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Bitter medicine

Never mind whether USFDA regulations are irrationally stringent. Let's take corrective measures for the sake of our pharma exports

The US Food and Drug Administration's (USFDA) ban on import of active pharmaceutical ingredients from Ranbaxy's plant at Toansa in Punjab – in addition to three other of its earlier blacklisted manufacturing sites – has implications for more than just the beleaguered company. To start with, Ranbaxy Laboratories is not alone. The USFDA has also identified "significant violations of current good manufacturing practice (cGMP) regulations" at two facilities belonging to Wockhardt, apart from issuing warning letters to a host of other firms such as Dr Reddy's, Lupin, Sun Pharma and Aurobindo Pharma. While Ranbaxy may be the only company to have been prohibited from manufacturing drugs from all its Indian plants for the US market, the matter is serious enough for the Centre to sit up and take notice. The Drug Controller General of India and other authorities must work closely with the pharma industry to evolve systems for enforcement of compliance with global cGMP standards. At stake is India's $15 billion-a-year pharma exports, over a quarter of which goes to the US.

The industry may well say that irrespective of the USFDA inspections revealing significant deviations from the cGMP standards, there is no evidence to suggest that the exported drugs are of substandard quality. In fact, what the USFDA calls "adulterated" drugs includes any medicine not manufactured under conditions confirming to its cGMP regulations – it does not necessarily mean the product is inadequate. Ranbaxy continues to export to other regulated markets and the fact that many of its finished pharmaceutical products are listed under the World Health Organisation's Prequalification of Medicines Programme supports such a claim.

But there is little to be had in pushing such a line of argument. The truth is that if a company hopes to export to the US, it has no option but to meet the latter's regulatory requirements, howsoever stringent they may be. In this case, Ranbaxy's alleged transgressions aren't minor: the analytical instruments in the laboratory of its Toansa plant were found "not calibrated, qualified or maintained appropriately", while the sample preparation room had "Too Numerous To Count (TNTC) flies". The deviations at its Mohali unit included use of dirty glassware and black fibre embedded in a tablet originating from "hair from an employee's arm". These only point to the absence of robust and sustainable systems to monitor production processes at the shopfloor. The company's top management is no less responsible here, especially when the USFDA's first import alert against its facilities goes back to 2008. Also, some drugmakers have taken corrective measures following the detection of manufacturing lapses by the US health regulator, which suggests the problem is far from intractable. But it is time that the industry – and perhaps the government as well – started by at least recognising the existence of the problem.