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

RAJYA SABHA
UNSTARRED QUESTION NO. 2683
TO BE ANSWERED ON 12TH AUGUST, 2025

OVERHAUL OF PRESCRIPTION DRUGS UNDER SCHEDULE H

2683: SHRI DEREK O' BRIEN:

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

(a) whether Government is planning an overhaul of the medicines listed under Schedule H of the Drugs and Cosmetics Act, 1940 and the details thereof;

(b) the measures being taken and the studies being done by Government to gauge the deviations and strengthen enforcement of Schedule H and prevent unauthorized over-the counter sale of listed drugs; and

(c) whether Government is considering implementation of any digital tools to track the sales of Schedule H drugs and the details thereof?

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

(a): The Drugs Technical Advisory Board (DTAB) had considered the agenda to revise the Schedule H of Drug Rules, 1945 in its 92nd DTAB meeting held on 24.04.2025.

Drugs Technical Advisory Board (DTAB) is a statutory body constituted under Section 5 of Drugs and Cosmetics Act, 1940 and Rules thereunder to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

(b): The sale and distribution of drugs including Schedule H drugs are regulated by State Licensing Authorities under Drugs Rules 1945. Further, sale of Schedule H drugs without prescription of a registered medical practitioner is a punishable offence and the State Licensing Authorities (SLA) are empowered to take action for the same.

Further, the State Drugs Controllers/other stake holders have been sensitized about concerns regarding sale of prescription drugs by retail without prescription of Registered Medical Practitioners. Various Notices/Advisories/Letters have been issued to State Drugs Controllers and other stake holders for strict compliance of the requirements of Drugs and Cosmetics Act and Rules.

(c): Presently, there is no such proposal under consideration to implement any specific digital tool to track the sales of Schedule H drugs. However, on 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023

providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

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