DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-71

VETERINARY DRUG PRODUCTS DECLARED SUBSTANDARD
BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 17th September, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals-Veterinarians
- Farmers/consumers

Alert Summary:

Drug Testing Laboratories from Provinces informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned **Veterinary products** have been declared as '***Substandard***'.

S#	Product Details	Batch #	Manufacturer details	Remarks
1	**INJECTION VARIAX 100ML** EACH ML CONTAINS: VITAMIN A 15.000 I , VITAMIN D3 1,000 IU, VITAMIN E 20MG, VITAMIN B1 10MG, VITAMIN B SODIUM PHOSPHATE 5MG, VITAMIN B6 3MG. NICOTINAMIDE 35MG, PANTOTHENOL 25MG, VITAMIN B12 50MCG	EI-1654	**M/s. Eterna Pharma (Pvt) Ltd.** Plot No. 99, 100, 101 &198-C, Sector D1, Old Industrial Estate, Mirpur, AJK Pakistan. (DML # 000923)	**'Adulterated'** with respect to Assay test performed for Vìtamin B1 and is "Adulterated" as defined under clause (iv) of sub-section (a) of section 3 of The Drugs Act, 1976 as it contains Ascorbic Acid, Ambrosic Acid and Peiminine as ingredients other than the labelled ingredients.
2	**Ivermex Injection 100 mL** Each ml contains Ivermectin …. 10 mg	IV348	**M/s Wimits Pharmaceuticals (Pvt) Ltd.** Plot No. 129 Sundar Industrial Estate Lahore. (DML # 000789)	**'Substandard'** quality on the basis of the result of test for related substance, sterility & assay of Ivermectin.

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3	**PRIMOX injectable suspension 50mL** Each ml contains amoxicillin (as trihydrate) …. 150 mg	PP9789	**M/s Prix Pharmaceutical (Pvt) Ltd.** Plot No. 5 Pharmacity 30-Km Multan Road Lahore. (DML # 000587)	**'Substandard'** quality on the basis of the result of sterility test.
4	**Injection Lumpyvac 50** After reconstitution, each 2ml dose contains: Attenuated Lumpy Skin Disease Virus (Neethling strain) ……. $\geq 10^{3.5}$ $TCID_{50}$ **Diluent for Lumpy Skin Disease Vaccine for Cattle (For Veterinary Use)** Potassium Chloride 0.2mg Potassium Phosphate monobasic 0.2 mg Sodium Chloride 0.8mg, Sodium Phosphate dibasic 1.14mg per 2 mL **(Reg # 111128)**	25/LSD/01	**Importer:** M/s Huzaifa International. Commercial Area, Aziz Bhatti Town, Dist. Sargodha. **Manufacturer:** **Vetal animal Health Product S.A** Organize Sanayi Bolgesi, Petrol Mah. 14. Cad. No. 01, Adiyamam, Turkey	**'Substandard'** on the basis of the result of sterility test.
5	**Injection Oxytocin 50ml** Oxytocin 10 IU/Ml Reg# 014564	V-06725	M/s Venus Pharma. 23-Km Multan Road. Lahore. (DML # 000300)	**'Substandard'** on the basis of the result of sterility test.

6	**Injection Oxytovetz 50ml** Oxytocin (USP) … 10 IU/mL Reg. # 111468	25129639	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot No. Q-1 SITE Kotri Sindh (DML # 000813)	**'Substandard'** on the basis of the result of sterility test.

Risk Statement:

Use of the above-mentioned veterinary drug products poses **serious risks** to animal health and public safety:

- **Treatment failure** and **loss of therapeutic efficacy** in livestock.
- **Microbial contamination** leading to sepsis and animal deaths.
- **Ineffective vaccination** against Lumpy Skin Disease, increasing risk of outbreaks.
- **Adverse economic impact** on farmers due to animal health losses.
- **Food safety risks** through compromised milk and meat supply chains.

Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Advice for Veterinarian: -

This alert applies strictly to the specific batches listed above and does not apply to other batches of the **same** products. Veterinarians are therefore advised not to prescribe, administer, or stock these identified batches under any circumstances. In case any of the above-mentioned batches have already been administered, treated animals should be closely monitored for possible signs of infection, treatment failure, or adverse reactions, and appropriate supportive care must be provided. Any suspected adverse events or quality-related problems linked to these batches should be reported immediately to **DRAP's Pharmacovigilance Centre** and to the Provincial Livestock & Dairy Development Departments**.** Practitioners are further advised to ensure that only alternative registered and quality-assured batches are used in veterinary practice.

Advice for Farmers and Livestock Owners:

Farmers, dairy owners, and animal keepers are strictly advised not to use these identified batches for their cattle or other livestock, as they may cause serious illness, infection, treatment failure, or even death in animals. If any of these batches have already been given, animals should be observed carefully for unusual symptoms such as fever, weakness, swelling at the injection site, or lack of recovery, and immediate veterinary assistance should be sought. Farmers are further advised to return such products to their supplier and use only safe, registered, and quality-assured veterinary medicines and vaccines to protect the health of their animals and avoid financial losses.

Drug Regulatory Authority of Pakistan

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