PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Indian Express, Delhi
Thursday 6th February 2014, Page: 12
Width: 10.34 cms, Height: 16.44 cms, a4, Ref: pmin.2014-02-06.35.83

Public health first

Drug regulation needs an overhaul. Start with more investment in human resources, infrastructure

AFTER the fourth unit of Ranbaxy Laboratories was banned from shipping to the US, its Food and Drug Administration commissioner is set to visit India to resolve several of these persistent contentions with the health ministry. Other Indian pharmaceutical companies, like Wockhardt and RPG Life Sciences, have also received notices from the US regulator about their shoddy manufacturing practices.

When the Ranbaxy scandal first broke, the commerce ministry's first reflex was denial, or to see this in nationalist terms alone, as a Big Pharma plot to undermine India's plucky and successful businesses. While India does have economic interests in the success of this $15 billion export industry, it needs solid regulation to ensure this success is sustainable. In response to the FDA's monitoring of Indian firms, the Central Drugs Standards Control Organisation (CDSCO) fought for the right to check manufacturing facilities abroad, apparently to make sure that drugs coming into India meet quality standards. This claim would be taken more seriously if the CDSCO had not been such a visible failure—a parliamentary standing committee on health in May last year laid out the remarkable chaos in domestic drug regulation, even in terms of granting licences. Manufacturing laxity aside, it found that many drugs were being marketed before being put through the required clinical trials and drugs banned in other markets were available here. Regulatory dossiers were missing for several drugs, and in many cases, approvals were granted by non-technical staff. Expert testimonials were suspiciously similar in many cases. State issued licences operated in their own orbit, and these authorisations were not sent back to the central regulator.

The Centre has moved a new drugs and cosmetics amendment bill, which conceives of a professionally managed Central Drugs Authority like the FDA, to swallow the existing CDSCO. But it will take more than surprise inspections to change this regulatory culture — it will involve breaking the collusion between certifiers and companies, and more than anything, it will require greater investment. The US FDA has a strength of some 14,000 people, while the Indian regulator had 327 in 2012. While the pharma industry is exploding, and the CDSCO's workload is growing by 20 per cent every year, it lacks the staff and infrastructure, advisors and independent testing labs to do its job. That needs to change first, if the government is serious about a regulatory overhaul.

Mrs Cellaneous.