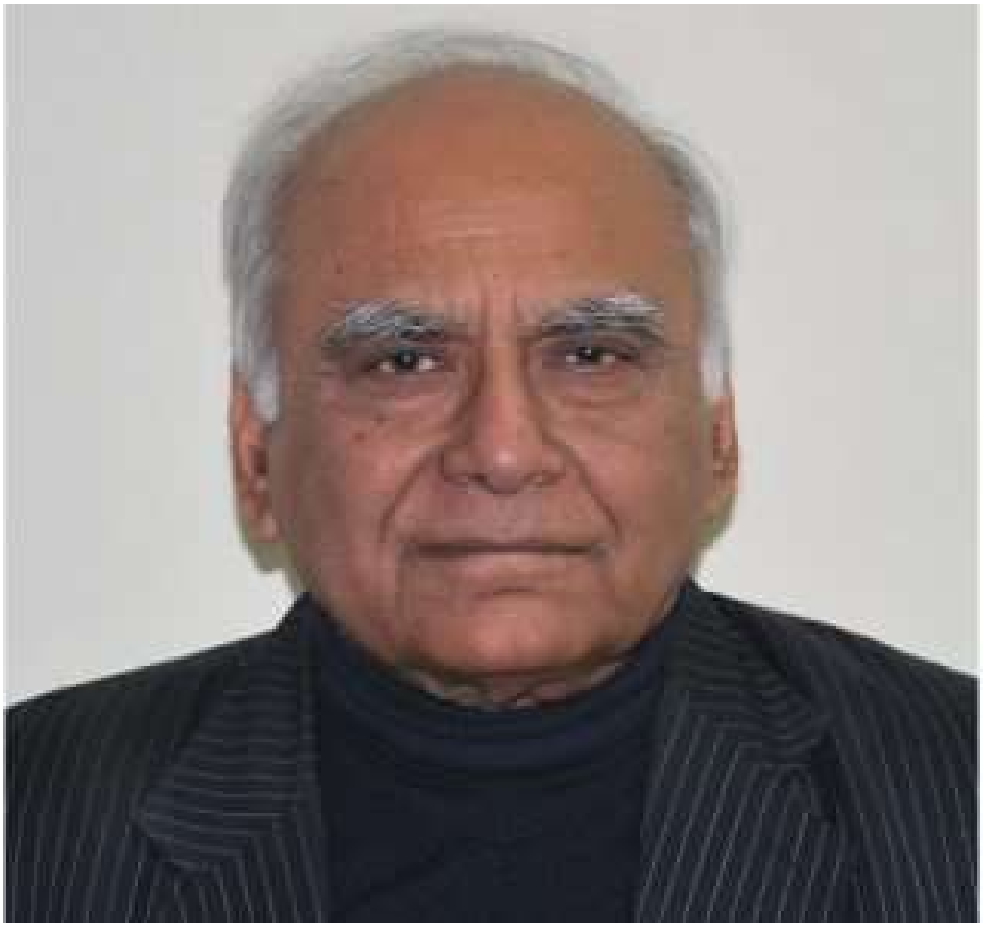
Indian pharma: Driving excellence in quality and patient centricity

Dr NK Ganguly, former Director-General, Indian Council of Medical Research (ICMR), outlines measures to enhance India Pharma Inc's expertise in manufacturing and exporting high-quality generics, and cement its position as the 'Pharmacy of the World'



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The Indian pharma industry has recorded tremendous growth over the decades, more so during the pandemic. The Indian pharma sector has continued to be one of the key stakeholders in the pharma supply chain, providing access to affordable and quality medicines. Even at a time when COVID-19 posed several challenges to manufacturing and transport, the Indian pharma industry was driven to meet domestic and export needs while ensuring the safety and quality of medicines. Companies toiled relentlessly to ramp-up production and ease out disruptions to ensure uninterrupted supply of medicines.

Considering the production capacity that the country enjoys, several countries across the world export from India. The US imports close to one-third of generics used, from India. This is due to the availability of a high volume of quality drugs at cost-efficient prices compared to other manufacturing hubs in the world. While volume is certainly key, quality is of equal importance and cannot be comprised with as patient-

maintained by every pharma company.

Considering India's expertise in manufacturing and exporting high-quality generics, diligent adherence to the USFDA guidelines is evident. A recent study published by the Centre for Drug Evaluation and Research (CDER) and the USFDA concluded the high-standards of Indian drugs. The study, conducted between February to November 2019, assesses the quality of imported drugs from outside the US. The sample size included 252 difficult-to-make drug products, of which 36 per cent of sampled products and nine per cent of finished dosages were from India.

Researchers stated these products met the US market standards for dosage unit uniformity and dissolution, indicating acceptability for use by patients regardless of manufacturer or region.

What could this mean for the Indian pharma industry?

It is evident that the stringent regulations set forth by the USFDA and Indian companies' compliance of the same imply that the quality of drugs is assured. Furthermore, the lure of Indian generics in the international community is undeniable. While Trump's recent call to 'Buy American' – a means for the American pharma industry to move towards self-reliance prompted countries across the world to delve into the larger implications this move would have on the global pharma ecosystem, such a shift is easier said than done. The high costs incurred in manufacturing drugs in the US coupled with the low-profit margins the companies would face, given the drug prices in the country, would make importing drugs from countries like India an attractive option.

Having said that, there is scope to further strengthen the Indian regulatory system. The Indian pharma sector must become more stringent when it comes to the quality of drugs and the manufacturing process. The Indian drug regulatory system is complex. To meet the global standards of manufacturing and quality assurance, the institution of a regulatory authority independent of bureaucracy is imperative. This will ensure transparency in the entire manufacturing ecosystem. Providing impetus to pharma companies which, over the course of COVID, have forayed into new drug discovery is also essential. Driving innovation through a single window, fast-track approvals without compromising on quality will be crucial, going forward.

To surmise, the guidelines set out by the USFDA, along with the industry's commitment to provide high-quality, affordable generics to the country and the world are evidenced by both the CDER study and India's position as the leader in the generics space, specifically in the exports market. However, there is further scope in the regulatory ecosystem to be further strengthened. Companies complying with the guidelines following safe manufacturing practices which in turn ensure the export of high-quality, safe and efficacious therapeutics should be incentivised. In doing so, India will certainly cement its position as the 'Pharmacy of the World'.

Dr NK Ganguly | Indian drug regulatory system | Indian generics | Indian Pharma Industry | Pharmacy of the world | USFDA

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