



**STRENGTHENING QUALITY ASSURANCE IN
DEVELOPING COUNTRIES THROUGH SOUTH-TO-SOUTH
COLLABORATION - KENYAN PERSPECTIVE PAPER**

**ACCELERATING ESSENTIAL HEALTH
COMMODITY SECURITY THROUGH SOUTH
TO SOUTH COLLABORATION**

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Presented by:

DR. CHARLES KIPLAGAT KANDIE

PHARMACIST-IN-CHARGE,

KENYA MEDICAL SUPPLIES AGENCY



INTRODUCTION

Drug Regulation in Kenya is carried out by Pharmacy and Poisons Board (PPB).

PPB is vested with authority to regulate the practice of Pharmacy and manufacture and trade in drugs and poisons.

Department of Pharmacy administers

Functions of PPB

- Registration of drugs
- Ensure drugs are of good quality, safe and efficacious



EXPANDED MOVEMENT OF PHARMACEUTICALS

- ◆ 1993: Kenyan economy liberalized
- ◆ Increased access and affordability but over-stretched the PPB's capacity



KENYA NATIONAL DRUG POLICY

Developed through a series of workshops by major stakeholders

Adopted, published and launched in July, 1994

Overall goal:

“To use available resources to develop Pharmaceutical Services to meet the requirements of all Kenyans in the preventive diagnosis and treatment of diseases using efficacious, high quality, safe and cost effective pharmaceutical products”



Specific goals

- Constant availability of safe and effective drugs
- Affordability of drugs by majority of the population in Kenya
- Rational use of drugs
- Ensure drugs imported and manufactured in Kenya meet internationally accepted quality standards
- Encourage self sufficiency through local manufacture of drugs for consumption and export
- NQCL to be the official PPB regulatory Laboratory
- Adherence to Good manufacturing practices
- KNDP is one document that other partner countries can learn from us; Policy Framework is in place



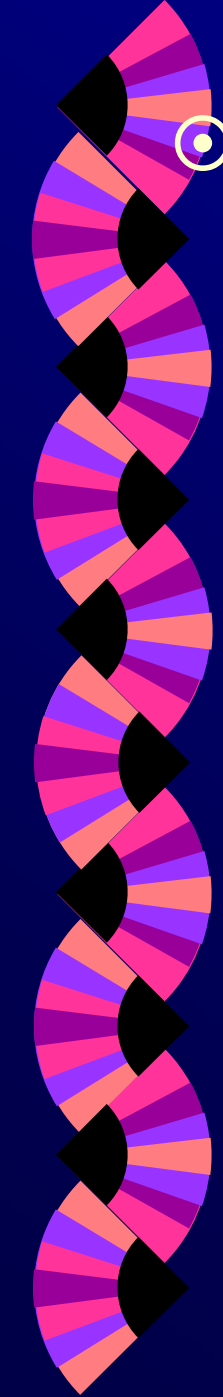
Current problems faced in PPB and QA

- Inability to keep abreast with current Drug Regulatory Authority practices globally
- Insufficient exercise of the powers of the Board as a body corporate
- Poorly remunerated staff
- Bureaucracy in issue of Licences
- Lack of Standard Operating Procedures
- Inadequate Quality Assurance surveillance system
- Inadequate Legal enforcement and provision for pharmaceutical inspectorate function
- Over reliance on paper documentation (for Quality Assurance) before registration of a medical product.



QUALITY ASSURANCE

- ◆ Involves all activities undertaken at all levels from the time decisions are made to manufacture and procure medicinal products up to the time it is dispensed to the end user to ensure that the products are safe, efficacious and of good quality.



⊙ Levels at which Quality Assurance can be done

- During preshipment inspection
- At the ports of entry
- Registration of medicinal/pharmaceutical products
- Distribution outlets
- Quality surveillance
- Manufacturing stage



Recommendations and areas that need close sharing with partner countries

- Drug registration and licensing

- harmonization of guidelines; fast-track process; pricing criteria; pre-registration testing for all drugs certifying registration by random inspection

- PPB regulation and legislation

- body corporate (incl. NQCL)
- Scheme of service for staff
- Capacity building

- SOPs for

- Registration of pharmaceutical industries (incl. EPC)
- Handling of pharmaceuticals at every level
- Drug disposal
- Policy issues regarding regional/international collaboration with DRAs and relevant bodies



Local production and standards

- Pharmaceutical inspectorate strengthening
- Provide legal provision (in accordance with KNDP)
- Adequate funding
- SOP's in
 - GMP
 - Minimum drug outlets standards
 - Quality manual for pharmaceuticals



NQCL

- Develop a quality manual to include guidelines for laboratory standards, third party certification and contracting laboratory services
- Post market surveillance
- Accreditation of NQCL & other independent labs with ISO 9000 certification
- promotion of regional harmonization of pharmaceutical inspectorate visits

Implementation, monitoring and evaluation