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Adopt Best Practices in Pharmaceutical Sector

Signing off her 9-day visit to India, US Food and Drug Administration commissioner Margaret Hamburg has given a wake-up call to Indian pharmaceutical companies: "If you want to sell in the US, you need to comply with our standards, practices and expectations." The advice was offered by her after prolonged interaction with the heads of leading pharma companies and officials involved in regulating the drug industry in India. The US is increasing scrutiny of generic drugs made in India, and has in the past nine months banned imports from four plants belonging to Ranbaxy Laboratories Ltd and Wockhardt Ltd, apart from servicing notices to others.

Indian drug manufacturers and regulators will do well to take Hamburg's advice seriously. India's pharmaceutical industry supplies 40 per cent of over-the-counter and generic prescription drugs and up to 80 per cent of active pharmaceutical ingredients to the US. Over 560 pharmaceutical firms based in India that manufacture or market drugs for the US are under the FDA's scrutiny. Last year, nearly 160 India-based firms, including over a 100 manufacturing plants, were inspected by FDA investigators to ensure quality control and compliance.

India's drug industry is one of the country's most important economic engines, exporting $15 billion in products annually, and some of its factories are world-class. But others suffer from serious quality control problems. The WHO estimated that one in five drugs made in India are fake. The Drug Controller General of India is reported to have said that India can't afford to apply US safety and quality standards as this would mean shutting down bulk of the manufacturing facilities. This is unacceptable. If India wants to maintain its share in the global pharmaceutical market, it will have to comply with international standards. It is time the Indian government beefed up its regulatory mechanism for the pharmaceutical sector by providing it with required skilled staff and infrastructure and the industry adopted the best international practices in production of drugs.

Regulatory