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AFRICAN UNION DEVELOPMENT AGENCY

AMRH
African Medicines Regulatory Harmonisation Programme

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In this Edition

Extra-ordinary Steering Committee Meeting on Regulatory Systems Strengthening and Harmonization Initiatives in Africa (AMRH SC) held 22 April 2021

The Africa Regulatory Task Force (ARTF) on Covid-19 Vaccines was created in December 2020 as a collaboration between the African Union Development Agency-NEPAD (AUDA-NEPAD), the Africa Centres for Disease Control and Prevention (Africa-CDC) and the World Health Organisation Regional Office for Africa (WHO-AFRO) to address regulatory barriers on access to COVID-19 vaccines. Subsequently, a meeting of Heads of National Medicines Regulatory Authority (NMRA) was convened by the ARTF on 12 January 2021, to consult on the African Union Guidance on Emergency Expedited Regulatory Authorization and Access to COVID-19 Vaccines in Africa (AU Guidance). A communique and the AU Guidance were eventually published to guide AU Member States on the three regulatory pathways which were identified to facilitate approval. In the establishment of the ARTF, the AU Guidance calls for inclusion of Heads of NMRA and for the establishment of an Expert Advisory Group (EAG) composed of subject matter experts across Africa, drawn from different medical and public health fields relevant to the COVID pandemic. The AU Guidance also recognizes the role played by the African Medicines Regulatory Harmonization (AMRH) Initiative, the African Vaccines Regulatory Forum (AVAREF) and regional economic communities (RECs) over years in facilitating regulatory approvals and safety monitoring of medical products across the continent.

In this regard, on 22 April 2021, an extra-ordinary session of the African Medicines Regulatory Harmonization (AMRH) Steering Committee and expert Advisory Group for Emergency Expedited Regulatory Authorization of COVID-19 Vaccines in Africa was held virtually to operationalize the AU Guidance. The meeting also deliberated on how to manage future pandemics as the continent is moving towards operationalization of the African Medicines Agency (AMA). The Chairperson of the AMRH SC, Prof. Moji Christianah Adeyeye moderated the session and emphasised that COVID-19 has presented a challenging time for most African regulators especially in recent times with vaccine trials and approvals being central to overcoming the pandemic. She highlighted that the AMRH Initiative was formed with the intention of assisting countries to overcome such challenges and now more than ever the continent needs to be united and aligned in terms of regulatory systems strengthening.

WHO was represented by Dr Petra Doerr, who presented on global mechanisms for in-country processes for COVID-19 Vaccines' authorization. She emphasized that the major aim of mechanisms being put in place by WHO, is to assist countries to obtain the fastest and most robust emergency authorization for use and to avoid unnecessary steps that could delay the process. She went on to list the streamlined processes based on Emergency Use Listing issued by WHO Pre-qualification as well as tools for support to Member States such as technical support and acess to assessment and inspection reports. She also presented on the coordination mechanisms by WHO such as WHO Regulation and Prequalification Department working with Members States through its Regional Offices with assigned Regional Advisors. Dr Doerr also presented on the number of countries with regulatory approval categories based on AZ-SK and SII process and gave an overview of the current status. Lastly Dr Doerr gave a summary of the next steps such as that the Janssen vaccine was emergency-use listed on 12 March 2021 and regulatory authorizations should be issued as allocations will be made soon.

Mrs Margareth Ndomondo-Sigonda of AUDA-NEPAD gave a brief background of the Africa COVID-19 Vaccine Development and Access Strategy endorsed by the AU Bureau of the Assembly Heads of State and Government in August 2020, following the WHO Declaration of the COVID-19 pandemic in early 2020. The strategy includes accelerating African involvement in clinical development, ensuring Africa's access to sufficient vaccine supply, preparing for at-scale delivery of the vaccine in Africa. The AU Guidance was subsequently issued in January 2021. She explained that the purpose of the AU Guidance is to advise on emergency expedited regulatory authorization procedures that provide the required checks without causing unnecessary delays by proposing 3 regulatory pathways:

- **Scenario 1**, for vaccines becoming available which have received WHO EUL/PQ approval.
- **Scenario 2**, for vaccines becoming available that have received approval from one or several Stringent Regulatory Authorities (SRAs), but not yet through WHO EUL/PQ.
- **Scenario 3**, for vaccines becoming available that have received neither of the two options above.

Mrs. Ndomondo-Sigonda also presented the names appointed as members of the AMRH SC and EAG who were selected based on the following criteria: NMRA Maturity level and/or regulatory capacity, NMRA is a regional coordinating agency for joint dossier reviews and/or GMP inspections, a country with a high number of

vaccines clinical trials or it is a vaccine manufacturing country, and those coordinating regional medicines regulatory harmonization initiative.

Dr Diadié Maiga representing WHO-AFRO and Mrs. Sakhile Dube-Mwedzi representing SADC Coordinating Agency gave a detailed overview of the regulatory pathways under the AU guidance document. Dr Maiga gave and overview of the current approved AVAREF governance structure as well as a detailed overview of the three regulatory pathways/scenarios and processes to be followed including how AVAREF contributes to the processes. He also gave an overview of vaccines per scenario in Africa as well as vaccine authorization status in Africa. Mrs. Sakhile Dube-Mwedzi presented on the SADC experience using the 3 scenarios. She highlighted regulatory efforts in vaccine regulation so far in SADC including monthly regional Covid-19 update meetings, formation of a technical working group for joint review of Covid-19 vaccines and adoption of the 3 scenarios. She further highlighted how the 3 scenarios have been used in SADC region, although scenario 2 has no examples at the moment. The main challenges in the SADC region have been manufacturer/applicant hesitancy to grant consent for regional joint review process.

However, the South African Health Products Regulatory Authority (SAHPRA) has successfully agreed with Sputnic V manufacturer to subject the dossier application through the regional ZAZIBONA joint review process.

Mr. Hudu Mogtari of AUDA-NEPAD presented on AU Smart Safety Surveillance Progamme which is a 10-year programme aimed at strengthening the pharmacovigilance (PV) capability in Africa, including a background of the history of PV in Africa. AUDA-NEPAD began the AU-3S programme with the aim to improve medicines and vaccine safety for patients in Africa and globally, to enable African ownership and the ability to act on their own data, to strengthen PV expertise among country and continental stakeholders, increase confidence in accelerated product development and in an emergency response. The 4 countries currently piloting the programme are Ethiopia, Ghana, Nigeria and South Africa and criteria for selection was outlined. AU-3S solutions are being piloted for COVID-19 vaccines and it was agreed that there is need to scale up the 3S Model to more countries following lessons learnt from the 4 pilot countries. The outcome of the pilot will also be shared with the AMRH Steering Committee.

There was extensive discussion on the 3 scenarios outlined in the AU Guidance, with the conclusion that ideally there should be an

additional scenario as some countries have internal capacity and a legal mandate to fully approve COVID-19 vaccines and in some cases can also leverage regional joint review processes. The AMRH Secretariat agreed to further consultation with member states and the AMRH SC.

The meeting closed off after very fruitful deliberations which will enrich the approval processes of COVID-19 vaccines in AU member states. As the continent continues to fight the pandemic, continued collaboration and information between stakeholders is encouraged.

Training on Regulation of Medical devices including IVDs: Focus on technical files approaches and Post Market/Market Surveillance for COVID19 assays

The African Medical Device Forum (AMDF) in collaboration with the Saudi Food and Drugs Authority (Saudi FDA) and with the support from the WHO conducted a six (6) days training on Regulation of medical devices including IVDs: Focus on technical files approaches and Post Market/Market Surveillance for COVID19 assays from 22-25 February & 1-2 March 2021. The objective of the workshop was to provide an overview of the components of the medical device technical file and the expected documentations in each section based on international standards. The workshop also provided a unique platform for regulators to share experiences on in-country approvals of COVID - 19 assays and utilization of reliance and recognition principles.

The workshop was attended by 144 participants from 36 countries namely; Ethiopia, South Africa, Togo, Rwanda, United Republic of Tanzania, Nigeria, South Sudan, Egypt, Guinea, Chad, Tunisia, Kenya, Botswana, Cameroon, Côte d'Ivoire, Ghana, Eswatini, Madagascar, Gabon, Cabo Verde, Zimbabwe, Mauritania, Comoros, Sierra Leone, Senegal, Somalia, Romania, Burkina Faso, Malaysia, Mozambique, Uganda, Tunisia, Congo, Zambia, Malawi, and Liberia. The topics which were covered included: classification and classification rules; labelling and instruction for use (IFU) requirements; design and manufacturing information; essential Principles, QMS-ISO13485 standard as applicable in medical devices and risk management file. Other topics included verification and validation, clinical evaluation and post market surveillance including Saudi Food and Drug Authority investigation process on Medical Devices incidents. An overview of post market evaluation studies including two clinical evaluation studies. An update of the new WHO Post Market and Market Surveillance Guidance was also discussed. Participants were able review four AMDF guidelines. Lastly, AMDF application of reliance and recognition approaches during the current AMDF COVID-19 emergency was discussed.

AMDF e-Learning course on basic level fundamentals of in vitro diagnostics medical devices regulation

In June 2021, the African Medical Devices Forum with the support from WHO has launched a basic level e-Learning course on fundamentals of in vitro diagnostics medical devices regulation for National Regulatory Authorities. The course seeks to develop a program that will provide ongoing professional development to staff from African regulatory agencies, ensuring an educational solution to establish a strong regulatory science workforce and infrastructure. The program will provide these staff with the skills necessary to conduct their activities according to internationally recognised best regulatory practice. The program should be contextually appropriate whilst resulting in skills that are internationally transferrable.

The course is based on best regulatory practice as identified by the World Health Organization (WHO)[1] and the International Medical Device Regulators Forum (IMDRF)[2] and has included the following broad learning modules, that will address the topics within each module not only from a regulator's perspective but also a manufacturer's and user's perspective, where appropriate:

- *Overview of IVDs, including their lifecycle including their manufacture, carry forward to their regulation, using the WHO model regulatory framework as the basis*
- *Design and risk management for IVDs*
- *Product safety, including performance studies for IVDs*
- *Classification of IVDs and essential principles, IVD Technical documentation*
- *Conformity assessment, including use of standards*
- *QMS for IVDs, also addressing PMS*

Each topic has identified learning objectives as well as assessment activities and therefore regulators are encouraged to join this important course by writing to kijoa@who.int copying doucelinc@who.int

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[1] https://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/

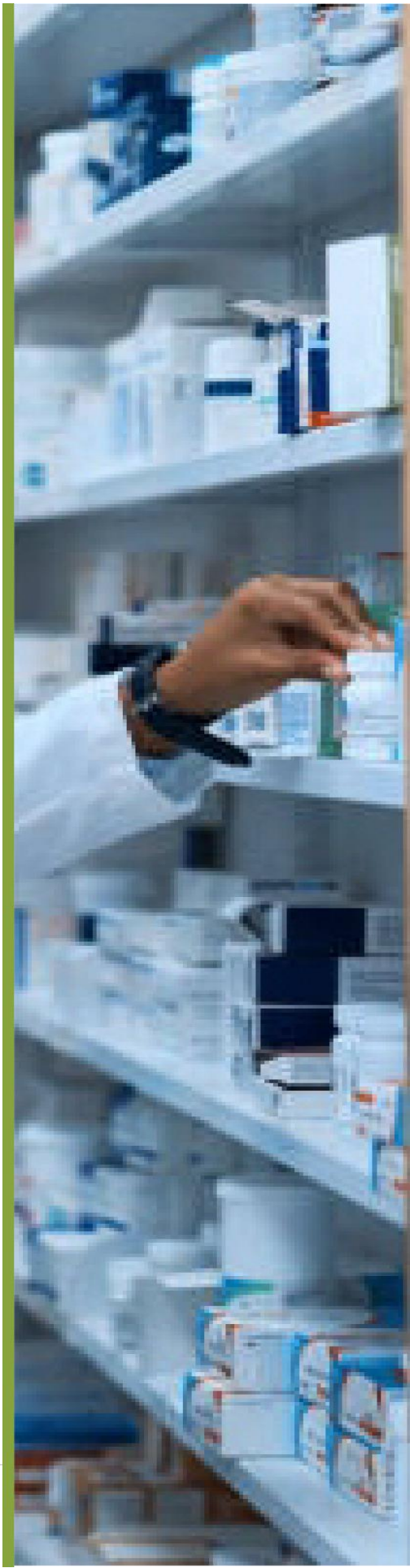
[2] http://www.imdrf.org/index.asp

The AMRH PP Business Meeting, April 2021

The fifth meeting of the AMRH Partnership Platform (AMRH PP) for medical products regulatory systems strengthening and harmonisation was attended by sixty (60) participants representing thirty two (32) institutions, including AUDA-NEPAD, EDCTP, PATH, DNDi, The World Bank, IFPMA, EMA, UKZN, WHO, UNFPA, ASLM, PEI, DIA, fhi360, AUC, IAVI, MCAZ, USP, LSHTM, BFArM, World Self Care Federation, EDQM, BMGF, CHMP, ISBT, USAID, Swiss Medic, CIRS and the Swiss Agency for Development Cooperation.

The AMRH PP Business Meeting was held to share information on the AMRH Partnership Platform's developments in 2020 and developments concerning the WHO's Coalition of Interested Parties (CIP) with the community of partners operating on the continent to strengthen regulatory harmonisation. The primary goal was to facilitate greater partner alignment with the AMRH Technical Committees and their 2021 work-plans and thereby to support a more coordinated approach to regulatory harmonisation, create opportunities for partners to support specific AMRH activities in 2021 and beyond, and highlight the plans for the CIP's Africa regional network.

Dr Margareth Ndomondo-Sigonda, Head of Health at AUDA/NEPAD, provided the official opening remarks at this meeting, highlighting the historical need for establishing a platform to discuss how partners and AU Members States can work together to improve coordination and remove duplication of efforts and resources. In just four years, the AMRH PP has increased from four to six partners to over thirty who we see participating today. The current moment, amid the COVID-19 pandemic, provides an opportunity to discuss the achievement and challenges of the AMRH PP over the past four years and to reflect on lessons learned and strengthening coordination of activities and resources flowing within the context of regulatory system strengthening and harmonisation on the continent. Dr Ndomondo-Sigonda noted that the effective functioning of the African Medicines Agency (AMA) will require highly effective and coordinated partner engagement, so this work is an essential precursor to that. AUDA-NEPAD will be issuing a survey to enable partners to provide feedback and insights to allow for continuous improvement within the partnership to enable ongoing partner support to AMRH harmonisation activities.



Dr Petra Doerr, Head of Unit Regulation and Safety at the World Health Organization, highlighted the overall aim of the Partnership Platform and its relationship with the Coalition of Interested Parties (CIP), a global coalition of partners led by the WHO working to establish various continental regional chapters.

Mrs Nancy Ngum, Public Health Officer at AUDA-NEPAD, moved on to offer updates on partner activities and support for each of the active AMRH Technical Committees. She reported that new and existing partners for the Africa Blood Regulators Forum (ABRF) include PEI, EFS, USFDA, ISBT and the Muskoka Foundation. In addition, EDCTD, UKZN and AfSBT are expected to start supporting various ABRF activities. In 2021, some of the Forum's activities that were implemented under partners' support will include a WHO training workshop on hemovigilance; advocacy for blood regulation; development of the ABRF Position Statement on use of COVID-19 Convalescent Plasma and ABRF Task Groups on COVID-19 and on stepwise development of blood regulation.

Meeting participants agreed that more effort is needed to ensure more fun is are available for implementation of unfunded ABRF activities, including through ongoing discussions with EDCTP, UKZN and AfSBT to determine the support (both financial and technical) that they will provide in 2021. In support of this, the advocacy messages and strategy for blood regulation need to be more clearly defined and this is an ongoing task for the Technical Committee and its partners.

Mrs Ngum also reported that the partners who currently support the African Medical Devices Forum (AMDF) include PEI, ASLM, USP, UNFPA and BMGF including developing five guidelines (assessment tools and basic regulatory training modules for medical devices and IVDs); establishing and strengthening platforms for sharing regulatory developments (such as the Online Diagnostics Hub on the ASLM website); building a strong network of technical experts; training of NRA experts on the assessment of technical files and sharing information on how COVID 19 assays are authorized for use in Saudi Arabia. EDCTP, PATH, UKZN, MTaPS, Africa CDC, DIA, UNITAID are in discussions with AMDF concerning future support. Although much progress has been made, more support is needed for AMDF to enable roll-out and ensure countries take up the platforms and guidelines that have been developed.

On the African Medicines Quality Forum (AMQF), Mrs Ngum reported that new and existing partners include USP, fhi360, CHMP, CENQAM, Swiss Medic, EDQM, BMGF, IFPMA and EDCTP. With partner support, AMQF developed ILT documents, conducted one round of ILT, developed guidelines for design of

new and upgrade of existing national quality control laboratories (NQCLs), supplied leadership and management training. Some partners who are working towards common goals are also supporting individual countries e.g., FHI360 s Cote D'Ivoire to attain ISO 17025 accreditation. Participants agreed that sustained efforts will be needed in 2021 to take forward this work, particularly additional financial support from partners, including to finalize the development and rollout of the training manual and technical training on quality control, the peer audits to at least three NQCLs and the creation of a post-marketing surveillance (PMS) database.

The Chairs of the Technical Committees (TCs) presented their 2021 Workplans. Mrs Mimi Darko of Ghana FDA, Chair of AVAREF, described how in 2021 AVAREF intends to develop guidance documents for ethics and regulation on products development as part of the improved regulation of clinical trials; to build capacity on regulatory oversight of clinical trials, authorization of medicines and vaccines against COVID-19 (including joint reviews); and to strengthen monitoring of safety and vigilance (especially or COVID and nOPV2 vaccines- including active surveillance) including through Meetings of the African Advisory Committee on Vaccine Safety (AACVS). The AVAREF information sharing webinars generated the interest and support of partners. Whilst AVAREF has made tremendous progress and responded to the demands of the current COVID-19 pandemic, most of their ongoing activities are not yet funded and more partner support is needed.

Linda Mudyiwenyama of MCAZ presented the ABRF workplan on behalf of the Chair, Khamusi Mutoti of SAHPRA. For 2021, ABRF's focus will be on finalization of 2020 ABRF guidance documents (including ABRF Guidance on Collection and Use of COVID-19 Convalescent Plasma, GMP, and framework for blood regulation), training on blood regulation and In-country projects to further advance blood regulation and hemovigilance. Most of the ABRF activities are not yet funded and training materials, translation costs, blood products regulation experts were all areas requested for partners to consider supporting.

On the AMDF, Paulyne Wairimu of the Kenya Pharmacy and Poisons Board (KPPB) highlighted that for 2021, AMDF's focus will be on advocacy to create awareness of AMDF and the need for improved medical device regulation across the continent, to include quarterly sensitization and consultative webinars with African regulators. AMDF will also establish a list of assays, medical devices, PPEs and domestic manufacturers in Africa (concerning COVID 19 related products); support capacity building and implementation of harmonized medical devices regulation; strengthen platforms for sharing updates on medical devices regulation, research and innovations including MedNET; and

establish a Regional Center of Regulatory Excellence (RCORE) for training of relevant regulators and experts.

Bridget Dube of the Medicines Control Authority of Zimbabwe (MCAZ) revealed that the African Medicines Quality Forum (AMQF)'s focus for 2021 will be on capacity building through development of various guidelines and training, ILT, quality management system implementation, risk based post-marketing surveillance and strengthening advocacy to generate resources to support these continental activities.

In the spirit of continuous improvement, participants indicated the need to share AMRH guidance on how to establish and join Joint Action Group (JAGs), which are the main partner-based mechanism for sharing information, aligning on activities and supporting in the coordination and resource mobilisation effort for the AMRH.

The meeting moved on to provide a more detailed overview of the Coalition of Interested Parties (CIP), whose Africa regional network will be launched before the end of June 2021. Hiiti Sillo, of WHO, described the CIP, which aims to establish and promote a unified strategic and coordinated approach to strengthening national and regional regulatory systems and increase the effectiveness of collective efforts to achieve impact. CIP works in various settings to improve the effective use of resources; enhance capacity; promote sharing and adoption of best practices and improve coordination (that subsequently reduces duplications). Updates from Rwanda since the launch of CIP in January 2020 were presented, showing the benefits of the approach for the local regulatory system, via the creation of the Institutional Development Plan (IDP), around which interested parties can coalesce and offer support.

A key highlight was the transitioning of AMRH PP into a CIP Regional Steering Group, ensuring the avoidance of any duplication of what AMRH PP and the partners are already doing on the continent. Terms of Reference (ToRs) for the CIP have been created, with membership criteria, governance, code of conduct, and application criteria all described. Further clarification was invited on the CIP's potential relationship with the AMRH Technical Committees and the AMRH PP, the process of applying for CIP membership and the transitioning of the AMRH PP to the CIP regional network.

Towards the end of the meeting PATH and USP spoke of the support they each plan to offer to AMRH. PATH will support advocacy and ensure AMRH achievements are well-communicated at national level, especially in Kenya and South Africa, and at regional level.

They will advocate for stronger regulatory systems through a webinar and support translation of learnings from country to regional and vice versa. At continental level, PATH will continue to support AUDA NEPAD, country engagement on ratification of AMA and support the AU AMA Special Envoy, Hon. Minister Michel Sidibe. PATH has also prepared a paper on the value preposition and economic analysis for AMA formation to help build further support for the AMA.

USP updated the meeting participants that they have recently received financial resources under the PQM+ Project to work with AMRH Technical Committees to train and build the capacity of regulators and other key actors on 'Assessment of Quality Attributes of COVID-19 Vaccines', based on the toolkits being developed to support laboratories that need to develop and validate assays and other parameters for vaccine release.

In the final discussion, partners requested the AMRH Joint Secretariat to create a Technical Committee to take forward regulatory capacity strengthening. The Secretariat indicated that most of the Technical Committees were also focusing on regulatory capacity strengthening. The Joint Secretariat also notified partners of their intention to reach out to partners with a short survey to get feedback on how best to coordinate this platform and to strengthen advocacy and fund-raising for the Technical Committees.

Regional joint assessment of medicines (JA) in addition to harmonization of technical requirements are the key pillars that led to the establishment of African Medicines Regulatory Harmonisation (AMRH) initiative in 2009. The main objective of JA is to increase access to essential medicines and provide a sustainable medical supplies security for the continent especially during this time of the COVID-19 pandemic. JA also provides a larger market access and generally reduces regulatory cost to the industry. JA is important and beneficial to countries and Regional Economic Communities (RECs) because it reduces registration timelines and build trusts and capacity in countries and RECs.

As part of the greater AMRH agenda, various RECs have over the years been developing their regional systems for medicines regulation. These RECs have so far defined key areas of priority, among them the JA of medicines application and the associated joint GMP certifications. Additionally, various reliance models have been piloted and some actualized in the continent at country and regional level. This has been a multi-stakeholder effort in the wider goal of supporting regulatory systems strengthening in the continent.

The regions have made progress in terms of harmonisation of regulatory procedures for greater efficiency and fasten access to medicinal products to patients in Africa. Reliance, collaboration and work-sharing are essential components for an efficient coordination of joint activities such as joint assessment of marketing authorization dossiers. While some of the RECs have made significant strides for example the East African Community and the Southern African Development Community, others are following at an increased pace.

One of the observations from industry and other stakeholders however is that despite the clear benefits of these additional regulatory pathways, there is still limited uptake by applicants leading to continued utilization of mostly the traditional national and full evaluations. Stakeholders have over time provided feedback as necessary pointing out some of the challenges facing applicants, key among them lack of awareness, unclear administrative process, lack of holistic coverage of entire regulatory chain (e.g. no substantive regional variation / PAC guidelines), limited eligible products among others.

It was against this backdrop that the Stakeholders Day on JA brought continental stakeholders together on 11 May 2021, to deep dive into the topics of regulatory harmonization, specifically joint assessment, cooperation among agencies and regions, use of alternative regulatory pathways among others.

The below were the main objectives of the webinar:

1. Creating an avenue for dialog, experience sharing and networking between regulators, RECs, Industry, and stakeholders.
2. Foster and increase joint assessment of medicines (JA) in various RECs and among industry and stakeholders.
3. To highlight best practices and foster increased awareness of JA in Africa.
4. To identify the challenges and seek for the opportunities to overcome them.

Though a lot of challenges were highlighted in the webinar, most of them remain to be addressed by countries, RECs, and industry. The importance of regulators, industry, and RECs working together, creation of a platform for dialogue and sharing of experience to increase speedy approval of medical products without compromising the quality we emphasized. The need to build trust, increase collaboration and encourage dialogue between regulators and industry was discussed. Transparency and open communication, sharing of information about procedures and requirements, updating of REC/NMRA websites, honoring of timelines and faster domestication of regional decision at country level while avoiding different processes and requirements that do not add value was highlighted as a key challenge in JA in Africa. It was also noted that there was misalignment of documentation requirements and procedures between national and REC levels due to lack of collaboration, clear guidance, adherence to timelines. Regulatory reliance, work sharing, cooperation and collaboration serves as an important pillar to increase JA. It was proposed that technical group be established to follow up on webinar recommendations.

The scope of activities covered in JA should be viewed as continuous activity throughout the product life cycle and expanded to include all products vaccines and biologicals, post approval changes, pharmacovigilance, clinical trials, and research with harmonization of retention and renewals of marketing authorization. Registration and technical requirements in some is different and bureaucratic such as country specific labeling requirements, different quality information summary templates and of pre-registration testing of samples instead of establishing robust in-country post market surveillance. Such requirements hamper access of medicines increases registration/regulatory costs.

There is need to create awareness between industry and RECs. NMRAs were encouraged to take ownership at national levels. RECs were encouraged to leverage digital technology in their processes to increase awareness. The lack both human and financial resources to support JA was also noted and that should continuously be built.

A significant progress made in various RECs was highlighted, for example, JA in EAC and SADC regions, had demonstrated significant impact by

reducing the median registration timelines to 7-9 months. Also highlighted was the linkage of Pharmaceutical Manufacturing plan for Africa (PMPA) and AFTCTA pharma initiative in promoting local manufacturing through bulk pooled procurement to ensure sustainability of JA. The industry also committed and was ready to pay a fee-for-service if the processes are optimized and there is adherence to timelines and regional standards for sustainability of JA.

Inaugural meeting of the AMRH Joint Action Group on Information Management Systems

The IMS Joint Action Group (JAG) is a collection of partners who are members of the AMRH Partnership Platform and interested in supporting AMRH to advance this agenda.

The IMS JAG met virtually on 18th May 2021 where representatives from WHO, AUDA-NEPAD, the Bill and Melinda Gates Foundation, the World Bank, CENQAM, the Self-Care Federation, MTaPs, African Society for Laboratory Medicine (ASLM), Medicines Control Authority of Zimbabwe (MCAZ), Kenya Pharmacy and Poisons Board (KPPB), The National Agency for Food and Drug Administration and Control (NAFDAC), and The Food and Drugs Authority (FDA) of Ghana were inattendance.

At the meeting, the JAG considered the IMS Technical Committee's progress, some of which include review of the Continental Regulatory Information Management System (C-RIMS) and the development and approval of a Project Plan to help take forward its advancement.

As an early step, the Continental Information Sharing Platform is being developed to become interoperable and integrated with the AUDA-NEPAD Portal. An information-sharing portal is also under development, which AUDA-NEPAD is hosting during the development and testing phase. The portal will include data on countries that have Information Management Systems on the various regulatory functions such as the database of Registered Products: manufacturing sites; license and inspection status; laboratory capacity; pharmacovigilance information as well as institutional details, new applicant section and user information.

The system to be developed in due course would be a user-friendly (web-based) national, Regional R-IMS solution and ultimately the continental R-IMS solution for National Medicines Regulatory Agencies (NMRAs). It will be an integrated IMS for medicines regulation in Africa for the AMRH Programme that links the NMRAs on the continent (relying on proper naming conventions and standard data structures). The system would also adhere to WHO GBT requirements for good regulatory procedures, communication and transparency and will have modules specifically Product Registration Module; Inspections for both GDP and GMP; Pharmacovigilance; Clinical Trials and Licensure for Professionals and Premises among others.

Information in the system would be provisioned in two parts. First, public information part where external stakeholders would have access to public information, and second, the private/restricted information for internal stakeholders. This would be managed by AUDA-NEPAD staff and would be shared only with a member country that would have the right or privilege to. For example, NEPAD can give an extended right to Nigeria to view what Kenya is doing if the two countries are working on a similar project and have agreed to this. AUDA-NEPAD can also invite interested parties in other countries to see similar information as NEPAD if the parties are also participating in a similar project. Member States can agree at their discretion to place their data in the public domain to support research or other efforts. While AUDA-NEPAD will have the main administration rights to maintain the platform, member countries will have rights to update their information and will be encouraged to do this on a regular basis.

AUDA-NEPAD is keen to align with other systems that have been developed to share regulatory information, such as MTaPS' (supported by USAID) efforts to work with countries on digitization of their regulatory data concerning medicines registration and pharmacovigilance. In its next phase AUDA-NEPAD is planning to take forward meetings with all partners to explore their existing efforts and how they can support and align with continental RIMS for AMRH.

High-level meeting convened by AU Special Envoy called on behalf of patients and industry for urgent action to set up a Single Continental Regulatory Agency in Africa

The COVID-19 pandemic has highlighted the importance of international cooperation. Health challenges and crises have no borders. Promoting the consultation, development and implementation of a common strategy among African countries, the African Medicines Agency will provide an essential technical support in the prevention and the fight against emerging diseases.

Moreover, it represents, for many countries, the promise of the development of local production, and the development, across the continent, of centers of excellence for research, the strengthening and security of supply chains, for the maintenance of a healthy environment and the fight against falsified medicines.
While the functions and status of the Agency are now clearly defined, a common vision and strategy is currently underway, that will give it its impetus and enable it to outline the first lines of work.

It is in this framework, and at the initiative of the Special Envoy of the African Union for the African Medicines Agency, Mr. Michel Sidibé, that the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the French pharmaceutical association (Leem) and the International Alliance of Patients' Organizations (IAPO), organized on 22 June 2021 a high level meeting entitled "–The African Medicines Agency Vision and Strategy for the African Continent" that brought together Ministers of Health from four African countries (Algeria, Cabo Verde, Democratic Republic of Congo and Egypt), representatives from international organizations, patient groups and the pharmaceutical industry.

Kicking off the Ministerial panel, Mr. Michel Sidibé, said that we are at a critical moment to establish the African Medicines Agency (AMA). The COVID-19 crisis is not only a public health crisis, but also a human security crisis. While incredible efforts have been undertaken to develop safe and effective vaccines, only a fraction of vaccines have been administered on the African continent. This brings forth the need for the AMA to provide a system to encourage research excellence and local production of medicines.

Dr Margareth Ndomondo Sigonda, Head of Health, AUDA NEPAD, explained that AMA has its roots in the African Medicines Regulatory Harmonization (AMRH) initiative, which was started as a mechanism to address regulatory challenges on the continent. Working with different partners, including the African Union Commission, the Bill and Melinda Gates Foundation, the AMRH has been able to deliver positive results in helping countries harmonize regulatory standards, starting with the registration of medicines and slowly expanding the scope from generic medicines to new chemical entities to vaccines. The scope was also expanded in terms of functions – such as safety monitoring, clinical trials. The positive results achieved by the AMRH can be shown through:

- The reduction of timelines for granting marketing authorizations
- The creation of robust legal frameworks at national level, through the AU model law for medical production The creation of 11 regional centres of regulatory excellence to sustain capacity-building.

It is important to build on the current momentum gained with the ratification of the AMA Treaty. The Treaty was adopted in February 2019 by the AU Assembly and there are currently 9 ratifications, inching closer to the 15 ratifications needed to bring AMA into existence. Preparations for the establishment of the AMA therefore need to be started and there are a few critical elements:

- **to ensure a smooth transition from the AMRH to the AMA.** There are good governance structures put in place, including steering committees, political committees that have provided guidance to Member States including during the COVID-19 pandemic. Guidance has been issued to all Member States, so they are able to approve COVID-19 vaccines faster.
- **to safeguard a financial stability for AMA.** The AMRH is currently funded by donor countries. Luckily, the Treaty provides for this aspect, with contribution from Member States, industry and through grants.
- **to reinforce the human resource capacity.** There is a robust team of experts in place, but expertise needs to also be mapped at national, regional level.
- **to establish a proper regulatory infrastructure to deal with, for instance, self-monitoring of medical products.**

Ms. Emer Cooke, Executive Director, European Medicines Agency (EMA)**,** explained the benefits of regulatory harmonization seen over the years at the level of the European Union, helping countries work together. While the EU model is an excellent fit for the AMA, the regulatory network was not established in one day. The European regulatory system has significantly evolved over the last five decades from cooperation to collaboration to working within a unique set of laws, regulations, processes and scientific standards. She outlined some ideas on how EMA can help the development of AMA and build regulatory and scientific capacity, and to support regulatory reliance:

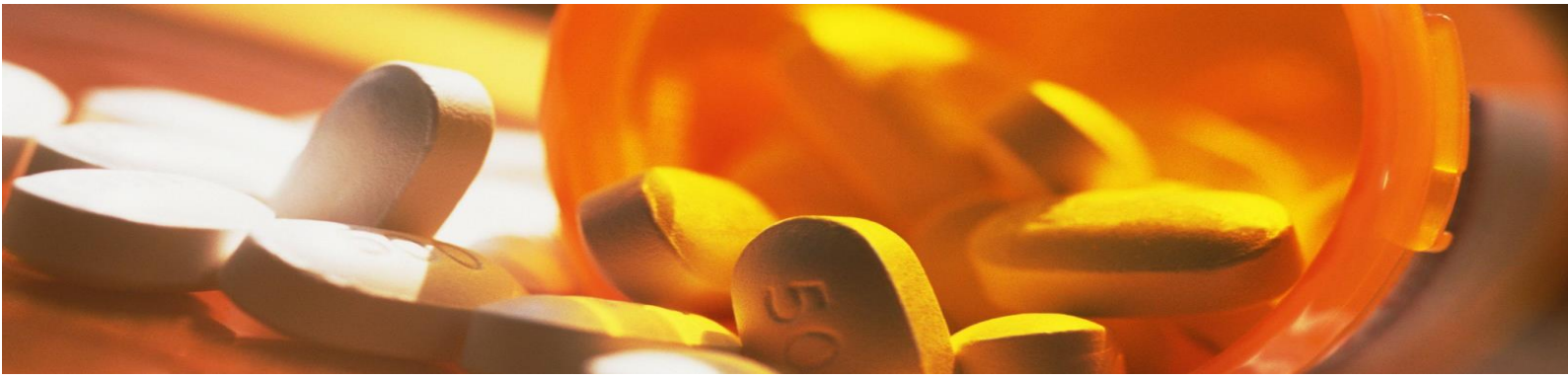
- The EMA is providing support to many African regulators through capacity-building on medicines regulation
- The EMA can share its experience on joint clinical assessment

Dr. Karim Bendhaou, Chair of Africa Engagement Committee, IFPMA, reiterated industry's support for the establishment of the AMA. The AMA will contribute to regulatory harmonization

across Africa, enable collaboration and work sharing, and the use of reliance procedures, which will mean a win-win for national regulators, patient, and industry. It will also be a pillar for Universal Health Coverage in Africa. A strong unified regulatory system could contribute to fight falsified products and to bring high quality, safe, and innovative products to the market.

Mr. Kawaldip Sehmi and Ms. Bisi Bright of the International Alliance of Patients' Organizations (IAPO), invoking the motto “nothing about us without us”, highlighted the importance of involving African patient groups in advocating for the ratification of the Treaty, and also continuing to carry the patient voice once the Agency is operational. They suggested to put in place permanent structures, similarly to the ones that exist at the EMA and FDA, to assist more meaningful patient engagement in medical product development discussions withinAMA.

The high-level meeting closed with the announcement of the official launch of the **African Medicines Agency Treaty Alliance (AMATA),** a multi-stakeholder alliance spearheaded by the patients to advocate for the ratification and implementation of the AMA Treaty and for meaningful engagement with patients and other relevant parties, in all aspects of the new continental Agency framework and development.



Thank you to our Quarter 1 and Quarter 2 Contributors:

- AUDA-NEPAD
- World Health Organisation
- Intergovernmental Authority on Development
- International Federation of Pharmaceutical Manufacturers & Associations
- AMRH Partnership Platform
- AMRH TC on Regulatory Information Management Systems
- African Medical Device Forum

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