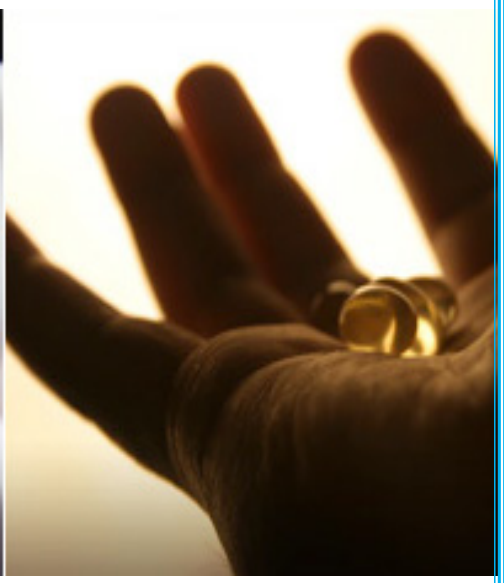
AMRH NEWSLETTER

Quarter 1: January - March 2017

African Medicines Regulatory Harmonization





A study by Janssen reveals 40-60% reduced review time for medicines regulation in East Africa

Implementation of AU Model Law gains momentum

ABOUT AMRH
African Medicines Regulatory Harmonization (AMRH) Programme

The African Medicines Regulatory Harmonization (AMRH) initiative is a programme of the African Union (AU) implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Under the theme "Strengthening of Health Systems for Equity and Development in Africa", the AU Conference of Health Ministers (AUCHM) in April 2007 responded to the AU Assembly Decision 55 (Assembly/AU/Dec.55 (IV) taken during the Abuja Summit in January 2005 which mandated the African Union Commission (AUC) to develop the PMPA within the framework of the NEPAD. The programme started in 2009 as a response to addressing challenges faced by National Medicine Regulatory Authorities (NMRAs) in Africa. These challenges include; weak or non-coherent legislative frameworks, redundant/duplicative processes, sluggish medicine registration processes and subsequent delayed decision, inefficiency and limited technical capacity, among others. The work of AMRH is guided by three focus areas: policy alignment, regional integration and harmonization, and human and institutional capacity development.

The programme works in collaboration with the AUC, Pan-African Parliament (PAP), World Health Organization (WHO), Bill and Melinda Gates Foundation, World Bank (WB), UK Department for International Development (DFID) and US Government-PEPFAR and Global Alliance for Vaccines and Immunization (GAVI). The AMRH Strategic Plan defines the strategic direction for the medicines harmonization agenda in Africa and provides direction to advance the development of the pharmaceutical sector and provides guidance in monitoring and evaluation.

Our Vision in Africa
African people have access to essential medical products and technologies

Our Mission in Africa
Provide leadership in creating an enabling regulatory environment for pharmaceutical sector development in Africa

Content - Highlights

AU Member States review key AMA documents on the margins of the STC on Health, Population & Drug Control

African Union (AU) Member States, stakeholders and partners met in Addis Ababa, Ethiopia on the margins of the Specialized Technical Committee (STC) on Health, Population and Drug Control for the 2nd stakeholder consultation on the Legal and Institutional Framework for the proposed establishment of the African Medicines Agency (AMA). The stakeholder consultation took place from 19 – 23 March and is a follow up on the 1st AMA stakeholder consultation held in Johannesburg, South Africa from 20 – 22 February 2017.

AMA Legal documents ✔
AMA 1st Consultation with AU Member States ✔
AMA 2nd Consultation with AU Member States ✔
AU STC-HPDC Briefing on AMA ✔

The 1st AMA stakeholder consultation provided a platform for AU Member States and Regional Economic Communities (RECs) to deliberate on the draft Legal and Institutional Framework and Business Plan, take stock of progress made on the implementation of the AU Executive Council decision to establish AMA. The aim of the 2nd Consultation was to revise these documents and develop a roadmap for the next steps in subsequent consultations. During both consultations, feedback was received from the stakeholders and this will be incorporated.

As a result, the 2nd AMA consultation meeting brought together legal experts and medicines regulators experts from AU Member States, representatives from the RECs, AMA Task Team members and joint Secretariat. After the feedback from the stakeholders, the three documents will now be revised and circulated with the African Union Commission (AUC) legal team for final review before presentation on the next STC on Health Population and Drug Control for endorsement. African leaders have expressed optimism to transition the work of the African Medicines Regulatory Harmonization (AMRH) in to the AMA to ensure harmonization at continental level. AMA will be a specialized technical institution of the AUC established through a treaty. It will not replace National Medicines Regulatory Authorities (NMRAs) but will work with them collaboratively to ensure that medicines regulatory strengthening and harmonization work is well structured and coordinated in Africa to ensure sustainability. AMA will also be the entry point of various stakeholders and partner ready to work and invest in medicines regulatory strengthening and harmonization in Africa and will occupy a coordination role to ensure that there is no duplication of work and to make effective use of the scarce resources.

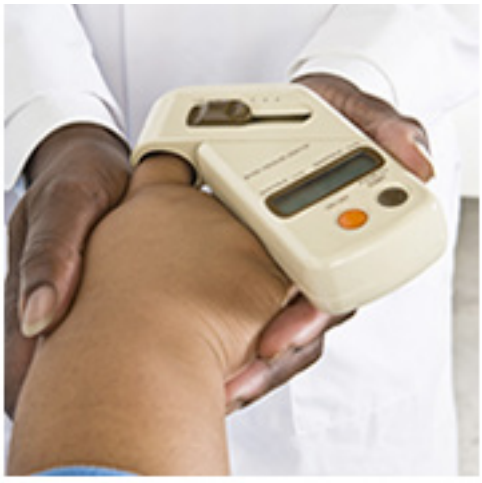
Joint assessments in East Africa reduce medicines regulatory review time by 40 – 60%

Implementation of the African Medicines Regulatory Harmonization (AMRH) Initiative in the East African Community (EAC) has reduced drug approval times for a number of branded medicines by about 40-60% through joint dossier assessments between EAC Partner States and has also contributed to saving the already scarce resources.

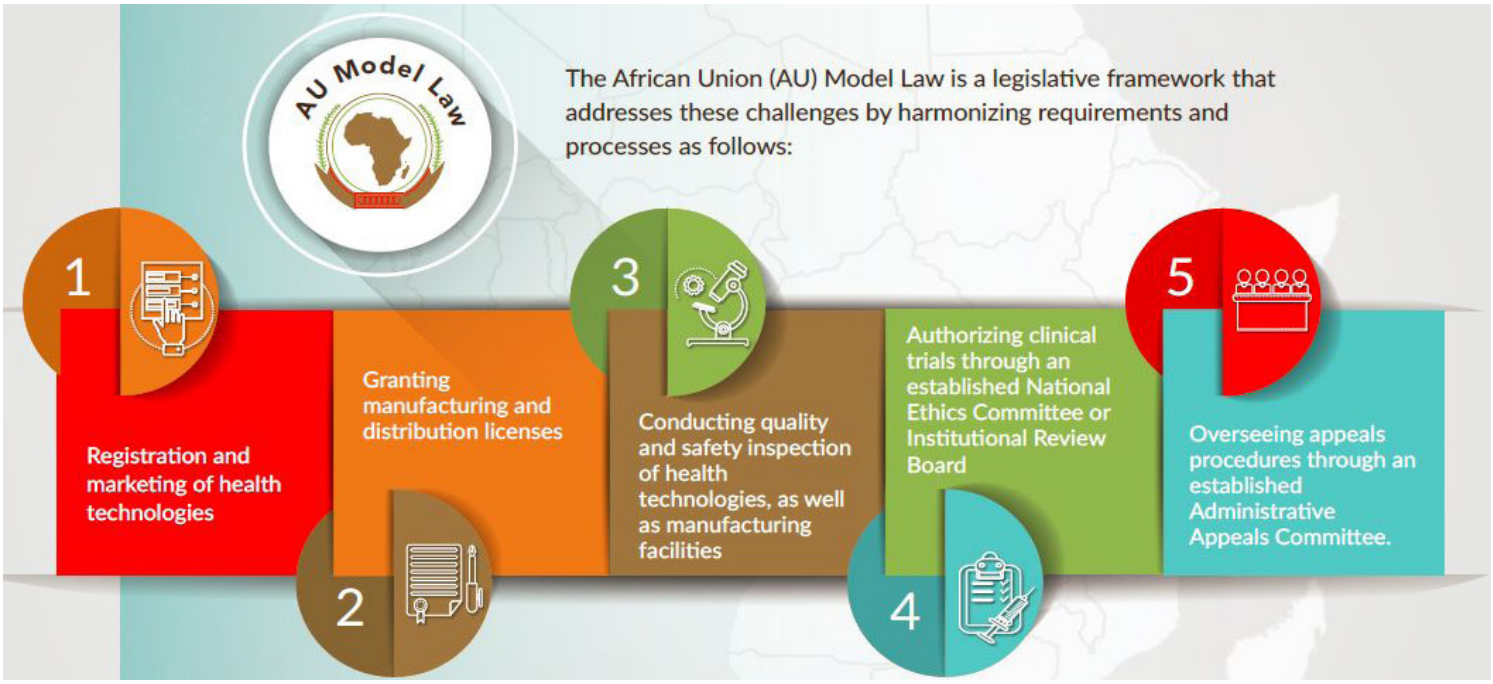
A joint assessment pilot carried out with a number of drugs in all the EAC Partner States in 2015-2016 showed that the median timeline from dossier submissions to national marketing authorization was reduced to seven (7) months since implementation of joint assessments compared to the previous 1 – 2 years characterised by national applications.

The reduced approval timelines are helping to improve patient access to safe, efficacious and quality medicines and there is value in sustaining this momentum to ensure sustainability and continue to strengthen and harmonize medicines regulatory systems in Africa. The new AMRH strategy covering the period 2018 – 2022 has been developed and agreed upon by Partners. The direction of the AMRH initiative is dictated by the needs and priorities of the countries themselves rather than having a top down approach of imposing one regulatory model. It is expected that the AMRH initiative will champion alignment with other programmes and expand to include clinical trial approvals, pharmacovigilance activities and marketing authorization.

African leaders have expressed optimism to transition the work of AMRH in to the African Medicines Agency (AMA) to ensure harmonization at continental level. The conception of the AMRH in 2009 was driven by the need to remove the barriers that hinder patient access to healthcare products, a problem that afflicts many Low- and Middle-Income Countries (LMICs) but is particularly pressing in Sub-Saharan Africa. Research has shown that the introduction of new vaccines and medicines in poor countries can take four to seven years longer on average in poorer countries than in richer ones.



Zanzibar uses AU Model Law to amend medical products legislation



These are some of the legislative functions addressed by the AU Model Law

Zanzibar House of Representatives has successfully approved the Bill amending the legislation on medical products regulation based on the African Union (AU) Model Law on medical products regulation. Following this development, H.E. the President of Zanzibar, Ali Mohamed Shein is expected to append his signature before the statute is officially published in the Government Gazette.

Other AU Member States that have already utilized the AU Model Law to review and develop their national laws include Lesotho, Seychelles, Swaziland, Zimbabwe, and Ivory Coast. The aim is to have at least 25 AU Member States using a version of the AU Model Law on medical products regulation that befits their country context by 2020. The AU Model Law is available in English, French, Portuguese and Arabic. A summary video of the AU Model Law can be accessed by clicking here.

Zanzibar Food and Drugs Board (ZFDB) Registrar, Dr Burhani Othman Simai thanked the different stakeholders and partners for their endless support and encouragement that has led to this achievement as it will benefit the people of Zanzibar. The AU Model Law on medical products regulation addresses the challenges of weak or non-existent medical products regulatory systems and assists African countries in addressing the gaps and inconsistencies in their legislations. The aim of the AU Model Law is to accelerate access to innovative, lifesaving health technologies to the African population by facilitating harmonization of medical products regulatory systems on the continent.

The AU Model Law was officially endorsed by the Heads of State and Government at the AU Summit in Addis Ababa, Ethiopia in January 2016. Following the endorsement, Regional Roadmaps for implementation of the AU Model Law have been developed and African countries can enact a version of the AU Model Law to strengthen their national regulatory capacity.

The African Medicines Regulatory Harmonization (AMRH) Initiative played a critical role in getting the AU Model Law adopted by the AU Heads of State and Government. The AMRH Initiative is a partnership comprised of the NEPAD Agency, African Union Commission (AUC), Pan African Parliament (PAP), the World Health Organization (WHO), World Bank (WB), Bill and Melinda Gates Foundation (BMGF), and UK Department for International Development (DFID). The goal of AMRH is to strengthen the capacity for regulation of medical products in Africa and promote harmonization of medicines regulatory systems. The development process of the AU Model Law was also supported by the United Nations Development Programme (UNDP).

A pilot study by Janssen reveals that Collaborative Regulatory Procedures (CRP) reduce drug registration timelines in Africa

A pilot study conducted by Janssen Pharmaceutica Inc., which is part of Johnson and Johnson has shown that Collaborative Regulatory Procedure (CRP) work. The study was conducted in 11 African countries implementing the African Medicines Regulatory Harmonization (AMRH) Initiative with a focus on three Stringent Regulatory Authorities (SRA) approved medicines; (1) a pediatric formulation of Janssen's antiretroviral drug Intelence (ectravirine) 25mg of oral tablets (2) another Janssen's antiretroviral, Prezista (darunavir) (3) and a Tuberculosis drug Sirturo (bedaquiline) which is currently undergoing the pilot with the first submission made in February 2016.

Janssen Pharmaceutica Inc. has described the results from the pilot as very encouraging and they are looking at options to improve this process. According to an earlier survey conducted by Bill and Melinda Gates Foundation (BMGF) the median for drug approval was 20 months, but the results from the pilot study by Janssen Pharmaceutica Inc. indicate that a median of 7 months was recorded from a total of 9 countries out of the 11 sampled.

The target review time for the pilot study was pegged at 90 days. In the first pilot, Namibia was able to meet this target by registering antiretroviral drug Intelence (ectravirine) in 86

days, just 4 days below the target. This shows that it is possible to reduce drug approval times. In the second pilot involving Prezista (darunavir), submission of the product began in November 2015 and the first drug approval was granted under the CRP in August 2016.

The SRA used in this study was European Medicines Agency (EMA). The national authorities' under study were encouraged to use EMA assessment reports and inspection reports. There is need to continue working with African Union (AU) Member States and Regional Economic Communities (RECs) through the AMRH Initiative to encourage them to rely on SRAs and not duplicate assessments if one has already been done and promote joint assessments.

AMRH Champions Initiative #Hour4AMRH Campaign

Madame Precious Matsoso designated as 1st AMRH Champion

Madame Precious Matsoso - AMRH Champiom

African Medicines Regulatory Harmonization (AMRH) has embarked on an initiative to identify and designate AMRH Champions who will occupy a critical role in the implementation of AMRH events and activities, and engage with political leadership, establish partnerships and ensure responsibility at the highest level to sustain the momentum of AMRH activities in Africa and ensure sustainability. Madame Precious Matsoso, Director General of the South African Department of Health has been identified and designated as the first AMRH Champion.

The aim of the initiative is to leverage the AMRH Champions influence and power to generate public awareness and understanding of the AMRH medicines regulatory strengthening and harmonization agenda in Africa, and inspire broad and positive action in support of NEPAD Agency and African Union Commission (AUC) mandate and priorities. The Champions shall support and collaborate with AMRH and its Partners in efforts to ensure sustained and increased momentum of AMRH implementation beyond 2017 in four (4) key areas;

1. **Public policy advocacy**
2. **Collaboration and resource mobilization**
3. **Public awareness**
4. **Accountability, monitoring and reporting**

A very clear and specific criteria for identifying and designating AMRH Champions has already been developed with associated Terms of Reference (ToRs). AMRH Champions are expected to participate in various AMRH events and activities and also be the brand ambassador of the work of the AMRH Initiative across Africa and the world.

African Medicines Forum to improve quality control of medicines

A team of experts from NEPAD Agency, USP, WAHO and directors of quality laboratories in Africa

The prevalence of sub-standard and falsified medical products in Africa is a huge challenge. NEPAD Agency, United States Pharmacopeia (USP) and the Economic Community of West African States – West African Health Organization (WAHO) have agreed to work together to establish a medicines quality control forum to address this challenge to ensure that African people have access to safe, efficacious and quality medical products.

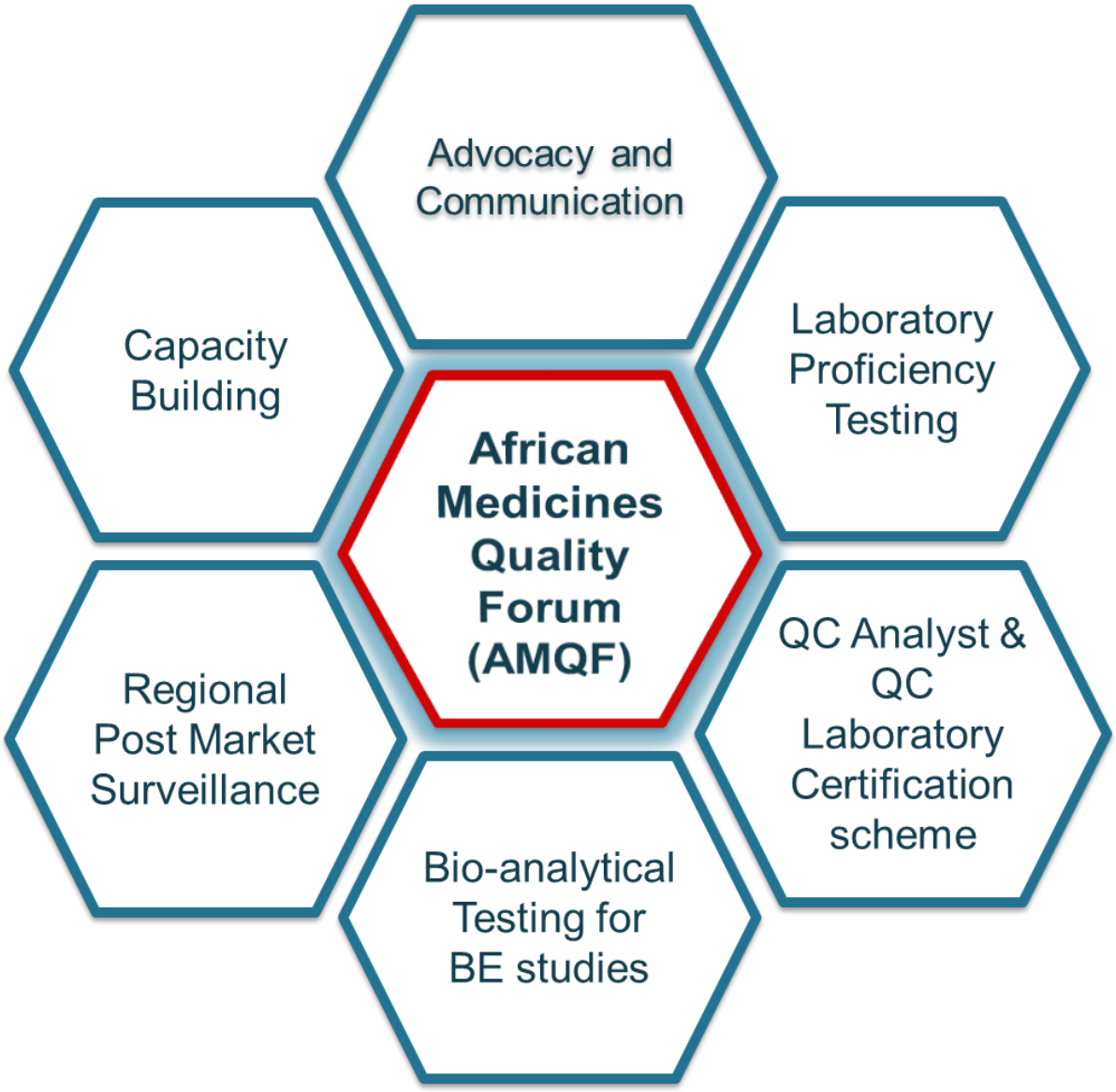
The organizations have agreed to transform the Network of Medicines Control Laboratories in Sub-Saharan Africa (NOMCoL–SSA) in to the African Medicines Quality Forum (AMQF). AMQF shall represent the new vision of NOMCoL and will expand its scope to cover all countries on the continent in alignment with the African Medicines Regulatory Harmonization (AMRH) Initiative. The end goal of AMQF is to significantly reduce the prevalence of sub-standard and falsified medical products in circulation on the African markets.

USP has already been supporting activities under NOMCoL since 2009 with initial funding from the United States Agency for International Development (USAID). Similarly, NEPAD Agency has also designated Regional Centers of Regulatory Excellence (RCOREs) for quality control of medicines and WAHO runs several programs aimed at strengthening capacity of medicines quality control laboratories in West Africa. These organizations shall now align these initiatives under the umbrella of the AMQF to help prevent duplication of work, foster consolidation of resources and help to sustain the activities over

an extended period of time.

The new AMQF will be aligned to the AMRH governance structure and sub working groups to address various activities that impact the quality control of medicines in Africa. A detailed roadmap for this new direction of NOMCoL Africa shall include the creation of a platform for a holistic continental quality control agenda that facilitates sharing best practices, promoting cooperation between quality control laboratories, setting conformity assessment standards, providing technical leadership in quality control and serving as an advocacy platform to raise national and international visibility of the quality control laboratories.

The decision to establish AMQF was made during a USP facilitated meeting in Accra, Ghana that took place from 02 – 03 March 2017. The meeting was attended by directors of quality control laboratories from Cote D'Ivoire, Senegal, Sierra Leone, Liberia, Uganda, Nigeria, Burkina Faso, Burundi, Mali, Seychelles, Malawi, Ghana, Zimbabwe, Zambia, Ethiopia, Mozambique, and Botswana. The NEPAD agency and ECOWAS-WAHO were also in attendance.



Proposed structure and functions of the African Medicines Quality Forum (AMQF)

AMRH partners agree on new strategic direction & structure

David Mukanga (c) and Vincent Ahonkhai (r) during the meeting

Global partners and regional stakeholders of the African Medicines Regulatory Harmonization (AMRH) have plotted the next five year strategic direction and agreed to establish a lean governance structure for the successful implementation of the next phase of the programme in Africa. The proposed governance structure aims to bring on-board other partners and contributors to harmonize similar initiatives. This took place during a workshop co-organized and hosted by NEPAD Agency from 8 – 9 February 2017 at its Head Office in Johannesburg, South Africa.

During the workshop, the long term vision and short term goals of the AMRH new strategy and related key performance metrics to monitor and measure desired programme outcomes were expounded. Consensus was reached on realignment of other similar programmes with AMRH activities to provide end to end programme impact in Africa from Clinical Trials Authorization (CTA), Marketing Authorization (MA) to Pharmacovigilance (PV) which mainly deals with drug safety surveillance. NEPAD Agency was identified as the hub that shall hold the coordinating role to bring together new and existing actors working in these areas to avoid duplication of activities and ensure maximum utilization of the already scarce resources in Africa.

In the opening remarks, NEPAD Agency Head of Industrialization, Science, Technology and Innovation (ISTI), Prof. Aggrey Ambali welcomed the participants and sent greetings on behalf of the NPEAD Agency CEO, Dr Ibrahim Mayaki. He said the new strategy development of the AMRH comes at a critical stage as there is need to support and sustain the momentum of the achievements recorded in Phase One of the programme.

"Now is the time to reflect on what has worked well and how we can do better going forward," Prof. Ambali said.

Outgoing Bill and Melinda Gates Foundation (BMGF) Senior Advisor Global Health, Dr Vincent Ahonkhai thanked NEPAD Agency for hosting the workshop and

acknowledged the organizations mandate on the continent. Dr Ahonkhai reminded participants that the very first planning meeting that led to the establishment of AMRH took place as a result of NEPAD Agency's coordination and the organization is again playing a pivotal role in providing this platform to discuss and agree on the strategic direction of the next phase of AMRH. This is an opportunity to re-align activities in Africa and make key decisions going forward.

"Various partners and stakeholders have to be on the same page and understand each other's roles and their added value in the medicines regulatory harmonization agenda," Dr Ahonkhai said.

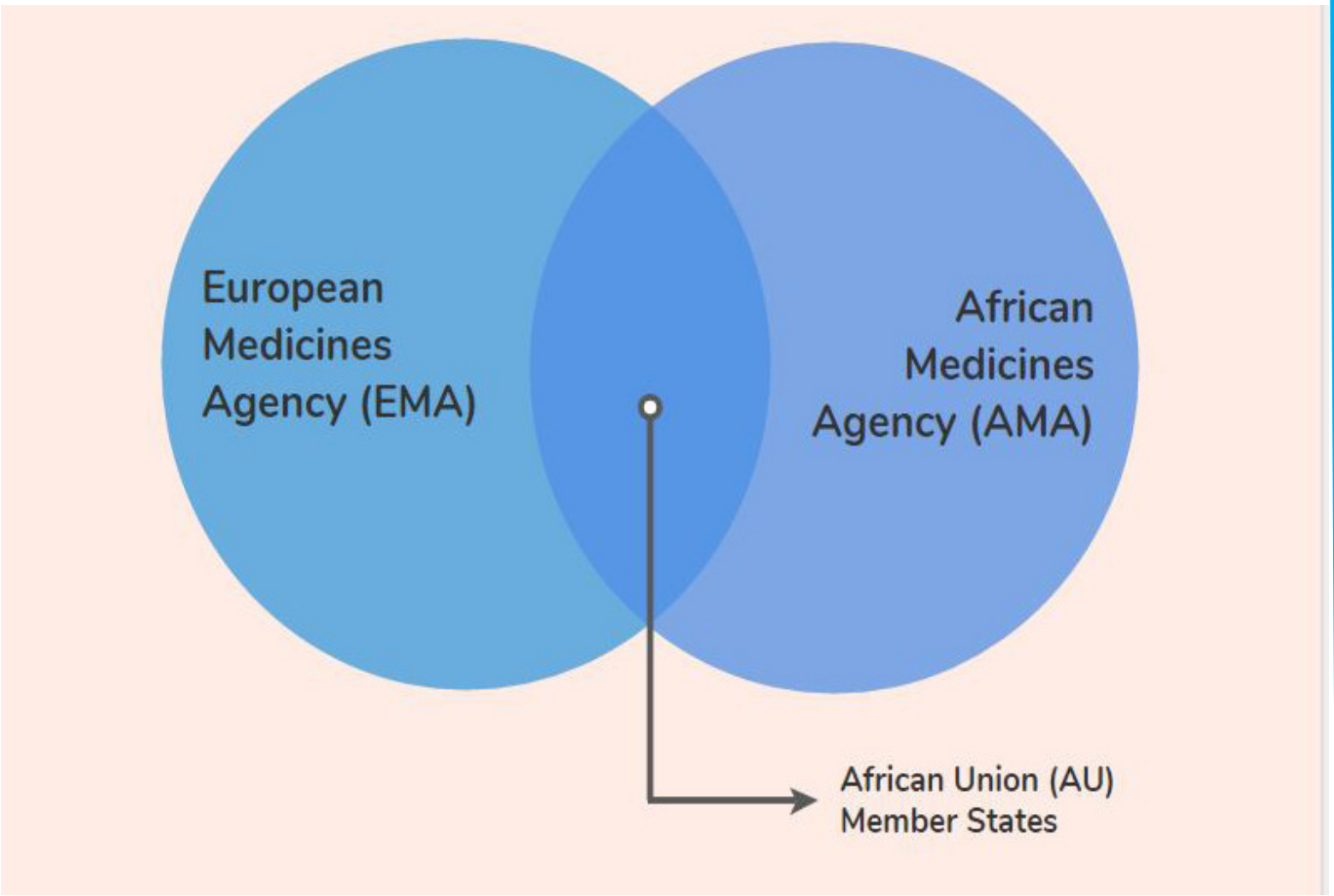
World Health Organization (WHO) Coordinator, Regulatory Systems Strengthening, Essential Medicines and Health Products, Mike Ward also acknowledged the tremendous efforts that have brought the medicines regulatory harmonization agenda this far and emphasized that now is the time to focus on the how. He said that the why and what are very clear but now we have to focus on the how, as well as take in to account the global initiatives to ensure harmonization.

The World Bank (WB) Senior Health Specialist, Andreas Seiter said that it is now time to reconvene and reconsider where we have come from and what we have achieved and take these lessons with us as we map out the new strategic direction. He mentioned that this is a dynamic field and there is need to prioritize activities and be smart in the crafting of the approaches to implementation.

The meeting was attended by NEPAD Agency, WB, WHO, United States Pharmacopoeia (USP), Swiss Medic and representatives from Regional Economic Communities (RECs): East African Community (EAC), Southern African Development Community (SADC), Economic Community of West African States (ECOWAS), West African Health Organization (WAHO) and West Africa Economic and Monetary Union (WAEMU) as regional organizations, and InterGovernmental Authority on Development (IGAD) and consultants.

AMRH strategic meeting took place at the NEPAD Agency Head Office in Johannesburg, South Africa

European Medicines Agency (EMA) collaboration with Africa to get a boost



EMA and proposed AMA have a common interest to improve availability of quality and safe medcines in African countries

Collaboration between the European Medicines Agency (EMA) and Africa is destined to get a boost that will result in improved availability of high quality, safe and effective medicines and accelerate implementation of Article 58 in Africa in view of the planned establishment of the African Medicines Agency (AMA). EMA experts met with African Union (AU) Member States regulators from 2 - 3 March 2017 in Malta to discuss opportunities for collaboration and address misconceptions about the Article 58 procedure.

The meeting increased African regulators understanding of the work of EMA and discussed reliance and harmonization concepts. Capacity building of African regulators across different regulatory functions and product categories forms an integral part of this collaboration. EMA's collaboration with Africa is cushioned by the African Medicines Regulatory Harmonization (AMRH) Initiative which has made strides to strengthen the capacity for regulation of medical products and promotion of harmonization of medicines regulatory systems in Africa.

NEPAD Agency as the Secretariat of the AMRH

Initiative occupy an important coordinating role in this collaboration to avoid duplication of activities and ensure prudent utilization of limited resources. One of the identified roles is to effectively communicate the benefits of Article 58 to the AU Member States to address misconceptions. Secondly, NEPAD will also take the lead in coordinating the implementation of robust risk management plans including pharmacovigilance systems to monitor safety of medical products post-authorization by AU Member States based on Article 58 positive scientific opinion.

Article 58 is a cooperation between World Health Organization (WHO) and EMA to allow EMA's Committee for Medicinal Products for Human Use (CHMP) to give expert opinions on medicines and vaccines for human use that are intended exclusively for markets outside of the European Union (EU). Using the expert opinions and assessment reports, African countries can commission an abridged review, subsequently reducing medicines approval timelines and assuring fast access to critical drugs, particularly those under Neglected Tropical Diseases (NTDs).

The aim of Article 58 is to address public health challenges existing in Low and Middle Income Countries (LMICs) to improve global health. Some of the products eligible for processing through Article 58 procedure include (i) Vaccines or medicines used to prevent or treat public health priority diseases; (ii) Vaccines used in the WHO Expanded Programme on Immunization; (iv) Medicines for protection against diseases, such as HIV/AIDS, malaria and tuberculosis; (v) and medicines for maternal and new-born healthcare. However, since the inception of Article 58 in 2004, only 8 products have received positive scientific opinion.

The planned establishment of AMA serves as a unique platform to enhance the EMA-Africa collaboration and accelerate implementation of Article 58. The AU leadership have expressed optimism to transition the work of AMRH in to AMA. The first stakeholder consultative meeting with AU Member States on the AMA Legal and Institutional Framework and Business Plan was held in Johannesburg, South Africa in February 2017. The second consultative meeting is planned to take place on 20th March 2017 at the AU Head Office in Addis Ababa, Ethiopia. After these consultations and review of the AMA documents, they will be submitted to the Specialized Technical Committee on Health, Population and Drug Control for consideration in March 2017.

African regulators with EMA delegates in Malta

The meeting in Malta was jointly organized by EMA and the Malta Medicines Authority as part of the Maltese Presidency of the European Union and was funded by the Bill and Melinda Gates Foundation (BMGF) supported by WHO.

Upcoming Events

- World Economic Forum (WEF) on Africa AMRH Inteactive Dinner Discussion focussing on Transforming Pharmaceutical Regulatory Landscape for Increased Investment in Africa - Durban, South Africa: 02 March 2017
- 3rd Biennial Scientific Conference on Medical Products Regulation in Africa: Accra, Ghana: 27 - 29 November 2017
- NEPAD Agency-PATH co-organized event at the World Economic Forum (WEF) on Africa focussing on Powering African Innovation For Health - Durban, South Africa: 02 March 2017
- NEPAD Agency and World Health Organization (WHO-AFRO) meeting on coordination of Health and Pharmaceutical programmes -Brazaville, Congo: 13 - 17 May 2017

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