

US to help Indian cos comply with FDA

Jan 09, 2008

Hyderabad: Following some unsavoury incidents in regard to safety and quality of imported drugs, the US government is talking to the producers of the imported drugs and the respective governments to put in place uniform manufacturing practices in compliance with the regulations of its Food and Drug Administration (USFDA).

In order to make it imperative for the exporting countries to comply with the US regulations, the USFDA would expedite approvals in the case of those companies where similar ecosystem prevails as in the US. US secretary of health and human services, Michael O Leavitt, said here on Tuesday that the USFDA would depute its officials to India for framing regulations and practices which would conform to the USFDA norms. He along with USFDA commissioner Andrew C von Eschenback, is visiting various facilities in the country that produce food and medicines for export to the US. They are also visiting healthcare facilities that deliver polio vaccine and provide care and treatment for HIV/AIDS and tuberculosis.

Leavitt said that they had already held talks with the Chinese government on safety and quality aspects and extended their support to facilitate USFDA-compliant practices there. "We have also met the ministers for agriculture, health and commerce in India and are hopeful of their efforts to usher in uniform practices as sought in the US", he said.

To a query on the need for such exercise, the US secretary said that their country imported \$2 trillion worth drugs every year through about 300 border points. "About 8 lakh manufacturers export their drugs to the US, we have felt that the current system for ensuring safety and quality of imported drugs is insufficient. Hence, our exercise to ensure that quality and safety are built into every stage in the making of drugs in the countries where our suppliers are located," he explained.

Leavitt and Eschenback visited the facilities of Dr Reddy's Laboratories at Bachupally and Bharat Biotech Ltd at Genome Valley. Praising the standards as well as affordable medicines at both the facilities, Leavitt said that, "for us the safety of Americans comes first. We will expedite approvals for those falling in line with us, and make it hard for those not adapting to our requirements."