Regulatory Status and Quality Assurance of UN Commission on Life Saving Medicines in Malawi, August 2015

**Background**

A study was conducted to understand the regulatory environment and quality assurance mechanisms in Malawi for life saving medicines. The objectives were to assess the registration status of a selection of life saving medicines, determine the number of manufacturers and brands registered, and assess the quality assurance mechanisms in place.

**Methods**

The study involved reviewing regulatory data and conducting site visits to inspect the quality assurance infrastructure. The registration status of selected medicines was assessed, and the number of manufacturers and brands registered was counted. Quality assurance mechanisms were evaluated to ensure medicines circulating in the country are safe, effective, and of acceptable quality.

**Results**

- Of the medicines assessed, 13/23 were registered in the country, with 18/23 having at least two manufacturers.
- Quality assurance is primarily through inspection of manufacturing plants and sampling prior to registration.
- The Central Medical Stores Trust (CMST) is responsible for storing and delivering essential medicines, coordinated by the MOH through the Reproductive Health Directorates.

**Conclusions and Recommendations**

- The regulatory environment in place ensures medicines circulating in the country are safe, effective, and of acceptable quality.
- There is a need to improve the registration and quality assurance systems to ensure medicines are available and of good quality.

**Authors**

By Michael, Foster, Enock, Roy, Twambilire, Wilfred, and Foster