PO - (8475) - ENHANCING THE CAPACITY OF THE LIBERIA MEDICINES AND HEALTH PRODUCTS REGULATORY AUTHORITY IN POST-MARKETING SURVEILLANCE OF IN VITRO DIAGNOSTICS

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BACKGROUND: The Quality Control Laboratory (QCL) of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) lacks capacity to assess the quality of in vitro diagnostics (IVDs). The LMHRA needs be strengthened to develop post-market surveillance (PostMS) regulations in order to comply with its supervisory role on IVD used in research and healthcare settings. IGORCADIA, an EDCTP-funded LMHRA-Barcelona Institute for Global Health (ISGlobal) project, started in December 2017 with the purpose to build LMHRA diagnostics assessment capacity. METHODS: Project activities targeting the QCL include: the constitution of an in-house Technical Working Group and a Diagnostic Steering Committee involving national stakeholders to develop PostMS regulation; a Training Program in Diagnostics Research (TPDxR) including a malaria diagnostics performance study as its post-TPDxR exercise. RESULTS: The QCL is translating knowledge and networking gained into improved mechanisms to enact its supervisory mandate. QCL staff contributed to the development of Post-MS guidance. Private sector and government stakeholders helped the LMHRA identify unlicensed premises where IVDs of presumably poor accuracy are available over-the-counter. Following the TPDxR, the QCL planned quality assurance to oversee the conduct of quality assessments on suspected substandard IVDs. Quality control tools, staff training requirements, standard inspection procedures, and PostMS registers and reports were re-designed in accordance with Good Laboratory Practice and guidance from the TPDxR. CONCLUSION: The LMHRA is strengthening its regulatory, inspection and PostMS capacities thanks to a partnership with an European research institution with expertise in malaria diagnostics development. To ensure that the Liberian population access safe quality diagnostics in routine healthcare provision and in future infectious diseases outbreaks, it is of utmost importance that the LMHRA has capacity to assess the accuracy of the non-WHO prequalified IVDs that are currently available outside the healthcare system, as well as well-equipped to recall those IVDs identified as substandard.