GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3979
ANSWERED ON:26.08.2011
REGISTRATION OF PATENTED PHARMACEUTICAL PRODUCTS/DRUGS
Mani Shri Jose K.

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

(a) whether all the patented pharmaceutical products/drugs including those imported from outside which are being marketed in the country are approved and registered with the Central Drugs Standard Control Organisation (CDSCO);

(b) if so, the details thereof;

(c) the details of criteria and procedure for grant of approval/registration to the imported and newly introduced drugs alongwith the provisions made for the purpose in the Drugs and Cosmetics Act;

(d) whether above procedure and provisions have been followed for granting approval/registration to the imported and newly introduced drugs in the country; and

(e) if so, the details thereof?

Answer

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

(a) & (b): Drugs, irrespective of their patent status, imported into the country are regulated by the office of Drug Controller General (India) under the Drugs and Cosmetics Act & Rules made thereunder through the system of registration & import licenses.

(c): The criteria and procedure for grant of registration of the imported drugs and approval for marketing of new drugs have been prescribed under the Drugs and Cosmetics Rules, 1945.

For the purpose of grant of Registration Certificates, the manufacturer abroad or his agent in India is required to make application to the office of the Drugs Controller General (India) in Form 40 along with specified fees, power of attorney in favour of the agent in India and the information and undertakings as specified in Schedule D(I) and D(II) of the said Rules duly signed by or on behalf of the manufacturer. Thereafter, the importer is required to obtain the import licence from the said authority for the import of drugs registered for import.

For the purpose of import of newly introduced drugs i.e. new drugs, prior permission is required to be obtained from the office of the Drugs Controller General (India) for marketing the drug in the country. The applicant is required to submit application in Form 44 along with the specified fees and technical data in respect of safety and efficacy of the drug for grant of permission to import the new drug in to the country. The applicant is then required to get the drug registered for import into the country.

(d) & (e): Yes. The said permissions are granted in accordance with the provisions laid down in the Drugs and Cosmetics Act and Rules there under.