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

LOK SABHA
UNSTARRED QUESTION NO.3191
TO BE ANSWERED ON 6TH DECEMBER, 2019

SUSPENSION OF LICENCES TO DRUG MANUFACTURERS

3191. CH. MEHBOOB ALI KAISER:

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

(a) whether Central Drugs Standard Control Organization (CDSCO) has recommended to each and every State Drug Licensing Authority to suspend manufacturing Licenses of all 14 unqualified Lipid/Liposomal Amphotericin B of the 10 manufacturers that were identified as unqualified for the lack of evidence for Dose, extent of antifungal efficacy and extant of Kidney Toxicity and if so, the details thereof;

(b) whether all State Drugs Licensing Authorities have complied with and if not, the reasons therefor;

(c) whether the CDSCO has written to all State Drugs Licensing Authorities not to issue any new manufacturing license to manufacture Lipid/Liposomal Amphotericin B and suspend manufacturing Licenses that escaped inclusion in the list of 14 unqualified Lipid/Liposomal Amphotericin B and if so, the details thereof;

(d) whether CDSCO is aware that Amfy-Lipid/Liposomal Amphotericin B of Intax known to have life-threatening Nephrotoxicity that cause high morbidity and mortality are being pushed in premier hospitals of the country including defence hospitals thereby risking the lives of patients and soldiers, if so, the details thereof;

(e) whether any State Drug Licensing Authority revoked the suspension of any manufacturer of Liposomal Amphotericin B without having been provided the proof of quality, safety and efficacy of the product; and

(f) if so, the names of such companies and manufacturers whose license was reissued/suspension revoked without having been provided the proof of quality, efficacy and safety?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): The Central Drugs Standard Control Organisation (CDSCO) had, on 11.03.2016, requested the State Licensing Authorities concerned to suspend the licenses of 10 manufacturers of Liposomal Amphotericin B in public interest. This was done after examination by an expert Committee of the data regarding the quality, safety and efficacy of Liposomal Amphotericin B which was submitted by these manufacturers. The expert Committee had observed that the safety and efficacy of the products had not been established.

(b): CDSCO has received compliance reports from the four State Licensing Authorities where their manufacturing plants are located.

(c): No.

(d): CDSCO has not received any such report.

(e) & (f): For manufacture of any new drug, the applicant is required to obtain permission from CDSCO before obtaining manufacturing license from the concerned State Licencing Authority. In accordance with the said provisions and based on the documents submitted and recommendations of expert committee, CDSCO granted manufacturing and marketing permission for Liposomal Amphotericin B Injection 50mg/vial to two firms, namely M/s Cipla Ltd & M/s Bharat Serums and Vaccine Ltd.