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

LOK SABHA
STARRED QUESTION NO. 49
TO BE ANSWERED ON THE 26TH FEBRUARY, 2016
SALE OF LIPOSOMAL AMPHOTERICIN B

***49. SHRI MEHBOOB ALI KAISER:**

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

(a) whether the Government has instituted any expert Committee on Liposomal Amphotericin B in order to determine its safety and efficacy;

(b) if so, the details and findings thereof along with the action of the Government thereon;

(c) whether the Drug Controller General of India (DCGI) has prohibited the sale and manufacture of the aforementioned drug in view of findings of the said Committee; and

(d) if so, the details thereof and if not, the reasons therefor along with the time by which the ban on the manufacture and sale of said drug is likely to be enforced?

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

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA

STARRED QUESTION NO. 49* FOR 26TH FEBRUARY, 2016

(a) The Department of Health and Family Welfare had constituted an Expert Committee to examine the quality, safety and efficacy of the drug Liposomal Amphotericin B.

(b) In its findings, the Committee recommended to regulate Liposomal Amphotericin B Injection marketed in India under Section 26A of the Drugs and Cosmetics Act, 1940. The manufacturers of Lipid/ Liposomal Amphotericin B Injection were thereafter provided an oppurtunity to prove the quality, safety and efficacy of their products on the basis of various criteria determined by the Committee.

(c) & (d) Show cause notices had been issued to 10 manufacturers to reply within 3 weeks as to why the manufacturing licenses issued to them for their products Liposomal Amphotericin B Injection should not be suspended. Out of 10 manufacturers, 07 have responded and prima facie, it has been found that their responses are not satisfactory to conclude that the products are safe and efficacious. Accordingly, the State Licensing Authorities are proposed to be requested to suspend the manufacturing licenses of the ten manufacturers of the product in public interest.