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Need to Change Organisation Culture

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If you reward behaviour that justifies shortcuts, recognise and promote people who use whatever means to get the outcome the management wants, and this happens over decades, it gets ingrained in the DNA of the organisation.

Replacing the executive team and the board or hiring highly-paid consultants and lawyers will not make the people who are responsible for day-to-day activities do things differently.

How often does a plant operator in Toansa or Mohali get to meet and hear directly from the CEO on the organisation's new values? It's probably from a behaviour management consultant who makes an hour-long presentation at the manufacturing facility and we all know how effective that is.

Investing money in upgrading facilities, paying top-notch consultants to develop change management strategies cannot substitute for a few "teachable moments" that leaders within the organisation can create, when they choose to join hands with scientists and operators at the lowest rungs. The FDA's inspectors at Toansa document repeatable actions that can only be called "data fraud". People destroying test results they don't like, backdating them, the list goes on. This is not the first time we have seen this behaviour; it was the reason why Paonta Sahib and Batamandi facilities had to be mothballed. People who were not even present at those sites had signed off on validation documents. To make this behaviour relatable, would you go to a lab for a lipid profile if they first asked you what you wanted the result to be?

IS RANBAXY AN EXCEPTION?

We have seen similar observations by FDA at other pharma companies. It is important to ask why such behaviour is pervasive. In my opinion, the industry is run by a very small and closed professional society. People rotate among these companies frequently, moving into successively higher positions of authority. Unfortunately, they also take the baggage from their previous employer to the new workplace. What has worked well in the past and has given them the "success" they think they have achieved is the first thing they implement at the new workplace. This is how these behaviours spread.

I was amused to read in an article in ET last year about a senior executive in Ranbaxy acknowledging that they had only fudged the data to obtain expedited approvals from FDA but had not compromised on the manufacturing process. I always wondered how one could stop people from emulating behaviour that was acceptable in one part of the organisation to another and call it unacceptable there, especially when two different sets of standards exist by design. If this is an example of how bad behaviour spreads within the organisation, why are we surprised when representatives in management from one company join a different one and the second company is then pulled up for similar violations by foreign regulators?

IS OUR DRUG SUPPLY SAFE?

This brings us to the fundamental question: Is the drug supply in India really safe? Why is it that these egregious violations have all been detected by foreign regulators? But for my case against Ranbaxy and FDA's regulation in the US, the behaviour which has now become so objectionable would have gone unnoticed, even by foreign regulators. "Experts" have argued that these are merely "documentation-related" violations; they have no bearing on the quality of the product. I wonder what these "experts" consider as violations that impact drug quality.

When we say that we have different standards compared to the West, are we saying that we accept people lying about or backdating test results? How about substituting lower-quality ingredients to save a few hundred rupees? Is that acceptable by our standards? Or is that merely a "documentation" problem? It makes a good talking point to say that the western pharma industry is out to malign the industry in India, but given all the data, this argument is wearing thin. More importantly, we are beginning to lose credibility. Rather than fixing our ills, we continue to blame others. That is never a good long-term strategy.

CURING THE ILLS

The cure is not a band-aid approach that addresses one issue at a time, but to fundamentally rethink what it means to put your brand on a product that people rely on when they are sick, when they are most vulnerable. We need to get back to a time where doctors trusted the medicines that they prescribed to work as intended and patients trusted them to make them better. We need a fundamental change in our approach to quality.

We need to think in terms of "risk" to our supply chain of medicines and how we mitigate these "risks" in a continuous fashion. We need to be able to monitor what happens at these sites when the inspectors are not there, on a continual basis so that we can correct the operator who repeats testing the sample that failed the first time and destroys the original record. We need to inculcate a sense of responsibility among the scientists who are developing our formulations that unless it passes the quality test, it won't go down the supply chain to get packaged.

It will take a long time to undo the ills of the past, but this approach will give us lasting results, unlike the solutions we have focused on thus far. Hopefully then, we can say with confidence that we really stand behind every pill, every injection and every prescription that we fill for patients.

(As told to Soma Das)

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