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EDITORIAL

HARMONIZATION AND RELIANCE MECHANISMS IN MEDICINES REGULATION

Product recalls, alongside product withdrawals and safety alerts, are common phenomena in consumer goods manufacturing industry and regulation, and constitute part of corrective and preventive actions in quality management systems. Product recalls transcend several manufacturing sectors including automotive, telecommunications, pharmaceutical, furniture, food, clothing, cosmetic, and personal hygiene industries, among others. At their core, product recalls seek to protect consumers from potential harm that could arise from unworthy, defective or injurious goods. In the pharmaceutical industry, product recalls are a critical intervention in the preservation of public health, one of the mandated functions of the national medicines regulatory authorities (NMRAs). In the execution of this mandate, the NMRAs are obligated to ensure, inter alia, that health products and technologies (HPTs) within their jurisdictional clinical market meet set specifications for quality, safety and efficacy (QSE) throughout the products lifecycle to benefit the country's population as well as safeguard public health needs of the global citizenry. In virtually all jurisdictions globally, the marketing authorization holders are required by law to ascertain that marketed drug products meet the requisite QSE attributes, and the role of the NMRA is to oversight, and where necessary, enforce this fiducial requirement using unbiased regulatory guidelines in the interest of the public.

To achieve their intended purpose, the regulatory guidelines for product cycle management, including product registration, recalls, market withdrawals and safety alerts, should facilitate timely and cost-effective availability of medicines that are compliant with requisite QSE specifications. Globalization of pharmaceutical markets necessitates that the regulatory frameworks be enforceable and harmonized across jurisdictions to allow for exploitation of reliance mechanisms, a global best practice advocated by the World Health Organization (WHO). In the Good Reliance Practices technical report series, the WHO defines reliance as, "*The act whereby the NMRA in one jurisdiction may take into account and give significant weight to assessments performed by another medicines regulator or trusted institution, or to any other authoritative information in reaching its own decision*." The relying authority retains independence, responsibility and accountability for the decisions taken. Reliance mechanisms are premised on the understanding that robust regulatory systems for medical products are a critical component of optimally functioning healthcare systems and fundamental contributors to improving access to essential HPTs and ultimately achieving universal health coverage. The establishment of strong and sustainable regulatory systems requires adequate resources in the form of technically competent human capital and significant financial investment, both of which are in dire scarcity in most resource-constrained low- and medium-income countries. Nevertheless, leveraging regulatory outputs from each other through mutual recognition and exploitation of reliance approaches enables cooperating NMRAs to utilize their finite resources and expertise in the most efficient manner to verify compliance of pharmaceutical products with the requisite QSE specifications. Subsequently, this allows seamless application of regulatory interventions in the shared markets while fostering confidence in healthcare systems and avoiding duplication of efforts.

It is well recognized that weak or non-coherent regulatory standards and requirements among countries is not only a major hindrance to the availability of safe, effective and high-quality medicines, but may also hamper regulatory oversight for defective health products. In this issue of the *Journal*, Otieno *et al*. reviewed and compared regulatory guidelines for pharmaceutical product recall procedures and requirements among three East African Community (EAC) member states namely Kenya, Tanzania, and Uganda. Their study revealed that the NMRAs of the three countries share similarities in only three out of twelve product recall parameters, and overall, the recall procedures across the three countries are largely divergent. This is quite worrying and does not portend well for a region that shares common political, socio-cultural, healthcare, and economic ecosystems. The findings of this study are at variance with the current

global best practices and trends that emphasize cooperation, harmonization, convergence, and transparency among NMRAs to promote reliance mechanisms in drug product regulation. In a nutshell, the observations give a snapshot of the state of regulatory disharmony in the African pharmaceutical market. Nonetheless, the findings underscore the compelling need for concerted efforts to nurture and fortify collaborative practices among NMRAs at regional, continental and global levels.

It is quite befitting that the African Medicines Regulatory Harmonization (AMRH) initiative, conceptualized in 2007 and implemented since 2009 through the New Partnership for Africa's Development (NEPAD) Agency, has been afoot for several years now and is credited with spearheading continental integration and harmonization of pharmaceutical product regulatory processes while providing a launchpad for the establishment of African Medicines Agency (AMA) in 2019. With an eye to the future, the NEPAD-AMRH initiative has championed collaborative medicines regulatory arrangements among partner states by instituting medicines regulatory harmonization (MRH) projects embedded within African regional economic communities (RECs) namely the EAC, the Southern African Development Community (SADC), the Economic Community of West African States (ECOWAS), the Intergovernmental Authority on Development (IGAD), and the Economic Community of Central African States (ECCAS). Phase one of the AMRH initiative focused principally on harmonization of registration requirements for pharmaceutical products including facilitation of joint dossier evaluations among partner states in each REC. Notably, the EAC and SADC have realized meaningful strides in this endeavour over the past few years. It is envisaged that each of the regional MRH projects will continually strengthen and expand collaborative arrangements to include other aspects of product lifecycle management such as pharmacovigilance and post-market surveillance. Attainment of these key milestones will undoubtedly provide a much-awaited reprieve for the disjointed and incoherent medicines regulatory landscape in Africa, and subsequently capacitate AMA operations. Analogous to other continental medicines regulatory bodies such as the European Medicines Agency, expanded functionalization of the AMA will greatly improve efficiency in product lifecycle management, optimize utilization of limited regulatory resources especially for innovative medicines, hasten access to safe, efficacious and high-quality products, and deliver improved treatment options and outcomes for the African populations.

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