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Quality shouldn’t be an afterthought but an integral part of manufacturing process: Dr Rajeev Raghuvanshi, DCGI

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At the 63rd Annual Day Celebrations of the Indian Drug Manufacturers' Association (IDMA) held in Mumbai from Feb 8th, Dr Rajeev Raghuvanshi, Drugs Controller General of India (DCGI), emphasised the importance of execution over excessive regulation. Speaking at the event, themed Innovating Today For Healthier Tomorrow, Raghuvanshi advocated for a balanced approach where compliance is strengthened through practical implementation rather than regulatory overreach. Addressing MSME challenges, he extended the Schedule M compliance deadline to December 2025, allowing companies time to upgrade. He has called for industry-wide collaboration, urging larger pharma companies to mentor MSMEs and elevate standards.

How does the revised implementation of Schedule M align India’s pharmaceutical sector with global GMP standards?

Schedule M has been revised to align Indian pharmaceutical manufacturing with global Good Manufacturing Practices (GMP), bringing India closer to international regulatory expectations, and making our pharmaceutical products globally more competitive. The objective is to ensure consistent quality, safety, and efficacy, thereby strengthening India's reputation as a trusted supplier of medicines.

MSMEs often struggle with regulatory compliance. You had announced an extension for the compliance deadline to December 2025. What prompted this decision?

MSMEs play a crucial role in the pharmaceutical ecosystem, but many of them face financial and infrastructural challenges in meeting stringent compliance requirements. The extension to December 2025 gives them additional time to upgrade their facilities, adopt new technologies, and implement best practices without disrupting their operations. The goal is to enable them to comply effectively rather than rush and face setbacks.

There have been concerns regarding repeated instances of Not of Standard Quality (NSQ) drugs. What are the key areas that require urgent attention to improve quality?

The most common quality concerns involve dissolution, assay content, and microbial control. By focusing on these areas, we can significantly reduce the occurrence of NSQ drugs. Companies must invest in robust quality control measures, regular training, and stringent internal audits to ensure that their products consistently meet the required standards.

Collaboration was a key theme of your speech. How can larger pharmaceutical companies support MSMEs?

Larger pharmaceutical companies have the resources, expertise, and infrastructure that MSMEs may lack. By mentoring smaller players—offering technical guidance, helping with compliance strategies, and even sharing best practices—they can elevate the overall industry standards. This will create a stronger, more self-reliant pharmaceutical ecosystem where quality and affordability go hand in hand.

"Give the regulator a chance not to regulate." This statement is meant to highlight the importance of self-regulation. If the industry proactively adheres to quality standards and best practices, there will be less need for regulatory intervention. The goal is for companies to take ownership of compliance rather than seeing regulations as an external burden. A proactive approach will not only reduce regulatory pressure but also boost confidence in Indian pharmaceuticals globally.

What is your vision for India's pharmaceutical industry in the coming years?

I envision a pharmaceutical industry that is self-regulated, quality-driven, and collaborative. We must maintain our position as a global leader in affordable, high-quality medicines while empowering MSMEs to grow sustainably. By focusing on execution, compliance, and industry partnerships, we can build a resilient pharmaceutical sector that contributes to both national and global healthcare.

Do you have a final message for industry stakeholders?

I urge all stakeholders—regulatory bodies, pharmaceutical companies, and MSMEs—to work together in a spirit of collaboration. Quality should not be an afterthought but an integral part of the manufacturing process. If we focus on execution with sincerity, India’s pharmaceutical industry will continue to thrive and set new benchmarks globally.

Bhagwati Prasad