GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
STARRED QUESTION NO. 186
TO BE ANSWERED ON 1ST AUGUST, 2025.

TESTING OF ANTI-RABIES VACCINES

***186. ADV. DEAN KURIAKOSE:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the details of mandatory requirements prescribed for ensuring the quality of Anti-Rabies vaccines procured by the State procurement corporations for distribution through public hospitals;

(b) whether it is mandated that the manufacturers supplying anti-rabies vaccine are required to have quality testing reports from Central Drug Lab for distribution through public hospitals and if so, the details thereof;

(c) the details of the patient safety issues of administering the anti-rabies vaccines that has not undergone mandatory quality tests;

(d) whether the manufacturers supplying anti-rabies vaccine to Kerala Medical Services Corporation has done the mandatory tests from Central Drug Lab during the last five years and the current year; and

(e) if so, the details thereof, year-wise?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (e): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.186 FOR 1ST AUGUST, 2025

******

(a) & (b): For manufacturing/import of new drugs including vaccines, the manufacturers/importers are required to comply with the standards of quality, safety and efficacy as prescribed in Drugs and Cosmetics Act, 1940 and Rules thereunder.

The following mandatory quality requirements are prescribed to ensure the quality of anti-rabies vaccines being manufactured in the country:

(i) Manufacturing Licence/import license issued under the Drugs and Cosmetics Act, 1940 and Rules thereunder.

(ii) Compliance with Indian Pharmacopoeia (IP) - The anti-rabies vaccine must comply with the standards specified in the current edition of the Indian Pharmacopoeia.

(iii) In-House Quality Control Testing - Each batch must undergo complete in-house quality control testing at the manufacturer's facility as per validated procedures and IP standards.

(iv) Batch Release from Central Drugs Laboratory (CDL) - Each batch/lot of vaccines manufactured/imported in the country is required to be released by Central Drugs Laboratory (CDL), Kasauli, Himachal Pradesh, before release of vaccines for sale and distribution.

(v) Cold Chain Maintenance- Proper cold chain logistics 2°C to 8°C must be maintained throughout storage and transportation to preserve vaccine potency.

(vi) Shelf Life and Packaging- Vaccines must have a valid remaining shelf life at the time of supply and should be packaged to ensure protection during transit and storage.

(c): As per Rule 2(w) of New drugs and Clinical Trial Rules, 2019, vaccines are always be deemed to be new drugs. All manufacturers of vaccines have to comply with the conditions of mandatory quality tests apart from other conditions of license as prescribed under Rules 78 & 78A of Drug Rules, 1945 and both the Central License Approving Authority (CLAA) and State Licensing Authorities are empowered to take stringent action against violation of provisions of the Act and Rules.

(d) & (e): As informed by Kerala Medical Services Corporation (KMSCL), all Rabies Vaccines and Equine Anti-Rabies Immunoglobulins procured and distributed by them from the tender year 2016-17 onwards have obtained Batch Release Certificates from Central Drugs Laboratory (CDL), Kasauli, as mandated in the tender terms and conditions. KMSCL has not procured or distributed any batch of Rabies vaccine or Equine Anti-rabies Immunoglobulin without a batch release certificate from CDL.

****