REVIEW ARTICLE

The African Medicines Regulatory Harmonization Initiative: Progress to Date

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Abstract

The African Medicines Regulatory Harmonization Initiative (AMRH) has contributed to reduce marketing authorization timelines in East African Community and the Southern African Development Community member states. Challenges still exist in using the outcome of the regional joint dossier review processes for national decision making processes by the national medicines regulatory agencies.

Progress in domestication of the African Union Model Law on Medical Products Regulation by twelve countries provides basis for improving regulatory systems. This is coupled by the designation of eleven regional centers of regulatory excellence which will ensure sustainable training programmes and subsequent increase in Africa's regulatory workforce.

The Biennial Scientific Conferences on Medical Products Regulation in Africa is a strategic platform for knowledge and ideas exchange among key stakeholders in the pharmaceutical sector. The ongoing alignment of the African Vaccines Regulators Forum, the Network of Medicines Control Laboratories in Sub-Saharan Africa, Pan African Harmonization Working Party on the regulation of medical devices and diagnostics, the planned establishment of a forum for blood and blood with AMRH serves as a solid foundation for establishment of the African Medicines Agency (AMA). AMA will be a key driver to remove technical barriers for trading among the region countries by contributing to the continental socio-economic development agenda.

Key points:

1. The African medicines regulatory harmonization has improved registration timelines in East African Community and Southern African Development Community.
2. The African Union Model Law on Medical Products Regulation and Regional Centres of Regulatory Excellence serve as useful tools for improving regulatory capacity in Africa.
3. Alignment of regulatory systems strengthening and harmonization efforts provide a foundation for establishment of the African Medicines Agency.

1. Introduction

Marketing authorisation (MA) and clinical trials authorization (CTA) for global health products such as vaccines and medicines in many low- and middle-income countries (LMICs) have experienced delays ranging from 4-7 years in comparison to most of high-income countries (HICs) [1]. In Africa, barriers causing these delays include weak or non-coherent regulatory standards and requirements among countries; lengthy medicine registration processes that lead to delays in approval decisions; technical capacity and capability; overall resource constraints; and failure to leverage regulatory review activities already performed by better-resourced regulatory authorities and the World Health Organization (WHO). In addition, delays in CTA have been largely attributed to the lack of role clarity and transparency between national medicines regulatory authorities (NMRAs) and national ethics committees (NECs) [1].

Conception of the African Medicines Regulatory Harmonization (AMRH) Initiative in 2009 was driven by the need to remove these barriers that hinder patient access to healthcare products in Africa [2]. The AMRH initiative's aim is to support African countries to overcome these constraints by building effective medicines registration through regional harmonization and capacity building [3]. A consortium of partners comprised by NEPAD Agency, African Union Commission (AUC), Pan African Parliament (PAP), WHO, Bill and Melinda Gates Foundation (BMGF), the UK Department for International Development (DFID) and Clinton Health Access Initiative (CHAI) was established to facilitate the needed political, technical and financial support required by NMRAs working through their respective regional economic communities (RECs) [3]. A global medicines regulatory harmonization multi-donor trust fund (GMRH-MDTF) was created in 2011 under the fiduciary oversight of the Word Bank to promote the harmonization of medicines regulations, strengthening governance and regulatory systems [4].

Leveraging on NEPAD Agency's continental reach and its mandate as the technical arm of the African Union (AU) with WHO providing technical lead role, AMRH has launched regional Medicines Regulatory Harmonization (MRH) projects that have proven to be instrumental in guiding NMRAs to determine priority areas of action for medicines regulatory strengthening and harmonization in Africa [3]. With initial funding from the Bill and Melinda Gates Foundation (BMGF), the GMRH-MDTF has enabled pooling of donor funds, assure fiscal accountability, drive projects through the Bank's in-

country management capabilities and ensure that RECs receive the necessary resources in a flexible and coordinated manner. Other donors who have committed or contributed to the fund include DFID, US Government/PEPFAR and GAVI, International Federation of Pharmaceutical Manufacturers Associations (IFPMA). Contributions outside the Trust Fund were received from the Swiss Agency for Development and Cooperation (SDC), World Bank SWEDD (Sahel Women Empowerment and Demographic Dividend) project and BMGF for clinical trials authorization through the AVAREF Additionally, the BMGF made grants to NEPAD Agency for coordination, communication and advocacy, and to WHO to support the African Vaccine Regulatory Forum (AVAREF) for harmonization and regionalization of CTAs. The initiative received policy and political backing under the AU Pharmaceutical Manufacturing Plan for Africa (PMPA), which specifically recognises the need for African countries to strengthen their medicines regulatory systems by pooling their resources in order to achieve public health policy priorities [3, 5].

The aim of AMRH Initiative is to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional and simplified one [3,6]. The AMRH pathway is to use regional regulatory platforms to harmonise technical requirements and guidelines for registration of medicines, conducting joint regional dossier assessments and good manufacturing practice (GMP) inspections, work sharing and pooling of resources with subsequent streamlined decision-making process at national level. The end result is a reduced registration cycle time starting with generics and extending to other product categories such as new chemical entities (NCEs), vaccines, diagnostics and further extending to other regulatory functions over time such as clinical trials, safety surveillance, just to mention a few. The plan was to pilot in one regional economic community for learning before extending to other African regional blocs.

This review paper aims to provide an overview of the AMRH initiate including documented successes so far on collaboration in MA of medical products; pharmacovigilance and ongoing alignment of similar initiatives. It will serve as a pre-cursor for an in-depth analysis of the East African Community (EAC) medicines regulatory harmonization (MRH) project to identify gaps, challenges and opportunities for improvement. Lessons learnt from other RECs will also be explored with a view to provide recommendations for a sustainable mechanism for transitioning the AMRH into the African Medicines Agency (AMA).

The paper is structured in a way that provides baseline status of medicines regulation before AMRH inception; progress on harmonization of registration requirements and joint assessment in RECs; the status of implementation of AU Model Law on medical products regulation; efforts to accelerate the fight against sub-standard and falsified medical products and approaches to institute sustainable regulatory capacity development programmes. The paper further provides strategies for implementing phase two of the AMRH Initiative focusing on CTA, pharmacovigilance and post marketing surveillance; as well plans for alignment of various regulatory systems strengthening and harmonization initiatives as a foundation for establishment of the AMA.

2. Baseline assessment and development of regional medicines regulatory harmonization projects

Prior to the launch of regional MRH Projects, AMRH partners conducted a situation analysis of the status of medicines regulation in the EAC, the Southern African Development Community (SADC) and the Economic Community of West African States (ECOWAS). The assessment in the EAC region indicated variation in countries laws and regulations, absence of a mutually recognized legal framework and marked differences in capacity among the NMRAs within the region [7]. Reports in SADC and ECOWAS regions revealed similar results with varying comprehensiveness of legal frameworks between countries which in turn affects the capacity to effectively regulate the market [8, 9, 10]. The inconsistency between regulatory frameworks and procedures within RECs and within the African region more broadly imposes further burdens on both innovator and generic pharmaceutical manufacturers, who face the added expense of adapting MA requirements to the particularities of different countries [1]. The implication of these findings is that there's not only an efficiency loss for manufacturers and registrants of medicines, but there is also considerable and inefficient efforts duplication by over-burdened NMRAs, resulting in delays that ultimately impact on patient health [1].

As a result of these studies, regional MRH projects were developed with the initial funding and launching of the EAC MRH Project in 2012 followed by SADC and ECOWAS MRH Projects launched in 2015. The EAC MRH Project specifically aimed to; implement an agreed common technical document for registration of medicines in EAC Partner States; implement a common information management system (IMS) for medicines registration in each of the EAC; build a quality management system (QMS) in each EAC Partner States' NMRAs; construct regional and national capacity to implement medicines registration harmonization in the EAC; create a platform for information sharing on the harmonized medicines registration system to key stakeholders at national and regional level; and develop as well implement a framework for mutual recognition based on Chapter 21, Article 118 of the East African Community Treaty [11, 12]. The EAC MRH project marked the beginning of the implementation phase of the AMRH initiative across Africa, aiming to achieve a harmonized medicines registration process in its member countries – Uganda, Kenya, the United Republic of Tanzania, Rwanda and Burundi – based on common documents, processes and shared information systems [13].

In the SADC region, an MRH Project proposal was developed by NMRAs with support from the AMRH Partners in 2011. Due to limited funding under the GMRH-MDTF, a DFID funded project, the Southern African Regional Programme Access to Medicines and Diagnostics (SARPAM) initiated and supported a ZAZIBONA scheme among four (4) NMRAs in the SADC region since October 2013. The founding member countries of ZAZIBONA scheme namely; Zambia, Zimbabwe, Botswana and Namibia agreed to work together under a collaborative procedure for medicines registrations technically supported by WHO [14]. This was part of breakthrough activities in support of implementation of a broader MRH Project developed in 2011. It was during the same year when the MRH Project for ECOWAS region was developed and validated by the NMRAs in the region under the coordination of the West African Health Organization (WAHO) in

collaboration with the West African Economic and Monetary Union (WAEMU). The SADC and ECOWAS MRH Projects were officially launched in 2015 [15].

3. Progress on harmonization of registration requirements and joint assessments in RECs

3.1. EAC: As of April 2017, the EAC Joint Assessment Procedure received a total of 32 applications, of which 27 were evaluated, resulting in 4 product registrations and 23 applications queried with an estimated 30 - 40% faster completion of evaluation procedure than the national levels, resulting in significant cost and time savings [11]. In 2015/2016, the median timeline from dossier submissions to national marketing authorization in the EAC region was reduced to seven (7) months since implementation of joint dossier assessments compared to the previous 1 – 2 years [16]. A recent study conducted by Janssen Pharmaceutica Inc. showed a reduction of approval times by 40 – 60% for a number of branded medicines through joint dossier assessments in the EAC [17].

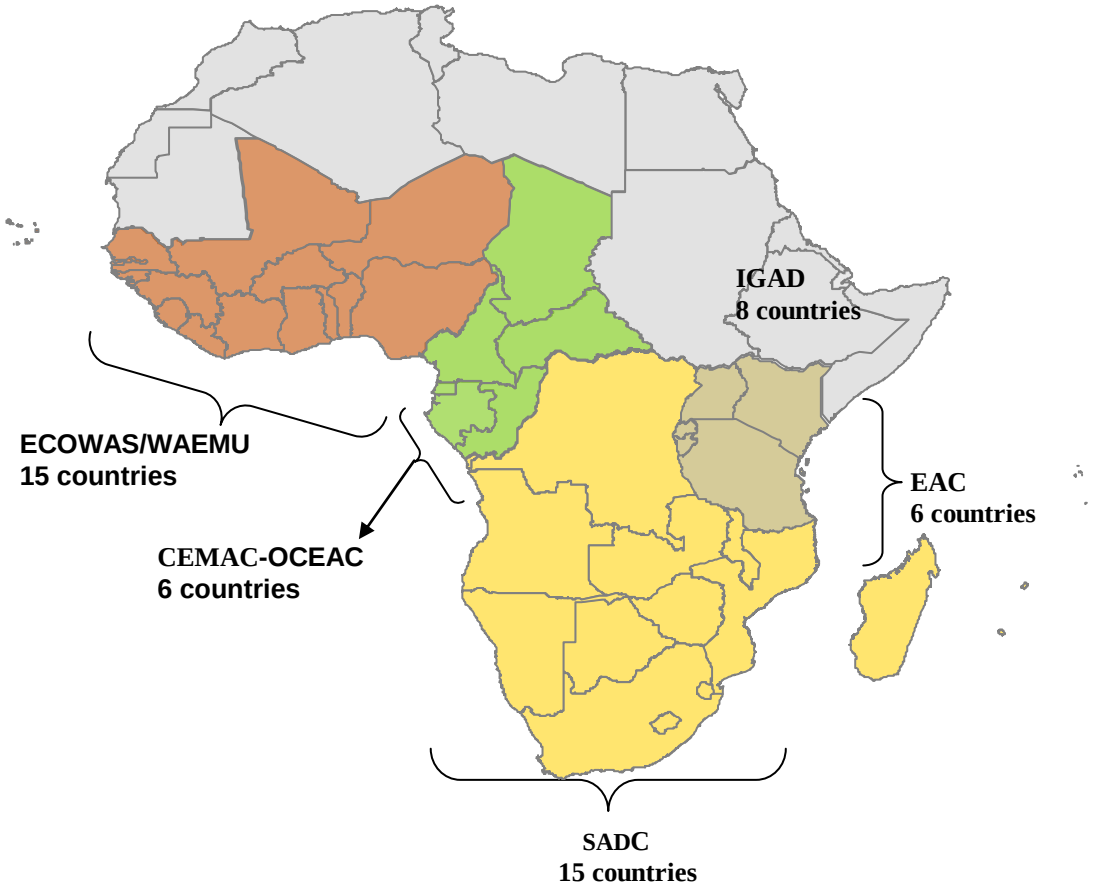
3.2. SADC: Building on the success of the EAC MRH project joint dossier assessments, the SADC region initiated a platform in 2013 called ZAZIBONA, initially composed of Zambia, Zimbabwe, Botswana and Namibia to coordinate joint assessments in the region. The ZAZIBONA process was established with a view to facilitate availability of good-quality medicines through work-sharing in assessment of medicines and inspection of medicine manufacturing and testing facilities. The aim is to significantly reduce time taken to grant MA in the individual countries; and ensure efficient utilisation of resources among NMRAs in the region through work sharing [18]. The ZAZIBONA initiative has evaluated 179 product applications over 15 meetings from October 2013 with a final decision reached for more than 90 products and a mean time to recommendation estimated at nine months [19,20]. While the ZAZIBONA scheme was officially adopted as a SADC MRH Programme in 2014, a total of ten (10) countries (including the four founding members) have now joined the scheme with different membership status including; South Africa, (active), Swaziland (active), Democratic Republic of Congo (active), Angola (non-active), Seychelles (non-active) and Malawi (non-active) [16].

3.3. Implementation of MRH Projects in other RECs: Implementation of MRH regional projects has stretched from SADC and EAC regions to include West Africa where WAHO and WAEMU are working collaboratively to implement a common technical document. A joint dossier assessment will be initiated in 2017 with technical support from WHO. The Economic and Monetary Community of Central Africa (CEMAC) region has established since 2016, a Steering Committee to provide oversight on MRH Project and SF products under the leadership of the Organization of Coordination for the Fight Against Endemic Diseases in Central Africa (OCEAC). Similarly, Member States NMRAs of

the Intergovernmental Authority on Development (IGAD) have agreed and signed the Call for Action to initiate the implementation of a regional MRH Project since 2016. The overall coverage of the AMRH Initiative across the continent is more than 85% as indicated below in **Figure 1**.

Figure 1: AMRH Coverage across Sub-Saharan Africa

> 85% of Sub-Saharan Africa covered with medicines registration harmonization (MRH) Projects at different levels of implementation



Source: AMRH Publications

Key:
CEMAC - The Economic and Monetary Community of Central Africa
EAC – East African Community
ECOWAS – Economic Community of West African States
IGAD - Intergovernmental Authority on Development
OCEAC - Organization of Coordination for the Fight Against Endemic Diseases in Central Africa
WAEMU – West African Economic and Monetary Union

Note: *Most countries in Africa belong to more than one regional economic bloc*

Here it is important to note that, while positive progress has been registered on the implementation of regional MRH Projects, there is need for a critical review of the existing regional joint review processes undertaken in EAC and SADC through ZAZIBONA approach to determine the best option which will ensure efficiency and effective decision making process at country levels. On this regard it is important to consider variations in regulatory capacities among countries, regions size and different historical heritage among countries.

4. The Status of implementation of African Union (AU) Model Law on Medical Products Regulation

In order to address the barrier of non-existent, weak or non-coherent medicines laws in African countries, the AMRH Initiative developed the AU Model Law on medical products regulation to ensure effective regulation and promote harmonization [21, 22]. The Model Law endorsed by the AU Assembly in January 2016, is at different levels of domestication and implementation by twelve (12) African countries. 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 [23].

The AU Model Law is available in English, French, Portuguese and Arabic and the aim is to have at least 25 AU Member States using a version of the Model Law on medical products regulation by 2020. In order to facilitate implementation of the AU Model Law, AMRH has established a continental Technical Working Group on Policy and Regulatory Reforms (TWG-PRR) composed of regulators and legal experts from AU Member States, RECs and RHOs to guide the domestication process. Currently, regional roadmaps for implementation of the AU Model Law have been developed and AU Member States are able to update their regulatory frameworks and enact a version of the AU Model Law that befit their country context to strengthen their national regulatory capacity.

According to WHO, "the highest attainable standard of health is a fundamental right of every human being and this right includes access to timely, acceptable, and affordable healthcare of appropriate quality" [24]. The Model Law will contribute to facilitate review or enactment of national laws in Africa in line with international standards contributing to and facilitating availability of medical products.

4.1. Accelerating efforts combat Sub-Standard and Falsified medical products

It is estimated that the pharmaceutical market size in Africa will be worth between USD 40 Billion to USD 65 Billion by 2020 [25]. However, more than 70% of the medicines consumed on the continent are imported making regulation by most of African countries difficult, fuelling illicit transactions of drugs and contributing to health problems [26].. A recent report on counterfeit medicines in Central Africa indicates that illicit trade in drugs accounts for 25% of the pharmaceutical market size in countries where it is poorly developed and up to a high of 55% in countries where it is well developed [27]. Since the problem of sub-standard and falsified (SF) medical products is not unique in Central Africa alone, implementation of the AU Model Law on medical products by AU Member States can assist to strengthen national and regional regulatory systems while at the same time complementing the war against SF medical products through enforcement of a specific provision for prohibition of

Sub-Standard and Falsified medical products [28, 29].

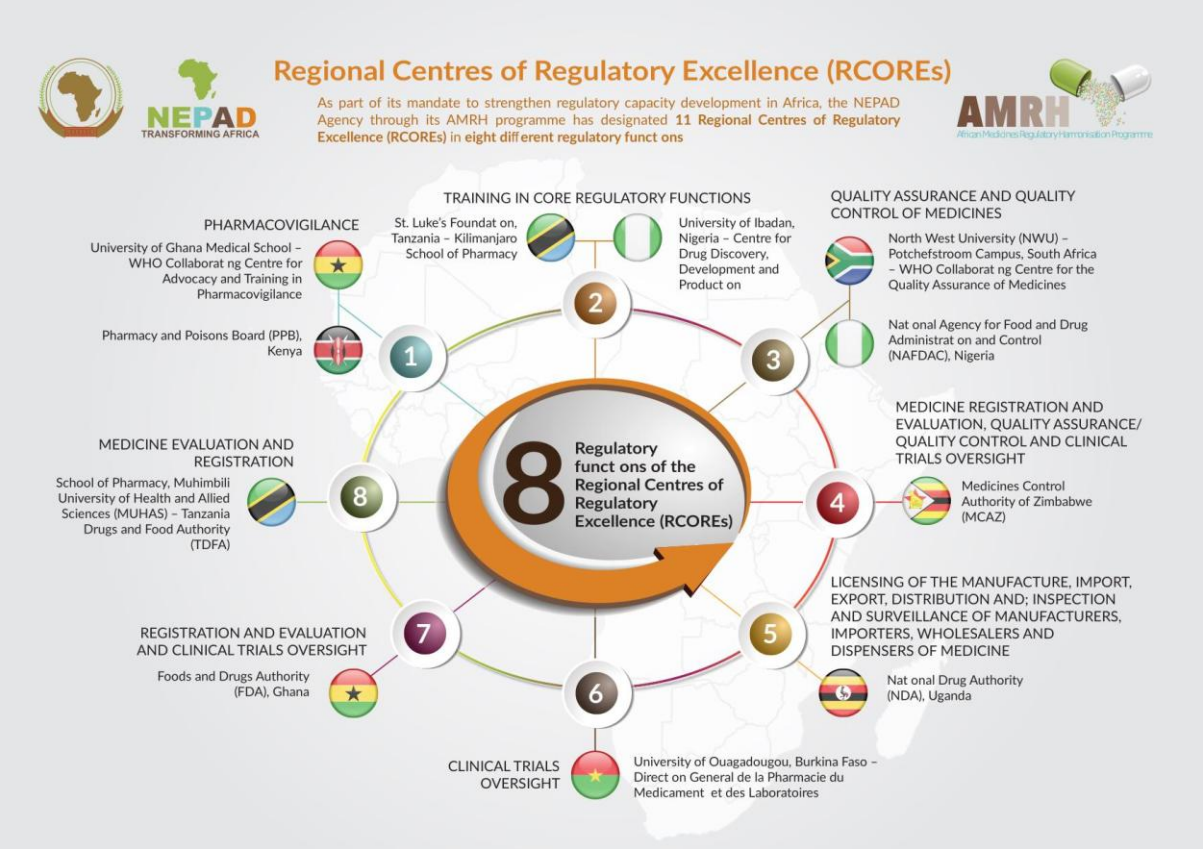
In addition, NEPAD Agency together with United States Pharmacopeia (USP) and the West African Health Organization (WAHO) have agreed to work together towards transforming the Network of Medicines Control Laboratories in Sub-Saharan Africa (NOMCoL–SSA) into the African Medicines Quality Forum (AMQF) to address the challenge of prevalence of SF medical products on the continent [30]. AMQF will complement the work of the AU Model Law in addressing issues of medicines quality control and post marketing surveillance ensuring that an appropriate legal framework is instituted to facilitate establishment of quality control laboratories as part of the NMRAs. The NOMCOL-SAA is now being co-led by the USP and NEPAD Agency, and expanding in the scope and reach, to cover all African countries as part of the newly developed AMQF. The AMQF will continue to build laboratory and regulatory staff technical capabilities, while also playing an advocacy role to reduce the prevalence of SF medical products in circulation on the African markets [31].

4.2. Instituting sustainable regulatory capacity development programmes

Beyond MRH regional projects, the AMRH also initiated in 2014 a programme to establish Regional Centres of Regulatory Excellency (RCOREs) as part of its mandate to develop and strengthen regulatory capacity in Africa. The AMRH recognizes the importance of regulatory capabilities development in delivering quality healthcare services and addressing regulatory capacity gaps and challenges experienced by NMRAs and the pharmaceutical sector in Africa. As a result, AMRH, through the NEPAD Agency, has designated a total of 11 RCOREs in eight (8) different regulatory functional areas across the continent. [32]. The USP Centre for Pharmaceutical Advancement and Training (CePAT) in Ghana serves as a Reference Centre of Regulatory Excellence (RefRCORE) for NEPAD, providing capacity building support and expertise to the 11 RCOREs.

RCOREs are institutions or partnership of institutions with specific regulatory science expertise, as well as training capabilities and their role is to produce regulatory workforce in Africa through performing four (4) key functions. These include; providing academic and technical training in regulatory science applicable to different regulatory functions and managerial aspects; contributing to skills enhancement through hands-on training, twinning and exchange programmes among NMRAs; encouraging practical training through placement pharmaceutical industry; and spearheading operational research to pilot-test innovations and interventions to inform best practices and promote scaling up activities [13]. RCOREs have been designated in the following key areas; pharmacovigilance, clinical trials oversight, quality assurance and medicines quality control , medicines registration and evaluation, licensing of manufactures, importers, exporters, distributors, inspectors and surveillance, as well training in core regulatory functions. The eleven (11) designated RCOREs in different areas of regulatory expertise are indicated in **Figure 2.**

Figure 2: AMRH Regional Centres of Regulatory Excellence



Source: NEPAD AMRH Publications, 2017

4.3. Biennial Scientific Conferences on Medical Products Regulation in Africa:

In addition to RCOREs, AMRH also initiated the Biennial Scientific Conferences on Medical Products Regulation in Africa (SCoMRA) as a continental platform for sharing lessons learnt and best practices, facilitating networking and collaboration, reflect on the work accomplished so far and rejuvenate actions towards sustaining the momentum for regulatory strengthening and harmonization in Africa. The Scientific Conference sets the medicines regulatory strengthening and harmonization agenda for the future through strategic exchange of knowledge and ideas. The inaugural Biennial Scientific Conference was held in Johannesburg, South Africa in 2013 with the theme *Building Partnerships for Sustainable Capacity Development in Medicines Regulation in Africa*. This was followed by the 2nd Biennial Conference which took place in 2015 in Addis Ababa, Ethiopia under the theme *Regulatory Systems Strengthening for Advancing Research, Innovation and Local Pharmaceutical Production in Africa*. In 2017, the theme of the 3rd Biennial Scientific Conference is *Sustaining the Momentum for Regulatory Harmonization in Africa* and will take place in Accra, Ghana from 27 – 28 November 2017. It will be the first time that the Biennial Scientific Conference is held at the same time as the AVAREF Assembly which will take place on 29 November 2017 in the spirit of collaboration and harmonization. These will

also be followed by the African Medicines Regulators Conference (AMRC) from 30 November to 01 December 2017 [33].

5. Alignment of regulatory systems strengthening and harmonization efforts as a foundation for AMA

The original thinking under the AMRH Initiative has been to gradually expand the scope of work from registration of generic medicines to other regulatory functions and products including oversight on vaccines clinical trials, pharmacovigilance, New Chemical Entities (NCEs), medical devices and diagnostics, just to mention a few; and a step-wise geographical expansion to cover all African countries [34]. Expansion of the scope of this work demands improved coordination and harmonization of the different partners and stakeholders to avoid duplication, fragmented priorities and ensure resource optimization.

In order to ensure alignment and define the next scope, AMRH Partners convened a strategic workshop in February 2017 bringing together AMRH global partners, regional and national stakeholders to plan on implementation of phase two of the Initiative [35]. *A five year strategic direction and establishment of a lean governance structure for the successful implementation of phase two of the programme were agreed*. Furthermore, there was consensus reached on realignment of other similar programmes with AMRH activities to provide end to end programme impact in Africa from CTA, MA to safety surveillance of medical products. 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 [32]. Subsequently, a Steering Committee on Medical Products Regulatory Systems Strengthening and Harmonization has been established to provide oversight [32].

This implies scaling up the work of AMRH and creating linkages with other similar initiatives on regulation of medical devices and diagnostics, and blood products such as; AVAREF, NOMCoL-SAA and Pan African Harmonization Working Party (PAHWP). This alignment will be coordinated by NEPAD Agency through the AMRH Partnership Platform (AMRH-PP) as Africa chapter of the Global Coalition of Interested Partners (CIP), operating under the oversight of the AMRH Steering Committee [32]. While the existing continental Technical Working Groups (TWGs) under the AMRH Initiative namely, TWG on Regulatory Capacity Development, TWG on Policy and Regulatory Reforms and EWG on Good Manufacturing Practice (GMP) standards will be maintained, new TWG on registration and PV will be established to develop continental frameworks which can be adopted by RECs and NMRAs. Existing networks such as AVAREF and NOMCOL-SAA will be transformed into continental TWGs.

On the PV front, a consensus reached by PV stakeholders in 2015 shall serve as basis for establishment of a continental framework for sustainable capacity development on PV in Africa with a view to assist countries to have a national PV system which meets internationally acceptable standards as recommended by WHO [36]. PV requirements and guidelines will be harmonised to ensure availability of complementary and simplified tools to be used by NMRAs, MA holders and all other stakeholders in PV in Africa. A database of PV experts in Africa, regional expert working groups and an Africa PV Advisory

Group (APAG) will be established to ensure coordination of the many fragmented PV initiatives on the continent and the development of a coherent framework for PV in Africa. The RCOREs on PV will be used as vehicle for sustainable regulatory capacity development to ensure increased workforce and institutional capacity to undertake training programmes to address Africa's needs and priorities and as a long term strategy to support the ongoing regional MRH Projects. Advocacy for increased investment by international partners and governments on PV including financial and technical resources is key.

AVAREF, as a regional regulatory network founded in 2006 by WHO, was initiated at a time when the focus on clinical trials of vaccines began to shift from developed countries to developing countries, including those in sub-Saharan Africa [37]. Starting with nineteen (19) NMRAs and ethics committees of the countries in the WHO African region, the forum had expanded to 23 member countries by 2016 when a new governance structure was agreed. The New AVAREF Goal is to strengthen clinical trials regulatory authorization and oversight in Africa by increasing system's efficiency and building an optimal clinical trial infrastructure through harmonized requirements for CTA and ethics committee approval, to develop and implement guidelines for joint review of clinical trial applications at regional or multi-country level for vaccines and drugs candidates [38]. Key among AVAREF's achievements has been the establishment of innovative regulatory pathways for clinical trials; the development and use of common guidelines for submission of clinical trial applications, and the use of joint reviews of multi-country clinical trial applications and joint good clinical practice (GCP) inspections. As a result, AVAREF has registered improved timelines for product development joint reviews and GCP inspections have played a key role in ensuring timely regulatory authorization and approvals of MenAfriVac®, the meningococcal A conjugate vaccine whose rollout in the meningitis belt of Africa has eliminated epidemic meningitis due to Group A Neisseria meningitides as a public health problem [37]. A joint review approach was also used to coordinate and expedite the review of the multi-country Phase III clinical trial for the lead malaria candidate vaccine, RTS,S/AS01, which is about to conclude in seven African countries. The platform that has been instrumental in providing regulatory support to accelerate product development during public health emergencies, as exemplified with products in development against Ebola [37]. In view of these achievements, AVAREF future is destined to support the work of African regulators on vaccines for diseases such as HIV, tuberculosis and malaria, which are affecting millions of people on the continent.

Concrete achievements registered under AMRH and AVAREF serve as a foundation for establishment of AMA in line with the call by the AUC-WHO Joint meeting of the Ministers of Health held in 2014 in Luanda, Angola and the AU Executive Council Decision EX.CL/DEC.857 (XXVI) of 2015 [39, 40, 41]. The AU leadership has called upon Member States to prioritize investment for regulatory capacity development; to pursue the efforts towards convergence and harmonization of medical products regulation in RECs and to allocate resources for the operationalization of the AMA [42]. The AMRH and AVAREF success stories provide an enabling reg-ulatory environment for research and development, innovation and local production of pharmaceuticals, optimizing competitiveness and expanding market [32].

It is important to note that Africa needs strong institutions that can address the challenges of access to quality, safe and efficacious medical products and technologies, so establishment of the AMA is a very important step in the right direction [42]. AMA does not seek to replace NMRAs national sovereignty, instead it will complement NMRAs, RECs and RHOs' efforts in the process of establishing an enabling environment for the development of the pharmaceutical industry through better coordination of different partners and stakeholders undertaking medicines regulatory strengthening and harmonization efforts on the continent [43] [44]. It is therefore necessary for Africa to lay a sound ground for pharmaceutical market growth while at the same time taking advantage of the increasing political stability; rapid economic development; increasing investment in public health; maturing regulatory environment; and rising consumerism [45].

Sustaining the AMRH and AVAREF momentum and a smooth transition into AMA will contribute to reducing technical barriers to trade especially at this time when the RECs are rapidly moving towards stronger economic integration [3]. The EAC Common Market and the Customs Union which have been operational since 2010, are just some examples [46].

6. Conclusion

Phase one of the AMRH Initiative has recorded significant success in harmonising registration requirements and facilitating joint reviews of dossiers in EAC and SADC with resultant reduction in approval timelines. Review of gaps in the regional joint review process is critical to inform scale up to other RECs. Phase two of the AMRH Initiative entails expansion of regulatory scope and products including establishing continental frameworks for registration of medical products, CTA, PV and PMS. The AU Model Law on Medical Products Regulation and RCOREs will facilitate improvement in regulatory capacity.

Looking forward, AMRH will continue to work towards improving medicines regulatory and harmonization landscape in Africa in line with its vision of ensuring that African people have access to the needed essential medical products and technologies. Alignment of regulatory systems strengthening and harmonization efforts and advocating for establishment of AMA is key for optimizing pharmaceutical markets and sustainability in the supply of medical products and technologies for diseases disproportionately affecting Africa.

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