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Are Indian Pharma Cos Overdosing on Lethal Drug of Fraud?

SCEPTICAL: Thakur says the short-term, band-aid approach of Indian pharma industry doesn't seem to be working

DINESH S THAKUR

Ranbaxy and Wockhardt not alone, practice likely industry-wide

We now know that the behaviour that led Ranbaxy to sign the "unprecedented" consent decree in 2012 with the US Food & Drug Administration (FDA) was not limited to just two manufacturing sites. In 2013, the US regulator brought its Mohali facility and last week its Toansa API facility under the consent decree. Clearly, public representations made by the company in the past citing investments in upgrading facilities and other corrective actions don't seem to have affected its operating culture. The recent FDA observations on the company's Toansa facility remind me of similar instances when I was asked to investigate the extent of data fraud back in 2005.

Regulatory action has not been limited just to Ranbaxy either; we have read about a similar situation at Wockhardt and to a lesser degree at other firms. Clearly, Ranbaxy is under greater scrutiny but that doesn't mean this behaviour doesn't pervade the rest of the industry.

An objective evaluation of the observations made by regulators at other companies' facilities indicates that symptoms aren't very different from those at Ranbaxy and Wockhardt. In that sense, both Ranbaxy and Wockhardt are the leading indicators of the status of compliance and quality of the industry in general.

A root-cause analysis shows that the short-term, band-aid approach isn't working.

Culture in any organisation doesn't change easily. It is formed over a number of years from the actions and behaviour of management and employees.

Need to Change Culture ▸▸ 15

IMA will Seek Clarity on Drugs

The Indian Medical Association, a grouping of 78,000 doctors from across the country, would be seeking clarity from the Indian drug regulator on the quality of Ranbaxy's drugs, its general secretary Narendra Saini told **Soma Das**.

~~Advocacy~~ Regulatory