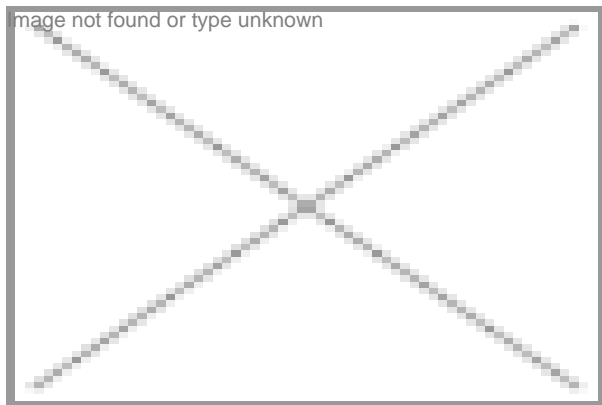


## Mission: Vaccine to fight pneumonia deaths

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*Utilizing the funding from BIPP, Tergene Biotech initiated a project to develop an indigenous vaccine to tackle pneumonia that kills more children under the age of five than any other disease*



Pneumonia kills an estimated 1.6 million children under the age of five globally, every year, according to statistics available with the World Health Organization. The number is more than the combined deaths due to AIDS, malaria and tuberculosis in this age group. The report card released by the International Vaccine Access Center says, in India, 1.6 million children die every year.

The above facts together with the realities that indigenously manufactured vaccines for the disease are non-existent in the country and the high cost of imported vaccines necessitate the development of affordable indigenous technology and manufacturing capabilities. Keeping this in mind, Hyderabad-based company Tergene Biotech launched a project to develop a 15-valent pneumococcal polysaccharide

conjugate vaccine with CRM 197 as the carrier protein. The objective is to make it India-specific and affordable to the common man.

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The company, a third generation technology development company in the field of vaccines and therapeutic proteins, received a grant of ₹15 lakh from the Department of Biotechnology (DBT) to demonstrate proof-of-concept at lab-scale under the Biotechnology Industry Partnership Programme (BIPP) scheme. The company received the grant after the DBT called for affordable healthcare technologies with specific reference to pneumococcal conjugate vaccine in November 2010.

Explaining the technology, Dr M Kuppusamy, managing director of Tergene Biotech, says, “The 15 serotypes used in our vaccine account for 80 percent of the total serotype prevalence in India. The company has developed its own in-house technology to manufacture the carrier protein. CRM 197, the safest and highly immunogenic carrier protein of choice, together with the flow chemistry-based conjugation constitutes the platform technology for all its polysaccharide-based conjugate vaccines.”

Tergene also had the options to develop a Haemophilus influenzae B conjugate vaccine and acellular pertussis vaccine directed to prevent the main causative bacterial agents of pneumonia, but is presently focused on the pneumococcal polysaccharide conjugate vaccine.

“We are thankful to the DBT for the timely initiative. A public private partnership is a real opportunity for start-ups promoted by scientists with technology as the prime investment,” says Dr Kuppusamy.

#### The way forward

The company is setting up a manufacturing facility (as per Good Manufacturing Practices norms) near Chennai, Tamil Nadu. The state-of-the-art facility will be operational by mid 2013 and will be used to manufacture vaccines, biopharmaceuticals and probiotics. This will give Tergene a manufacturing facility matching the specifications of the US Food and Drug Administration.

The company is hopeful of receiving further support from the DBT to complete the cGMP clinical lot manufacturing, clinical trials and eventually commercial manufacturing. “According to estimates, we would be in a position to launch the vaccine in 24 months,” says Dr Kuppuswamy. He said they were confident of pricing the vaccine at one-third the cost of the imported vaccine, which is available at an MRP of Rs 3,800 per dose. “As per recommendations, infants require four doses of the vaccine,” he adds.

**Rahul Koul** in NewDelhi