By

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It is no secret that India is the world's largest exporter of quality generic drugs and the pharmacy of the world. India currently contributes 26% by volume of generic therapeutics globally and supplies over 60 per cent of global demand for various vaccines & ARV drug supplies, 30% of UNICEF's annual supply globally and about 60%-80% UN purchases of drugs, approximately 57% of APIs and 69% Finished Pharma Products (FPP) to the Pre-Qualified list of WHO. This faith in Indian drugs and competitive advantage could be further enhanced by strengthening and simplifying regulatory systems in India. The Indian pharmaceutical sector has an unshakeable set of laws and initiatives, at state and federal levels, to ensure the highest level of quality and safety for its drugs. Upskilling state drug licensing authorities, strict compliance with the Drugs and Cosmetics Act 1940 and the ongoing fight against spurious drugs are a few measures in place, reinforcing the pharma sector's commitment to delivering the best therapeutics to patients across the world. Regulatory bodies are also enhancing their capabilities for developing systems and processes

for enforcing quality control measures

With quality, efficacy and price taken care of, there is a perception mêlée that needs to be put to rest. Majority of the healthcare ecosystem operates under the assumption that if something is available at a lower price, it is of questionable quality. This brings forth a dire need to boost public confidence in medical products from Indian pharma industry.

Most of the healthcare ecosystem, including doctors tend to prescribe branded drugs over the more affordable generic alternatives. This is because of the misconceived notion that affordable drugs tend to be of lower quality. Often, medical practitioners also cite ineffectiveness of the generics in treating ailments as reason for not recommending them to patients. However, misdiagnosis of the condition, prescribing wrong therapeutics and low patient compliance can impede treatment just as much. Instead of addressing these issues, most doctors allege that the problem lies with the quality of the drugs. It will be incorrect to ascertain that all generic drugs are substandard or all branded drugs genuine.

For effective addressal of the issue, the Government should bring in drug testing laboratories, wherein any stakeholder, including patients, can get generic drugs tested for their quality. Since only a few state governments have such facilities in place, it often takes weeks, even months to receive results. The Government should work on such capacity building at National Institute of Pharmaceutical Education and Research (NIPER) and other academic research facilities with such state-of-the-art quality-testing infrastructure. Over and above, the Government should also ensure that all medical colleges in the country have elementary drug testing facilities. They should also have an empanelment of National Accreditation Board for Testing & Calibration Laboratories (NABL) labs.

The Government must ensure that all the drug

manufacturing units, irrespective of size or manufacturing capacity, strictly adhere to the WHO's Good Manufacturing Practices (GMP). Establishing a central body as a watchdog for all the manufacturing facilities in the country will set the benchmark for its quality.

In addition to expending efforts on quality, the government should deliberate on leveraging technology in the pharma space. While ensuring correct prescriptions for drugs, there should be supplementary efforts to educate the public on keeping track of the batch numbers of the drugs. Through this, the medicines can be tracked and tested for quality and efficacy as well. Furthermore, the Government should explore the use of Blockchain to track the drugs – from manufacturer to patient, to ensure complete safety and transparency.

Though much progress has been made in the pharmaceuticals and healthcare sector, India should also drive an increased thrust on developing new and improved drugs, biologics, medical devices, diagnostics and vaccines. This will provide further impetus to quality, accessibility and affordability of medicinal products thorough innovation and stringent regulatory oversight.

There is a strong need to create collaborative synergy between academia, industry, research laboratories and regulators along with conducive policy framework to foster innovations. Through consultative process with stakeholders and appropriate policy changes within stipulated time frame, India's leadership position as a provider of safe and high-quality medicines around the world will be reinforced.

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