GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:425
ANSWERED ON:06.12.2013
APPROVAL OF DRUGS
Das Shri Khagen;Venugopal Shri P.

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

(a) whether the Central Drugs Standard Control Organisation (CDSCO) has approved certain drugs without clinical trials in the country;

(b) if so, the details thereof and the reasons therefor indicating the number of such drugs approved by CDSCO during each of the last three years and the current year;

(c) whether the Government has collected the post-marketing surveillance data of such drugs and if so, the details thereof and if not, the reasons therefor;

(d) whether the Government has received any report in this regard; and

(e) if so, the details thereof and the follow up action taken/proposed by the Government thereon?

Answer

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

(a)&(b): Yes. 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 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 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 drugs (new drug molecules of Non-Biologicals and Biologicals) approved by CDSCO without local clinical trials in the country is as under:

Year	Number of drugs approved without clinical trial
2010	13
2011	03
2012	08
2013(upto 05.12.2013)	02

(c) to (e): These drugs are approved by CDSCO with the condition that as Post Marketing Surveillance, the applicant shall submit Periodic Safety Update Reports (PSUR) every six months for the first two years. For subsequent two years, the PSUR shall be submitted annually. Of the above drugs, CDSCO has received PSUR data for the drugs which have been launched in the country as per the above requirement. Further, the Government had constituted an Expert Committee under the chairmanship of Prof. Ranjit Roy Chaudhury to formulate policy guidelines and SOPs for approval of new drugs, clinical trials, banning of drugs. The Government has already examined the recommendations of this Committee and has decided on the action to be taken thereon, which have also been posted on the CDSCO website.