AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

World Health Organization

# The fifth **Scientific Conference on Medical Products Regulation in Africa** (SCoMRA V) and the seventh **African Medicines Regulators Conference** (AMRC VII)

## Report

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# 1. List of Acronyms

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| ADRs | Adverse Drug Reactions |
| AMA | African Medicines Agency |
| AMRC VII | The seventh African Medicines Regulators Conference |
| AMRH | African Medicines Regulatory Harmonization |
| AMDF | Africa Medical Devices Forum |
| AUC | African Union Commission |
| AUDA-NEPAD | African Union Development Agency-NEPAD |
| AVAREF | African Vaccine Regulatory Forum |
| AU3s | African Union Smart Safety Surveillance |
| CTD | Common Technical Document |
| CoSP | Conference of States Parties |
| CORAQ-LAB | Cooperation for the Strengthening of Quality Assurance in the Quality Control Laboratories |
| EAC | East African Community |
| ECCAS | Economic Community of Central African States |
| ECOWAS | Economic Community of West African States |
| e-CTD | Electronic Common Technical Document |
| e-labelling | Electronic Labelling |
| EMA | European Medicines Agency |
| FAPMA | Federation of African Pharmaceutical Manufacturers Associations |
| FFA | Framework for Action |
| GMP | Good Manufacturing Practice |
| IGAD | Intergovernmental Authority on Development |
| INMD | International Classification, Coding and Nomenclature for Medical Devices |
| IRB | Institutional Review Boards |
| IVDs | In Vitro Diagnostics |
| NAFDAC | National Agency for Food and Drug Administration and Control |
| NMRA | National Medicines Regulatory Authority |
| NQCLs | National Quality Control Laboratories |
| PAVM | Partnership for African Vaccines Manufacturing |
| PMPA | Pharmaceutical Manufacturing Plan for Africa |
| PMS | Post-Market Surveillance |
| PQM+ | Promoting the Quality of Medicines Plus |
| RCOREs | Regional Centres of Regulatory Excellence |

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|---|---|
| RECs | Regional Economic Communities |
| RIMS | Regulatory Information Management System |
| RSS | Regulatory System Strengthening |
| SAGMA | Southern African Generic Medicines Association |
| SADC | Southern African Development Community |
| SAHPRA | South African Health Products Regulatory Authority |
| SCoMRA V | The fifth Scientific Conference on Medical Products Regulation in Africa |
| SOPs | Standard Operating Procedures |
| TCs | Technical Committees |
| USP | United States Pharmacopeia |
| UHC | Universal Health Coverage |
| WAPMA | West African Pharmaceutical Manufacturers Association |
| WHO | World Health Organisation |
| WHO EUL-FP | WHO Emergency Use Listing-Facilitated Procedure |
| WHO GBT | WHO Global Benchmarking Tool |
| WHO ML3 | World Health Organisation Maturity Level three |

## 2. Message from the Conference Organising Committee

The convening of the fifth Scientific Conference on Medical Products Regulation in Africa (SCoMRA V) and the seventh African Medicines Regulators Conference (AMRC VII) could not have come at a better time as the African continent is addressing medical products supply chain disruptions caused by the COVID-19 pandemic. The discussions that emanated from the two meetings will contribute to the implementation of the African Union policy and strategic frameworks aimed at facilitating and accelerating access to medical products. The SCoMRA and AMRC serve as useful platforms for knowledge exchange and information sharing among the various stakeholders.

Key areas identified include:

- There is a need for strengthened collaborations among the various stakeholders, including researchers, academia, manufacturers, regulators, and civil society across and beyond the continent, to advance product development for diseases that affect Africa disproportionately.
- Africa has begun to manufacture and export vaccines to other countries. The receiving countries need to ensure that they can trust the regulators and countries in which the vaccines are manufactured. Attainment of WHO Maturity Level 3 (WHO-ML3), particularly by NRAs of vaccine manufacturing countries, is a priority to support continental efforts to locally produce 60% of vaccines needed on the continent by 2040.
- Regulators across Africa need to transform their regulatory practice through reliance on one another's regulatory assessments and regulatory reports to improve efficiencies of regulatory review processes.
- There is a need to build regulatory infrastructure and capacity along the regulatory ecosystem from research and development, laboratory testing, lot release and post market surveillance. This needs to be coupled with a stringent product lifecycle management practice.
- Governments need to strengthen regulatory authorities to be able to set up efficient systems that are certified by the World Health Organisation (WHO), so as to ensure good quality vaccines. Support from reference agencies is critical as these have an important role to play in certain phases of the trials.
- Monitoring and evaluation of performance within NRAs, REC MRH efforts, Technical Committees and Regional Centres of Regulatory Excellence (RCOREs) is essential for sustaining improvements in results.
- Digitalisation is essential to support the ability to share real-time data and reporting of adverse events, as well as increasing regulatory efficiencies throughout the product life cycle.

- Capacity strengthening is still needed across the NRA workforce, drawing on the RCOREs. Some learning opportunities have emerged from the pandemic, which can be continued, particularly through online and virtual working.

Deliberations and lessons learnt from the discussions will help shape the regulatory landscape in Africa during and post-COVID-19.

On behalf of the SCoMRA V and AMRC VII Organizing Committee, we take this opportunity to thank all participants for taking time to present and contribute to the discussion, which promoted knowledge sharing to facilitate the documentation of good practice. We look forward to seeing you again in 2023.

**Dr Margareth Ndomondo-Sigonda**
Head of Health Programme, AUDA-NEPAD
Co-Chair, Organizing Committee

**Prof Jean Baptiste Nikiema**
Adviser, Essential Medicines, WHO AFRO
Co-Chair, Organizing Committee

## 3. Background to SCoMRA V & AMRC VII 2021

The COVID-19 pandemic has had massive global impact, leading to a dramatic loss of human life and an unprecedented challenge to public health, including disruptions in the supply of medical products and essential commodities. The emergency caused by COVID-19 has disrupted the healthcare systems of all countries, irrespective of their level of income. The pandemic has further exacerbated the substantial inequities in access to health care, which have existed for many years between countries. Vulnerable populations have continued to face a higher burden of morbidity and premature mortality as a result of easily preventable and treatable causes. Their limited access to affordable and quality essential services, as well as underinvestment in primary healthcare systems, is a major impediment to achieving Universal Health Coverage (UHC).

In response to COVID-19, the search for effective and equitable access to quality medical products for its prevention, containment, diagnosis, and treatment has served to highlight the critical role regulators play in providing access to quality assured products. The pandemic has led to a sharp increase in global demand for diagnostic kits, personal protective equipment, oxygen plants and concentrators, as well as vaccines and therapeutics which need to be rapidly developed, manufactured, and deployed. This has put pressure on regulators to innovate and expedite regulatory processes. To address delays in supply, policymakers have recognised an urgent need to strengthen manufacturing capacities on the continent for vaccines and other medical products, as part of building strengthened systems after COVID-19.

To cope with global supply challenges, regulators across the globe have had to adopt various regulatory pathways to facilitate the approval of essential medical products and health technologies. Reports show that there has been more than a 12-fold increase in regulatory workload in some countries, mostly due to medical products designed to prevent exposure to, test for or treat COVID-19. Regulators have had to find ways to support the expedited development and distribution of novel coronavirus-related vaccines, tests, and treatments. The circulation of substandard and falsified medicines and the prevalence of unauthorised importation of medical products have exacerbated the challenge for regulators.

More than ever, we have witnessed collaborations between regulators across the globe. There has also been collaboration between regulators, scientists and researchers working to accelerate the development, production, and equitable distribution of new COVID-19 essential health technologies as they become available. A common thread in collaborative efforts for regulation is the introduction of increased regulatory flexibility within an international framework that offers consistent standards to be met for quality, safety, and efficacy of medical products. For instance, regulators were called upon to support the African Union's (AU's) goal of attaining at least 60% population coverage by facilitating regulatory approval of COVID-19 vaccines through three regulatory pathways that were considered essential to expedite regulatory approval at country levels.

In the context of advancing the Pharmaceutical Manufacturing Plan for Africa (PMPA), the AU is taking steps to strengthen research and innovation towards local production of pharmaceuticals and vaccines. The AU is further advancing the Partnerships for African Vaccines Manufacturing (PAVM) Framework to accelerate access to vaccines for the African population. The need to strengthen regulatory systems cannot be overemphasised in terms of speeding up time to approve medical products and the subsequent monitoring of the safety and quality of products circulating in various markets.

In this regard, the African Medicines Regulatory Harmonisation (AMRH) initiative and its corresponding Technical Committees (TCs), such as the African Vaccines Regulatory Forum

(AVAREF), have played a key role in facilitating clinical trial oversight as well as the joint review of COVID-19 vaccines and subsequent approvals. The African Medical Devices Forum (AMDF) has played a role in providing regulatory guidance to the AU Member states in the marketing authorisation, procurement, donation, and management of substandard and falsified (SF) COVID-19 medical device and diagnostic products. Other TCs, such as the African Medicines Quality Forum (AMQF) and the African Blood Regulators Forum (ABRF), have been instrumental in providing technical guidance in post-marketing programmes and regulation of blood and blood products respectively.

On 5th November 2021 the African Medicines Agency (AMA) was formally established as an institution of the African Union. AMA's main objective is to improve access to good quality, safe and efficacious medical products on the continent through:

a) Coordinating and strengthening of ongoing initiatives to harmonise medical products, technical standards, and optimisation of regulatory processes, and promote cooperation and reliance on and recognition of trusted regulatory decisions.
b) Conducting regulatory oversight of selected medical products (AMA products) and providing technical guidance to State Parties and Regional Economic Communities (RECs).
c) Pooling expertise and capacities and strengthening networking for optimal use of the limited financial and scientific resources available.

The creation of the AMA is the final component of the African Union's vision of a networked African medical products regulatory system. The AMA offers the opportunity to address several of the regulatory obstacles seen during the COVID pandemic. These include the leveraging of limited expertise to assess complex products including vaccines, the high prevalence of substandard and falsified medical products, as well as a better coordinated African response to emergency and non-emergency health challenges.

## 4. Conference Overview

Under the theme "***Regulatory systems in Africa: lessons from COVID-19 and strategies to build back better after the pandemic***", SCoMRA V and AMRC VII were held from the 22nd to the 26th of November 2021.

While the former is a broad platform for policy makers, regulators, the research community, product developers, manufacturers and other stakeholders, the latter is dedicated to regulators across the continent.

**SCoMRA V** was hosted virtually by the Government of Rwanda across two consecutive days.

The conference runs every two years and brings together over 300 participants from African and global organisations involved in regulatory systems strengthening and harmonisation. It serves as a platform for the discussion and advancement of regulatory sciences in Africa. The meeting format included plenary presentations, panel discussions and parallel tracks.

A key goal of SCoMRA is to facilitate experience and information exchange among stakeholders. Stakeholders included:

a) Policymakers from ministries responsible for health, finance, trade and industry, research and innovation, and other relevant ministries
b) National Regulatory Authorities (NRAs) in Africa
c) Other NRAs partnering with Africa
d) Researchers
e) Academia
f) Ethics Committees and Institutional Review Boards (IRB)
g) Clinical trial sponsors and industry representatives
h) Regional Economic Communities (RECs)
i) African Union Development Agency-NEPAD (AUDA-NEPAD)
j) African Union Commission (AUC)
k) World Health Organisation (WHO)
l) African Medicines Regulatory Harmonisation (AMRH) Partners and other non-AMRH partners involved in regulatory work in Africa
m) Development partners in health and pharmaceutical sectors in Africa
n) Patient organisations
o) Media representatives
p) Other relevant stakeholders.

Deliberations of the SCoMRA fed into the AMRC, which was held immediately after SCoMRA. The AMRC took place across three consecutive days following the meetings of the AMRH Technical Committees, which fed into the AMRC meeting.

The AMRC runs every two years and brings together heads of NRAs working on the African continent. It also serves as an overarching high-level body to provide technical, policy and strategic guidance, and set priorities to the African Union Policy Organs and to the WHO.

The SCoMRA V and the AMRC VII brought together stakeholders to reflect on progress, define priorities, and set the agenda going forward. The two meetings ran consecutively. They provided complementary platforms for stakeholders to share experiences about how they managed various challenges, and to share lessons that will assist in the management of future emergencies and facilitate progress in the continent's ability to regulate medical products. These events also provided an opportunity to re-define priorities for the AMRH, which serves as the foundation for the establishment of the AMA as per The African Union's Executive Council decision of January 2015.

Strengthening regulatory systems for medical products in Africa through the implementation of harmonised regulatory frameworks and the application of work-sharing, reliance and capacity strengthening models at national, regional, and continental levels, is an integral part of health systems resilience.

Health actors, institutions and populations need to have capacity to prepare for and effectively respond to crises, maintain core functions when a crisis hits and be informed by lessons learned during the crisis, and to reorganise if needs be. The Ebola outbreak was a learning point for Africa that enabled the establishment of the Africa Centres for Disease Control and Prevention (Africa-CDC). The continent is now able to manage the COVID-19 response, which includes medical products and commodities security.

## 5. Objectives of SCoMRA and AMRC 2021

The shared objective of the two conferences is to support countries in accelerating patients' access to safe, efficacious, and good quality medical products through strengthened regulatory systems and collaborations between NRAs, researchers, academia, procurement agencies, industry, and patient organisations.

### SCoMRA

1. Is the continent's regulatory infrastructure capable of addressing public health emergencies?
2. Shaping regulatory policy direction and landscape to support public health emergencies in Africa.
3. What is the role of national regulatory agencies in advancing the Partnership for African Vaccines Manufacturing (PAVM) Framework?
4. What lessons can be learnt on collaborations in advancing research and development of medical products on the continent?

AMRC

1. Review the progress in the implementation of the sixth AMRC and AMRH Technical Committee recommendations.
2. Review the progress on the establishment of the African Medicines Agency.
3. Obtain agreement on the resources and intangible assets of AMRH that should be prioritised with the operationalisation of AMA.
4. Share experiences and best practices on regulatory preparedness during public health emergencies.
5. Write recommendations on technical, policy and strategic priorities for regulatory systems strengthening and harmonisation initiatives.

## 6. Summary of Recommendations from the SCoMRA IV

Nancy Ngum, Programme Officer at AUDA-NEPAD, presented progress in the implementation of the recommendations from the last SCOMRA (held in 2019) by the AMRH Secretariat. She shared the following recommendations from the SCOMRA IV Conference:

*Recommendation 1:* Increase collaboration between regulators, researchers, academia and the industry for improved capacity on regulation and drug discovery on the continent.

*Implementation Progress:*
A number of platforms have been utilised to achieve this recommendation, including the following:

- EDCTP, working to advance ethics and regulatory oversight and research.
- African Academy of Science (AAS) through the Alliance for Accelerating Excellence in Science in Africa (AESA) to create a clinical trials community to facilitate collaboration between researchers and regulators.
- High-Level Panel by the Union on Innovation and Emerging Technologies, implemented through the Calestous Juma Executive Dialogue on Innovation and Emerging Technologies (CJED).
- Pan-African stakeholders webinar, which provided an opportunity for interaction between the regulators, Regional Economic Communities and industry to gain a better perspective of experiences on the joint assessment procedures.

*Ongoing Plans & Next Steps:*
- There are ongoing plans to enhance the number and quality of collaborative initiatives.

*Recommendation 2:* Training on research and development (R&D), and on regulatory oversight.

*Implementation Progress:*
The following activities have been undertaken:

- AVAREF, an AMRH Technical Committee, has focused on capacity building for expedited clinical trials approvals.
- Collaborations with universities, working to advance training on regulatory science, research and knowledge (including knowledge sharing through publications). This includes collaborations with:
  - University of KwaZulu Natal (UKZN) on the use of convalescent plasma as a remedy for Covid-19, feeding into the African Blood Regulators Forum (ABRF), another of the AMRH Technical Committees.
  - University of the Western Cape in South Africa and the AMRH secretariat supporting Masters courses in regulatory sciences.
  - Muhimbili University of Health and Allied Sciences (MUHAS) in Tanzania and TMDA Tanzanian Regulatory Authority.
  - Kenya Pharmacy and Poisons Board and the Kenyatta University.
  - There is also a clinical assessment post that has been ongoing for the past year.

*Ongoing Plans & Next Steps:*

- Ongoing establishment of Regional Centres of Regulatory Excellence (RCOREs). There are currently 11 RCOREs, and the plan is to establish more to advance regulatory oversight on vaccines manufacturing, regulation of medical devices, in vitro diagnostics, and regulations of blood and blood products. The plan is to drive this in 2022.

*Recommendation 3:* Increase advocacy for regulatory systems strengthening and harmonisation of political support and sustained efforts.

*Implementation Progress:*

- The AMRH Secretariat developed an advocacy training manual for AMRH, AMA and the AU Model Law, used to train parliamentarians, media civil society regulators, and legal and communication experts.
- e-tools are being used to collect data from Member States and Regional Economic communities in support of medicines regulatory harmonisation, to evaluate the performance of the harmonisation initiative in the RECs. Some good work has been achieved in the evaluation of the ZaZiBoNa project and other regional initiatives using the process effectiveness and efficiency questionnaire rating.

*Ongoing Plans & Next Steps:*
There are plans to roll out ZaZiBoNa to evaluate the East African Community (EAC) in 2022.

*Recommendation 4*: Countries were encouraged to use creative tailor-made tools that respond to their needs for reporting adverse drug reactions electronically.

*Implementation Progress:*
The African Union 3S initiative was launched to enable African ownership of the tools and data systems to facilitate pharmacovigilance analysis and decision making, to increase information sharing and collaboration and improve pharmacovigilance data and signals across national programs and African countries. The aim was also to strengthen the PV expertise among countries and continental stakeholders, and to improve medicines and vaccine safety for patients in Africa.

- The next step will be to extract lessons learnt from this Pilot initiative in four countries and explore using it for the entire continent in the next few years.

*Recommendation 5:* Strengthen regional collaboration post-marketing surveillance (PMS) programmes to fight against substandard medicines.

*Implementation Progress:*
To date, cross border pharmacovigilance has been implemented in the East African Community and implemented as a regional PMS program. There are plans to roll these out across the continent.

- AVAREF has been adopted as one of the AMRH Technical Committees, and has supported the development of tools and guidelines, including the joint review procedures for clinical trial applications.
- The Treaty of the African Medicines Agency came into effect on 5th November 2021, following the 15th instrument having been deposited on 5th October 2021.
- The African continent needs to adopt the Electronic Common Technical Document (e-CTD) to increase industry efficiency, reduce costs, and improve consistency of evaluation.

*Ongoing Plans & Next Steps:*

- In terms of the way forward on the AMRH and AMA, their working relationship has been formalised by the African Union policy organs. Currently there are 18 member states that have ratified the AMA Treaty. The next step will be to get the 55 member states to be part of this process.

*Recommendation 6:* Adopt and adapt the global curriculum and competency framework, and learn from countries that are already utilising it, such as Zimbabwe, where the global curriculum and competency framework to undertake regulatory science training is already being used.

# 7. Key Take-Aways from SCOMRA V & AMRC VII

1. Collaboration and trust are essential for ensuring an effective regulatory response to the COVID-19 pandemic. This requires focused processes and structures as well as adequate time for implementation, where possible.
2. Virtual working has brought some efficiencies to selected regulatory processes and supported reliance efforts. However, there are cases in which physical presence is essential, including for some elements of on-site manufacturing inspection. Coordination and internet connectivity are fundamental for success.
3. The quality of dossier submissions by manufacturers to African NRAs needs improvement and requires capacity strengthening. Submissions that fail to meet requirements fail to receive marketing authorisation or registration and prevent access for patients.
4. Monitoring and evaluation of performance within NRAs, REC MRH efforts, Technical Committees and RCOREs is essential for sustaining improvements in results.
5. Digitalisation is essential, supporting the ability to share real-time data and support reporting of adverse events, as well as increasing regulatory efficiencies throughout the product life cycle.
6. Capacity strengthening is needed across the NRA workforce, drawing on the RCOREs. Some learning opportunities have emerged from the pandemic, which can be continued, particularly through online working.

# 8. SCoMRA V Conference Presentations & Discussions

## Day 1 - Monday 22 November 2021

**Introduction and Welcome**

Dr Amine Idriss Adoum: Director, African Union Development Agency (AUDA) (speaking on behalf of Dr Ibrahim Mayaki, CEO AUDA-NEPAD), opened the conference. It was explained that Africa represents 17% of the world's population and is responsible for 60% of worldwide healthcare expenditure but represents less than 1% of the world market in pharmaceutical products. Clear policies are needed for access to quality medical products. National regulation authorities and academic institutions have an important role to play in stimulating medicines regulation and production. The AMA is a pillar supporting efforts to increase production capacity at local and continental level. Parallel interventions and partnerships are, and will be needed, in the fight against epidemics. A common medicines market in Africa is needed.

Dr Gulin Gedik: WHO- Regional Office for the Eastern Mediterranean (WHO-EMRO) (representing Dr Awad Mataria, Regional Director of WHO-EMRO), explained that Covid-19 has imposed additional challenges regarding access to medicines, vaccines, and medical devices, causing shortages and price increases. Local manufacturing capacity in the region is needed, in line with target 3.8 of the Sustainable Development Goals (SDGs). Currently, only four countries in the region are manufacturing the five Covid-19 vaccines found on the continent. These are Egypt, Iran, Pakistan, and the United Arab Emirates. Innovative technologies using e-documents have made information available to be able to approve vaccines within 15 days. However, further efforts are still needed to improve regulatory systems.

Dr Margaret Agama-Anyetei, Acting Director of Health and Humanitarian Affairs, AUC, spoke about the opportunities afforded by the AMA. The AMA, which came into effect on 5 November 2021, aims to strengthen regulatory capacity on the continent and to provide an enabling environment for the production of medical products and the development of technologies that meet international standards in quality, safety and efficacy. The goal is to advance local manufacturing capacity in Africa in order to meet the AUC's target for African products to make up 60% of the overall pharmaceuticals market by 2040. The African Continental Free Trade Area (ACFTA) provides an opportunity for the expansion of the market and will be complemented by collaboration between researchers and industry. Collaboration will be necessary to meet these targets.

The Honourable Michel Sidibé: AU Special Envoy on the African Medicines Agency, stated that there is an urgent need for adequate preparation for the development of protective measures for anticipated future diseases and pathogens. A sound regulatory environment will enable access to high-quality critical products and assist in identifying and eliminating substandard and falsified products. This will require a team effort. Resources are needed to support researchers, scientists, and academic institutions in the identification of new and emerging threats. Partnerships and data sharing through multi-party relationships among researchers, manufacturers and the private sector will be important. It is also important to drive Africa-led research and development to ensure that research relates to the continent's relevant demographic, health, and contextual needs.

Nancy Ngum: AUDA-NEPAD, presented recommendations from, and progress since, the SCoMRA IV Conference of 2019. There has been an increase in collaboration amongst regulators, researchers, academia, and industry. Facilitation platforms have included EDCTP (Ethics and Regulatory Oversight, and Research), the Alliance for Accelerating Excellence in Science in Africa (which has conducted clinical trials) and the Calestous Juma Executive Dialogue (CJED) (which has facilitated innovation and emerging technologies).

To build capacity, organisations involved in research and development (R&D) and regulatory oversight have been active. This has included AVAREF, which has conducted capacity building for expedited clinical trials, and universities which have delivered training on regulatory science, research, and knowledge sharing. The AMRH Secretariat developed an advocacy training manual for the AMRH, the AMA and the AU Model Law. The manual is used to train parliamentarians, media, civil society regulators, legal and communication experts. RCOREs have been established. There are currently 11 RCOREs to advance regulatory oversight on vaccine manufacturing, regulation of medical devices, in vitro diagnostics and regulation of blood and blood products.

The African Union 3S initiative was launched to enable Africa to have ownership of the tools and data systems to facilitate pharmacovigilance analysis and decision-making in order to increase information sharing and collaboration across African countries.

AVAREF has been adopted as one of the AMRH Technical Committees to support the development of tools and guidelines, including the joint review procedures for clinical trial applications. The e-CTD provides regulators with an opportunity to increase efficiency, reduce costs and improve consistency of evaluation. This should be adopted by regulators across the continent.

## Regulatory policy direction and the regulatory landscape to support public health emergencies in Africa

In the next segment, speakers discussed various approaches to shaping regulatory policy direction and the regulatory landscape to support public health emergencies in Africa.

**Key Points to Note:**

- From a large multinational company's perspective (Pfizer), continuous data flow will unlock new possibilities and bring more insights to support regulatory preparedness for health emergencies, which the industry will need to adapt to. Cloud-based solutions are important and will allow for better data analysis.
- The shift in mindset from conducting onsite good manufacturing practice (GMP) inspections to virtual inspections provides a timely alternative to protect, promote, and preserve public health.
- There is a gap between regulatory expectations for marketing authorisations, drug development and registration strategies. A collective effort from both the regulator and the manufacturer is needed to improve the quality of market authorisation applications for generic medicines.
- An effective regulatory response in Ethiopia included partnership and trust building as well as streamlining of regulatory procedures including registration, emergency use authorisation, conditional approval of products and reliance on other national medicine

regulatory authorities to ensure that there was no duplication of efforts. Monitoring and evaluation of all efforts was supported by electronic application systems and communication with the public, police, and other institutions.

- Partnerships for capacity building in regulatory processes to oversee manufacturing and technology transfer are essential components of a vaccines Research and development (R&D) strategy in Rwanda.
- Guidance on the availability of medicines for use in a Public Health Emergency (PHE), alongside conditional registration of applications and phased submissions of evidence, supported access to vaccines in South Africa.
- Collaboration among NRAs, under AMA leadership, and capacity strengthening are two essential elements for the pandemic response.
- From the International Federation of Pharmaceutical Manufacturers Association's (IFPMA) perspective, challenges with clinical trials, regulatory processes and product supply shortages could be overcome with more effective use of reliance between NRAs.
- An additional capacity building effort, VaccTrain, is in place to support the development of clinical trials oversight for public health emergencies through building structures, supporting RCOREs and harmonising standards at the Pan African level.

Judith Macdonald: Global Regulatory Policy Development, Pfizer provided a company perspective on how to pandemic-proof regulatory review systems using a cloud-based approach to build trust by sharing data and reviews more efficiently and securely. She highlighted their role in building a more sustainable approach for data to be applied as usable evidence. Although the Common Technical Document (CTD) and eCTD offer a standardised approach, data is locked in formats that are hard to analyse and there is a need to find new ways to integrate and analyse new information alongside clinical trial data. Continuous data flow will unlock new possibilities and bring more insights, which the industry will need to adapt to.

Washington Dengu: GMP Consultant, noted that the Covid-19 pandemic disrupted much of the routine regulatory inspections, both in Africa and globally. Many nations closed their borders and regulatory authorities were unable to send inspectors to conduct GMP inspections to support product marketing authorisations and routine quality assurance surveillance. This led to potentially substandard and falsified medicines with limited or no assurance on safety, efficacy, and quality.

The shift in mindset from conducting onsite inspections to virtual inspections was a challenge but provided a timely alternative to protect, promote, and preserve public health. Documents were shared using various cloud systems. More people participated in the inspection process via Zoom or Teams. The process enabled the training of inspectors and improved capacity development.

Brilliant T. Samunda: Policy regulator, Medicines Control Authority of Zimbabwe presented findings concerning the refusal of marketing authorisations in Zimbabwe. He highlighted common deficiencies and processing timelines for generic medicines market authorisation, explaining that there is a gap between regulatory expectations, drug development and registration strategies.

A collective effort from both the regulator and the manufacturer is needed to improve the quality of market authorisation applications for generic medicines.

Heran Gerba: Director General, Ethiopian Food and Drug Authority offered lessons learned from Ethiopia in terms of how it developed regulatory agility to support the country's response to the Covid-19 emergency. For example, key partners were identified to develop a mitigation strategy for emergency health threats including regulatory preparedness. Regulatory pathways were streamlined, including registration, emergency use authorisation, conditional approval of products and reliance on other national medicine regulatory authorities to ensure that there was no duplication of efforts. Electronic application systems; communication with the public, police, and other institutions; media engagement and monitoring and evaluation all played important roles in being able to respond effectively to the pandemic.

Dr Emile Bienvenu: Director General, Foods and Drugs Authority, Rwanda (presented on behalf of the Honourable Minister of Health of Rwanda, Dr Daniel Ngamije) explained that there are several critical requirements for advancing research and development of medical products. Partnerships (among NRAs, FDAs, and others) for the preparation of vaccine manufacture, especially around regulations, are a priority. A strong and aggressive capacity building plan must drive the success of the vaccine programme, including using expatriates or mentors. Technology skills transfer and training are vital as vaccine manufacturing will involve the use of new technology.

Khamusi Mutoti, of The South African Health Products Authority (SAHPRA), provided an overview of the strategies and approaches implemented by SAHPRA to facilitate the availability of Covid-19 vaccines. He highlighted the challenges experienced with the review of Covid-19 vaccines applications. In response to the pandemic, SAHPRA implemented a guidance document regarding the availability of medicines for use in a Public Health Emergency (PHE). It also permitted conditional registration of applications to facilitate the availability of vaccines while manufacturers gathered additional information in terms of efficacy, quality, and safety. Exceptions were made to allow for the submission of information in a phased approach, even without the complete documentation.
Fatima Guiet Mati: PhD student, Universite de Strasbourg discussed the major challenges and lessons learned with regulatory collaboration and reliance during the public health crisis. Authorities need to be able to collaborate efficiently under the leadership of the AMA. The capacity of authorities should be strengthened to enable them to better respond to emergency situations. It is necessary to involve legal and national authorities in the process.

Dr Bumni Femi-Oyekani: International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) explained that in the wake of the Covid-19 pandemic there were challenges with clinical trials, regulatory processes, and product supply shortages. Regulatory reliance (where the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution) could present a plausible solution in addressing some of these challenges.

Day 1 concluded with an overview by Solomon Owusu Sekyere of the Global Health Protection Program (GHPP) VaccTrain strategy, which has three focus areas relating to clinical trials oversight for public health emergencies: building structures, supporting RCOREs and harmonising standards at the Pan African level.

## Day 2 - Tuesday 23 November 2021

### Regulatory systems in Africa: Lessons from COVID-19 and strategies to build back better after the pandemic

The plenary speakers on day 2 framed the day's discussions in the context of the current status and future vision for clinical trials on the continent and overarching regulatory preparedness during public health emergencies on the continent.

Professor Lembit Rago: Secretary General, Council for International Organizations of Medical Sciences (CIOMS), highlighted that there is a huge need to develop more capacity for clinical trials in Africa, involving all stakeholders (including industries, regulators, research fellows, academics, patients, and funding organisations). Regulators have an important role in facilitating good quality, timely clinical trials and should share resources and guidance on the use of electronic health records in their investigations.

Dr Nicaise Ndembi: Africa-CDC, spoke about regulatory preparedness during public health emergencies and lessons learned from the COVID-19 response. He highlighted the importance of establishing a pathway for regulation in an emergency. This will involve creating an adequate legal environment, harmonising NRA, and developing vaccine manufacturing, knowledge, and expertise.

The opening panel on Day 2 discussed the role of national regulatory agencies in advancing thePAVM Framework.

Professor Christianah Mojisola Adeyeye: Director-General, National Agency for Food and Drug Administration and Control (NAFDAC), highlighted that the African Medicines Regulatory Harmonisation Framework (AMRH) was adopted in October 2019 to provide strategic direction, regulatory system strengthening and harmonisation at regional and continental levels. She urged Member States to use the AU Model Law to improve their legislative frameworks. She also encouraged NRAs to use RCOREs for capacity building and for partners to support RCOREs with funding. AMRH should catalyse local manufacturing through engagement with regional manufacturing associations such as Federation of African Pharmaceutical Manufacturers Associations (FAPMA), West African Pharmaceutical Manufacturers Association (WAPMA) and Southern African Generic Medicines Association (SAGMA).

She closed by urging NRAs to join the global traceability initiative. This is a means of verification and traceability and an organ of market control.

Dr Boitumelo Samete: CEO, South African Health Products Regulatory Authority (SAHPRA), suggested that African regulators have an important role to play in supporting one another in generating local data and strengthening safety monitoring. As Africa begins to manufacture vaccines, and export these vaccines to other countries, the receiving countries need to know that they can trust the regulators and countries in which the vaccines are manufactured. Harmonisation and realignment of regulatory practices in the various countries is needed. Regulators across the region need to be able to rely on each other's regulatory assessments and reports. Stringent product lifecycle management practices that involve the analysis of products, even when they are already in the market, are essential.

Heran Gerba: Director General, Ethiopian Food and Drug Authority highlighted that Africa needs to strengthen its manufacturing capability. To do this, strengthening of the regulatory system is crucial, drawing on clear regulatory policies and procedures. NRAs should be trained to ensure that they are competent and learning from each other across countries through the African Medicines Harmonisation.

Mimi Darko: Chairperson, African Vaccine Regulatory Forum (AVAREF), explained that AVAREF has a scientific forum that provides information through different platforms, including webinars. This has enabled the strengthening of the regulatory authorities. Regional economic growth should be driven through collaboration. A move away from working as individual countries is necessary. Regulators must be involved in the vaccine development process from the beginning. Governments need to strengthen regulatory authorities to be able to set up effective systems that are pre-qualified by the World Health Organisation (WHO) to ensure good quality vaccines. Support from reference agents is critical as they play an important role in certain phases of the trials.

Speakers in the next session *explored the lessons that can be learned from collaborations in advancing research and development of medical products on the continent.*

**Key Points to Note:**

- Regulatory oversight of vaccine manufacturing in Nigeria during the pandemic relied on virtual inspection, which resulted in increased productivity and reduced response times.
- Pharmacists played an important role in self-care during the pandemic. Digital platforms should be extensively used to manage health, support remote monitoring, assist with consumer education and enable fast communication.

Effective regulatory frameworks should ensure a balance between under- and over-regulation; encourage the inclusion of self-care policies; prepare scheduling lists and set up forums to allow for risk-based reviews.

- The move from print to electronic labelling (e-labelling) to enable ease of information and instant accessibility has proven to be important.
- Validation of Sars-Cov-2 Rapid Covid-19 IgM/Igg Combo Test Kits to ensure the accuracy of test results has assisted with screening of individuals who had previous contact with the COVID-19 infection.
- Guidance on crisis management for pharmacovigilance and the issuing of timely communication can assist in creating public trust of vaccinations. Adverse events reporting, improved capability for signal detection, review of safety update reports, risk management plans and internal processes to be able to put SOPs together, as well as digital app-based reporting are all needed.
- Developing a regulatory framework; defining stakeholders' roles and responsibilities; improving local expertise in clinical trials through mentorship and skills training; prioritising global partners for regulatory capacity in a systematic manner (Maturity Level 3) and obtaining funding to support electronic platforms were all essential components of Liberia's regulatory response to the Ebola crisis.
- An online platform to assist joint assessments by an unlimited number of NRAs and evaluators is under development. This allows for interaction between the evaluator, the lead evaluator, and the applicant to upload and manage information easily and to generate various assessment reports. It enables the submission of dossiers from different countries and their evaluation within the countries. Access is limited to those users sponsored by AMRH.

Khadijah Ade-Abolade: Deputy Director, National Agency for Food and Drug Administration And Control (NAFDAC) gave highlights of Nigeria's activities concerning the regulation of medical product manufacturing during the Covid-19 pandemic between March 2020 and February 2021. Confirming Washington Dengu's experiences, she described how onsite inspection was affected and a virtual approach had to be adopted, which resulted in increased productivity and reduced response times. The migration to full electronic documentation and communication is recommended.

Deepa Maharaj & Evah Amwayi: GSCF - Africa Self Care Strategy - Co-Chair, Sanofi & Head of Regulatory Affairs East and West Africa GlaxoSmithKline Limited respectively spoke about the crucial role of non-prescription medicines in healthcare systems. Presenting lessons learnt during the COVID-19 pandemic, they described how pharmacists played an important role in facilitating selfcare, becoming the first point of contact and easing the burden on the healthcare system. Digital platforms should be extensively used to manage health, support remote monitoring, assist with consumer education and enable fast communication.

Effective regulatory frameworks should ensure a balance between under- and over-regulation; encourage the inclusion of self-care policies; prepare scheduling lists and set up forums to allow for risk-based reviews.

Nevena Miletic: Global Regulatory Policy, F. Hoffmann-La Roche Ltd spoke about the role of electronic labelling in improving patient safety and health system resilience. The move from print to e-labelling to enable ease of information and instant accessibility has proven important. All stakeholders including patients, NRAs, healthcare providers, and industry itself patients, stand to benefit from creating a more agile, digitalised regulatory environment. e-Labelling will improve informed decision-making by patients, consumers, and providers to help with the treatment journey.

Kanu Nkiru: Assistant Chief Regulatory Officer National Agency for Food and Drug Administration and Control described the validation of Sars-Cov-2 Rapid Covid-19 IgM/Igg Combo Test Kits to ensure the accuracy of test results. Ten different brands of IgG/IgM Combo Kits were used with a total number of 712 cassettes. The findings indicate that the validated test kits can be used for screening of individuals who had previous contact with the Covid-19 infection.

Mafora Matlala: South African Health Products Regulatory Authority (SAHPRA) gave an overview of the impact of COVID-19 on Pharmacovigilance in South Africa. Pharmacovigilance systems are improved by establishing guidance on crisis management and issuing timely communication to create public trust of vaccinations. Adverse events reporting, improved capability for signal detection, review of safety update reports, risk management plans and internal processes to be able to put Standard Operating Procedures (SOPs) together, are all needed. A Med Safety App improves reporting over paper-based systems.

Juwe Darnuwele Kercula: Manager Liberia Medicines & Health Products Regulatory Authority (LMHRA) described Liberia's experiences in clinical trials regulation during the Ebola and COVID-19 emergencies. He recommended developing a regulatory framework; defining stakeholders' roles and responsibilities; improving local expertise in clinical trials through mentorship and skills training; prioritising global partners for regulatory capacity in a systematic manner (Maturity Level 3) and seeking funding to support electronic platforms.

Valerio Reggi Executive Secretary, IMPACT, World Health Organization (WHO) & Gedion Murimi: Head ICT, Pharmacy and Poisons Board, Kenya, presented the current status of regulatory information management systems in Africa and the need for an online platform to assist joint assessments by an unlimited number of NRAs and evaluators. A dedicated server is essential for the Regulatory Information Management System (RIMS) to work as a cloud-based system would not provide the privacy required. The system allows for interaction between the evaluator and the lead evaluator.

It also allows the applicant to upload and manage information easily and to generate various assessment reports. It enables the submission of dossiers from different countries and their evaluation within the countries. Access can be public but can also be restricted to selected users through a login process to enable the security of national data. The system provides access through registration on AMRH. Users must be sponsored by one of the institutions, such as NEPAD.

# 9. AMRC VII Conference Presentations & Discussions

### Day 3 - Wednesday 24 November 2021

The African Medicines Regulatory Conference (AMRC) is the overarching governance body for AMRH, comprising all the heads of agencies across the continent. The AMRC meets every two years immediately following SCoMRA to deliberate on strategic, policy and technical issues facing regulatory systems.

#### AMRC Status Update

Key points to note from Sunday Kisoma: Consultant, Regulatory Systems Strengthening, WHO – AFRO & Houda Langar: WHO were as follows:

- The concept of “reliance” throughout the medicinal products’ life cycle was promoted.
- The concept of RCOREs was promoted.
- The African Medical Device Forum (AMDF) supported the strengthening and normalisation of regulations on medical devices and in vitro diagnostics (IVDs).
- The Medicines Policy and Regulatory Reforms (MPRR) Technical Committee was tasked with supporting RECs and Member States in the review or development of policies and regulatory framework.
- The AU Model Law was successfully adopted in more than 17 countries on the continent.
- The African Medicines Agency (AMA) became operational on 5 November 2021.

**Key Points to Note:**

- The African Medicines Regulatory Governance Framework was adopted in October 2019.
- Regulatory activities were organised across groups of countries within RECs.
- A performance framework was under development to enable performance management of all key partners.
- Engagement took place with regional manufacturing associations such as FAPMA, WAPMA and SAGMA to own and catalyse local manufacturing.
- In terms of the Paediatric Regulatory Network (PRN), RECs are asked to join the PRN and NRS to review their paediatric drug approval processes and the legal framework.

- National regulatory Agencies (NRAs) are urged to join the global traceability initiative.

## African Medical Devices Forum Status Update

Paulyne Wairimu: Interim Chairperson of the Africa Medical Devices Forum (AMDF) Technical Committee, reported on progress of the AMDF. She explained that the Terms of Reference for AMDF were approved and adopted in 2019, with the following recommendations:

1. To support implementation of the harmonised Regulatory Framework for Medical Devices, including in vitro diagnostic medical devices.
2. To establish and strengthen platforms for sharing developments in regulation, research, and innovations.
3. To improve human resource capacity with online courses and workshops.

**Key Points to Note:**

- AMDF activities should be included in the REC's Work Plan through sub-groups.
- An AMDF Covid-19 Taskforce was established in April 2020 to respond to challenges such as the lack of access to information on Covid-19 health products.
- A Short-Term Work Plan and Longer-Term Strategic Plan have been developed for the AMDF.
- There is a need to move towards Standardisation Nomenclature for Medical Devices as well as harmonised and standardised International Classification, Coding and Nomenclature for o Medical Devices (INMD). It would be available to all Member States.
- Regulators are encouraged to take advantage of the WHO Collaborative Procedure for Prequalified IVDs to accelerate authorisation of these products.
- The WHO Emergency Use Listing-Facilitated Procedure (WHO EUL-FP) is an innovative mechanism, similar to the WHO Collaborative Registration Procedure, designed specifically for Covid-19 assays to allow for availability of emergency tests in five days instead of 30 days and 15 days for regulatory decisions instead of 90 days.
- The European Union Medical Devices Regulations now have stricter pre-market assessments of high-risk devices; reinforcement of the criteria for designation and oversight and a new risk classification system for in vitro diagnostic medical devices based on international guidance. The rules on clinical investigation have been reinforced. A comprehensive EU database and a device traceability system have improved transparency.

**AMDF Draft Short-Term Work Plan**

Dr Dimakatso Mathibe, SAHPRA, presented the AMDF Draft short-term Work Plan (January to December 2022) which has the following objectives:

- To advance and promote African continent harmonisation, mutual recognition, and reliance on medical device regulations in Africa.

- To encourage innovation in medical devices, including in vitro diagnostics, on the continent.
- To advance the sensitisation, adoption and roll out of AMDF strategic priorities across Member States, partners, and stakeholders.
- To continue to build the technical capacity of national regulatory agencies.

**AMDF Strategic Plan 2022-2027**

Professor Willy Urassa: SHIBA Consulting, presented the draft longer-term AMDF Strategic Plan 2022-2027 which has the following objectives:

- To support the establishment and operational implementation of the African Medicines Agency (AMA).
- To advance and promote continental harmonisation, mutual recognition, and reliance on medical devices regulations.
- To promote innovation and local manufacturing of quality-assured medical devices and in vitro diagnostics.
- To enhance partnership advocacy at continental level and priority countries.
- To build technical capacity of national regulatory agencies on medical devices and IVDs regulatory frameworks, guidelines, and quality management systems.
- To facilitate the registration, validation, joint activities, and post marketing surveillance related to quality, safety, and efficacy of medical devices and IVDs.

Agnes Kijo, on behalf of the WHO, gave an update on Medical Devices including in vitro diagnostics which included the following key points:

- The WHO Global Model Regulatory Framework for Medical Devices including IVDs was published in 2017 and is currently under revision.
- The WHO Global Benchmarking Tool (WHO GBT), endorsed in May 2014, is being revised as it currently only covers medicines, vaccines, and blood and blood products.
- Registration procedures for in vitro diagnostics were piloted in 2019 through to 2021.
- Regulators were encouraged to take advantage of the WHO Collaborative Procedure for Prequalified IVDs to accelerate authorization of these products.
- The WHO Emergency Use Listing-Facilitated Procedure (WHO EUL-FP) is an innovative mechanism similar to the WHO Collaborative Registration Procedure. It is designed specifically for Covid-19 assays to allow for availability of emergency tests in five days instead of 30 days and 15 days for regulatory decisions instead of 90 days.

Adriana Velazquez Berumen: Group Lead Medical Devices and In Vitro Diagnostics World Health Organization discussed the need to move towards Standardisation Nomenclature for Medical Devices. The goal is to have a harmonised and standardised international classification, coding, and nomenclature for medical devices (INMD) that would be available to all Member States.

Some countries currently use the Universal Medical Device Nomenclature System (UMDNS), while others use the Global Medical Device Nomenclature System (GMDNS).

Professor Willy Urassa: SHIBA Consulting, provided an update on the European Union Medical Device Regulation and In Vitro Diagnostics Medical Device Regulation. He explained that the European Union Medical Devices Regulations now have stricter pre-market assessment of high-risk devices; reinforcement of the criteria for designation and oversight and a new risk classification system for in vitro diagnostic medical devices based on international guidance. The rules on clinical investigation have been reinforced. A comprehensive EU database and a device traceability system have improved transparency. Coordination between Member States in the field of vigilance and market surveillance has improved. Periodic safety update reports have been compiled and a unique device identification has been implemented.

## African Medicines Quality Forum (AMQF) Status Update

**Key Points to Note:**

- The AMQF 2021 Work Plan aims to strengthen the capacity of AMQF members; strengthen Quality Management Systems; implement risk-based PMS regionally; facilitate communication and information sharing; strengthen advocacy to mobilise funding and deliver effective oversight and governance.
- The WHO should consider a Quality Control Programme and training to build capacity in Africa.
- United States Pharmacopeia (USP) is supporting WHO training on testing of PMS; guidance for the design and maintenance of Pharmaceutical QCLs; funding and organising ILT (instructor-led training) programmes and promoting the Quality of Medicines Plus (PQM+).
- PATH supports capacity-building towards the adoption of the AU Model Law and AMA ratification and the building of the business case for AMA.
- Swiss Medic supports the AMRH initiative at the regional level by providing training on QMS (Quality Management Systems), the function of OMC laboratories, PMS, and the handling of quality deficiencies.
- CHMP is providing capacity building and supporting National Quality Control Laboratories (NQCLs) towards attaining WHO qualification.
- PTB is in the process of finalising the appointment of a representative to be based in Midrand, South Africa.

Freda Kissi: Technical Program Coordinator at United States pharmacopeial convention presented progress on the AMQF 2021 Workplan, which aims to strengthen the capacity of AMQF members; strengthen Quality Management Systems; implement risk-based PMS regionally; facilitate communication and information sharing; strengthen advocacy to mobilise

funding and deliver effective oversight and governance.

Progress by the World Health Organisation (WHO) was presented by Gaby Vercauteren. Training, focused on the Global Health Protection Programme (GHPP) and on Cooperation for the Strengthening of Quality Assurance in the Quality Control Laboratories (CORAQ-LAB), was delivered. It was proposed that the WHO should consider a Quality Control Programme and training to build capacity in Africa.

### *Progress Reports by Existing and New Partners of AMQF*

Kwasi Boateng: USP, gave an overview of projects that the USP is contracted by WHO to implement in Africa. It includes training on the testing of PMS; guidance for the design and maintenance of Pharmaceutical QCLs; funding and organising ILT programmes and promoting the Quality of Medicines Plus (PQM+).

John-Paul Omollo: Global Health Policy Specialist, PATH, highlighted PATH's focus on advocacy support for regulatory harmonisation projects. He gave an overview of work to support the adoption of the AU Model Law and efforts to support AMA ratification and capacity-building. He described a study on the health and economic impacts of AMA.

Lodovico Paganini: Scientific Officer Stakeholder Engagement Swissmedic described how Swiss Medic supports, in collaboration with the Bill and Melinda Gates Foundation and the WHO, the AMRH initiative at the REC level. The initiative provides training on QMS, the function of OMC laboratories, PMS, and the handling of quality deficiencies.

CHMP, a French non-profit association, described how it has been supporting AMQF by providing capacity building and supporting NQCLs towards attaining WHO qualification.

Saida Bunk: PTB Germany, explained that PTB is in the process of finalising the appointment of a representative to be based in Midrand, South Africa.

**The AMQF Workplan**

Bonaventure Chilinde: Director, National Drugs Quality Control Laboratory, Zambia Medicines Regulatory Authority presented the AMQF 2022 Workplan. The objectives are as follows:

- To strengthen capacity of AMQF members
- To implement risk-based PMS regionally
- To facilitate communication and information sharing
- To strengthen advocacy to mobilise funding
- To deliver effective oversight and governance of the AMQF.

### R-IMS Technical Committee Status Update

Tosin Abayomi: National Agency for Food and Drug Administration and Control (NAFDAC) described the plan for the Regulatory Information Management System (RIMS),

including identification of the system that will be used going forward to achieve an information sharing platform for the entire continent.

Gedion Murimi: Head ICT, Pharmacy and Poisons Board, Kenya presented on the Zanzibar System. It provides the opportunity for the regulator to share information among various parties, including other regulators, direct clients, manufacturers, patients, general traders, donors, media groups and the public. It is necessary to look at how to integrate systems at country levels. The platform needs to serve the AMA.

## Summary of Recommendations from SCoMRA V

Nancy Ngum: Programme Officer, AUDA-NEPAD gave feedback from SCoMRA V, summarising the recommendations that emerged from the discussions, as follows:

1. National governments should leverage on the Africa Medicines Agency to increase the continent's local production of medicines.
2. The African Medicines Regulatory Harmonisation Initiative should play an important role in the establishment and operations of the African Medicines Agency.
3. Research and development investment is needed to ensure security for medical products and supplies.
4. Regulatory submissions and reviews need to be fit-for-the-future and pandemic-proof (using a cloud-based approach).
5. NRAs should use regulatory flexibilities and rely on best practices that proved to be effective during the pandemic. In addition, they should consider adopting such practices and approaches into the national regulations, guidelines, and regulatory processes through the products' entire lifecycle.
6. NRAs should use digital tools and virtual processes to facilitate inspections and other regulatory processes, such as virtual GMP inspections, dossier submissions (eCTD), e-signatures, e-labelling, and collection of adverse drug reactions (ADRs).
7. The WHO, AMRH and partners should continue strengthening regional and continental capacities, using the 11 existing RCOREs to advance regulatory oversight and regulatory system strengthening on the continent.
8. The African Union 3s (AU3s) initiative is called upon to advance and implement lessons learned during the COVID-19 pandemic for pharmacovigilance and post-market surveillance activities on the continent.
9. NRAs are encouraged to enhance regulatory capacity during the operationalisation of the African Medicines Agency.
10. Member States need to support and implement the critical components of Africa COVID-19 vaccine medicine manufacturing and access strategy approved by the AU in 2020.
11. The Partnership of African Vaccines Manufacturing (PAVM) Framework should bring together all key stakeholders to attain the African Union vision of local supply of 60% of all vaccines that are needed in Africa by 2040.
12. NRAs should utilise the African Union guidance on expediting approval of COVID-19 vaccines as a useful tool to fast-track approval of vaccines.

13. NRAs should support and ensure that the regulatory policy environment is conducive to the implementation of the PAVM Framework for Action (FFA) for vaccine manufacturing.
14. The AMRH and AMA will be useful platforms to drive vaccine regulatory excellence by the African National Regulatory Authorities.
15. The AMRH should designate new RCOREs that will focus on vaccine manufacturing.
16. NRAs must ensure that clinical trials observe international ethics.
17. Regulatory System Strengthening (RSS) is key to help national regulatory authorities to attain the WHO Maturity Level three (WHO ML3).
18. The African Medicines Regulatory Harmonisation Initiative and Africa Medicines Agency should be used as the platforms to strengthen regulatory systems across the continent.
19. AVAREF should continue to facilitate timely approval of vaccines and clinical trial applications.
20. NRAs should consider the validation of SARS-COV-2 IgM/IG combo which is crucial to ensure accuracy of results.

## Day 4 - Thursday 25 November 2021

### Session 1 – AMRH Technical Committee Status Updates

Session 1 involved updates from the various chairmen of the AMRH's active Technical Committees, AVAREF, AMDF, AMQF and ABRF.

**Key Points to Note:**
Mimi Darko: Chief Executive, Food and Drugs Authority, Ghana outlined how the AVAREF Secretariat should pursue a formal agreement with the European Medicines Agency (EMA) to grant access to original dossiers that are submitted to the EMA and all assessment reports of relevant evaluations. An adverse events strategy and guidance for emergency preparedness should be developed. A webinar with research scientists and product development partners and sponsors is to be developed. Training for ethics should continue for Ethics Committees in the various countries. Technical support for the assessment of clinical trial functions against the WHO Global Benchmarking Tool, should be provided.

Paulyne Wairimu: Chair Africa Medical Device Forum (AMDF), presented recommendations for the AMDF which include:

- Advance and promote harmonisation, mutual recognition, and reliance on medical devices in Africa.
- Encourage innovation in medical devices, including in vitro diagnostics, through local production of quality-assured devices and diagnostics.
- Advance the sensitisation, adoption and roll-out of AMDF strategic priorities across all Member States, partners, and stakeholders.

- Continue to build technical capacity of NRAs in medical devices and IVDs regulatory frameworks, guidelines, and quality management systems.

Bonaventure Chilinde: Director, National Drugs Quality Control Laboratory, Zambia Medicines Regulatory Authority, presented recommendations from the AMQF (and its partners USP, PATH, Swiss Medic, CHMP and PTB), which are to:

- Strengthen capacity
- Strengthen Quality Management Systems
- Implement risk-based PMS regionally
- Facilitate communication and information sharing
- Strengthen advocacy to mobilise funding.

Aminata Nacoulma: WHO-AFRO, stressed that the AMA, as an association of regulatory agencies in Africa, needs to have a single head to interpret or explain the role and function of the Technical Committees to the ministers at the Conference of Parties.

### Session 2 - African Medicines Agency Status Update

Progress on the AMA was discussed during this session. Dr Margareth Ndomondo-Sigonda, AUDA-NEPAD & Professor Jean-Baptise Nikiema, WHO, described the engagement between AUC, AUDA-NEPAD and WHO to map a way forward for the operationalisation of the AMA.

**Key Points to Note:**

- Mimi Darko: Chief Executive, Food and Drugs Authority, Ghana, and Professor Bouchra Meddah: Director of Pharmacy and Medicines, explained that there are currently 27 AMA member countries, 26 of which had signed the Treaty (and 17 of which had ratified it at the time of the AMRC).
- Concerns for NRAs include the governance structure and the autonomy or independence of regulatory agencies.

## Day 5 - Friday 26 November 2021

The final day of the conference involved discussion of a range of issues of strategic interest for the African Union Commission (AUC) and the people of Africa.

### Regulatory preparedness and response

**Key Points to Note:**

- Rutendo Kuwana: WHO, explained that each Member State mechanism needs a focal point network to guard against substandard and falsified medical products.

The network should be empowered to cooperate closely with quality control laboratories, national pharmacovigilance centres, national poison centres and other relevant government entities that will channel any queries and information concerning medical products to the WHO Global Surveillance and Monitoring System (GSSMS).

- The GSSMS is a global database of substandard and falsified medical products.
- Three pillars can be used to reduce and prevent SF products: prevention, detection, and response.

### Local manufacturing

Hiiti Sillo: Unit Head, Regulation and Safety, Department of Regulation and Prequalification at World Health Organization (WHO) discussed WHO's aim of supporting Member States in strengthening regulatory capacities based on global benchmarking.

**Key Points to Note:**

- The WHO strategy is to support countries that are on Maturity Level 1 to move to Maturity Levels 2 and 3. This is important in the context of local production.

Dr Manish, (Speaking on behalf of Dr Sunil Gairola; Serum Institute of India, gave an overview of the Serum Institute, which is the world's largest vaccine manufacturer by number of doses.

**Key Points to Note:**

- Regulatory authorities helped the Institute to supply the vaccines.
- Success is based on:
  - The large investment made to add new facilities, resources, and testing services
  - Building state-of-the-art indigenous facilities
  - Trained human resources at all production stages from raw materials to the final product
  - Collaboration from international organisations (including the WHO, GAVI, Bill and Melinda Gates Foundation, NIBSC, CBER, PATH) and academic institutions (Oxford University, Jenner Institute, IAVI)
  - The support of the Indian Government.

## Closing Address

### Dr Margaret Agama-Anyetei: AUC

In closing, Dr Agama-Anyetei, Head, Health Nutrition and Population Social Affairs at AUC, thanked everyone who attended the two-day conference on the 5th Scientific Conference and 7th meeting of the Regulators.

She noted that the discussion would support efforts in building back better after the Covid-19 pandemic. She highlighted that the lessons learned, and practical experiences shared and the recommendations made should now be put into practice.

The recommendations made from the scientific conference and those made in the AMRC as well as the technical committee's recommendations and steering committees should be implemented.

Going forward, engagements from the African Medicines Regulation Conference should be operationalized.

She went on to thank the conference organising committee; and all the partners, WHO, PATH, DMGF, the World Bank, the Wellcome Trust and other partners. She thanked the moderators and speakers who committed their time to the discussions.

### Dr Donatien Kabamb Kabey: Chair of the AMRC Assembly

Dr Donatien Kabamb Kabey closed the conference, by thanking participants for their contributions and sharing their knowledge and vast experiences during the five day proceedings. Dr Kabamb thanked participants for their commitment towards regulatory systems strengthening and harmonisation, which will enable access to good quality, safe and efficacious medical products on the African continent.

# 10. Members of the Conference Organising Committee

| S/N | Name of Sub-Committee | Members |
|---|---|---|
| 1. | Scientific Sub-Committee | Dicky Akanmori (Lead)<br>Samvel Azatyan<br>David Mukanga<br>Diadié Maiga<br>Dr Margareth Ndomondo-Sigonda<br>Chimwemwe Chamdimba<br>Paul Tanui<br>Sarah Adams<br>John Mwangi<br>Nevena Milisavljevic<br>Rachelle Harris<br>Sakhile Dube-Mwedzi<br>Anthony Toroitich<br>Jane Mashingia<br>Aime Djitafo Fah<br>Sybil Ossei Agyeman Yeboah |
| | AMRC Sub-Committee | Prof Jean-Baptiste Nikiema (Lead)<br>Houda Langar<br>Samvel Azatyan<br>Abraham Kahsay<br>Dr Margareth Ndomondo-Sigonda<br>Chimwemwe Chamdimba<br>Paul Tanui<br>Vanessa Msengezi<br>Anthony Toroitich<br>Sakhile Dube-Mwedzi<br>Jane Mashingia<br>Aime Djitafo Fah<br>Sybil Ossei Agyeman Yeboah |
| 2. | Resource Mobilization Sub-Committee | David Mukanga (Lead)<br>Rachelle Harris<br>Dr Margareth Ndomondo-Sigonda<br>Vanessa Msengezi |
| 3. | Communication Sub-Committee | Vanessa Msengezi (Lead)<br>Nancy Ngum<br>Joseph Kabatende<br>Andriette Ferreira<br>Sarah Adam<br>Ana Maria Nia<br>Rachelle Harris<br>Shingai Gwatidzo<br>John Paul Omollo<br>Anthony Toroitich |

| S/N | Name of Sub-Committee | Members |
|---|---|---|
| 4. | Local Organising Sub-Committee | Vanessa Msengezi (Lead)<br>Joseph Kabatende<br>Nancy Ngum<br>Abraham Kahsay |
| 5. | Conference Report & Recommendation Implementation Sub-Committee | Chimwemwe Chamdimba (Lead)<br>Dr Margareth Ndomondo-Sigonda<br>Nancy Ngum<br>Vanessa Msengezi<br>Rachelle Harris<br>Paul Tanui<br>Rachelle Harris |

# 11. List of Participants

| First Name | Last Name | Organisation | Position | Country |
|---|---|---|---|---|
| Mercedes | Leburu | AUDA-NEPAD | AU-3S programme officer | South Africa |
| Ian | Hudson | Bill and Melinda Gates Foundation | Senior Advisor, Integrated Development, Bill and Melinda Gates Foundation | United States |
| Liberty | Chirinda | Medicines Control Authority of Zimbabwe | Senior Regulatory Officer - Pharmacovigilance and Clinical Trials Division | Zimbabwe |
| Vanessa | Msengezi | AUDA-NEPAD | Program Officer | South Africa |
| Lodovico | Paganini | Swissmedic | Scientific Officer Stakeholder Engagement | Switzerland |
| Angelika | Joos | MSD | Executive Director Global Regulatory Affairs | Germany |
| Eliangiringa | Kaale | Muhimbili University | Lab Director | United States |
| Portia | Nkambule | SAHPRA | Chief Regulatory Officer | South Africa |
| Niya | Bowers | BMGF | SPO | United States |
| Katiza | Mangueira | Armed | Head of Agency | Angola |
| Mawien Atem | Arik | | Secretary General | South Sudan |
| Jane | Mwangi | USAID | Pharmacist | United States |
| Keturah | Smith | The Liberia Medicines and Health Products Regulatory Authority | Managing Director | Liberia |
| Tich | Nyovhi | Self | Regulatory systems Expert | Zimbabwe |
| Stephen | Ghanie | Botswana Medicines Regulatory Authority | Chief Executive Officer | Netherlands |

| First Name | Last Name | Organisation | Position | Country |
|---|---|---|---|---|
| Guy | Njambong | ICN Business School | Ph.D. & MPH candidate | France |
| Amira | Younes | AbbVie | Associate Director, Regulatory Policy and Intelligence , Eastern Europe, Middle East & Africa | Germany |
| Anastacia | Naidoo | MSD | PV Country Lead | |
| Taonga | Chilalika | PATH | Senior Advocacy Associate | United States |
| Carol | Ruffell | DNDi GARDP Southern Africa | Head South Africa | South Africa |
| Kwasi | Boateng | United States Pharmacopeia - Ghana | Director | Nigeria |
| Jana | Bante | PTB | Project Coordinator | Germany |
| Anna | Thomas | MMV | Senior Director Regulatory Lead - Geneva | Netherlands |
| Sarah | Adam | IFPMA | Associate Director Regulatory Affairs | France |
| Shingai | Gwatidzo | Medicines Control Authority of Zimbabwe | Projects and Public Relations Officer | Zimbabwe |
| Thabo | Shabangu | MSD (Pty) Ltd | Specialist, Regulatory Affairs | |
| Mark | Laws | Concept Foundation | Senior Regulatory Advisor | United Kingdom |
| Nevena | Miletic | F. Hoffmann-La Roche Ltd. | Regulatory Policy Head EEMEA (Eastern Europe, Middle East & Africa) | Switzerland |
| Diadié | Maïga | WHO AFRO | | Mali |
| Evah | Amwayi | GlaxoSmithKline Limited | Head Of Regulatory Affairs East and West Africa GSK consumer Healthcare | Kenya |
| Olga | Rassokhina | Paul-Ehrlish-Institut | Scientist at International collaboration and regulatory service department | Germany |

| First Name | Last Name | Organisation | Position | Country |
|---|---|---|---|---|
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| First Name | Last Name | Organisation | Position | Country |
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| First Name | Last Name | Organisation | Position | Country |
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| First Name | Last Name | Organisation | Position | Country |
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| First Name | Last Name | Organisation | Position | Country |
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| First Name | Last Name | Organisation | Position | Country |
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