GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:252
ANSWERED ON:26.11.2010
QUALITY OF IMPORTED DRUGS
Vivekanand Dr. G.

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

(a) whether the Government has outlined any policy in respect of import of drugs from overseas manufacturing units and those produced domestically in order to maintain the quality of drugs in the country;

(b) if so, the norms and regulations laid down, particularly in respect of human trials of imported drugs and site inspection of overseas drugs manufacturing units before granting them registration;

(c) whether reports of approval to import some drug formulations including an anti-diabetes drug in violation of the said norms and regulations have been received by the government;

(d) if so, the details thereof;

(e) whether any probe has been conducted in this regard; and

(f) if so, the details and the findings thereof alongwith the action taken against those found guilty?

Answer

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

(a)to(f): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 252 FOR 26TH NOVEMBER, 2010

(a): The quality, safety and efficacy of the imported drug as well as domestically produced drugs are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made thereunder. The said Act provides for the regulation of imported drugs by the Central Licensing Authority appointed by the Central Government and of the drugs manufactured in the country by the State Licensing Authorities appointed by the State Governments.

(b) The Clinical trials are required to be carried out in accordance with the requirements and guidelines specified in Rules 122DA, 122DAA, 122DB, 122E and Schedule Y of the Drugs & Cosmetic Rules, 1945. Schedule Y also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Government of India. As per the provisions of the Drugs and Cosmetic Rules, 1945 relating to import of drugs, the overseas manufacturing sites as well as the drugs to be imported are required to be registered with the Drugs Controller General (India) [DCG(I)] before the drugs are imported into the country. Details of the procedures and requirements for import and registration of drugs are mentioned in Part IV (Import & Registration) of the Drugs & Cosmetics Rules, 1945. However, for import of new drugs, before the registration of the product and the site, the applicants are also required to obtain permission under rule 122A of the said rules.

(c) to (f): Reports had appeared in media about the permission given for the import and marketing of oral human insulin aerosol suspension (anti diabetic) to M/s Shreya Life Sciences Pvt. Limited, Mumbai without Clinical Trial. The matter has been examined by the Government. M/s Generex Biotechnology, Mumbai, the authorized agent of Generex Biotchnology Corporation, Canada in India, had made an application on 28.5.2007 under the provisions of the Drugs and Cosmetics Rules, 1945 for import and marketing of human insulin oral suspension (Generex Oral-Lyn) from M/s Farmacid S.A, Ecuador. Phase II Clinical trials had been done on the said drug. The firm was granted permission by the order dated 15.10.2007 of the CDSCO to import and market 10 million packs of human insulin oral suspension (Generex Oral-Lyn) from the said source for generation of post marketing surveillance (PMS) data with annual reporting. Subsequently, by following due procedure, the import and marketing permission for the said product was transferred under order dated 25.4.2008 of the CDSCO from M/s Generex Biotechnology Corporation, Mumbai to M/s. Shreya Life Sciences Pvt. Ltd., Mumbai under the same terms and conditions. In the light of the media reports, the CDSCO reviewed the permission granted for the said drug and by order dated 26.3.2009 withheld the import and marketing of the drug including the drugs stocked for generation of PMS data till further orders. The drug is accordingly not being marketed in the country currently.

M/s Shreya Lifesciences Pvt. Limited, Mumbai was subsequently granted permission on 26.11.2009 for conducting Phase III clinical trial so as to further evaluate the safety and efficacy of the said oral insulin in Type II Diabetes cases.

The Ministry of Health and Family Welfare has initiated investigations into the matter to ascertain any irregularity.

There are no such reports on other drug formulations. However, in case of import of bulk drugs, the office of DCG(I) had received some complaints in September, 2009 about the genunity of the Good Manufacturing Practices (GMP) Certificates submitted by some applicants to the office of DCG(I) in respect of the already registered sites of drugs being imported from China. Upon verification of the GMP status from the Chinese Regulatory Authority i.e. State Food and Drugs Administration (SFDA) in April, 2010, the office of DCG(I) has cancelled ten registration certificates and the corresponding 75 import licenses of various bulk drugs during the period June, 2010 to August, 2010. Later on, 5 other firms surrendered their Registration Certificates during the period from May, 2010 to August, 2010. Subsequently, these certificates along with 34 import licenses issued under the said registration certificates were also cancelled by the DCG(I) during the period from May, 2010 to August, 2010.