

## Shortage of drug inspectors hurting pharma exports: Study

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India has a meager number of 1,500 well equipped inspectors for more than 10,000 factories engaged in pharmaceutical products leading to the country's products facing regulatory hurdles in the overseas markets like the US which follow stringent protocols for the manufacturing processes, a sectoral study done by The Associated Chambers of Commerce of India (ASSOCHAM) and research firm RNCOS has pointed out.

It said the Indian pharmaceutical sector which made rapid strides in the global markets, is now faced with several regulatory hurdles, especially in the US and EU, according to a study on 'Focus on Quality Management in Pharmaceutical Manufacturing,' jointly conducted by The Associated Chambers of Commerce and Industry of India (ASSOCHAM) and RNCOS.

"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. 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," ASSOCHAM Secretary General Mr D S Rawat said while releasing the study.

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. In the long run, the pharmaceutical exports during the fiscal year 2013-14 reported US\$ 14.8 billion of drug exports would take a setback.

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

The domestic pharma market was valued at \$15.4 Billion in 2014, and is expected to expand at a CAGR of 13.3% to \$32.7

Billion by 2020. Driven by favourable demographics including growing aging population, increasing lifestyle diseases, steep growth in disposable incomes and increasing penetration of Indian drug players in the global market, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size, noted study.

The pharmaceutical manufacturing is managed by multiple regulatory authorities, which include the Central Regulatory Agency, the office of the DCGI (Drugs Controller General of India) under Central Drugs Standard Control Organization (CDSCO) with zonal offices and the State FDAs. This makes the process of obtaining license, for pharmaceutical product manufacturing complex.

There are numerous patent offices in metro cities all over India. Each of these offices follows non-uniform patent practices. Thus, these varied practices and poor centralized controls affect the quality of the pharmaceutical products.

The pharmaceutical industry in India has a concurrent regulatory practice, which is sometimes poorly manned and poorly headed by less knowledgeable pharmacists who are not properly trained. Lower awareness among such personnel regarding the quality norms leads to non-uniform implementation of regulatory standards.

Small and Medium size manufacturers in the Indian pharmaceutical industry do not have the funds and the capacity to carry out the quality checks. The government provides subsidies to only those pharmaceutical companies, which are present in special economic zones. Manufacturers which are not present in these zones are not able to avail these benefits, which they can use for the implementation of quality standards in their manufacturing sites.

With the absence of global harmonization of quality systems makes it all the more challenging for India that exports to US, Europe, Australia, Japan, etc, to comply with a plethora of regulatory guidelines across the globe, said Mr Rawat.