News Details

Korean FDA approves Bharat Biotech's manufacturing facility

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News Delhi: BHARAT Biotech International Limited (BBIL) has become the first pharma-biotech company to be audited and approved by the Korean FDA.

"The approval of BBIL's state-of-the-art manufacturing biotech facility by the Korean Food & Drugs Administration (KFDA) exemplifies the fact that we, Indians are on par with the world's best in attaining the highest quality in establishing systems, manufacturing products and envisaging our facilities," said Dr Krishna M Ella, the chairman & managing director of BBIL.

Bharat Biotech can now manufacture and export human vaccines to Korea, which is one of the regulated markets in the world for pharmaceuticals. "Bharat Biotech's approval by KFDA will create a level playing field and help reposition Indian entry into global markets in the sphere of injectables (small volume parentals). So far very few Indian companies have only been successful in manufacturing and exporting injectables to US and Europe," remarked Dr Ella.

Citing this development as propitious, Dr Ella said, "The only countries around the globe with regulated markets are the US, Europe, Korea and Japan. To export preservative-free vaccine to these markets need highest quality standards. There is absolutely no room for even the slightest error. In fact, in the history of vaccine manufacturing, this is the first time that a preservative-free has been moved out of the US to be manufactured in India and at Bharat Biotech. This makes us the first pharma-biotech company in the country to achieve this distinction. This development will have global implications for Indian biotech sector itself," he added.

Giving an overview of the export scenario, Dr Ella said, "Most Indian API (Active Pharmaceutical Ingredients) manufacturers (bulk drugs) have been approved by USFDA (United States Food & Drugs Administration) and UKMCA (United Kingdom Medical Council Authority) for exporting formulations like capsules and tablets and do not include injectables. In this context, KFDA approval for BBIL for export of injectables is quite an achievement."

"For the first time, a vaccine is moving from developing country to regulated market. The approval of Bharat Biotech's facility is the acknowledgement of our quality, stringent manufacturing processes and our products," Dr Ella added.

Speaking about the global scenario, Dr Ella remarked that till recently, countries with regulated markets such as US, Europe, Japan and Korea dominated the vaccine industry business by contributing such products worldwide.

"Things are changing in the present scenario, there is a conscious effort within South East Asian countries to mobilise resources and forge new alliances in the light of the post GATT agreemnt," observed Dr Ella. "Such developments go a long way in strengthening our credibility.

The current example shows that we have the capability not only to establish highest Quality, but pool prodigious talent and resources in establishing world class facilities to make the vision of our country - of a disease-free tomorrow - a reality."

Korean FDA has been playing a key role in facilitating policy changes that have contributed a great deal in

revitalising South Korea's pharmaceutical markets. KFDA has a vision - To set the highest standards and specifications for food, drugs and ensure safety in manufacturing, distribution and consumption.

In the recent times, the KFDA has revolutionarised many aspects of its approvals by making efforts to explore newer avenues to manufacture drugs and therapeutics.

"The entire global pharmaceutical sector faces a variety of regulatory, economic, political, social and technical pressures," stated Dr Ella. "Bharat Biotech has once again proven that we have achieved the global standards and are better equipped to face such challenges, which have been hitherto limited to the developed economies," he added.