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

LOK SABHA
UNSTARRED QUESTION NO. 3298
TO BE ANSWERED ON 18TH DECEMBER, 2015

SAFETY OF DRUGS

3298. SHRI PREM DAS RAI:
DR. SANJAY JAISWAL:
SHRI R. DHRUVA NARAYANA:
DR. K. KAMARAJ:

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

(a) whether use of untested liposomal amphotericin B reportedly poses a threat to life of patients and if so, the details thereof along with the corrective measures being taken by the Government in this regard;

(b) whether certain approved fixed dose combinations of drugs are reportedly unsafe and not recommended internationally, if so, the details thereof along with the reasons for their approval and the remedial steps being taken by the Government to test/screen all drug combinations in order to ensure their safety;

(c) whether the Government proposes to introduce a centralized prescription drug system which can serve as a valuable investigative and preventive for the health care community, regulatory boards and law enforcement and if so, the details thereof;

(d) the other steps taken/proposed to be taken by the Government to ensure safety and standards of drugs; and

(e) the measures taken/proposed to be taken by the Government to avoid misappropriation in supply of drugs and the action taken against the offenders in this regard during the last three years?

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

(a): Any untested drug poses risk to patients and liposomal amphotericin B is no exception. As per Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder, manufacturers are required to test each batch of the drugs either in their own laboratory or in any laboratory approved by the Licensing Authority.

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(b): New Drugs including Fixed Dose Combinations (FDCs) are approved as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. However, some FDCs considered as New Drugs under the Drugs & Cosmetics Rules, 1945 for which approval of the Drugs Controller General (India), is required, have been manufactured and marketed with the approval of the State Drug Controllers / Regulators. DCG (I) had on 15.01.2013 requested all State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months. Notices had been issued to all manufacturers of such FDCs and the responses received from them have been analysed by a Committee of experts, which has submitted its report to the Government. Action as per decision taken by the Government has been initiated in respect of all such cases except 294 FDCs, the matter relating to which is currently sub-judice in the Hon'ble High Court at Chennai.

(c): No such proposal is under consideration of the Government at present.

(d): For evaluation of the safety and efficacy of New Drugs, the Government has approved 25 panels of experts of various therapeutic areas. Further, Pharmacovigilance Programme of India has been launched on 14.07.2010 for monitoring, recording and reporting of Adverse Drug Reactions (ADRs) in the country.

(e): No case of misappropriation in the supply of drugs has been reported during the last three years in Medical Store Organisation/Government Medical Store Depots and Central Government Health Scheme. Standard Operating Procedures have been developed to avoid any misappropriation in the supply of drugs.

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