Concept Note

3rd Biennial Scientific Conference on Medical Products Regulation in Africa

Theme: Sustaining the Momentum for Regulatory Harmonization in Africa

27th - 29th November 2017

Accra, Ghana

1. Background

Following the African Union (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 Pharamaceutical Manufacturing Plan for Africa (PMPA), the AU Conference of Health Ministers (AUCHM) was convened in 2007 under the theme "Strengthening of Health Systems for Equity and Development in Africa" to respond to the AU Decision. This led to the development of the African Medicines Regulation Harmonization (AMRH) initiative[1] which was launched in 2009 within the PMPA Framework to facilitate the creation of an enabling regulatory environment for pharmaceutical sector development in Africa through harmonisation of regulation by the Member States through the Regional Economic Communities (RECs). The ultimate vision is African populations having access to essential medical products and health technologies. It was envisioned that through harmonisation, the regulatory capacity challenges that the continent is facing which imped access to medical products and technologies will be surmounted.

Access to good quality, safe and efficacious medical products and health technologies for preventing, diagnosing and treating medical conditions is an essential component of any public health system. Estimates indicate that medical products are an important component of the total government health expenditure accounting for as high as 67% in some Low and Middle-Income Countries (LMICs).[2] The inappropriate use and management of medical products contributes to inefficiencies in health systems.. It is also known that unavailability of medical products as well as variability in the quality of medical products on the market with the proliferation of substandard, spurious, falsified, falsely-labelled and counterfeit medical products reduces public confidence in the health care delivery system.[3] Therefore, regulation of medical products is an important step towards facilitating access to quality medical products.

The AU recognises the important role of regulation in improving access to medicines. It is in recognition of this fact that the decision to develop the PMPA was adopted by the AU in 2005 to enhance investment in the continent's production of pharmaceuticals for sustainable access by the people of Africa. Furthermore, the AU Summit endorsed the Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa in 2012. Pillar II of this Framework focuses on ensuring accelerated access to affordable and quality assured medicines and health-related commodities. In addition, one of the policy measures of the AU Agenda 2063 is the need to make health services accessible to all through sustainable social policies. The United Nations Sustainable Development Goal (SDG) 3 further emphasises the importance of strengthening African countries' health system and ensuring that the populations have sustainable access to the needed medical products. Hence, strengthening national capacity for regulation of medical products and harmonisation plays an important role in facilitating delivery of medical products to the population that require them.

Over the last nine (9) years, the AMRH hasmade a difference in strengthening regulatory systems in Africa. The initiative focusses on addressing gaps in regulatory capacity at national and regional levels. These gaps are well documented in a number of situation analyses and studies conducted in Africa. Some of these challenges include limited human and institutional capacity, lack of comprehensive legal frameworks giving a mandate to the governments to regulate medical products, inconsistent regulatory processes, and variable technical standards and guidelines that do not meet international standards.

The year 2018 will mark the first 10 years of the African Medicines Regulatory Harmonisation Initiative since its initial consultation phase in 2008. The AMRH built on initial efforts in RECs such as the East African Community (EAC) harmonization efforts which started in 2000 but took shape in 2006 as well as Southern African Development Community (SADC), West African Economic and Monitory Union (WAEMU) and West African Health Organization (WAHO), and other initiatives including South, Eastern African Medicines Regulatory Authority Conference (SEAMRAC) which started in 1995.

1 AMRH is implemented as a partnership pf NEPAD Agency, African Union Commission (AUC), Pan African Parliament (PAP), the World Health Organization (WHO), the World Bank (WB), the Bill and Melinda Gates Foundation (BMGF), the UK Department for International Development (DFID), and the Clinton Health Access Initiative (CHAI)

2 Lu Y, Hernandez P, Abegunde D, Edejer T. Medicine expenditures. In: The world medicines situation 2011. Geneva: World Health Organization; 2011 (http://apps.who.int/medicinedocs/documents/s18767en/s18767en.pdf, accessed January 2015)

3 The world health report. Health systems financing: the path to universal coverage. Geneva: World Health Organization; 2010. http://www.who.int/whr/2010/en/, accessed January 2015

Upon the inception of the initiatives, African countries agreed to start with the harmonisation of registration of generic medicines as a pathfinder for moving towards other regulated products, regulatory functions and new molecules. The initiative was designed to achieve the following outcomes: (i) adoption of standardised technical guideline requirements; (ii) joint regional assessment of applications; (iii) joint regional Good Manufacturing Practices (GMP) inspections; (iv) regulatory capacity building; and (v) adoption of legal frameworks to support regulation and harmonisation. The EAC-Medicines Regulatory Harmonization project was the first to be launched and has so far achieved a number of results including (i) the adoption and domestication of joint regional guidelines; and (ii) initiation of joint regional assessments and inspections which has led to quicker registration of the products that have been jointly reviewed.

The projects for Economic Community for West Africa States (ECOWAS)[4], SADC, Intergovermental Authority for Development (IGAD) and the Economic and Monetary Community of Central Africa (CEMAC) through its Organization for the Fight Against Endemic Diseases in Central Africa (OCEAC) have also been initiated the harmonization process with progress at different levels. At the continental level, there has also been progress in tackling challenges on legal frameworks through the adoption and domestication of the AU Model Law on Medical Products Regulation. Furthermore, Regional Centres of Regulatory Excellence (RCOREs) have been designated to ensure sustainable regulatory capacity development programmes that will contribute to increasing regulatory workforce in the continent. The process for the establishment of the African Medicines Agency (AMA) by 2018 has also made tremendous progress with the drafting of the Legal and Institutional Framework and business plan. There is also progress on expanding the scope of AMRH to cover other regulatory functions such as clinical trials,[5] post-marketing surveillance and pharmacovigilance as well as other regulated products.

The 10-year mark of harmonisation efforts in Africa, therefore, presents the continent with an opportunity to redesign and sustain the momentum on regulatory systems strengthening and harmonisation in Africa. The following key questions for reflection are fundamental as we move towards 2018:

I. Has the progress on harmonisation been significant in addressing regulatory capacity challenges?

II. What role has regulatory systems strengthening and harmonisation played in bridging the gap between research and development and availability of medical products?

III. Which areas of regulatory systems strengthening and harmonisation should the continent focus on moving forward?

IV. How best should AMRH expand to cover other regulatory functions and medical products?

V. What needs to happen to sustain the momentum of harmonisation in Africa?

VI. What is the future of National Regulatory Authorities in the advent of regional harmonisation and establishment of regional agencies and AMA?

The third Biennial Scientific Conference on Medical Products Regulation in Africa will, therefore, provide a platform for stakeholders to reflect on the progress that has been made in regulatory systems in Africa over the past 10 years and map the trajectory moving forward. The theme of the conference: "Sustaining the Momentum for Regulatory Harmonization in Africa" will enable participants to contribute towards the future of regulation and harmonisation in Africa. The conference will also provide a platform for stakeholders to brainstorm on the role of ethical and regulatory approval of clinical trials in bridging the gap between research and development given the existing vacuum in advancing clinical trials that are relevant for diseases affecting African countries.

4 A joint project of West Africa Health Organisation and West Africa Economic and Monitory Union (WAENU)
5 This work is being done through the alignment of the efforts of AVAREF with AMRH

2.0 Goal and Objectives

2.1 Overall Goal

The overall goal of the third Biennial Scientific Conference on Medical Products Regulation in Africa is to review progress and deliberate on actions for sustaining the momentum for regulatory systems strengthening and harmonisation in Africa for addressing diseases that affect the continent.

2.2 Specific Objectives

The following specific objectives will be addressed:

I. To review progress in regulatory systems strengthening and harmonisation in Africa for improved access to medical products and health technologies.

II. To identify actions towards sustaining the momentum of regulatory harmonisation in Africa.

III. To facilitate a platform to share lessons learnt and best practices in regulatory systems strengthening.

IV. To facilitate collaboration and networking among different stakeholders including regulators, policymakers, academia, scientific community, private sector and civil society.

2.3 Expected Outcomes

The conference will have the following outcomes:

I. Increased commitment from key stakeholders on regulatory systems strengthening and harmonisation.

II. Actions for sustaining the momentum on regulatory harmonisation in Africa identified.

III. Increased knowledge on regulation of medical products and harmonisation efforts in Africa.

IV. Stakeholder awareness on the progress made in medical products regulatory systems in Africa.

V. Agreed framework for collaboration and networking among regulators, researchers and industry in advancing research and development and subsequent commercialization of products for diseases disproportionately affecting Africa.

2.4 Conference Outputs

I. Conference book of abstracts

II. A publication of conference proceedings

3.0 Conference Structure

The third Biennial Scientific Conference on Medicines Regulation in Africa is designed to provide a platform for a participatory process in designing the future of regulatory systems strengthening and harmonisation in Africa. The conference will thus utilise both plenary discussions and parallel sessions to facilitate experience and information exchange among stakeholders. There will also be social media presence to broadcast proceedings.

The sessions of the conference will include:

I. Opening session

II. Harmonisation of regulation of medical products in Africa, where are we?

- AMRH
  - Continental overview
  - Regional progress
- African Vaccines Regulatory Forum (AVAREF)
- Pan African Harmonization Working Party (PAHWP)

III. Contextualising medical products regulation in the health systems

- Country experiences
- Efficiency of the health systems: availability and access to medical products
- Monitoring the impact of regulation and harmonisation

IV. Africa's capacity for regulation of medical products after 10 years of harmonisation

- RCORES
- Institutional capacity

V. Using technology to improve medical products regulation

VI. Sustainable financing of medical products regulation in the advent of harmonisation

- Sharing best practices and lessons learnt

VII. Shaping the future of medical products regulation in Africa: Sustaining the momentum after 10 years of harmonisation efforts.

- Future models for regulation and harmonisation
- The African Medicines Agency

VIII. Closing session

4.0 Call for Abstracts

Presentations on the above topics will be solicited from applicants through a call for abstracts that will be submitted to the organising committee. A technical team will be setup to review the abstracts and make recommendationsfor either oral and/or poster presentations. Successful applicants will be called upon to submit full papers for further evaluation and publication in the conference proceedings. The posisbility to publish the articles in a reputable peer-reviewed academic journal will be explored.

5.0 Participants

The conference will bring together over 300 participants including:

- Policy Makers from ministries of health, finance, trade and industry and other relevant ministries;
- Legislature including national parliaments, regional parliaments and the Pan African Parliament;
- Regulators from National Medicines Regulatory Authorities (NMRAs) in Africa;
- Regulators from other NMRA partnering with Africa;
- Members of Ethics Committees/Institutional Review Boards (IRB);
- Clinical Trials sponsors;
- Industry representatives;
- AMRH Partners and other partners involved in regulatory work in Africa;
- Stakeholders involved in other aspects of medical products regulations including control of food, cosmetics; control of narcotics and psychotropic substances etc;
- Representatives from Regional Economic Communities;
- Researchers;
- Academia;
- Development Partners in Health and Pharmaceutical Sectors in Africa.
- And other relevant stakeholders

6.0 Draft Programme (To be shared as Annex 1)

7.0 Venue and Dates

The third Biennial Scientific Conference on Medicines Regulation in Africa will be held in Abidjan, Côte d'Ivoire Coast from 29th November – 1st December 2017

8.0 Working Languages

- The conference will have two working languages: English and French with simultaneous interpretation provided.
- Working documents will also be available in both languages.

9.0 Conference Budget

The total budget for the conference is US $ 422,331.00. A detailed conference budget is attached as Annex II.

Contact Persons and Addresses

Additional Information can be obtained from the following focal points:

1. African Medicines Regulatory Harmonization (AMRH) Programme
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