

## Vaccine launches on the rise

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*Indian companies have stepped up the introduction of indigenously developed vaccines.*

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Advances in immunology and vaccinology have increased the hope that new vaccines will target other diseases such as cancers, immune system disorders, allergies and autoimmune diseases. A large number of vaccines under development prove to make the vaccines market an interesting and dynamic one over the next five years. There are currently more than 1,000 vaccines in research and development stage worldwide, and in the future, they are expected to be a cost-effective alternative to conventional treatment. Developing countries such as India, China, and Brazil with their significant innovative scientific capabilities and resources are likely to play a major role in contributing to the global R&D efforts in developing novel vaccines. Though most of the technologies are currently in the initial stages of development, they are excitingly close to reality.

The development of new therapeutic vaccines targeting cancer and other life-threatening diseases is also sharpening the focus on this area of medicine, while driving greater investment in more advanced processing techniques. Dominant players in India include Shantha Biotechnics, Serum Institute of India, Bharat Biotech, Bharat Serums and Vaccines, Biological E, Indian Immunologicals and Panacea Biotech.

Indian companies are looking at penetrating the European and American markets in the future and are producing products that adhere to international standards of good manufacturing and clinical standards.

In August-September this year alone several major announcements have been made.

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Serum Institute of India Ltd, India's largest vaccine manufacturer, launched its indigenously manufactured low-cost Haemophilus influenza type b conjugate vaccine under the brand name of HibPRO in India. HibPRO has been priced at MRP Rs 375 for a monodose vial. HibPRO is considered to be a vaccine with clinically proven efficacy and safety at an affordable price. HibPRO has undergone a series of clinical trials to prove its efficacy and safety in comparison with commercially available Hib conjugate vaccines. With the launch of HibPRO, Serum can extend the benefits of pentavalent or quadravalent vaccines at a very affordable price. The benefits are mainly fewer numbers of injections, lesser pain to the child and protection against multiple diseases such as H. influenza type b, Hepatitis-B, Diphtheria, Pertussis and Tetanus in one injection. Serum Institute had launched Q-Vac, combination vaccine, and Td-Vac, tetanus and diphtheria vaccine, in the year 2005-06.

Serum Institute of India is one of the largest manufacturer of measles vaccine and DTP group of vaccines in the world. Panacea Biotec, the number three-ranked company, is the top oral polio vaccine supplier in the country.

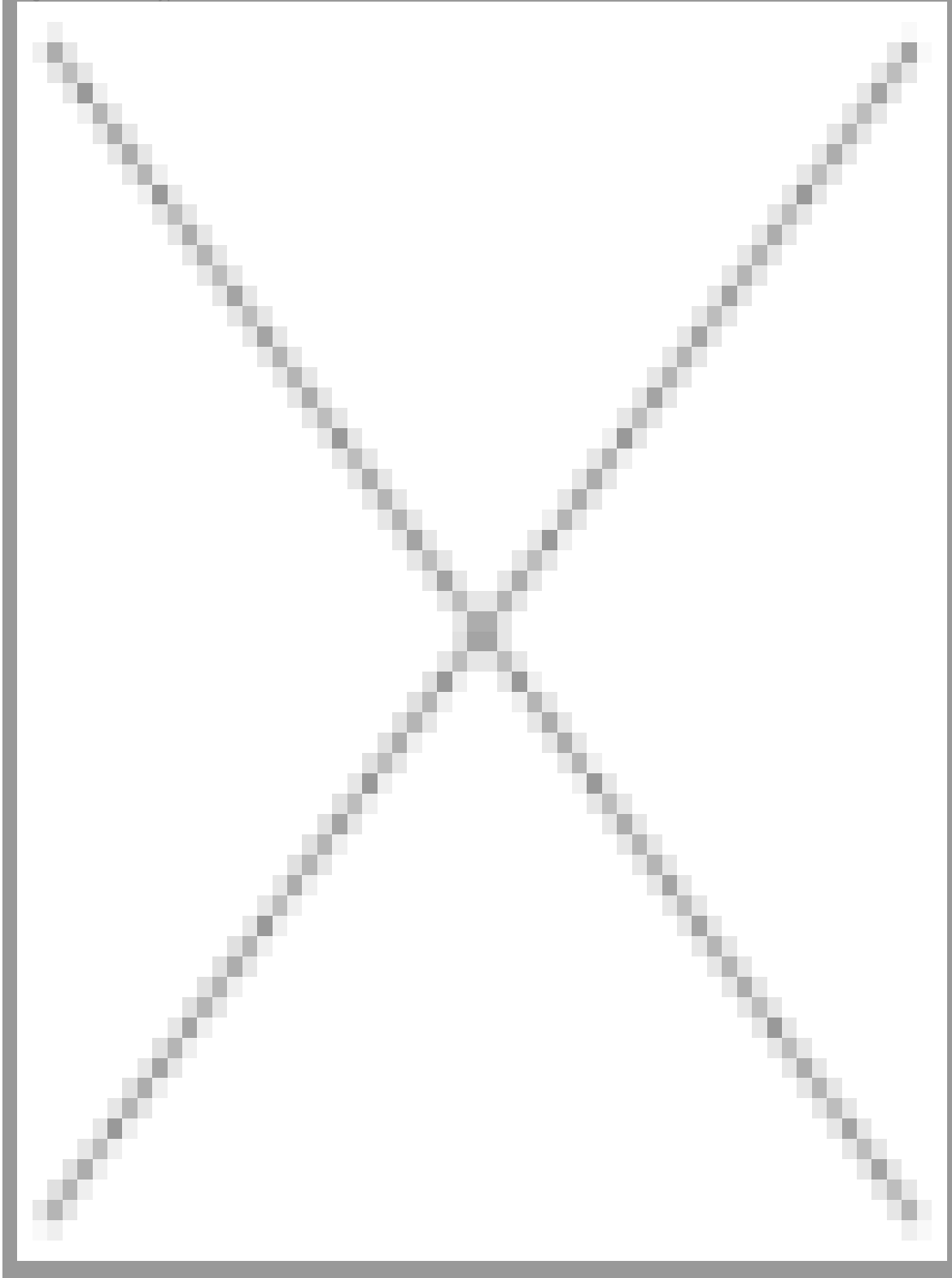
Biotechnology firm Bharat Biotech International (BBIL) has also launched BioHib, Haemophilus Influenza Type b (Hib) vaccine in India, and Comvac 4-HB, a tetravalent combination vaccine. Comvac4-HB and BioHib enable the deployment of a combination pentavalent vaccine in a single injection.

BioHib too is a safe and affordable vaccine that offers complete protection against Hib Infection. BioHib is a conjugate vaccine that has proven its safety and efficacy in multi-centric clinical trials. According to Bharat Biotech officials, while other Indian manufacturers had imported conjugation and manufacturing technologies from Europe and the US, the scientific

manufacturing and product development teams at Bharat Biotech have developed all processes required to manufacture BioHib in-house. The company had made huge investments in the last four years into its R&D capabilities and its manufacturing facilities to develop and manufacture BioHib vaccine.

Haemophilus influenza type b (Hib) bacterium causes serious disease, often life-threatening illnesses in young children. Hib can cause meningitis and severe pneumonia, leading to about 3 million cases of serious illness and 4,00,000 deaths each year in children below five years of age. Hib is difficult to treat in the developing world, with infected children in developing countries several times worse than those in industrialized countries. Invasive disease can be treated with antibiotics but lack of access to adequate medical facilities and increasing levels of antibiotic resistance lead to a high mortality rate: 20 percent of children in developing countries with Hib meningitis will die (rising to an even higher percentage in Africa and Asia). About 15- 35 percent of children suffering from Hib meningitis will go on to develop life long disabilities such as mental retardation or hearing loss.

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Panacea Biotec, one of the largest vaccine producers in India, will rollout a Foot and Mouth Disease (FMD) vaccine in the coming 18-24 months. The company has collaborated with National Research Development Corporation (NRDC) for in-licensing of technology to produce and market the Foot and Mouth Disease (FMD) vaccine developed by Indian Veterinary Research Institute (IVRI). Panacea's entry into the animal vaccine segment will give additional width to its product portfolio. In fact, most of the companies in the vaccine arena do have a veterinary arm as an offshoot to the human vaccine segment. The FMD vaccine will be one of the products at Panacea's multi vaccine facility.

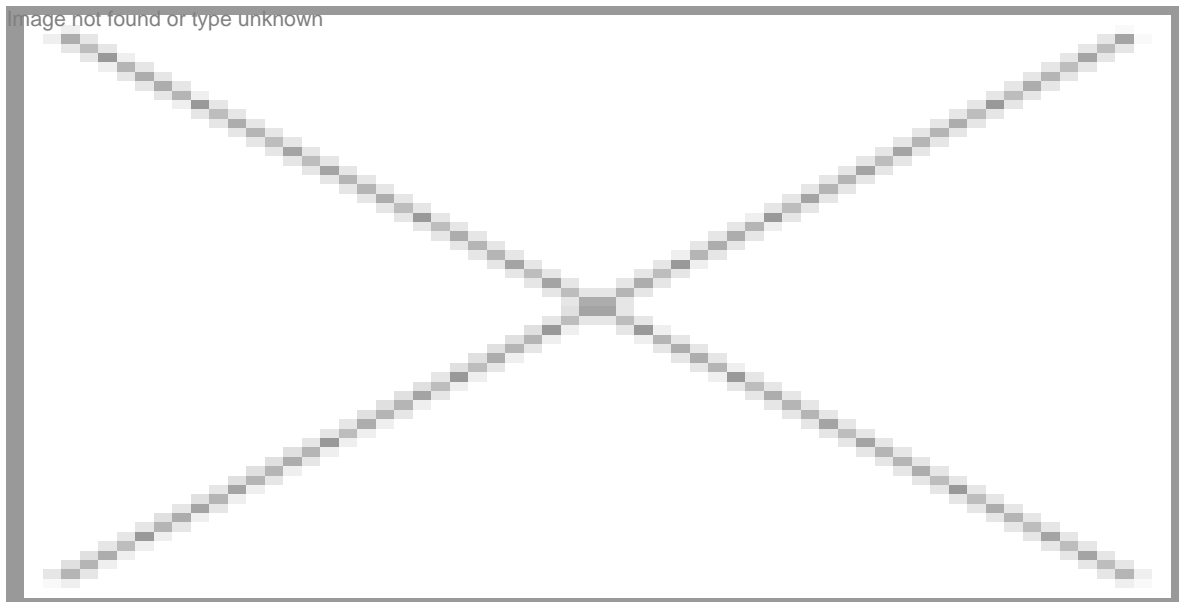
Panacea Biotech recently inaugurated its greenfield construction vaccine formulation plant (VFP) at Baddi in Himachal Pradesh. The plant has been commissioned with several filling lines for bacterial and viral vaccines complying with WHO, cGMP norms for liquid vaccines in pre-filled syringes, liquid and lyophilized vaccines in vials. The total production capacity of this facility is one billion doses per annum.

Panacea Biotech had entered joint ventures for vaccine manufacturing with Chiron Vaccines (Emeryville, CA) and thermostable vaccine production with Cambridge Biostability (Cambridge, UK). Panacea Biotech is also negotiating a collaboration with ApoLife (Detroit), for using ApoLife's yeast-based technology for the production of therapeutic humanized antibodies.

Hyderabad-based biotech company, Shantha Biotechnics, in collaboration with the global nonprofit health organization PATH, is developing a multivalent vaccine against rotavirus. The technology has been licensed from the US National Institutes of Health (NIH). Shantha and PATH are working in partnership to accelerate the development of this new vaccine. There are two licensed vaccines for rotavirus, Merck's RotaTeq and GSK's Rotatrix, and both these vaccines are currently not available in India.

Shantha carries the credit of developing and commercializing India's first recombinant Hepatitis-B vaccine and other combination vaccines with the DTP platform. Shantha's vaccines (Shanvac-B and Shantetra, DTP-Hepatitis B) are WHO pre-qualified and are supplied in various countries in Asia-Pacific, Africa, CIS and Latin America by the international agencies like UNICEF and PAHO.

Biological E will be launching the Hib vaccine and the DPT + Hepatitis b combination vaccine in the next few weeks. It will be followed by the injectable polio vaccine and the pentavalent combination vaccine, Hib + DPT+ Hepatitis b which is under development. The company has also set up a new vaccine division - Origyne in the biotech park which would take care of the marketing. In addition, Biological E has recently signed an agreement with Merck under which Merck will be manufacturing its vaccines in the Shameerpet unit.



A major portion of global research efforts is being directed towards developing DNA vaccines. While DNA vaccines for humans are still in preclinical development or in the early-stage clinical trials, they show immense potential for effectively targeting HIV, herpes, malaria, and influenza, meningitis and various types of cancer. Moreover, DNA vaccines have the ability to stimulate potent immune responses without the drawbacks of conventional vaccines.

The greatest advantage is that they are noninfectious and can be used for producing vaccines against diseases such as HIV, where inoculation with a dead or attenuated virus is too risky. In addition, DNA vaccines are inherently stable and do not require constant refrigeration. These vaccines are expected to be particularly popular in developing countries since it is feasible to produce and purify large amounts using simple and inexpensive procedures.

Rapid advances in biotechnology and immunology have been a constant driving force behind the development of vaccines. While a detailed understanding of immune responses has been applied to different stages of vaccine development, advances

in biotechnology based on genomics, DNA platforms, and delivery systems offer significant opportunities for developing new vaccines and expanding the number of target diseases.

Researchers are looking at proteins from genetically engineered plants to create edible vaccines. Although its commercial viability is yet to be proven, oral vaccination provides a cost-effective and convenient alternative to conventional vaccines. Moreover, an oral vaccine not only elicits a good immune response, it is also likely to eliminate the geographic limitations inherent in most vaccination programs.

Therapeutic vaccines development is seeing an increasing trend towards the use of multiple antigens and adjuvants, to attack cancers or HIV from multiple angles. Combinations of therapies, and novel approaches such as prime-boost regimens are expected to yield exciting results. Partnerships will therefore become much more important.

Therapeutic vaccine development is currently heavily weighted towards cancer vaccines, which account for 60.6 percent of all pipeline projects. However, the early-stage pipeline is starting to show greater interest in other therapeutic areas, from HIV and infectious disease, CNS and cardiovascular diseases.

## **Challenges**

Policy challenges at the national level contribute to the delay in making new vaccines accessible to people. In India, the public health research is overburdened, underfunded, and poorly coordinated. Some of the key factors responsible for the current state of affairs include the absence of a directional consistency and lack of coordinated planning, limited infrastructure, inadequate funding, and insufficient interaction and collaboration with industry. Inadequate public funding to support R&D has a negative impact on both public and private sector efforts. In addition, venture capital funding is quite limited for health-related R&D.

Vaccine R&D poses a number of risks to companies, which choose what they perceive as the best business opportunities. The vaccine business is expensive, risky and with a smaller market than pharmaceuticals. Marketing vaccines can be uncertain with significant risk. Demand for certain vaccines can be variable and unpredictable.

Uncertain demand for vaccine is one obstacle, especially since much of the anticipated market is in developing countries, where the ability to pay for a vaccine is limited so the companies fear that they will not be able to charge commercially feasible prices.

Indian biotech and pharmaceutical firms have strong product development capabilities but increasingly focus on export markets. Most leading Indian pharmaceutical and biotechnology firms earn more than half of their revenues from export markets.

The many layers of regulatory approvals and inadequate funding result in inordinate delays and, ultimately, slow down the innovation process.

Indian players perceive that any potential product would be country/region specific; given the different strains of virus across countries and regions, they are concerned that a vaccine developed in India would not be exportable to other countries and regions.

However, India's high population makes it an important player in this industry and several domestic players are competing in this market. In India about 15 companies are involved in the marketing of over 50 different brands for 15 different vaccines. Clearly, there is a high competition on the price front and companies are launching newer vaccines into the market to increase their revenue. The largest markets for vaccines in India are for Tetanus Toxoid, polio, DPT, Typhoid, BCG, measles and Hepatitis B. Indian and international research organizations and agencies are developing vaccines for anthrax, HPV, HIV, typhoid, Japanese encephalitis, malaria, cholera, rotavirus, colitis, HIB meningitis and other diseases.

It is becoming clear, however, that to make more significant progress in the future, some changes need to be implemented to the strategies applied in the past for vaccine development, safety checks, global distribution, and disease monitoring. The heterogeneous needs of different world areas, the emerging of specific problems in certain countries, the shifts in the world economic equilibrium, as well as several other factors all have to be taken into account to sustain as a leader in the vaccine business.

