	MA	VI
SAHPRA TMDA- MUHAS EDA FDA Ghana	SAHPRA TMDA- MUHAS EDA FDA Ghana	SAHPRA TMDA- MUHAS FDA Ghana

LT	CT	RI
SAHPRA TMDA- MUHAS EDA FDA Ghana	SAHPRA TMDA- MUHAS EDA FDA Ghana	SAHPRA TMDA- MUHAS EDA FDA Ghana

MC	LI	LR
SAHPRA TMDA- MUHAS FDA Ghana	SAHPRA FDA Ghana	SAHPRA EDA

Regional Centers of Regulatory Excellence (RCOREs):

- South African Health Products Regulatory Authority (SAHPRA), South Africa
- Tanzania Medicines and Medical Devices Authority (TMDA) in collaboration with The School of Pharmacy of the Muhimbili University of Health and Allied Sciences (MUHAS), Tanzania
- Egyptian Drug Authority (EDA), Egypt
- Food and Drugs Authority (FDA), Ghana

Transforming Africa

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The emerging continental regulatory ecosystem

- AMA will not replace RECs or NRAs - it will coordinate and complement certain aspects of their work, with the majority of regulatory work still performed by RECs and NMRAs
- RECs are important coordination structures at the regional level: collaboration draws on the expertise and capacity of national authorities to undertake the work
- AMRH an important foundation for the operationalisation of AMA
- NRAs will have responsibilities for provision of expertise and technical leadership to RECs and AMA. They will also use the recommendations from their REC and from AMA to inform their own formal regulatory decisions
- Not all countries are AMA members yet. They still need to participate in regulatory harmonisation and systems strengthening – AMRH remains an important component of the ecosystem

Looking ahead…..

- Finalization of the composition of the AMA Board & DG recruitment
- Technical component of AMA building on AMRH technical work
- Continued advocacy for ratification of the AMA Treaty to reach all Member States
- Building RECs & national capacity key for successful collaboration across and regions and continent.
- Networking, information sharing and leveraging on available capacities – REC platforms
  - Anchor NRAs – ML 3 at the regional level to facilitate learning and mentoring through twining
    - Benchmarking of NRAs
    - Supporting countries to implements IDPs – mobilizing technical and financial support
    - Monitoring implementation and identifying bottlenecks
  - RCOREs – training and research

Looking ahead….. (2)

- Work-sharing at the regional and continental level
  - Regional and continental TCs
  - Joint assessment and inspections
  - NQCL networking
- Strengthened reliance framework on regulatory decision – Reliance framework
- Inter-REC learning & knowledge sharing
  - Continental harmonisation will only be successful if RECs collaborate
- Coordination, technical support, monitoring & evaluation, and learning

Thank you

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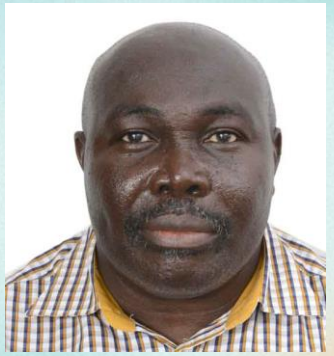

Keynote speech by:

Samuel Asante Boateng

FDA Ghana

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Victoria Palmi Reig
International Affairs officer
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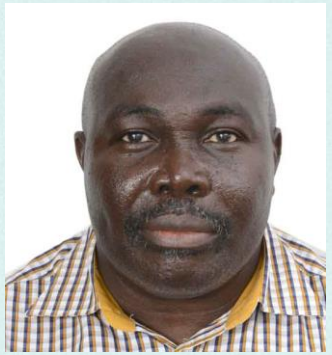
Gabriela Zenhäusern
Deputy Head Stakeholder Engagement
Swissmedic



Samuel Asante-Boateng
Director of Drugs and Herbal medicine Registration Directorate
Ghana FDA

Sakhile Dube
Co-ordinator for the SADC MRH Project
SADC

Mohammed Ismail
Team Lead of Medicine Supply, Health Infrastructure Equipment Maintenance
WHO

Uchenna Adesugba
Head, RA Policy & Strategic Operations
Novartis

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KEY TAKEAWAYS – AfRC Track 08

- **All actors and stakeholders** are needed to **join forces** and help facilitate the use of the following best practices:
  - **Transparency and reliability** through the organization of joint activities,
  - **Reliance** to ensure equitable use of resources.
  - **Harmonization of regulatory policies** in line with global standards, scientific evidence-based regulatory decision making, leading to accelerated, transparent, streamlined and predictable review processes spanning the full product lifecycle
  - NRA **capacity building,** via Regional Centres of Regulatory Excellence (RCORES)
  - **Timely communication** amongst stakeholders.
  - Cooperation at levels, Improve **interagency collaboration**.
  - Adoption of **digital and technology solutions**
  - **Sustainable** funding mechanism.

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Conference Closing Remarks

Jacqueline Acquah

Associate Director, Global Public Health

Vaccines Regulatory Affairs (EMEA)

Johnson & Johnson

IFPMA ARN Co-chair

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Join on 18 September AfRC satellite session

Pharmacovigilance expertise: The importance of collaboration and learning

10:00 -13:00 CET

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