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

RAJYA SABHA
UNSTARRED QUESTION NO.2359
TO BE ANSWERED ON 6TH DECEMBER, 2016

POOR QUALITY OF MEDICINES

2359. SHRI SANTIUSE KUJUR:

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

(a) whether it is a fact that several pharmaceutical companies are manufacturing and marketing many medicines which failed quality tests conducted by the Drug Controller General of India (DCGI);

(b) if so, the details thereof and the action taken against pharmaceutical companies by Government thereto;

(c) how many medicines have been banned/stopped during the current year; and

(d) how many pharmaceutical companies have been stopped by Government during the current year?

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

(a) & (b): Both the Central Drugs Standard Control Organisation (CDSCO) and the State drug regulators pick up a large number of samples of drugs from all over the country and have them tested and analysed in the Laboratories of the Central and State Governments. In a few cases, the samples tested and analysed do not meet the prescribed standards. As per information available with CDSCO, 77483 samples were tested and analysed during 2015-16 out of which 3818 samples were found to be 'Not of Standard Quality'. The State Licensing Authorities direct such manufacture whose products do not meet the standards to recall the products and take action as per provisions of the Drugs and Cosmetics Act, 1940 is taken against them.

(c): During current year, the Government of India had, *vide* Gazette Notifications dated 10.03.2016, prohibited the manufacture for sale, sale and distribution for human use, 344 Fixed Dose Combinations (FDCs) (medicines) with immediate effect in public interest as these FDCs were likely to involve risk to human beings and safer alternatives were available. A large number of petitions have been filed in different High Courts in respect of most of these FDCs. The Honourable High Court of Delhi has quashed the notifications prohibiting the drugs vide its Judgement dated 01.12.2016.

(d): The CDSCO and State Drug Regulatory Authorities have carried out Joint Risk Based Inspections of pharmaceutical units to check compliance with the Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) and shared the reports both with the manufacturers as also State Licensing Authorities. However, under the Drugs & Cosmetics Act, 1940 and the Rules, 1945 the regulatory control over manufacture, sale and distribution of drugs vests in the State Licensing Authorities. Accordingly, action against companies not conforming to the prescribed standards has to be taken by the States/UTs.