Roadmap to validation and verification of IVDs in Kenya;

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MINISTRY OF HEALTH
Kenya Medical Lab Technicians and Technologists Board
KMLTTB; Background


KMLTTB

Provide general supervision and control over
• medical laboratory training
• Employment
• Business of all medical lab services
• Advisor to the government on all aspects of medical lab Kenya
Vision, Mission and Core Values; KMLTTB

To be an accountable, effective and efficient regulatory body promoting quality medical lab services for all Kenyans by ensuring compliance with standards for training, research, practice and business in medical lab services.

MISSION

• To protect the health of all Kenyans by ensuring compliance with standards for training, research, practice and business in medical lab services

VISION

CORE
VALUES

• Professionalism
• Excellence
• Integrity
• Accountability and transparency
• Innovation
• Ethical
• Team work
1st KMLTTB functions

- Indexing/examinations
- Registrations and Renewals
- Continuing development Practice
- Laboratories

- Unique reference no. for identification throughout training and practice
- Registration of all lab staff and due annual renewals
- Regulation of conduct, licenses and business practices in medical lab issues
- Development of CDP policy guidelines for implementation of CPD activities
Legal Notice 113 (2011)

Parliament of Kenya

Mandated KMLTTB

Manufacturers of IVD products approached relevant programs directly without proper verifications

5th KMLTTB function

Regulation of all IVDs intended for laboratory use in Kenya

- safety
- quality
- Control
- effectiveness
Regulation of IVDs; Five Strategies

- Setting timelines
- Priority list
- Classification of IVDs
- Product registration policies
- Product evaluation protocols
Barriers of implementation of legal notice 113(2011)

Hurdle 1
Overlapping mandates with PPB

Hurdle 2
lack of a harmonized method to conduct
1.validation
2.certification and
3.registration of all products intended for laboratory use

Hurdle 3
Inadequate uptake of post-market surveillance by some manufacturers

Only 3 IVDS registered
Current best practices

1. **Policies**: Harmonized Stringent regulation policies in place

2. **MoUs**: Memorandum of understanding with the validating labs on
   1. Protocols
   2. Availability of reagents and consumables
   3. Allowances

3. **Site audits**: Periodic site audits to the manufacturing plant

4. **Strategic Information**: Updated database of all registered companies

5. **Manufacturer authorization letters**: All local distributors must have letters authorizing distribution, supply and transaction on behalf of manufacturer

6. **Post market surveillance**: Periodic post market surveillance on all registered IVDs
Overview of KMLTTB IVDs registration process

1. Duly filled registration form
2. Submission of form & Dossier to KMLTTB
3. Registration payment
4. Submission of IVD product to KMLTTB
5. Validation report from lab
6. IVD released to validating lab
7. Training of ToT on IVD usability
8. Recommendation to manufacturer
9. Certificate of approval
10. IVD product is returned to manufacturer
Registration of IVDs Growth

Outcome

- Remarked increase in number of IVDs duly registered and certified by KMLTTB.

- Nearly 70% of all registered IVDs fall under WHO Class IV
Conclusions

• The new IVD regulation policies developed by KMLTTB is the surest way
  - to accelerate equipment validation and enhance access to laboratory test services
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Conflict of interest

- There was no conflict of interest