

## News Details

### **Bharat Bio gets Korean FDA nod**

Jan 25, 2005

BHARAT Biotech has bagged the Korean Food and Drugs Administration (KFDA) approval for its manufacturing facility and products. This means that Bharat Biotech can now manufacture and export human vaccines to Korea, one of the world's four regulated markets for pharma products.

It has bagged an initial order of Rs 2 crore and would be sending two batches of 200,000 doses of preservative-free vaccines. "The only countries with regulated markets are the US, Europe, Korea and Japan. To export preservative-free vaccines to these to these markets requires highest quality standards. For the first time, a vaccine is moving from a developing country to regulated markets," Mr Krishna Ella, chairman and managing director of Bharat Biotech, told reporters.

Regulated markets being much higher value realization for pharma firms. It took the company one-and-a-half years to get the Korean FDA approval. In the post-WTO era, the company has about 25 patents of which it owns about 10. It was also acquired six patents and has alliances for eight more. The company is stepping up its R&D; focus on combating infectious diseases. The new product in the pipeline is a recombinant human epidermal growth factor. The company has already completed clinical trials on diabetic foot ulcer cases. It is now awaiting regulatory approval, he added.