

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

**LOK SABHA
UNSTARRED QUESTION NO. 4180
TO BE ANSWERED ON 20TH DECEMBER, 2024**

APPROVAL OF ANTIBIOTICS AS NEW DRUGS

4180: SHRI S JAGATHRATCHAKAN:

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

- (a) whether the national regulatory body, Central Drugs Standard Control Organisation (CDSCO) is considering a proposal to treat all antibiotics as “new drugs” and, thereby, making centralized approval mandatory for launching any drug in this category;
- (b) if so, the details thereof; and
- (c) if not, the reasons therefor?

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

(a) to (c): The Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act, 1940, deliberated that Antimicrobial resistance can be caused due to misuse of antibiotic, antiviral, antifungal drugs, etc. 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 DTAB on any matter tending to secure uniformity throughout India in the administration of the said Act.
