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Indiaâ??s next pharma leap depends on fixing last-mile drug safety

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Final stretch of pharmaceutical distribution is where the most variables collide



Consider a temperature-sensitive biologic moving from a manufacturing hub to a hospital in a Tier II city. It may pass through three or four storage points, two logistics partners, and any number of handling environments before it reaches a patient. At each of those transitions, what matters is not just how the medicine was made, it is how it was carried, stored, and watched over.

India's pharmaceutical reputation has been built, rightly, on the strength of its manufacturing. But the industry is at a turning point. The products leading the next phase of growth demand something more.

India exported pharmaceutical products worth $30.47 billion in FY25, reinforcing its position as one of the world's leading suppliers of medicines to global markets. Yet the medicines driving the next phase of growth will look very different from the generics that first put India on the global map.

Biologics, biosimilars, specialty therapies, advanced vaccines, these are not products that travel well under ordinary conditions. They are sensitive, they are expensive, and when something goes wrong in transit, you often cannot tell by looking at them.

The New Quality Challenge

For most of pharma's history, quality was a manufacturing conversation. You built the right facility, followed the right processes, passed the right audits, and the product was considered safe to release.

That thinking has a gap in it, and the gap is growing.

A biologic that leaves a temperature-controlled facility and then sits in an inadequately cooled vehicle for two hours has not been protected. It may look identical to an uncompromised vial, but its molecular structure may have shifted in ways that reduce its effectiveness. The patient receiving it has no way of knowing. The prescribing doctor has no way of knowing. The failure only shows up as a treatment that didn't quite work, and by then, the chain of events that caused it is long buried.

This is not a hypothetical. It is an operational reality that the industry has been slow to fully reckon with.

Manufacturing quality and distribution quality have long been treated as separate domains, different teams, different audits, different accountability. But from a patient's standpoint, there is no such distinction. A medicine that was made correctly but

handled incorrectly is a compromised medicine.

India's geography makes this particularly pressing. As better healthcare infrastructure reaches smaller cities and towns, advanced therapies are following. That access is genuinely important, but it also means cold chains now need to perform reliably in places where the conditions are harder and the backup systems thinner.

Why the Last Mile Matters More Than Ever

The final stretch of pharmaceutical distribution is where the most variables collide.

Manufacturing happens in controlled, audited, purpose-built environments. The last mile does not. It involves different carriers, unpredictable road or weather conditions, multiple handoffs, and often a lack of real-time information about what is happening to the shipment. For conventional cargo, that is manageable. For a cancer biologic or a pediatric vaccine, it is a risk that needs to be actively managed, not assumed away.

Direct-to-patient delivery has added another layer to this. Patients now expect medicines to arrive at home, and as that model grows, the cold chain needs to follow them there. Speed matters to patients. But a medicine that arrives on time in a compromised state is not a delivery success. It is a quiet failure.

What has changed in recent years is the definition of what good pharmaceutical logistics actually means. It used to mean availability, the right product, in the right place, at the right time. That remains necessary, but it is no longer sufficient. Today, the question is whether the product that arrived is the same product that left. Whether its integrity held across every kilometre of the journey.

Those are not the same question, and the industry needs to be honest about that difference.

Distribution Is Becoming a Competitive Differentiator

Pharmaceutical companies investing in biologics and specialty medicines are making long bets, years of R&D, significant capital, complex regulatory pathways. The idea that the distribution of those products is someone else's problem, a back-office concern, is increasingly hard to defend.

How a product is delivered affects how it performs. How it performs affects whether healthcare providers trust it. Whether they trust it affects whether it gets prescribed. The chain is direct.

Globally, the more sophisticated pharmaceutical companies have already drawn this conclusion. They are building visibility into their supply chains, extending quality systems beyond their own walls, and holding distribution partners to standards that were once reserved for manufacturers. The question they are asking is not just whether a batch passed quality control, it is whether its integrity can be verified all the way to the patient.

That shift will reach India, and it will reshape how pharma companies here think about who they work with and what they expect from them.

Regulation Is Reflecting This New Reality

CDSCO's Good Distribution Practices guidelines represent a meaningful shift in how India's regulatory framework thinks about pharmaceutical quality. The guidelines place increasing emphasis on temperature controls, traceability, storage standards, transport validation, documentation, and chain-of-custody monitoring, reflecting a broader shift towards end-to-end product integrity across the pharmaceutical supply chain. The focus on temperature controls, chain-of-custody documentation, transport validation, and traceability is not bureaucratic box-ticking. It reflects a genuine understanding that a drug's quality is only as good as the conditions it was kept in throughout its journey.

The inclusion of logistics providers, transporters, and distributors within the compliance perimeter is significant. It closes a gap that has existed for too long, the idea that once a product left a licensed manufacturer, the quality responsibility transferred to someone operating under far less scrutiny.

Companies that take these guidelines seriously, rather than treating them as the minimum bar, will be better prepared for where regulation is clearly heading.

Technology Is Enabling a Safer Future

The practical tools for doing this better are not new or experimental. They are available and increasingly affordable.

IoT-based temperature sensors can track a shipment's conditions continuously and flag a breach the moment it happens, not after delivery, not at the point of dispensing, but while the product is still in transit and something can still be done. Real-time visibility platforms give supply chain managers a live view of where shipments are and what conditions they are moving through. Predictive tools can flag routes or timeframes that carry higher risk before a truck even pulls out of the depot.

The value here is not complexity, it is timing. The difference between catching a temperature excursion mid-journey and discovering it on arrival can be the difference between a recoverable situation and a lost batch, or worse, a compromised treatment reaching a patient.

For an industry where trust is everything, the ability to demonstrate, not just assert, that a product's integrity was maintained is fast becoming a baseline expectation.

The Next Leap Will Be Defined by Delivery

No single organisation can fix last-mile drug safety on its own. It requires manufacturers, logistics providers, healthcare institutions, and regulators to take shared ownership of what happens after production ends.

India has proved it can make medicines to world-class standards. The harder, less glamorous challenge is making sure those standards travel with the product. Every storage facility, every refrigerated vehicle, every last-mile delivery agent is part of that commitment, whether or not they currently see themselves that way.

The future of this industry runs through biologics, through personalised medicine, through therapies that were unimaginable a generation ago. Those medicines will reach their potential only if the systems carrying them are worthy of them.

India has earned its place as the pharmacy of the world through manufacturing excellence. The next chapter will be defined by whether that excellence can be preserved all the way to the patient. In an era of biologics, precision therapies, and increasingly complex treatments, the last mile is no longer a logistics challenge.

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