## GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:816 ANSWERED ON:01.03.2013 HARASSMENT BY DRUG OFFICIALS Jeyadural Shri S. R.

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

- (a) whether cases of harassment and wrong interpretation of provisions of the Drugs and Cosmetic Act by Drug Control Inspectors/Officials have been reported to the Government;
- (b) if so, the details thereof, State/UT wise;
- (c) whether the Government has issued any directions to the Drug Control authorities of the States/UTs in this respect;
- (d) if so, the details thereof; and
- (e) the steps taken/proposed by the Government to ensure that pharmacists/manufacturers of drugs are not unnecessarily harassed by the drug control authorities of the Centre and States/UTs?

## **Answer**

## THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (e): - No such incident has been reported in respect of inspectors / officials of Central Drugs Standard Control Organisation (CDSCO). Information relating to cases of harassment and wrong interpretation of the provisions of the Drugs & Cosmetics Act by the State Drug Inspectors is not maintained centrally. However, one case was reported to CDSCO from Rajasthan where some Drugs Control Officers interpreted wrongly that the Fixed Dose Combination (FDC) of Thiamine Mononitrate + Riboflavin+ Pyridoxine HCl + Vitamin B12 +Niacinamide+ Calcium Pantothenate+ Folic Acid+ Biotin+ Ascorbic acid (Becosule Capsules) and the FDC of Thiamine Mononitrate+ Riboflavin+ Pyridoxine HCl + Vitamin B12 +Niacinamide+ Calcium Pantothenate+ Folic Acid+ Biotin+ Ascorbic acid + Zinc (Becosule Z Capsules) manufactured by M/s. Pfizer Ltd, Mumbai were covered under the notification G.S.R 702 (E), dated 14.10.1999 prohibiting fixed dose combination of Vitamin B1, Vitamin B6 and Vitamin B12 for human use. The firm was ordered not to dispose of stocks of worth Rs.1.14 Crore. The Office of Drugs Controller General (India) {DCG(I)} informed the Drugs Controller, Rajasthan that these preparations do not fall under the ambit of the said notification.