GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 986
TO BE ANSWERED ON THE 09th DECEMBER, 2025

Quality of Indian medicines exported abroad

986 Shri Meda Raghunadha Reddy:

Will the Minister of **Chemicals and Fertilizers** 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 the country'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 taken by Government 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 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 CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (d): In this regard, the Department of Health and Family Welfare has informed as under:

(i) Isolated report of the drugs not meeting prescribed standards have appeared in sections of the media and websites of certain foreign regulatory authorities.
(ii) Manufacturers are required to obtain license for manufacturing of drugs for export as per the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder, as well as to comply with the requirements of the importing country and address deficiencies observed during the inspections, if any.
(iii) Government has amended the Drugs Rules, 1945 on 28.12.2023, revising its Schedule M related to good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products manufactured for consumption in India.

With a view to increase the uptake and to help pharmaceutical industry to align its production process with the revised Schedule M standards, the Revamped Pharmaceuticals Technology Upgradation Scheme has been launched. Under the scheme, applicants are provided support up to a maximum of ₹2 crore for such upgrade. A total of 192 applications has been approved so far, with total sanctioned amount of ₹181.59 crore.

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