Regulatory Reliance Workshop

Host: Kenya Association of Pharmaceutical Industry (KAPI) and Medical Technology Industry Association of Kenya (MEDAK) on March 20, 2025 – Nairobi, Kenya

Rapporteur's Report

The Regulatory Reliance Workshop held on March 20, 2025, in Nairobi, Kenya featured a series of insightful presentations from leading experts in the pharmaceutical and medical device sectors and discussions among participants. The presentations delved into the concept of regulatory reliance, its implementation, benefits, and challenges across different regions and sectors.

Dr. John M. Mwangi, representing Bayer and the Kenya Association of Pharmaceutical Industry (KAPI), opened the discussion by emphasizing the increasing role of reliance in modern and efficient regulatory authorities. In his presentation, He delineated the pivotal role of regulatory reliance as essential for modern and efficient regulatory frameworks, particularly highlighted by its accelerated adoption following the COVID-19 pandemic. He introduced the World Health Organization's Listed Authorities (WLA) as a transparent, evidence-based system for identifying trusted authorities and advocated for a risk-based approach to maximize the utility of reliance options like work sharing and abridged pathways. Dr. Mwangi pointed out the critical state of approximately 70% of countries with weak regulatory systems, emphasizing the necessity of enhancing access to quality-assured medical products and building regulatory capacity. He argued for reliance as a strategy to optimize resource use and bolster global regulatory oversight. Further, he explored the implementation of reliance, advocating for voluntary participation, a shift in mindset, and the importance of incremental learning. He addressed the challenges and opportunities presented by globalization, the complexity of supply chains, and the rapid evolution of science, stressing the need for transparency and managing public expectations. The presentation also outlined the principles of Good Reliance Practices, including universality and sovereignty of decision-making, and introduced the Continental Regulatory Reliance Framework as a cooperative, multi-country strategy to streamline regulatory pathways. Concluding, Dr. Mwangi dispelled common misconceptions about reliance, clarifying its role beyond time-saving or sovereignty concerns, and highlighted the necessity of resources like project management and IT systems for its effective practice, emphasizing that reliance extends beyond innovator products or new drug applications.

Dr. Ali Arale from the Department of Drug Registration at the Pharmacy and Poisons Board – Kenya, presented an overview of the reliance practices, policies, and guidelines as part of Kenya's collaboration with national, regional, and international institutions on the regulation of medicinal substances. Highlighting the Pharmacy and Poisons rules of 2022, Dr. Arale detailed the legal framework supporting reliance and recognition, including Clause 24 which allows the board to recognize and use clinical trials decisions, reports, or information from other competent authorities instead of conducting new clinical trials, and Clause 3(d) which facilitates generating data on health products registered in Kenya through recognition, reliance, or a work-sharing arrangement. He also discussed Legal Notice 96 on pharmacovigilance and post-market surveillance, which permits the board to rely on decisions from other regulatory authorities where necessary, and Legal Notice 100 on the registration of health products and technologies, emphasizing collaborative measures and the establishment of timelines for application assessments and performance indicators for registration activities. Dr. Arale mentioned Kenya's collaboration with WHO PQ CRP, WHO SRA CRP, AMRH, EU Medicines 4 All, and Swiss MAGHP, and directed attendees to resources like the Health Products and Technologies Guidelines and the Guidance on Reliance for Regulatory Decision Making in Kenya available on the Pharmacy and Poisons Board's website. His presentation underscored Kenya's commitment to implementing regulatory reliance practices.

Dr. Rim Mahmoud, Biologics Variation Unit Manager at the Egyptian Drug Authority (EDA), delivered a presentation detailing the EDA's engagement with reliance practices, underpinned by Law no. 151 of 2019 and Decree No. 777 of 2020. She outlined reliance as a strategic approach allowing regulatory authorities to leverage evaluations from other trusted institutions, emphasizing its role in enhancing efficiency, harmonization, and access to safe medicinal products. Dr. Mahmoud highlighted EDA's achievements, including reaching WHO Maturity Level 3 for both medicines and vaccines, becoming a Transitional WHO Listed Authority, and joining the International Council for Harmonisation as the first African and second Arabic member. The presentation covered the application of reliance throughout a product's life cycle, including initial authorization, vigilance, and post-authorization activities, stressing the importance of "sameness of product" for reliance application. She detailed the reliance pathways for marketing authorization, including fast track and normal track processes, and discussed the extension of reliance to biologics lot release and post-approval changes. Dr. Mahmoud also addressed challenges such as regulatory differences, data quality, and confidentiality, and concluded with future recommendations for expanding reliance pathways, strengthening data sharing, and building capacity for reliance assessment,

showcasing EDA's commitment to leveraging reliance for regulatory efficiency and international collaboration.

In a detailed presentation, Radwa Ahmed Saad El Gamil, Unit Manager at the Administration of Human Pharmaceuticals Regulatory Affairs – Egyptian Drug Authority (EDA), outlined the EDA's strategic adoption of a reliance approach for the regulation of human pharmaceutical products, marking a significant milestone in achieving WHO Maturity Level 3 (ML3) for both medicines and vaccines, a first for an African National Regulatory Authority (NRA). She detailed the reliance approach, which leverages assessments from stringent regulatory authorities or WHO prequalification to expedite access to healthcare solutions, highlighted by the Emergency Use Approval (EUA) guidelines and updated variation guidelines for post-approval changes. The presentation also covered the issuance of unified decrees for the registration and re-registration of pharmaceutical products, with updates to reliance guidelines that include detailed pathways, eligibility criteria, and an expanded list of reference countries, including South Korea and Singapore. Despite the progress, El Gamil acknowledged challenges such as the absence of clear legal provisions, managing internal changes, enhancing capacities, and difficulties in obtaining required documents, emphasizing the need for continuous improvement to overcome these hurdles and further streamline the regulatory process for pharmaceuticals in Egypt.

Arit Onwusah from Novartis provided an overview of reliance in Ghana and Nigeria, detailing the strengths, opportunities, and areas for improvement in both countries. Onwusah detailed how both the Nigerian Agency for Food and Drug Administration and Control (NAFDAC) and the Ghana Food and Drugs Authority (FDA) have achieved Maturity Level 3 (ML3) status, with NAFDAC also recognized as an ICH observer, indicating their advanced regulatory capabilities. In Ghana, since the reliance policy's adoption on January 2, 2019, it has been actively utilized with application fees mirroring those of the normal pathways, though improvements are needed in areas such as timeline variability and the requirement for products to be registered in an ICH member country for over six months. Nigeria's reliance guidelines, established in 2023, have led to significant reductions in timelines for New Drug Applications (NDAs) and Clinical Trials, particularly through the African Vaccine Regulatory Forum (AVAREF), with reliance applications generally considered low risk. However, challenges such as the need for alignment with internationally accepted registration categories and a requirement for registration in a Stringent Regulatory Authority (SRA) country for over six months were identified. Onwusah emphasized the ongoing development of the

reliance framework and the critical need for engagement and collaboration with regulators to address these challenges and further align with international standards.

Rana Chalhoub, the Regulatory Affairs Director at MECOMED, presented on the topic of regulatory reliance within the Middle East and Africa (MEA) region, emphasizing its recognition as a 21st-century best practice for enhancing regulatory efficiency across both resource-constrained and well-resourced agencies. She delineated the distinction between convergence and reliance, underscoring reliance as a cooperative interaction between regulators from different jurisdictions to increase efficiency while maintaining independence and accountability. Chalhoub highlighted the importance of Good Regulatory Practices (GRPs) as a quality control mechanism for developing regulations that are internationally aligned and cost-effective, serving as a precursor to regulatory cooperation. The presentation addressed the growing focus on post-market surveillance, traceability, and the impact of international changes on local registrations within the MEA region. It was noted that most MEA countries recognize IMDRF approvals, mainly CE/FDA, as part of their review process, with increased engagement with international associations like IMDRF, GHWP, and AMDF, and MOUs signed between African countries to facilitate regulatory cooperation. Country-specific examples from Qatar, Oman, Kenya, and Bahrain were provided, showcasing reliance pathways for product registration based on approvals by listed medical device reference regulatory agencies and/or prior safe marketing history. Chalhoub recommended accepting global clinical trial data, leveraging real-world evidence, ensuring predictability, supporting innovation, adopting GRPs, implementing a risk-based approach, and optimizing labeling as strategies for implementing reliance in the MEA region. She concluded with a call for capacity building and reliance training for National Regulatory Authorities (NRAs) in the region, highlighting MECOMED's role as an official liaison member for GHWP and its efforts in working closely with regulators to support the implementation of reliance principles.

In a presentation focused on utilizing regulatory reliance practices to mitigate product shortages during the handling of Post-Approval Changes (PACs), Angelika Joos outlined the complex process from the core quality dossier filed in the EU and US to the global implementation, highlighting the challenges of complex inventory management and the risk of drug shortages due to delayed approvals in various countries. She emphasized the significant workforce and resources dedicated to generating and maintaining additional or country-specific documentation, which contributes to delays in global submissions and ultimately slows down the access to medicines and vaccines

with the latest enhancements. The presentation also compared reporting categories and suggested review timelines between WHO, EMA, and other regulatory frameworks, noting that many markets lack streamlined filing pathways, leading to extended review timelines for changes considered minor in the EU or US. Joos advocated for a core set of EU documents as useful tools to apply reliance for PACs, suggesting streamlined documentation requirements to incentivize the use of reliance, thereby leading to timely access of products to patients. She stressed the importance of verifying product sameness for reliance, where differences in documentation should not preclude the use of reliance approaches, and highlighted the ongoing work towards global harmonization of dossier structure and content. Acknowledgments were given to Tatiana Gaban (MSD), the IFPMA Reliance Task Force, and the EMA Reliance Focus Group for their contributions to the development and promotion of reliance practices.

Dr. Francesca Mangia from F. Hoffmann-La Roche presented on the topic "Ignite the future - our exciting PAC reliance journey with 48 NRAs." The presentation highlighted the critical role of Post-Approval Changes (PACs) in maintaining the continuous supply of high-quality medicines and vaccines, supporting innovation, and addressing unmet medical needs. Dr. Mangia outlined the challenges posed by the diverse regulatory frameworks for managing PACs globally, which slow down innovation and can lead to delayed patient access to medicines or vaccines. She illustrated the differences in dossier requirements across countries, emphasizing the need for regulatory convergence. A significant focus was on a major drug substance process change for a monoclonal antibody (mAb), where unilateral reliance on the EMA's assessment by 48 participating regulatory agencies reduced global approval and implementation timelines from 2.5 years to 6.5 months. This pilot project, impacting 84 countries with a 57% participation rate, demonstrated a strong interest in reliance practices for PACs, with 83% of NRAs approving within 6.5 months and 96% within 12 months. The use of the Accumulus platform for real-time Q&A sharing among NRAs was proposed to enhance transparency and efficiency. Dr. Mangia's presentation underscored the importance of transparency, dialogue, and the role of regulatory affiliates in each participating country, highlighting the pilot's success in significantly reducing review timelines and expressing a strong willingness among NRAs to engage in reliance practices for PACs.

These presentations collectively underscored the critical role of regulatory reliance in enhancing the efficiency of regulatory processes, facilitating access to quality-assured medical products, and fostering international cooperation among regulatory authorities. The discussions highlighted both

the achievements and the ongoing challenges in implementing reliance practices, pointing to a future where reliance is a key component of global health governance.

**********END OF REPORT**********