

### "New formulation is more potent than existing Hib vaccines�

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# Q: Please explain to us the research behind preparing the improved version of Hib vaccine? Were the preclinical results on expected lines?

Hib conjugate vaccine plays a vital role in national immunization programs and also forms a main part of the pentavalent vaccine is the costliest component and hence developing countries such as India can benefit from more cost effective formulations.

Hib component vaccine is an important part of pentavalent vaccines and as it contributes maximum to the cost, we attempted to design experiments to test different Hib polysaccharide sizes for developing most potent conjugates. When the length of the polysaccharide was optimized, it dramatically improved immunogenicity in preclinical models, thus making it more powerful and effective. It was also found that the new formulation was 4 to 10 times more potent when compared to the existing licensed vaccines. Hence the results of the preclinical immunogenicity study from the lead candidate developed by Hilleman Labs were on expected lines.

# Q: How does the new formulation help in the creation of an affordable quality product in the longer run? What is the way forward?

Capsular polysaccharide conjugates of Hib are important components of several mono-or multivalent vaccines for children. However, the access to needy people is limited due to the relative high cost of the Hib vaccine. This new formulation will be a step towards developing a cost-effective and a more immunogenic vaccine. It is an encouraging breakthrough in bridging the gap and making Hib vaccine accessible and affordable.

The new conjugate vaccine developed by Hilleman is a more immunogenic preparation of Hib capsular polysaccharide (PRP) - tetanus toxoid (TT) conjugates using optimized PRP chain length and conjugation conditions. This new and unique

cost-effective formulation developed by the company will significantly reduce the cost of Hib vaccine, which in turn, will help in reducing the market price of the pentavalent vaccine, thus making it accessible to a larger number of people. Our next step now would be to look at collaboration with like-minded stakeholders who can work together towards cost effective solutions with the aim of bridging existing gaps.

#### Q: What is the approximate duration in which the final product expected to be launched?

Expected duration of final product is totally based on getting successful collaborations and partnerships. We can expect affordable pentavalent vaccine to be launched in next 3-4 years.

#### Q: What is the progress on the Hilleman's rotavirus vaccine development programme?

The pre-clinical toxicology studies of thermostable, pentavalent rotavirus vaccine formulation have been completed successfully without any adverse finding. We are currently preparing for phase 1 clinical trials and simultaneously developing the packaging device.

### Q: How are the programs at Hilleman Labs shaping up of late? Any new tie ups or initiatives?

Hilleman labs has been progressing quite well in all its vaccines R&D programs. We are working on different projects like Rotavirus, Oral Cholera Vaccine, Meningococcal vaccine etc.

Last year, we attained world-wide rights to the Oral Cholera vaccine candidate in a strategic collaboration with Gotovax AB, to offer increased shelf life and reduce the projected gap in supply of cholera vaccine by the current manufacturers.