This Evening’s Seminar**: Introduction to Medicines Quality

Discuss the basic principles of quality assurance (QA) and (QC) of medicines

– Provide an introduction to what QA entails throughout a medicine’s entire life cycle.
  • Stakeholders involved in ensuring the quality of medicines
  • Tools and mechanisms available

**A Special Thank You to Mr. Adrian Barojas, PAHO, Specialist in Medicines and Health Technologies
Objectives of Seminar: Part 1

• Medicines play an important role in maintaining and/ or improving the health and well-being of individuals and populations

• To work effectively, they must exhibit three fundamental characteristics: quality, efficacy, & safety

• A medicine’s quality can be evaluated through the following characteristics: Identity; Purity; Strength; Performance; Packaging; Labeling
Objectives of Seminar: Part 2

- Key concepts & definitions related to ensuring the quality of medicines
- Introduction to medicines quality standards
- Estimated prevalence of poor quality medicines worldwide
- Negative impact of utilizing poor quality medicines
- Activities implemented by Promoting the Quality of Medicines (PQM) program
Key Medicine Quality Terms

- **Quality Assurance (QA)** encompasses quality control and more. It is the sum of all activities, individually or collectively, intended to ensure that pharmaceutical products meet all applicable quality standards.

- **Quality Control (QC)** is the process of ensuring that all materials utilized to manufacture a pharmaceutical product conform to established manufacturer or pharmacopeial specifications for identity, strength, purity, and other characteristics.
Definitions of Poor Quality Medicines: Substandard vs Counterfeit

- Many different definitions/classifications
  - I use WHO definition-SSFFC-Substandard/spurious/falsey-labelled/falsified/counterfeit medicinal products
    - http://apps.who.int/gb/ssffc/
  - Institute of Medicine also has an excellent report:
Prevalence of Poor Quality Medicines

• Availability of poor quality medicines is a vast and underreported problem
  – Estimated up to 25% of medicines in developing countries are substandard or counterfeit

• Obtaining precise estimates is difficult due to several limiting factors
  – weak or absent regulatory/legal oversight
  – lack of adequate and/or standardized detection and reporting methodologies
  – counterfeiting is clandestine in nature
  – poor dissemination of info/lack of education on medicine quality (*more focus on access*)
Tales from the Field: Oddar Meanchey, Province, Cambodia
My colleagues: hmmm rush hour here is a bit different
But it may be better than this!

HCMC, Vietnam
Consequences of Poor Quality Medicine Use

• Increased morbidity & mortality via treatment failure and adverse drug events (ADE)
  – 2008 Baxter recalled heparin from the US market due to a contaminant.

• Development of antimicrobial resistance
  – Fake artesunate, joint investigation with INTERPOL and SE Asia medicine regulatory authorities

• Waste of financial resources

• Erode the public’s trust in national and regional health systems
Current Global Reality

There is no shortage of medicines … BUT, there is a shortage of quality-assured medicines
Quality Standards

– Cannot talk about quality without the concept of standards
– Cannot talk about standards without the authority to enforce them
PQM Program Objectives
For further information: www.usp.org/pqm

Build capacity and strengthen QA systems
- Strengthen medicines quality control labs
- Establish Medicines Quality Monitoring programs

Help increase supply of QA medicines
- Improve manufacturers’ GMP compliance
- Support WHO Prequalification Programme

Promoting the Quality of Medicines
(PQM Program, 2009-2019)

Combat counterfeit and substandard medicines
- Collaborate with IMPACT, INTERPOL, RAS & other initiatives
- Raise awareness w/PSAs, communication campaigns

Provide technical leadership
- Advocate globally about importance of medicines quality
- Promote new counterfeit/substandard detection technologies
PQM Countries (as of 2015)

Africa
- Angola, Benin, Burkina Faso, Burundi, Ethiopia, Ghana, Guinea, Kenya, Liberia, Mozambique, Nigeria, Senegal, Zimbabwe

Asia
- Bangladesh, Burma, Cambodia, China, India, Indonesia, Laos, Nepal, Pakistan, Philippines, South Korea, Thailand, Vietnam

Latin America and Caribbean
- Brazil, Colombia, Ecuador, Guatemala, Guyana, Peru, Suriname

Europe/Eurasia
- Kazakhstan, Ukraine, Uzbekistan
Monitoring Medicines Quality

Quality failures of medicines
- Physical/Visual inspection
- Verification and Confirmatory testing

Lack of registration
- Leakage (donated medicines being sold on black market)
- Deficiencies in procurement practices and supply chain

For more information:
The Three-Level Approach: A Framework for Ensuring Medicines Quality in Limited-Resource Countries
Pribluda et al., Pharmaceut Reg Affairs 2014
Minilab® Training: Philippines
Good Laboratory Practice Training: Philippines FDA
Raising Awareness: Public Service Announcements and Artwork in Cambodia
Thank You
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Questions