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Drug approvals without clinical trials on decrease: Govt data

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A drug banned or 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.

Recently the CDSCO 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.

The number of drugs (new drug molecules of non-biologicals and biologicals) approved by CDSCO without clinical trials in the country has reduced over the period of time. During the year 2010, the number of drugs approved without clinical trial remained at 13 which went to three in 2011, eight in 2012 and finally two upto July, 2013. These statistics were revealed by the union minister of health and family welfare, Ghulam Nabi Azad in written reply to a question in the Parliament.

Elaborating on the procedures, Azad mentioned, "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."Â

"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", explained the minister.