**Gentamicin 80mg/2ml is registered**

- **Recommendation 4 of the UN Commission.** All maternal health and child health products are registered.

Each category of commodities has a registered product.

The number of GMP qualified manufacturers of the various commodities so as to impede the security of the medicines in the country. There is need for the Authority to consider supporting the increase in the number of registered medicines for newborn sepsis limits the choice of treatment.

The current regulatory environment ensures safety and acceptable quality of all imported and circulating medicines in the country. Only Ceftriaxone Inj. and Amoxicillin dispersible tablet have at least 3 manufacturers registered.

The objective of the review was to establish the regulatory status and quality assurance of UN life saving medicines in the country. The study also evaluated the evaluation prior to registration, production of pharmaceutical products, screening of the products against the approved product specifications, and import control of all medicines, cosmetics and medical devices for all.

The functions of TFDA include, product promotion control, laboratory analysis for quality, safety and effectiveness, periodic post marketing surveillance, screening of samples at ports of entry, evaluation prior to registration, random evaluation, review of regulatory status and quality assurance activities undertaken by the manufacturers in the country.

The Tanzania Food and Drugs Authority (TFDA) is to be the leading African Regulatory Authority in ensuring safe, quality and effective food, medicines, cosmetics and medical devices for all. The functions of TFDA include, product promotion control, laboratory analysis for quality, safety and effectiveness, periodic post marketing surveillance, screening of samples at ports of entry, evaluation prior to registration, random evaluation, review of regulatory status and quality assurance activities undertaken by the manufacturers in the country.

The objective of the review was to establish the regulatory status and quality assurance of UN life saving medicines in the country. There is need for the Authorities to consider supporting the increase in the number of registered medicines in the country. The current regulatory environment ensures safety and acceptable quality of all imported and circulating medicines in the country.

**Regulatory Status and Quality Assurance of UN Life Saving Medicines in Tanzania, August 2015**

**Abstract**