

# AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH) INITIATIVE



## ANNUAL REPORT 2017



OUTPUTS	PROGRESS
<p><b>OUTPUT 1:</b> At least 2 regions and 10 countries implementing the African Union (AU) Model Law on Medical Products Regulation</p>	<p>Following endorsement of the AU Model Law on Medical Products Regulation by the AU Heads of State and Government Summit in January 2016 in Addis Ababa, Ethiopia, twelve (12) out of 55 countries have either reviewed or are in the process of reviewing their national laws, in line with the AU Model Law. These countries are: Ivory Coast, Burkina Faso, Seychelles, Zimbabwe, Lesotho, Namibia, Swaziland, the Gambia, United Republic of Tanzania (Zanzibar), Republic of Rwanda, Republic of Burundi and the Republic of Mozambique.</p> <p>Terms of Reference for a network of legal experts have been developed for discussion with relevant stakeholders in the spirit of domestication of the AU Model Law. NEPAD shared a framework for domestication of the AU Model Law for benchmarking exercise and national multi-stakeholder consultation on review, updating and harmonization of national medicines laws undertaken by the EAC Partner States NMRAs in June 2017.</p>
<p><b>OUTPUT 2:</b> One additional region and 5 countries implementing harmonised medicines policies and guidelines for regulation of medical products in alignment with AMRH Framework</p>	<p>Five regional economic communities (RECs) and organizations are at different stages of implementation of medicines regulatory harmonization (MRH) Programs are at different stages of implementing harmonised medicines policies and guidelines for regulation of medical products in alignment with the African Medicines Regulatory Harmonization (AMRH) Framework. They include; the East African Community, Southern African Development Community and Economic Community of West African States (collaboration between West Africa Health Organization (WHO) and the West African Economic and Monetary Union (WAEMU) Each REC and RO implementing MRH Program will make A presentation on</p>

<p style="text-align: center;">--- CONTINUED ---</p> <p><b>OUTPUT 2:</b> One additional region and 5 countries implementing harmonised medicines policies and guidelines for regulation of medical products in alignment with AMRH Framework</p>	<p>progress based on the agreed priority areas.</p> <p>The AMRH monitoring and evaluation (M&amp;E) Guidelines and Indicators for NMRA and RECs have been developed to provide stakeholders involved in implementation at the continental, regional and national levels; a unified, clear and objective results measurement framework. A web-based database will be developed to integrate and institutionalize the M&amp;E Framework under the NEPAD structures and ensure linkage with AU Health Statistics Platform which requires Member States reporting on implementation of AMRH Framework.</p>
<p><b>OUTPUT 3:</b> Legal and institutional framework for establishment of African Medicines Agency (AMA) endorsed by the AU Policy Organs by end of 2017</p>	<p>The African Union Commission (AUC) in collaboration with NEPAD Agency with the support of the World Health Organization (WHO) concluded three rounds of continental consultations with experts from AU Member States to deliberate on the Legal Framework, Institutional Framework and Business Plan for establishment of AMA.</p> <p>The first and second round of consultations took place on 20 to 22 February 2017 in Midrand, South Africa and 20 March 2017 in Addis Ababa, Ethiopia respectively, on the margins of the 2nd Session of the African Union Specialised Technical Committee on Health, Population and Drug Control. The third round of experts' consultations meeting took place in Tunis, Tunisia on 12 to 13 July 2017 to review the draft AMA Treaty. This meeting was attended by over Eighty Seven (87) experts (legal and medicines regulators) from 33 member states namely: Algeria, Angola, Benin, Burkina Faso, Burundi, Cape Verde, Central Africa Republic, Cote D'Ivoire, Egypt, Eritrea, Guinea, Gabon, Ghana, Kenya, Libya, Malawi, Mali, Mauritius, Mozambique, Morocco, Namibia, Rwanda, SADR, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Tanzania, Togo, Tunisia, Zambia and Zimbabwe. Representatives from three regional economic communities and health organisations also attended the meeting namely; the EAC, OCEAC and WAHO. Ten (10) of the Members of the AMA Task Team as well as the members of the joint secretariat of the Task Team were also present.</p> <p>After the continental consultations, and incorporating feedback and comments from legal and regulatory experts of AU Member States, the AMA Treaty was presented to the African Ministers of Health in Victoria Falls, Zimbabwe on 19th August 2017 on the side-lines of the 67th Session of the Regional Africa Committee</p>

<p style="text-align: center;">--- CONTINUED ---</p> <p><b>OUTPUT 3:</b> Legal and institutional framework for establishment of African Medicines Agency (AMA) endorsed by the AU Policy Organs by end of 2017</p>	<p>(RAC) of the WHO. The Ministers of Health met as a working group of the Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) of the African Union (AU).</p> <p>The AMA Treaty is due for consideration by African Union Ministers of Health on the 19th of May 2018 on the margins of the World Health Assembly (WHA) in Geneva, Switzerland.</p>
<p><b>OUTPUT 4:</b> Fifteen (15) Regional Centres of Regulatory Excellence (RCOREs) operational by end of 2017</p>	<p>The eleven RCOREs designated since 2014 have been operational providing training programmes in different streams of regulatory functions based on their mandate. During 2017, training on bioequivalence was conducted by Tanzania Food and Drugs Authority in collaboration with Muhimbili University; training on Clinical Trials conducted by Ghana Food and Drugs Authority (FDA) and training on quality control laboratory conducted by Medicines Control Authority of Zimbabwe.</p> <p>A Clinical Trials Training Manual was also published and widely circulated in collaboration with University of Ghana School of Public Health, Ghana FDA, International Aids Vaccines Initiative (IAVI) and NEPAD Agency. The published Clinical Trials Training Manual was piloted at the University of Ghana in June 2017. The Clinical Trials Training Manual includes modules ranging from Trial Management, Trial Implementation, Quality Assurance in Clinical Trials and End of Study Process. Other modules include Post Marketing Approval and Safety Monitoring, Risk Management and Signal Detection, as well as Clinical Trial Protocol Development and Developing Clinical Trial Applications, among others.</p> <p>Plans are underway to designate more RCOREs in 2018 based on identified needs. A detailed report on RCOREs performance is attached as Annex 1.</p>
<p><b>OUTPUT 5:</b> Number of RECs with Health and pharmaceuticals research, monitoring and evaluation frameworks operational</p>	<p>Two academic articles entitled ‘Medicines Regulation in Africa – Current State and Opportunities’ and “The African Medicines Regulatory Harmonization: Progress to Date” were published in Pharmaceutical Medicines Journal and Medical Research Archive respectively. AMRH articles, Op-Eds, blogs and opinion pieces were also published on various online platforms as follows; i) Redoubling efforts to transform the African pharmaceutical industry – published in the African Health Journal; ii) Challenges and opportunities in Africa’s blossoming pharmaceutical industry – published in the Africa Policy Peer (APR); iii) Developing</p>

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**OUTPUT 5:** Number of RECs with Health and pharmaceuticals research, monitoring and evaluation frameworks operational

Africa's pharmaceutical sector: efforts to accelerate investment – published in the Drug Information Association (DIA) Global Forum; iv) A call to stakeholders to enhance the East African Community centralized medicines evaluation process - published in the Drug Information Association (DIA) Global Forum and (v) The future African Medicines Agency: increased access to affordable, life-saving, life-prolonging medicines, also published in the Drug Information Association (DIA) Global Forum.

Furthermore, an Issue Brief on the AU Model Law was published in collaboration with the United Nations Development Programme (UNDP) titled: "African Union Model Law for Medical Products Regulation: Increasing access to and delivery of new health technologies for patients in need".

**OUTPUT 6:** Number and types of AMRH knowledge products and communication materials produced and disseminated by end of 2017

Quarterly AMRH Newsletters were published and disseminated widely using the AMRH database, email listserv, online and social media platforms. Infographics were also produced to support AMRH work in different programmatic areas. An AMRH podcast audio was produced to support the side event at the World Economic Forum on Africa which took place in Durban, South Africa in May 2017. NEPAD also jointly published an article with PATH titled "Powering African innovation for health and economic growth" in the Mail and Guardian in May 2017.

The 3rd Scientific Conference on Medical Product Regulation, the 1st African Vaccines Regulatory Forum Assembly and the 6th African Medicines Regulators Conference were convened in Accra, Ghana on 27 November – 03 December 2017. SCoMRA provided a platform for stakeholders to review progress achieved under the AMRH Initiative, and other similar Pan-African Initiatives, over the past decade and map the trajectory moving forward in a consultative manner. Discussion on the AU Vision to establish the AMA as an offshoot of the AMRH Initiative were high on the agenda. A video teaser was produced to support the SCoMRA and it featured the AMRH Champion, Precious Malebona Matsoso explaining the benefits of attending the event. At the end of the Conference, a video summary of key take home messages was produced and widely disseminated to partners, stakeholders and the public. In addition, three SCoMRA information snippets were developed and circulated ahead of the event. And two blog articles published on Devex as follows; (i) Regulatory Harmonization, Africa's blueprint to healthcare success (ii) Towards medicines regulatory harmonization: lessons from Zimbabwe. Furthermore to the publications, a mobile app was also developed and dedicated to the SCoMRA.

**OUTPUT 7: Health and Pharmaceutical Programmes effectively coordinated**

Principal Programme Officer Regulatory Systems Support; Senior Programme Officer Public Health and Monitoring and Evaluation Officer were recruited as part of strengthening the NEPAD Secretariat.

The 1st AMRH Steering Committee convened on 5-6 September 2017 discussed the following agenda items:

1. The draft governance framework for the AMRH Steering Committee for medical products regulatory systems strengthening and harmonisation;
2. Progress on implementation of the February 2017 Strategy workshop agreed action points;
3. Progress on the 5- year priorities of RECs and implementing partners;
4. Progress on alignment of AVAREF, NOMCoL, PAHWP with AMRH;
5. The proposal for establishment of the AMRH Partnership Platform as the Africa chapter of the Global Coalition of Interested Partners (CIP);
6. The AMRH Monitoring & Evaluation Framework.

Progress on implementation will be presented as separate agenda items.

## ANNEX I: Performance Progress for RCOREs in 2017

NEPAD Agency designated 11 regional centres of regulatory excellence (RCOREs) in 2014 and 2015 through a series of extensive and inclusive consultations with all key stakeholders and experts primarily to help fill an existing gap and contribute to the alleviation of regulatory capacity challenges that are experienced by National Medicines Regulatory Authorities (NMRAs) and the pharmaceutical industry. Among the In addition the Centre for Pharmaceutical Advancement and Training (CePAT-Ghana) was designated as reference centre of regulatory excellence to support RCOREs based on a NEPAD-USP MoU.

Over the last 3 years RCOREs have been involved in a range of activities in their field and category of expertise including: training and capacity building; information dissemination; implementation of national / regional programmes and activities at country/regional level in support of medical products regulation and harmonization; organization of events (e.g. conferences, meetings, workshops); and work sharing.

As existing institutions or partnership of institutions with specific regulatory science expertise as well as training capabilities RCOREs continue to carry out their key mission to produce regulatory workforce in Africa through: provision of academic and technical training in regulatory science applicable to different regulatory functions and managerial aspects; skills enhancement through hands-on training, twinning and exchange programmes among NMRAs; practical training through placement in NMRAs and pharmaceutical industry and execution of operational research to pilot-test innovations and interventions to inform best practices in capacity building. Key highlights for 2017 include the collaboration of Tanzania Food & Drugs Authority (TFDA) / School of Pharmacy Muhimbili University of Health and Allied Sciences (MUHAS) and WHO to conduct a bioequivalence (BE) course in the East Africa Community; Pharmacy and Poisons Board (PPB) Kenya as an RCORE in Pharmacovigilance (PV) led the development of the EAC PV Strategic Business Plan in collaboration with other EAC Partner States and AMRH Partners. It is expected that the Business Plan will be approved by the EAC Policy Organs in 2018 and the activities the 2-phase implementation programme effected from 2018. The Centre for Drug Discovery, Development & Production at the University of Ibadan Nigeria continued conducting courses in regulatory sciences and organized a highly successful scientific conference on improving access to quality medicines through appropriate legislations and policies. The key thematic areas addressed by the conference included: Regulations guiding access to quality medicines in Africa: A critical Appraisal; and Strategies for improving access to quality medicines in West Africa Sub-region.

In Ghana the Food & Drugs Authority (FDA) in collaboration with the University of Ghana School Of Public Health, as an RCORE in medicine evaluation and registration and clinical trials oversight conducted a pilot programme on the RCOREs Clinical Trials Manual with the financial support of IAVI. Other institutions such as Kilimanjaro School of Pharmacy; St. Luke's Foundation Tanzania; the WHO Collaborating Centre for the Quality Assurance of Medicines NWU - Potchefstroom Campus South Africa and USP Ghana Center for Pharmaceutical Advancement and Training (CePAT) continued conducting courses within the scope of their institutional programmes. National Drug Authority (NDA), Uganda as an RCORE in in licensing of the manufacture, import, export, distribution and; inspection and surveillance of manufacturers, importers, wholesalers and dispensers of medicines collaborates with Makerere University to provide post graduate courses in regulatory sciences with hands on learning at the Ugandan NMRA. Medicines Control Authority of Zimbabwe (MCAZ) and National Agency for Food and Drug Administration and Control (NAFDAC) Laboratory as RCOREs in medicine registration and evaluation, Quality Assurance/Quality Control and clinical trials oversight; and Quality Assurance and Quality Control of Medicines continued sharing their best practice experiences in different forums.

Exchange programme visits included MCAZ visits to Kenya to learn best practices in pharmacovigilance.