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

LOK SABHA UNSTARRED QUESTION NO. 1012 TO BE ANSWERED ON 22ND JULY, 2016

SUSPENSION OF DRUG MANUFACTURING LICENSES

1012. SHRI MEHBOOB ALI KAISER:

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

- (a) whether the Central Drug Standard Control Organisation (CDSCO) has requested to each States/UTs Drug Licensing Authority to suspend the manufacturing licenses of all the 14 products of 10 manufacturers identified/ recommended by an expert committee not having satisfactory safety and efficacy of their products including Liposomal Amphotericin B, if so, the details thereof;
- (b) whether CDSCO has received compliance reports from the State Licensing Authorities in this regard, if so, the details thereof and if not, the reasons therefor; and
- (c) whether there is any unqualified Lipid/Liposomal Amphotericin B being manufactured/imported/available in the country and if so, the details thereof?

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

- (a): The Central Drugs Standard Control Organisation (CDSCO) has, with the approval of the Ministry of Health & Family Welfare, requested the Licensing Authorities of concerned States to suspend the manufacturing licenses of Liposomal Amphotericin B of ten manufacturers in public interest.
- (b): CDSCO has received compliance reports from 04 State Licensing Authorities where their manufacturing plants are located.
- (c): CDSCO does not have any information in this regard.