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

RAJYA SABHA
UNSTARRED QUESTION NO.2354
TO BE ANSWERED ON 6TH DECEMBER, 2016

PROHIBITIONS ON FDCS

2354. SHRI A.U. SINGH DEO:

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

(a) whether the Central Drugs Standard Control Organisation has issued a notification prohibiting the manufacture, sale and distribution of Fixed Dose Combination (FDC) of Drugs, if so, the details thereof;

(b) whether Government has taken cognisance of FDCs entering the Indian market illegally, if so, the details thereof and the action taken, if any, if not, the reasons therefor; and

(c) whether Government has undertaken measures to strengthen the legal and regulatory framework on pharmaceutical regulations, if so, details thereof, if not the reasons therefor?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)

(a): The Government *vide* Gazette Notifications dated 10.03.2016 prohibited manufacture for sale, sale and distribution for human use 344 FDCs in public interest as these FDCs were likely to involve risk to human beings and safer alternatives were available. The notifications were issued after a detailed scientific assessment and examination of all pertinent issues. However many manufacturers filed a number of cases in different high courts. The Hon'ble High Court of Delhi has quashed these notifications vide its Judgment dated 01.12.2016.

(b): As per information available with the Government, no new FDCs are now being allowed to be manufactured by the State Licencing Authorities except with the prior approval of CDSCO. However, most of the FDCs approved earlier by State Licencing Authorities (SLAs) are being marketed by the manufacturers.

(c): Fixed Dose Combinations (FDCs) containing drugs combined together for the first time are treated as 'New Drugs'. These, therefore, require permission from the Drugs Controller General (India) [DCG(I)] before these could be licensed by the State Licensing Authorities (SLAs) for manufacture for sale in the country. In order to address this issue, the Department of Health and Family Welfare had issued statutory directions to the State/Union Territory Governments to instruct their respective drugs licensing authorities to refrain from granting such licenses. The State Licencing authorities are sensitized from time to time in the matter to ensure that they accord approval in accordance with the Drugs and Cosmetics Rules.

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