PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Business Line, Delhi
Monday 27th January 2014, Page: 17
Width: 24.77 cms, Height: 23.64 cms, a3r, Ref: pmin.2014-01-27.23.94

'Our propensity for jugaad comes in the way of developing quality'

Ranbaxy whistle-blower Dinesh Thakur on the importance of accountability starting at the very top of a company

PT JYOTHI DATTA

The year has barely begun and Ranbaxy is already weighed down by bad news: following a regulatory observation against its plant in Toansa, Punjab, the US last week imposed a ban on imports from this facility citing manufacturing violation.

Why do drug companies fall short of regulatory standards?

"Accountability begins at the top, not the other way around," says Dinesh Thakur, a former Ranbaxy executive who exposed [illegible] manufacturing [illegible] the company eventually paid up $500 million to settle fraud and criminal charges against it in [illegible] runs the US-[illegible] Global Compli[illegible] [illegible] year. [illegible] an email interview to *Business Line* days before Ranbaxy received its second regulatory rap on Toansa in less than two weeks. Excerpts from the interview:

The year began with regulatory trouble for Ranbaxy in the US. Tough times for Indian drug-makers this year too?

The simple answer is yes, I think scrutiny is only going to increase based on data. And here's why. First, the US Food and Drug Administration in India has increased its strength to 19.

We have read comments from the UK regulatory officials about their confidence in the integrity of data from Indian companies. Clearly, regulatory attention and focus on compliance and quality has increased.

Second, it seems that the corrective actions being taken by India-based companies are falling short of what is needed to fix the problems. Third, national regulators are collaborating because individually they don't have all the resources needed to inspect every manufacturing facility effectively. This will result in more comprehensive inspections going forward.

Lastly, when the news broke last May, there was a lot of pushback that what happened at Ranbaxy was an isolated incident. Clearly that was not the case. We have seen dominos continue to fall after my case became unsealed at other India-based pharma companies. All this points to difficulties continuing for Indian pharma companies for some time before things get better.

How does a regulator haul up a drug-maker [illegible] process and [illegible] consump[illegible] due to [illegible]

[illegible] let us understand what actually happened. When the US FDA invoked the Application Integrity Policy against Ranbaxy in September 2008, the only drug exempted from the import alert was Ganciclovir Sodium.

Over 30 other drugs made by Ranbaxy at the Dewas and Paonta Sahib facilities were banned from being imported into the US. Ranbaxy was the sole supplier of Ganciclovir oral capsules to the US. Consequently, it was exempted from the import ban.

Ganciclovir is an anti-viral used to treat infections. There are other generic drugs in this class available in the US that address the same therapeutic need. The import alert never said the FDA did not suspect the quality of the drug; in fact, the FDA included this drug among the list of drugs manufactured by Ranbaxy at manufacturing sites put under import alert. In doing so, the agency allowed physicians to make a decision on whether to continue use of the drug (identified as questionable by including it on the import alert list) or use one of its competitors in treating patients.

Was it an ideal outcome? Clearly the answer is no. The important point here is that the USFDA recognised that their dependence on foreign manufacturing sites, where their oversight was lacking, led to this undesirable situation. Subsequently, they have created a new policy under the FDAsia regulation to ensure it doesn't ever find itself in similar situations in the future.

Ranbaxy received an inspection observation from the USFDA on its plant at Toansa. How does this [illegible] despite the company saying it is on the mend?

Consultant [illegible] on how to do [illegible] not have [illegible] ment and [illegible] vice. This [illegible] responsib[illegible] don't change their behaviour because some consultant asked them to.

Based on what I experienced at one company, for far too long, people accepted and imbibed a culture that was encouraged and rewarded. Scientists and operators were incentivised to act in a manner that produced results desired by the management by whatever means necessary.

The means always justified the end. This culture led to what you see happening to these companies today. It's a very small professional circle within the industry; people take their lessons, both good and bad, when they leave one organisation and join another.

> *It is common knowledge that we have two standards for quality; one for "regulated markets" which include the US and Western Europe. There is a lower quality threshold for markets where regulations are not as stringent.*
>
> DINESH THAKUR
> Founder, Medassure Global Compliance Corporation

Does India have cultural issues? For instance, people on the shop-floor not understanding the gravity of good manufacturing practices?

Yes, I do. I have argued that our propensity for *jugaad* (quick-fix solutions) comes in the way of us developing quality systems and products. Public conversation after Ranbaxy pleaded guilty to felony charges last May was hijacked by talking heads who argued that the violations at Ranbaxy were nothing more than paperwork. If these "experts" want us to bury our heads in the sand rather than acknowledge a real concern, why do we blame people on the shop-floor for lack of understanding of the [illegible] If the tone of the communication is that violations are downplayed as nothing more than paperwork, do you expect people on the shop-floor to take it seriously?

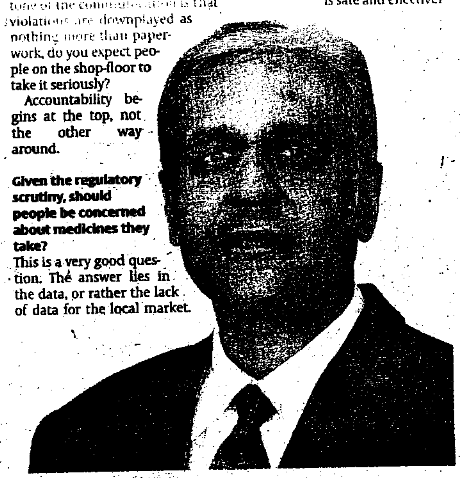
Accountability begins at the top, not the other way around.

Given the regulatory scrutiny, should people be concerned about medicines they take?

This is a very good question. The answer lies in the data, or rather the lack of data for the local market.

Regulators such as the USFDA and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) take decisions based on hard data. There are systems available, for example the Adverse Event Reporting System in the US which captures side effects from all prescription drugs. Data collected by such systems are used to arrive at fact-based conclusions by these regulators.

What data to we have to make similar decisions in India? Does our adverse-event reporting system capture a majority of side-effects from drugs sold in the country? How long have we had a system to assess the history of any company with its products for quality? Do we know the frequency of lack-of-effect cases in our patient population? In the absence of this data, on what basis does anyone conclude whether our drug supply is safe and effective?



miscellaneous.