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Indian pharma industry: From cultural practices to quality intensive; what lies ahead?

Satish Reddy February 28, 2020

It is a matter of pride for India and a feather in our economy's hat that the Indian pharmaceutical industry is the world's third largest by volume, today. The industry's journey started out with the export of active pharmaceutical ingredients (APIs) to meet global requirements and subsequently evolved to develop world-class capabilities in formulation development, coupled with the vision of creating the best possible patient-health outcomes.

Today, the industry has scaled the annual revenues of \$40 billion and aspires to grow up to \$120 to \$130 billion by 2030 at a compound annual growth rate (CAGR) of eleven to twelve per cent. It will mean that the Indian pharmaceutical market will break into top 5 markets in the world from its current ranking of 11th market by value and number one in volume terms.

The Indian pharmaceutical industry has taken robust strides in ensuring the highest possible standards in quality and efficacy of medicines at affordable costs to patients.

This has significantly advanced public health outcomes in India. The disease burden measured in disability adjusted life years (DALY) has declined by 36% since 1990. The treatment costs of life-threatening diseases like Hepatitis C and Leukemia has reduced by 95% due to the availability of high-quality medicines at a significantly lower cost.

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We export pharmaceutical products in more than 200 countries across the world for the prevention and treatment of diseases, this goes on to demonstrate the faith in the quality of Indian drugs.

The industry designed and built its entire quality management universe with the patient as the nucleus. Initially, the quality efforts were directed at improving manufacturing infrastructure and processes to deliver quality drugs consistently.

This was followed by augmenting the R&D sector and today the field has evolved tremendously. It now includes analytics and the latest technologies in manufacturing.

The industry has invested in developing an extensive framework for integrated quality management systems to move beyond the use of good manufacturing practices (GMP) checklists to embrace total quality management (TQM) practices which span the product development life cycle.

In my opinion, adopting this quality culture has led to noteworthy advancements throughout the supply chain and has ultimately created a positive feedback loop wherein incremental improvements in processes have led to vast improvements in the quality system as a whole.

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The improvement in quality systems is further highlighted by a 200% reduction in official action indicated (OAI) as a share of total inspections by the USFDA from 2014.

Employees in a patient-centered culture understand how their work impacts the lives of patients and strive to develop products and solutions that improve patient outcome.

Thus, the industry has transformed its cultural practices to be quality intensive. This has been possible by conducting capability building workshops, periodic trainings and internal forum discussions which has improved awareness amongst employees at all levels.

The urge for framing policies to be quality driven and consequently, patient centric has been taken up in earnest by the industry and it will only evolve in the years to come.

The grand vision of the industry is to be the global benchmark in quality. In order to do so, I believe it must consistently deliver the best patient outcomes- better quality of life at a lower cost burden while accounting for the needs and expectations of the end-user.

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The Indian industry has surged towards this vision by having the highest number of USFDA approved plants (665) outside of the US as well as 42% of global abbreviated new drug applications (ANDA).

The diligent focus on quality has made the Indian industry a significant contributor towards shaping global vaccination; it accounts for nearly 60% of vaccine production worldwide.

The key priorities for the industry in quality management, going forward, will be to implement best practices on product robustness, analytical method development and continuing the thrust on culture transformation.

The knowledge sharing and training programs conducted in collaboration with academia will serve to improve the talent pool and upskill the employees across all levels.

(The author is President, Indian Pharmaceutical Alliance and Chairman, Dr Reddy's Laboratories.)

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