GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2917
ANSWERED ON:13.03.2015
SAFETY OF FIXED DOSE COMBINATIONS
Jayadevan Shri C. N.;Rao Shri Rayapati Sambasiva

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

(a) whether as per the study report of an international medical journal, India`s Drug Act has aided proliferation of harmful combination with little medical rationale and makes it possible for fixed dose combinations to evade clinical trials and the Central Drugs Standard Control Organisation`s approval;

(b) if so, the details thereof along with the reaction of the Government thereto;

(c) whether certain fixed dose combinations including those for diabetes control being used in the country are not recommended by national or international treatment guidelines;

(d) if so, the details along with the facts in this regard; and

(e) the corrective measures being taken by the Government to test/screen all drug combinations being sold in the country in order to ensure that these have scientific rationale for their safety?

Answer

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

(a) to (d): A report published in a journal 'Lancet' mentions that the Indian Act relating to drugs makes it possible for companies to evade Central Drugs Standard Control Organization (CDSCO) approval for Fixed Dose Combinations (FDCs). It is also mentioned in the report that Metformin FDCs are not recommended by international or national treatment guidelines for management of type 2 diabetes. The licenses for manufacture of FDCs can be granted by the State Licensing Authorities after approval by Drugs Controller General (India) in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. In the past, however some FDCs have been approved by the State Licensing Authorities without obtaining approval of DCG(I).

(e): The DCG (I) had, on 15.01.2013, directed all State Drug Controllers to ask the manufacturers of such FDCs to prove the safety and efficacy of FDCs being manufactured by them within a period of 18 months failing which manufacture and marketing of such FDCs in the country was to be prohibited. 6220 applications were received in response to the direction of the DCG (I). The applications so received have been scrutinized by an Expert Committee constituted for the purpose.