

Conditional extension of timeline to small and medium pharmaceutical manufacturers for compliance with revised Schedule 'M' notification

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The Ministry of Health & Family Welfare has conditionally extended the due date for implementation of revised Schedule M (Good Manufacturing Practices provision) in respect of small and medium manufacturers having turnover of Rs. 250 crores or less, up to 31st December, 2025.

On 28th December, 2023, the Government of India had notified revised Schedule M requirements wherein “good manufacturing practices” was upgraded to “good manufacturing practices and requirements of plan and equipment for pharmaceutical products”. The category of manufacturers was divided into two; the first category was of large manufacturers having turnover more than 250 crores. A timeline of 6 months was given to such manufacturers for compliance. For small and medium manufacturers having turnover less than or equal to 250 crores, a timeline of 12 months was given for compliance. The revised Schedule M requirements have been implemented for large manufacturers w.e.f. 28th June, 2024.

Small and medium manufacturers had represented for extension of timeline to enable improvement in infrastructure, training of personnel and arranging financial resources. The same has been considered and the small and medium manufacturers have been given a time of 3 months from 11th February, 2025 to submit their plan for upgradation in Form A to the Central License Approving Authority. For such manufacturers who submit these details, the timeline of implementation would be extended till 31st December, 2025.

The revised Schedule M requirements are a positive step towards ensuring the quality and safety of pharmaceutical products being manufactured in India. The new regulations would enable the pharma companies to not only strengthen their domestic position but also become more competitive globally.

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HFW/Extension of Revised Schedule M/12Feb2025/1

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