

Press Release

Drugs Control Administration, Telangana cancelled the product manufacturing licence of Mylan Laboratories Ltd., Unit-7, Pashamylaram, Patancheru Mandal, Sangareddy District for the drug 'Alprazolam'

The details are as follows:

Mylan Laboratories Ltd., Unit-7, Pashamylaram, Patancheru Mandal, Sangareddy District was issued a licence by the Drugs Control Administration, Telangana, to manufacture the drug '**Alprazolam**' (Active Pharmaceutical Ingredient). The licence issued by DCA includes permission for the activities of manufacturing the bulk drug Alprazolam (API) and supplying the drug exclusively to the formulation (tablets/injections) manufacturing units."

'Alprazolam' is a **psychotropic substance** under Narcotic Drugs and Psychotropic Substances Act (NDPS Act) and is used as a **medicine** to treat anxiety disorders, panic disorders, anxiety associated with depression, insomnia. The addiction / habit-forming potential of Alprazolam is very high. The **abuse** of Alprazolam can lead to various adverse effects including addiction, physical dependence, tolerance and withdrawal symptoms upon discontinuation.

Misuse of Alprazolam can result in sedation, drowsiness, dizziness, confusion, impaired coordination, memory problems, and respiratory depression, **particularly when combined with alcohol** or other central nervous

system depressants. Long-term abuse of Alprazolam can have serious consequences for physical and mental health, including cognitive impairment, mood disturbances, and increased risk of accidents.

There were reported events of 'Alprazolam' drug being mixed with toddy (adulterating toddy) which leads to serious health consequences.

The unauthorized diversion of 21.250 kilograms of the psychotropic substance 'Alprazolam' from the licensed premises of Mylan Laboratories Ltd., Unit-7, through certain employees who were working as chemists and production officers at the site, was detected by Prohibition & Excise Authorities. In connection with this, a seizure of 4.850 kilograms of Alprazolam was carried out in February 2023 by Prohibition & Excise Authorities from the consumables room of Mylan Laboratories Ltd., Unit-7.

The event of unauthorized diversion, which could potentially lead to abuse of the drug 'Alprazolam', came to the notice of the Drugs Control Administration, Telangana, from the Excise Authorities.

DCA Telangana issued a Show Cause Notice to Mylan Laboratories Ltd., Unit-7, upon carrying out an inspection of the site, as the firm failed to notify the Drugs Control Administration, Telangana, regarding the unauthorized diversion of Alprazolam from the licensed premises and for certain violations reported by DCA officers regarding the lack of adequate controls for the prevention and detection of such unauthorized diversion of Alprazolam from the licensed premises.

Considering the nature of the violations reported regarding the drug 'Alprazolam', which is a psychotropic substance, and its unauthorized diversion from Mylan Laboratories Ltd., Unit-7, upon assessment of the existing controls

and practices at the site, **the manufacturing licence for the drug 'Alprazolam' has been cancelled by the Drugs Control Administration, Telangana**, with immediate effect, in the larger public interest.

Manufacturers who are producing narcotic drugs and psychotropic substances must implement stringent measures to prevent unauthorized diversion, pilferage, or theft of the drugs they manufacture, in order to prevent abuse.

Surprise raids shall be intensified on manufacturing units holding licences to manufacture **narcotic drugs and psychotropic substances** to verify reconciliation data. Stringent action shall be taken as per the law against violators.

Date: 14-02-2024

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DIRECTOR GENERAL**