GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1151
ANSWERED ON:30.11.2005
IMPORT OF SUB- STANDARD DRUGS
Kathiria Dr. Vallabhbhai

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

(a) whether sub-standard medicines are being imported by the drug suppliers in the country;

(b) if so, the details thereof;

(c) the action taken by the Government in this regard ;

(d) whether the Government has started registration of foreign companies which are into importing drugs in order to check the inflow of sub-standard medicines in to the country;

(e) if so, whether a number of foreign companies have been registered without any inspection of the premises as laid down in the Drugs and Cosmetics Act; and

(f) if so, the concrete steps taken by the Government in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (d) : No sir, Adequate provisions have been laid down under Drugs & Cosmetics Rules to ensure that sub standard drugs are not imported into the country. These registration of overseas manufacturers and of each drug grant of import licence in Form 10 and checking of every import consignment by the port officers.

(e) & (f): Registration requirements for a drugs were introduced in April 2003. Inspection of overseas manufacturing sites is not mandatory criteria for registration of import of drugs. Presently, such imported drugs, which have been in use in the country for considerable period, and are duly approved, have been registered, provided all formalities prescribed in Schedsule D(I) and D(II) of the Drugs & Cosmetics Rules are complied with. The applicants are required to submit regulatory status of the drug, free sale certificate and GMP certificate in WHO format or certificate of pharmaceutical product (COPP), issued by regulatory authority of the country of origin and Free Sale approval, issued by the regulatory authorities of other major countries.