

## **US Food & Drug Administration (USFDA) agrees to expedite the process of approving Indian drugs based on safety, efficacy and quality framework**

**NEW DELHI, February 11, 2014.** The US Food & Drug Administration (USFDA) is in the process of reorganizing its structure and speeding up the process of approvals. This would help clear the backlog of inspection for Indian drug manufacturers who have applied for approval from USFDA to export their products to the US.

This was stated here today at a roundtable industry interaction with **Dr. Margaret Hamburg, USFDA Commissioner**, organized by **FICCI**.

Dr. Hamburg said that the FDA office in India has a mandate to conduct inspections of pharmaceutical manufacturing premises and was working towards bringing awareness about US regulatory requirements and standards amongst industry through capacity building workshops. Strong and smart regulation in a clear, predictable and transparent ecosystem creates a level playing field for all players in the market.

Dr. Hamburg said that safety, efficacy and quality of the product are the three pillars of the regulatory framework and USA and India need to work in collaboration for getting affordable drugs made available to the patients not just from both the countries but also meet the global requirement. She added that India provides generic medicines to almost 200 countries and is the second largest exporter of generic medicines to the US. Hence, strengthening and extending this relationship was of utmost importance. The focus for both the industry and the regulator should be to keep pace with the changing scenario due to rapid advancements in science and technology that lead to new drug discovery, biosimilars etc. and at the same time new tools for regulators to assess safety, efficacy and quality.

She added that FDA was looking forward to enhancing partnership with its Indian counterparts and working towards bilateral as well as global partnership. There are opportunities for joint training and educational opportunities for sustainable partnership. The USFDA was thinking of ways to involve academia, industry and government, she said.

**Mr. G N Singh, Drug Controller General of India (DCGI)**, emphasized that patient safety was of prime importance and suggested that over regulation should be avoided. The round table interaction was one of the best ways to discuss the concerns of the industry with the USFDA Chief and more such interactive sessions must be held on a regular basis to streamline the process of approvals and strengthen the regulatory framework.

**Dr. Habil Khorakiwala, Past President FICCI, Chairman, Wockhardt Group & Chairman FICCI Life Sciences Council**, said that developments in Indian pharmaceutical industry is science based. He further suggested that the Indian regulatory standards need to be aligned with the US regulatory requirements as India is becoming a manufacturing base for some of the generic companies. India is playing an important role in generics and is keeping up with the competitive environment. Also, Indian research will play a significant role in research and drug discovery in the coming future.

**Dr. A Didar Singh, Secretary General, FICCI**, said that both industry and USFDA need to work together towards streamlining issues of efficiency of approval process, rationalising definitions for common understanding to avoid adverse impact on the industry and develop a system of qualified opinions to ease the cost and time burden on pharmaceutical manufacturers. FICCI has been conducting GMP strengthening workshops in partnership with Department of Pharmaceutical, GoI and WHO and has initiated talks with NIPERs for developing curriculum with focus on quality assurance, regulatory guidelines, drug applications etc. for students and executives.

**Mr. Pankaj Patel, Chairman, FICCI Pharma Committee & Chairman , Zydus Cadilla Healthcare Ltd.** expressed FICCI's the willingness to work jointly with the USFDA and DCGI to facilitate adoption of best practices by the Indian pharmaceutical industry .The round table was also addressed by **Dr. Altaf Lal, India Country Director, USFDA.**

\*\*\*\*\*

**FICCI MEDIA DIVISION**