The 4th Biennial Scientific Conference on Medical Products Regulation in Africa
(SCoMRA IV)

Theme: A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
30 September – 01 October 2019
Victoria Falls, Zimbabwe

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 on the continent. Following this decision, the African Medicines Regulatory Harmonisation (AMRH) initiative\(^1\) was launched to facilitate the creation of an enabling regulatory environment for pharmaceutical sector development in Africa through harmonisation and alignment of regulation in the Regional Economic Communities (RECs). The ultimate vision is for African populations to access quality, safe and efficacious essential medical products and technologies. It was envisioned that through harmonisation, the regulatory capacity challenges that the continent is facing which impede access to quality medical products and technologies will be surmounted.

The AMRH has over the last ten years (2009-2019) made a significant difference in strengthening regulatory systems in Africa. The initiative focuses on addressing gaps in regulatory capacity at national and regional levels as revealed by a number of studies conducted in Africa. These gaps include; weak or non-coherent legislative frameworks, sluggish medicine registration processes and subsequent delayed approval decision, inefficiency and limited technical capacity, inconsistent regulatory processes, and variable technical standards and guidelines that do not meet international standards among others.

The work of AMRH is guided by three focus areas; (a) policy alignment (b) regional integration and harmonisation (c) and human and institutional capacity development. AMRH achieves these through implementation of Medicines Regulatory Harmonization (MRH) projects at regional level through the Regional Economic Communities (RECs) and Regional Health Organizations (RHOs). The impact of this approach trickles down to the national level, thereby benefitting AU Member States by providing guidance to NMRAs to determine priority areas of action for medicines regulatory strengthening and harmonisation in Africa.

In order to promote effective medicines regulation, ensure quality, safety and efficacy of medicines and facilitate information exchange between medicines regulators in Africa, the World Health Organization (WHO) organized the first African Medicines Regulators

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\(^1\) The AMRH Initiative is comprised of all the African NMRAs and RECs, AU Commission, Pan African Parliament, the World Health Organization (WHO), New Partnership for Africa’s Development (NEPAD), Bill & Melinda Gates Foundation, UK’s Department for International Development (DFID), US Government, Gavi, Swissmedic, Swiss Development Cooperation, and the World Bank.
Conference (AMRC) in Addis Ababa, Ethiopia in 2005 covering the 46 Sub-Saharan countries. The second AMRC was jointly organized by WHO, the NEPAD Agency and the Ministry of Health of Mozambique from 24 to 26 November 2009 excluding the 10 AU Member States which fall under the WHO Regional Office for the Eastern Mediterranean (WHO-EMRO) region. In recognition of the need to bring together all the AU Member States NMRAs (including those in the WHO-EMRO region), the WHO, NEPAD Agency and the Republic of South Africa, convened the third AMRC in December 2013.

The Biennial Scientific Conference on Medicines Regulation in Africa (SCoMRA) has been held every two years since 2013 as a platform for stakeholders’ inputs into the AMRC deliberations and decision-making process. While the former brings together policy makers, regulators, industry, academia, research organizations and scientists to network and exchange information on innovative approaches for pharmaceutical sector development in Africa, the latter is solely dedicated to African Regulators and their respective regional economic communities. It is against this background, the African Union Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) held in Addis Ababa, Ethiopia in April 2015, in recognition of the need of convening all the AU Member States, adopted a decision to ‘institutionalize the biennial AMRC as a platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision making processes’.

As a practice, SCoMRA is convened as a pre-conference to AMRC which has been institutionalized in the AU Structures and brings together all AU Member States NMRAs to deliberate on issues of common interest and concern. SCoMRA also makes recommendations to the AMRC as a technical organ of the AU to discuss, approve and endorse recommendations emanating from SCoMRA for further consideration by the Policy Organs of the AU. There is equally feedback from AMRC to SCoMRA on progress and challenges in regulatory systems strengthening in Africa.

The third SCoMRA held in Ghana in 2017 was convened under the theme: Sustaining the Momentum for Regulatory Harmonization in Africa”. As a follow-up, the fourth SCoMRA (IV) will be held in Victoria Falls, Zimbabwe from 30th September – 1st October 2019 with the
theme: “A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?”

Overall Goal
The overall goal of the fourth Biennial Scientific Conference on Medicines Regulation in Africa is to stimulate discussion on progress made over the last decade of regulatory harmonization and alignment of regulatory networks, identify regulatory challenges facing Africa and lessons learnt, and propose to the AMRC the path forward for the next decade with a special focus on the new African Medicines Agency (AMA).

Objectives
The following are the objectives of SCoMRA IV:

a) To review progress, identify challenges and lessons learnt in the implementation of AMRH, and the alignment of various regulatory networks and forums within AMRH.

b) To serve as a platform for African Regulators to share results on regulatory practice operational research with a view to provide evidence-based policy and decision making.

c) To review methods and new approaches for measuring regulatory outcomes and progress of harmonization, and regulation through reliance.

d) To facilitate discussions on the role of national medicines regulatory agencies, regional economic communities, the AMRH partnership platform, and other stakeholders in advancing regional and continental harmonization agenda.

e) To discuss AMA’s value proposition and operating model.

Conference Sub-themes

a. Harmonisation of regulation of medical products – Innovative approaches to measuring regulatory outcomes, reliance and harmonization; What have been the access gains at country level?

b. The role of harmonization in pharmacovigilance and post-market surveillance.

c. Alignment of regulatory networks and forums, and role of partnerships.

d. Regulation of medical devices, blood/blood products & clinical trials – where are we?

e. Human resources - Models for capacity building and skills retention.
f. Innovation, Research and Development as a driver for local pharmaceutical production.
g. A review of financing models for regional harmonization initiatives – towards sustainability.
h. AMA value proposition and operating model.

Participants
The conference will bring together over 300 participants including: Policy Makers from ministries of health, finance, trade and industry and other relevant ministries; Regulators from 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; WHO and other AMRH Partners and other non-AMRH 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; Representatives from Regional Economic Communities; Researchers; Academia; Development Partners in Health and Pharmaceutical Sectors in Africa; Legislatures including national parliaments, regional parliaments and the Pan African Parliament; Patient organizations; and other relevant stakeholders.

Conference Structure
SCoMRA IV is intended to provide a platform for a participatory process in designing the future of regulatory systems strengthening and harmonisation in Africa. The conference will utilise plenary, panel discussions, poster sessions and exhibitions to facilitate experience and information exchange among stakeholders.

The purpose of this Call for Abstracts is to request potential participants of the conference to submit abstracts that relate to the overall theme, and specific objectives and topics presented in the conference structure. The presentations will be made orally or by poster presentation based on the ranking of the abstract by the review panel.

Interested participants should submit an abstract of no more than 300 words using the online submission form found in the following link: http://www.nepad.org/scientificconference/index.php by 15th July 2019. All submitted
abstracts will undergo a blind review. All abstracts must be submitted in English and/or in French using an ‘Abstract Submission Form’.

### Schedule of Key Dates

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