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INDIAN IMMUNOLOGICALS LIMITED

STATEMENT ON ABHAYRAB®

Human Biologicals Institute (A division of Indian Immunologicals Limited). Date: 04.09.2026

We have received queries from healthcare professionals regarding Abhayrab® (Rabies Vaccine, Human I.P.), Batch Number KE25012. This statement sets out our position.

What has happened

During an enforcement action, the Central Drugs Standard Control Organisation drew vaccine samples (vials) from an unlicensed residential premises located at Mukherjee Nagar, Delhi. The vials carried the label of Abhayrab®, Batch No. KE25012. The samples were subsequently forwarded to the Central Drugs Laboratory, Kasauli, for testing. Upon analysis, the samples were reported as Not of Standard Quality (NSQ) and misbranded.

The same laboratory report records (17) seventeen differences between that vial and the retention samples of the same batch held at the Laboratory, which we had submitted for batch release.

On that basis, the vials examined are not a product manufactured by Human Biologicals Institute.

The genuine batch

The particular Batch was tested and released by the Central Drugs Laboratory vide Batch Release Certificate CDL/2025/8392 dated 07.11.2025. The released quantity of 83,370 vials was supplied only through our authorised distribution channel. No market complaint has been received in respect of the batch Number KE25012.

What this means for a patient who has been vaccinated

Every batch of Abhayrab® is released for sale only after independent testing and batch release certification by the Central Drugs Laboratory. Vaccine administered at a hospital, clinic, government facility or licensed pharmacy reaches the patient through that released and authorised supply chain and is not affected by this matter.

What we have done

We submitted our batch manufacturing, quality control, reconciliation and distribution records to the Central Drugs Standard Control Organisation on 14.08.2026. Through our specific representation dated 04.09.2026 to DCGI, we have asked the authorities to trace the source of these vials and to act against those responsible, and we are extending our full cooperation to the investigation.

Authorized Signatory

Sunil Tiwari
VP & Head of Quality Management
For Indian Immunologicals Limited

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