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US fumes, but UK agency OKs Indian pharma

EXPERTSPEAK Is the USFDA indirectly hitting India's patent regime?

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NEW DELHI: Concerns about quality control in India's ₹86,800-crore drug industry have worried the US industry regulators, but its British counterpart finds no such concern on a significant scale.

"The majority of inspections of Indian manufacturing sites result in a satisfactory outcome," Jennifer Kyne, press officer at UK's Medicines and Healthcare Products Regulatory Agency told HT by e-mail. "There is not a significant difference in the number of critical findings identified at UK sites versus those in India or other third countries."

In contrast, the US Food and Drug administration commissioner Margaret Hamburg, during her visit to India last month, conveyed some apprehensions. "In recent years, the FDA has identified lapses in quality by some companies. This is unacceptable," she wrote in her blog.

Drug makers smell a witch-hunt in this, as US giants face competition from cheaper Indian versions of their patented drugs.

The US is seen by critics as bullying Indian pharmaceutical companies over the nation's patent regime – with a push from US-based big pharma companies. "It is unfair that sometimes they (FDA) does not give appropriate time to take corrective measures," said an official at a domestic pharma firm.

"It is not easy to believe that they do not follow the ethical practices. Data integrity might be an issue but the safety of drugs will not be compromised," said Zarir H Charna, former corp comm director at Ranbaxy.

BIG DIFFERENCE

- The FDA has announced to its number of inspectors in India from 12 to 19
- The UK's MHRA does not have any inspectors in India. Nor does it plan to depute one or open office in India

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