

India boosting regulatory forces by double

23 May 2014 | News | By BioSpectrum Bureau



Singapore: India has finally responded to the regular alerts issued by the top US drug regulator Food and Drug Administration (US FDA). In its strong worded response to the FDA, India has said that it would be making a \$500 million investment to expand its inspection team widely.

The country's top drug regulatory body, that recently sat across a table and discussed regulatory issues with about 40 different countries, made it a point to ensure that apt action is taken.

The Drugs Controller General of India, Mr G N Singh said on the sidelines of an event that more than half a million dollars will be invested into the system over the next three years to make certain noticeable improvements.

The country has further decided to increase the number of inspectors in the central government to 1,000 from 500. The DCGI also mentioned that as many as 3,000 inspectors would be deployed at various state levels.

Mr Singh was responding to the appeal made by the FDA Commissioner Ms Margaret Hamburg who visited the country earlier this year and urged the nation to boost its regulatory standards. She also insisted that all the companies must upgrade to the highest international standards - especially because India's export growth was being affected due to increasing quality concerns.

"While following a zero tolerance policy for any laxity, the government will more than double the number of regulators in three years and set up state-of-the-art testing labs at ports to ensure the pharmaceuticals and drugs exports shipments meet global quality standards," Mr Singh mentioned in a news report.

News reports further substantiated that the country's important drug export business has been harshly affected because of the growing FDA action. In the last one year, the US regulator has issued several warning letters and import bans have been placed on units by top Indian companies. Growth in drug exports from India fell to 2.6 percent in the year ending March 31, about \$15 billion. Two years ago it reported a 23 percent rise in drug export value.

FDA had added that India makea 40 percent of US generic and OTC products had emphasized that it is important that the Indian drug regulators and the FDA work together to resolve compliance issues and reinstate India's position in the global

drug market.