

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

**LOK SABHA
UNSTARRED QUESTION NO. 2238
TO BE ANSWERED ON 15TH DECEMBER, 2023**

DRUG TESTING LABORATORIES UNDER CDSCO

2238: SHRI POCHA BRAHMANANDA REDDY:

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

- (a) whether it is a fact that the reason behind Indian manufactured drugs failing quality parameters is due to persisting issues in the industry which include a lack of laboratories to test samples by comparing to the thousands of generic manufacturing plants, as per various reports in the country and if so, the details thereof;
- (b) the steps taken/proposed to be taken by the Government to increase drug testing laboratories in the country;
- (c) the details of the number of United States Food and Drug Administration (US FDA) approved drug testing laboratory in the country set up under Central Drugs Standard Control Organisation (CDSCO);
- (d) whether the Government proposes to set up a Central Drug Testing Laboratory under CDSCO in Andhra Pradesh; and
- (e) if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

- (a): Failure to meet quality parameters of drugs manufactured by the manufacturers can be due to various reasons like failure to adhere strictly the requirements as per conditions of manufacturing license including Good Manufacturing Practices, Good Laboratory Practices etc.
- (b): For strengthening the drug regulatory system in the country both at the Central and State level, the Government had approved Rs.1750 Crore. Out of this, Rs. 900 Crore was for strengthening the central drug regulatory structures and Rs. 850 Crore is for the Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS) which envisages to strengthen the laboratory infrastructure an up-gradation of existing State Drug Controller offices in States. So far under the SSDRS scheme, funds to the tune to Rs. 695.66 Crore have been released as part of the Central Share.
- (c): There is no such procedure for approval of laboratory under Central Drugs Standard Control Organization (CDSCO) by United States Food and Drug Administration (US FDA).
- (d) and (e): Funds to 3 State Government laboratories in the State of Andhra Pradesh have been released under the scheme.
