GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2146
ANSWERED ON:24.08.2012
APPROVAL OF NEW DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the policy formulated by the Government in respect of clinical trials of new drugs before granting them approval for their marketing in the country;

(b) whether the Government has taken note of approval of certain drugs by the Central Drugs Standard Control Organisation (CDSCO) in violation of the established procedures and without proper clinical trials in the country;

(c) if so, the facts in this regard;

(d) the number of drugs approved by the Central Drugs Standard Control Organisation (CDSCO) and the number out of them undergone clinical trials in the country during each of the last three years and the current year so far;

(e) the action taken/proposed by the Government against the officials involved in the approval of drugs without their clinical trials in the country; and

(f) the measures taken/proposed by the Government to check such regulatory lapses and streamline the mechanism of approval of new drugs in the country?

Answer

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

(a) to (f): New drugs are approved as per the guidelines and requirements specified in Rule 122A, 122B, 122D and Schedule Y of the Drugs and Cosmetics Rules, 1945. As per the Schedule Y, for new drug approved outside India, phase III clinical trials need to be carried out primarily to generate evidence of efficacy and safety of the drugs in Indian patients when used as recommended in the prescribing information. However, as per Rule 122 A (2) and Rule 122 B (3), the requirement of such local clinical trial may not be necessary if the drug is of such a 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 of 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.

The number of new drug molecules of Non-Biologicals and Biologicals approved by CDSCO and the number out of them, which underwent clinical trials in the country are as under:

Year	Number of drugs approved	Number of drugs approved with clinical trial
2009	72	60
2010	65	52
2011	41	38
2012 (upto July)	14	9

New drug applications are examined in consultation with twelve New Drug Advisory Committees (NDACs) consisting of experts / specialists from various reputed institutions and medical colleges across the country.

The Department-Related Parliamentary Standing Committee on Health and Family Welfare has made certain observation regarding the approval of new drugs without clinical trials on Indian subjects. An Action-Taken-Report would be submitted to the Committee.