USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTAPS) PROGRAM

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Mother and child at a health clinic in Mozambique. Photo credit: Cora Peterson

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Building Capacity to Assess Bioequivalence Studies for MNCH Medicines in Mozambique

Technical Highlight | September 2022 | Mozambique

Virtual Training on Assessment of Bioequivalences Studies for MNCH Generic Medicines for Marketing Authorization in Mozambique

Background

The process of product registration or marketing authorization is a key regulatory function of a national medicines regulatory authority (NMRA) to ensure the safety, quality, and efficacy of medical products on the market. A country's NMRA must assess product dossiers to determine if the product warrants marketing authorization for import, distribution, or sale.

Most medicines for maternal, newborn, and child health (MNCH) are available as oral generic formulations. Oral generic medicines have to be compared to the comparator or innovator product to assess their bioequivalence (BE) to ensure therapeutic equivalence. Fully functional NMRAs must have the capacity to conduct BE assessment studies to ensure the quality and efficacy of all oral medicines, including those used for MNCH.

Problem Statement

The Mozambican Medicines Law (Act 12/2017) provides the legal framework for the regulation of medicines, vaccines, and biological products and is implemented by the country's NMRA—*Autoridade Nacional Reguladora de Medicamento* (ANARME). A recent study[1] found that in low- and middle-income countries most MNCH tracer medicines were registered, but barriers to this included limited reliance on other national regulatory authorities' decisions, registration of MNCH medicines not being prioritized, and registration procedures not streamlined. As a result of the study, the ANARME recognized the importance of implementing good review practices and building the capacity of assessors to evaluate BE studies to streamline and strengthen the registration process. Approximately 60% of the registered MNCH products in Mozambique are oral medicines, demonstrating the importance of the task of assessing BE. While the ANARME has a department for product registration and for granting marketing authorization, the 15 registration personnel responsible for performing generic medicines assessments, including evaluation of BE studies, have little experience or knowledge and required additional specialized training.

Technical Approach

In Mozambique, the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program engaged an expert from Uganda to provide a three-day virtual training to build the knowledge and skills of ANARME registration personnel to evaluate BE studies as part of generic medicines dossier assessments. The training included sessions on safety and efficacy and why BE studies are needed, reviewing BE study information, assessing clinical and non-clinical considerations, and preparing a BE study assessment report. It also included case studies and examples as well as a pretest and post-test to measure acquired knowledge.

The goal of the training was to increase the capacity of ANARME registration technical personnel to review and write BE assessment reports on data submitted for medicine registration applications in accordance with World Health Organization (WHO) and Mozambiquan regulatory guidelines. An overarching goal of this training was to contribute to the ANARME's transformation into a semi-autonomous regulatory authority with the capacity to assess BE studies for generic MNCH medicines.

MTaPS trained nine female and four male ANARME registration personnel on undertaking quality assessments of BE studies as part of the evaluation of generic MNCH medicine dossiers in Mozambique. The training used a mix of methods, including lectures and presentations, plenary and small group discussion, question and answer sessions, and individual exercises to consolidate and reinforce the learning.

Results and Achievements

Pretest and post-test results of the training showed between **17 and 65 percentage point increases** in terms of knowledge acquired by 6 of the 9 course participants who completed the pre and post-tests,[2] with a median post-test result of 93% compared to a median pretest result of 40%. Trainees felt empowered and gained confidence to apply their new learning to assess BE studies—an area they had not previously felt confident in. They agreed that the training will be beneficial in future dossier review exercises. While in-person training is often more impactful, the consultant was not able to travel to Mozambique due to COVID-19 travel restrictions. However, this experience showed that virtual training was possible through simultaneous interpretation capabilities on the Zoom platform. Additional effort ensured that trainees remained engaged throughout the process by asking specific questions to check understanding, group discussions, and reviewing case studies together.

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[1] MTaPS. Improving Access to Maternal, Newborn, and Child Health Medical Products in Low- and Middle-Income Countries: Considerations for Effective Registration Systems. 2021. Available at: https://www.mtapsprogram.org/our-resources/improving-access-to-maternal-newborn-and-child-health-medical-products-in-low-and-middle-income-countries-considerations-for-effective-registration-systems/

[2] Of the 13 trainees, only 7 completed both pre- and post-tests, 2 completed only the pre-test, and 4 did not complete either test. However, all participants completed the training course.

"… the training was very useful for the ANARME team, and the facilitator was very well selected for this training. The knowledge acquired during the training is slowly and step-by-step being useful for our daily work".

- **Dr. Velma Capote**, *Division of Evaluation of Medicines and Biological and Health Products for Human Use,* ANARME

Conclusions

The MTaPS training increased ANARME assessors' capacity to perform quality assessments of BE studies for generic medicines to ensure that applicants comply with registration requirements. Building capacity to assess BE studies contributes to meeting the WHO global benchmarking tool requirements for marketing authorization. The assessors are putting into practice their newly acquired skills in assessing BE studies and can reach out to the regional expert who conducted the training with questions. A follow-up meeting/refresher training is recommended to maintain the skill level. Participants were introduced to international references such as from WHO to continue building their knowledge.

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About USAID MTaPS:

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.