3rd Biennial Scientific Conference on Medical Products Regulation in Africa

Theme: Sustaining the Momentum for Regulatory Harmonization in Africa

27th November – 29th November 2017

Accra, Ghana

Call for Abstracts

Background

African countries made a bold decision in 2009 to harmonise regulation of medical products with an overall goal of strengthening regulatory systems. Following this decision, the African Medicines Regulation Harmonization (AMRH) initiative[1] was launched to facilitate the creation of an enabling regulatory environment for pharmaceutical sector development in Africa through harmonisation of regulation in the Regional Economic Communities (RECs). The ultimate vision is African populations having access to essential medical products and technologies. It was envisioned that through harmonisation, the regulatory capacity challenges that the continent is facing which impede access to medical products and technologies will be surmounted.

The AMRH has over the last nine (9) years made a difference in strengthening regulatory systems in Africa. The initiative focusses on addressing gaps in regulatory capacity at national and regional levels as revealed by a number of 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 Third Biennial Scientific Conference on Medical Products Regulation in Africa will be held in Accra, Ghana from 27th November – 29th November 2017. The theme of the 3rd conference is ***"Sustaining the Momentum for Regulatory Harmonization in Africa"*****.** The Third Biennial Scientific Conference on Medical Products Regulation in Africa builds on progress made since the first and second conferences were held in Johannesburg, South Africa (2013) and Addis Ababa, Ethiopia (2015).

[1] AMRH is implemented as a partnership of 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)

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 regional harmonisation initiatives being implemented through RECs and regional organizations (ROs) in Africa for addressing diseases that affect the continent.

Specific Objectives

The following are the specific objectives of the conference are:

1. To review progress in regulatory systems strengthening and harmonisation in Africa for improved access to medical products and health technologies.
2. To identify actions towards sustaining the momentum of regulatory harmonisation in Africa.
3. To facilitate a platform to share lessons learnt and best practices in regulatory systems strengthening.
4. To facilitate collaboration and networking among different stakeholders including regulators, policymakers, academia, scientific community, private sector and civil society.

Expected Outcomes

The conference is expected to attain the following outcomes:

1. Increased commitment from key stakeholders on regulatory systems strengthening and harmonisation.
2. Actions for sustaining the momentum on regulatory harmonisation in Africa identified.
3. Increased knowledge on regulation of medical products and harmonisation efforts in Africa.
4. Stakeholder awareness on the progress made in medical products regulatory systems in Africa.

5. 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.

Conference Structure

The third Biennial Scientific Conference on Medical Products 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.

The outline of the sessions of the conference include:

1. **Opening session**

   Official opening ceremony

   Keynote Presentation: *Regulatory Harmonization in Africa: The Journey and the Future outlook* that will be presented by Ms. Gugu Mahlangu, Director-General, Medicines Control Authority of Zimbabwe (MCAZ) and Chairperson, African Medicines Agency (AMA) Task Team

2. **Plenary Session I: Harmonisation of regulation of medical products in Africa, where are we?**

   Session objectives: *Harmonisation of medical product regulation in Africa was initiated with the aim of increasing access to essential medical products and health technologies to the continent's population. The African Medicines Regulatory Harmonization (AMRH) was launched in 2009 to galvanise Regional Economic Communities' (RECs) efforts towards achieving regional harmonisation. This session, therefore, aims at reviewing the progress that has been made in regulatory systems strengthening and harmonisation at the regional and continental levels. The session will also review the opportunities, challenges and lessons learned with the aim of designing strategies for moving forward and sustaining the momentum that has been gained so far.*

3. **Plenary Session II: Learning from other harmonisation and collaborative efforts, and partnerships for regulatory harmonisation**

   Session objectives: *This session will aim at learning from other regulatory harmonisation and collaborative efforts within the African continent and beyond. Focus will be made on regional efforts beyond Africa such as the EMA and WHO driven collaborative efforts. The session will utilise these efforts and recommend how they can be adapted to contribute to the success of harmonisation in Africa. In addition to learning from other regulatory harmonisation and collaborative efforts, the session will also look at strategies for fostering collective impact and mutual accountability through partnerships for regulatory systems strengthening and harmonisation.*

4. **Plenary Session III: Contextualising medical products regulation in the health systems**

   Session objectives: *The ultimate goal of regulatory systems is to contribute to health systems resilience by ensuring availability of safe, quality and efficacious medical products to the population. This enhances confidence among the public of their health system. This session will therefore aim at assessing the impact of medical products regulation and harmonisation on health systems strengthening. These discussions will contribute towards re-designing regulatory efforts on the road to Universal Health Coverage and Sustainable Development Goals.*

5. **Parallel Session I: Investing in Africa's Pharmaceutical Industry: The role of regulation**

   Session objectives: *The African Union, through the adoption of the Pharmaceutical Manufacturing Plan for Africa demonstrated the commitment to improving local production of pharmaceuticals. To this end, a number of activities have been implemented. The session will therefore review progress that has been made and recommend actions that need to be taken to sustain progress.*

6. **Parallel Session II: Post Marketing Surveillance and the Role of QC Laboratory**

Session objectives: *The session aims to provide a platform for learning and sharing experience on Post Marketing Surveillance (PMS) Programmes implemented by National Medicines Regulatory Authorities and their contribution to addressing the problem of sub-standard and falsified medical products. Special emphasis will be on the role of national medicines control laboratories*

7. **Plenary Session IV: Africa's capacity for regulation of medical products after 10 years of harmonisation**

Session objectives*: One of the greatest challenges to regulatory systems strengthening is limited capacity to building core regulatory activities, including those that can only be ensured at local level. To circumvent this challenge, a number of partners have been engaged in regulatory capacity development in Africa. Upon the inception of the AMRH, the Continental Technical Working Group (TWG) on regulatory capacity development recommended the establishment of Regional Centres of Regulatory Excellence (RCOREs) with the view to support sustainable regulatory capacity development in Africa. Furthermore, a pool of regulatory experts in Africa has been established to ensure effective utilisation of existing capacity in regulatory systems strengthening. This session is therefore aimed at reviewing the progress that has been made in regulatory capacity strengthening and how the existing capacity can be effectively utilised to support efficient undertaking of core regulatory functions. The session will recommend the most effective and sustainable models for strengthening regulatory capacity on the existing efforts.*

8. **Plenary Session V: Expanding the scope for regulatory harmonisation in Africa – opportunities and challenges**

Session objectives: *The initial focus on regulatory harmonisation was on registration of generic medicines. The primary focus on registration was meant to facilitate learning before expanding to other regulatory functions and other regulated products. This session will therefore look at the lessons that have been learned so far with the view to recommend the strategy for expansion to other product and regulatory functions.*

9. **Parallel Session III: Sustainable financing of medical products regulation in the advent of harmonisation**

Session objectives: *Sustainable financing is key for sustaining regulatory activities at the national and regional harmonization. However, one of the challenges currently facing the NMRAs is limited funding to support their functions.*

This session will therefore explore available options and make recommendations on models for funding regulatory activities.

10. **Parallel Session IV: Using technology to improve medical products regulation**

    Session objectives*: Use of technology facilitates efficiency and effectiveness in undertaking regulatory functions. A number of technologies have been introduced at the national level to facilitate regulation of medical products. This session will take stock of these technologies and assess their benefits in strengthening regulatory systems. Furthermore, the session will explore technologies that could be deployed at the national and regional levels to ensure efficiency and effectiveness in regulation and harmonisation.*

11. **Plenary Session VI: Shaping the future of medical products regulation in Africa: Sustaining the momentum after 10 years of harmonisation efforts**

    Session objectives: *This session will build on the outcomes from the various conference session to build a case for the future of regulatory systems strengthening and harmonization in Africa. The session will recommend actions to be undertaken at the national, regional and continental levels.*

12. **Closing Session**

    Official closing ceremony

The purpose of this Call for Abstracts is to request potential participants in the third Biennial Scientific Conference on Medical Products Regulation in Africa to submit abstracts that respond to the overall goal, specific objectives and session objectives as presented in the conference structure above. The presentations can be made orally or poster presentations.

The conference is expected to bring together participants from a wide range of professions and practitioners including Regulators form National Medicines Regulatory Authorities (NMRAs) in Africa; Regulators from other NMRAs partnering with Africa; Members of Ethics

Committees/Institutional Review Boards (IRB); Clinical Trials sponsors; Industry representatives; Policy Makers in Health, Finance and Trade and Industry, law makers from National, Regional Parliaments and the Pan African Parliament (PAP); 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 ; RECs representatives; Researchers; Academia; and Development Partners in Health and Pharmaceutical Sectors in Africa.

Interested participants should submit an abstract of at least 250 words and not more than 300 words using the using the online submission form found in the following link: http://www.nepad.org/scientificconference/index.php/ct-menu-item-5 **by 31st July 2017.**

Schedule of Key Dates

Deadline for Abstracts	31st July 2017
Information of Acceptance	30th September 2017
Submission of Full Paper	31st October 2017
Submission of PowerPoint presentation	15th November 2017
Submission of Poster Presentation	15th November 2017
Conference Dates	27th Nov – 29th Nov 2017

Participants who would like to apply for financial support to attend the conference and make presentations should indicate in the online abstract submission forms.