THEME: SUSTAINING THE MOMENTUM FOR REGULATORY HARMONIZATION IN AFRICA

3rd Biennial Scientific Conference on Medical Products Regulation in Africa

27 – 28 November 2017

#SCoMRA

Important Discussion Topic – THREE!

End-to-end programme impact in medicines regulation in Africa

Initial regulatory harmonisation efforts in Africa focussed on registration of generic medicines under the umbrella of the African Medicines Regulatory Harmonization (AMRH) Initiative and the African Vaccines Regulatory Forum (AVAREF) focussing on vaccines. After many years of this work and the successes recorded, the time is now ripe to expand the scope to other product ranges and regulatory functions. Alignment of these initiatives will ensure end to end programme impact from Clinical Trials Authorization (CTA), Marketing Authorization (MA) to Pharmacovigilance (PV) which mainly deals with drug safety.

Pharmacovigilance systems and infrastructure in Africa is mainly outdated. Therefore, what can Africa do to achieve end to end programme impact and develop pharmacovigilance toolkits that are up-to-date and relevant?

No need to re-invent the wheel

Implementation of AMRH and AVAREF has brought success on registration of generic medicines and vaccines on the continent. These initiatives form a solid foundation for end to end programme impact. What are the lessons learnt and best practices under AMRH and AVAREF, and how can experts guide alignment to ensure better coordination and devise a strategy that will enhance the scope to include other product ranges and regulatory functions.

In addition, this will also feed in to effective examination of existing Pharmacovigilance systems and infrastructure and guide clinical development and oversight of new therapies and vaccines for prevention and treatment of diseases that disproportionately affect the African population.

Join us at the 3rd Biennial Scientific Conference to participate in the process and learn more

http://www.nepad.org/scientificconference/

World Health Organization NEPAD IFPMA FDA