

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

**LOK SABHA  
UNSTARRED QUESTION NO.†1784  
TO BE ANSWERED ON 16<sup>th</sup> DECEMBER, 2022**

**COMBINATION OF UNSCIENTIFIC MEDICINES**

**†1784: SHRI AJAY NISHAD:**

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

- (a) whether the Government is aware of the fact that the several unscientific combinations of medicines are being sold as a prescribed quantity of fixed dose combination;
- (b) if so, the details thereof;
- (c) whether the Government is aware of the fact that lax regulatory framework has led to such a situation across the country; and
- (d) if so, the response of the Government thereto?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(DR. BHARATI PRAVIN PAWAR)**

(a) to (d): A few cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

In all cases, where unapproved FDCs have been licensed by SLAs, CDSCO took up the matter with respective SLAs for necessary action. Further, the State Drugs Controllers have also been requested in the Drug Consultative Committee meetings to ensure that new drugs and FDCs are not permitted without approval of DCG(I).

Manufacture, sale and distribution of prohibited/banned drugs is a punishable offence under section 18 of the Drugs and Cosmetics Act. State Licensing Authorities are empowered to take action in this regard.

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