Quality Matters!- Challenges & Development concerning Quality Standards of Locally Produced and Imported Medicines”

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Why Does Quality Matter?

1. Drugs by their nature affect and alter health.

2. Every year, billions of dollars of government health budget expenditure is on medicines.

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What challenges do local manufacturers face in their drive to produce quality medicines?

- The predominate challenges that cuts across most manufacturers especially in Africa are:

1. Absence of National Drug Regulatory Agency and Weak regulatory environment.
2. Lack of relevant manpower
3. Lack of basic infrastructure and utilities.
4. Limited access to relevant input materials such as APIs, Excipients, and reagents to run the quality control labs.
5. Low financial strength and lack of access to funds.

Impact of Absence of National Drug Regulatory Agency and Weak regulatory environment.

The quality of products in the market is at risk if regulators and those being regulated fail to apply and monitor principles of good practice in production, supply and distribution of medicines, and post-marketing surveillance.

-WHO

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Impact of Absence of National Drug Regulatory Agency and Weak regulatory environment.

The three main components of regulatory stewardship in the medicines market are:

- Product registration: assessing and authorizing products for market entry, based on quality, safety, and efficacy; and monitoring their quality and safety after entry.
- Regulation of manufacturing, importation, and distribution.
- Regulation of medicine information and promotion.

IMBALANCE HAVE BEEN IDENTIFIED IN REGULATORY PRACTICE BY WHO.

1. More effort and time is assigned to pre-marketing assessment than to post-marketing surveillance.
2. Product registration is given more attention, then regulation of drug distribution channels and information.
3. GMP inspection receives more attention and resources than inspection of distribution channels.

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IMAPCT OF REGULATORY IMBALANCES ON QUALITY OF MANUFACTURED & IMPORTED PRODUCTS (1)

1. More effort and time is assigned to pre-marketing assessment than to post-marketing surveillance

IMPACT

- Registration samples are usually of high quality to enable registration take place.

- Weak regulation and lack of routine inspection of production site by regulatory staff to monitor the level of compliance to National GMP after registration for locally manufactured products could give rise to production of low quality products. Eg the case of My Pickin in Nigeria

- Weak post-market surveillance would lead to non detection of manufacturers or importers whose quality standard has dropped after their products registration.

IMAPCT OF REGULATORY IMBALANCES ON QUALITY OF MANUFACTURED & IMPORTED PRODUCTS (2)

2. Product registration is given more attention, then regulation of drug distribution channels and information.

Impact

Without regulation of distribution channel, high quality products can deteriorate in the pipeline during transportation, or storage. This can cause adverse drug reactions, therapeutic failure due to inefficacy and loss of resources.

Due to poor regulation of distribution channel, product recall when the need arise becomes difficult.

Chaotic distribution is a medium for the successful introduction of counterfeit products in the products supply chain.

Development to address weak regulatory Environment

- Strengthen Pharmacy and Drug Regulatory Authorities via capacity building to be able to carry out necessary quality test and inspection
- Government or Private sector investment in building and equipping analytical laboratory to meet the demand for testing of medicines.
- Appointing independent WHO prequalified lab as independent analyst for all imported products.
- Information sharing about product registration status with WHO and other regulatory bodies.
- Financial and political support for post-market surveillance and pharmacy inspections as a way to monitor the quality of products on the market.

Impact of Lack of relevant manpower.

IMPACT

Lack of skilled workers would lead to personnel related errors which is a major sources of quality failure or quality variation. Staff must be well trained with adequate experience, adequate instructed with well defined responsibilities and highly motivated.

DEVELOPMENTS IN MANPOWER MANAGEMENT

UNIDO/ German GTZ are increasing skilled manpower via a programme called Advanced Industrial Pharmacy Teaching Unit (IPTU) at the Kilimanjaro School of Pharmacy / St. Luke Foundation in Moshi, Tanzania.

USP/USAID project of Promoting Quality of Medicines is helping interested manufacturers obtain WHO certification so far 21 manufacturers of TB medicines have benefited.

Impact of Lack of basic infrastructure and Utilities on quality

- **Unreliable and expensive utilities.**

  The high cost and erratic supply of water and electricity make manufacturing difficult. Supply interruptions will cause batches to be rejected, thus affecting product quality the factory's ability to produce in the most efficient manner.

  Equipment may also be old and inefficient, and brake down often increasing utility costs leading to undue delay on production floor and possible contamination which affects quality.

- **Poor transport infrastructure.**

  Bad road network which cause road accidents, absence of railways and/or absence of seaport, means that input materials and imported finished goods are not delivered in time and may be stored in unfavourable conditions before it gets to the manufacturer or wholesaler. This will certainly affect the product quality.

Impact of Limited access to relevant input materials on Quality.

The prices of APIs are very volatile, they may fluctuate on a monthly or even a daily basis. Many manufacturers do not sourcing their APIs from WHO certified companies due to cost and low volume of purchase.

Use of debatable quality APIs and excipients purchased from questionable sources would undoubtedly affect the finally quality of the products.

Impact of Low financial strength and lack of access to funds.

- Local manufacturers have problems in maintaining working capital due to customer debt. They are unable to inject the necessary funds to upgrade factory to international standard, recruit the right skills and purchase the input materials

- Limited access to credit: Banks do not understand the pharmaceutical business and are not interested in providing lines of credit or loans at reasonable interest rates.

WHAT CAN BE DONE

- *Encourage local financial institutions to lend to health care businesses. Educate* banks about pharmaceutical business models and constraints.
- *Promote alternative finance services such as cooperative pharmacy banks*

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Conclusion

- *The quality standard of many manufacturers are below international standard.*
- *This is mainly attributed to weak regulatory backbone.*
- *Where countries have regulatory authorities, insisting on Absolute compliance to international standard could mean death to a budding manufacturing sector.*
- *African can still produce high quality products by adhering to approved national GMP guidelines which are distilled from WHO guidelines.*

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