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

LOK SABHA
UNSTARRED QUESTION NO.1042
TO BE ANSWERED ON 4TH DECEMBER, 2015

BANNED DRUGS

1042. DR. K. KAMARAJ:

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

(a) the drugs banned/unapproved by the Government during the last three years and the current year indicating the reasons therefor;

(b) whether certain instances of manufacturing and marketing of drugs banned/unapproved inside/outside the country have been reported in the recent past;

(c) if so, the details thereof indicating the number of such cases reported and the action taken by the Government thereon during the said period, State/UT-wise; and

(d) the measures taken/proposed to be taken by the Government to stop manufacturing and marketing of banned/ unapproved drugs in the country?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a): Keeping in view the likely risk to human beings and availability of safer alternatives in the country, the following drugs have been banned during last three years and the current year:

(i) Dextropropoxyphene and formulations containing Dextropropoxyphene for human use.

(ii) Serodiagnostic test kits for diagnosis of tuberculosis.

(iii) Fixed dose combination of Flupenthixol + Melitracen.

(b) & (c): No such reports of manufacturing and marketing of banned drug has been received. However, one case of manufacturing of new unapproved FDCs in Uttaranchal was reported and the matter was taken up with the State Licensing Authority, Uttaranchal and the license for manufacture has been cancelled by the State Licensing Authority.

(d): As per provisions of the Drugs and Cosmetics Act, 1940, anybody manufacturing or selling drugs in contravention of the prohibition under any notification under Section 10A and 26A are liable for imprisonment/fine. Further, on 1st October 2012, the Central Government issued statutory directions under Sections 33 P of Drugs and Cosmetic Act, 1940 to all State / UT Governments to instruct their respective Drug Licensing Authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules, 1945 for grant of manufacturing licenses for drugs falling under the definition of “new drug” and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said rules. Further, in the meetings of the Drugs Consultative Committee, the State Drug Controllers have been requested to ensure that New Drugs and FDCs are not permitted without approval from the office of DCG (I). State Governments have also been advised to strengthen the infrastructure for better enforcement and also develop vigilance mechanism over the drugs available in the market.