RAPID ALERT

DRAP ALERT No: Nº I/S/09-24-37

SUSPECTED FALSIFIED RABIES VACCINE (SURE RAB)

Date: 27th September, 2024

Target Audience:

- Regulatory Field Force of DRAP and Drug Control Administration of all federating units.
- Healthcare Professionals (Physicians, Pharmacists and Nurses, etc)
- Pharmacies, Medical stores and Healthcare Institutions

Problem Statement:

DRAP has received information about the presence of a suspected rabies vaccine in the supply chain. The product is not registered by DRAP and may be a falsified product.

The details of the suspected product are as under:

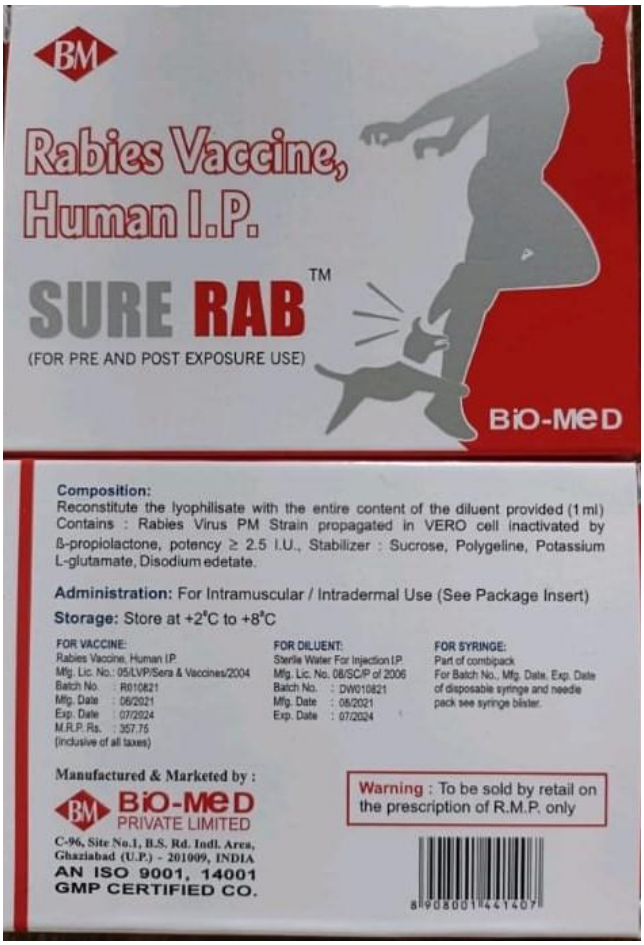
Product Name	Batch/Lot No.	Stated Manufacturer	Mfg. date	Exp. date
Rabies Vaccine, Human IP (**SURE RAB**) **(unregistered)**	RO10821	M/s Bio-Med Private Limited, C-96, SITE No. 1, B.S. Rd. Indi, AREA, Ghaziabad (U.P.) – 201009, INDIA.	10-2023	10-2026

Risk Statement:

Rabies vaccine is used for the prevention of rabies in children and adults resulting from dog bite. Falsified rabies vaccines pose a significant threat to public health as the safety and efficacy of such products cannot be established therefore failing to provide adequate immunity, leaving individuals vulnerable to rabies infection.

DRAP, Islamabad **+ 92 051 9255969** **gsms@dra.gov.pk**

Identification and details of Suspected falsified product:



Rabies Vaccine, Human IP - Lot No. RO10821

Rabies Vaccine, Human IP - Lot No. RO10821

DRAP, Islamabad

+ 92 051 9255969

gsms@dra.gov.pk

Action Initiated: -

The Regulatory Field Force has been directed to increase market surveillance to detect and confiscate the unregistered suspected falsified product and to investigate the entire supply line. Pharmacist and Chemists working at distributions, pharmacies, medical stores and other supply chain points are directed to immediately check their stock and stop supplying the suspected product if found. The information of its supplier should immediately be provided to the Regulatory Field Force (DRAP and Provincial Inspectors) to ensure removal of suspected product from market.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of above mentioned product.

Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Consumers / General Public: -

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad
+ 92 051 9255969
gsms@dra.gov.pk