AMRH
African Medicines Regulatory Harmonisation Programme

4th QUARTER 2020 NEWSLETTER EDITION

2nd AMRH Week and the 8th Steering Committee on Regulatory Systems Strengthening and Harmonization Initiatives in Africa (AMRH SC)

The 2nd AMRH Week took place from the 9th to the 10th of December 2020. Due to wide travel restrictions in many countries because of the COVID-19 pandemic, the event was held virtually. The meeting gathered over 120 participants from Africa and other parts of the world and showcased the good work done by regulators and ethics committees in preparation for COVID-19 clinical trials review, preparations for registration and monitoring of the safety of vaccines, listing of medical devices including in vitro diagnostics and manufacturing of devices and PPEs as part of COVID-19 response.

The meeting was opened by a high level panel made up of senior dignitaries who are leading in organisations that are assisting African member states to gain the capacity, resources and expertise necessary to fight the challenges COVID-19 has brought about. The panel members were; Dr. Murray Lumpkin, Deputy Director Integrated Development, Bill and Melinda Gates Foundation (BMGF), Dr. Petra Doerr, Head of Regulation and Safety, World Health Organisation (WHO), Dr. Ibrahim Assane Mayaki, CEO, African Union Development Agency-NEPAD (AUDA-NEPAD), Hon. Michel Sidibe, AU Lead Advocate for AMA and H.E. Amira Elfadil Mohammed Elfadil, AUC Commissioner for Social Affairs. In their presentations, the panelists all underscored the importance of African Union member states rallying behind the treaty to establish an African Medicines Agency (AMA). As an organ of the African Union, legally mandated by Member States, AMA's goal will be to increase the availability of safe and affordable medicines and other health products on the continent. AMA, will enter into force once ratified by fifteen (15) African Union member states. With the challenges faced by countries in ensuring fast approval of clinical trials, marketing authorisation, importation and procurement of good quality, safe and efficacious medical products for the prevention and/or treatment of COVID-19, the establishment of AMA has become critical.

Special thanks goes to all AMRH stakeholders who made this first virtual AMRH week possible, as well as the high level panel that contributed to these important discussions.

The second half of the meeting was focused on highlighting the work of the African Vaccines Regulators Forum (AVAREF) Technical Committee (TC), the African Medical Device Forum Technical Committee, The African Medicines Quality Forum TC, The AU Smart, Safety Surveillance Project (AU-3S) in order to showcase how regulators on the continent have through innovations and adaptation provided regulatory oversight of products against COVID-19, galvanizing partnerships, promoting collaboration and harmonization, and how this can rapidly lead to the establishment of the AMA.

Day 2 of AMRH Week was the 8th AMRH SC was held on to deliberate on among other things, progress on implementation of regional medicines regulatory harmonization initiatives in the East African Community (EAC), Southern African Development Community (SADC), the Intergovernmental Authority on Development (IGAD), the Central African Economic and Monetary Union (CEMAC) and the Economic Community of West African States (ECOWAS).The SC also took note of progress made by the Continental Regulatory Information Management System (RIMS) technical committee. The AMRH SC further held a discussion on Collaboration among Heads of NMRAs which focused on feedback from Regional Consultations with Heads of Agencies representing RECs.

Significant lessons were shared throughout AMRH week, and it is hoped that these will help to inform future strategies for pandemic preparedness.

Effectiveness of the Regulatory Approval Process - Moving from measuring performance to operational excellence

> ***Effectiveness*** *relates to getting the right things done. It is "the capability of producing a desired result or the ability to produce desired output."* *e.g. number of approvals within target timelines.*
> ***Efficiency*** *is about making the best possible use of resources* *e.g. time taken to approve a new medicine.*

In 2020 a virtual workshop was held by the Centre for Innovation in Regulatory Science (CIRS) for agencies and companies operating in Asia and Africa to discuss measuring the effectiveness of the regulatory approval process. This workshop was attended by 15 regulatory agencies from Asia (6 agencies), Africa (7) and the Middle East (2). The programme also included a presentation by AUDA-NEPAD on the African Medicines Regulatory Harmonisation (AMRH) initiative.

This article summarises the need to evaluate effectiveness and using discussions from the workshop, areas for consideration by agencies looking to evolve metrics for measuring effectiveness.

Why evaluate effectiveness?

A recent study (Margareth Ndomondo-Sigonda et al 2020) assessing financial sustainability of National Medicine Regulatory Agencies (NMRAs) in the East African Community (EAC) concluded that "government and industry fees are the main sources of funding while donor contributions vary from country to country. Government policy, legal framework, and fees structure are the key enablers of NMRAs funding sustainability". This integral link between funding and the enablers is critical to ensure the quality, safety and efficacy of new medicines being registered, which in turn requires agencies to have both an effective and efficient regulatory process.

Regulatory authorities are already being evaluated quantitatively, from the point of view of measuring the overall time spent on the approval of new medicines, and qualitatively to assess the quality of the regulatory review process as defined by Good Review Practices. Indeed, agencies are challenged to improve the approval process and ensure they "say what they do, do what they say, prove it and improve it". This in turn requires operational measures to be put in place. Agencies are very focused on ensuring that the review is done in a timely manner, thereby balancing the effort vs. resource vs. cost, which relates to the efficiency of the process.

However, the question for agencies when identifying areas that need improvement is how can they go beyond efficiency and ensure that they are also effective? Are they focusing on the right aspects of the review and utilising the correct pathways/tools? Measures of effectiveness will help agencies to ensure that they are adding value to the process and that the quality of the review is not being compromised.

W*hat specific activities could an agency consider taking, which would improve its effectiveness and help optimise its performance with respect to authorisation reviews?*

Suggestions from the CIRS workshop included the following considerations:

- Agencies should harmonise requirements to international standards, which both strengthens the agency and supports the use of reliance within and across jurisdictions.
- Internal training is critical to align reviewers on being effective, such as distinguishing between 'need to know' and 'nice to know' questions.
- Adherence to timelines is important to both manage expectations and strengthen the focus during review
- Agencies should implement quality measures and monitoring e.g. by updating IT infrastructure.
- Agencies should also improve clarity of guidance documents and improve transparency so there is clear definition of agency needs and decision-making practices.
- It is important for agencies to learn from other agencies e.g. measures taken or expertise available.

What are the main activities/processes that an agency undertakes in the approval of medicines for which Key Performance Indicators for effectiveness need to be considered?

The workshop discussions identified a number of key areas for consideration as agencies evaluate potential effectiveness measures:
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- Outcome measures of the regulatory process and timelines, such as percentage of applications processed (approved /rejections/withdrawals) within the target time.

- Development of information management/quality management systems to enable routine assessment/audit reports including management and quality control indicators.
- Increase capacity and improve competency of staff.
- Identify the level of satisfaction with training provided by the agency.
- Review applicability of international standards to the agency review process.
- Increase transparency in the decision-making process and practices.
- Ensure adequate and appropriate pathways such as reliance procedures (and other non-standard regulatory pathways).

However, the workshop also identified key challenges or barriers that need to be dealt with to aid agencies to improve their effectiveness:

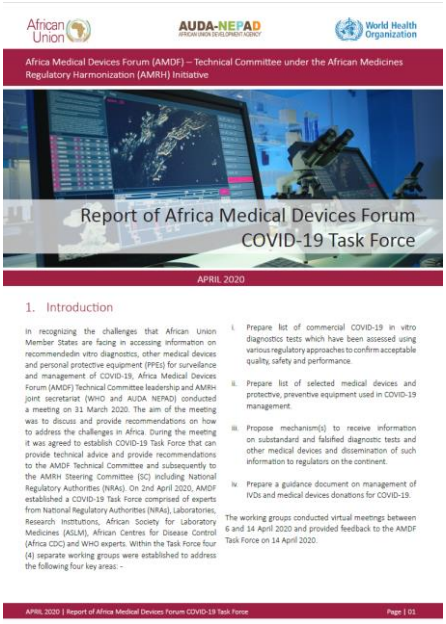
- High workload per reviewer and insufficient number of assessors/experts.
- Quality of applicant submissions and response to questions.
- Lack of monitoring - timeline consistency linked to a need for a fit-for-purpose IT infrastructure.
- The need to change mindsets - both at the individual and agency level.

In addition, the discussions identified that agencies will be challenged with knowledge barriers as new areas of technology evolve, meaning that resource, skillset and/or legislation may need to change to ensure an effective review process.

The need for agencies to have formalised measures of effectiveness through outcome measures and regular reporting is clear. The effectiveness of an agency can be enabled through regulatory convergence and adoption of international standards; well-trained assessors through formal and regular in-house seminars and training workshops; and an IT infrastructure that is fit for purpose. As the rapidly evolving regulatory landscape changes, it is important for agencies to ensure that they are assessing not just efficiency but also effectiveness to ensure timely medicines that are good quality, safe and effective.

A report summarising the presentations and recommendations from the workshop is available from CIRS. CIRS will utilise the outcome of the workshop within the OpERA programme (AUDA-NEPAD newsletter 2020) to enable agencies to embed a performance driven culture to measure not only efficiency but also effectiveness.

Key knowledge products



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Upcoming Events

- AMRH Partnership Platform Business Meeting- 8 April 2021
- African Medicines Quality Forum 4th Annual Meeting- 29-31 March 2021
- 5 th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA V) and the 7 th African Medicine Regulators Conference (AMRC) - November 2021

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