GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1393
ANSWERED ON:18.07.2014
APPROVAL TO DRUGS
Patel Smt. Jayshreeben

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

(a) the details of the provisions/ guidelines laid down by the Government with regard to approval of new drugs and grant of licences for import, manufacture and sale of drugs in the country;

(b) the mechanism put in place by the Government to ensure the compliance of the above provisions/guidelines in the country;

(c) whether instances of approval to certain new drugs by the Central Drugs Standard Control Organisation (CDSCO)/ Drug Controller General of India (DCGI) in contravention of the prescribed rules have been reported in the country;

(d) if so, the details thereof; and

(e) the corrective steps taken/proposed to be taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

(a) & (b): Approval of New Drugs, import, manufacture and sale of drugs in the country are regulated under the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945. Approvals of New drugs are granted under the rules 122 A, 122 B, 122D, 122 DA, 122 DAA, 122 DAB, 122 DAC, 122 DB, 122 DD and 122 E of Schedule-Y of said Rules. New drugs are approved by the CDSCO based on non-clinical data, clinical trial data of safety and efficacy of drug generated abroad as well as local clinical trial data, regulatory status in other countries etc. as per the guidelines and requirements specified in rule 122A, 122B, 122D and Schedule-Y of the Drugs and Cosmetics Rules, 1945. However, as per rule 122 A (2) and rule 122 B (3), the requirement of local clinical trials may not be necessary if the drug is of such nature that the Licensing Authority may, in public interest, decide to grant permission to import / manufacture the new drug on the basis of data available from other countries. Further, as per clause 1(3) of Schedule Y, for drugs indicated in life threatening / serious diseases or diseases of special relevance to the Indian health scenario, clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority. For grant of permission to import / manufacture the Fixed Dose Combinations (FDC), the requirements are prescribed under Appendix-VI of Schedule-Y. As per these requirements, clinical trial on Indian patients is required in certain category of FDCs.

Import of drugs is regulated by Central Drugs Standard Control Organization (CDSCO) under the said Acts & Rules. Under the provisions, Import Registration Certificate and License are required to be obtained from CDSCO for Import of any drug into the county.

The provision relating to the manufacture and sale of drugs are regulated by the State Drug Control Authorities appointed by the State Governments, which monitor the quality of drugs that are manufactured in the country, through the system of licensing, inspection and testing of drugs.

(c) to (e): There is no instance of approval of New Drug by CDSCO in contravention of the prescribed Rules. However, in order to strengthen the process of approval of new drugs, following steps have been taken:

(1) Applications for approval of New Drugs are evaluated by the 12 New Drug Advisory Committees (NDAC), now renamed as Subject Expert Committee (SEC), consisting of leading experts from the Government Medical Colleges, Institutes from all over the country and decision to approve is taken or otherwise action is taken as per the recommendations of these committees.

(2) Applications of Investigational New Drugs (IND) i.e, New Drug Substances which have never earlier been used in human beings, are evaluated by the IND committee, chaired by the Director General, Indian Council of Medical Research.