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Ranbaxy taking steps to meet US FDA concerns

27 September 2013 | News | By BioSpectrum Bureau

Singapore: Ranbaxy Laboratories that has been in the face of controversy after the US Food and Drug Administration (FDA) cracked down on its third manufacturing unit this year, has now said that it is taking stringent measures.

"I would like to assure you that the issues that were raised by the US FDA in 2012 have been addressed and we have taken stringent steps to ensure that we meet all US FDA concerns," Ranbaxy CEO and managing director Arun Sawhney wrote in a letter to the media.

"Since the last inspection by the US FDA at Mohali in 2012, Ranbaxy has strengthened its management, manufacturing and monitoring systems and processes, to ensure quality and compliance in all areas," the letter added.

Further discussing the background of the issue, Mr Sawhney said in the letter, "As you would know, on September 16, 2013, Ranbaxy received a communication from the US FDA about an import alert on its Mohali plant. The US FDA also advised that the Mohali plant will be subject to certain terms of the consent decree (CD), filed in late January 2012 for Ranbaxy's Paonta Sahib and Dewas plants. We are assessing the terms and practical applications of this CD. We will continue to work closely with the US FDA on remediating the issues at our Mohali facility and will take all necessary measures to keep our facilities in full compliance to all global regulations. We are focusing on resuming submissions and supplies to the US from our Mohali plant once we satisfy the US FDA stipulations."

It further said, "In terms of the CD with the US FDA for its Paonta Sahib and Dewas plants, we are committed to further strengthen procedures and policies to ensure data integrity and to comply with current good manufacturing practices (cGMP). So far we have met all obligations under the CD and are making good progress in its implementation. We will continue to invest in R&D to enrich our global product pipeline and install state-of-the-art technologies at our manufacturing facilities. We have a pipeline of new products including First-To-File (FTF) product exclusivities and the Company will seek to maintain the value of its product portfolio."

He also highlighted the accomplishments of the company in the last two years, that would prevent it from being barred from the US market due to the controversies.

"In the last two years, Ranbaxy has launched several products in the US including Atorvastatin, Absorica, Desvenlafaxine, Cevimeline (Evoxac) and continues to market to the US Federal Government. In India, we launched the first New Chemical Entity (NCE), SynriamTM for the treatment of malaria and we are now working towards taking this product to other developing countries. In the emerging markets of Africa, Latin America, CIS and Asia, Ranbaxy continues to provide a wide range of World Health Organization prequalified (WHO PQ) ARVs in addition to supplying high quality generic medicines. About 1 million patients worldwide use Ranbaxy's ARV products for their daily treatment needs," he added

Mr Sawhney has reassured in his letter, "All Ranbaxy products being supplied in India and globally are safe and efficacious. Ranbaxy remains strongly committed to providing high quality, affordable drugs to patients in India and other parts of the world. We are guided by our philosophy of 'Quality and Patients First', and will uphold the highest quality standards that patients, prescribers, government and all other stakeholders expect from Ranbaxy."