

# India drafting drug quality norms to match US FDA standards

**Himani Chandna**

■ himani.chandna@hindustantimes.com

**NEW DELHI:** After facing harsh criticism over drug manufacturing quality in the recent past, government is now set to draft a new set of guidelines to regulate drug quality in India.

Health ministry and Central Drug Standards Control Organisation (CDSCO), jointly, plan to study the guidelines of global health regulators.

While the new set of regulation guidelines will be referred from top global health regulators such as, the government plans to study regulations of lesser developed countries and Brics countries as well.

## FRESH CASES

**March 2015** US FDA bans imports from two Ipca Laboratories plants

**April 2015** Wockhardt withdraws about a dozen drugs from US market on manufacturing concerns

**May 2015** Cipla recalls its asthma inhalant from US following FDA warning

"Government is worried over the promises made to the US Food and Drug Administration off late. However, due to the certain quality lapses by Indian drug makers, US FDA still con-

tinues to take harsh action against India drug-production plants," said a senior bureaucrat from ministry of health and family welfare.

Government is taking several other measures to save brand image of pharmaceuticals industry which majorily includes overhauling of CDSCO, the regulatory body for drug quality standards in India.

"We have floated a cabinet note on revamping CDSCO where it would be upgraded into a world-class health regulator. CDSCO will also be renamed as Central Drug Administration," said an official. "The Cabinet may take up the proposal in this month."

*Regulatory*