



Government of Maharashtra

Commissioner
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Ref No. Drug Alert / 716 -2026/10

Date 28/09/2026

PUBLIC ALERT

Subject : Drugs and Cosmetics Act 1940 & Rules thereunder.

Public Alert regarding suspected falsified "Rabies Vaccine, Human I.P. (Freeze- Dried)" bearing the name and particulars of Serum Institute of India Pvt. Ltd., Pune

Reference: Letter received from M/s Serum Institute of India Pvt. Ltd., Pune, dated 24.09.2026.

As per the communication received from M/s Serum Institute of India Pvt. Ltd., Pune. Food and Drug Administration, Maharashtra, hereby alerts all concerned stakeholders, including hospitals, healthcare institutions, medical practitioners, pharmacists, distributors, wholesalers and members of the public, regarding a suspected falsified Rabies Vaccine bearing the name and particulars of M/s Serum Institute of India Pvt. Ltd. (SIPL), Pune.

The matter came to the notice of the authorities pursuant to information received from The 4033 Field Hospital, Sukna, Darjeeling, West Bengal, concerning receipt of a vial of Rabies Vaccine reportedly without the accompanying diluent.

Upon verification of the particulars appearing on the vial/label with the manufacturing records of SIPL, the following discrepancies have been reported:

Particular details:

Product Name-Rabies Vaccine, Human I.P. (Freeze-Dried)

Batch No. appearing on vial-1630T092

Manufacturing Date appearing on vial-February 2026

Expiry Date appearing on vial-January 2029

Manufacturer stated on label-Serum Institute of India Pvt. Ltd., Pune

Complainant-The 4033 Field Hospital, Sukna, Darjeeling, West Bengal

Nature of complaint-Vaccine vial reportedly received without accompanying diluent

Verification by manufacturer-Batch No. 1630T092 does not correspond to any batch of Rabies Vaccine manufactured or released by SIIPL

As per the information furnished by SIIPL, the batch number 1630T092 could not be traced in its manufacturing records and the product bearing the said batch number has not been manufactured or released by SIIPL.

It has further been informed by SIIPL that its Rabies Vaccine is supplied in the specified configuration along with the corresponding diluent. Receipt of a vaccine vial without the accompanying diluent is therefore also inconsistent with the manufacturer's standard product supply configuration.

PUBLIC HEALTH ADVISORY:

In view of the above, all concerned are advised as follows:

1. DO NOT USE any Rabies Vaccine vial bearing Batch No. 1630T092, irrespective of the source from which it has been obtained.
2. Hospitals, healthcare institutions, vaccination centres, medical practitioners, pharmacists, distributors, wholesalers and other establishments should immediately segregate and quarantine any stock bearing the above batch number and prevent its sale, distribution or administration.
3. Healthcare institutions and vaccine suppliers are advised to verify the batch number, manufacturer details, packaging and accompanying diluent before use or administration of Rabies Vaccine.
4. Any person or institution having stock of the suspected product should not destroy, discard or return the product through an unauthorised channel. The product should be securely segregated and retained for inspection/investigation by the Drug Regulatory Authorities.
5. Any suspected availability, sale, distribution or use of the above product should be immediately reported to the nearest office of the Food and Drug Administration, Maharashtra, along with details of the supplier/distributor, quantity available.
6. Members of the public who may have obtained or received a vaccine bearing the above particulars are advised to contact the treating healthcare professional and the appropriate Drug Regulatory Authority immediately and provide details of the source of procurement.

This alert concerns a product suspected to be falsified on the basis of the discrepancy in the batch number and the information presently available from the manufacturer. Further regulatory examination/investigation is in progress.

The Food and Drug Administration, Maharashtra, is taking the matter seriously in the interest of public health and patient safety and will initiate/continue appropriate regulatory and enforcement action as warranted under the applicable provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

Members of the public, healthcare professionals, and trade stakeholders are encouraged to report any sale or distribution of above drugs to the Food and Drug Administration for appropriate action on email jchq.fda-mah@nic.in.

Issued in Public Interest.

Digitally signed by
GANESH RAMCHANDRA ROKADE
Date: 27-09-2026 20:32:20

(Ganesh .R. Rokade)
Joint Commissioner (HQ) &
State Drugs Controller,
Food and Drugs Administration,
Maharashtra State

Copy is forwarded for information & necessary action to :-

1. The Drugs Controller General of India, CDSCO, FDA, Bhawan, Kotla Road, New Delhi.
2. The Commissioner and Project Director, NRHM, Public Health Department, Government of Maharashtra.
3. All Joint Commissioners (Drugs)/, Assistant Commissioners (Drugs), Drugs Inspector, FDA Maharashtra to keep vigil in their jurisdiction to check the occurrence of the said impugned batch of the drug and initiate appropriate action.
4. Director, Public Health Department, Government of Maharashtra.
5. Health Department, Brihanmumbai Municipal Corporation.
6. Employee State Insurance Corporation Hospital, Mumbai.
7. President, Maharashtra State Chemists & Druggists Association, Mumbai for circulation to all their members.