

## India wants its officials during FDA inspections at drug units

Hyderabad

Perturbed by Indian drug-makers frequently running into overseas regulatory problems, the government has requested the US health watchdog FDA to allow its officials during inspections of domestic pharma units, reports PTI.

While Indian pharma exports continue to grow and may touch USD 16.5 billion this year, many Indian pharmaceutical companies have faced regulatory action by the US Food and Drug Administration (FDA) in the recent past for alleged violation of 'good manufacturing practices' and other irregularities at

the drug facilities in different parts of the country.

In many cases, these companies have been barred from selling their drugs in the US and other countries, although Indian firms account for a significant share of generic drug market in those places.

"Cultural differences and body language may sometime widen the gap (during FDA inspection). We are requesting them (FDA) to allow Indian regulators also to be present during the inspections," PV Appaji, Director General Pharmexcil (Pharmaceuticals Export Promotion Council), under the Ministry of Commerce and Industry told PTI.

*Regulation*