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Ndomondo-Sigonda, Margareth

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EVALUATION OF MEDICINES REGULATORY INTERVENTIONS IN THE EAST AFRICAN COMMUNITY REGION



UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

BY:

Margareth Ndomondo-Sigonda

Student No. 766425

Supervisors:

Dr Jaqueline Miot; Health Economics and Epidemiology Research Office, Department of Internal Medicine, School of Clinical Medicine, Faculty of Health Sciences, University of Witwatersrand.

&

Prof Shan Naidoo; Public Health Medicine Department, School of Public Health, University of Witwatersrand.

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ABSTRACT

The study assessed the effect of the Medicines Regulatory Harmonization (MRH) initiative in improving regulatory capacity in the East African Community (EAC) Partner States. An exploratory mixed-method design using both qualitative and quantitative data, was employed. Data was collected from six National Medicines Regulatory Authorities (NMRAs) and the EAC Secretariat through a combination of semi-structured interviews, questionnaires, and checklists for the period 2011/12-2014/15 while 2010/11 data served as baseline. Interviews were conducted with heads of agencies; regulatory and monitoring and evaluation experts; and the EAC Seretariat Project Officer. NMRAs performance was measured using a set of 29 indicators grouped into 9 categories. In addition, document review using published reports, grey literature and media articles was conducted. Collaboration, harmonization, joint dossier reviews and inspections of manufacturing sites; reliance and cooperation were identified as key factors for building trust and capacity among NMRAs. Results show that 83.3% of the EAC Partner States have comprehensive medicines laws with autonomous NMRAs. All the NMRAs have functional registration and inspection systems for pharmaceutical manufacturing sites. They all use regional harmonised guidelines for registration, inspection, quality management and information management system. 80% of the NMRAs have attained ISO:2015 certification. Efficiency of registration processes has improved by 66.6% Industry concerns on joint review process; transparency; and accountability are areas to be addressed by EAC NMRAs. Different financing models are used to regulate pharmaceutical markets in the region with Burundi NMRA relying on government funding while others use a combination of sources of revenue. Zanzibar NMRAs is financed through government (50.40%), industry fees (40.60%) and donors/other sources (9%). For Tanzania-Mainland; the industry fees contribution increased from 60% ($2,018,608.88) in 2011 to 86% ($8,123,093) in 2015 with Government contributing on average 19.60% ($1,168,299.09) over the studied period. The Ugandan NMRA depends 98.25% on industry fees ($8,077,238.20). The indicators generated out of this research can be replicated for evaluation of similar initiatives across and beyond the African continent and contribute to public health policy.

Key words: medical products regulatory capacity, regional harmonization in Africa, collaboration, cooperation, efficiency, transparency, sustainability, East African Community, governance, NMRA financing.