Company: M/s Biological E. Pvt. Ltd., Hyderabad
Project: Setting up manufacturing facilities for Pneumococcal Conjugate Vaccine.

TDB is delighted to announce financial assistance to Biological E (BE) through its Loan Scheme for the production of Pneumococcal Conjugate Vaccine, which is a preventive treatment for childhood pneumonia, meningitis, ear infections and bacteremia Infection caused by Streptococcus pneumoniae.

Brief Background of Pneumococcal Conjugate Vaccine (PCV):
World Health Organization (WHO) estimates that Streptococcus pneumoniae, the causative organism of pneumococcal infections, kills close to half a million children under 5 years of age worldwide every year, with most of these deaths occurring in developing countries. Although, Pneumococcal Conjugate Vaccine (PCV) that protects against these diseases was first introduced in 2000, five of the highest burden countries—India, Indonesia, Chad, China, and Somalia—have not been using the vaccine in their routine immunization programmes.

Collectively, pneumonia and meningitis are responsible for more than 160,000 deaths each year among Indian children aged 1-59 months. More than 130 countries worldwide have introduced PCV into their national immunization programs. However, PCV is not yet part of India’s Universal Immunization Programme (UIP). In August 2015, the Government’s National Technical Advisory Group on Immunization (NTAGI) made the historic decision to recommend that PCV be introduced into the UIP.

The Ministry of Health and Family Welfare has approved the PCV, and the government with the support of Global Alliance for Vaccines and Immunization (GAVI) aims to introduce PCV into the first cohort of states. The government through initiatives like Mission Indradhanush is working to reduce the burden of bacterial infections by improving access to sanitation and promoting childhood vaccination at an unprecedented scale.

Background of Company:
Biological E was originally founded in 1953 as Biological Products Private Limited. It was among the first Private Sector Companies in India to manufacture Biological Products. It pioneered Heparin production in India. During the 1960s and 1970s, the Company developed formulations in cough and digestive enzymes, started manufacturing anti-tetanus serum and launched anti-TB Drugs, TT and DTP Vaccines. By the turn of the new millennium, the Company embarked upon the journey to specialize in Low Cost Vaccines Manufacturing. The Company started manufacturing its Flagship Vaccine Product Pentavalent (DTH Hib HepB) in 2008. The Company presently led by Dr. Mahima Datla (Managing Director, highly accolade women entrepreneur) is a major supplier of Vaccines International Development and Aid Organizations like WHO, UNICEF, BMGF.
Background of the Product:

The vaccine is predominantly used for infants (below 5 years) and adults (above 60). The product is conjugate vaccine wherein polysaccharides from different etiologically important strains of *Streptococcus pneumonia* are chemically coupled to a carrier protein (CRM197) that is known to trigger protective immune response in the vaccinated subjects. Each dose of the vaccine consists of several different polysaccharides conjugated to a carrier protein (CRM197) in a liquid formulation.

BEL has developed the product through an in-house research and has filed two process patents for the vaccine composition and polysaccharide purification. BEL has redesigned the vaccine formulation to 14 valent, which offers broader protection than those available in the market with 13 and 10 valent conjugate vaccine. The vaccine composition is unique containing 14 serotypes of *Streptococcus pneumonia* that have the highest propensity to cause respiratory disease in children. The company initially plans to produce around 25 million doses, which will be eventually scaled up to 100 million doses annually. With the facility in India this superior product, including more number of serotypes can be provided to the mass at a reasonable price.

This project has been approved by TDB for a loan assistance of Rs. 100.00 core with a project cost of Rs 320.00 crore.

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Shri Y. S. Chowdary, Hon’ble Minister of State for S&T and ES with TDB family