GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1622
TO BE ANSWERED ON THE 06TH AUGUST, 2024

Guidelines to control essential drugs

1622 # Shri Narhari Amin:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government has issued any guidelines to control essential drugs in the country;
(b) if so, the details of such guidelines issued in this regard;
(c) whether Government has prepared a list of essential drugs;
(d) if so, the number of such drugs included in the list along with their names; and
(e) the details of the action proposed to be taken against those who violate the guidelines issued by Government?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (e): The Essential Commodities Act, 1955 under the Section 2(A) defines 'essential commodity' as commodity specified in the Schedule of the Act. 'Drugs' is listed as first item in the Schedule of the Act. Although all drugs are essential, however, Ministry of Health and Family Welfare notifies the National list of Essential Medicine (NLEM) from time to time to serve purposes like promoting the rational use of medicines; guiding safe and effective treatment of priority disease conditions of a population; and, optimizing the available health resources of the country etc. In the current NLEM - 2022, 384 drugs are included and may be seen at https://cdsco.gov.in/opencms/opencms/en/consumer/Essential-Medicines/.

Under the Drugs and Cosmetics Act, 1940 and Rules thereunder, manufacturers of drugs are required to comply with conditions of manufacturing licence and the requirements of Good Manufacturing Practices (GMP). As per the Drugs Rules, 1945, the manufacturing, testing, labelling, packaging, storage and distribution are required to be carried out in compliance with the conditions of license including the Good manufacturing practices (GMP) as prescribed under the Schedule M of the Drugs Rules, 1945. In case of violation, the Licensing Authority is empowered to take the action as per the said Act and Rules.

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