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'Only 1,500 inspectors for regulating over 10K pharma factories in India'

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The country's top drug regulator, Drug Controller General of India (DCGI) has just 1,500 well-equipped inspectors deployed for regulating more than 10,000 factories engaged in pharmaceutical products, as a result Indian pharma products often face regulatory hurdles in the overseas markets like the US where stringent protocols for manufacturing processes are followed.

The latest study on Focus on Quality Management in Pharmaceutical Manufacturing jointly conducted by industry association ASSOCHAM and research firm RNCOS has highlighted the concerns in the report released on Thursday.

"While at times, the US Food and Drug Administration (FDA) gets into minute details which have more to do with the cumbersome procedure rather than quality, we need to get our own house in order by way of continuous skilling of the regulators at the national and State levels in sync with the best global practices, ASSOCHAM Secretary General DS Rawat said while releasing the report here.

Rawat further said, "However much we may wish otherwise, the pharma sector is and will always remain one of the most regulated sectors all across the world for the sake of public health."

The mismatch between the domestic regulatory mechanism and the international regime is resulting in recall and rejection of drugs made by even some of the well-known companies, leading to unrest and frustration.

According to the study, India ranks the 4th in pharmaceutical production in the world with a production output of about US$ 31 Billion in 2014. The country has a 1.4 per cent share by value and 10 per cent by volume in the global pharma industry. India is one of the leaders in pharmaceutical exports.

The study notes that while there were numerous patent offices in metro cities all over India, each of these offices follows non-uniform patent practices. Thus, these varied practices and poor centralised controls affect the quality of the pharmaceutical products.

The absence of global harmonisation of quality systems makes it all the more challenging for India that exports to US, Europe, Australia and Japan to comply with a plethora of regulatory guidelines across the globe, Rawat added.

Regulatory