AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

2020

African Medicines Regulatory Harmonisation Initiative

ANNUAL REPORT

AMRH
African Medicines Regulatory Harmonisation Programme

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Abbreviations

ABRF	African Blood Regulators Forum
A-CDC	Africa Centres for Disease Control and Prevention
AMA	African Medicines Agency
AMDF	African Medical Devices Forum
AMU	Arab Maghreb Union
AMRC	African Medicine Regulators Conference
AMRH	African Medicines Regulatory Harmonisation
AMRH-PP	African Medicines Regulatory Harmonisation Partnership Paltform
AMRH-SC	African Medicines Regulatory Harmonisation Steering Committee
AMQF	African Medicines Quality Forum
AU	African Union
AUC	African Union Commission
AUDA-NEPAD	African Union Development Agency-NEPAD
AU Model Law	African Union Model Law on Medical Products Regulation
AVAREF	African Vaccines Regulatory Forum
BMGF	Bill and Melinda Gates Foundation
EAC	East African Community
ECCAS	Economic Community of Central African States
ECOWAS	Economic Community of West African States
GBT	Global Benchmarking Tool
GMP	Good Manufacturing Practices
IDP	Institutional Development Plan

ISO	International Organization for Standardization
IGAD	Intergovernmental Authority on Development
JAG	Joint Action Group
M&E	Monitoring and evaluation
MPRR	Medicines Policy and Regulatory Reforms
MRH	Medicines regulatory harmonization
NMRA	National medicines regulatory authority
NRA	National Regulatory Authority
NQCL	National Quality Control Laboratory
PAP	Pan African Parliament
PMPA	Pharmaceutical Manufacturing Plan for Africa
REC	Regional Economic Community
RIMS	Regulatory Information Management Systems
SADC	Southern African Development Community
SCoMRA	Scientific Conference on Medical Products Regulation in Africa
TC	Technical Committee
WHO	World Health Organization

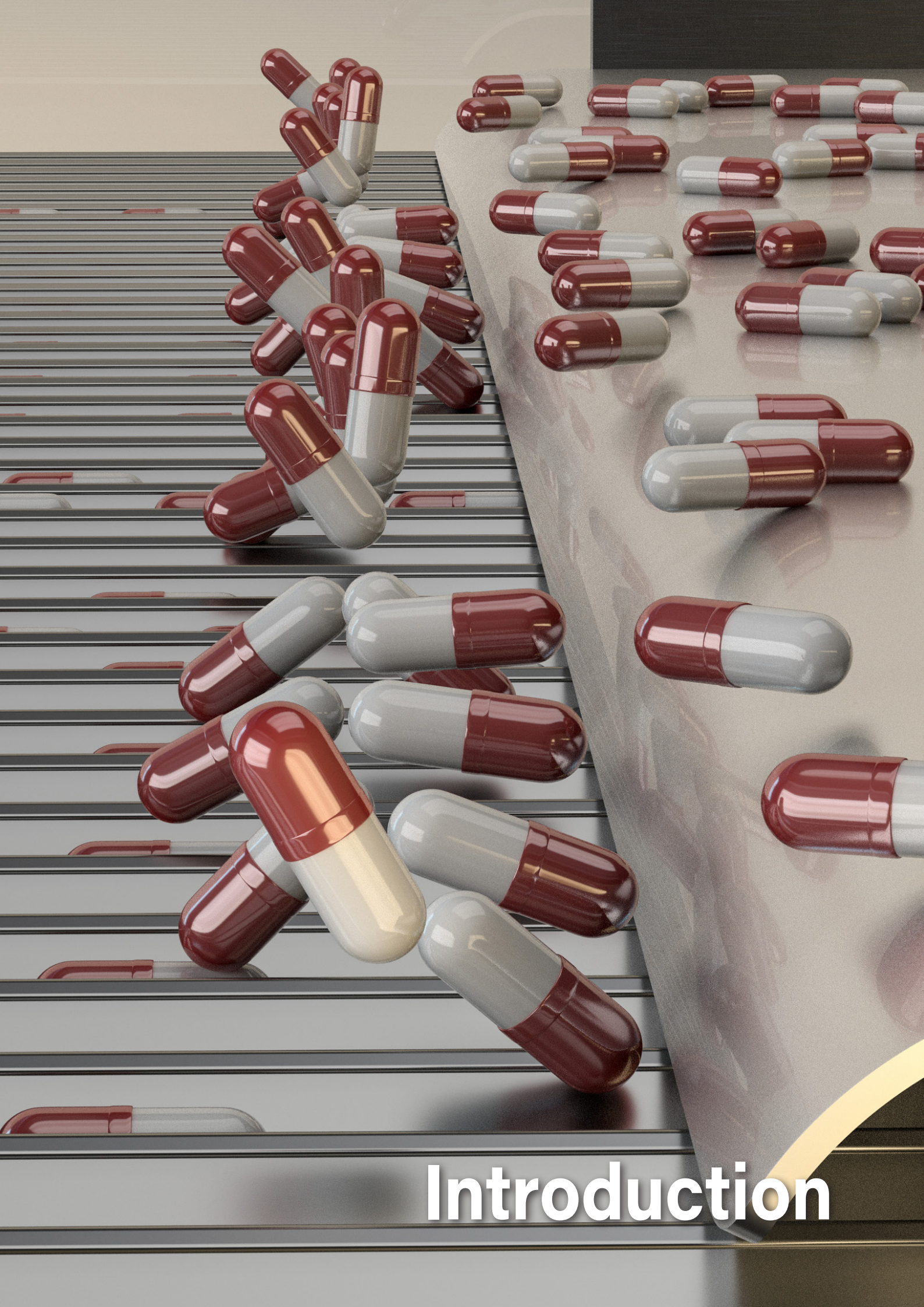
Foreword

2020 was a unique year for Africa and the rest of the world, as it battled the COVID-19 pandemic and its devastating effects to public health systems, economies, and societies at large. The African Union Development Agency-NEPAD (AUDA-NEPAD) was amongst the leading institutions tackling the multi-sectoral challenges brought on by pandemic in Africa.

It goes without saying that there was a high demand on initiatives such as the African Medicines Regulatory Harmonisation initiative (AMRH), to deal with continent wide challenges such as shortages of critically needed medical supplies while at the same time striving to ensure the quality, safety, efficacy, and performance of the available COVID-19 medical products. AMRH managed to forge strategic partnerships and accelerate efforts to ensure that African Union Member States were guided appropriately in a time of crisis. Working closely with the African Union Commission (AUC), World Health Organisation (WHO), The Africa Centres for Disease Control and Prevention (Africa-CDC) and many others, much progress was recorded in 2020 amidst the challenges.

This report presents the progress and achievements made, as well as the challenges and lessons learnt throughout 2020 by the AMRH initiative. It is the hope of AUDA-NEPAD that African Union Member States will note these updates and continue to find ways to work in unity as the continent fights the COVID-19 pandemic and beyond.

Dr Ibrahim Assane Mayaki
AUDA-NEPAD CEO



Introduction

The Pharmaceutical Manufacturing Plan for Africa (PMPA) led to the establishment of the AMRH Initiative in 2009 to address weak, outdated, and fragmented regulatory systems on the African continent. AMRH, led by the African Union Development Agency-NEPAD (AUDA-NEPAD) was established in collaboration with the National Regulatory Agencies (NRAs), Regional Economic Communities (RECs), the African Union Commission (AUC), Pan African Parliament (PAP), the World Health Organization (WHO), the Bill and Melinda Gates Foundation (BMGF), the World Bank and other development partners.The AMRH Initiative has so far been implemented in 5 RECs namely, East African Community (EAC), Southern African Development Community (SADC), the Economic Community of West African States (ECOWAS), the Economic Community of Central African States (ECCAS) and, the Intergovernmental Authority for Development (IGAD).

In January 2015, the AU Executive Council recognised the AMRH Initiative as the foundation for establishment of the African Medicines Agency (AMA) in advancing the development of the pharmaceutical industry through the PMPA policy framework. The AMA Treaty was subsequently adopted by the AU Summit in 2019 as a Specialized Agency to improve access to quality, safe and efficacious medical products in Africa.

As a result of this global crisis which has had a far more severe impact on the global south[1], Africa recognized the urgent need to intensify efforts towards strengthening the capacity of the local manufacturing industry to minimize the impact of medical supply shortages. The work of regulators across the continent has been characterized by high pressure to deliver and ensure access to COVID-19 vaccines and other medical products. Five outcome areas were agreed in 2020 under the AMRH programme to strengthen the continental efforts in the fight against COVID-19. The first outcome was to promote harmonization and reliance across countries, regions, and the continent; while the second focused on country adoption of technical guidelines for regulation of medical products. The third outcome aimed to document and disseminate best practices across RECs and evidence of update of those including development of quarterly newsletters and publication of other information, education, and communication (IEC) materials showcasing AMRH success stories and results. Fourthly, the programme was to communicate the key performance indicators (AMRH KPIs) to all stakeholders at least twice a year. The fifth outcome focused on enhanced performance of AMRH Secretariat in support of the AMRH governance, RECs and partners; while the sixth outcome aimed to ensure that the African Medicines Agency (AMA) is launched by supporting the AMA engagement plan with stakeholders.

[1] COVID-19 in the Global South: Impacts and policy responses: http://southernvoice.org/wp-content/uploads/2021/02/COVID-19-Impacts-Policy-Responses-Alcazar-et-al-2021.pdf

Main Achievements in 2020

The summary below is a highlight of some of the main achievements and challenges observed in the year 2020:

Regional Economic Communities

Introduction

In 2020, the main outcome for the AUDA-NEPAD was to have an effective technical coordination mechanism for all African RECs in joint medicine assessment process to assure the 6-month timeline for a regional decision following joint dossier assessment. To achieve this outcome, the AUDA-NEPAD as AMRH secretariat was expected to ensure that, regular planned joint dossier assessments and GMP inspections were held for each REC MRH Programme (EAC, SADC, IGAD, CEMAC/OCEAC/ECCAS, ECOWAS, AMU), and reported on. In addition, quarterly conference calls and at least two face-to-face meetings were to be convened for all REC MRH Programme officials to review progress and share experiences. The AMRH portal was to be developed and maintained under the AUDA-NEPAD website. Furthermore, RECs had to supported through bi-annual monitoring visits, and quarterly monitoring support calls convened with RECs.

The following progress and achievements have been recorded during the reporting period:

Coordination and monitoring of REC MRH Programs

To ensure effective implementation of RECs MRH Programs, AUDA-NEPAD is entrusted with the responsibility of coordination, monitoring and evaluation of the program through engagement with regional MRH Program Officials. This is done through quarterly conference calls and at least two face-to-face meetings a year to review progress and share experiences, and report. However, due to COVID-19 Pandemic travel restrictions, only conference calls were held in 2020.

In 2020, the AMRH Secretariat convened five quarterly conference calls with all REC MRH Program Officials to review progress and share experiences. Meetings held with RECs critically discussed i) implementation of institutional development plans (IDPs) by NMRAs following the WHO Global Benchmarking Tool (WHO-GBT) assessment; ii) Utilisation of Continental Technical Guidelines; iii) Status of ISO Certification; iv) Sustainability of REC-MRH Programs; and v) Challenges faced in the implementation of REC MRH Programs.

To strengthen the monitoring and evaluation (M&E) capacity, four support calls were held for NMRAs and 3 virtual meetings held for the RECs (SADC, EAC and IGAD). The meetings reviewed and finalised the 2018 M&E report for SADC and ECOWAS while planning for data collection for 2019. Awareness was also created on the AMRH M&E indicators and data collection tool for new M&E focal points. New indicators were introduced to be collected at the REC level. With assistance from IGAD, the data collection tool was transformed into google forms for ease of data analysis. The google forms are still to be translated into French and Portuguese.

Joint dossier assessments and GMP inspections

RECs experienced limited joint reviews and good manufacturing practice (GMP) inspections in 2020 due to COVID-19 pandemic travel restrictions. Also, RECs noted long periods of time to conclude virtual dossier reviews.

However, despite the disruptions from the lock down in 2020 due to the COVID-19 Pandemic, the EAC had 3 Joint Assessments and Registration Procedure for Medical Products. Just before the lockdown, two (2) face to face meetings were held between January to February 2020; Four (4) virtual sessions of Joint Assessment running for 4 days (7hrs) was held between April to September 2020; 8 medical products were recommended for registration in 2020; Monitoring timelines for Joint Assessment and Joint GMP Inspections is still ongoing. The EAC reported on its Virtual Joint Review experience in 2020 indicating that online meetings served as a platform to continue with EAC joint regulatory activities during COVID-19 pandemic. However, there was minimal productivity as the number of dossiers reviewed virtually was low compared to face-to-face sessions. It was also not easy to have full quorum during virtual joint reviews due to internet connectivity challenges and schedule of other meetings. There was increase in number of meetings and workload. There is great need for motivation to improve participation of assessors and experts in virtual meetings.

Remote GMP inspections was explored by SADC and several NRAs with a total of 4 joint assessments in 2020. One face-to-face in February and three virtual sessions held with the first virtual joint assessment held from 9 -10 June. Half day sessions were held over two days in August, September, and October 2020. 13 countries participated in the joint assessments– 9 Active members, and 4 Non-active/Observer. On Virtual Joint Inspection experience, SADC reported that 4 manufacturing sites were jointly inspected, including remote inspection. 5 manufacturing sites were assessed through desk review. 15 NMRAs participated in at least one regional joint GMP inspection. Main challenges encountered was the time difference with most applicants as this meant early start to inspections. Also, on connectivity, facilities generally have WIFI in the offices but not manufacturing blocks. Another challenge was that of managing the process where mobile gadgets were used to view parts of the plant.

ECOWAS: 3 manufacturing sites were jointly inspected by the NMRAs (Drugfield, Juhel, CIPLA-Uganda). Three (3) NMRAs were selected (Burkina Faso, Ghana and Nigeria) as eligible NMRAs to serve as the Coordinating NMRAs for the regional joint assessment process. However, FDA, Ghana is currently serving on behalf of the three (3) for effective and efficient work screening and communications with the manufacturers, Expert Working Groups (EWGs), and WA-MRH Secretariat.

IGAD: The region had its first joint assessment meeting in February 2020. On Virtual Joint Review Experience, IGAD had two virtual joint reviews in August 2020 and October – November 2020. The November joint review was held concurrently with a WHO facilitated BE capacity building of more than 40 assessors. Most member states however had Internet connectivity issues. Many virtual meetings also affected the availability of experts.

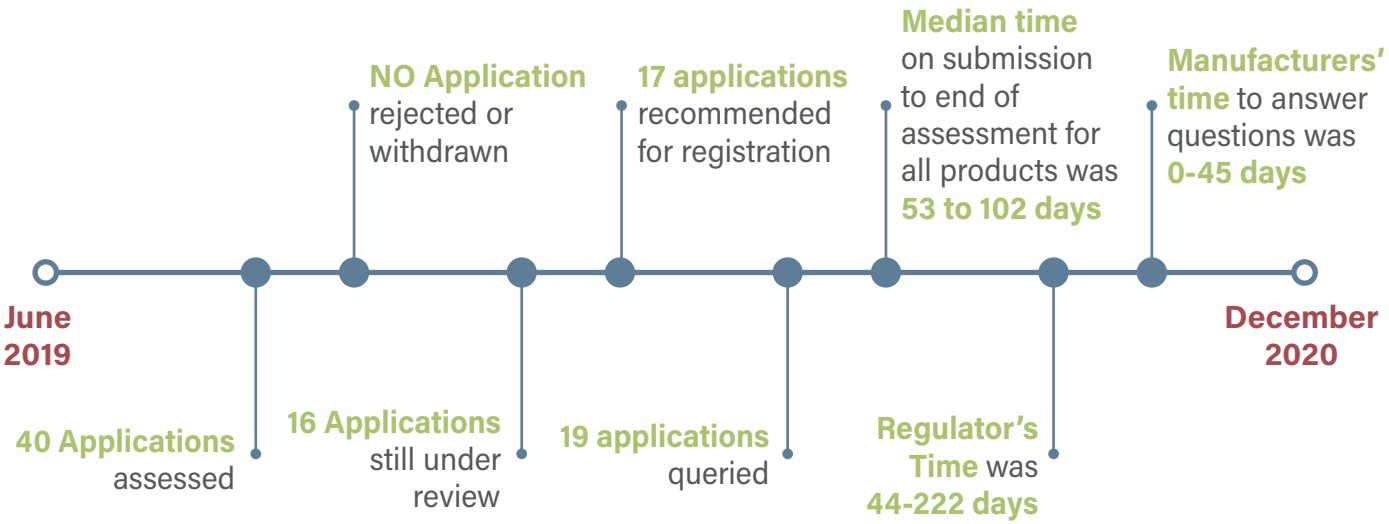
No virtual joint reviews were held in 2020 in ECCAS. However, the plan is to hold several sessions in 2021 including the diagnostic test technical meetings in August and September 2021. No manufacturing sites were jointly inspected by NMRAs.

Timelines for regional decision following joint dossier reviews

All 5 RECs recorded significant progress in meeting the 6-month timeline for regional decision for all applications both at regional and NMRA levels.

EAC

56 Applications were received in the EAC-MRH joint assessment process



Significant improvement on regulators time that has **decreased** in the EAC **from 44-391 days from 2015 to 44-222 days in 2020**

Manufacturers' time has drastically **reduced from 9-927 days to 0-45 days in 2020**

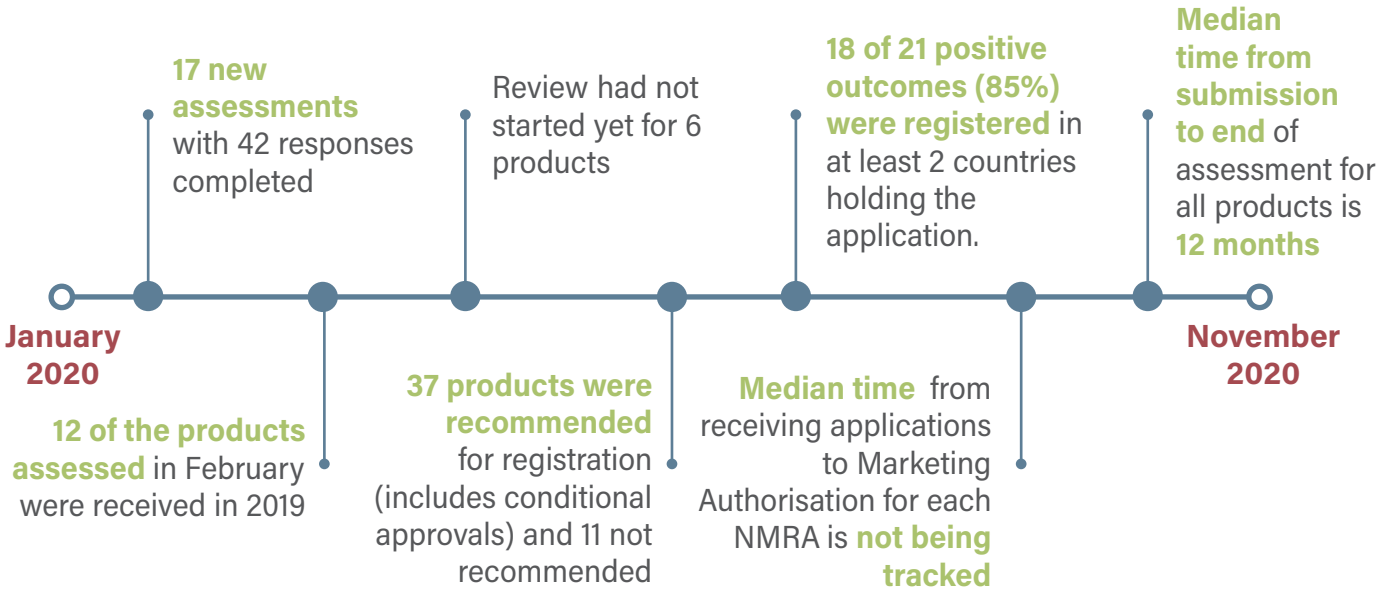
No product was registered in the remaining 3 NMRAs (Rwanda FDA, ZFDA and Burundi DPML)

Out of the 17 applications recommended for registration in 2020 in the EAC, the number of **products registered at NMRA level** also varied greatly with **TMDA registering all 17 products, NDA 7, PPB 4**

Median time from receiving applications to Marketing Authorisation for each NMRA also **reduced significantly to 30-90 days**

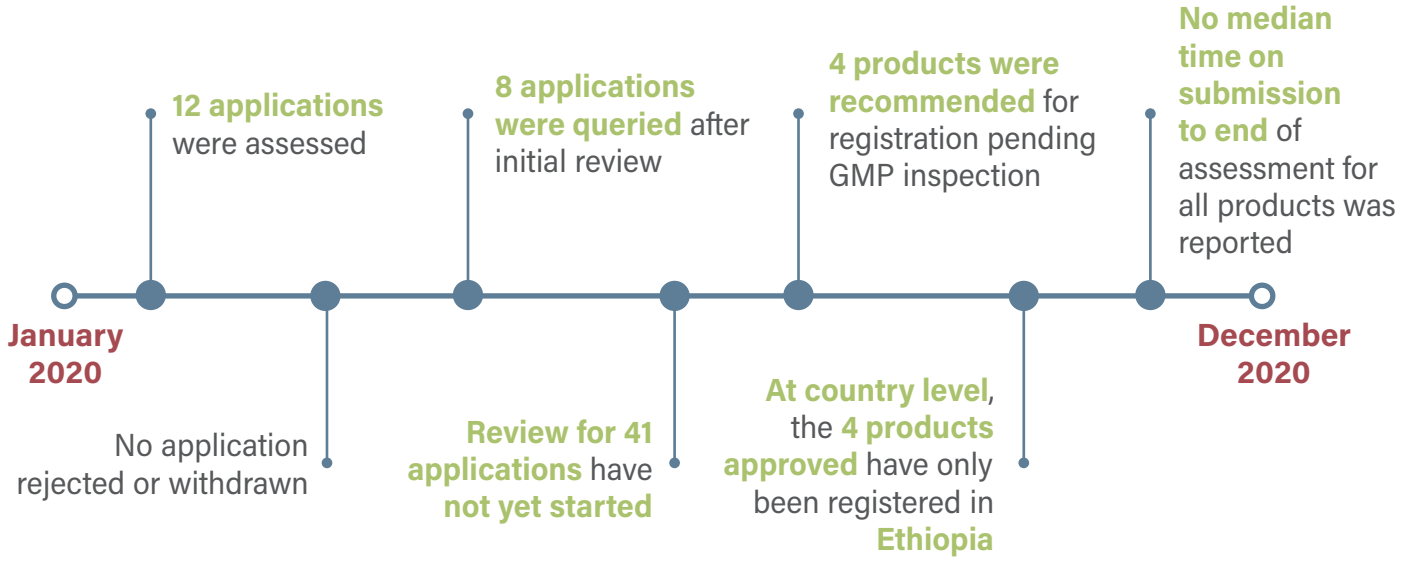
SADC

Key regulatory outcomes for SADC for 2020 (January-November) from the 17 products submitted for joint assessment



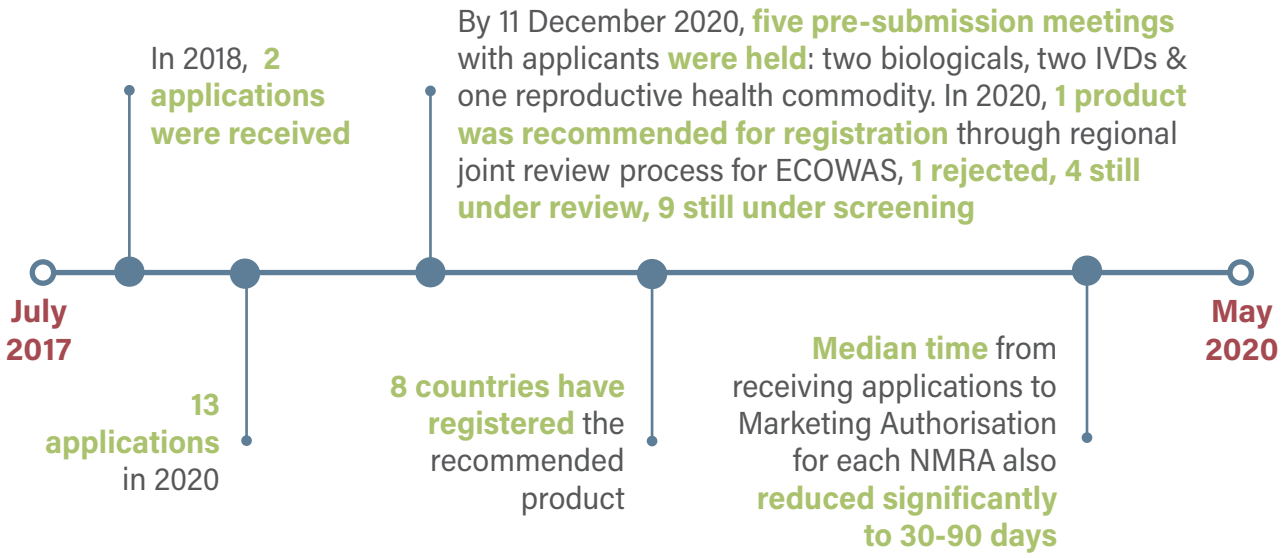
IGAD

A total of 53 applications were received in the IGAD-MRH joint assessment process in 2020



ECOWAS

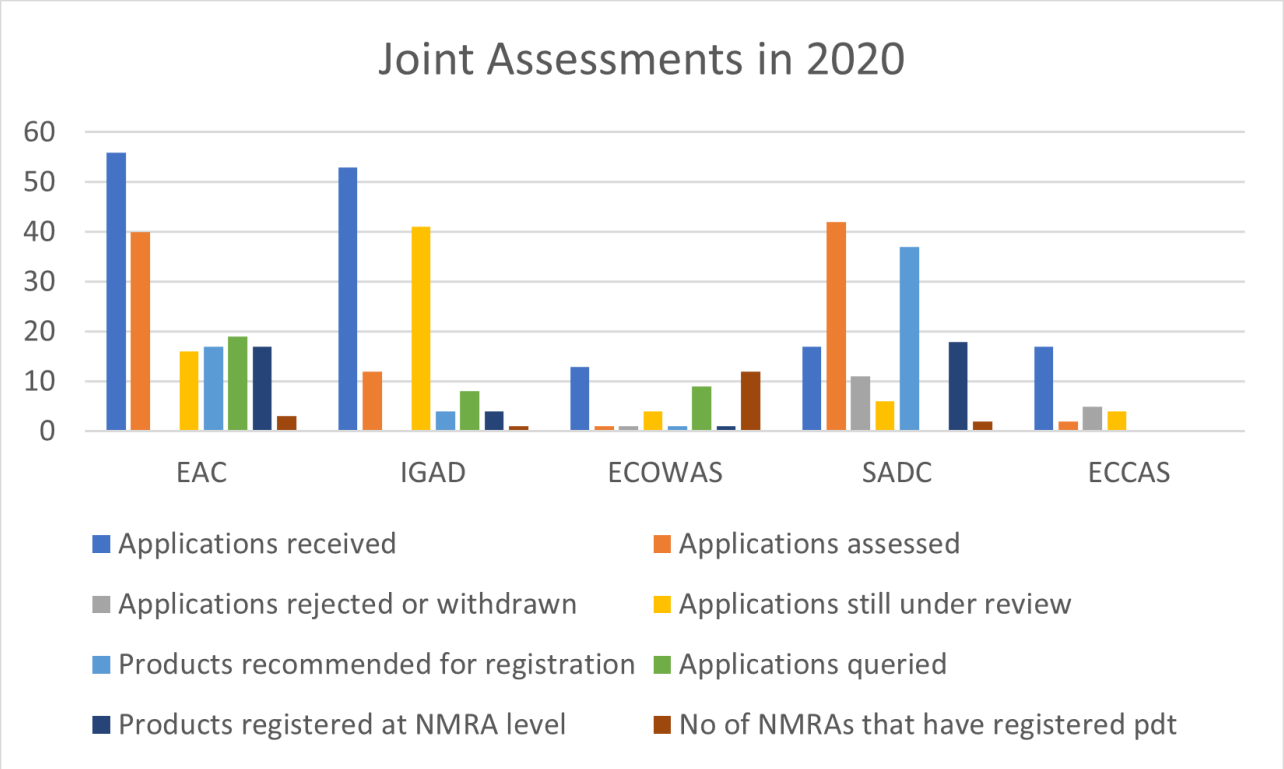
The West African Medicines Regulatory Harmonization (WA-MRH) Project spans from July 2017 to May 14th, 2020.



ECCAS

During 2019/2020 a total of 17 applications were received for the ECCAS-MRH joint assessment process

Table 1: Outcome of Joint Assessments in 2020



Utilisation of Continental Technical Guidelines

Regarding the utilisation of continental technical guidelines, AVAREF guidelines were adopted by the EAC in December 2019. Resources are required to support the domestication of AVAREF guidelines in Member States. In July 2020, AMDF guidance document for assessment of medical devices, list of medical devices, PPEs and laboratory diagnostic test for management of COVID-19 was adopted by Heads of EAC NMRA.

In SADC, Technical experts were nominated for the various Technical Working Groups. There was active participation of the SADC REC in AMDF and AVAREF activities. Domestication of guidelines was not reported.

For ECOWAS, domestication of the AVAREF guidelines in ECOWAS is done through the collaboration of the WAHO and WHO AFRO. ECOWAS aligned the regional registration pathway to the COVID-19 Vaccines to AVAREF' regulatory pathway. ECOWAS is also committed to domesticating the AMDF guidelines and used the guidelines for the 2nd EOI publication. ECOWAS has two Member States represented in AMDF Technical Committee and 6 Member States in the various Sub-Technical Working Groups of AMDF.

IGAD circulated and sensitised to member states for domestication, the AMDF and AVAREF continental guidelines during the Head of NMRAs meeting held in August 2020 and Horn of Africa Initiative Workshop that took place in October 2020.

Central Africa has welcomed the use of these guidelines as they have not yet been developed in the region and are willing to adopt these continental guidelines. Currently, the guidelines are being implemented at different levels in the Member States. The clinical trials (AVAREF) guidelines have been of great benefit to the ethics national committee and NRA in the conduct of a few clinical trials that occurred prior to the occurrence of COVID-19 and they will be useful in assessing the effectiveness of the new therapies regarding ongoing Covid-19. The AMDF guidelines- a sub-regional roadmap will be presented to the meeting of this technical working group including reporting on the establishment of the technical working group on medical devices in Central Africa. Cameroon has conducted a series of tests on COVID – 19 medical devices. OCEAC continues to encourage other member countries to move in this direction.

Implementation of IDPs

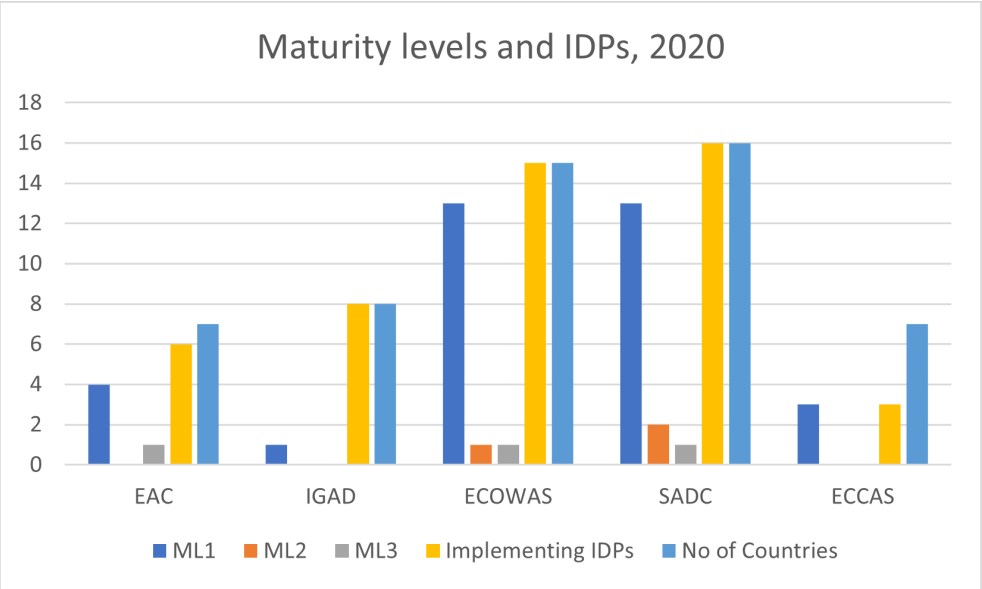
For the EAC NMRAs, apart from Burundi, NMRAs were all at different stages of implementation of IDPS and maturity levels (ML). 4 NMRAs at ML1 and 1 NMRA at ML3.

SADC support to NMRAs included face-to-face training and twinning activities; convening sensitisation workshops for dissemination of guidelines and QMS documents; and conducting online GMP diploma. Virtual training was supported through hiring of consultants and partnering with WHO & Swissmedic. NMRAs continued with implementation of IDPs and reported progress using a simple tracking tool that allows NMRAs to share progress.

In IGAD, Implementation of IDPs is on-going in all the member states.

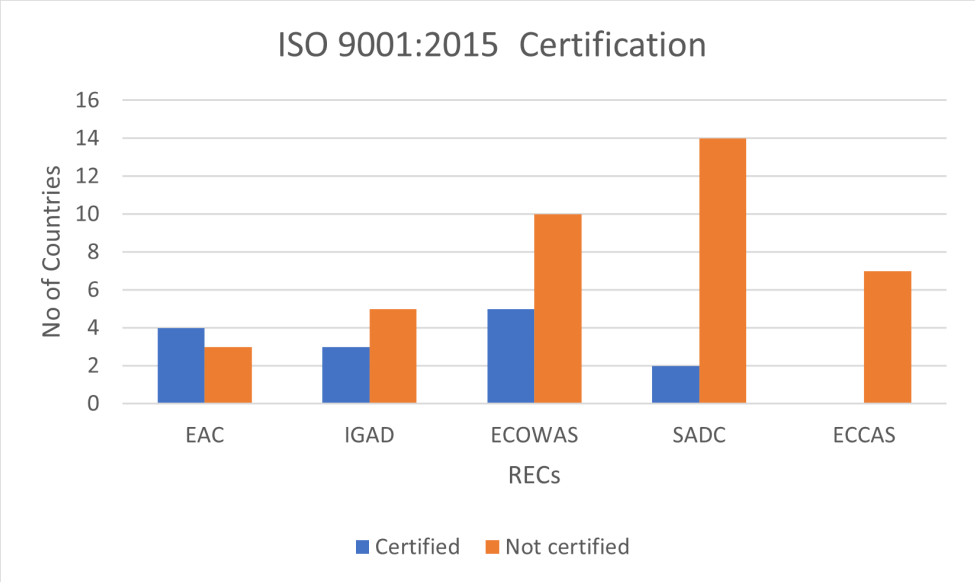
In ECOWAS, the FDA-Ghana achieved the WHO GBT ML3 effective from 15 April 2020. NAFDAC-Nigeria is working towards ML3 from the current ML2. With the WA-MRH project funds most of NMRAs have strengthened their specific key components (QMS, IMS, Registration process, aligned policy and regulation, GMP inspection, Websites, Governance structures-autonomous, documentations). WHO provided support to NMRAs to ensure that the IDP of each NMRA is completed by addressing the key indicators.

IDP implementation in the ECCAS Member States is still at its infancy especially as the first self-assessments using the GBT Tools only started in February 2020 and was interrupted by COVID-19. This exercise was restarted again in July/August 2020 and will be finalised in January 2021. Despite the COVID-19 pandemic, OCEAC, WHO and the World Bank are actively following up on member states for the implementation of the IDPs. To date, Cameroon, Chad, Gabon finished the self-assessment exercise and their IDPs are ready for implementation. In July & August 2020, 40 experts were trained online including financial managers.



Status of ISO Certification

In the EAC, four (4) out of the seven (7) EAC NMRAs are ISO 9001:2015 certified. These include 2 from United Republic of Tanzania (TMDA & ZFDA), Republic of Kenya (PPB) and Republic of Uganda (NDA). In SADC, out of the 16 Member States, 2 NMRAs were ISO certified. Tanzania certified in 2009 and Zimbabwe certified in May 2019. In ECOWAS, 5 NMRAs have achieved ISO 9001:2015 (Ghana, Nigeria, Sierra Leone, Liberia, and The Gambia). In the IGAD region, 3 member states are ISO certified namely Ethiopia, Kenya, Uganda. In ECCAS, no NMRA in the region has finalised the ISO certification process. Gabon is considering it in the short term after its effective transition to an autonomous agency. LANACOME (National Control Laboratory of Cameroon) is in the process of ISO certification.



Challenges experienced by RECs

RECs experienced various challenges in implementing the MRH Projects in 2020. These include limited resources (finance) to sustain program activities; limited information sharing platforms due to lack of IT infrastructure; Internet connectivity which hindered effective participation in regional joint activities by experts from less resourced NMRAs. Although virtual meetings have allowed continuity of harmonization efforts, they are however, not always optimal due to disruptions noted during joint review sessions and meetings. Generally, less productivity has been observed through virtual meetings. There is need for facilitation of experts with internet bandwidth and other incentives to facilitate full participation.

Support To AMRH Governance Structure

Introduction

The AMRH Governance Structure was established in 2017 with a view to provide strategic direction on regulatory systems strengthening and harmonization interventions, ensure convergence and alignment at regional and continental levels while fostering ownership by Member States, collective responsibility, mutual accountability, and sustained impact.

It is comprised of the African Medicines Regulators Conference (AMRC), the AMRH Steering Committee, AMRH Technical Committees (TCs), AMRH Partnership Platform (AMRH-PP) and the AMRH Joint Secretariat with clear roles of all the entities. The AMRC is an assembly of all heads of NRAs in AU Member States and serves as a platform for the overall decision-making in the AMRH governance framework. AUDA-NEPAD in collaboration with WHO serve as Joint AMRH Secretariat to support the governance structure while the three institutions (AUDA-NEPAD, WHO and AUC, jointly support the work of the African Medicines Agency (AMA).

The AMRH Steering Committee composed of Heads of NRAs representing the AU geographic regional and RECs coordinators of MRH Programs, is responsible for identifying priorities and providing strategic direction in strengthening regulatory systems and harmonization initiatives for medical products in Africa. The SC is responsible for monitoring the work of AMRH TCs and RECs MRH Programs while providing oversight and guidance in the management of the AMRH PP. This included resource

mobilization strategies and sustainability plans for strengthening regulatory systems and harmonization initiatives for medical products in Africa.

AMRH Steering Committee

Introduction

Due to the COVID-19 pandemic, the meetings of the AMRH SC were all held virtually in 2020. In March 2020, the pandemic had just hit many countries around the world. 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. Later in the year, members of the 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. The last meeting of 2020 was held during the second AMRH week which took place from the 9th to the 10th of December 2020. Despite the challenges faced by RECs and TCs in terms of the new virtual environment in which they had to carry out their work, they still manged to report many successes. The SC was also able to provide the guidance needed during the challenging period.

Progress and achievements for the reporting period

In March 2020, The AMRH SC considered reports from RECs on MRH Projects implementation status; progress on AMRH Partnership Platform; updates on the Paediatric Regulatory Network (PRN); updates on development of continental Regulatory Information Management System (RIMS); updates from AMRH-TCs; AMRH-AMA Operational Strategy proposal; and proposed country engagement plan for AMA; and updates on traceability. The SC also took note of progress made by the AVAREF, AMQF, MPRR, AMDF and ABRF. During this meeting, the AMRH SC also approved the proposal to establish an interim continental 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 and the AMRH partnership platform.
The AMRH SC advised Member States to adhere to timelines for submission of their WHO Global Benchmarking tool (GBT) assessment reports and institutional development plans to WHO and to 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 for example the WHO Listed Authority (WLA) Policy Framework. The SC agreed with a proposal to include medical devices in the GBT and in the REC work plans. On the 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 included; 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 and iv) The need for tracking RECs progress using AMRH indicators.

The 7th AMRH SC discussed on among other things, progress on implementation of regional medicines regulatory harmonization initiatives,

progress made by the AMRH Partnership Platform, and the four (4) AMRH TCs namely AVAREF, AMQF, AMDF, ABRF TC and 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 mechanisms 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 RECs 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) held in October 2019. It was agreed that the planning for SCOMRA V and AMRC VII 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.

The 8th AMRH SC took place during the 2nd AMRH Week which took place from the 9th to the 10th of December 2020. The AMRH week gathered over 120 participants from Africa and other parts of the world and showcased the good work done by regulators and ethics committees in preparation for COVID-19 clinical trials review, preparations for registration and monitoring of the safety of vaccines, listing of medical devices including in vitro diagnostics and manufacturing of devices and PPEs as part of COVID-19 response. The meeting was opened by a high-level panel made up of senior dignitaries who are leading in organisations that are assisting African member states to gain the capacity, resources, and expertise necessary to fight the challenges COVID-19 has brought about.

The second half of the meeting was focused on highlighting the work of the TCs and the AU Smart Safety Surveillance Project (AU 3S) to showcase how regulators on the continent have through innovations and adaptation provided regulatory oversight of products against COVID-19, galvanized partnerships, promoted collaboration and harmonization, and how this can rapidly lead to the establishment of the AMA. The AMRH SC to discussed progress on implementation of the RECs MRH and the RIMS TC technical committee. The AMRH SC further held a discussion on collaboration among Heads of NMRAs which focused on feedback from Regional Consultations with Heads of Agencies representing RECs.

AMRH Partnership Platform

Introduction

The AMRH Partnership Platform (AMRH-PP) was established in 2018 by the AMRH Steering Committee 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 30 partners constituting the AMRH-PP providing support in different thematic areas based on needs identified by the AMRH Technical Committees. This is in addition to the AMRH Core Partners, including those that direct their support for regulatory systems strengthening and harmonization through WHO and AUDA-NEPAD as Joint Secretariat. These include the Bill & Melinda Gates Foundation (BMGF), the Swiss Agency for Development and Cooperation (SDC) and the World Bank Multi-Donor Trust Fund for Global Medicines Regulatory Harmonization (which included funds from BMGF, DFID, now FCDO, and Gavi-the Vaccines Alliance).
Members of the AMRH-PP do participate in Joint Action Groups – or JAGs – linked to each AMRH

Technical Committees to discuss thematic areas that require technical and/or financial support. Most of the JAGs meet quarterly to enable partners to update each other on their activities and to learn about the progress in each Technical Committee. While AVAREF TC is actively engaging with various partners on the AMRH-PP, this report focuses on the African Medical Devices Forum (AMDF), the African Quality Medicines Forum (AMQF), and the African Blood Regulators Forum (ABRF) TCs.

Progress and achievements for the reporting period

In 2020 the AMRH Joint Secretariat held bilateral discussions with about twenty partners, focusing on the workplans of AMDF, AMQF, and ABRF, exploring areas needing immediate or longer-term support and collaboration. This 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. AMRH-PP is becoming a vibrant platform that is growing year by year, seeking to enrich the efficiency and effectiveness of regulatory systems strengthening and harmonisation efforts on the continent. The support needed has never been more important than now in the face of a global COVID-19 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 joint reviews for key groups of essential medical products. The AMRH-PP offers an important channel for galvanising a coordinated and effective response to the COVID-19 crisis to ensure that such support systems are sustainable, relevant and have the potential for the best possible impact on public health.

Partners provided support to TCs based on identified thematic areas as part of the annual workplan as follows:

AMQF TC: Strengthen capacity and quality management systems (QMS: and regional post marketing surveillance studies.

AMDF TC: Development and implementation of a harmonized regulatory framework for medical products regulation; establishment and strengthening information sharing platforms; and support to improve human resource capacity

ABRF TC: Training workshop on hemovigilance; general funding and technical assistance; financial support and translation services.

Annex 1 provides in detail the type of support provided by different partners to the various TCs, including the implementation status.

AMRH Technical Committees

African Medicines Quality Forum (AMQF)

Introduction

The African Medicines Quality Forum (AMQF) is the quality assurance arm of the AMRH initiative playing a key role in assuring the quality of medicines circulating on the African markets. It is an evolution emanating from the Network of Official Medicines Control Laboratories (NOMCoL)-Sub Saharan Africa, whose 2009 inception was funded by United States Agency for International Development (USAID) and subsequently supported by United States Pharmacopoeia (USP). The AMQF was established in 2017 as a collaboration between USP, AUDA-NEPAD and West Africa Health Organization (WAHO) to build and strengthen the capacity of African countries in medicines quality control and regional post market surveillance (PMS) which in turn, will contribute into efforts to reduce sub-standard and falsified (SF) medical products circulating in the African markets. AMQF is expected to drive the harmonization of QC standards and practices and, ultimately, the mutual recognition of QC tests among African countries. It is a platform for a holistic continental QC agenda that facilitates sharing of best practices, promoting cooperation among National Quality Control Laboratories (NQCLs), setting conformity assessment standards, providing technical leadership in quality control, and serving as an advocacy platform to raise the national, regional and international visibility of the work of NQCLs in Africa. AMQF is a forum open to heads of NQCLs from all African countries and the Technical Committee (TC) is made up of 13 members. The TC reports to the AMRH Steering Committee.

Progress and achievements for the reporting period

Three annual AMQF meetings have been held since 2018. At the Forum's first annual meeting held in February 2018 in Tanzania, the draft Terms of Reference (ToR) for AMQF and its TC were deliberated, members of the TC were proposed, approaches and concrete actions to address key administrative, organizational and technical issues that impede effective operations of NQCLs were recommended. The latter recommendations informed the content of the Forum's 2018 workplan. The proposed TC members were subsequently endorsed by the AMRH steering committee, and the first AMQF-TC meeting was held in August 2018. During this meeting, the AMQF governance structure was finalized, the chair, vice-chair, rapporteurs, and communications focal person of the TC (who are to serve also in the same capacity for AMQF) were elected.

During the second annual AMQF meeting held in February 2019 in Morocco, the TC members were formally introduced to the entire Forum. Other issues discussed during the meeting were, solutions to financial sustainability of AMQF under AMRH. The successful accomplishment of the 2018 workplan activities was also reported and a 2019 workplan was finalized. A second AMQF-TC meeting was held in Victoria Falls, Zimbabwe as part of AUDA-NEPAD's fourth scientific conference on medical products regulation in Africa. During this meeting progress on the 2019 workplan implementation was reviewed and AMQF members and the Joint Action Group (JAG) representatives were accorded the opportunity to interact. In addition to this, the ToR was revised to conform to the new model ToR for AMRH TCs (this resulted in the change of name from AMQF-TWG to AMQF-TC). The new ToR model stipulates that AMQF reports to the AMRH through the AMQF-TC which is responsible for steering the affairs of the network.

The third annual meeting was held in February 2020 in Abuja, Nigeria where the AMQF 2020 work plan was presented. There was a presentation on the roadmap for strengthening the NQCL infrastructure and systems where several NQCLs were categorized into four groups according to their capacity. The various NQCLs were also sensitized on the importance of drafting laboratory strategic and business plans as well as having the right legal mandate and the importance of instrumentation and analytical techniques were emphasized. There was also a break-out session to design regional RB-PMS programmes that AMQF could play a role in, followed by an interactive panel discussion on financial sustainability of AMQF.
The third annual African Medicines Quality Forum (AMQF) meeting took place from February 24 to 28, 2020 in Abuja, Nigeria. The objectives of this 3rd annual meeting were to:

1. Finalize the draft 2019 AMQF report including implementation of the 2019 AMQF workplan and present this in plenary.
2. Reinforce the importance of quality control laboratories in post marketing surveillance by drawing up a proposal for regional/cross border survey of medicines of Public Health Importance in Africa.
3. Complete the roadmap for strengthening NQCL infrastructure and systems to help make informed, reliable and consistent regulatory decisions.
4. Emphasize the importance of instrumentation and analytical techniques in quality control for the entire drug approval process: Manufacturing to Post-marketing.
5. Sensitize NQCLs on the importance of drafting laboratory strategic and business plans as well as having the right legal mandate to ensure continual provision of QC testing that meet international standards of quality.
6. Generate a discussion with international partners for future funding of AMQF meetings and activities.
7. Review result from 2019 ILT and plan for 2020 round of ILT
8. Finalize, present and advocate for the 2020 AMQF workplan including sharing lessons learned from 2019, focusing on the challenges and how they can be overcome in 2020.
9. Detailed thematic areas which were supported, and implementation status is provided in Annex 1.

African Medical Devices Forum (AMDF)

Introduction

The African Medical Devices Forum (AMDF) formerly known as Pan Africa Harmonization Working Party (PAHWP) was formed by medical devices regulators in Africa with the aim of improving access to safe, quality and performance of medical devices including in vitro diagnostics in Africa though harmonized regulation. AMDF aims to study and recommend ways to ensure medical devices and diagnostics are safe and effective while minimizing delays and allowing faster access to varieties of medical devices and diagnostics. The AMDF was conceived in 2012 following stakeholder meetings in East Africa, with an interim secretariat within the East African Community under a project facilitated by the London School of Hygiene & Tropical Medicine (LSHTM) with grant funding from Grand Challenges Canada (GCC) collaborating with the Asian Harmonization Working Party AHWP and the Latin America IVD Association ALADDIV. Founding members include the East African Community Health Secretariat (EAC) and the EAC Partner States (United Republic of Tanzania, Uganda, Kenya, Rwanda and Burundi), Ethiopia, Nigeria and South Africa and the London School of Hygiene & Tropical Medicine. Partners include German International Co-operation (EAC-GIZ), the African Society for Laboratory Medicine (ASLM) and the World Health Organization (AFRO, WHO).

The formation of AMDF was announced in a satellite symposium at the African Society for Laboratory Medicine Conference on 3rd December 2012 in Cape Town. The EAC Regional Task Force on Regulation of Medical Devices and Diagnostics meeting which was held in April 2013 in Dar-Es-Salaam approved the proposed structure which was presented at the 1st African Regulatory Forum on Medical Diagnostics in July 2013. In the same year, June 2013, AMDF officially requested to work under the AMRH Framework so that AMDF Secretariat is set up at AUDA-NEPAD and the Chairperson was given seat as a member of the AMRH Advisory Committee.

It is based on this background that in April 2018, the 2nd meeting of the Steering Committee (SC) on Regulatory Systems Strengthening and Harmonization Initiatives in Africa, as a successor of the AMRH Advisory Committee, approved the alignment of AMDF as part of

the new AMRH Governance Framework. The SC directed the AMDF to work out modalities of establishing a Technical Working Group (TWG) on medical devices and diagnostics regulation in Africa under the AMRH Program.

This is in line with alignments of various harmonization initiatives and networks that have been ongoing 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. 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.

Progress and achievements for the reporting period

Africa Medical Devices Forum (AMDF) TC leadership and AMRH Joint Secretariat conducted a meeting on 31 March 2020 to discuss and provide recommendations on how to address the COVID-19 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), Africa CDC and WHO experts. The Task Force created four (4) separate working groups to address challenges faced by AU 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. In addition, technical working groups (TWGs) to work on specific areas such as pre-market and post-market surveillance were established. Other areas that AMDF TC had worked on in 2020 are provided in Annex 1.

The following guidance documents have been developed for use by the AU Member States:

1. Guidance documents to facilitate importations, regulatory approvals, procurement, donations and manufacturing of in-vitro diagnostics (IVDs), medical devices and protective personal equipment (PPEs) were developed and shared with AU Member States.
2. A list of COVID-19 NAT diagnostic tests; more than 374 medical devices and PPEs; licensed domestic manufacturers of medical devices and PPEs; authorised ventilators and masks were developed.
3. Reporting form for substandard and falsified in vitro diagnostics and medical devices; and Guidance for donations for in-country use during emergencies issued and available on AUDA-NEPAD and WHO websites were also developed.

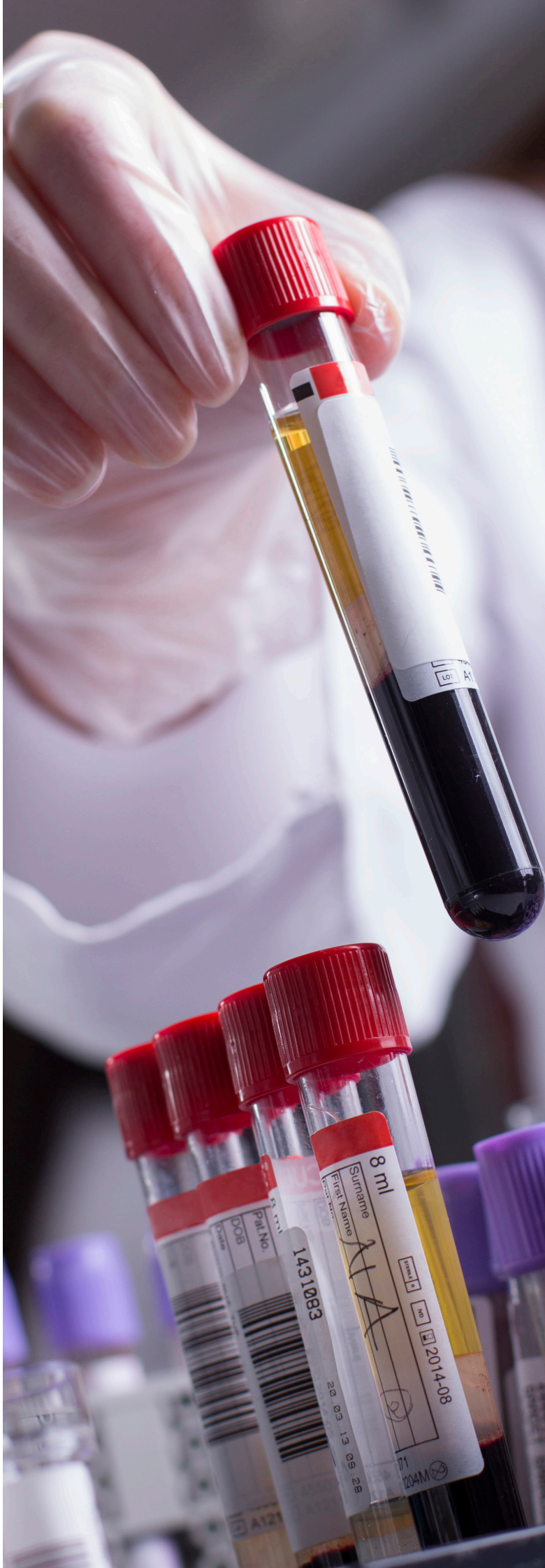
African Blood Regulators Forum (ABRF)

Introduction

The concept of a Forum for blood regulators in Africa was raised several times as a possible continental approach toward promoting national advancements as well as international harmonization in this area. At a WHO hosted Regional Workshop on the Regulatory System for Blood and Blood Products, held in Douala, Cameroon in March 2018, representatives of NRAs and blood operators in 20 African countries spanning all the eight Regional Economic Communities (RECs) of Africa reached a consensus to cooperate in establishing a Forum for blood regulators in Africa. The concept to establish the ABRF as a Continental Technical Working Group (CTWG) of the African Medicines Regulatory Harmonization (AMRH) Initiative was endorsed by the AMRH Steering Committee (AMRH SC) in December 2018. The Africa Blood Regulators Forum (ABRF) was officially launched during the sixth African Medicines Regulators Conference (AMRC) held from 2nd-4th October 2019, in Victoria Falls, Zimbabwe.

Progress and achievements for the reporting period

A Joint Action Group (JAG) meeting for the ABRF was held on the 17th of November 2020. The aim of this JAG meeting was to advocate to partners to support technical committees of the ABRF. The meeting focused on activities for 2020/2021, highlighting planned outputs and expected outcomes as well as the activities that urgently need support from the partners. The partners also gave an update on how the ABRF can secure funding and support from their institutions. Participating partners in the meeting the included PEI, EFS, US FDA, ISBT, EDCTP, BMGF, WHO, AUDA-NEPAD.



A Haemovigilance workshop for Burundi and Zambia funded by the ISBT took place from the 20 – 23 October 2020. A workshop report was prepared and submitted to the ISBT for publication in the March 2021 issue of Transfusion Today (ISBT magazine for members). Under the umbrella of ABRF, WHO AFRO with the EFS was to identify follow-up activities that can be implemented for Burundi. The PEI was working with the team in Zambia to support the development of haemovigilance system documents such as, the Haemovigilance framework, reporting guideline and supporting them in the process of developing their Blood Regulations. WHO expressed the need replicate the haemovigilance workshops in other countries in the African region in 2021 subject to availability of financial support and human resources.

Three Sub Working Groups from ABRF Task Groups to develop specific guidelines for the ABRF for use in Africa. Progress made by the SWG is provided below:

COVID-19- The SWG on COVID-19 developed a COVID guidance that supports countries in Africa to establish organized systems around the collection and use of convalescent plasma therapy[2] in their countries. The guideline is also aimed at providing a means of harmonizing the collection of convalescent plasma by regions in different African countries.

Guideline on GMP and GMP inspecting for blood establishments- The SWG on GMP aims to develop the following guidelines which started in 2020:1) guidance documents on GMP for blood establishments in Africa; 2) guidelines for the submission of quality documentation for authorization and licensing of blood establishments and 3) Guideline on inspection. Initially, three groups were formed in 2020 and were tasked to develop outlines for the mentioned three guidance documents. The plan was to then develop the guidelines simultaneously. However, due to the workload involved, it was agreed that the whole SWG works on one guideline at a time. Beginning with the GMP guideline for Blood Establishments in Africa. Several meetings have been held to put together and review the first draft document and the SWG is now in the process of finalizing the draft GMP guideline.

Development of stepwise approach and framework for blood regulation in Africa- The SWG several times so far and now have an almost final draft of the guideline. In the next meeting planned for the 3rd of March, this draft will be finalized, and later sent to external experts for comments. Once the expert comments are integrated, it will be circulated to the members for their comments after which the draft guideline will be finalized.

Information Management System (IMS) Technical Committee

Introduction

The Information Management System Technical Committee (IMS TC) for the AMRH Initiative was established in 2019. Members of this TC are composed of IT experts and REC representatives from all 5 RECs implementing MRH Programs namely IGAD, EAC, ECCAS, ECOWAS and SADC. The scope of this technical committee is to support and develop information systems and work sharing platforms as an essential component of regulatory convergence and reliance among the RECs in African Continent in alignment with African Medicine Regulatory Harmonization (AMRH) Initiatives. The development and maintenance of the AMRH portal is therefore part of the scope of the IMS TC. To achieve this objective, the IMS TC through two (2) face-to-face meetings and fifteen (15) virtual meetings.

Progress and achievements for the reporting period

- Developed terms of reference (TOR) for the Technical Committee on Regulatory Information Management System
- Developed Continental IMS Project Work plan.

[2] Convalescent plasma therapy uses blood from people who have recovered from an illness to help others recover

- Developed System Requirement Specification for Continental Information Sharing Platform
- Developed Prototype Continental Information Sharing Platform
- Developed Prototype AMRH Website
- Developed TOR for Consultant conducting situation analysis for the Continental Regulatory information Management System (C-RIMS)
- Reviewed the Continental Regulatory information Management System (C-RIMS) Consultant Project Plan and its approval
- Reviewed the Continental Regulatory information Management System (C-RIMS) Consultant's work and final report on scoping of Regulatory Information management systems in Africa.
- Configured Server for Hosting Continental Information Sharing Platform
- Revising the backend structure of the Continental Information Sharing Platform to allow interoperable to the Drupal (PHP) front end and Integration to the new NEPAD front END on the Website

African Medicines Agency (AMA)

Introduction

The African continent in 2020 faced significant challenges of fast approval of clinical trials, marketing authorisation, importation and procurement of good quality, safe and efficacious medical products including medicines, vaccines, in-vitro diagnostics, and medical devices for prevention and/or treatment of COVID-19. The establishment of the African Medicines Agency (AMA) a specialised Agency of the African Union (AU) is critical at this time and will be instrumental in the coordination of joint review of specialised medical products with a view to provide scientific opinion and guidance to AU Member States. AMA will also coordinate the ongoing regulatory systems strengthening and regional harmonization programs under the African Medicines Regulatory Harmonisation Initiative (AMRH) while at the same time providing AU member states with improved sovereign control in the regulation of medical products. AMA will support AU Member States with improved regulation, to eradicate the continent of substandard and falsified medical products.

Progress and achievements for the reporting period

The AMA Treaty[3] was adopted by the 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. As of December 2020, four (4) countries ratified the AMA treaty, namely, Burkina Faso, Mali, Rwanda and Seychelles while eighteen (18) countries signed the Treaty, namely, Algeria, Benin, Cameroon, Congo, Chad, Gabon, Ghana, Guinea, Madagascar, Mali, Morocco, Niger, Rwanda, Sahrawi Arab Democratic Republic, Senegal, Seychelles, Sierra Leone, Tunisia. It is important to note that for a member state to be considered as a country that has ratified the Treaty, they need to deposit their instrument of ratification and accession at the Office of Legal Affairs of the AUC.

In recognition of the need to facilitate the AMA Treaty ratification process, the AUC convened a consultation meeting with AUDA-NEPAD and WHO on 20-21 February 2020 in Addis Ababa, Ethiopia which was aimed at ensuring a coordinated effort from all stakeholders towards the establishment of AMA. The objective of the consultation was to map the activities to be undertaken leading up to the establishment of the AMA once the fifteenth (15th) instrument of ratification has been deposited.

To streamline the process of engaging Member States regarding the Treaty ratification, an AMA country engagement plan was developed and approved for use in March 2020. The main objective of the plan is to acquire 15 countries ratification by end of 2021 with the country engagement being guided by four strategic priorities including, supporting ratification for member states which have signed the AMA Treaty as well as those who have embraced the Treaty objectives, Leverage engagement opportunities using existing platforms to build support for AMA, as well as creating widespread awareness through publications and media engagement.

The AMA engagement plan also encourages the use of Champions or senior advocates to support advocacy for AMA ratification. According to AUC, the AU Champions are at the Heads of State and Government level but there is need to engage the senior advocates at the level of Ministers in regions where there has been very low signing of the AMA Treaty. Hon. Michel Sidibé, former Minister of Health of Mali and Former Executive Director of UNAIDS, served as the senior advocate for AMA in the West African region in 2020.

[3] AMA Treaty: https://au.int/sites/default/files/treaties/36892-treaty-0069_-_ama_treaty_e.pdf

AUDA-NEPAD also took part in the SADC Ministers of Health Meeting in November 2020 and had the opportunity to engage on the need for urgent ratification of the AMA Treaty by SADC member states with commitments to ratify coming from Eswatini and Namibia.

To reach different target audiences, a package of communication tools was developed which included:

1. Briefing notes for NMRAs on the ratification process of each country
2. A Model Cabinet Paper on the AMA ratification process
3. An AMA video, which explains the role of AMA and encourages AU Member States to sign or ratify the Treaty
4. AMA Knowledge Portal Page on the AUDA-NEPAD website
5. AMA Brochures with information on what the AMA Treaty is all about; why is it necessary, what is AMA's purpose and its benefits to the Member States, and what do Member States need to do to ratify the Treaty.

Advocacy partnerships were also established with the AUC, WHO, World Bank, PATH, International Federation of Pharmaceutical Manufacturers & Associations, and other partners to deliver the strategic priorities of the AMA engagement plan through financial and/or technical support.

African Union Model Law On Medical Products Regulation

Introduction

The adoption of the African Union Model Law on medical products' regulation was borne from the realisation of Africa's Heads of State and Ministers for Health concern about impact of the proliferation of substandard and falsified medical products on public health. Therefore, to ensure that Africa to ensure the products circulating African pharma markets are of assured quality, safety and efficacy, the regulatory systems within and across countries need to be strengthened and this requires the right legislative environment. The AU Model Law was officially adopted by African Heads of State and Government at the AU Summit in January 2016, in Addis Ababa, Ethiopia. It provides a template for countries to harmonize their regulatory frameworks and outlines the key functions and standards which should form part of the regulatory system.

> *"A unique feature of the Model Law process is the extent of stakeholder consultation and participation in the development of the legislation, which took place during 2014-2015. The Model Law process is not an isolated development, but is complemented by partnerships, regional integration initiatives, incorporation of global best practices in medicines regulation, and a pharmaceutical plan for the continent. These elements will go towards ensuring the Model Law's relevance and sustainability."*[4]

Progress and achievements for the reporting period

In 2018/19 through 2020 with the support of the Technical Working Group on medicines policy and regulatory reforms, RECs, UNDP and World Bank, AUDA-NEPAD undertook to assess through various surveys the status of alignment of the countries' laws on medical products regulation and how aligned they are with the AU Model Law. The aim was to identify gaps and provide targeted technical assistance. According to the AMRH strategic plan which ended in 2020, the target was to have 25 countries domesticate the Model Law by 2020.

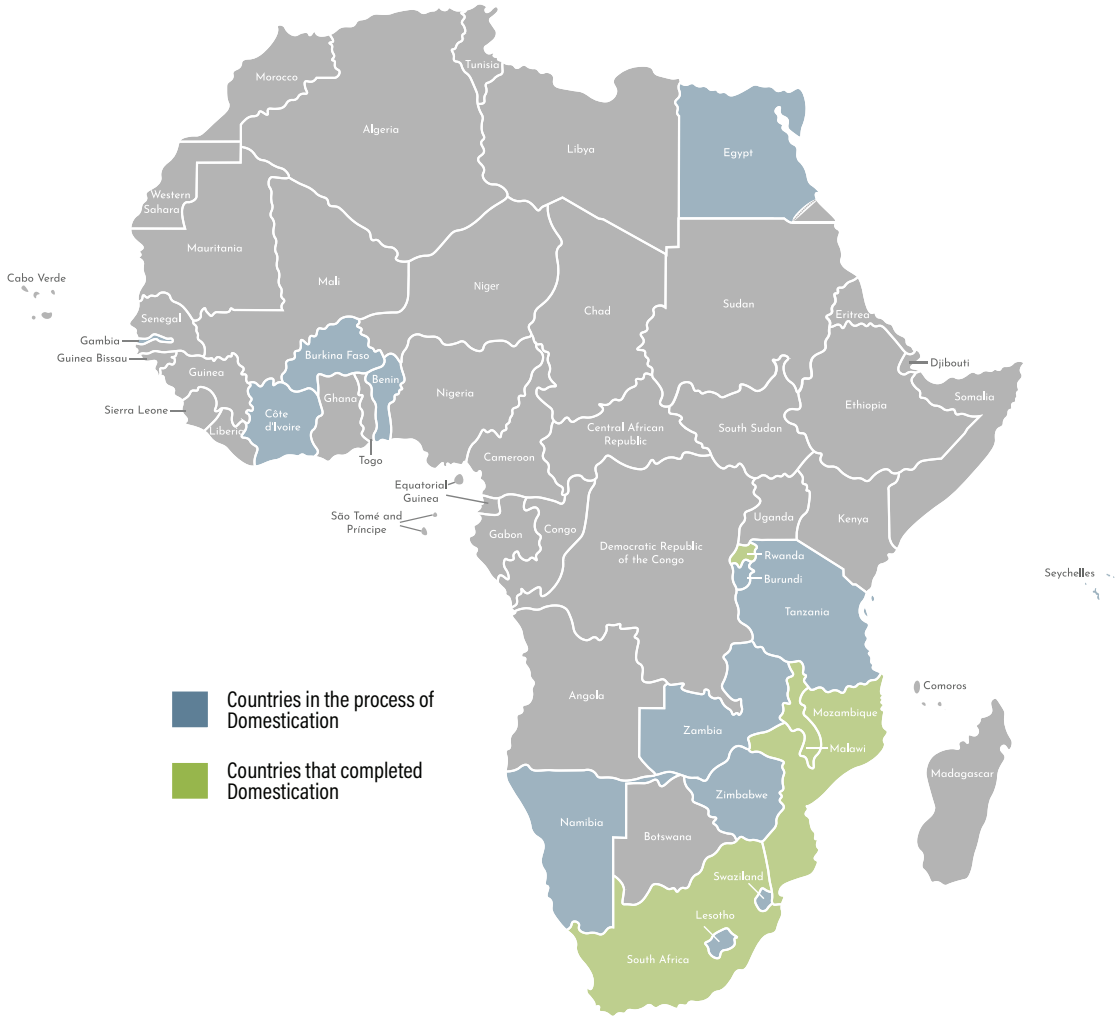
Based on the survey findings, AUDA-NEPAD with the support of UNDP undertook to draft guidance documents that provide countries with material on understanding key concepts of the model law; guidance on how to draft legislation; and a chapter-by-chapter analysis of the Model Law, explaining the meaning of each provision and the reason for its inclusion thereby enabling countries to align their regulatory laws to the Model Law, and not

[4] African Union Model Law for Medical Products Regulation: Increasing access to and delivery of new health technologies for patients in need, ADP Issue Brief (2017). Available at: https://adphealth.org/upload/resource/AU%20Model%20Law.pdf

only facilitate effective regulation in country, but also advancing the goal of the harmonization of regulatory systems.

AUDA-NEPAD has initiated engagement with UNDP and ECCAS secretariat to commence the conduct of a survey in 5 ECCAS countries namely Angola, Burundi, DRC, Rwanda and Sao Tome & Principe while in the ECOWAS region two countries namely Ghana and Senegal are being supported with the domestication process. In 2021, in addition to publishing the survey report, guidance documents and training materials for targeted training of media, civil society and parliamentarians developed in 2020 will continue to engage in advocacy and capacity building activities to increase awareness and speed up the domestication of the AU Model law on medical products regulation.

To date of the 55 AU member states, seventeen (17) countries have domesticated the model law on medical products regulation in part or in full.



ANNEX 1: Partners Support to Technical Committees (TCs) Based On 2020 Workplans

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
AMQF	Strengthen capacity & QMS	FHI 360	▪ Offering to fund some participants from Cote D'Ivoire to join the AMQF QMS training pilot. ▪ Subject to availability of financial resources to support the training pilot for 25% of AMQF membership. ▪ Update on FHI 360's technical trainings (QMS, technique specific): ▪ Physico-chemical: Executing an inter-lab with the lab for 2 products (Alu and ASU Inj; given funds are from malaria) ▪ Micro: Executing an inter-lab with the lab for 1 product (ASU Inj) and working to do a hands-on training for endotoxin analysis.	Ongoing
		CHMP	▪ Support training for Francophone countries (CORAQ Lab) ▪ Developing e-learning and ongoing training (on going activity) ▪ Leadership and management training through seven sessions between November 2020 and January 2021 (Head of 3 labs Benin, Mauritania, Niger). ▪ Currently finalising development of training materials ▪ Creating a CORAQ e-learning platform ▪ Training via e-learning for laboratory staff in Benin, Niger, Mauritania, Burkina Faso (45 participants for CQ and AQ Modules) between 16 March and 7 April 2021	Ongoing Ongoing Completed Ongoing Ongoing Completed

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
		FHI 360	▪ Support Cote D'Ivoire to attain ISO 17025 as follows: ▪ LNSP is comprised of various labs (e.g., physico-chemical, microbiology, toxicology). LNSP has a mix of different accreditations depending on the scope of activities. Specific for medicines, the physico-chemical lab has a scope of accreditation that is limited (also see next point) and does not encompass a large proportion of the work executed by the lab. The micro lab does not have accreditation. ▪ The physico-chemical lab's current accreditation is issued by TUNAC and is being retracted as LNSP has been given a mandate to only utilize SOAC as an accrediting body. To this end LNSP has developed a scope of accreditation that captures a larger proportion of activities in the physico-chemical lab and one particular test in the micro lab (that does not require advanced air handling system, for example sterility testing). ▪ The lab is working to submit the request to SOAC and is aiming to undergo the SOAC assessment in the coming months	Ongoing
		IFPMA	▪ Technical support for the training pilot offered.	Ongoing
		Swiss Medic	▪ Technical support for the training pilot offered.	Ongoing

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
		EDCTP	▪ Discussion with EDCTP Networks of Excellence CANTAM & TESA to support this activity ▪ The next SAC meeting is scheduled to take place (virtually) on 11-12 May 2021. NEPAD has been invited to present during this meeting	Ongoing
		WHO, USP, CENQAM	▪ Developed training manual and technical training in Quality Control content. ▪ Pilot training requires new resource.	Ongoing - Training still requires resources
		USP	▪ Developed ILT documents, 1 round of ILT conducted; guidelines developed for design of new and upgrade of existing NQCLs.	Completed
		WHO	▪ Peer review audits in 3 NCQL in Africa	Not completed
		PATH	▪ Advocacy support to socialise and encourage adoption of the technical work.	Ongoing
	Regional PMS Study	USP/WHO	▪ Draft tool for Phase 1 survey under review/being populated by countries to capture PMS work that has been done to-date	Completed
		EDQM	▪ Potential to provide technical support for the establishment of regional PMS study based on risk considerations, although financial resource cannot be offered. ▪ EDQM is offering technical support (advisory) in respect of its control laboratory Network (General European OMCL Network).	Ongoing

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
		CHMP	▪ Potential support for regional PMS report and creation of PMS database. ▪ Identified needs of four laboratories regarding COVID. ▪ Purchasing materials for QC of anti-COVID products (masks, gels, tablets) (both within the CORAQ project, specific to COVID-19)	Ongoing Completed Ongoing
		FHI 360	▪ Support for Cote-D'Ivoire participation in regional PMS study ▪ Awaiting further input from WAHO on how to support Cote D'Ivoire's participation in the study.	Ongoing
AMDF	Develop and implement a harmonized regulatory framework	ASLM	▪ Collaborated with WHO to organize a two days Webinar for NRA and Laboratory experts to support countries in establishment of a sound foundation for the regulation of medical devices including in vitro diagnostics (IVDs) through better understanding of the basic and expanded controls as specified in the WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostics (GMRF) and other internationally recognized guidance documents. ▪ Another webinar is planned in 2021.	Completed In progress

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
		WHO	▪ Contracted a consultant to develop four guidelines i.e. Requirements for issuance of market authorization, Quality Audit based on ISO 13485, Registration of Establishment and Import/Export control. WHO has also supported editorial and technical support on the four guidelines. ▪ Develop critical guidance documents for assessment and approval to accelerate access of medical devices including in vitro diagnostics during emergencies. ▪ Developed six (6) modules of the basic level regulatory training modules for medical devices and IVDs.	Completed In progress Completed
		WHO	▪ Survey report of regulatory landscape for medical devices including in vitro diagnostics in Africa has finalized and report has been shared with key stakeholders including NRAs. ▪ Change in priority to address challenges faced by regulators in the control and prevention of COVID 19 pandemic through the AMDF COVID 19 Task Force and later on AMDF Sub Working Groups. The support include: Development of ToRs and establishment of the AMDF COVID-19 task force, organize and lead discussions/meetings of AMDF COVID-19 task force experts, development of monthly list of COVID-19 assays, medical devices and manufacturers of PPEs in Africa, development of four guidelines, development of basic level training materials on regulation of medical devices and in vitro diagnostics.	On going Completed

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
			▪ Supported AMDF Annual meeting (hosted by PPB), Webinar with Heads of Agencies in Africa through the AMRH ▪ Support monthly leadership meetings for AMDF and its sub working groups. ▪ Mapping of regulatory and laboratory testing capacity in Africa.	On going Completed
		AUDA-NEPAD	▪ Commissioned a consultant to update the list of medical devices and PPEs recommended in different jurisdictions ▪ Contributed in the development of the following: » Guidelines for Emergency Response and Preparedness » Guideline for Import and Export for Medical Devices » Guideline for Inspection of Medical Devices of Manufacturing Site(s) ▪ Developed materials for basic training of regulators on medical devices regulation ▪ Reviewed training materials/manual for medical ▪ devices regulators developed by NSF ▪ Provided technical advice to monthly AMDF	Completed

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
			▪ leadership meetings: October & November ▪ Contributed to draft guideline for licensing of ▪ premises – pending ▪ Draft guideline on listing of medical devices has been developed ▪ Survey of technical expertise on medical devices regulation in Africa initiated	
		PEI	▪ Reviewed the four draft guidelines developed by WHO/consultant	Completed
		USP	▪ Discussion on development of AMDF 5 years strategic plan	In progress
	Establish and strengthen information sharing platforms	ASLM	▪ Create an online Diagnostics Hub within their ASLM website, to increase visibility, attract interest and build support - with a direct link to the AMDF web-page – a community of practice	Ongoing
		WHO	▪ Promote use of MedNet platform. Three platforms have been created i.e. AMDF, AMDF COVID-19 Task Force and Pre Market Sub Working group ▪ Coordinate meetings of AMDF sub working groups ▪ Work with NRAs and recommend appropriate policy and legal frameworks based on the WHO Global Model Regulatory Framework	Ongoing

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
		EDCTP	▪ Concept being developed for EDCTP Networks of Excellence to support this activity. ▪ The next SAC meeting is scheduled to take place (virtually) on 11-12 May 2021.	Ongoing
	Support to improve human resource capacity	ASLM	▪ Create a network of Lab contacts responsible for in-country evaluations and performance evaluation ▪ Support creation of network of technical/Lab experts in diagnostics QA ▪ Support AMDF in building a strong network of technical experts.	Ongoing dialogue
		PEI	▪ Sponsor Fellows in the RCOREs for 2021 ▪ Technical expertise for 2021 training	Ongoing
		EDCTP	▪ Concept being developed for EDCTP to support the creation of an RCORE, the creation of a twinning programme & exchange of experts ▪ The next SAC meeting is scheduled to take place (virtually) on 11-12 May 2021	Ongoing
		BMGF	▪ Support for consultant for translation and interpretation services	Ongoing
		DIA	▪ Interest in developing a collaborative model for offering training based on World Bank model	Ongoing dialogue

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
		UNFPA	▪ Technical workshop for training on assessment of condoms. ▪ Support AMDF RCORE for 2021	Completed Ongoing
		SFDA	▪ Training of NRA experts on the assessment of technical files and share experience on how the COVID 19 assays are authorized for use in Saudi Arabia.	Completed
		WHO	▪ Development of Advanced level training materials ▪ Conduct training for NRA experts on assessment of IVDs in emergency and non-emergency situations.	Ongoing
		PATH	▪ Advocacy: socialisation of developed materials, particularly for COVID-19. ▪ Progress is subject to receipt of materials from AMDF	Ongoing
ABRF	Training workshop on hemovigilance	EFS	▪ October 2020 WHO training workshop on hemovigilance ▪ Provided moderators, speakers and panellists ▪ Supported implementation and planning ▪ Supported translation of slides from French to English at no cost to ABRF or WHO	Completed
	General funding and technical assistance to ABRF	US FDA	▪ Funded Consultant to assist WHO as part of the ABRF Secretariat ▪ Participated in the Task Group on COVID-19 ▪ Provided technical assistance to ABRF members on advocacy for blood regulation	Completed

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
	Financial support to WHO	US FDA	▪ Funding WHO that enabled the establishment and continuation of ABRF	Completed
	Technical inputs	ISBT	▪ Expert inputs as an Observer at plenary meetings of ABRF and provided funding and technical support for activities	Completed
	Training workshop on hemovigilance	ISBT	▪ Training workshop on hemovigilance in October 2020 ▪ Funded on-site participation in Burundi and Zambia ▪ Provided moderators, speakers and panellists through the ISBT Working Party for Hemovigilance	Completed
	Translation	Muskoka Foundation	▪ Provided funding for language translation at the ABRF JAG meeting	Ongoing
	Technical support	PEI	▪ Confirmed to provide coordination and support function to the Technical Committee from 2021 ▪ Provided expert inputs as an Observer at plenary meetings of ABRF ▪ Provided rapporteurs for plenary meetings of ABRF	

TC	THEMATIC AREA	PARTNER	TYPE OF SUPPORT	IMPLEMENTATION STATUS
			▪ Provides liaison to WHO RSS Unit and AUDA-NEPAD on benchmarking of blood regulation ▪ Cooperated in development of the ABRF Position Statement on use of COVID-19 Convalescent Plasma ▪ Participated in planning and implementations of the August 2020 WHO training workshop on blood regulation and the October 2020 training workshop on hemovigilance ▪ Provided speakers at both workshops and co-moderation at the hemovigilance workshop ▪ Participates in the ABRF Task Groups on COVID-19 and on stepwise development of blood regulation	Completed Completed Ongoing Completed Completed Completed Ongoing
	Guidance and policy development	EDCTP (CANTAM and TESA), UKZN and AfSBT	Details being scoped	Outreach ongoing

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