GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 5806
TO BE ANSWERED ON THE 3rd April, 2018

Licences for New Drugs

5806. DR. P. VENUGOPAL:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Central Drug Quality Regulator has prohibited the States from issuing manufacturing licences for new drugs, unless approval has been granted by the Drugs Controller General of India;
(b) whether the order has been issued in the wake of the National Pharmaceutical Pricing Authority's crackdown on leading pharmaceutical companies found selling over 200 medicines without price approval; and
(c) if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): As per the provisions of Drugs & Cosmetics Rules, 1945, no New Drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in clause (b) of Rule 21 of Drugs and Cosmetics Rules, 1945 i.e. Drug Controller General of India (DCG(I)). Central Drugs Standard Control Organization (CDSCO) has issued circulars from time to time to the State/UT Drugs Controllers requesting them not to issue any licence for manufacturing for sale of new drugs falling under definition of new drug as defined in Rule 122E of Drugs and Cosmetics Rules 1945 without prior approval of DCG(I).

(b) & (c): As per the information received from CDSCO, circulars have been issued by them to ensure implementation of the Drugs and Cosmetics Rules in respect of New drugs and not in the wake of the National Pharmaceutical Pricing Authority's decision regarding new drugs launched without taking prior price approval.

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