

## Quality monitoring of anti-TB drugs in Tanzania, 2012-2018

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### Summary

#### Background:

The use of substandard and falsified (SF) anti-tuberculosis (ANT-TB) drugs may lead to treatment failure and the development of drug resistance. It is claimed that SF medicinal products are more prevalent in developing countries with high disease loads. National regulatory bodies should therefore ensure systematic monitoring of the quality of these life-saving drugs. We conducted marketing surveillance studies to determine the quality of anti-TB medicines in the mainland Tanzanian market.

#### Methods:

This is a prospective cross-sectional study conducted between 2012 and 2018. Sampling techniques of interest were used to collect samples of a total of 777 anti-TB drugs. In 16 districts of mainland Tanzania, samples are collected from immigration, medical stores (MSDs) and medical institutions and healthcare facilities. All collected samples were screened using the Global Pharma Health FUND® (GPHF) Mini Lab Kit. Only samples collected from MSD and healthcare facilities will undergo product information review. Samples collected from MSD and healthcare facilities that do not meet the requirements of the GPHF Protocol or produce questionable results of compliance with the Tier II confirmatory test of compliance with Tanzania's complete pharmacopoeia monographs and 10% (10%) of medical S and medical device (TMDA) quality control labor It is pre-qualified by the world Healthy organization.

#### Results:

All 777 samples met the requirements of the GPHF mini-laboratory protocol and the respective pharmacopeial monographs at the time of screening and confirmatory testing. Of the samples collected from drug distribution outlets, 71.3% (176/247) did not meet TMDA labeling requirements and approved product information requirements.

#### Conclusions:

These results call for continuous strengthening and monitoring of Ant-TB drugs to ensure that only good quality and appropriate information is circulating in the Tanzanian mainland market.

**Keyword:** post-marketing monitoring; quality of the drug; Substandard; Forge; TLC screening; Tuberculosis.

**Link:** <https://m.23michael.com/open-access/quality-surveillance-of-antituberculosis-medicines-in-tanzania-20122018-64562.html#>