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GOVERNMENT OF INDIA
भारत सरकार

Deccan Herald, Delhi
Thursday 6th February 2014, Page: 10
Width: 8.09 cms, Height: 21.34 cms, a4, Ref: pmin.2014-02-06.40.92

Failing the test

The decision of the US Food and Drugs Administration (FDA) to ban drugs produced at a plant of India's major drug manufacturer Ranbaxy is not only a setback to the company. It might reflect badly on the reputation of other drug manufacturers also. The US regulator's inspections found numerous lapses in the company's production unit at Toansa in Punjab. The company has faced US regulatory action in the past also. The Toansa plant is the fourth facility of the company in India to be found having unacceptable production standards. It was found that the company was using substandard instruments and there were flies in the sample preparation room at Toansa. These details make a shocking comment on the working of a drug manufacturing company. Ranbaxy had paid a $ 500 million fine to the US department of justice last year after admitting fraud and adulteration charges. At that time one drug was found to contain glass powder.

It is surprising that the company's manufacturing processes and practices did not improve even after they were repeatedly found to be faulty. Indian companies in other sectors have also been found lax in maintaining the best production standards. The reasons for such poor performance records may be threefold. The first is the prevalence in India of less than best international standards. The second is the poor implementation of these standards by the industry even where they are prescribed. The third and most important is the failure of regulatory oversight by agencies which are responsible to monitor and enforce those standards. The response of the Drug Controller General of India, which is India's regulatory authority in the sector, to the Ranbaxy decision was an admission of failure. It was stated that the US standards are too high for most Indian companies and it would take many years for India to reach them. This would show the entire Indian drug industry in a poor light.

Indian drug companies have made a mark overseas but their aspirations can be impacted by such setbacks as in the case of Ranbaxy. Only if the best quality and standards are maintained can any industry hope to be competitive. There cannot be a compromise when the life and health of consumers are involved. Indian consumers also have added reason to worry about the quality of the products offered to them.

Regulatory