

AMRH
African Medicines Regulatory Harmonisation Programme

2nd QUARTER 2020 NEWSLETTER EDITION

More African Union Member States ratify the African Medicines Agency Treaty



African Union (AU) member states need to rally behind the AU vision for a single continental medicines agency that will be responsible for contributing towards positive health outcomes for African people. The COVID-19 crisis has posed significant challenges on the continent, across almost every sector of the economy and this may take many years to recover. As September 2020, great progress has been made as 17 countries have signed the AMA treaty, out of which Rwanda, Mali, Burkina Faso, Ghana and Seychelles have ratified.

AMA, will enter into force once ratified by fifteen (15) African Union member states. As an organ of the African Union, legally mandated by Member States, AMA's goal will be to increase the availability of safe, good quality and efficacious medical products on the African continent. With the challenges faced by African countries in ensuring fast approval of clinical trials, marketing authorization and the importation and procurement of good quality, safe and efficacious medical products for the prevention and/or treatment of COVID-19 and other diseases, the establishment of AMA has become critical.

AUDA-NEPAD encourages all its Member States to sign and ratify the treaty for the establishment of AMA to ensure African people have quality of life, sound health and wellbeing, a priority area of the African Union agenda 2063.

For information on the ratification process, member states are encouraged to contact:

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7th Steering Committee on Regulatory Systems Strengthening and Harmonization Initiatives in Africa (AMRH SC)

Members of the Steering Committee on Regulatory Systems Strengthening and Harmonization Initiatives in Africa (AMRH SC) met in a virtual meeting on the 14th to the 15th of July 2020. Deliberations were mainly on the AMRH response to COVID-19 as well as progress made since the last steering committee held in March 2020. It is noteworthy to mention that the delivery of AMRH work areas by its technical committees (TCs), regional economic communities (RECs, National Medicine Regulatory Authorities (NMRAs) and partners has been challenging mainly due to the COVID-19 travel restrictions which has meant undertaking harmonisation virtually or online. However, it was positively noted that the much progress has been made as well.

Since March 2020, The AMRH joint secretariat has conducted various meetings and webinars in recognition of the challenges faced by the African Union Member States in accessing information on recommended in vitro diagnostics, other medical devices and personal protective equipment (PPEs) for surveillance and management of COVID-19. The meetings were also aimed to provide technical guidance on regulatory and ethics on approval of COVID-19 vaccines and therapeutic treatments for clinical trials conducted in Africa.

The 7th AMRH SC discussed on among other things, progress on implementation of regional medicines regulatory harmonization initiatives in the East African Community (EAC), Southern African Development Community (SADC), the Intergovernmental Authority on Development (IGAD), the Central African Economic and Monetary Union (CEMAC) and the Economic Community of West African States (ECOWAS).

The SC took note of progress made by the AMRH Partnership Platform and the four (4) AMRH TCs namely the African Vaccines Regulatory Forum (AVAREF) TC on clinical trials oversight; African Medicines Quality Forum (AMQF) TC on quality control and post market surveillance; the African Medical Devices Forum (AMDF) TC on regulation of medical devices and in-vitro diagnostics; the African Blood Regulators Forums (AfBRF) TC on regulation of blood and blood products; and the Continental Regulatory Information Management System (RIMS). Much progress was noted regarding the role of the TCs in response to COVID-19 through facilitation of technical support and regulatory guidance to AU member states.

The AMRH SC further considered the AMRH funding sources and mechanism to sustain regional medicines regulatory harmonization initiatives and agreed on the need to secure other sources of funding in addition to donor funds. It considered various options employed by regional economic communities implementing medicines regulatory harmonization initiative. Such financing mechanisms include through uses fees for inspection of manufacturing sites; joint reviews of dossier applications and member states contributions.

Other discussions at the 7th AMRH SC included recommendations from the 4th Scientific Conference on medical products regulation (SCoMRA IV) and The 6th African Medicines Regulators Conference (AMRC VI). It was agreed that the planning for SCOMRA V will commence before the end of 2020. In addition, progress on AMA ratification as well as implementation of the Country Engagement Plan for AMA were discussed with updates that the AMA Treaty had so far 16 signatories and 3 ratification countries (Rwanda, Mali & Burkina Faso) as of July 2020.



Operationalisation of the AMRH Partnership Platform

The AMRH Partnership Platform (PP) was created in 2018 by the AMRH Joint Secretariat as the central entry point for institutions wishing to amplify the efforts of regulatory harmonization in Africa. It was created in response to a growing need to improve coordination and alignment of efforts on the continent and to enable partners to bring technical and financial resources forward to support the AMRH agenda. To-date there are approximately 40 institutions in the AMRH PP, 25 of which are very active.

On joining the AMRH PP, institutions are invited to express interest in one or more of the AMRH Technical Committees and to join Joint Action Groups – or JAGs – linked to each Technical Committee. The JAGs are a key forum for partners to engage with the Technical Committees and with each other to discuss capabilities, resources and activity areas related to particular technical areas. The African Quality Medicines Forum (AMQF), African Medical Devices Forum (AMDF) and African Blood Regulatory Forum (ABRF) Technical Committees are currently highly active and their JAGs meet quarterly to enable partners to update each other on their activities and to learn about the progress in each Technical Committee. AVAREF is actively engaging with various partners, and others on the AMRH PP have expressed strong interest in support AVAREF activities.

Partners are actively invited to provide technical and financial inputs to the work of the Technical Committees, committing to activities that have been pre-defined in each Technical Committee's workplan for the year. In the last six months the joint Secretariat has held bilateral discussions with around twenty partners, focusing on the workplans of AMQF, AMDF and ABRF, exploring areas needing immediate or longer-term support and collaboration. This has led to rich discussions among and between partners on the work of the AMRH and how they might bring their resources to bear to further advance the various agendas. For AMQF, in addition to WHO, the WHO Collaborating Centre for the Quality Assurance of Medicines at North-West University (CENQAM) and United States Pharmacopoeia (USP), who provide ongoing support, the following partners have offered to provide a range of new support to strengthen technical capacity and quality management systems (QMS) in the region: fhi360; Centre Humanitaire des Metiers de la Pharmacie (CHMP); International Federation of Pharmaceutical Manufacturers & Associations (IFPMA); European & Developing Countries Clinical Trials Partnership (EDCTP) through its regional Networks of Excellence, CANTAM and TESA; and Swiss Medic. USP, EDQM, CHMP and fhi360 have also expressed interest in support the development of a regional, cross-border post-marketing surveillance study that is currently being scoped to help quantify the levels of sub-standard and falsified medicines in circulation for a selected basket of essential medicines.

For AMDF, in addition to WHO, the African Society for Laboratory Medicine (ASLM),
Paul-Ehrlich-Institut (PEI) and USP have expressed support to ADMF to further develop and implement a harmonized regulatory framework for medical devices. USP, ASLM and EDCTP's CANTAM and TESA networks have also begun to explore support for a range of interventions to establish and strengthen platforms for sharing developments, information and knowledge. USP, ASLM, EDCTP's CANTAM and TESA networks, PEI, DIA and UNFPA have also expressed support in various activities intended to support human resource capacity in medical devices regulation, tailored to specific country needs and depending on the level of maturity of respective national medicines regulatory authorities and their legal frameworks in relation to medical devices. The USAID/MTaPS programme is also exploring avenues of support for AMDF.

The ABRF is at an earlier stage of implementation, but already has the following partners actively engaged and exploring support opportunities: Paul-Ehrlich-Institut (PEI) is looking at offering ongoing technical support and training workshops; International Society for Blood Transfusion (ISBT) is looking *to* assist in capacity strengthening related to Blood and Blood Product availability and regulations in Africa; the University of Kwazulu-Natal (UKZN) has expressed interest in providing publications or written inputs on request; Etablissement Français du Sang (EFS) is exploring a number of areas of support for capacity strengthening and technical assistance within the context of a five-year partnership arrangement with AMRH; and EDCTP is currently exploring areas for partnership.

It is enthusing to note that AMRH PP is becoming a vibrant platform that is growing year on year, seeking to enrich the efficiency and effectiveness of the regulatory harmonisation effort in the continent, which has never been more important than now in the face of a global pandemic.

AMRH Technical Committees are actively adapting their work to ensure that there is and will be prompt access to safe and effective COVID-19 related medical products, in some cases undertaking or preparing to undertake joint reviews for key groups of essential medical products (e.g. vaccines, personal protective equipment, therapeutics and diagnostics). The AMRH PP offers an important channel for galvanising a coordinated and effective response to the COVID-19 crisis to ensure that such procedures are sustainable, relevant and have the potential for the best possible impact on public health.

To this end, all AMRH partners are invited to take part in the AMRH Week, from 23rd to 27th November 2020, where they can participate in the AMRH PP session on 25th November and observe discussions of the AMRH Technical Committees in the surrounding days. The hope is that partners take opportunity of the AMRH week to announce formalised commitments to the advancement of AMRH Technical Committees and AMRH programme overall. All partners are urged to liaise with the Secretariat via amrh@nepad.org by [15th October] so that announcements can be communicated and factored in by the Technical Committees when undertaking preparations for developing their 2021 Workplans. Agendas for the various virtual events in AMRH Week will be available in the coming weeks.

Discussions are also now underway with institutions who have expressed interest in joining the platform as new members. Institutions who are interested in applying to become members of the AMRH PP are actively encouraged to do so and should email amrh@nepad.org to find out more.

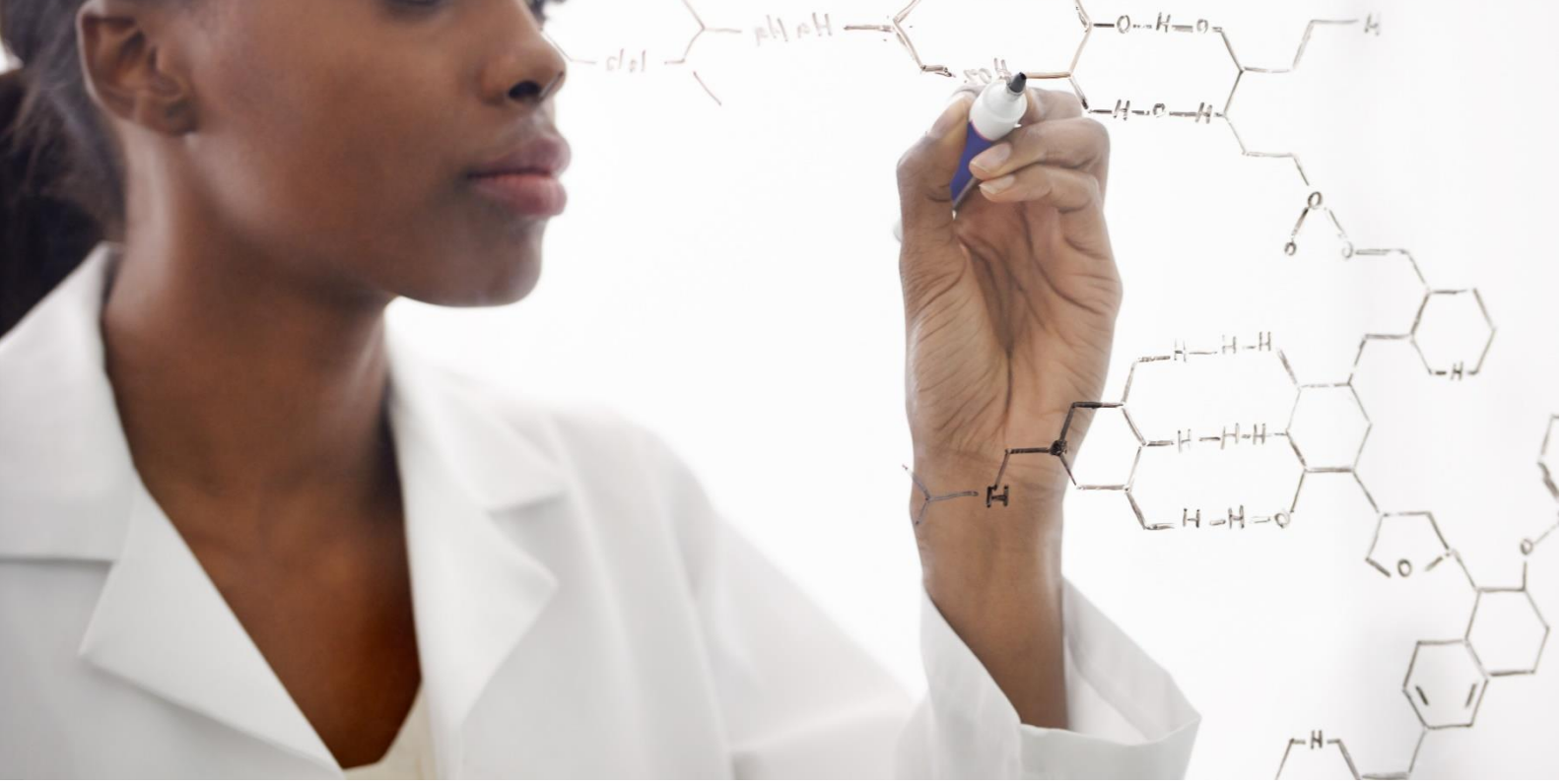
CIRS OpERA and AMRH M&E tool: How their Synergistic Applications can Strengthen the Regulatory Process

Strengthening regulatory systems is key to ensuring that regulatory agencies are providing effective and efficient services to their stakeholders. Around the world, medicine regulatory agencies have been growing in importance regarding ensuring that safe, effective, quality medicines are being made available in a timely manner to their served populations. However, assessments by various organisations, including the World Health Organization (WHO), have observed that agencies in most low- and middle-income countries (LMICs) are inadequately resourced and do not have adequate systems in place to monitor, track and report their regulatory activities. Importantly, a number do not have a culture of self-monitoring and process improvement.

As a results, the WHO have created a Global Benchmarking tool (GBT), which enables national medicines regulatory agencies (NMRAs) to “self-evaluate their own strengths and areas for improvement; facilitates the formulation of an institutional development plan to build upon strengths and address the identified gaps and prioritizes interventions; and facilitates the monitoring of progress and achievements.” To support and complement the WHO GBT in the African continent, a monitoring and evaluation (M&E) framework for the African Medicines Regulatory Harmonization (AMRH) has been designed by AUDA-NEPAD to add value to existing efforts under the WHO’s assessments of NMRAs. The AMRH M&E Framework focuses on assessing the performance of registration systems and related good manufacturing practices (GMP), quality management systems (QMS) and information management systems (IMS) implemented by the NMRAs of participating countries. GBT mainly focuses on national regulatory systems while the AMRH M&E addresses the regional regulatory networks.

Both the GBT and AMRH M&E tools identify which indicators are implemented within the NMRA to strengthen the regulatory system. The WHO GBT focuses on the systems and processes within the regulatory agency (i.e., registration, pharmacovigilance, inspections, clinical trial oversight, etc.), while the AMRH M&E framework focuses on outcomes and impacts of changes and/or improvements in the systems and processes at the national level as well as in harmonised systems. These tools allow agencies to conduct gap analyses to identify which functions are effective within their regulatory system and which of those require improvement.

One of the remits of a regulatory agency is to ensure timely access of medicines to patients without compromising the quality of the review. This role primarily sits within the registration division of the NMRA. Whilst the GBT and AMRH M&E frameworks measure what processes are present to ensure an effective and efficient registration process, it does not measure the actual review process in terms of the details of the process and the associated timeliness of the components of the review process.



The OpERA programme continuously measuring and evaluating the timelines associated with the regulatory assessment of a Marketing Authorisation Application (MAA) is pertinent to any continuous improvement initiative. The Centre for Innovation in Regulatory Science (CIRS) has collected regulatory assessment data for over 20 years, initially with ICH-founding member agencies. To expand the initiative to a global platform including LMICs, CIRS developed the **"Optimising Efficiencies in Regulatory Agencies" (OpERA) programme** in 2013 with regulators from Asia, Latin America, Africa and the Middle East. Since then, CIRS has expanded this programme to over 30 countries and several regional alignment initiatives. OpERA is a global programme, available to all regulatory agencies irrespective of their size, mission or maturity. OpERA looks at the detail/granularity of the regulatory approval process, which is not captured by the GBT or M&E tools. There are two components to the OpERA programme:

1. A qualitative methodology assessment [(A Process Report for a country or RRI (Figure. 1)]

2. Quantitative assessments (based on performance metrics).

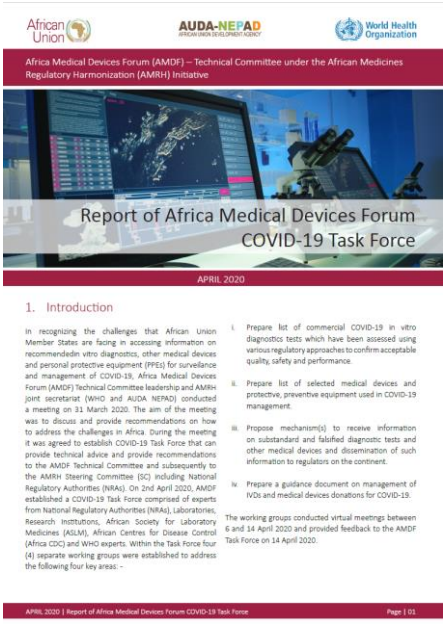
Both components complement each other to give a detailed picture of the regulatory assessment activities of an agency at any stage of maturity.

The OpERA programme has been designed to:

- Encourage agencies to continuously **evaluate** their process for medicines MAA review in detail so that they can identify barriers and opportunities to optimise their processes
- **Collect** factual agency-driven metrics that document how regulatory optimisation investments are helping agencies improve their effectiveness and productivity
- **Monitor** the use and effectiveness of work-sharing/referencing among agencies and Regional Regulatory Initiatives (RRIs)
- **Embed** a culture of ongoing monitoring and self-assessment to provide practical feedback that is used to recommend and document policy improvements and implement regulatory best practices to support activities, such as those using the WHO GBT and AMRH M&E framework.

As demonstrated by many agencies, the CIRS OpERA tool complements international benchmarking tools, such as the WHO GBT and AMRH M&E tool. Together, these serve as useful tools for optimising regulatory capacity for strengthening and harmonising the African continent for NMRAs and RECs. This will, ultimately provide foundation for the establishment of the African Medicines Agency.

Key knowledge products


African Union | AUDA-NEPAD | World Health Organization

Africa Medical Devices Forum (AMDF) – Technical Committee under the African Medicines Regulatory Harmonization (AMRH) Initiative

Report of Africa Medical Devices Forum COVID-19 Task Force

APRIL 2020

1. Introduction

In recognizing the challenges that African Union Member States are facing in accessing information on recommendedin vitro diagnostics, other medical devices and personal protective equipment (PPEs) for surveilance and management of COVID-19, Africa Medical Devices Forum (AMDF) Technical Committee leadership and AMRH joint secretariat (WHO and AUDA NEPAD) conducted a meeting on 31 March 2020. The aim of the meeting was to discuss and provide recommendations on how to address the challenges in Africa. During the meeting it was agreed to establish COVID-19 Task Force that can provide technical advice and provide recommendations to the AMDF Technical Committee and subsequently to the AMRH Steering Committee (SC) including National Regulatory Authorities (NRAs). On 2nd April 2020, AMDF established a COVID-19 Task Force comprised of experts from National Regulatory Authorities (NRAs), Laboratories, Research Institutions, African Society for Laboratory Medicines (ASLM), African Centres for Disease Control (Africa CDC) and WHO experts. Within the Task Force four (4) separate working groups were established to address the following four key areas: -

i. Prepare list of commercial COVID-19 in vitro diagnostics tests which have been assessed using various regulatory approaches to confirm acceptable quality, safety and performance.

ii. Prepare list of selected medical devices and protective, preventive equipment used in COVID-19 management.

iii. Propose mechanism(s) to receive information on substandard and falsified diagnostic tests and other medical devices and dissemination of such information to regulators on the continent.

iv. Prepare a guidance document on management of IVDs and medical devices donations for COVID-19.

The working groups conducted virtual meetings between 6 and 14 April 2020 and provided feedback to the AMDF Task Force on 14 April 2020.

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Africa Medical Devices Forum (AMDF) – Technical Committee under the African Medicines Regulatory Harmonization (AMRH) Initiative

Report of Africa Medical Devices Forum COVID-19 Task Force

5 -15 MAY 2020

1. Introduction

AMDF Covid -19 Task Force through its working groups have been conducting discussions and developing series of documents from 6th April to 20th May 2020. To date, three reports have been developed and submitted to the AMRH SC, endorsed and later on shared with Regulators for the purpose of addressing some of the challenges that have been reported by NRAs.

2. Working group 1: List of COVID -19 diagnostic and surveillance tests

The group updated the COVID-19 Nucleic Acid tests to include assays which were recently listed for Emergency Use by WHO Diagnostics Prequalification, United States Food and Drug Administration (US FDA), Nigeria Centre for Human Virology and Genomics and Uganda (Annex 1). Included in the list is a link to the Foundation for Innovation of New Diagnostics (FIND) showing results of ongoing performance evaluation of commercial NAT assays https://www.finddx.org/covid-19/sarscov2-eval-molecular/molecular-eval-results/

In addition, the list of COVID-19 serology assay which have been listed by United States Food and Drug Administration, Therapeutic Goods Administration (Australia), Singapore FDA and Nigeria Agency for Food and Drug Administration (NAFDAC) was updated (Annex 2). WHO does not recommend used of serology assays for diagnosis of COVID-19. Therefore, these Serology assays are only indicated for identification of individuals who have been infected by the virus causing COVID-19.

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Africa Medical Devices Forum (AMDF) – Technical Committee under the African Medicines Regulatory Harmonization (AMRH) Initiative

Report of Africa Medical Devices Forum COVID-19 Task Force

20 - 24 APRIL 2020

1. Introduction

In recognizing the challenges that member states in the African region are facing in accessing the recommended, in vitro diagnostics, other medical devices and PPEs, African Medical Devices Forum (AMDF) leadership WHO continued to support virtual meeting of AMDF COVID-19 Working Groups between 20 and 24 April 2020. The objective was to further consolidate and update the outputs which were achieved during earlier meetings held between 6 and 14 April 2020. Below is the summary of the proceedings and outputs.

2. Working group 1: List of COVID -19 diagnostic and surveillance tests

The group updated the COVID-19 Nucleic Acid tests to include assays which were recently listed for Emergency Use by WHO Diagnostics Prequalification and United States Food and Drug Administration (US FDA) (Annex 1). Following previous recommendation, a list of COVID-19 serology assay which have been listed by United States Food and Drug Administration, Therapeutic Goods Administration (Australia), Singapore FDA and Nigeria Agency for Food and Drug Administration (NAFDAC) has been compiled (Annex 2). WHO does not recommend used of serology for diagnosis of COVID-19. Therefore, these assays are only indicated for identification of individuals who have been infected by the virus causing COVID-19. Lastly, the group has been working on developing performance specification, and verification protocol for COVID-19 serology assays. This is work in progress.

3. Working group 2: List of medical devices and other products for surveillance, prevention control and case management of COVID-19

In global response to COVID-19 pandemic the World Health Organization has published a recommended list of medical devices and personal protective equipment (PPEs) that are critical in supporting other medical and non-medical interventions embarked

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Upcoming Events

- ❑ AMRH WEEK: 8 – 10 December

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AMRH African Medicines Regulatory Harmonisation Programme

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