

# 'USFDA alerts to have no impact on pharma exports'

ENS ECONOMIC BUREAU

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IMPORT alerts by the US drug regulator is not likely to have any material impact on the existing US exports revenue of Indian pharma manufacturers though the industry will face increased inspections by the regulator, says a report.

According to the report by India Ratings, Indian pharmaceutical industry will have to ensure high quality standards and strict compliance and record-keeping regime "urgently" to capitalise on the opportunity.

"To grasp the opportunity, Indian pharmaceuticals manufacturers have registered the largest number of manufacturing facilities with USFDA and also accounted for 39 per cent of the total generic drug approvals during 2013," the rating agency said in its report adding that the industry will be able to establish quality assurance processes as well as a compliance culture to reduce import alerts.

However, given the increased dependence on Indian pharmaceuticals manufacturers and "the bad press earned by Indian pharmaceuticals on account of the recent

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**WITH THE bad press earned by Indian pharmaceuticals on account of the recent spate of import alerts, US inspections will increase, an India Ratings report says**

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According to the industry, however, it is documentation, ill-trained manpower, public perception, bad press and work culture and not the quality that has earned it a bad name. These factors have helped the US in forming the perception that Indian drugs are sub-standard and hence unsafe, industry players who export to the US market and refused to be quoted, told *The Indian Express*.

"Public perception has been made such that even small mistakes translate into quality issues. It is more of a cultural issue than the lapse per se," an industry executive said when asked about the heat being faced by the Indian industry in the global market.

Exports.