Stricter GMP Norms: Revised Schedule M to Take Effect from New Year, says DCGI

The revised Schedule M for Good Manufacturing Practices (GMP) will be fully implemented by January 1, 2025. Dr. Rajeev Raghuvanshi, DCGI, highlighted the stricter standards, urging companies to upgrade their systems. These changes aim to improve manufacturing quality and safety. Additionally, mandatory testing of cough syrup batches for export is now required to prevent past contamination issues.

New Delhi: India's drug regulatory framework is set for a significant upgrade as the revised Schedule M, which governs Good Manufacturing Practices (GMP), will be fully implemented by January 1, 2025.

Speaking at the sidelines of an OPPI Annual Summit exclusively with ETPharma, Dr. Rajeev Raghuvanshi, Drug Controller General of India (DCGI), highlighted the importance of Schedule M as a crucial part of the regulatory value chain.

"Post-January 1, our audits will follow the new checklist which has been prepared as per the new revised Schedule M. So that will be a little more stricter aligned with the revised Schedule M. The standards have become much more higher in many of the parameters," said Dr Raghuvanshi

"Companies who have to basically comply with Schedule M they will have to, if they do not already have . They will have to upgrade their infrastructure, their systems, procedures, and manpower. Whatever is being asked . And that in turn will take the whole regulatory system to the next level," he added.

Drugmakers with a turnover of ₹250 crore or more had to adhere to the revised Schedule M of the Drugs and Cosmetics Rules (1945) by July 2024, whereas for companies with a turnover of ₹250 crore or less were additional six months till December 2024 to adhere to the revised norms.

However, this year in July the Federation of Pharma Entrepreneurs (FOPE) an industry body which represents small and medium drug makers had written to the health minister seeking an extension of two years for adhering to the revised schedule M norms which were notified in January this year.

Answering about last year's controversy over contaminated cough syrups allegedly linked to child deaths in Gambia and Uzbekistan, Dr. Raghuvanshi outlined proactive measures taken by the DCGI. "One key initiative was the mandatory testing of all cough syrup batches intended for export. This step has significantly strengthened the system by inducing systemic improvements across various regulatory areas," he explained.

Dr. Raghuvanshi informed that the revised standards will strengthen the overall regulatory system, driving higher quality and safety in pharmaceutical manufacturing. He emphasised that revised Schedule M has to be implemented in totality it will change the whole face of the pharma industry. This move is expected to set a new benchmark for manufacturing excellence, urging companies to align with the upgraded framework or risk non-compliance.

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