Newsletter

AMRH

African Medicines Regulatory Harmonisation Programme

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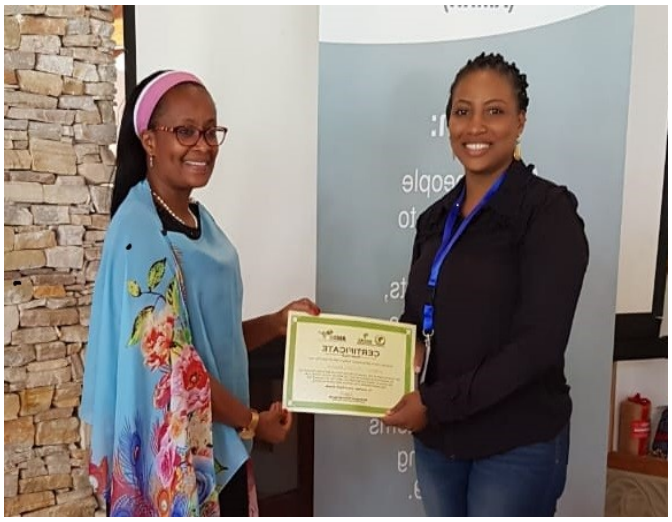
Model Law: 25 by 2020

After in-depth presentations, active participation and intensive group work, the African Union Development Agency (AUDA-NEPAD) & UNDP facilitated a successful 3 day regional training workshop for 31 legal experts and regulators from SADC and ECOWAS regions in Johannesburg on 1 to 3 May 2019. The objective was to create an enabling legal environment for improving access to medical products through the domestication of the African Union Model Law on medical products regulation. The workshop aimed to accelerate the domestication process and to achieve the set target of 25 AU Member States domesticating the AU Model law by 2020. The AU Model Law which was adopted by AU member states in 2016 is a guide towards harmonization of the regulatory systems in the continent, 14 countries thus far have domesticated the model law to some degree in their respective countries. The prevalence of Sub-standard and Falsified (SF) medical products in Africa remains a major challenge, hence why the domestication of the model law by African governments is pivotal.

Member States determining how domestication of the Model Law should take place in their own countries was one of key outcomes of the workshop. Domestication is the process by which



Model Law training workshop in Johannesburg

IN THIS ISSUE

- **Model Law training workshop for 31 legal experts and regulators from SADC and ECOWAS regions in Johannesburg.**
- **SADC AMRH Project Launch in Botswana**
- **RCORE M&E Tool Validation Workshop a Success in Accra.**
- **AMQF JAG Meeting Kickoff.**
- **Model Law Training for Media, Civil Society and Parliamentarians in Kigali.**
- **Sensitization of WAHO WA-MRH M&E Focal Points on the AMRH Monitoring & Evaluation tool.**

AU member states take steps to either (a) incorporate the provisions of the Model Law into national law or (b) ensure that the national law is aligned with the Model Law. Domestication will differ from country to country depending on various factors, such as the existing national law, the national priorities as well as the resources available. To avoid confusing the problem of substandard and falsified products with the protection of intellectual property rights, WHO made a key recommendation that the term 'substandard/spurious/falsely-labelled/falsified/ counterfeit (SSFFC)" should be changed to "substandard and falsified products".
Countries that attended are at different stages of completion of the domestication process which requires continued development and refinement, there is a need to align national laws to Model Law to provide for Pharmacovigilance; S/F Products; Administrative Appeals; Harmonisation: Protection of & Access to information. Funding and political support are the key factors needed to aid and facilitate the domestication process. SADC, MRH and WAHO-UEMOA MRH projects were encouraged to mobilise resources to support domestication, while SADC and WAHO-UEMOA will create inter REC learning opportunities for other RECs. Building on the issues, needs and time-frames identified in the country reports on the national law outlines, workshop delegates developed roadmaps indicating the milestones to domestication for their respective countries, AUDA-NEPAD and RECs secretariats aims to assist with technical support with regards to roadmap implementation.

SADC MRH Project Dinner in Botswana

The SADC MRH Project Launch

The African Union Development Agency (AUDA – NEPAD) Agency, together with the African Medicines Regulatory Harmonisation (AMRH) Programme partner the World Health Organisation, the World Bank, the Bill & Melinda Gates Foundation launched the Southern African Development Community (SADC) MRH Project on the evening of the 19th June 2019 at the Masa Square Hotel in Gaborone, Botswana. The launch was attended by Government Officials, SADC Secretariat, NMRA Heads of Agencies and Regional Economic Communities (RECs).

"From 4 countries in 2013, we now have almost all the 16 SADC NMRAs involved in Zazibona scheme with 11 active members. Tremendous progress has been recorded with 261 products reviewed; 110 products recommended for registration; 41 products have recommended for rejection; and 48 products have been withdrawn from the process." said Coordinator of AMRH Margareth Ndomondo-Sigonda.

The launch marked the beginning of the implementation phase of the SADC MRH Project. The primary goal of the launch was to celebrate and publicise the significant milestone reached towards improving access to essential medicines in the SADC Region. The launch focus was on publicising the SADC

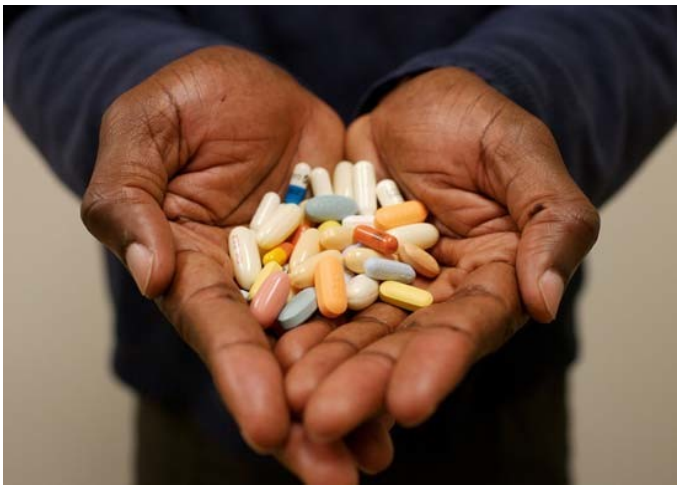
MRH Project, and progress made to date since the receipt of funds in February 2019. As well as harnessing the support of stakeholders, and building Zazibona brand awareness.

The African Medicines Regulatory Harmonisation (AMRH) initiative is a programme of the African Union implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). The overall objective of the AMRH initiative is to improve the health of the people in the region by improving the availability of safe, efficacious and good quality essential medicines for the treatment of neglected and priority diseases. This is achieved in part through the harmonisation of medicines regulation and standards at regional economic community levels.

"The regulation of medicines and harmonization of technical standards and legislative frameworks have emerged as important components of the regional economic integration efforts," said AUDA - NEPAD Agency CEO, Dr Ibrahim Mayaki.

Whilst the SADC Council of Ministers approved the harmonisation of medicines regulation in the region in 1999, in line with Article 29 of the Protocol on Health, which became effective in August 2004, limited funding stalled the roll out of the project. In mid-2015, the Region received initial funding from the World Bank Trust Fund for the first-year activities. Support from WHO and the BMGF together with the contributions of the National Medicines Regulatory Authorities (NMRAs) ensured the technical working group known as Zazibona continued to carry out joint assessment sessions and inspections.

"My plea to Heads of Agencies is to continue with the spirit of collaboration among countries, harnessing the potential that the youths who are joining the agencies bring on the table. We need to create an enabling environment for growth



which should feed into robust regional and continental structures including the AU Vision to establish the African medicines Agency (AMA) as an offshoot of AMRH. "Margareth Ndomondo-Sigonda concluded.

RCORE M&E Tool Validation Workshop a Success

The African Union Development Agency (AUDA-NEPAD) in collaboration with the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) program/FHI360, organized a workshop to validate the proposed RCOREs monitoring and evaluation tool that had been developed. The workshop took place in Accra, Ghana on the 25th and 26th June 2019. The M&E tool is being developed to monitor the performance of the 11 designated RCOREs to determine their progress since the initial designation in May 2014.

The workshop was attended by representatives from the designated RCOREs, AUDA-NEPAD, USAID MTaPS/FHI360, USP and USAID representatives. The participants reviewed the proposed tool and made suggestions for input into the tool before it is finally deployed. The workshop was officially opened by the Chief Executive Officer of the Ghana Food and Drug Authority Ms Mimi Delese Darko.

Ensuring availability of safe, good quality and reasonably priced medicines has been a challenge for many African countries. This is mainly due to many African countries lacking sufficient regulatory

capacity to approve medicines for sale (both in a timely fashion and in terms of ensuring acceptable quality, safety and efficacy standards). Manufacturers for their part are confronted with numerous and disparate regulations, frequent delays, and limited transparency processes.

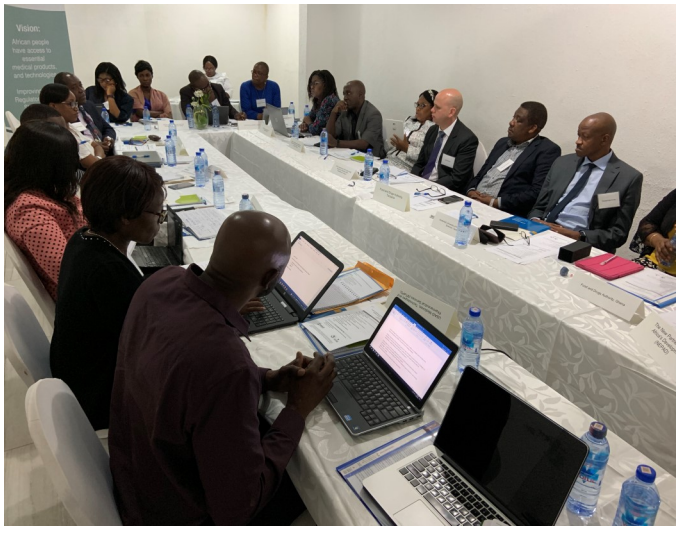
Frequent delays and lack of transparency in the review process have also resulted in limited availability of medicines that are often highly priced and out of reach for the majority of Africans. This is further compounded by the fact that registration of medicines is a complex process that requires submission of a lot of scientific information from applicants (potential investors) with consequent need for better NMRA expertise to conduct assessment and review of the respective applications from the marketing authorization holders (MAHs). In order to address the above, African Medicines Regulatory Harmonization Programme (AMRH) was set up so as to establish and improve standards and requirements related to the regulation of and access to safe, high-quality medicines for the African population. AMRH initiative aims to accelerate the access to products by improving the fragmented system of product registration in Africa. This calls for increased human and institutional capacity for regulation of medical products and technologies. Among the core elements of medicines regulatory systems in Africa, regulatory capacity has been identified as a key pillar that if strengthened will have cross cutting beneficial effects on other regulatory interventions. In order to improve the human and regulatory capacity of the NMRAs, AUDA-NEPAD designated Regional Centres of Regulatory Excellence (RCOREs). RCOREs are set up as institutions or partnerships of institutions with specific regulatory science expertise and training capabilities that they can transmit to other regulators with less expertise.

The mission of the RCOREs to provide academic and technical training in regulatory science applicable to different regulatory functions, as well as provide skills enhancement through hands -on training. The RCORES are setup with the following general objectives:

- Provide academic and technical training in regulatory science applicable to different regulatory functions and managerial aspects.
- Enhance skills through hands-on training, twinning and exchange programs among NMRAs.
- Provide practical training through placement in pharmaceutical industry.
- Execute operational research to pilot test innovations and interventions that inform best practices for scale up to other NMRAs.
- Utilize the designation status to enhance visibility, expand and/or upgrade existing capacity building programs, explore new ways in furtherance of the principles for which they were designated.
- Together with their partners strive to upgrade their capacity and maintain excellence of their facilities and expertise in their technical areas.
- Proper and consistent implementation of the above objectives would go a long way in improving the regulatory capacity of the NMRAs by using existing structures and learning from each other.

Currently there are 11 centres that have been designated as indicated in the link below:https://www.nepad.org/publication/regional-centres-

RCORE M&E tool validation workshop in Accra Ghana



AMQF JAG Kick off

The African Medicines Quality Forum (AMQF) Joint Action Group (JAG) had a kick off meeting on 2 July, 2019. The AMQF JAG is one of the Joint Action Groups of the AMRH Partnership Platform. The main purpose of the Kick off Meeting was to convene Partners interested in supporting the Laboratory Access and Testing, and Market Surveillance and Control thematic areas of the AMRH to begin a dialogue and begin to elaborate on the Joint action Plan for the JAG.

The meeting was attended by thirteen (13) participants representing 10 institutions; United States Pharmacopeial Convention (USP), International Federation for Pharmaceutical Manufacturers (IFPMA), DIA, Family Health International (FHI 360) , European Medicines Agency (EMA), Physikalisch-Technische Bundesanstalt (PTB), MCAZ, PATH, BMGF and AUDA-NEPAD.

The overall goal of AMQF is to build and strengthen capacity of national QC labs in Africa, with the aim of reducing the circulation of SF drugs in Africa. The major areas of focus include proficiency testing /inter-laboratory comparison schemes, regional post-marketing surveillance advocacy, communication and information sharing and building capacity for bio-analytical testing. The take away from the meeting was the need for partners to align their support to the activities of the AMQF Technical Working Group (AMQF TWG). Partners indicated how they would support the AMQF TWG.

It was reiterated that even though most of the focus of AMQF is on small molecules, it was recommended that AMQF looks also into strengthening capacities for the quality control of large molecules like biologics and also medical devices.AMQF Forum 3 (the annual AMQF meeting) will be held in Nigeria, in February 2020. It was agreed, that the next JAG meeting be held in Zimbabwe on the 2nd October at the margins of SCoMRA.

Collective Commitment on Advancing AMRH Initiative

Civil society organisations, parliamentarians and media left committed to taking forward the lessons learned from the workshop and advancing advocacy for regulatory harmonisation and improved access to medical products of assured quality that are safe and efficacious, this was after a 2 day training workshop facilitated by AUDA-NEPAD Kigali Rwanda on 12 to 13 June 2019. The aim of the workshop was to leverage the capacities and expertise of the different stakeholders to collectively contribute to improving access to quality, safe and efficacious medical products to all who need them.

There was a collective and individual willingness of the 26 expert participants to support the implementation of the African medicines regulatory harmonisation (AMRH) initiative and the domestication of the AU Model law in their countries in the context of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Through interactive discussions participants improved their knowledge and got an in-depth understanding of AUDA-NEPAD and Agenda 2063, AMRH initiative, PMPA business plan; AU Model law on medical products regulation; Substandard and falsified medicines (SFs) and Africa Medicines Agency (AMA). From the evaluation of the feedback forms from the participants on the conclusion of the training programme, 100% of participants agreed to have achieved the goal of networking with others, learning more about the AUDA and agenda 2063, the AMRH and AU Model Law. Before the start of the training, most participants had limited basic knowledge of the topics which were on the training agenda. However, an

assessment at the end of the training showed improved understanding of the subject matter discussed and ablility and willing to advocate for the objectives of the AMRH, Model law and AMA within their various work streams.

Some participants developed roadmaps for next steps and agreed to collaborate. PATH was tasked with supporting AUDA- NEPAD to develop and produce simplified materials on SFs, PMPA, AMRH, Model law and AMA which can be shared with the CSOs, media and parliamentarians across the continent. The participants undertook an exercise to demonstrate how they would engage communities on some of the lessons they had learned from the two days training. Three, 5 minutes videos were produced and recorded, which not only indicated the willingness of the participants to play their comparative role in advancing the AMRH initiative but also the need for AUDA-NEPAD to produce and share simplified material including audio and video messages to assist in harnessing the catalytic role of the parliamentarians, civil society and media groups.

AUDA-NEPAD with the support of PATH committed to produce and disseminate simplified documentation on different topics to aid in the advocacy. AUDA-NEPAD will continue its commitment to sustaining the engagement with the civil society, parliamentarians and media, to harness their capacities and expertise to collectively contribute to improving access to quality, safe and efficacious medical products, and advocating for the domestication of the AU Model law in their countries.

Model Law Training Workshop in Kigali

Sensitization of WEST AFRICA - MRH M&E Focal Points on the AMRH Monitoring & Evaluation tool. The African Union Development Agency (AUDA-NEPAD) and West African Health Organization (WAHO) on 3rd June, 2019 organised an audio conference with all the nominated M&E Focal Persons for the WA-MRH Project across the fifteen (15) ECOWAS region to discuss their collaboration towards achieving the global policy frameworks guiding the development of the M&E tool for the AMRH initiative, as part of the NEPAD Agency program support.

The overall objective of the meeting was to create awareness on the AMRH M&E tool, update the roadmap for implementation of the M&E guidelines, as well as create awareness on the AMRH M&E tool. Is was agreed that AUDA – NEPAD would provide technical support of the M&E Focal Points on all AMRH M&E tools to facilitate their work, and create a continental community of practice in which all AUDA-NEPAD support will go through the RECs and WAHO, as well as to support the engagement of National Statistical Offices through African Union Commission to integrate data for the Harmonization of Statistics in Africa and the organisation of data validation meetings. AUDA-NEPAD also committed to support participation of focal points to regional meetings and share all required technical information on M&E with the focal points as well as develop an online AMRH M&E tool. The tool was developed based on RECs and AMRH Results Framework with 17 indicators divided into 9 categories focusing on Manufacturing Practice and Inspection systems. Data collection for the ECOWAS region has been planned by AUDA-NEPAD and WAHO Secretariat for August 2019.

Upcoming Events

- **2nd RECs Representatives Meeting on AMRH implementation & AMRH Steering Committee meeting,** Johannesburg South Africa, 04—08 August 2019
- **M&E Focal Points on AMRH Online Data collection Tool,** Abijan Ivory Coast, 20—22 August 2019
- **Meeting to strengthen the implementation of AMRH Project in Central Africa (CEMAC),** 26 - 28 August 2019
- **AMRH Data collection workshop ECOWAS,** August 2019
- **AMRH Data Collection workshop SADC,** November 2019
- **Regional Workshop on Implementation of Blood and Blood Product Regulation,** Johannesburg, South Africa, 20—22 August 2019
- **Dossiers assessment at ZAZIBONA XXIV Assessors' meeting** Tanzania, 18—24 August 2019
- **Technical working groups of Regulatory Capacity Building,** Johannesburg South Africa, 17— 20 September 2019
- **LORENZ userBridge 19 Conference, Athens Greece,** 15 - 20 September 2019
- **Training workshop on AIM,** Johannesburg, South Africa, 25—26 September 2019
- **Fourth Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA),** Victoria Falls Zimbabwe, September 30 - October 1 2019
- **Medicines Policy and Regulatory Reforms (MPRR) Technical Working Group (TWG),**Victoria Falls Zimbabwe, 2 October 2019
- **African Medicines Quality Forum (AMQF) TWG & AMRH Partnership Joint Action Group on AMQF (JAG-AMQF),** Victoria Falls Zimbabwe, 2 October 2019
- **African Medicines Quality Forum (AMQF) TWG & AMRH Partnership Joint Action Group on AMQF (JAG-AMQF)** Victoria Falls Zimbabwe, 2 October 2019
- **The African Medicines Regulators Conference (AMRC) ,** Victoria Falls Zimbabwe, 3- 4 October 2019

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