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

RAJYA SABHA
UNSTARRED QUESTION NO.2030
TO BE ANSWERED ON 18TH MARCH, 2025

CENTRALISATION OF APPROVALS FOR NEW ANTIBIOTICS

2030. SHRI S NIRANJAN REDDY:

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

(a) whether it is a fact that Government plans to make the Central Government the sole authority to grant approval for antibiotics manufacturing in the country, if so, the reasons for the same and the details thereof;

(b) the manner in which Government intends to ensure that centralisation of approval process does not slow down the approval process and result in regulatory overburdening of Central Drugs Standard Control Organisation (CDSCO) and the details thereof; and

(c) the measures planned by Government to ensure that the centralised approval process for antibiotics manufacture does not limit the development and availability of new antibiotics and the details thereof?

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

(a) to (c): The Drugs Consultative Committee (DCC) under Section 7 of the Drugs and Cosmetics Act, 1940 is the advisory committee to advise the Central Government, the State Government and the Drugs Technical Advisory Board (DTAB) on any matter tending to secure uniformity throughout India in the administration of the said Act. The DCC in its 65th meeting held on 20.12.2024 deliberated the issues related to misuse of antibiotic, antiviral, antifungal drugs, etc causing antimicrobial resistance.

There is a regulatory framework under the provisions of Drugs and Cosmetics Act and Rules to regulate drugs, medical devices and cosmetics. Manufacture, sale and distribution of drugs is primarily regulated by the State Licensing Authorities (appointed by respective State Governments) through a system of licensing and inspection while the Central Licensing Authority is responsible for approval of new drugs, clinical trials in the country, laying down the standards for drugs, control over the quality of imported drugs and procedures for processing of various applications received in CDSCO

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