GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:6851
ANSWERED ON:07.05.2010
REGULATORY REQUIREMENTS FOR PHARMACEUTICAL COMPANIES
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) the details of the regulatory requirements set by the Drug Controller General (India) for the pharmaceutical companies in the country;
- (b) whether complaints have been received against some pharmaceutical companies for the violation of these requirements;
- (c) if so, the details thereof during the last three years and the current year alongwith the action taken against them;
- (d) whether the DCG(I) has recently asked some pharmaceutical companies to provide details regarding alleged favours to the doctors by them;
- (e) if so, the details thereof; and
- (f) the present status of the matter?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) to(f): The regulatory requirements / provisions with regard to the drugs and cosmetics, which are to be followed by all concerned including the pharmaceutical companies, are contained in the Drugs and Cosmetics Act, 1940 & the Drugs and Cosmetics Rules, 1945. The said Act / Rules, however, deal with only the safety, efficacy and quality of drugs and do not contain provisions for regulating the conduct of pharmaceutical companies in providing alleged favours to the doctors. Recently, the office of Drug Controller General (India) [DCG (I)] has received a request from Medical Council of India to ask one drug company to furnish them details in respect of a conference held in Hyderabad in January 2010 relating to particulars of the journey, cost of conference paid / reimbursed etc with regard to the participation of doctors. On receipt of the request the office of the DCG (I) has requested the concerned firm to provide the said information to Medical Council of India.