Pharmacovigilance Systems in Kenya: A cross sectional assessment of selected marketing authorization holders (MAHs) in Nairobi

Christabel Khaemba[1,2], Abbie Barry[1], Martha Mandale[2], Margaret Oluka[3], Anastacia Guantai[3], Eleni Aklillu[1].
1. Karolinksa Institutet, 2. Pharmacy and Poisons Board, 3.University of Nairobi

Introduction: The National Pharmacovigilance system in Kenya was launched in 2009 and is hosted by the Kenya Pharmacy and Poisons Board. This was followed by a national roll out of pharmacovigilance guidelines, adverse event reporting tools as well as other pharmacovigilance elements for monitoring the safety of medicinal products and health technologies. Market authorization holders (MAHs) are important pharmacovigilance stakeholders, they are responsible for monitoring the safety and quality of their marketed medicines and technologies.

Objective: The objective of this study was to assess the current pharmacovigilance systems of selected MAHs in Nairobi, Kenya.

Method: Key informants from nine MAHs in Nairobi were interviewed using the East African Community Harmonized Pharmacovigilance Indicators tool in October 2018. Supportive documents highlighting the pharmacovigilance processes were reviewed. Data was recorded and analyzed.

Results: Out of the nine MAHs that were assessed, six had a designated person responsible for pharmacovigilance (QPPV). Although, only three out of the six had clearly defined pharmacovigilance functions in their job descriptions. Seven of the MAHs had a procedure for collecting and reporting adverse events (individual case safety reports) and aggregate reports to the national pharmacovigilance centre. Only two MAHs had trained their sales representatives on pharmacovigilance. Six MAHs had standard operating procedures for risk management and communication of safety reports. None of the MAHs were submitting risk minimization plans to the national pharmacovigilance centre.

Conclusion: There was no legal provision for appointment QPPV and submission of safety reports and risk management plans at the time of assessment, however the MAHs were voluntarily complying with the requirements in the draft documents due to the continuous stakeholder engagement.
It is critical that pharmacovigilance regulatory requirements for MAHs are clearly laid down and adhered to for appropriate drug safety monitoring.

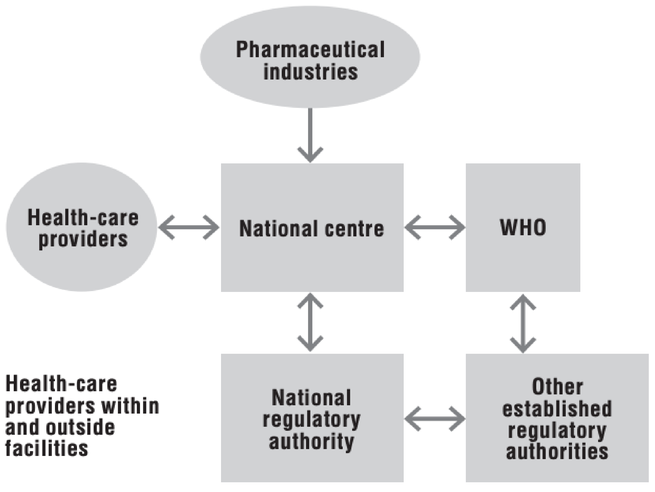

Fig 1:Diagrammatic representation of a pharmacovigilance system

Source: https://www.who.int/medicines/areas/quality safety/safety efficacy/EMP_PV_Indicators_web_ready_v2.pdf

Funding: This assessment was conducted as part of the PROFORMA project funded by the EDCTP-2 program supported by the EU (Grant number CSA2016S-1618) and SIDA.

Future Perspective: The finalization and implementation of the draft documents is key to ensure all Marketing Authorization Holders are responsible for monitoring the safety and quality of their products.

Christabel Khaemba
cnkhaemba@gmail.com
christabel.khaemba@ki.se

This project is part of the EDCTP2 programme supported by the European Union