Technical Assistance for Establishment & Strengthening of National Quality Control Laboratory (NQCL) in Somalia

Introduction

The WHO defines counterfeit medicine as "one which is deliberately and fraudulently mislabelled with respect to identity and/or source." Both branded and generic products are faked. In some parts of Africa, Asia and Latin America, more than 30% of the medicines on sale can be fake.

Somalia is a country where the quality of the pharmaceutical products has been criticized by the public, and where, due to the long and uncontrollable border lines with Kenya, Ethiopia and djbouti, huge amount of illegal, counterfeit, and sub-standard medicines are being imported into the country by land, sea or air.

Most of the medicines imported to Somalia come from India, Pakistan, Egypt, Bangladesh and Turkey. All companies and local distributors are private and registered at the ministry of Health and human resources. The medicines which are imported to Somalia by those private companies are never tested their quality, hence quality of the imported medicines by these companies needs to be controlled in proper and standard manner.

Dr. Fatuma Adan, The director of Health & Social Development for IGAD said in meeting "the presence of unregulated Sub-standard, Falsified, and Counterfeit medicines circulating within IGAD member states" was "a serious public health threat which if not prevented and controlled, will undermine confidence in the public healthcare systems and programmes"

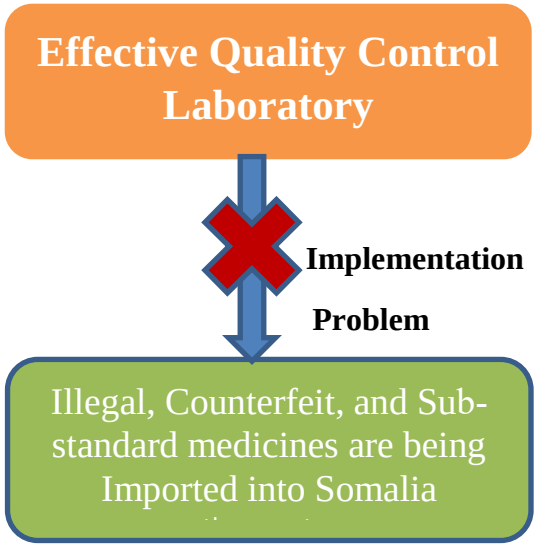
"No one can think of quality health services in the absence of safe, effective and good quality essential medicines." Said by Mr. Abraham Gebregiorgis, Technical Officer from WHO Headquarter in his opening at regional expert meeting on Medicine Regulatory Harmonization (MRH), on 17 July, 2017 which was conducted at the Intercontinental Addis Hotel, in Addis Ababa.

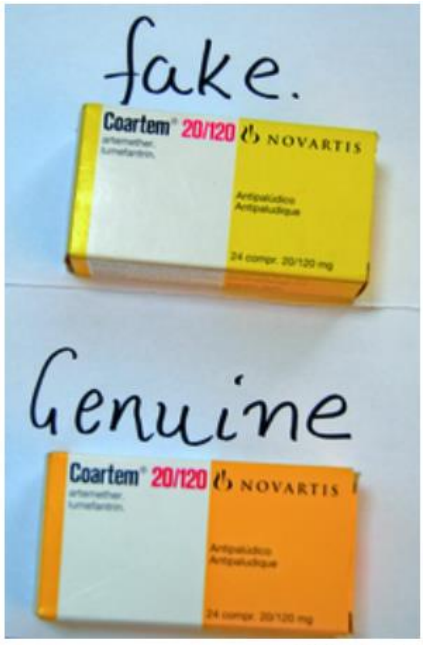
Statement of Problem

WHO established four minilabs at three hospitals in somalia, to monitor quality of essential medicines but these minilabs don't have the capacity to support the regulatory authority. Almost 100% of medicines imported to Somalia are unregulated and never tested their quality due to shortages of human and technical resources, therefore huge amount of illegal, counterfeit and substandard medicines are imported into the country by air, land and sea, this created serious public health threat. The overall cost associated with substandard drugs is immeasurable and sometimes cost human life.

Availability of data on medicines quality is a major priority for MOH's national disease control programs, as as well as procurement agencies, donors, and health professional communities. A highly functioning quality assurance system supports the identification of problems in the supply chain and amelioration of any issues related to the distribution or use of substandard or falsified medicines that could harm patients.

Taking these needs into account, establishment of national quality control laboratory is considered a critical step to ensure people's access to safe, effective, quality and affordable medicines. Establishing national quality control lab of high standard is huge task that carries steep price tag, and like other developing countries in Africa that lack adequate resources, equipment and trained staff, for Somali's; this is huge obstacle, hence this proposal is made.





© INTERPOL

More than 260 premises were visited during IMPACT's Operation Zambezi in November 2009.

http://www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1

Aim and Objectives

Aim

To Assist the Ministry of Health of Somalia to Establish & Strengthen National Quality Control Laboratory in Somalia.

Research Objectives

1. To assist the national regulatory authority of Ministry of Health of Somalia, to ensure that medicines available to the public are safe, effective and good quality
2. To identify illegal, falsified and substandard drugs imported into somalia
3. To Support the development of National Drug Policy
4. To facilitate harmonization of the regulation and the registration procedure of medicines in Somalia.

Research Questions

Are the establishment and strengthening national quality control laboratory ensures the availability of safe, effective and good quality medicine to Somali people?

Implementation Approach

This implementation research will adopt multiphase strategies, comprising **Phase 1**: Assessment phase **Phase 2**: Implementation phase and **Phase 3:** Monitoring and Evaluation Phase.

In Assessment Phase: National Regulatory Authority of Ministry of Healht of Somalia, together with PQM will carry-out base line assessment to find out the gaps and design country appropriate needs & response.

In Implementation of Lab Activities: after identifying country needs, gaps, priorities and resources, implementation plan is crafted to fit the goals of the national laboratory including the purchase of instruments, hiring technical expert staff, develop policies and SOPs and conduct inservice technical training and capacity building of laboratory personel.

In Continuous monitoring and Evaluation strategy: Through the efforts of PQM the National quality control lab will improve substantially to be indepdent, self-sufficient and sustainable, and full operation of the National Quality control laboratory will be handed over to Ministry of Health, Somali government. The technical support of PQM to the NQCL will continue throughout the project so that the NQCL can attain “WHO prequalification status”.

Implementation research Outcome to be measured

1) Availability of functional Quality control lab
2) Improved capacity of Ministry of Health to protect people's health by providing access to safe, effective and good quality medicines
3) Increased ability of the national quality control laboratory to to perform appropriate drug & medical product tests to identify the substandard drugs/products and prevent them from human consumption
4) Established drug quality management system
5) Improved National Quality Control laboratory legal framework to coordinate and manage laboratory services in both public and private health sectors
6) Increased skills and capacity of the National Quality control lab.staff at technical and operational level in management, coordination and leadership skills.
7) Increase public confidence and trust in Healthcare system and medicines.