

Weekly Surveillance Report

Issue No. 08

1st - 7th, June, 2026

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

WSR

Substandard and falsified medical products can have severe health consequences, including treatment failure, disease progression and prolonged illness, toxicity and harmful adverse effects, increased antimicrobial resistance, loss of public trust in healthcare systems and increased healthcare expenditure and economic losses.

TMDA emphasizes that ensuring the availability of safe, quality and effective medical products is essential for protecting public health in Tanzania.

In lieu to the above emphasis, TMDA implements various strategies to prevent, detect and respond to substandard and falsified medical products through:

- Strengthening regulatory frameworks and enforcement systems;
- Conducting inspections of manufacturers, importers, distributors and healthcare facilities;
- Carrying out post-marketing surveillance and laboratory testing of medical products;
- Monitoring medicine supply chains and distribution systems;
- Issuing safety alerts, recalls and regulatory actions where necessary;
- Collaborating with local and international stakeholders and regulatory authorities;

- Enhancing public awareness on the dangers of purchasing medicines from unauthorized sources; and
- Promoting the use of technological solutions and traceability systems to improve monitoring and detection.

Inspectors from the **Tanzania Medicines and Medical Devices Authority (TMDA)**, Central Zone Office, during routine Post Marketing Inspection successfully intercepted unregistered medicine with the name **BETASTAL-DB Injection** (Betamethasone as Sodium Phosphate & Betamethasone as Dipropionate Injection), 20 ampoules, manufactured by American Remedies Healthcare Pvt Ltd, USA on 08/2024 and expiring on 07/2027. The details are as seen in the picture No.1 below:

AMERICAN REMEDIES
Care & Cure with Research

Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection

BETASTAL-BD Injection

Each ampoule contains:

Betamethasone (As Sodium Phosphate) USP	4mg	Batch No.:	A24CW006
Betamethasone (As Dipropionate) USP	10 mg	Mfg. Date:	08/2024
Water for Injection USP	q.s.	Expiry Date:	07/2027

Dosage: As directed by the Physician.

Storage: Store in a cool, dry & dark place, at a temperature not exceeding 25°C. Protected from light. Do not Freeze.

Keep the medicine out of reach of children.

Do not use Injection if any foreign particle/suspended matter visible in the solution.

Marketed by:
AMERICAN REMEDIES
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001:2015 Certified Company)
ICO: American Remedies LLC, DE, USA
B-410, Western Edge II Premises CHS Ltd.
Behind Metro Mall, Western Express Highway,
Borivali (East), Mumbai - 400066.
E-mail: info@americanremedies.in

Scan for Batch Certificate

Furthermore, in the same inspection conducted in Morogoro Municipality and Kilolo District Council in Morogoro and Iringa regions respectively, several unregistered medicines which were donated to health facilities belonging to Faith Based Organizations (FBO) were seized. These medicines were donated to these health facilities contrary to health commodities donation guidelines issued by TMDA and Ministry of Health.

Table 1: Medicines Seized in Central Zone donated to Health Facilities without being approved by TMDA.

S/N	Medicine’s Name (Generic & Trade Name)	Batch Details	Manufacturer’s Name	Quantity
1	Soldesam 0.2% gocce orali (desa-metasone 10ml)	BN: 250043 MFG: N/A EXP: 01/2028	Titolare A.I.C Laboratorio Far-macologico Milanese, Italy	5 bottles
2	LANSOX 30mg capsule rigide (lan-soprazole)	BN: 519907 MFG: N/A EXP: 06/2026	Titolare A.I.C Takeda Pharma-ceutical Company Pharmaceuti-cal Company Ltd, Italy	84 tab-lets
3	Inhixa 4000 UI 40mg 0.4ml (enoxa-parina sodica)	BN: AB1275IA MFG:N/A EXP: 09/2027	Techdow Pharma, Netherlands	10 sy-ringes
4	Bacitracin zinc Ointment (Bacitracin Zinc)	BN: 800723 MFG: N/A EXP: 07/2026	China	208
5	Spironolactone 50mg	BN: N/A MFG: 06/2024 EXP: 06/2025	Oxford	270
6	Methocarbamol 750mg	BN: N/A MFG: 09/2024 EXP: 09/2025	Glanules	90
7	Azithromycin 500mg	BN: N/A MFG: 09/2024 EXP: 09/2025	Aurobindo	2
8	Pregabalin 150mg	BN: N/A MFG: 09/2024 EXP: 03/2025	Novadoz	60
9	Ibuprofen 200mg	BN: 151373 MFG: NIL EXP: 06/2027	Tm&©2024 Target Brands Inc, India	1000
10	Aspirin (NSAID)	BN: NAAEAXO MFG:NIL EXP:06/2026	Bayer Healthcare LLC Whippa-ny, NJ07981, USA	400

Pictures of medicines which were donated to health facilities without following donation guidelines.



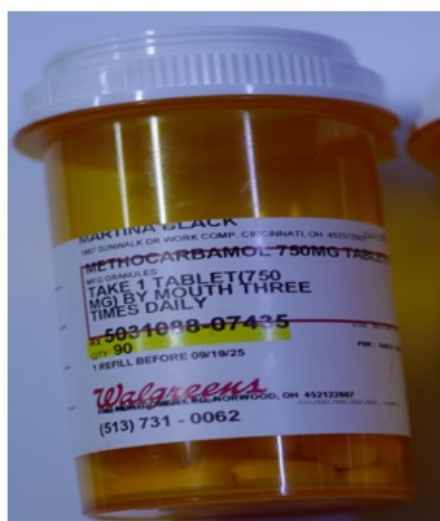
Picture No. 1: Donated Azithromycin 500 mg tablets



Picture No.2: Donated Spironolactone 50mg tablets



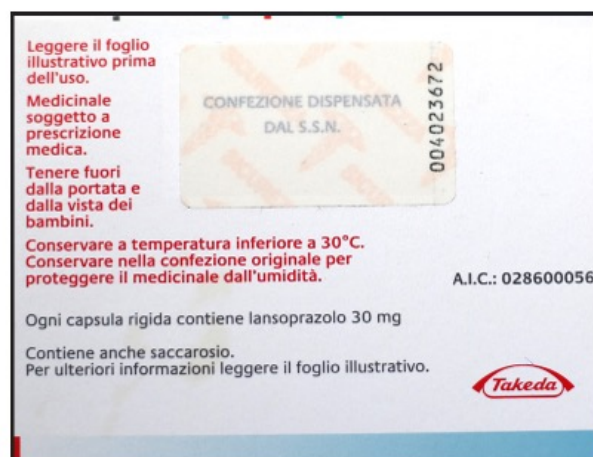
Picture No.3: Donated Pregabalin 50mg capsules



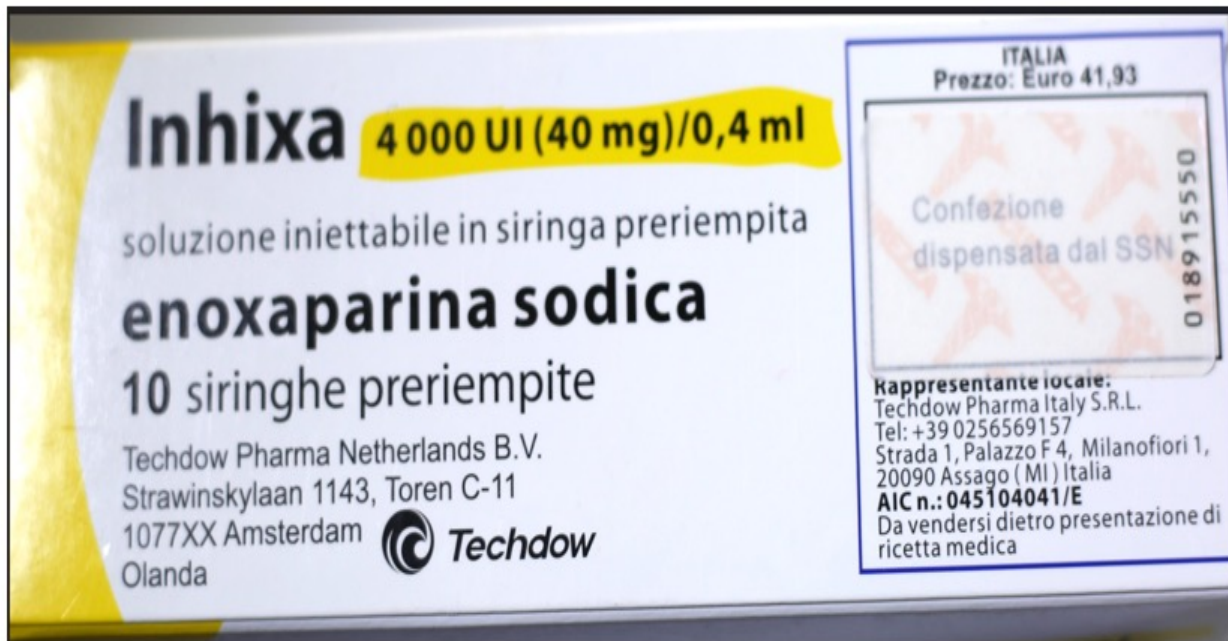
Picture No. 4: Donated Methocarbamol 750mg tablets



Picture No.5:
Donated Solde-
sam 0.2% (10ml)
solution



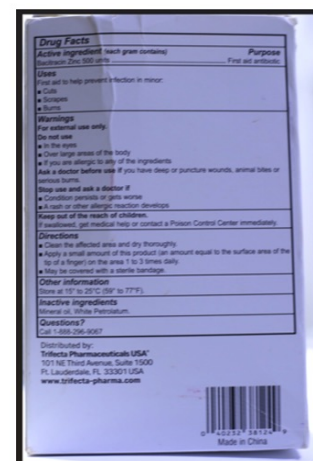
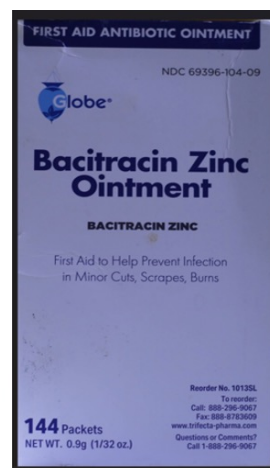
Picture No. 6: Unregistered Lansox 30mg capsules



Picture No.8: Donated Enoxaparin Inhixa 4000UI (40mg)/0,4ml injection



Picture No.9: Donated Ibuprofen 200mg tablets



Picture No.11: Donated Bacitracin Zinc Ointment



Picture No.10: Donated Aspirin 81mg tablets

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

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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Southern Zone

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