

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:4770

ANSWERED ON:04.05.2012

QUALITY OF DRUGS

Pakirappa Shri S.;Rama Devi Smt. ;Rao Shri Nama Nageswara;Singh Shri Ijyaraj

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

- (a) whether the Government has put in place any mechanism to ensure the quality and efficacy of imported as well as domestically manufactured drugs which are being marketed across the country;
- (b) if so, the details thereof;
- (c) the policy outlined alongwith the norms and regulations laid down in respect of import of quality drugs from overseas manufacturing units and those produced domestically;
- (d) whether the Central Drugs Standard Control Organisation (CDSCO) has initiated inspections of manufacturing sites of the drug manufacturers abroad; and
- (e) if so, the details alongwith the outcome of such inspections carried out till date?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) to (c): The quality and efficacy of drugs imported into the country or manufactured in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 made there under. The said Act and the Rules contain comprehensive provisions for the purpose inter alia regarding criteria and procedure of grant of registration certificates in the case of drugs imported into the country and grant of licenses for manufacture of drugs in case of domestically manufactured drugs.

(d) & (e) Yes. The CDSCO has so far inspected ten Chinese bulk drugs manufacturing firms. Following the inspections, the Registration Certificate of one firm and sixteen Import Licenses have been cancelled.