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“Updates on Substandard, Falsified (SF) and unregistered medical products”

WSR

Substandard and falsified (SF) medical products pose severe threats to public health, leading to treatment failure, disease progression, toxicity, and increased antimicrobial resistance. Furthermore, they erode public trust in healthcare systems and trigger substantial economic losses. To protect public health in Tanzania, the Tanzania Medicines and Medical Devices Authority (TMDA) is committed to ensuring that all medical products are safe, effective, and of high quality.

To achieve this, TMDA implements robust strategies to prevent, detect, and respond to SF products by:

- Strengthening regulatory frameworks and enforcement mechanisms.
- Inspecting manufacturing sites, importers, distributors, and healthcare facilities.
- Conducting post-marketing surveillance and rigorous laboratory testing.
- Monitoring medicine supply chains and distribution networks.
- Issuing timely safety alerts, product recalls, and regulatory sanctions when necessary.
- Collaborating with local and international stakeholders and regulatory peers.
- Educating the public on the dangers of purchasing medicines from unauthorized sources.
- Deploying technological solutions and traceability systems to enhance monitoring and detection.



Photo 1: Unregistered Vega 100 claimed to be manufactured by Signature



Photo 2: Unregistered Contrasef claimed to be manufactured by Senador Laboratories Pvt., Mumbai, India

TMDA Intercepts Six Unregistered Human Medicines in Southern Highland Zone

TMDA Southern Highland Zone (SHZ) inspectors successfully intercepted six (6) unregistered human

medical products during a routine Inspection. The specific technical details, including product names, manufacturers, batch numbers, and points of seizure, are compiled in Table 1 below.

Table 1: List of unregistered Medicines Seized at SHZ

S/N	Name of medical product	Batch No.	Manufacturer Name	Quantity
1.	VEGA (Sildenafil Citrate) Tablets	-	Signature	1 tab
2.	CONTRASAFE (Medroxyprogesterone Acetate) Injection	4003481	Senador Laboratories Pvt. Mumbai - India	21 vials
3.	Doxycycline Capsules 100mg	670125	Yash Life Science Ltd – Lusaka - Zambia	500 tabs
4.	Salbutamol Tablets BP 4mg	480524	Yash Life Sciences Ltd. Kafue, Zambia	900tabs
5.	Grindex (Oxytocin) injection 10IU/ml	0121910224	China	2 Pcs
6.	Erythromycin Stearate Tablets BP 250mg	631224	Yash Life Science Ltd – Lusaka - Zambia	300tabs

Some of the photographs of the unregistered medicines are as indicated below.

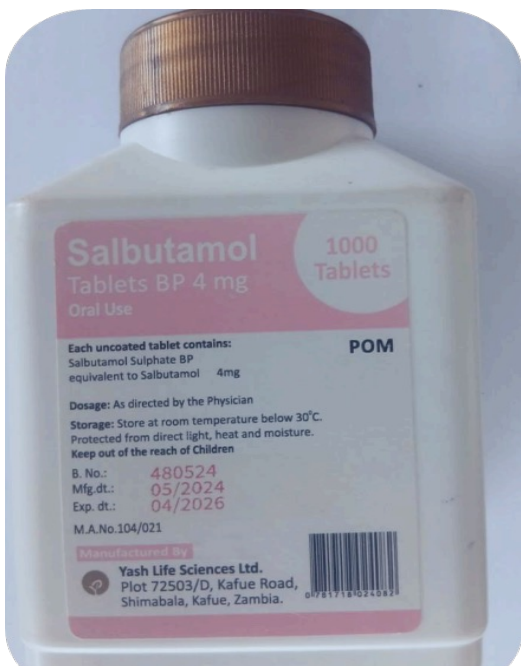


Photo 3: Unregistered Salbutamol claimed to be manufactured by YashLifeSciencesLtd. Kafue, Zambia



Photo 4: Unregistered Doxycycline tablets claimed to be manufactured by Yash Life Science Ltd, Lusaka, Zambia



Photo 5: Unregistered erythromycin tablets claimed to be manufactured by Yash Life Science Ltd, Lusaka, Zambia

The aforementioned unregistered medicines were intercepted during a routine inspection at Tunduma Town Council and Momba District Council in the Songwe Region. Being unregistered implies that the quality, efficacy, and safety of these products have not been verified. Unregistered medicines pose a se-

vere threat to public health by introducing unvetted products into the supply chain; these medications can cause serious adverse drug reactions, treatment failures, or poisoning because they completely bypass essential regulatory evaluations.

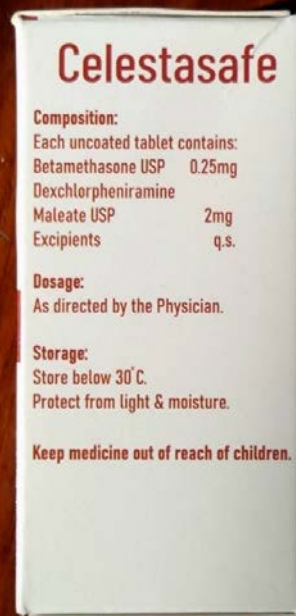
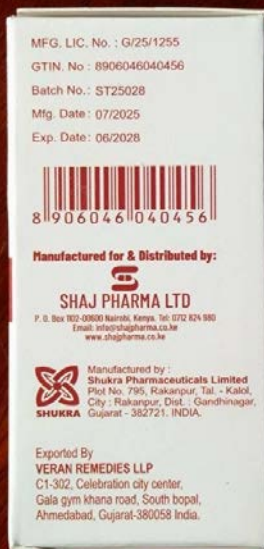


Photo 6:
Unregistered
Celestasafe
tablets

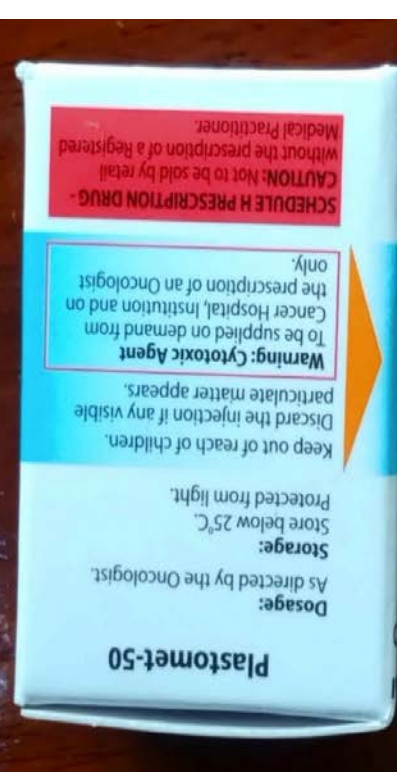


Photo 7:
Unregistered
Plastomet-50
(Methotrex-
ate Injection
IP)

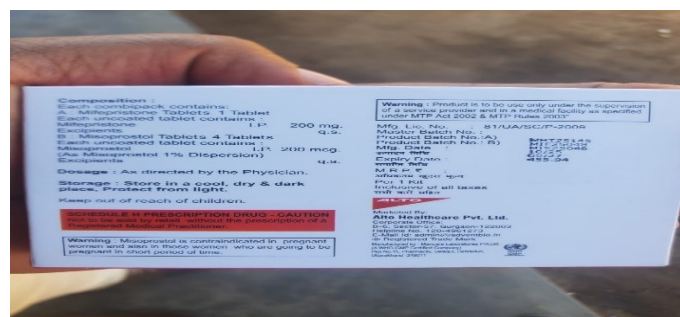
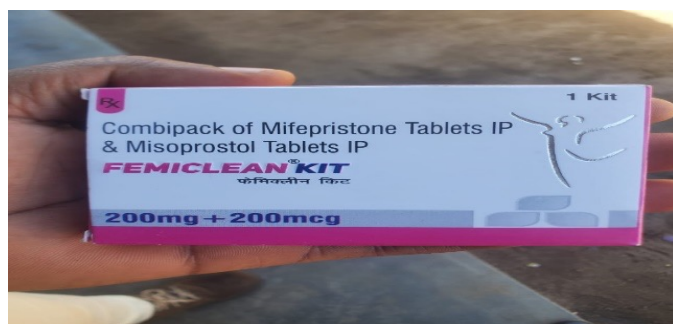


Photo 8: Unregistered Femiclean Kit

TMDA Intercepts Relabelled Expired Oncology, Falsified and Unregistered Medicinal Products in the Central Zone

During routine enforcement operations, TMDA Central Zone inspectors intercepted and confiscated four (4) illicit medicinal products at Mafinga TC and Ifakara DC.

The seized items present severe public health risks and involve multiple critical regulatory violations, specifically: -

- a. Two (2) re-labelled oncology products (indicating

- potential tampering or shelf-life manipulation of critical cancer therapies).
- b. One (1) falsified medicinal product (counterfeit).
- c. unregistered medicinal product (unauthorized for sale or distribution)

The specific technical details, including product names, manufacturers, batch numbers, and points of seizure, are compiled in Table 3 below.

Table 3: Unregistered medicines confiscated at Mafinga TC and Ifakara DC

S/N	Product Name	Dosage Form	Quantity	Manufacturer (Claimed)	Batch Details
1	Cisplatin Injection BP 50mg/50ml (Platol)	Tablets	24 vials	Venus Remedies Ltd, India	X5CC1012A
2	Docetaxel Concentrate for solution for infusion 120mg/3.0ml (Doxol)	Infusion	130 vials	Venus Remedies Ltd	X6CD0043C
3	Esb3	Water Soluble Powder	60 tins	Graniteside Chemicals (Pvt) Ltd, Zimbabwe	220138
4	Hi-Tet 120	Injection	3 pc	Pharma-Q(Pty) Ltd, South Africa	240632

The Photographs of these unregistered medicines are as they appear below;



Photo 16: Unregistered Cisplatin Injection BP 50mg/50ml (Platol)



Photo 17: Unregistered Docetaxel Concentrate for solution for infusion 120mg/3.0ml (Doxol)

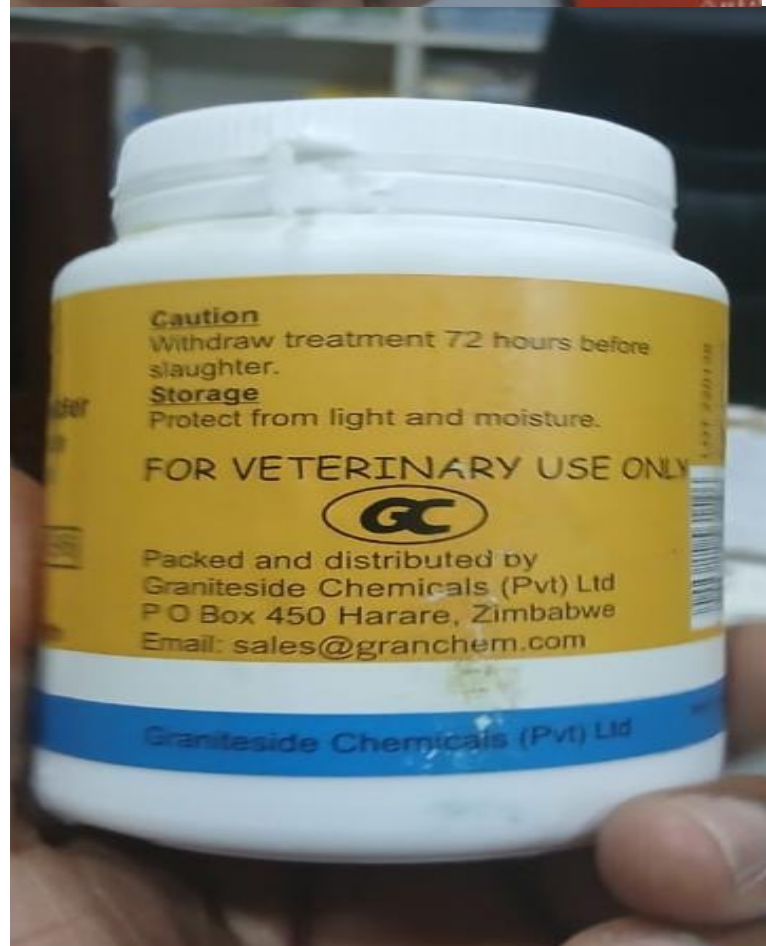
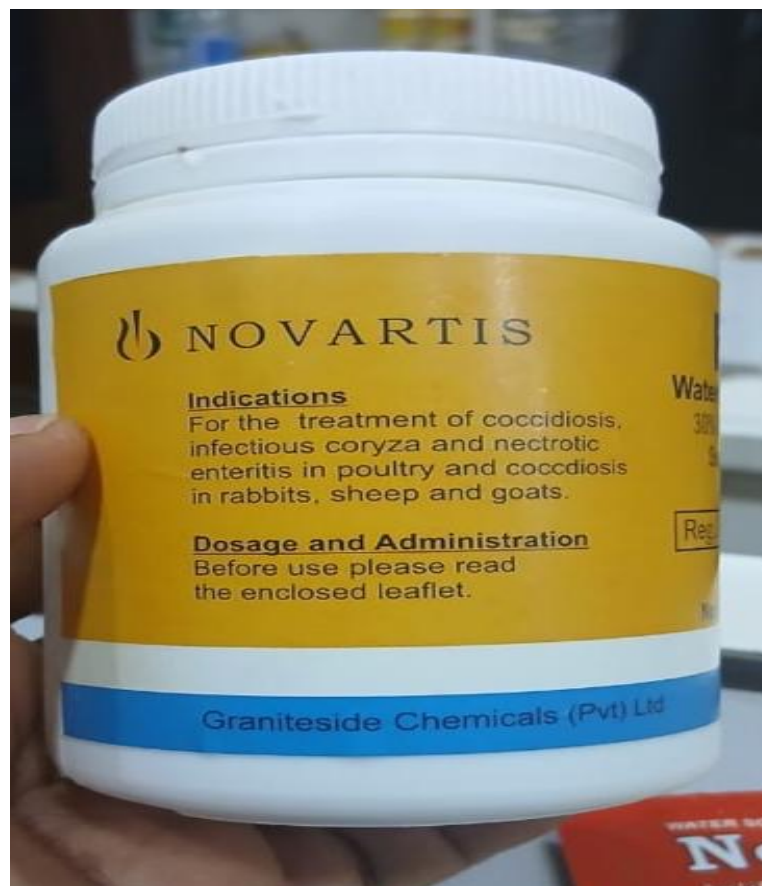


Photo 18: Esb3 water soluble powder



Photo 19: Un-registered Hi-Tet 120

All unregistered medicines were confiscated and will be disposed of at the owner's cost. Fines were imposed for those found with unregistered products.

Other products that were identified and confiscated as unregistered products were medical devices and invitro diagnostics, as detailed in Table 4 and Photo 20 below.

Table 4: Unregistered medical devices confiscated at SHZ

S/N	Name of medical product	Batch No.	Manufacturer Name	Quantity
1	One step Malaria (pf) Test (Advanced Quality in Medical Diagnostics)	GJ25121560	In Tec PRODUCTS. INC P.R. China	18 Strips
2	SUREVA Natural rubber latex powdered medical examination gloves	Not indicated	QUBE medical products SDN, Malaysia	100 -pieces

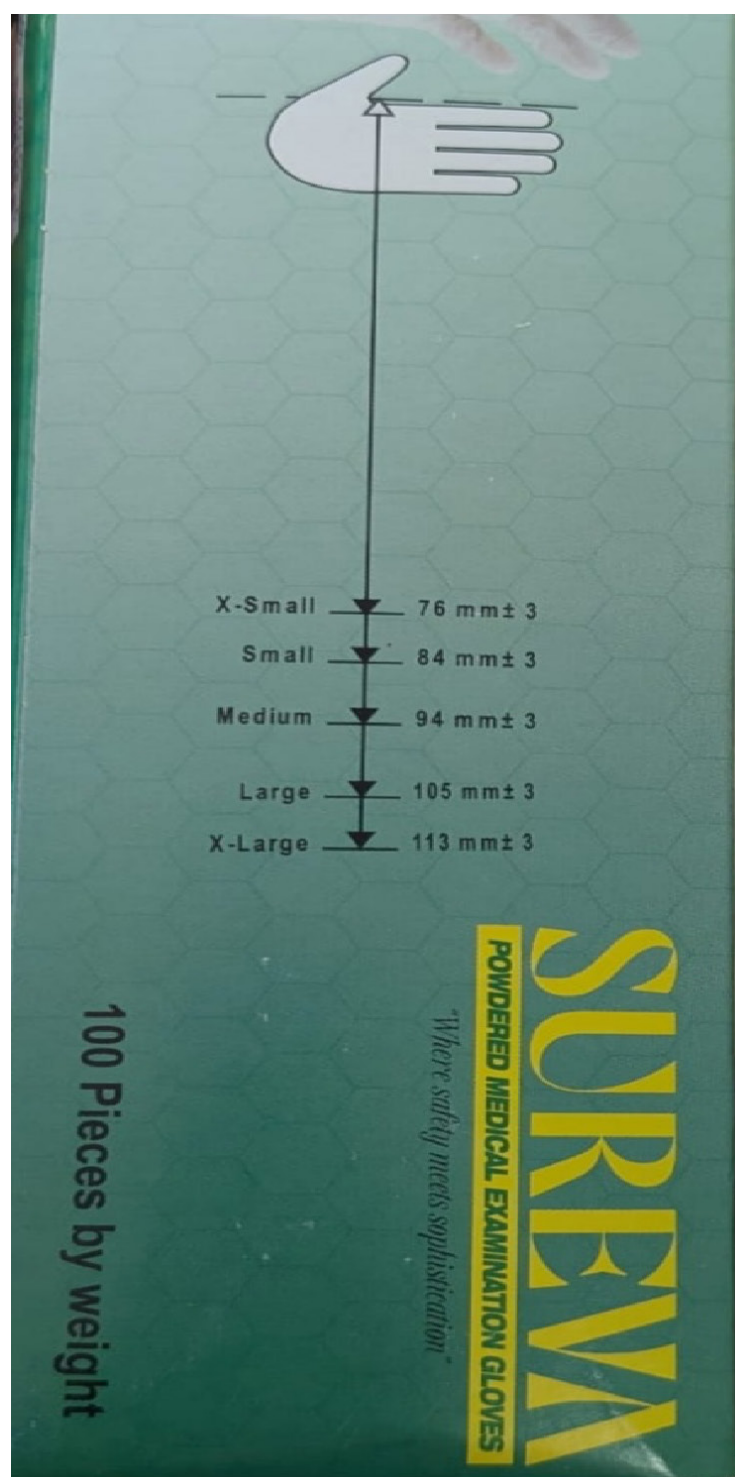


Photo 20: unregistered One step Malaria (PF) Test



Photo 21: Unregistered Natural rubber latex powdered medical examination gloves

The Authority continues to warn the public against purchasing or consuming any medicinal product that does not appear in the official register. If you encounter any suspicious or unregistered products, they should be reported immediately to the nearest TMDA office or via the toll-free number 0800110084.



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