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

RAJYA SABHA
UNSTARRED QUESTION NO. 1733
TO BE ANSWERED ON 10TH DECEMBER, 2024

ENSURING QUALITY OF DRUGS EXPORTED ABROAD

1733: SHRI GOLLA BABURAO:

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

(a) whether Government is aware about the recent reports by the US Food and Drug Administration (FDA) uncovering wide-ranging lapses at factories run by some of India's biggest pharmaceutical firms including unsanitary conditions in manufacturing plants, poorly trained staff, under-investigated customer complaints and evidence of exporting contaminated drugs to the US;

(b) if so, the steps Government has taken to ensure good quality of drugs exported abroad;

(c) the details of the new 'Good Manufacturing Practices' under the Drugs and Cosmetics Rules to check the deficiencies found during the inspections; and

(d) the mechanisms to ensure timely adoption of these upgraded standards by all manufacturers?

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

(a) & (b): Isolated reports of the drugs not meeting the prescribed standards have appeared in the media and on the websites of the regulatory authorities of foreign countries, etc. from time to time. Central Drugs Standard Control Organization (CDSCO) has not received any such report.

For export of drugs, the manufacturers are required to obtain license for manufacturing of such drugs from the State licensing Authority (SLA) concerned under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. Further, the manufacturer is also required to comply with the requirements of the importing country.

(c) & (d): The 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>250 crores from 29.06.2024.

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