Challenges Facing Pharma in Africa

Patrick Lukulay, Ph.D.

Founder & President, Technology Solutions for Global Health LLC

phl@tech-4health.com

+1 734-644-0627/ +233540893338

Background

- Highlight key challenges
- What has been done, being done and remains to be done to address these challenges
- Focus on one of the challenges which is the focus of my new organization: Technology Solutions for Global health LLC

Secondary Reference Standards (SRS)
Traceable to major pharmacopeias standards
Cost Effective, readily accessible
Developed following international norms
In collaboration with NMRA accredited labs

ASAPprime®
better decisions faster

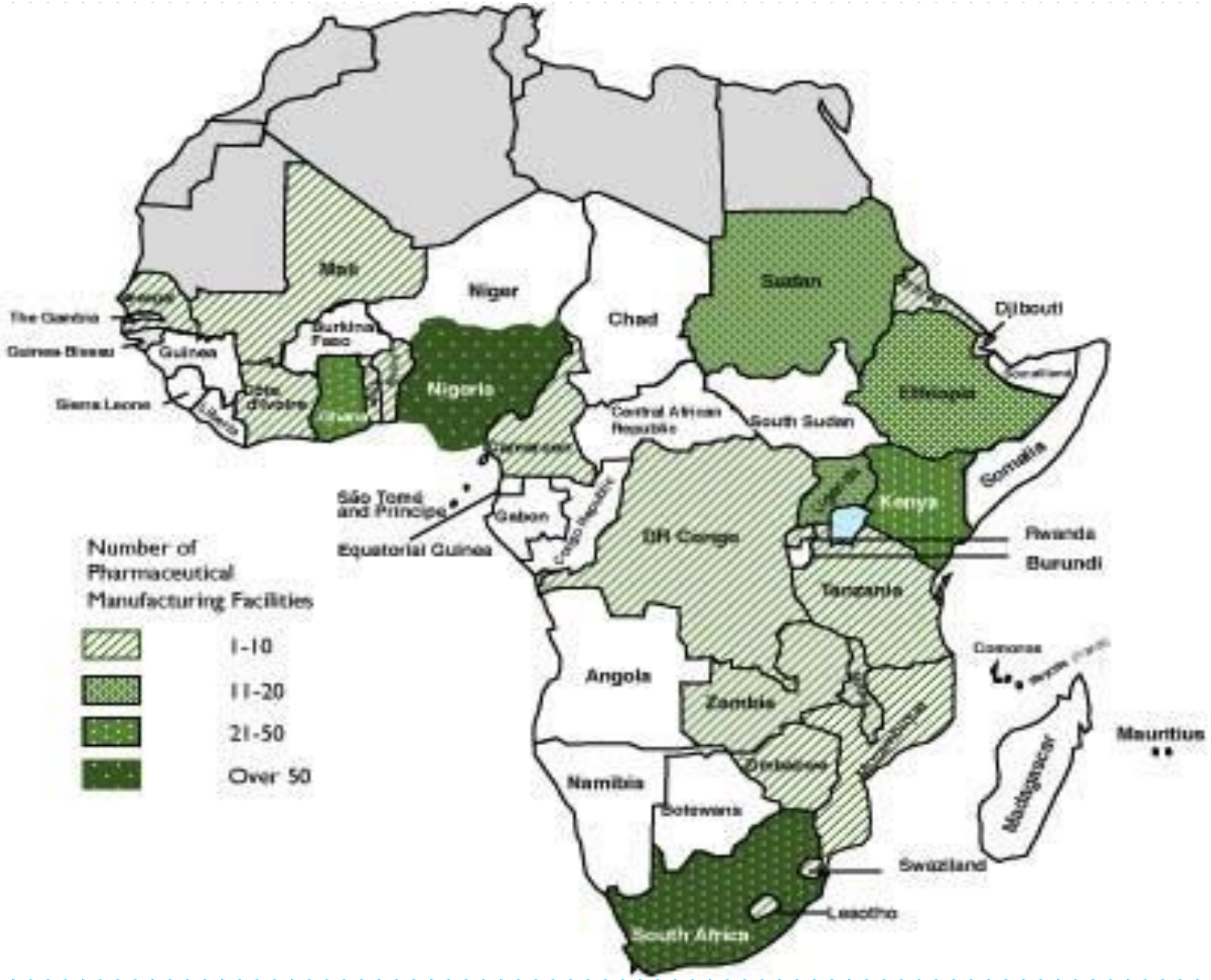
Partner with FreeThink Technologies, USA
To establish product shelf life in less than 6 weeks
Compared to the usual 6 months study @ Accelerated conditions

Develop technology platform in the form of APPS for the intelligent compilation of drug dossiers following CTD format

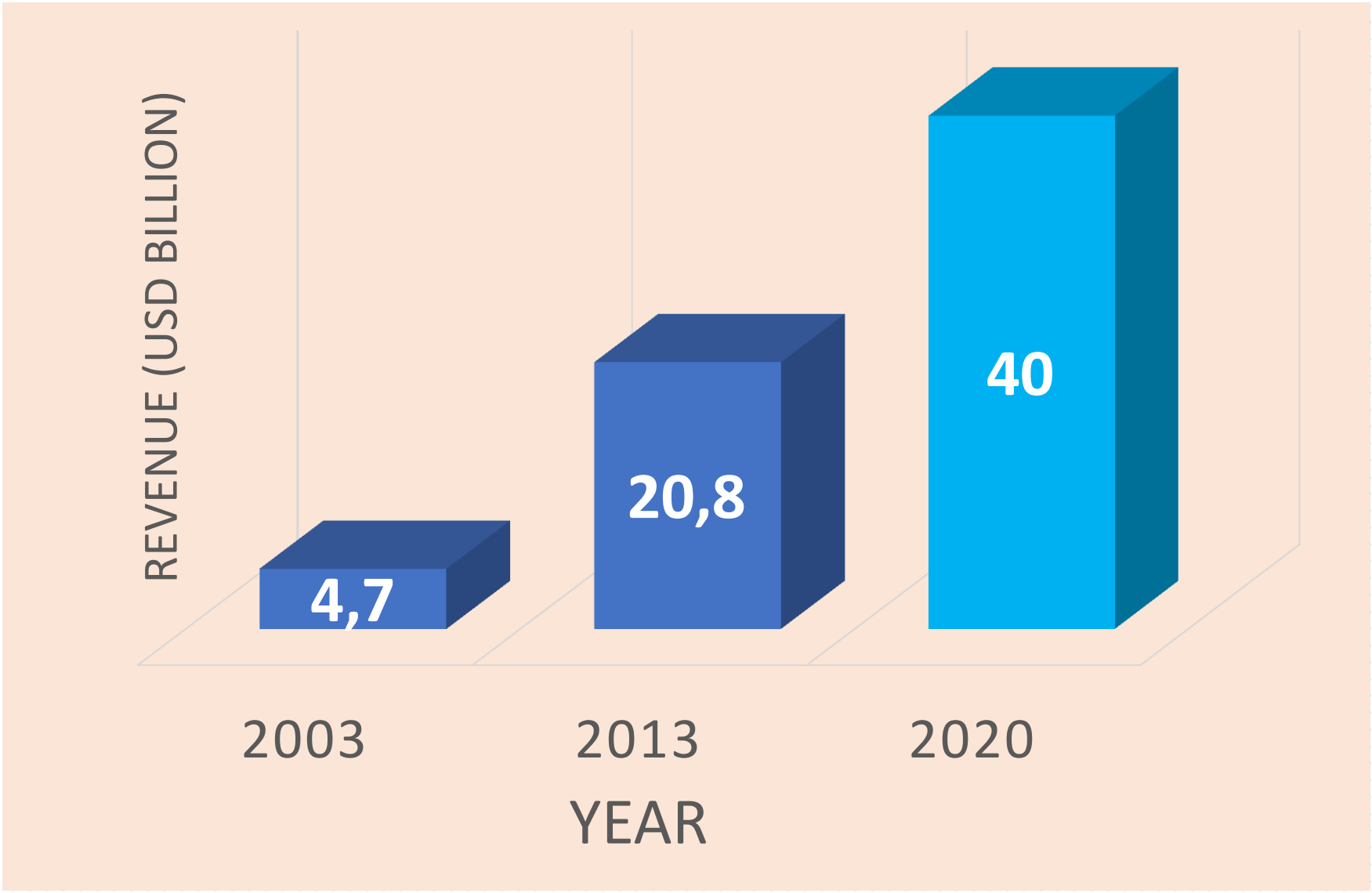
Background

- Multinationals first setup Pharmaceutical facilities in SSA:
  - Kenya: 1930,
  - South Africa: 1935
  - Nigeria: 1945
- Indigenous companies appeared in 1960s
- Today, there are about 300 manufacturing facilities
  - Nigeria: 128
  - South Africa: 68
  - Kenya: 42
  - Ghana: :32
- Local companies account for only 30% of demand,

Distribution of Pharma in SSA



Pharma market growth in SSA



Cumulative Annual Growth rate: 9% Since 2013

What is at stake

A well developed industry will be engine for economic development and improved health systems

Can meet national needs in times of emergency and epidemics and during stock out of imported medicines

Challenges

Poor Regulatory environment

- Desire to improve quality is driven by the regulatory regime
- Disparate regulatory requirements
- Uneven playing field

Solution

- Harmonization of regulatory requirements to address the disparate regulatory requirements: AMRH Initiative
- Raise standards and enforce standards evenly

Challenges cont.

Fragmented market and poor Patronage

- Fragmented markets creates no economy of scale
- Left out of major procurement opportunities by development partners

Solution

- Regional economic communities creating regional markets
- Open market treaty discussions underway
- Local companies participating in international procurement

Challenges cont.

Lack of capital

- All the initiatives risk failing when there is lack of capital for the manufacturers to implement
- Without infusion of capital by Government, companies are not positioned to improve standards

Solution

- African Union- NEPAD initiative known as: Fund for African Pharmaceutical Development (FAP-D)
- Provide low interest loans with supporting Technical guidance

Challenges cont.

Lack of Technical Capacity

- Expertise for pharmaceutical manufacturing in a GMP compliant facility still being developed

Solution

- UNIDO; WAHO initiative to map company capacities and design program for technical assistance
- NEPAD: RCORE- Regional centers for regulatory excellence
- USP:USAID Initiative to improve GMP and support manufactures toward WHO PQ

Challenges contd.

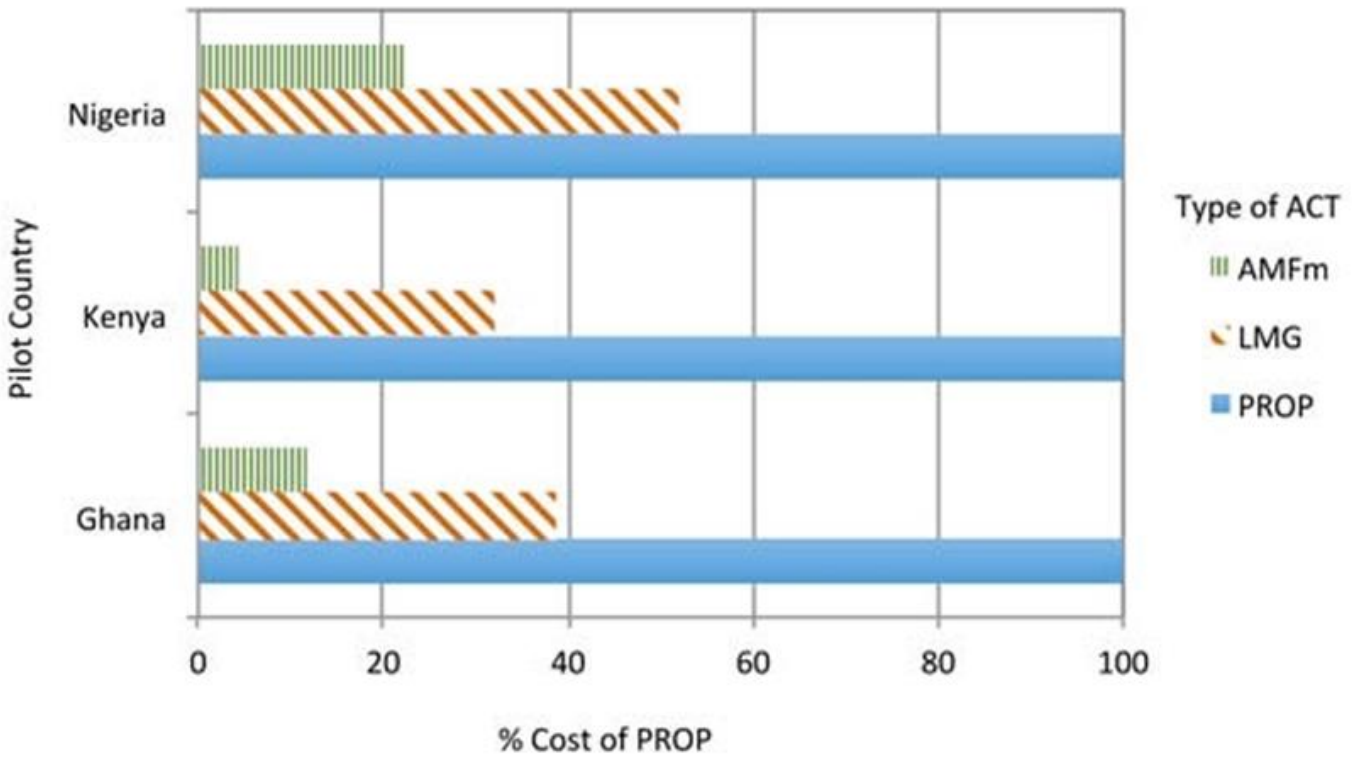
Inadequate Application of Business Principles

- Lack of sound financial and business management principles
- Poor data on market size, demand and competition

Challenges cont.

Lack of Government support and poor vetting of initiatives

- High tariffs on API but low on finished products
- Poor vetting of initiatives- example AMFm



Challenges cont.

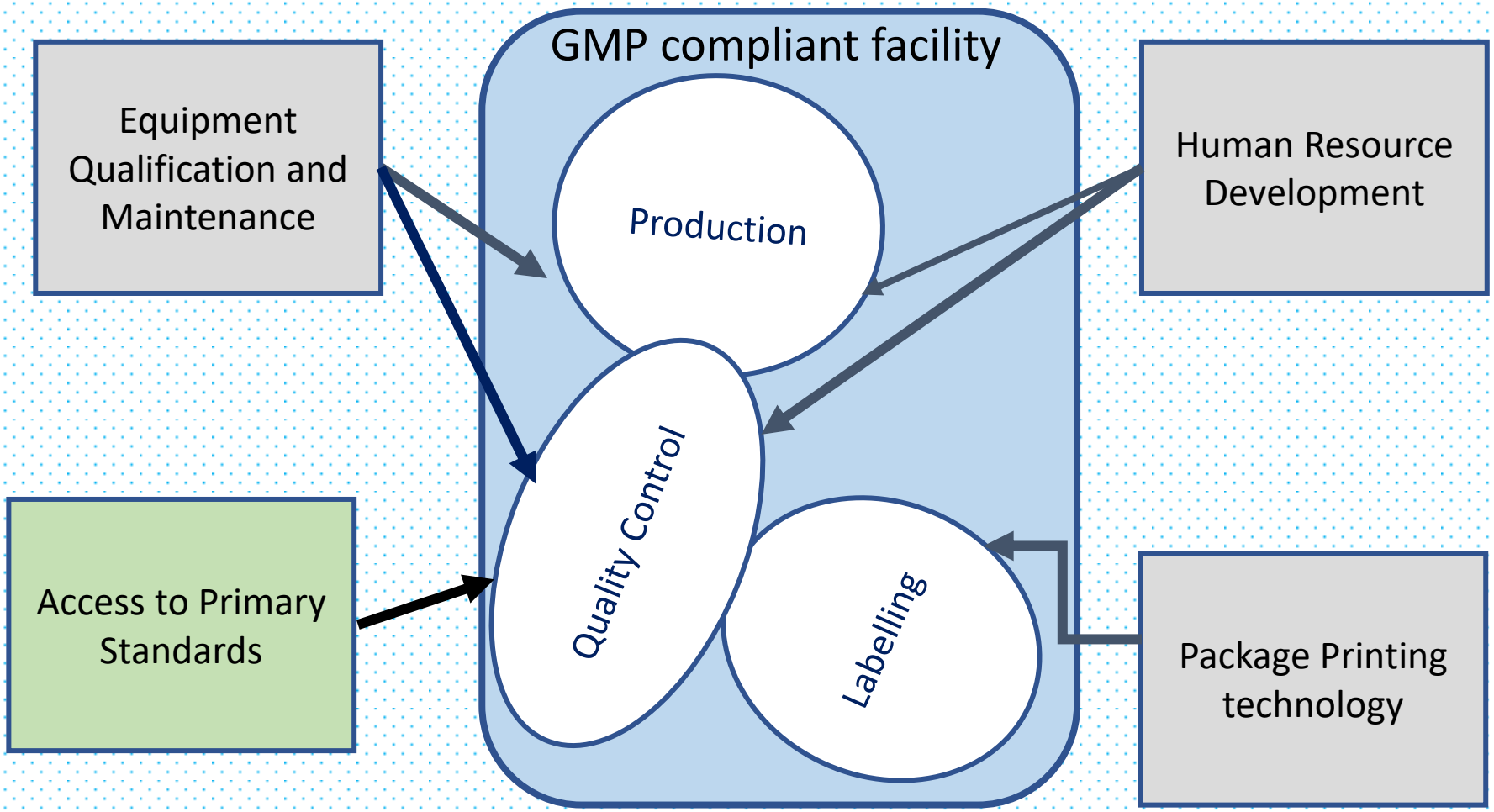
Lack of Auxiliary/Supporting Industries

- Cost of doing business is prohibitive
- Timeliness doing business is problematic
- Cost of compliance is high

Solution

- Domestication international norms: developing local capacity to comply
- Development of secondary standards
- Technology to speed up stability studies

Lack of Supporting Industries



Secondary Reference Standards Development

Affordability

- Cost-effective
- Low shipping cost, or dangerous goods cost

Accessibility

- Available locally and obtained readily as needed
- Procured with local currency

Quality-Assured

- Traceable to USP, BP and International Pharmacopeia
- Follow WHO guidelines on development of secondary standards

Status Quo

- In house standards used for quality control
- API used as standard to release finished product
- Skip batch testing

Tech4Health Secondary Reference Standards

Secondary Standards

Secondary Standard	Traceability
Paracetamol	BP
Artemether	Int. Pharm.
Lumifantrine	Int. Pharm
Trimethoprim	BP
Sulfamethoxazole	BP
Ciprofloxacin Hydrochloride	BP
Ibuprofen	BP
Metronidazole	BP
Diclofenac Sodium	BP
Albendazole	BP

Comparison of QC test results using Primary and secondary standards

Fixed Dose Combination Tablet	**Analyzed Vs. Int. Pharm. Std. (% label claim)**	**Analyzed Vs. Tech4Health Std. (% Label claim)**
Artemether	95.8 %	95.7 %
Lumifantrine	94.9 %	95.0 %

Conclusion

- The economic and health benefits of a robust pharmaceutical sector necessitates concerted efforts to address challenges
- Development of the industry must be accompanied by development of allied industries to support Pharma
- To make compliance sustainable, we must domesticate international norms by building capacity to comply rather than importing capacity to comply

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