

Patient-centricity must drive the pharma sector

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“You treat a disease: you win, you lose. You treat a person, I guarantee you you’ll win, no matter what the outcome.” These words by Hunter Doherty “Patch” Adams, the doctor-comedian-author, truly underline the patient-centric approach that is bringing in a paradigm shift in healthcare.

However, just as the Indian pharma industry needs to revise and revamp its operating model and offerings, of equal importance is the flexibility and evolution of the regulatory system.

Covid-19 has shown that a comprehensive patient-centric approach is the future of healthcare and the pharma industry. It must infuse and define the industry’s purpose and vision. With technology and digitisation pervading the industry at a far rapid pace than ever imagined, this shift will be much more immediate than imagined.

Today, physicians need better tele-medicine and training standards to ensure that a virtual touch translates to healing; equally, pharma companies have to look

beyond drug innovation to a digital revolution in how we do research, how we manufacture, and how we test products.

India enjoys an eminent position in the global pharmaceutical market — a position that was created through hard work and grit. The \$41-billion Indian pharma industry exports to 200 countries.

The industry is the largest provider of generic drugs globally and supplies over 50 per cent of the global demand for vaccines, 40 per cent of generic medication in the US and 25 per cent of all medicines in the UK.

For decades we have lived up to the proud claim of being the pharmacy of the world. Covid only served to reinforce it.

From ensuring supply of essential drugs, re-purposing existing drugs, expediting the supply of PPEs and testing kits, to supplying vaccines to other nations while balancing a huge domestic demand,

India has once again proven its leadership in supporting the world in tackling widespread health crises. It is humbling to see that we were once again given the



Quality manufacturing A long way off

opportunity to serve, and do what we have done during previous crises such as those associated with tuberculosis, HIV, and malaria.

Covid also showed us that despite the size and spread of the industry, being agile and adaptive are not management mantras, but are essential to our survival. From ensuring stable supply chains to being at the frontier of the latest developments in the pharma sector, the industry has made rapid progress.

A recent example is when a number of firms had to recall their batches of diabetes drug Metformin due to NDMA impurity levels. The industry took immediate action, addressed the issue and relaunched the drug, ensuring

supply to much-needy patients.

As a responsible global healthcare partner, the industry has always ensured compliance with global quality practices. However, as leaders we should set the bar. A lot more remains to be done for India to be the global benchmark in quality manufacturing. Pharmaceutical manufacture and testing is complex, with a lot of human touch.

Tap the data

In many ways, we are still manufacturing and testing the way we did 20 years ago. This cannot be the story for the next 20 years. Even if you keep aside areas like continuous manufacturing, there is a huge amount of data being generated by our machines and instruments that must be used.

Whether it is to optimise manufacturing yields, avoid batches that fail, or build in testing into the process, there is so much that can be done. Being patient-centric for the pharma industry means ensuring that patients are front and centre in all that we do — that today means boldly ushering in a new age of automation and digitisa-

tion to ensure controls like we never had before on our products, processes, and quality systems.

Part of being the global benchmark is a constant understanding of the benchmark. A frank exchange with bodies like the USFDA is a must.

While mission critical inspections of Indian facilities by the USFDA have resumed, the pace of these inspections has been limited by Covid. Other regulatory bodies such as those of Europe, the UK and Australia have shown openness to alternative modes of inspection such as virtual/remote audits.

In a Covid-19 world, hold up in approvals for new products and plants creates gaps in drug supplies and vulnerabilities in supply chains. Part of being patient-centric for regulators is to ensure that they get the innovation, approval and inspection cycle going, whatever it takes.

Patient-centricity in all we do is the much-needed shot in the arm for this industry to now rise to its true level.

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