AMRH
African Medicines Regulatory Harmonisation Programme

1st QUARTER 2020 NEWSLETTER EDITION

Success Stories Series: A decade of the AMRH Initiative

The 55th Decision of the African Union (AU) taken during the Abuja Summit in January 2005, requested the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the New Partnership for Africa's Development (NEPAD), now known as African Union Development Agency-NEPAD. The PMPA is aimed to improve access to good quality, safe and efficacious medical products, and health technologies for the African population.

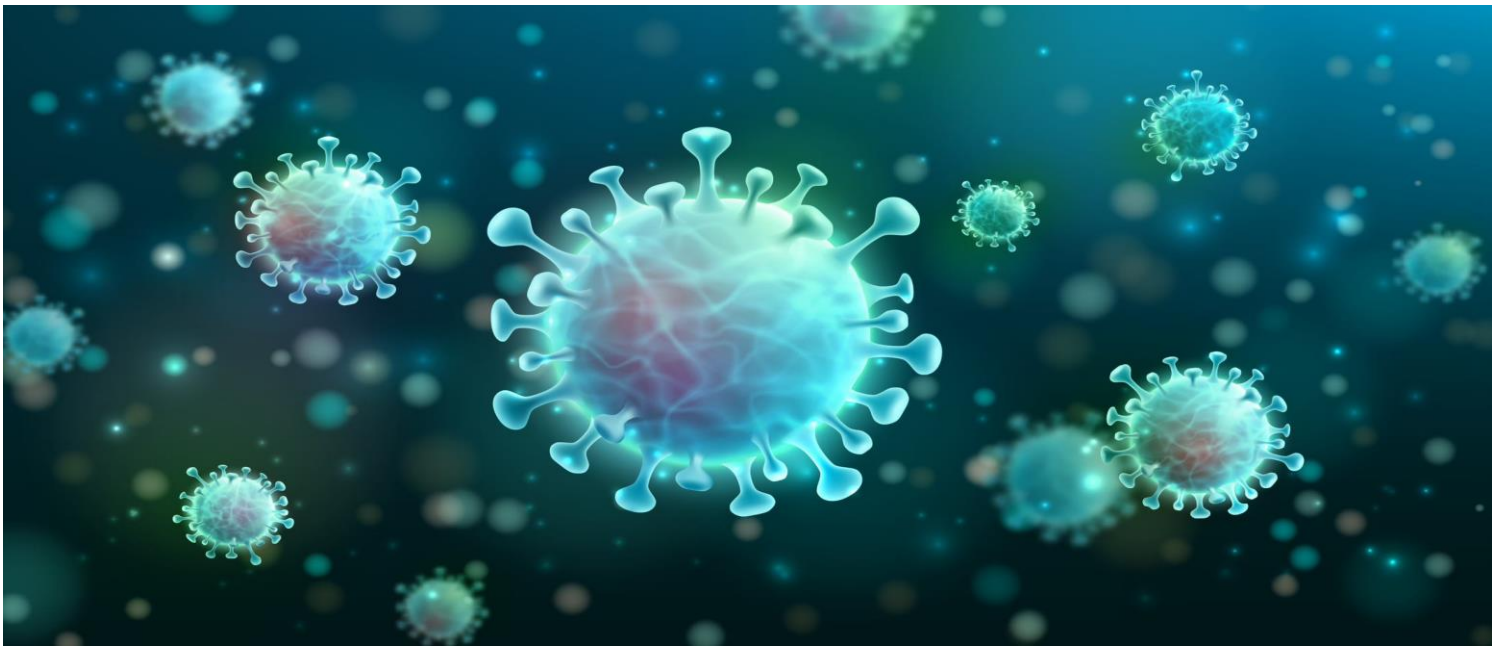
The African Medicines Regulatory Harmonization Initiative started in 2009 to address the fragmented regulatory systems on the African continent and provide an optimal environment for local production of medical products and health technologies on the continent. For over a decade now the continent has witnessed significant progress in harmonization of technical requirements for registration of medical products and good manufacturing practice (GMP) guidelines through the AMRH Initiative working with regional economic communities (RECs) and national medicines regulatory agencies (NMRAs). Consequently, countries have been able to conduct joint review of dossier applications and inspection of manufacturing sites with subsequent reduction of timelines for marketing approval to a median of 7-8 months as reported in the East African Community and the Southern African Development Community (SADC) regions. In addition, implementation of quality management systems by NMRAs through RECs MRH Projects have resulted in attainment of International Standards Organization (ISO) standard by a significant number of NMRAs. For instance, four out of 7 NMRAs in the EAC namely Kenya Pharmacy and Poisons Board (K-PPB), Tanzania Medicines and Medical Devices Authority (TMDA), Zanzibar Food and Drug Authority (ZFDA), and the National Drug Authority of Uganda (NDA) are 9001:2015 ISO-certified.

In the Economic Community of West African States (ECOWAS); five (5) NMRAs have attained ISO 9001:2015 certification under the MRH Project namely, the Food and Drug Authority of Ghana (FDA Ghana), the National Agency for Food and Drug Administration and Control (NAFDAC) Nigeria, Liberia medicines and Health Products Regulatory Authority (LMHRA), Pharmacy Board of Sierra Leone, and Medicines Control Authority (MCA) of The Gambia. Meeting the requirements for ISO certification provides a guarantee that ensure that its regulatory processes are conducted in a uniform and rigorous manner.

To address weaknesses in national medicines laws, seventeen (17) African Union (AU) Member States have domesticated the model law on medical products regulation with subsequent increase in the number of autonomous NMRAs. In the EAC region, five (5) out of seven (7) NMRAs (71.4%) are semi-autonomous namely KPPB, Rwanda Food and Drug Authority (RFDA), South Sudan Food and Drug Authority (SSFDA), TMDA, ZFDA and NDA. In the ECOWAS region, ten (10) out of fifteen (15) countries (66.6%) have autonomous agencies that provide guarantee in the coordination and financing of regulatory activities in a country. They are Benin, Burkina Faso, Cabo Verde, Cote d'Ivoire, The Gambia, Ghana, Guiné-Bissau, Liberia, Nigeria and Sierra Leone.

These noted results through implementation of the AMRH initiative are key in building robust regulatory systems in Africa including the establishment of the African Medicines Agency (AMA). Key success factors also include the harmonization of technical requirements and joint regulatory activities conducted by NMRAs coupled with sound governance systems such as Expert Working Groups (EWGs) and Steering Committees oversights.

- ***This article is part of series of success stories which will be documented and published to provide a knowledge platform for learning.***



Africa Medical Devices Forum Technical Committee establishes a Task Force for COVID -19 Response

African Medical Devices Forum (AMDF) is a technical committee under the African Medicines Regulatory Harmonization (AMRH) programme with a joint secretariat of WHO and the African Union Development Agency - NEPAD. AMDF was established with the aim of improving access to safe and effective medical devices including in vitro diagnostics in Africa through development of harmonized regulatory requirements based on internationally accepted requirements and standards.

AMDF main area of work is to study and recommend ways to ensure medical devices and diagnostics are effective while minimizing delays and allowing faster access to varieties of medical devices and diagnostics. This is in alignment with other various harmonization groups and networks that have been working on other categories of products and/or in different aspects of regulatory functions with a view to ensure that all the African Union (AU) Member States benefit from technical and scientific guidance provided through these efforts. The overall mandate of the AMDF is to identify technical needs, develop technical documentation in line with international guidelines and best practice and recommend to the AMRH Steering Committee for adoption. In executing its roles and responsibilities, the group among other things is expected to provide technical advice to the AMRH Steering Committee on matters related to regulation of Medical Devices (MDs) and In-vitro Diagnostics (IVDs). It is also expected that the AMDF will serve a technical role for the African Medicines Agency (AMA) once the latter is established and operational.

In view of this background and of the fast evolving COVID-19 pandemic worldwide and in Africa, AMDF leadership and AMRH joint secretariat conducted a meeting on 31 March 2020. During this meeting it was agreed to immediately establish a Task force comprised of experts to discuss & provide technical advice to the AMDF leadership and AMRH SC on some of the critical challenges that are currently faced by regulators in the fight against COVID-19 pandemic.

The objective of the task force as elaborated in its terms of reference is to provide technical advice and guidance to the Africa Medical Devices Forum (AMDF) on regulatory issues related to COVID -19.

Members of the task force were selected based on their expertise and experience in regulation, research and or laboratory work related to diagnostics. The experts were drawn from NRAs, laboratories, academia, WHO, African CDC, African Society for Laboratory Medicine (ASLM), AUDA-NEPAD, national research institutes, African Union Commission (AUC) as well as several interested AMRH Partners.

The expected deliverables of the task force were to:

- ❑ Develop a list of COVID-19 in vitro diagnostics which will be updated from time to time.
- ❑ Develop a list of medical devices and other products for surveillance, prevention control and case management.
- ❑ Establish mechanism to receive feedback on substandard and falsified IVDs, medical devices and PPEs and inform NRAs.
- ❑ Develop guidance on management of IVDs and medical device`s donations.

The work of the task force was planned to be undertaken by experts who will be divided into four priority areas: In vitro diagnostics tests for COVID-19; Medical devices and Personal Protective Equipment (PPE); Substandard and falsified IVDs; and Medical devices and PPEs and donations. The experts were divided into four working groups (WGs) in which each of the WG will oversee one priority area.

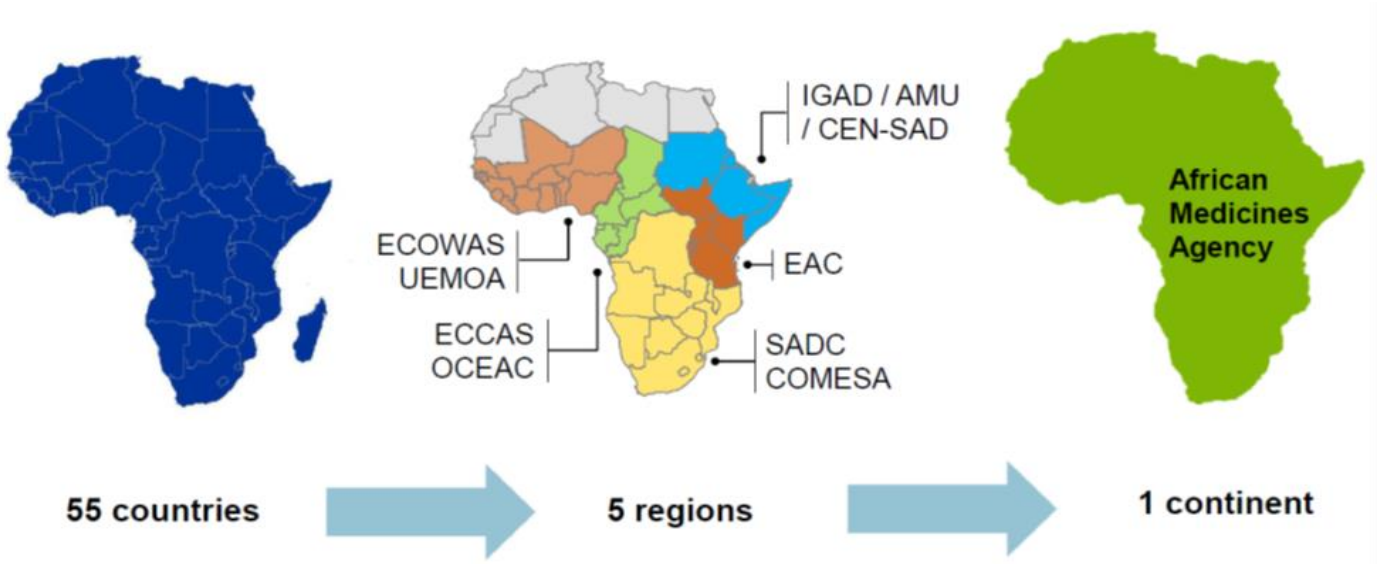
6th meeting of the Steering Committee on Regulatory Systems Strengthening and Harmonization Initiatives in Africa a Success

The AMRH SC has been operational since 2017 to provide strategic guidance and support in the implementation of the African Medicines Regulatory Harmonization (AMRH) initiative. The SC is an offshoot of the AMRH Advisory Committee resulting from review of the governance structure by AMRH Partners. The review also resulted in the formation of the AMRH Partnership Platform to bring together all partners with a view to provide collective political, technical and financial support to regional economic communities (RECs) and countries implementing medicines regulatory harmonization (MRH) projects. Eight (8) AMRH Technical Committees (TCs) were approved to provide technical guidance to RECs and Member States. The African Medicines Regulators Conference (AMRC) serves as the AMRH Assembly- the overarching decision-making body of the AMRH Governance structure. This is in line with the decision of the African Union Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) of April 2015 which endorsed the 'institutionalization of the biennial AMRC as a platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision making processes'.

It is against this background that the 6th AMRH SC meeting was held on 17th March 2020 to review progress on RECs MRH Projects and operationalization of AMRH governance structure as a building block for establishment of the African Medicines Agency (AMA) in line with the AU Executive Council Decision of January 2015. The AMRH SC considered reports from RECs on MRH Projects implementation status; Progress on AMRH Partnership Platform; Updates on Paediatric Regulatory Network (PRN); Updates on development of continental Regulatory Information Management System (RIMS); Updates on benchmarking of regulatory systems in Africa (regional and country specific updates); Updates from AMRH Technical Committees (AMRH-TCs); AMRH-AMA Operational Strategy proposal; and proposed country engagement plan for AMA; and updates on traceability. The SC took note of progress made by the five (5) AMRH TCs namely the African Vaccines Regulatory Forum (AVAREF) TC on Clinical Trials; African Medicines Quality Forum (AMQF) TC on quality control and post market surveillance; Medicines Policy and Regulatory Reforms (MPRR) TC on legal frameworks; The African Medical Devices Forum (AMDF) TC on regulation of medical devices and invitro diagnostics; and the African Blood Regulators Forums (AfBRF) TC on regulation of blood and blood products. The AMRH SC also approved the proposal to establish an interim continental Regulatory Information Management System (RIMS) TC and the proposed plan. Furthermore, the SC took note of progress in the operationalization of indicators for tracking progress of regional regulatory harmonization networks (i.e. MRH Projects) and the AMRH Partnership Platform (AMRH PP).

On WHO Global Benchmarking Tool (GBT), the SC advised Member States to adhere to timelines for submission of their GBT assessment reports and institutional development plan (IDPs) to WHO and RECs and to ensure close monitoring of implementation of progress in IDP through the RECs and AMRH SCs meetings. In addition, NMRAs were encouraged to participate actively in development of global regulatory policies and guidelines e.g. WHO Listed Authority (WLA) Policy Framework. SC agreed with the proposal to include medical devices in the GBT and in the REC work plans e.g. SADC has expanded scope of work to include medical devices.

On AMRH-AMA Operational Strategy and AMA country engagement, the SC took note of AMRH achievements and the projected roadmap for AMA and approved the proposal to establish a Technical Team (TT) to provide inputs in the proposed AMRH-AMA Operational Strategy. It was agreed that the TT should conduct a desk review on how other Treaty based AU Specialised Agencies have been operationalised. In addition, the SC supported and approved the AMA Country Engagement Strategy, plan and budget and directed AUDA-NEPAD to circulate the Strategy to RECs for comments before wider circulation and execution. Other outcomes of the 6th AMRH SC include; i) The work on sustainable financing options for AMRH Activities using lessons learnt from the ECOWAS, SADC and EAC regional joint reviews and inspection activities; ii) The need to have a comprehensive report on AMRH Funding under the Global Medicines Regulatory Harmonization Multidoor Trust Fund (GMRH-MDTF) and outside the Trust Fund including direct funding to RECs; iii) Preparations for the 2nd AMRH Week scheduled to take place in November 21-28th, 2020 in Abuja, Nigeria; and iv) The need for tracking RECs progress using AMRH indicators.



Strides Taken to Establish Single Continental Medicines Regulatory Agency in Africa

The African Medicines Agency will be a single, fully fledged continental medicines regulatory agency of the African Union, dedicated to assisting Member States to improve their capacities to regulate medical products and health technologies, and continue to build on existing AMRH initiatives. A single, fully fledged continental medicines regulatory agency can improve access to medicines to those most in need and disrupt the cycle of poverty in the African continent. However, in order for AMA to become a reality, all African Member States need to sign and ratify the AMA Treaty. The AMA Treaty was adopted by AU Assembly on 11 February 2019.

A minimum of Fifteen (15) Member States are needed to ratify the AMA Treaty in their national parliaments, for AMA to come into force. So far, sixteen (16) countries have signed and out of which, two (2) have ratified. They are; Algeria, Benin, Chad, Gabon, Ghana, Guinea, Madagascar, Mali (ratified), Morocco, Niger, Rwanda (ratified), Saharawi Arab Republic, Senegal, Seychelles, Sierra Leone and Tunisia. The AMA Treaty is open to signature by all AU Heads of State and Government and/or by Ministers of Foreign Affairs, either in person or by designation in writing to their Ambassador accredited to the African Union. Ratification processes vary by Member State, depending on whether legislative ratification or executive ratification applies. AMA, once legally mandated by AU Member States (MS), will be an established organ of AU and will facilitate availability of quality, safe and efficacious medical products and health technologies on the continent. This will be achieved through coordinating national and regional regulatory systems for medical products, providing regulatory oversight of selected medical products as well as promoting cooperation, harmonization and mutual recognition of regulatory decisions.The Agency offers the opportunity for a continental focus for certain activities, such as the opportunity to assess special classes of medicines (e.g. advanced therapies), Active Pharmaceutical Ingredients (APIs) and products that are currently not well regulated in many African countries (IVDs and devices, traditional medical products). AMA will collaborate with RECs and NMRAs in the identification of substandard and falsified medical products and facilitate information sharing across countries with the goal of providing a better environment for legitimate manufacturers to flourish and improve local manufacturing of quality products.

The Agency offers an opportunity to catalyse financial and technical support from countries and undertake certain activities more efficiently, while at the same time consolidating the RECs initiatives. It is also expected to play a key role by working closely with the Africa-CDC and WHO on the evaluation of, and oversight for the use of medical countermeasures for public health emergencies. Continent-wide alignment of regulatory technical requirements and standards through AMA is likely to make Africa a more attractive market for the pharmaceutical sector for both research and development, as well as introduction of innovations. AMA further plays a critical role in catalyzing trade in support of the African Continental Free Trade Area (AfCFTA).

African Medicines Quality Forum 3rd Annual Meeting in Abuja

The AMQF third annual meeting took place in Abuja, Nigeria from February 24 to 28, 2020. The meeting was hosted by the National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria, under the theme of the meeting was '2020: Perfect Vision for Quality Medicines in Africa'.
34 African countries were represented at the meeting which also included partners from African Union Development Agency-NEPAD, the United States Pharmacopoeial Convention(USP), Bill and Melinda Gates Foundation (BMGF), The Intergovernmental Authority on Development (IGAD), three Regional Economic Communities [ECOWAS(WAHO/WAEMU)], the World Bank, the World Health Organization (WHO), global health organization (PATH), International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and Southern African Development Community (SADC).

The first day of the meeting was a closed-door session which involved only the members of the AMQF Technical Committee (TC) and its partners AUDA-NEPAD, USP, World Bank, BMGF, PATH and IFPMA. During this meeting, the 2019 AMQF report, the 2020 AMQF workplan, and the roadmap to international accreditation using the evaluated results from the AMQF assessment tool were finalized. The main meeting open to all members of the AMQF started on February 25, 2020. A video documentary showing the quality infrastructure of NAFDAC Laboratories across the whole country was shown. Professor Mojisola Adeyeye, Director General of NAFDAC, the host of the meeting as well as the President of the AMRH, gave the welcome address. She emphasized the fact that the AMQF is the Quality Control voice of Africans in their need to have access to quality medicines and adequate regulations to safeguard their health. The meeting was officially opened by a welcome address by the Honourable Minister of Health, Dr. Osagie E. Ehanire.

He called on the AMQF to strengthen its collaboration among African Medicine Regulatory Authorities and assist member countries in developing capacities and put in place structures to combat menace of substandard and falsified medicines. The AMQF 2019 report and the 2020 workplan were presented in plenary by Ms. Bridget Dube, the Chair of AMQF and Prof. Benoit Koumare, the Vice Chair of AMQF respectively. During the three-day meeting, there were several informative scientific presentations made by AMQF members and other experts mainly on Quality Control and Post Marketing Surveillance. Presentations from three ISO accredited and/or prequalified labs - Nigeria, Kenya and Uganda were also made, laboratories shared their journey towards international recognition. Mr. Rutendo Kuwana, gave an update on WHO's Quality Control Laboratory (QCL) activities and its support for risk-based market surveillance. Mrs. Sybil Osei-Agyeman-Yeboah, ECOWAS-WAHO gave a presentation on 'ECOWAS Regional RB PMS; RECs regional PMS plans, QCL activities and anticipated role of AMQF'. While Mr. Johnpaul Omollo, PATH, presented on PATH's contributions in ensuring QC of medicines in Kenya and the East African Community.

There were lively exchanges after each of the presentations and recommendations were made, followed by a break-out session moderated by Dr. Farouk Umaru, USP, where proposals for regional/cross border survey of medicines of public health importance in Africa were drawn and regional RB-PMS programs that AMQF could play a role in. An interactive panel discussion on financial sustainability of AMQF moderated by Dr. Emily Kaine, USP was also conducted. The panelists were Mr. Ben Botwe (World Bank), Mrs. Sybil Osei Agyeman (WAHO), Prof. Mojisola Adeyeye (DG NAFDAC), Mrs. Margareth Ndomondo-Sigonda (AUDA NEPAD), Mr. David Mukanga (BMGF), Mr. Rutendo Kuwana (WHO) and Mrs. Gugu Mahlangu (MCAZ).

During the last day of the meeting, Prof. Mojisola Adeyeye shared her experience hosting the 3rd annual AMQF meeting and provided information on how different planning committees were constituted as well as on the challenges encountered in mobilizing funding for the meeting. This presentation was to inform as well as encourage other regulatory authorities to host the 4th annual AMQF meeting in 2021. The last day of the program was dedicated to pharmaceutical manufacturing and Quality Assurance with representatives from the Nigerian local manufacturing industry, AMQF members and partners.

Self-benchmarking of National Medicines Regulatory Authorities in the Central African Economic and Monetary Community (CEMAC)

In order to assess the strength, weakness and maturity level (ML) of National Medicine Regulatory Authorities (NMRAs), a comprehensive evaluation and monitoring tool with a set of indicators for assessing regulatory systems have been developed by WHO. The Global Benchmarking Tool (GBT) represents the primary means by which WHO objectively assesses regulatory systems. The AMRH Monitoring and Evaluation Framework compliments this tool as it assesses performance at the regional level. Strengthening of Regulatory system for medical products in the CEMAC region is a priority for the CEMAC Medicine Regulatory Harmonisation (MRH) project. The main objective of this self-assessment workshop was to identify the strengths and weaknesses of the regulatory system and the regulatory functions of medicines and vaccines in the CEMAC region.

The Specific objectives were to:

- Explain WHO's capacity-building model, evaluation process and WHO's role in promoting regulatory harmonization initiatives;
- Introduce the computerized comprehensive benchmarking tool and provide technical assistance in the execution of CEMAC's NMRA self-assessment;
- Identify existing gaps in harmonization initiatives, indicate the level of maturity of the regulatory system and the core regulatory functions of NRAs, and initiate the development of the IDP to address identified gaps and build on the strengths and strengths and
- Establish a baseline of existing capabilities and gaps in the Regional Medicines Regulation Harmonization (MRH) Initiative.

WHO and AMRH Partners have been supporting different REC's in Africa to assess their NMRAs. The process normally starts with a self-assessment where the NMRA assesses itself initially and then formally invites WHO for a full benchmarking which is conducted by WHO. These benchmarking exercises using the WHO Global Benchmarking Tool (GBT) has already been conducted in 4 RECs (ECOWAS, EAC, SADC and IGAD) in Africa. The Steering Committee of the Community of Pharmaceutical Policy of CEMAC held a meeting in August 2019 in Yaoundé Cameroon, whereby they recommended that a self-assessment of the national regulatory systems of CEMAC member countries be organized with the assistance of WHO.

It was recommended that this activity be carried out as part of the implementation of the regulatory harmonization program that OCEAC is coordinating in the region with the support of AUDA-NEPAD, WHO and the World Bank. It is against this backdrop that a self-benchmarking exercise was organized in Libreville, Gabon in February 2020 for the Central Africa Member States. The National Regulatory System (RS), Market Authorization (MA) and Regulatory Inspection (RI) were prioritized for completion during the workshop and the remaining functions and formulation of Institutional development plan (IDP) to be completed according to the agreed road map.

Attended by all CEMAC Member States (Cameroun, Congo, Gabon, Guinee Equatorial, RCA, Tchad), the following was achieved from the benchmarking exercise;

- ❑ Awareness was created on the WHO regulatory capacity building model including the existence of a global benchmarking tool that allows NMRAs not only to understand the strengths and weakness of their institutions, but more especially, the way forward in achieving the ML3 goal using the Institutional Development Plan (IDP) development and implementation process.

- ❑ The NMRAs learned to use the GBT tool and were able to have a global understanding of NMRA efficient processes needed to regulate the pharmaceutical market towards providing quality medicines for their population.

- ❑ The benchmarking exercise helped the NMRAs to interact among themselves, and with countries from other RECs and the various partners that were present at the training.

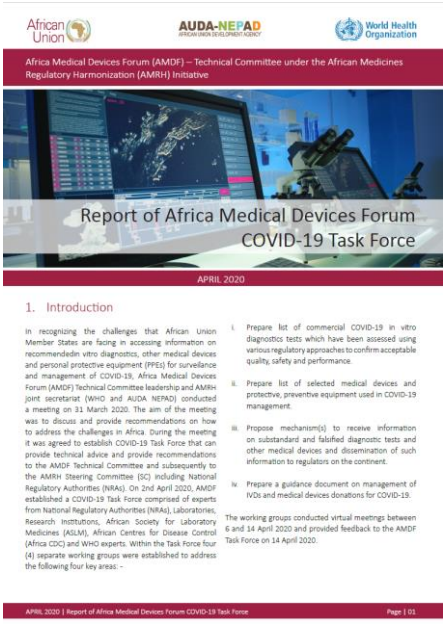
- ❑ All CEMAC Member States and OCEAC Secretariat now have at least two cGBT certified evaluators.

- ❑ Three regulatory functions were targeted as priorities for self-assessment during the workshop and at least maturity level one of the prioritized functions was completed

- ❑ CEMAC is now clearly engaged with the African medicine regulatory harmonization network.

Countries completing the assessment tool with the assistance of facilitators

Key knowledge products



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Upcoming Events

- Webinar-Updates on the African Medicines Agency (AMA): 1st July 2020
- 7th AMRH Steering Committee Meeting: 14th – 15th July 2020
- Africa Medical Devices Forum (AMDF) Technical Committee virtual meeting: 16 -17 July 2020
- Regulatory Flexibilities in the Africa Continent: 31 July 2020
- Webinar-Regulation of traditional herbal products: 31st August 2020

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