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Stiff dose

The US action against Ranbaxy calls for improving our own drug regulation

HAD it not been for the massive crash in their stock prices and huge erosion of shareholder wealth, the recent action of US Food and Drug Administration (FDA) against two large Indian pharmaceutical companies, Ranbaxy and Wockhardt, would have not made the headlines. It is about time the Indian authorities opened their eyes and looked at the manufacturing practices followed in the Indian pharmaceutical industry. Last week Ranbaxy's Toasna plant was banned from supplying drugs to the US or raw materials to its factories in that country because flies were found in the sample room at the Indian plant. In the case of Wockhart, urine spilling over open drains, soiled uniforms and mould in a raw material storage area are reported to be some observations of the FDA during inspection of an Indian factory of the company. It appears the Ranbaxy management learnt nothing from experience: Toasna is the company's fourth factory banned from supplying drugs to the US market. This, after Ranbaxy agreed to pay a fine of $500 million to settle a matter with FDA. What is of note is that these factories do not belong to small drug companies that mushroomed in certain industrial clusters following a government decision to give tax benefit to companies in hill regions. These are factories belonging to billion dollar market cap drug companies that at one point were showcased as jewels, which would some day, move the indigenous drug industry away from being copycats to being research and development-based. The inspections and subsequent findings of FDA raise multiple questions that both the companies, and central and state-level drug regulators must answer. The state-level controllers are being renamed food and drug administration departments with the responsibility of looking at drug factories in their jurisdictions. Why does it take a foreign regulator to come and inspect for us to know that the factories of our large drug firms are unhygienic? Has no Indian regulator ever carried out such inspections? If not, why shouldn't they be brought to book for negligence? And if they have carried out inspections, why have they failed to report the shoddy conditions take action against these companies? Are the regulators corrupt or incompetent, or both? If on inspection (assuming it was an honest exercise, not subverted with bribes) our regulators found nothing wrong, the only conclusion is that our standards of quality control are questionable. In that case, the onus is on the government to beef up regulations if only because we also deserve to have the same quality of medicines as anyone in a developed country. And of this is the state of affairs at large firms that have the money muscle to maintain quality (but don't), one shudders to think in what state the factories of small drug firms is. Small firms do not have large resources nor are inspected by FDA, but are big suppliers of medicines in tier II and III cities. Most of them claim the tax benefits and low marketing overheads make their drugs cheaper. The government needs to check whether they are compromising quality in the process of making cheap drugs and punish the black sheep. This can only be done if the regulatory mechanism is efficient and honest with the wherewithal to make proper inspections. Equally important, all such inspection reports should be made public.

mymind@mydigitalfc.com

Regulatory