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

RAJYA SABHA
UNSTARRED QUESTION NO. 3010 #
TO BE ANSWERED ON 19TH AUGUST, 2025

QUALITY MONITORING OF VETERINARY MEDICINES AND ANIMAL FEED STANDARDS

3010 # SHRI GOVINDBHAI LALJIBHAI DHOLAKIA:

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

(a) the actions the Ministry has taken in collaboration with the State Governments for regular monitoring of the quality of veterinary medicines as per the current international standards; and

(b) the measures implemented in collaboration with the State Governments for continuous assessment of the quality of animal feed as per the standards of Food Safety and Standards Authority of India (FSSAI)?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a): All drugs including veterinary drugs are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules made there under.

As part of quality monitoring, the samples failing in quality check, as received by Central Drugs Standard Control Organisation (CDSCO) are uploaded on the website of CDSCO as part of the monthly drug alerts to make it available publicly. Details of these drugs are available on the CDSCO website under the heading of Drug Alert (www.cdsco.gov.in).

In case of drug samples declared as NSQ by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the not of standard quality drugs in the market. Further, based on investigation outcome, actions are taken by the licensing authorities concerned under the provisions of Drugs & Cosmetics Act & Rules made thereunder such as stop production orders, stop testing orders, license suspensions/cancellations, warning letters and showcause notices.

Further, Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health and Family Welfare have taken following regulatory measures to ensure the production of quality drugs including veterinary drugs across the country:

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO, in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. As of now, 905 units have been inspected, resulting in 694 actions being taken. These actions include Stop Production Orders (SPO), Stop Testing Orders (STO), license suspensions/cancellations, warning letters, and showcause notices, depending on the severity of non-compliance. This initiative has provided valuable insights into the ground reality of manufacturing practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

(ii) On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

(iii) Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover > Rs. 250 crores from 29.06.2024. However, for manufacturers having turnover of less than Rs. 250 Cr, conditional extension up to 31.12.2025 is currently operational for those who submitted their upgradation plan for the extended compliance period.

(iv) In February, 2024 CDSCO published regulatory guidelines for the sampling of drugs, cosmetics, and medical devices by drugs inspectors of Central and State Drug Authorities in the Country. The guidelines provides a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology for drugs inspectors under state and central drug regulatory authorities in India. It covers various aspects of sampling, including sampling plans, selection, locations, number and quantity of samples, timelines, and role of testing laboratories. It stresses the importance of a structured sampling plan, risk-based sample selection, and covering diverse locations, including rural areas.

(v) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non bailable.

(vi) States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(vii) The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

(viii) To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

(ix) The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

(x) The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.

(xi) Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

(b): As informed by Bureau of Indian standards, it has published a number of Indian standards on animal feed including cattle feed, poultry feed, Pig feed along with specifications for feed ingredients, feed supplements, and the related test method standards for the manufacturers to comply.

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