

# **Theme**

Regulatory systems in Africa — Lessons from the COVID-19 experience and strategies to build back better after the pandemic

## **Dates**

Monday 22nd & Tuesday 23rd November, 2021

# **Virtual Host Country**

Republic of Rwanda









#### 1. BACKGROUND

The COVID-19 pandemic has disrupted healthcare systems of all countries, irrespective of their level of income. The pandemic has further exacerbated the substantial inequities in access to health care which has existed for many years between countries. Vulnerable populations have continued to face a higher burden of morbidity and premature mortality due to easily preventable and treatable causes. Their limited access to affordable and quality essential services, as well as underinvestment in primary health care systems, is a major impediment to achieving Universal Health Coverage (UHC).

In response to COVID-19, the search for effective and equitable accessible of quality medical products for its prevention, containment, diagnosis and treatment has served to highlight the critical role regulators play is providing access to quality assured products. The pandemic has led to a sharp increase in global demand for diagnostic kits, personal protective equipment, oxygen plants and concentrators as well as vaccines and therapeutics which need to be rapidly developed, manufactured, and deployed, putting pressure on regulators to innovate and expedite regulatory processes. To address delays in supply, policymakers have recognized an urgent need to strengthen research and development, manufacturing as well as regulatory capacities on the continent, both for vaccines and other medical products, as part of building back better after CO-VID-19.

To cope with global supply challenges, regulators across the globe have also had to adopt various regulatory pathways to facilitate approval of the essential medical products and health technologies. Reports show more than a 12-fold increase in regulatory workload in some countries mostly due to medical products designed to prevent exposure to, test for or treat COVID-19. Regulators have had to find ways to support the expedited development and distribution of novel coronavirus-related vaccines, tests, and treatments. The circulation of substandard and falsified medicines and prevalence of unauthorized importation of medical products have exacerbated the challenge for regulators.

The 5th Scientific Conference on Medical Products Regulation (SCoMRA V) will explore the potential collaborations between regulators and scientists/researchers working to accelerate the development, production, and equitable distribution of new medical products and essential health technologies on the continent.

## 2. SCOMRA V OVERVIEW

Under the main theme "Regulatory systems in Africa: lessons from COVID-19 and strategies to build back better after the pandemic", the fifth Scientific Conference on Medical Products Regulation in Africa (SCoMRA V), will be held from the 22nd to the 23rd of November 2021. The conference will bring together policy makers, regulators, research community, product developers, manufacturers, and other key stakeholders from the continent and across the globe to reflect on progress, define priorities and set the agenda going forward.

## 2.1 The SCoMRA V Sub-Theme:

Is the continent's regulatory infrastructure capable of addressing public health emergencies?

## 2.2 Topics:

- 1. Shaping regulatory policy direction and landscape to support public health emergencies in Africa.
- 2. What is the role of national regulatory agencies in advancing the Partnership for African Vaccines Manufacturing (PAVM) Framework?
- 3. What lessons can we learn on collaborations in advancing research and development of medical products on the continent?
- 1. Bulletin of the World Health Organization 2020;98:514-515. doi: http://dx.doi.org/10.2471/BLT.20.020820









## 3. CONFERENCE OBJECTIVES

## 3.1 Overall Objective

The objective of the conference is to support countries to accelerate patient's access to safe, efficacious, and quality medical products through strengthened regulatory systems and collaborations between NRAs, researchers, academia, procurement agencies, industry and patient organizations.

## 3.2 Specific Objectives

- a) To reflect on progress in the implementation of the recommendations from SCoMRA IV, held in Zimbabwe from 30 September 01 October 2019.
- b) To reflect on the continent's regulatory preparedness during public health emergencies to respond to supply chain disruptions.
- c) To discuss practical experiences from COVID-19 pandemic on collaborations between regulators and other stakeholders in advancing research and development, and production of vaccines on the continent.

#### 4. CONFERENCE PLAN

## 4.1 Structure and Method of Work

SCoMRA V will take place virtually, via internet based webinars, due to the uncertainties of the status of the COVID-19 pandemic and associated travel restrictions. It will be hosted virtually by the Government of Rwanda who will officiate the ceremony.

The conference will take place across two webinars, of four hours each, held on two consecutive days. Each day, the webinar will start at 13.00 (GMT + 1). Deliberations will feed into the African Medicines Regulators Conference (AMRC), which will be held immediately after SCoMRA.

The meeting format will include plenary presentations and panel discussions. A key goal of SCoMRA is to facilitate experience sharing and information exchange among stakeholders.

## 4.2 Call For Abstracts

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 attached submission form by 31 October 2021. All submitted abstracts will undergo a blind review. All abstracts must be submitted in English and/or in French using an 'Abstract Submission Form'.

Successful applicants will be called upon to submit full papers for further evaluation and publication as part of conference proceedings. The possibility to publish the articles in a reputable peer-reviewed academic journal will be explored.









#### SCHEDULE OF KEY DATES

Deadline for Abstracts Submission: 31 October 2021

Information of Acceptance: **08 November 2021** 

Submission of Full Paper: 15 November 2021

Submission of PowerPoint presentation: 15 November 2021

SCoMRA V Dates: 22 – 23 November 2021

## 4.3 Participants

The conference brings together over 300 participants from African and global organizations involved in regulatory systems strengthening and harmonization and serves as a platform for the discussion and advancement of regulatory sciences in Africa.

#### Participants include:

- a) Policymakers from ministries responsible for health, finance, trade and industry, research and innovation and other relevant ministries
- b) National Regulatory Authorities (NRAs) in Africa
- c) Other NRAs partnering with Africa
- d) Researchers
- e) Academia
- f) Ethics Committees/Institutional Review Boards (IRB)
- g) Clinical trials sponsors; industry representatives
- h) Regional Economic Communities (RECs)
- i) AUDA-NEPAD
- j) African Union Commission (AUC)
- k) World Health Organization (WHO)
- I) AMRH Partners and other non-AMRH partners involved in regulatory work in Africa
- m) Development partners in health and pharmaceutical sectors in Africa
- n) Legislatures including national parliaments, regional parliaments, and the Pan African Parliament
- o) Patient organizations
- p) Media representatives and
- q) Other relevant stakeholders.

For more information, please contact: