CDSCO Begins Online Registration for Securing Revised Schedule M Extension; Deadline: May 2025

Issuing a circular, the Central Drugs Standard Control Organisation (CDSCO) has announced the initiation of an online application process for manufacturers seeking an extension to comply with the revised Schedule M. To apply, manufacturers must register on the ONDLS portal.

New Delhi: Following the Union Health Ministry's announcement of an extended compliance deadline for small manufacturers under the revised Schedule M, the central drug regulatory body has launched an online registration process. Interested parties can now submit their applications to secure an extension for their respective facilities.

In a recent circular, the Central Drugs Standard Control Organisation (CDSCO) stated, "Online applications for an extension of time to comply with the revised Schedule M are now open. Manufacturers seeking an extension must register on the ONDLS portal and submit their applications online. No hard copy submissions will be considered."

The circular, issued by the Drugs Controller General of India (DCGI), further clarifies, "As per the Department of Health and Family Welfare's notification published on February 11, 2025, small and medium-sized manufacturers (SMEs) must apply to the Central Licence Approving Authority within three months from the date of publication of this notification—i.e., by May 11, 2025."

Additionally, manufacturers must submit an "upgradation plan" to the Licensing Authority. For those who comply, the implementation timeline will be extended until December 31, 2025.

The Online National Drugs Licensing System (ONDLS), developed by CDSCO in collaboration with the Centre for Development of Advanced Computing (CDAC), serves as a single-window platform for processing applications related to manufacturing and sales licenses. This includes licensing for Blood Banks and the issuance of certificates such as COPP, GMP, WHO-GMP, and Market Standing Certificates, among others.

Under the Drugs and Cosmetics Rules, 1945, Schedule M outlines the Good Manufacturing Practices (GMP) that pharmaceutical manufacturers in India must adhere to. These regulations cover premises, plant, equipment, and quality assurance to ensure that drugs are consistently produced and controlled according to quality standards.

In December 2023, the Union Health Ministry introduced revised Schedule M requirements, upgrading "Good Manufacturing Practices" to "Good Manufacturing Practices and Requirements of Plant and Equipment for Pharmaceutical Products."

The updated GMP guidelines came into effect for large manufacturers in June 2024. However, small manufacturers—particularly those with an annual turnover of less than ₹250 crore—were initially given a deadline of December 2024.

Following multiple representations from individual stakeholders and industry bodies such as FOPE and Laghu Udyog Bharati, the Ministry announced a conditional extension until December 31, 2025. This extension aims to facilitate infrastructure upgrades, personnel training, and financial resource allocation for small manufacturers.

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