GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1681
ANSWERED ON:16.08.2013
BANNED UNAPPROVED DRUGS .
Adhi Sankar Shri ;Ajay Kumar SHRI ;Jeyadural Shri S. R.;Kumar Shri P.;Mahendrasinh Shri Chauhan ;Naik Dr. Sanjeev Ganesh;Pandey Shri Ravindra Kumar;Patel Shri Devji;Premdas Shri ;Punia Shri P.L. ;Singh Shri Jagada Nand;Singh Shri Pashupati Nath;Sule Supriya ;Thakur Shri Anurag Singh

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

(a) whether cases of marketing and manufacturing of certain drugs which are banned/unapproved inside/outside the country have been reported in the country;

(b) if so, the details thereof indicating the number of such cases reported and the action taken against the offenders during the said period, State/UT-wise;

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

(d) if so, the facts in this regard along with the number of such drugs aproved by CDSCO without clinical trials in the country during each of the last three years and the current year; and

(e) the action taken/proposed by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE

(SHRI GHULAM NABI AZAD)

(a) & (b): A drug banned / restricted in one country may continue to be marketed in other countries as the respective government examines the usage, doses, indications permitted etc. and overall risk-benefits ratio and takes decisions on the continued marketing of any drug in that country. The State Drug Control Departments conduct raids to check the sale of banned drugs under their jurisdiction. The Central Drugs Standard Control Organization had also conducted raids in 2011 in and around Delhi and in Mumbai to check the withdrawal of Gatifloxacin, Tegaserod and Rosiglitazone after these drugs were prohibited. It was found that in 29 shops, banned drugs were sold after the issue of notification in the Gazette of India and in the remaining shops banned drugs were found stocked, but were not sold after the date of the said notification. Action was initiated in those cases as per the provision of the Drugs and Cosmetics Act, 1940.

Twenty three cases of new Fixed Dose Combinations (FDCs) considered as new drugs were also found to be licenced by State Licensing Authorities (SLAs) without approval of the Drugs Controller General (India). SLAs in all these cases were asked to take action under the Drugs and Cosmetics Act, 1940.

(c) to (e): New drugs are approved by the CDSCO based on non-clinical data, clinical data of safety and efficacy of drug, 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 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 clinical trials in the country is as under:

Year	Number of drugs approved without clinical trial
2010	13
2011	3
2012	8

2013 2
(upto July)