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Indian pharma's twin woes

Government, research bodies and doctors must share blame

The Indian pharmaceutical industry is beset by two adverse conditions — one is a recent development and the other a long-standing malady. Most recently, leading pharmaceutical company Ranbaxy met with yet another regulatory mishap: the United States Food and Drug Administration, or FDA, withdrew approval for the firm's Toansa plant because of significant lapses in manufacturing practices. The fourth Indian plant of the company to suffer such a setback from the US regulator, Toansa is the major supplier of low-cost active pharmaceutical ingredient, or API, a key raw material for some Ranbaxy products marketed in the US. Maintaining both volumes and margins in a market accounting for more than a third of consolidated global sales will now be difficult, if not impossible. The unique selling proposition of Indian exporters of generics – and the US market is the world's biggest – is their cost advantage. To lose it even temporarily is to be severely hampered. Ranbaxy is not the only Indian pharmaceutical company to face such developments as the FDA has tightened up its own act. All those affected have only one course ahead of them: satisfy the FDA, the global leader in pharmaceutical regulation whose actions are carefully monitored by other regulators around the world, so as to regain unhindered access to the world's most lucrative pharmaceutical market.

The longer-term adverse condition relates to the regulatory regime for clinical trials in India, which is getting so restrictive that several leading pharmaceutical companies are in the process of going to other geographies to conduct such trials. This represents a double whammy, since not too long ago India was seen to hold great potential in hosting such trials because of its cost advantage. The country is already losing earnings from the operations of global contract research organisations (CROs), as the number of clinical trials allowed has plummeted. Besides, the Indian pharmaceutical sector's cost advantage, on much of which the industry's global competitiveness is based, is likely to be dented if the cost of conducting clinical trials goes up substantially. These are needed to generate data to establish the bio-equivalence of generics that seek to replace drugs going off patent and on whose global sales the Indian pharmaceutical industry thrives. Who is responsible for this? Indian regulators and Ghulam Nabi Azad, who has been the Union health minister since 2009, owe an explanation.

In a repeat of what has been happening in the case of iron ore mining, lax regulation has led to serious wrong-doing by a section of business, causing citizens' interests to approach the Supreme Court. The latter has put business-as-usual on hold and asked the government to come up with new and elaborate rules and procedures. As these take shape, industry is claiming some of them to be excessively onerous, to the point of being "ridiculous". With death during clinical trials far higher in India than elsewhere and many instances of poor and barely literate patients being taken for a ride (they were not even told they were being roped in for an experiment, not to speak of obtaining proper consent), doctors and CROs also have a lot to answer for. All that can be hoped is that new procedures will be in place and working soon so that there is regulatory certainty.

Industry