

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

**LOK SABHA
UNSTARRED QUESTION NO.735
TO BE ANSWERED ON 23RD JULY, 2021**

BANNED/UNAPPROVED DRUGS

735. SHRIMATI SARMISTHA SETHI:

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

- (a) whether certain cases of manufacturing and marketing of banned/ 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 the Government proposes to put in place a comprehensive mechanism to stop manufacturing and marketing of banned/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) falling under the purview of Rule 122E of the Drugs & Cosmetics Rules, 1945 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.

44 cases of unapproved FDCs licensed by State Licensing Authorities (SLAs) considered as new Drugs, have been reported during the year 2018 to 2021 (till date). In all such cases, the office of DCGI took up the matter with respective SLAs for necessary action. The State/UT-wise and year wise details of these 44 cases is **annexed**. Further, the state Drugs Controllers have also been requested from time to time in the Drug Consultative Committee meetings to ensure that new drugs and FDC are not permitted without approval from the office of DCGI.

(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.

ANNEXURE

Name of the State	No. of FDCs for which licenses were granted by SLAs without new drug permission from DCG(I)
Uttarakhand	10
Maharashtra	07
Daman & Diu	3
Himachal Pradesh	4
Tamilnadu	1
West Bengal	1
Karnataka	2
Gujarat	3
Sikkim	6
Jammu	1
Uttar Pradesh	3
Bihar	1
Telangana	2
Total	44

Year wise details

Year	Number of cases
2018	08
2019	17
2020	14
2021	5
Total	44