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

LOK SABHA
UNSTARRED QUESTION NO. †5608
TO BE ANSWERED ON 04TH APRIL, 2025

AVAILABILITY OF BANNED DRUGS IN MARKET

†5608 MRS RUCHI VIRA:

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

(a) the number of medicines banned by the Government during the last five years, year and lists/category-wise;

(b) the reasons for such banned medicines still being sold and bought in the market, along with the steps taken/proposed to be taken by the Government in this regard;

(c) whether the Government is aware that banned medicines are still being prescribed/advised to be used by the doctors in Government and private hospitals and if so, the details thereof;

(d) the action taken/proposed to be taken by the Government against such doctors;

(e) whether new medicines under different names have been manufactured by the drug manufacturing companies by making minor changes in the composition of the medicines and selling them in the market and if so, the details thereof;

(f) the action taken by the Government against the drug licence issuing agencies and the drugs manufacturing companies; and

(g) the number of such cases reported by the Government during the last five years, year-wise ?

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

(a) & (b): The numbers of medicines banned by Central Government under the provisions of Drugs & Cosmetics Act, 1940 during last five years is as under:

Year	No. of Drugs Banned
2020	02
2021	Nil
2022	Nil
2023	16
2024	158
Jan 2025 to 28.03.2025	02

Under the Drugs & Cosmetics Act, 1940, manufacture, sale and distribution of any prohibited/banned drug is a punishable offence and State Licensing Authorities concerned are empowered to take action in this regard

As and when any such complaints/issues are received in Central Drugs Standard Control Organization (CDSCO) on selling of banned drugs, the matter is taken up with State Drugs Controller for necessary action.

(c) & (d): As per para 8.2 of the Medical Council of India (Professional Conduct, Etiquette and Ethics) Regulations 2002, any complaint with regard to professional misconduct can be brought before the appropriate Medical Council for Disciplinary action. Upon receipt of any complaint of professional misconduct, the appropriate Medical Council would hold an enquiry and give opportunity to the registered Medical practitioner (RMP) to be heard in person or by pleader. If the RMP is found to be guilty of committing -professional misconduct, the appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for specified period, from the register of the name of the delinquent RMP. Deletion from the Register shall be widely publicized in local press as well as in the publications of different Medical Associations /Societies/ Bodies. Ethics and Medical Registration Board (EMRB) exercises appellate jurisdiction on appeals filed by RMPs against actions of State Medical Councils as per Section 30(3) of the National Medical Commission Act, 2019.

(e) to (g): The manufacture, sale and distribution of drugs are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder. For manufacturing any drug, the manufacturer is required to obtain manufacturing license under the Drugs Rules, 1945 from the State Licensing Authority (SLA).

However, for manufacturing of new drug, new drug permission is required to be obtained by the manufacturer from CDSCO in accordance with the provisions of New Drugs and Clinical Trials Rules, 2019 before taking manufacturing license from the SLA.

In case there is any change in composition in respect of active ingredients of medicines, New drug permission from CDSCO is required before taking the manufacturing licence from SLA. Therefore, no drug with altered active ingredient composition can be manufactured without new drug permission from CDSCO and manufacturing licence from the concerned SLA.

Further, on 06.11.2019, the Drugs and Cosmetics Rules, 1945 were amended vide G.S.R 828 (E) making it mandatory that, in case the applicant intends to market the drug under a brand name or trade name the applicant shall furnish an undertaking in Form 51 to the licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

As and when any such complaints/issues regarding manufacturing/ marketing of any medicine with change in composition of active ingredients without CDSCO approval is received in CDSCO, the matter is taken up with the concerned State Drugs Controller for necessary action under provision of Drugs Act and Rules.

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