



Workshop

Drug lifecycle control in Sub-Saharan Africa

**From production to responsible safe disposal and elimination in
wastewater treatment plants**

(Med4Africa)



Risk Based Post Marketing Surveillance: A tiered approach to quality testing in a resource- limited setting

Proches Patrick –TMDA Northern Zone

02nd September, 2022

Venue: Gold Crest Hotel, Arusha Tanzania





PRESENTATION OUTLINE



- ① Overview of TMDA
- ② Why Minilabs
- ③ Selection of Medicines
- ④ What has been done
- ⑤ Achievements
- ⑥ Conclusion





Overview of TMDA



TMDA's Vision

To be the leading Regulatory Authority in ensuring safe, quality and effective, medicines, medical devices, diagnostics and other health related products for all.

TMDA's Mission

To protect and promote public health by ensuring quality, safety and effectiveness of medicines, medical devices, diagnostics and other health related products.

TMDA – Executive Agency under the MoH

- Established under the Tanzania Medicines and Medical Devices Act, Cap 219

The Act;

Mandate TMDA to regulate quality, safety, and efficacy of Medicines, Medical Devices and ***In-vitro diagnostics***

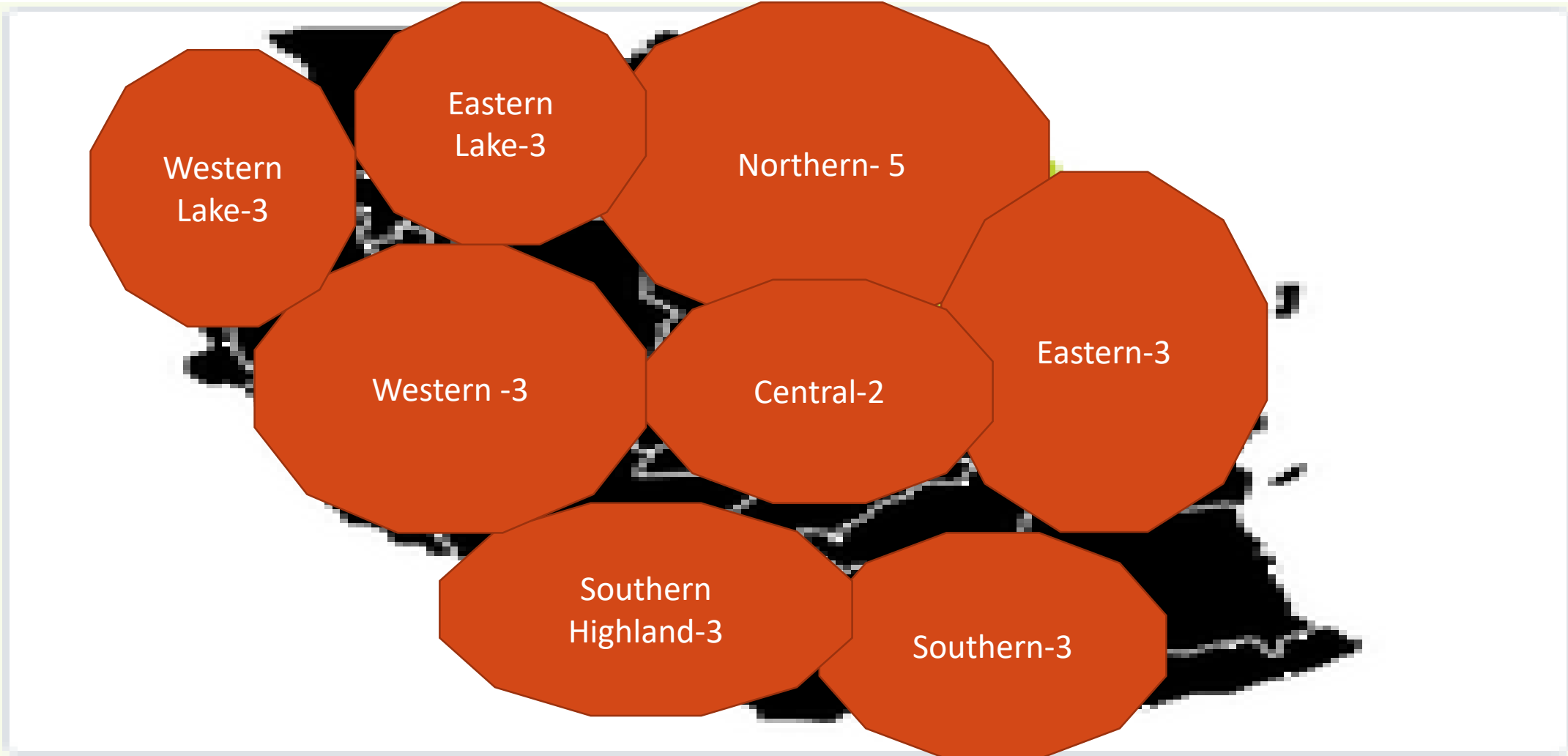


Accreditations





8 TMDA Zonal offices and Number of Minilab kits





History of GPHF Minilabs in Tanzania

- Started in 2002
- Ten (10) GPHF Minilabs - donated by WHO & Management Sciences for Health
- Objective - To fight against falsified products and test all batches of anti malarial, ARVs, anti TBs and selected antibiotics
- In 2012 five (5) Minilab kits were donated by Merck Chemicals Ltd
- In 2017 ten (10) Minilab kits were donated by Global fund
- Currently (2022) GPHF Minilabs available can screen 100 compounds such as anti malarial, ARVs, anti TBs, antibiotics, analgesics, antidiabetics, antihypertensives, antihelmenthics etc.



History cont...

- Minilabs are simple kits, easy to use and produce quick results
- Minilabs are just for screen purposes (qualitative & semi quantitative)
- Other mechanisms such as control of supply chain must be in place
- Can not detect impurities and serious case of dissolution problem
- Confirmatory testing using pharmacopoeia monograph is critical



Why Minilabs

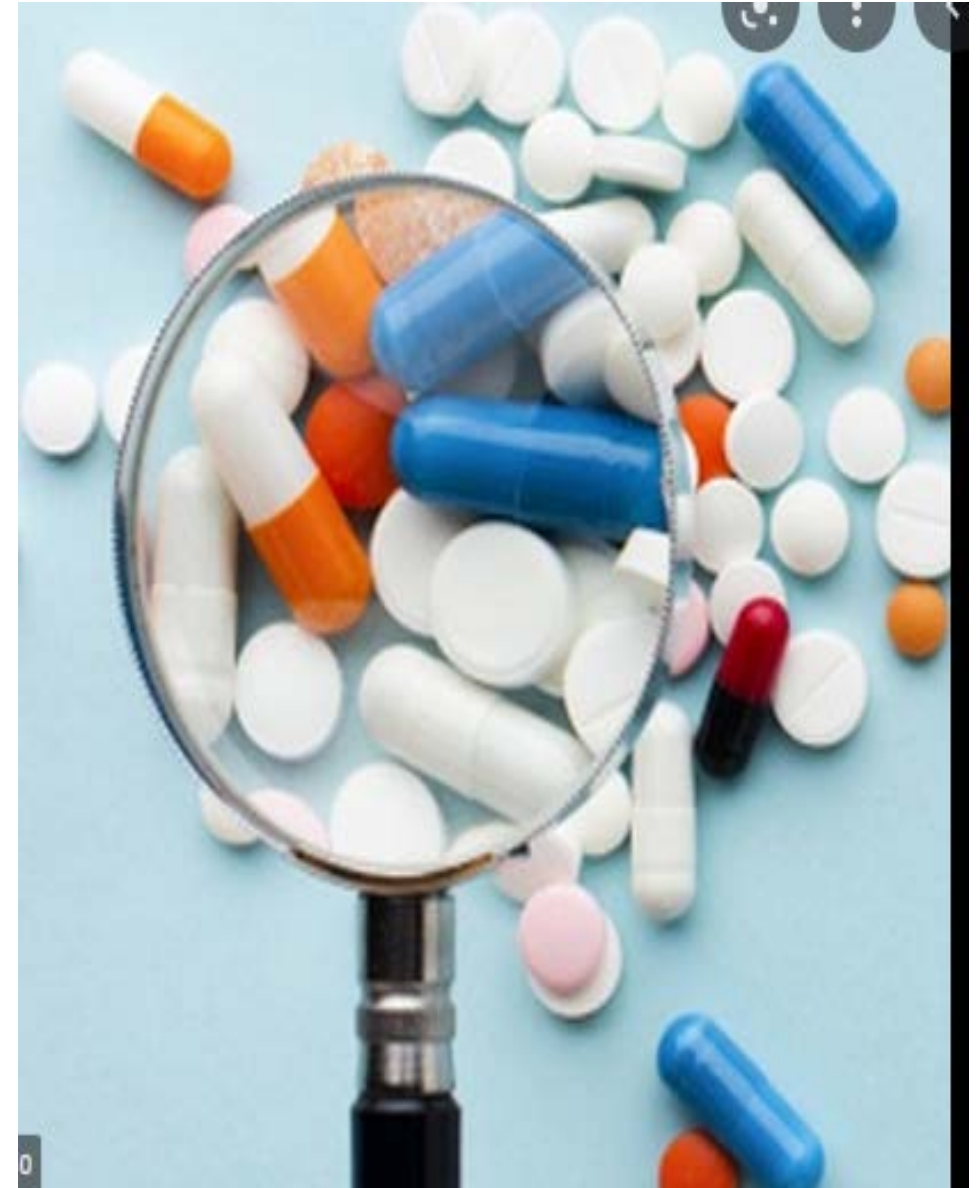


- ❖ To ensure quality of medicines – Protect and promote public health
- 17 PoEs without including ICDs
- Bordering with 8 countries with diversity in regulation of medicines
- 26 Regions and land size of about 945,087km sq
- Distance to Major Laboratories



Criteria for selection of medicines

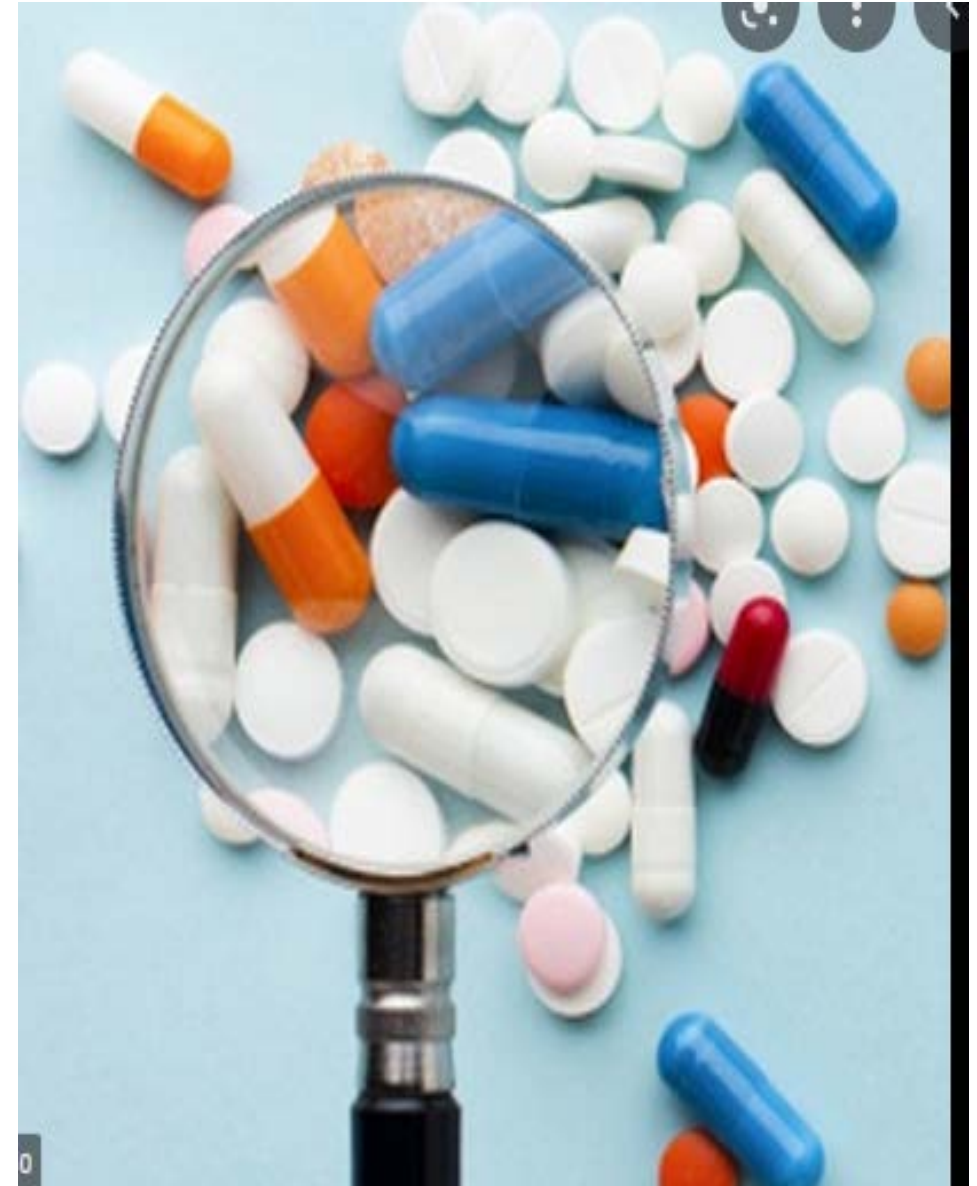
- Medicines selected are those for which a test protocol (method) is available
- Currently, test protocols are available for 100 drug compounds
- Most of them are anti-infective medicines from the list of essential medicines
- The current shortlist consists of vital antibacterials, antimycobacterials, antiretrovirals, antihelmintics, cardiovasculars, antidiabetics and some other medicines to treat communicable and non-communicable diseases.





Collection of Samples

- Ensure all inputs for testing are available
- Collect samples from;
 - ❖ PoEs
 - ❖ Regional Referral Hospitals & Other Health Facilities
 - ❖ Dispensing outlets (Buying) – Based on the Plan & Risk based Approach
- Register all received samples
- Conduct preparation
- Test the samples
- Record results
- Verify the results





What has been done?

From the financial year 2015 /2016 up to 2021/2022 TMDA collected and tested 8480 samples and all passed as described in the table below;

Financial Year	Number of samples tested	Number of sample Passed
2015/2016	602	602
2016/2017	612	612
2017/2018	985	985
2018/2019	1498	1498
2019/2020	1128	1128
2020/2021	1366	1366
2021/2022	2289	2289
Total	8480	8480



Achievements and Benefits

- Quality of products assured
- Quick results – improve service delivery – release of consignments
- Early Regulatory intervention in case of non conforming product
- Economical – low cost, less time



Conclusion

- GPHF MiniLabs are still very important in resource limited countries
- More GPHF Minilabs should be available
- Government should set aside funds for procurement of these kits and not relying on donation alone
- Further development of GPHF Minilabs should be considered to extend the range of compounds to be tested and probably quantifying the results



Thank you and Welcome to Tanzania



Serengeti National Park



Mt. Kilimanjaro

