September - October 2023
AMRH Updates

Greetings from the African Medicines Regulatory Harmonisation (AMRH) Joint Secretariat!
We are excited to bring you the latest edition of updates covering September to October 2023. This edition shines a spotlight on significant accomplishments during this period and offers a glimpse into upcoming events that will further bolster regulatory harmonization and support the operationalization of the African Medicines Agency (AMA).

AMRH Continental Technical Committees

Good Manufacturing Practice Technical Committee (GMP TC):

GMP TC successfully conducted the first Continental GMP Basic Training from October 3rd to 6th, 2023, for inspectors from AU Member States. This comprehensive training delved into the fundamental principles of GMP, featuring dedicated sessions on GMP considerations for vaccines and other biopharmaceuticals. Collaborating seamlessly with the World Health Organization (WHO) Inspection services and the European Medicines Agency (EMA), the TC secured financial support from the Bill and Melinda Gates Foundation (BMGF) to orchestrate this transformative event. The training attracted a diverse attendance of over 300 GMP inspectors hailing from various National Regulatory Authorities (NRAs) across the continent.

Building on this momentum, on October 13th, 2023, in anticipation of the pilot phase for the Continental Procedure on Evaluation of Medicinal Products under the EMP TC, a collaborative effort between the GMP TC and the EMP TC led to the publication of a call for expressions of interest (EOI) from experts. This call sought the selection of competent and experienced dossier assessors and GMP inspectors. The EOIs are pivotal in the establishment of a continental pool of assessors and inspectors, poised to support the African Medicines Regulatory Harmonization (AMRH) TCs in scientific activities crucial for the operationalization of the African Medicines Agency (AMA).

Evaluation of Medicinal Products (EMP) TC:

The EMP TC has initiated a pilot phase of the joint continental procedure on evaluation of applications for registration of medical products. In this regard, a call for Expression of Interest was circulated to Maturity Level 3 (ML3) NRAs in Africa in September 2023, with the aim of selecting an NRA that will support AMRH in providing a robust regulatory information management systems and eCTD platforms. The South African Health Products Regulatory Authority (SAHPRA) was selected by the EMP TC to provide the infrastructure for receiving and managing applications on behalf of the AMRH.

To support implementation of the pilot of a continental procedure on evaluation of applications for registration of medicinal products, the EMP TC with the support from the BMGF convened a workshop of technical working groups (TWGs) from the 6 – 13 October 2023. The working groups composed of EMP TC members, EMP subcommittee on vaccines and other biological products, co-opted experts from various NRAs and selected EMP TC technical partners comprehensively reviewed guidelines, procedures and other key documents identified by the AMRH secretariat to support the implementation of the continental pilot. The TWGs sessions were supported by the PharmTrain Project of the Germany's Federal Institute for Drugs and Medical Devices (BfArM) and the Pharmaceutical Supply Division of UNICEF. The TWGs reviewed, adopted and adapted:
Ten (10) Guidelines for Data Submission on Human Pharmaceuticals, Vaccines, Biotherapeutics and Similar Biotherapeutic Products and other procedural aspect guidelines.
Seven (7) Guidance for Assessors on pharmaceuticals, vaccines, biological and biotechnological products, bioequivalence as well as clinical and non-clinical data assessments.
Four (4) Continental Standard Operating Procedures (SOPs)on Processing and Managing Applications, Evaluations and Joint Dossier Assessments.
Various Templates, Forms and Checklists on Reporting and Submissions.

The draft guidelines and SOPs were tabled in the 6th Ordinary Meeting of the EMP TC held virtually on 3rd November 2023. The meeting was attended by all EMP TC members, partners as well as representatives of pharmaceutical industry associations.

African Medical Devices Forum (AMDF TC):

In a dedicated effort to bolster continental initiatives aimed at harmonizing regulatory requirements for medical devices, the AMDF played a pivotal role at the 24th session of the International Medical Device Regulators Forum (IMDRF) convened from September 25 to 27, 2023. The AMDF submitted an application during this session, seeking recognition of the Forum as a Regional Harmonization Initiative (RHI) specifically tailored for Africa, underlining a commitment to fostering unity in medical device regulation.

In a strategic move to enhance capacity and collaboration in assessing the safety, quality, and performance of In Vitro Diagnostics (IVDs) across the continent, the ADMF embarked on participation in the WHO sessions on Prequalification of IVDs (PQDx) in October 2023. The ADMF's involvement, slated for a rotational basis, saw two members of the AMDF Technical Committee attending their inaugural session from October 9 to 13, 2023.

A significant milestone was achieved on October 17, 2023, when the IMDRF formally recognized the AMDF as a Regional Harmonization Initiative (RHI) for Africa. This recognition serves as a catalyst for information exchange and the harmonization of medical device regulations, and alignment with global standards. The AMRH, through the AMDF, is now granted access to invaluable IMDRF guidelines and resources, empowering the establishment and fortification of medical device systems.

Furthering their commitment to regulatory excellence, the ADMF collaborated with the USAID MTaPS Programme to conduct a comprehensive workshop on capacity building for regulators in Africa. Held from October 31 to November 2, 2023, and hosted by the Tanzania Medicines and Medical Devices Authority (TMDA), the workshop brought together medical device regulators from 11 African countries. The primary focus was on enhancing the capacity of assessors in the pre-market evaluation of Maternal, Neonatal, and Child Health (MNCH) devices' technical files, with the ultimate goal of expediting the availability of essential medical devices and diagnostics for the MNCH population group. This initiative underscores the AMDF's dedication to advancing regulatory proficiency and ensuring the well-being of vulnerable populations.

African Medicines Quality Forum (AMQF):

On October 19th, 2023, the AMQF Subcommittee on QMS orchestrated a dynamic Consultative Meeting that brought together leaders from National Pharmaceutical Quality Control Laboratories and seasoned technical experts in equipment management.
In a lively exchange, participants passionately explored the challenges embedded in managing the equipment life cycle, collectively birthing innovative solutions with a commitment to pragmatism and sustainability. A unanimous decision emerged—to sculpt continental guidelines dedicated to lab equipment maintenance.

Next on the Horizon: Continental Guidelines
Crafting comprehensive guidelines on Lab Equipment Maintenance.
Forging guidelines on Peer Audits, fostering a culture of mutual improvement.
With resounding support, participants called upon the AMQF to take the lead in organizing targeted training sessions, a bespoke initiative aimed at empowering stakeholders in the realm of equipment maintenance. The collaborative spirit forged during this Consultative Meeting promises not only enhanced equipment management practices but also a strengthened network of professionals dedicated to elevating the standards of pharmaceutical quality control across the continent.

African Medicines Agency (AMA) Spotlight

Breaking Ground: Tanzania's Stamp of Approval on AMA Treaty Signals a Health Triumph for Africa

In a recent breakthrough, the government of Tanzania affirmed its commitment to advancing public health by approving the African Medicines Agency (AMA) Treaty during the 12th Parliament Session on October 31, 2023. This decisive move not only aligns Tanzania with the continent's health-focused objectives but also positions it as a pivotal player in fortifying the African regulatory ecosystem.

Tanzania's endorsement holds special significance due to its status as a WHO Maturity Level Three regulatory authority. This distinction underscores Tanzania's proactive role in contributing to a strengthened African regulatory framework. Beyond national borders, this move amplifies Tanzania's influence in the global health arena, signaling a commitment to fostering resilience and empowerment in the pharmaceutical sector across the continent.

The operationalization of the AMA itself is a watershed moment, symbolizing a dual triumph in the realms of public health and economics. At its core, the AMA seeks to guarantee access to high-quality medical products for the people of Africa, setting the stage for increased investments in local pharmaceuticals. This strategic initiative not only upholds a commitment to public well-being but also lays the groundwork for self-reliance and sustainability in the pharmaceutical landscape.

As the linchpin to realizing these benefits, the ratification of the AMA Treaty by AU Member States assumes critical importance. This step ensures that all member states can fully harness the wealth of recommendations and guidance provided by the AMA. Tanzania's recent approval is a tangible endorsement of this collective effort, propelling the nation and the continent towards a future marked by improved healthcare accessibility and a robust pharmaceutical sector.

Upcoming Events

Activity	Meeting Date	Venue
Annual RCOREs meeting	12 December, 2023	11hrs SAT; Virtual
AMQF SC-Vaccine, workshop: Conduct training in 'Vaccines analysis and Lot Release Procedures'.	27 Nov- 1 Dec 2023	Physical Meeting in Cairo, Egypt

Upcoming Events

Activity	Meeting Date	Venue
5th Meeting of the Interim Executive Committee on the College for African Regulatory Science Professionals (CARSP) (Closed meeting)	23 – 24 November 2023	Johannesburg, South Africa
5th GMP TC Meetings (Closed meeting)	28 – 30 November 2023	Johannesburg, South Africa
CARSP continental stakeholder's consultation	13-14, December 2023	14hrs SAT; Virtual
AMQF TC Leadership Meeting	6 December 2023	Virtual Meeting
SCOMRA VI	5 – 7 December, 2023	Cairo, Egypt