Hyderabad, Jan. 24: Setting a new benchmark for quality, Bharat Biotech International Ltd (BBIL) has become the first bio-pharma company to get a Korean Food and Drugs Administration (KFDA) approval for its manufacturing facility.

With the approval, the company can now manufacture and export human vaccines to Korea which is one of the regulated markets in the world for pharmaceuticals.

Disclosing this information to the media, Krishna Ella, chairman and managing director said: “The approval by KFDA will create a level-playing field and help Indian entry into global markets in the area of injectables.”

As of now, very few Indian companies have been successful in manufacturing and exporting injectables to the US and Europe, Dr Ella informed.

Citing this development as unique in the history of vaccines has been moved out of the US to be manufactured in India and at BBIL.

The company has already received a Rs 2-crore order following the KFDA approval.

Giving an overview of the export scenario, Dr Ella said, “Most Indian API manufacturers have been approved by the US FDA and UKMCA (United Kingdom Medical Council Authority) for exporting formulations like capsules and tablets but do not include injectables.

“Getting an approval for injectables by KFDA is an achievement and manufacturing vaccines in India and exporting to regulated markets offers credibility,” he said adding that KFDA has revolutionized its approvals by making efforts to explore newer avenues to manufacture drugs and therapeutics.