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What are **Substandard Medicines**?

Substandard medicines are products whose composition and ingredients does not meet correct scientific specifications and which are consequently ineffective and often dangerous to the patient. This was said by Bale Mwamba, provincial pharmacist from the Ministry of Health in Solwezi.



Speaking during a MeTA Zambia CSO workshop at Mwaaka Lodge Bale said causes of substandard medicines were many and these included negligence during manufacture, distribution and storage, human error, insufficient human resource, financial resources and counterfeiting.

What are **counterfeit medicines**?

Mwamba posed this question and went on to define counterfeit medicines. He said counterfeit medicines are substandard medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source.

“All counterfeit medicines are substandard, but not all substandard medicines are counterfeit,” he emphasized.



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Participants looking at packets of medicines. Are they fake, they seem to ask.

Mwamba explained the types of counterfeit medicines which he said included products with correct active ingredient but fake packaging, products with wrong ingredients (active/inactive), products without active ingredients and products with insufficient active ingredients.

“Counterfeiting can apply to both Branded-name and Generic medicines,” he added.

What leads to counterfeiting?

What leads to counterfeiting? Mwamba asked but without waiting for the reply he said these include Poverty and high prices of medicines and high price differentials between identical medicines, high demand, low production costs and absence of deterrent legislation.

“So all these combine to make counterfeiting possible,” he emphasized.

What medicines are commonly counterfeited?

In developed countries Mwamba noted medicines that are commonly counterfeited include new drugs and drugs reflecting the expensive lifestyles. He said lifestyle medicines include hormones, steroids and antihistamines

In developing countries on the other hand it is medicines that are used to treat life threatening conditions such as Malaria, Tuberculosis and HIV/AIDs.

Mwamba further observed that the internet was also becoming one of the major sources of counterfeit medicines. He also observed that of all drugs in the world Viagra appears to be the most counterfeited medicine.

Consequences of counterfeit and substandard medicines

The consequences of counterfeit and substandard medicines Mwamba said include treatment failure, drug resistance - resulting from drug resistant pathogens and in most cases also leading to death.

Extent of the Problem

On how extensive the problem of Counterfeit medicines was Mwamba said this made up 10% of the global medicines market. He also said counterfeit medicines were present both in developed and developing countries.

“Sadly,” he added “25% of the medicines consumed in poor countries are counterfeit or substandard.”

He observed that Global earnings from counterfeit medicines are over \$32 billion dollars annually.

Countries where counterfeit is common

According to Mwamba counterfeiting of medicines is common where Drug regulation and control is weak, where there is enforcement scarcity or where the Supply of medicines is erratic or Drug markets are unregulated or Medicine prices are unaffordable.

These countries include those in Africa, South America and south East Asia, he said.

Challenges of fighting Counterfeit Medicines

What are the challenges of fighting counterfeit medicines? These include lack of regulation and enforcement, smuggling and illegal importation, Mwamba said

Others are increasing national and international trade in alternative medicines/herbal medicines. He noted that herbal medicines were highly unregulated

Besides, Mwamba observed, some policy makers believe drug regulation presents unnecessary barrier to trade and should be reduced to a minimum.

Further medicines exported from industrialised countries tend to be not regulated to the same level as those consumed domestically.

Anti counterfeit measures



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What counterfeit measures can control counterfeiting? There was need to establish competent national drug authorities with necessary human and other resources to control the manufacture, importation, distribution and sale of medicines, Mwamba said.

In this regard Government should develop strategies to reduce corruption and criminal activity and promote inter sectoral cooperation between regulatory authorities, the police, customs services and the judiciary to effectively control the drug market and enforce regulation, he added.

Further and at international level pre-qualification Assessing of products and manufacturers and providing a list of those meeting WHO guidelines to countries and procurement agencies, in order to promote procurement of quality medicines.

Besides there was need for increasing public awareness within the country, harmonizing measures between trading countries.



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