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

RAJYA SABHA
UNSTARRED QUESTION NO.751
TO BE ANSWERED ON 13th DECEMBER, 2022

MANUFACTURING OF BANNED DRUGS

751: SHRI HARBHAJAN SINGH:

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

(a) whether certain cases of manufacturing and marketing of banned or unapproved drugs have been reported in the country;
(b) if so, the details thereof indicating the number of such cases reported during each of the last three years and the current year, State/UT-wise;
(c) the action taken against the offenders during the said period, State/UT-wise;
(d) whether Government proposes to put in place a comprehensive mechanism to stop the manufacturing and marketing of banned or unapproved drugs across the country; 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) to (c): A few cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

36 cases of unapproved FDCs licensed by State Licensing Authorities (SLAs) considered as New Drugs, have been reported during the year 2020 to 2022 (till date). In all such cases, the office of DCGI took up the matter with respective SLAs for necessary action. Further, the State Drugs Controllers have also been requested in the Drug Consultative Committee meetings to ensure that new drugs and FDCs are not permitted without approval from the office of DCGI. The State/UT-wise details of these 36 cases is as below:

Uttarakhand (10), Maharashtra (02), Daman & Diu (01), Himachal Pradesh (09), Karnataka (02), Gujarat (04), Sikkim (05), Uttar Pradesh (02), Telangana (01)

(d) & (e): Manufacture, sale and distribution of prohibited/banned drugs is a punishable offence under section 18 of the Drugs and Cosmetics Act. State Licensing Authorities are empowered to take action in this regard.

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