

## Launch the drug in six months or face the music, says CDSCO

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The Central Drugs Standard Control Organization (CDSCO) will cancel the permissions and licences given to the drug manufacturers, who fail to launch the particular product for marketing in the country within a period of six months after obtaining the permission from the CDSCO.

The drug controller general of India (DCGI), Dr GN Singh has sent a notice to all state licensing authorities to implement the order which puts a time limit for the manufacturers or applicants to launch their products after securing permission.

"Under the Drugs and Cosmetics (D&C) Rule, 1945, permission to manufacture a new drug is granted by CDSCO. Based on the permission received from the CDSCO, manufacturer obtains manufacturing licence from the concerned state licensing authorities. As per Schedule Y, periodic safety update reports (PSURs) of new drugs are required to be submitted every six months for the first two years after approval of the drug is granted," said the notice dated January 11, 2013 by the DCGI.

"For subsequent years, the PSURs need to be submitted annually. PSURs are important for assessing the safety and efficacy in post marketing scenario. However, it has been observed many times that the manufacturers do not launch the product even after years of getting approval from this office and the manufacturers do not submit the required PSUR, while the drug does not remain a new drug after a period of four years. Therefore, the assessment of safety and efficacy of such new drug in the post marketing scenario remains incomplete," he said.

It has been therefore decided in public interest that, just in case an applicant fails to launch the product for marketing in the country within a period of six months from obtaining the permission, the licence will be treated as cancelled, directing the state authorities to take necessary steps in this regard.