Viewing medicine discovery, development and approval as a continuum: the role of regulatory harmonization in Africa for better outcomes

Kelly Chibale

The 4th Biennial Scientific Conference on Medical Products Regulation in Africa, 2019
(SCoMRA IV)
30 September – 01 October 2019
Elephant Hills Resort
Victoria Falls, Zimbabwe

1. What is at stake? (consequences of not harmonizing the regulatory environment in Africa)

2. The problem with the value chain (Fragmentation. Use slide showing value chain)

3. Translational medicine challenges to address towards improving health outcomes for African patients
   - Highlight the fact that historically medicines are not optimised for African patient populations
   - Highlight that there is a low volume of clinical trials in Africa and explain why this is a problem
   - Provide some reasons for low volume of clinical trials in Africa – will link in with regulatory as an enabler/inhibitor
   - Highlight the external interest to correct this inequity
   - Showcase examples of how capacity has been built around real projects eg H3D and our malaria clinical candidate MMV048
   - Highlight AAS/BMGF project to build a database of African clinical trial sites

4. Recommendations
• Increased collaboration between regulators and Industry with academia on training that will strengthen understanding for students on innovation, drug development, and registration from both Industry and regulators perspectives.

• Rethinking conventional review process (i.e. frequent need for GMP inspections, samples etc) and move towards more innovative approaches based on the science and the supporting data for regulatory decision making. Such shift in mindset will also make reliance and harmonization more effective and eliminate redundancy and unnecessary delays in review and approval process.

• There is an appreciation for guidance documents from Health Authorities (HA) that provides clarity on processes, requirements, timelines etc. However, draft guidelines need to be balanced with an adequate period for comments from stakeholders (researchers, academics, industry). Additionally, in developing guidelines, local context and HA capability should be taken into consideration before implementation.

• The need for regulatory agencies to enhance their review capacity and efficiency to allow the simultaneous introduction of innovative products across African countries. Historically, it has taken 5-10 years before a new medicine which was available in US/Europe reached the African continent. Harmonization of the regulatory environment can go a long way in reducing this lag-time.

• As medical innovation is moving rapidly towards biologics and cell & gene therapy, agencies need to build review skills if African patients should benefit from such innovations in their respective country.

• The need to shorten timelines and enhance predictability for the approval of clinical trials, if more Africans are to be enrolled into clinical trials.

• Drive regulatory harmonisation as a means to enhance efficiency (similar to a mutual recognition procedure) where not only the workload can be reduced at
participating agencies but different regulatory expertise can be used for the benefit of multiple countries.

- African governments should require local clinical trial data. To make this a reality, there needs to be increased support for building capacity in clinical research

- Support for the development of research platforms that allow customization of medicines to the needs of African patients. This includes preclinical discovery platforms that can be used to prioritize drug candidates during their (chemical) lead optimization phase based on the predicted pharmacological profile in African patients