The 4th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA 2019)

Theme: A Decade of Regulatory Harmonization in Africa: Where are we? Where do we go from here?

30 September – 01 October 2019

Elephant Hills Hotel

Victoria Falls, Zimbabwe

Guidance to Speakers

Overall Goal of the 4th Biennial Scientific Conference on Medicines Regulation in Africa (SCoMRA 2019)

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.

Note for Speakers

This guidance document is meant to provide clarity on the various sessions planned for the fourth scientific conference on medicines regulation in Africa. It is recommended that this guidance be read together with the conference programme for better understanding on the dates and time for each session. Following a brief introduction, speakers are kindly requested to focus on the key issues identified in support of the session objective and overall conference goal and objectives.

Speakers are requested to limit their presentations to the maximum time provided in the programme. This is in order to provide sufficient time for discussion and comments from the floor.

Note for Chairs

The chairs have a very important role in ensuring the overall success of the conference and the sessions assigned to them. The Chairs should open each session with a brief overview of the session and the presentations to be made. Session Chairs are especially requested to familiarize themselves with the presenters and presentations to be made prior to the session commencing. The Session Chairs are requested to strictly enforce the time limit provided for speakers in the sessions assigned to them. Where provided for in the programme they should facilitate and moderate comments and discussions from other participants in support of session objectives. The Session Chairs should also conclude the discussion by providing a high summary of the discussions and make 1 or 2 recommendations for consideration to the African Medicines Regulators Conference.

Session Objectives

Opening Session

To introduce conference participants to the conference theme, conference objectives, welcome remarks by invited guests, remarks by the AMRH Partners, opening speech delivered by the guest of honour and the key note presentation.

Plenary Session I

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

Plenary Session II

To review progress, identify challenges and lessons learnt in the implementation of AMRH from a regional, country and individual presenters' perspectives

Parallel Session I

To share experiences and developments in PV and PMS including innovative approaches

Parallel Session II

To share regional, and country experiences in regulation of medical devices, blood and blood products and other regulatory functions

Plenary Session III

To review current status and initiatives aimed at aadvancing local production of medical products for Africa

Plenary Session III

To update participants on progress made in the establishment of AMA and share experiences from other regions outside Africa

Parallel Session III

To share innovative technologies in regulation, reliance models and country experiences in establishing autonomous agencies

Parallel Session IV

To provide participants with lessons learned working through regulatory forums, networks and partnership frameworks

Parallel Session V

To take stock of various models for capacity building that have been piloted and rolled out in Africa in recent times

Parallel Session VI

To share experiences in optimizing and measuring regulatory processes, outcomes, and experiences in harmonization and reliance

Plenary Session VII

To highlight future of medical products regulation in Africa within the broader scope of new tools and technologies and broader context of universal health coverage

Closing Session

To summarize proceedings, present awards and outline the next steps and officially close the conference