



Workshop

Drug lifecycle control in Sub-Saharan Africa

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

(Med4Africa)



DRUG QUALITY CONTROL IN KENYA: DECADAL RESULTS FROM TWO LABORATORIES (2011-2020)

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GOLD CREST HOTEL, ARUSHA



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DRUG ANALYSIS AND RESEARCH UNIT (DARU)

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MISSION FOR ESSENTIAL DRUGS AND SUPPLIES (MEDS) LABORATORY

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Study period



DRUG ANALYSIS AND RESEARCH UNIT (DARU)

2011 – 2015: Published

2016 – 2020: Accepted for publication

MISSION FOR ESSENTIAL DRUGS AND SUPPLIES (MEDS) LABORATORY

2013 – 2017: Published

2018 – 2020: Under compilation



Drug Analysis and Research Unit (DARU)



About DARU

- ❑ Established in 1977 – Dept of Pharmacy, UoN & MoH, Kenya
- ❑ 1982 – First publication of data
- ❑ Five-yearly reports since 1991
- ❑ 1992 – NQCL was an off-shoot of DARU
- ❑ Organogram – Head, supervisors, analysts, technical staff



DARU- Equipment





DARU- Mandate



Functions

- ❑ Perform pre-registration analysis for clients
- ❑ Teaching facility – undergraduate, masters, PhD
- ❑ Post market surveillance (PMS), pharmacovigilance – in collaboration with researchers & drug regulatory authority
- ❑ Stability studies (accelerated) – Zone IV conditions
- ❑ Research – methods development & validation, PMS, drug product development
- ❑ Technical support to the Kenyatta National Hospital production unit – clinical services E.g. morphine solution
- ❑ Participate in Proficiency Testing (PT) schemes



MEDS Laboratory



About MEDS laboratory

- ❑ MEDS established in 1986 as ecumenical partnership Kenya Conference of Catholic Bishops (KCCB) & Christian Health Association of Kenya (CHAK).
- ❑ MEDS lab was established in 1997 to support MEDS quality assurance functions
- ❑ Prequalification (PQ) of MEDS suppliers, drug testing, post market surveillance & pharmacovigilance
- ❑ Attained WHO-PQ in 2009, retained status in 2018
- ❑ Organogram – MD, Head – quality services, lab supervisor, lab staff, analysts, lab assistants
- ❑ 2021 – First publication of data for the 2013-2017 period



MEDS Lab - Equipment





MEDS Lab - Mandate



Functions

- ❑ Support the Quality Assurance pillar of the wider MEDS mandate
- ❑ Perform analysis of internal MEDS samples – supplier pre-qualification
- ❑ Perform pre-registration analysis for clients
- ❑ Post market surveillance, pharmacovigilance – in collaboration with strategic partners
 - ❖ GPHF-Minilab – field testing
 - ❖ Confirmatory testing at MEDS laboratory



MEDS Lab - Mandate



Functions

- Supply of Primary and Working Reference Standards (WRS)
- Supply of laboratory consumables including reagents, solvents, HPLC Columns and glassware
- Research function – in collaboration with University of Nairobi
- Participate in Proficiency Testing (PT) schemes



DARU results, 2011 -2015



	Number/Percentage		Details
Samples	Total	- 1972	Human – 87.5%
	Local	- 21.5%	Veterinary – 12.4%
	Imported	- 78.2%	PMS – 268
	Unknown	- 0.3%	PV - 29
Failure rates	Overall	- 4.5%	Local - 2.5%
			Imported - 2.0%
Drug classes failed	Uterotonics	- 37.5%	Oxytocin
	Hemostatics	- 33%	Tranexamic acid
	Anthelmintics	- 17%	Albendazole
	Anticancers	- 10.5%	Cyclophosphamide

PMS – post market surveillance, PV - pharmacovigilance



DARU results, 2011 -2015



Observations

- ❑ Highest number of samples since inception
- ❑ High level of imports - 78.2%
- ❑ Lowest failure rate since publication of QC results
- ❑ Improvement of quality performance of samples
- ❑ Erectile dysfunction drugs (sildenafil, tadalafil) received for the first time. All complied with quality tests



DARU results, 2016 -2020



	Number/Percentage	Details
Samples	Total - 326 Local - 32.5% Imported - 65.7% undeclared - 1.8%	Human – 88.0% Veterinary – 10.1% Excipients – 1.8%
Failure rates	Overall - 1.8%	Local - 0.6% Imported – 0.9% undeclared – 0.3%
Drug classes failed	Anti-ulcers, hypoglycemics, opioids, herbals – 1 sample each Antiseptics - 2	omeprazole, empagliflozin, morphine, iodine tincture, isopropyl alcohol, tadalafil



DARU results, 2016 -2020



Observations

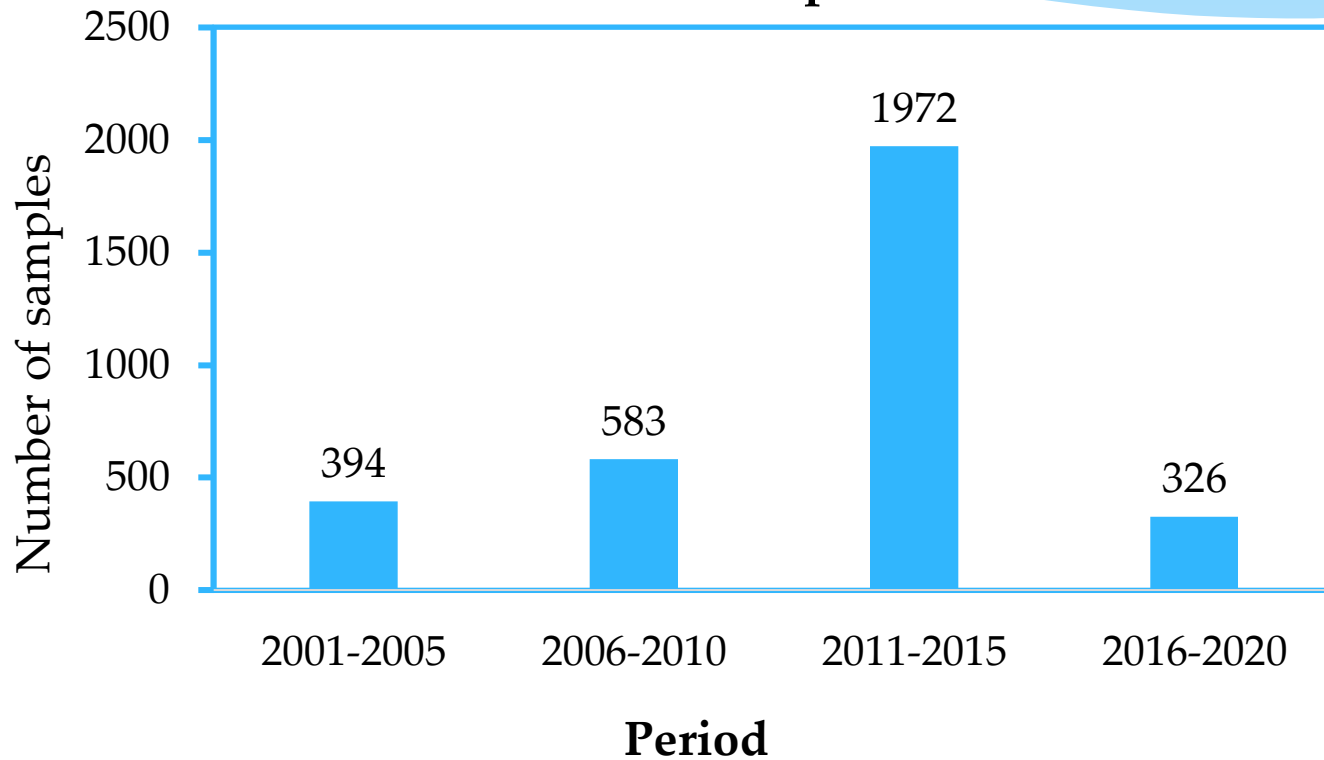
- ❑ Lowest number of samples since year 2001
 - ❖ Unfavourable policy changes in the Pharmacy & Poisons Board.
 - ❖ All pre-registration samples to be analyzed at the National Quality Control Laboratory (NQCL) – 2018
 - ❖ COVID-19 pandemic – Year 2020
- ❑ High level of imports *cf* locally produced products
- ❑ Lowest failure rate since publication of QC results
- ❑ Improvement of quality performance of samples



DARU results, Trends since 2000



Number of samples

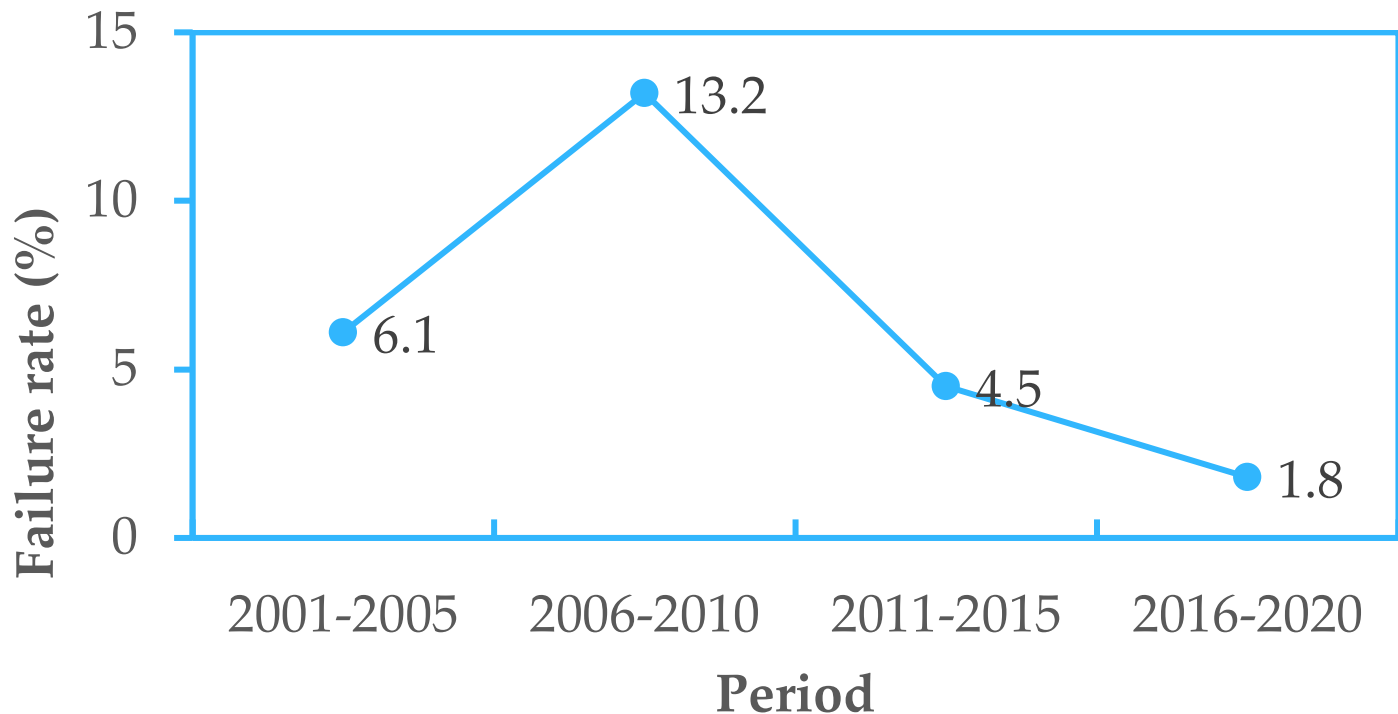




DARU results, Trends since 2000



Failure rate





MEDS results, 2013 -2017



	Number/ Percentage		Details
Samples	Total	- 6853	Human – 92.8%
	Local	- 31.9%	Veterinary – 1.4%
	Imported	- 67.9%	Non-drugs – 5.8%
	Unknown	- 0.1%	PMS - NC
			PV - NC
Failure rates	Overall	- 5.1%	Local - 1.2%
			Imported – 3.8%
			Unknown – 2 samples

PMS – post market surveillance, PV – pharmacovigilance, NC – not counted



MEDS results, 2013 -2017



	Number/Percentage	Details
Drug classes failed	Antimyasthenics - 50.0% Antiseptics - 24.7% Anthelmintics - 22.0% Thyroid/antithyroid - 20.0% Nutrient mixtures -18.5% Uricosurics - 12.5% Waters -11.6% Mixed anti-infectives - 11.1% Hemostatics - 10.0% Nootropics - 10.0%	Neostigmine Povidone iodine Albendazole Carbimazole Fe-sulphate/folic acid Febuxostat Purified water Norfloxacin/ tinidazole Tranexamic/ etamsylate Citicoline



MEDS results, 2013 -2017



Observations

- ❑ High sample load & throughput – 6853
 - ❖ Enhanced capacity - equipment, manpower
 - ❖ WHO PQ status – international clients
 - ❖ Analysis of internal MEDS samples
- ❑ High level of falsified medicines
- ❑ Quality assurance samples received from manufacturers
 - ❖ Environment monitoring (sterility, microbial load) – 365 samples
 - ❖ Water quality – potable water & purified water
 - ❖ Cleaning validation – API residues



MEDS results, 2013 -2017



Observations

Falsified medicines without API – 23 samples

- ❖ Spasmolytics - 2
- ❖ Antibacterials - 6
- ❖ Antimalarials - 13
- ❖ Anti-epileptics - 1
- ❖ Ovulants - 1

These were PMS samples

- ❖ Democratic Republic of Congo (DRC)
- ❖ Cameroun
- ❖ Nigeria



DARU - experiences



Challenges

- ❑ Analysis backlogs
 - ❖ Equipment shortage
 - ❖ Staffing constraints
 - ❖ Procurement delays – reagents, solvents, accessories
- ❑ Shortage of Reference Substances
 - ❖ Sourcing constraints
 - ❖ High cost
 - ❖ Clients provide WRS
- ❑ Lack of validated methods of analysis



MEDS lab - experiences



Challenges

❑ Analysis backlogs

- ❖ Equipment shortage
- ❖ Staffing constraints
- ❖ Lack of special reagents from local suppliers

❑ Shortage of Reference Substances

- ❖ Sourcing constraints
- ❖ High cost
- ❖ Clients provide WRS

❑ Capacity constraints due to high investment requirements e.g. Testing of medical devices



Drug disposal



Retained drugs are disposed according the PPB guidelines

- ❑ DARU lab - Dispose six months after issuance of CoA
 - ❖ List drugs in the prescribed form
 - ❖ DARU – Incineration within the University
- ❑ MEDS lab – one year after expiry
 - ❖ USAID – 10 years by arrangement
 - ❖ Contract licensed PQ firms
 - ❖ Certificate of destruction is issued



MEDS lab - innovations



Innovative approaches

- Sourcing and supply of Reference substances
 - ❖ USP, MHRA, EDQM
 - ❖ Indian companies - WRS
 - ❖ Reduce turnaround time for analysis
 - ❖ Supply of RS to laboratories – Kenya and East Africa
 - ❖ Affordable costs: 150-300 USD
 - ❖ Revenue generation for sustainability
- Sourcing and supply of glassware, HPLC columns, reagents, solvents, chemicals, purified water, LAL kits



MEDS lab - innovations



Innovative approaches

- ❑ Modern microbiology lab is under construction to enhance capacity
 - ❖ Construction completed - December 2022
 - ❖ Commissioning - February 2023



MEDS Microbiology Lab – under construction





Conclusions & implications



- ❑ Quality of medicines has improved over time
- ❑ Failure rates for anti-infectives is of concern
- ❑ Need to enhance capacity – equipment, staff
- ❑ Responsive procurement and approval systems
- ❑ Mainstream PMS and pharmacovigilance systems
- ❑ Strategies to improve local pharmaceutical manufacturing



Publications – DARU results



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Quality Control Report of Drugs Analyzed in the Drug Analysis and Research Unit during the Period 2011-2015

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During the period 2011-2015, the Drug Analysis and Research Unit (DARU) analyzed 1972 drug samples. The samples consisted of 21.5% locally manufactured and 78.2% imported products while the origin of 0.3% of products was indeterminate. Samples were

<http://uonjournals.uonbi.ac.ke/ojs/index.php/ecajps/article/view/714>



Publications – MEDS laboratory



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Quality Control Results of Pharmaceuticals Analyzed in the Mission for Essential Drugs and Supplies (MEDS) Laboratory During the Period 2013-2017

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During the 2013-2017 period, the MEDS laboratory received and processed 6853 samples. Samples were sourced from Kenya and other sub-Saharan Africa countries. The samples submitted comprised Kenyan manufactured (31.9%) and internationally manufactured products (67.9%) while nine samples were of unknown origin. Analysis was carried out

<http://uonjournals.uonbi.ac.ke/ojs/index.php/ecajps/article/view/969>



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Thank you

Asante