



India, an emerging global hub for vaccine industry

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ASIA is emerging as the vaccine hub of the world and India is poised to play a key role in the vaccine market. The global vaccine market is expected to reach \$10 billion during the current year 2011. This is forecast to climb up to \$23.8 billion by the year 2012 and to reach \$40 billion by the year 2015. A sharp increase in sales is expected in areas of influenza and hepatitis vaccines.

The vaccines for cancer are expected to have a phenomenal growth due to increased disease incidence in the areas of cervical, prostate and lung cancer. Though the paediatric vaccines were dominating the vaccine market in the past, a change in this trend is expected due to a

high demand forecast for the adult vaccines. Global adult vaccine market was around \$3.7 billion during 2005 and this market is estimated to reach \$7.5 billion in 2012. The major contributors to the growth of the adult vaccine market would be influenza vaccines, HIV vaccines and cancer vaccines. Cancer vaccines will also become a major player in the vaccine market, rising from its current level of \$135 million to more than \$8 billion by 2012.

The Indian scenario

The current revenue of the Indian vaccine market is estimated around US\$ 900 million in 2011 and is poised to grow at the rate of 23 per cent during 2011-12. Around 70 per cent of the total volume manufactured is exported. India is the major supplier of vaccines to UNICEF which in turn supplies 40 per cent of the total vaccine demand for childhood vaccination in more than 100 countries. The share of the

Phase III vaccines in development - pipeline			
Company	Product	Market	Indication
Bavarian Nordic	Imvamune	Adult	Smallpox
Bharat Biotech	116E	Paediatric	Rotavirus
Crucell	Flavimum	Adult	Yellow fever
GlaxoSmithKline	Next-gen flu vaccine	Adult	Inactivated influenza for the elderly
	Hib-MenCYTT	Paediatric	Neisseria meningitis groups C & Y disease & Haemophilus influenza type b
	Nimentrix	Paediatric	Neisseria meningitis groups A, C, W & Y disease prophylaxis
Merck	V503	Adult	Cervical cancer, 9 valent
Novartis	Menveo Infants	Paediatric	Meningitis
	Menveo Adolescent	Paediatric	Meningitis
Sanofi Pasteur	Pediacel EU	Paediatric	DTP, polio, Hib
	Menactra	Paediatric	Meningitis infant/toddler 9 - 12 months
	Adacel	Paediatric	DTP ages 4 - 6
	Hexaxim	Paediatric	DTP, Hepatitis B, polio, Hib

private sector in the total volume of vaccines exported is roughly around 40 per cent. The once neglected vaccine

market is now considered as a source of steady income. The evidence for this being the take-over of Shantha Biotech by Sanofi Aventis and the possible take-over of Biological Evans by GSK. The reasons which makes the Indian companies very attractive for take-over are, opportunity and assured income from exports and facilities on par with global standards which could be used for manufacturing to meet the global demand.

The rewarding vaccine market was brought to the limelight by the introductions of Prevnar, a vaccine for childhood infections by Wyeth and Gardasil, a vaccine for cervical cancer by Merck & Co. The last few years witnessed a remarkable growth in the vaccine market due to the avian influenza, Bioterrorism organisms and infections like SARS.

Major India players in the vaccine market

1. Serum Institute of India Ltd
2. Panacea Biotech Ltd
3. Venkateshwara Hatcheries Private Ltd
4. Indian Immunological Ltd

5. GlaxoSmithKline Pharmaceuticals Ltd
6. Aventis Pharma Limited
7. Shantha Biotechnics
8. Eli Lilly India
9. Haffkine Bio Pharmaceutical Corporation Ltd (HBCL)
10. Intervet India
11. Lupin
12. Avesthagen
13. Wyeth
14. Sanofi
15. Merck

Key drivers for the vaccine market

1. Relatively low cost of manufacturing
2. Reasonable R&D expenditure
3. Leading edge technology / combination Vaccines
4. Low cost of clinical trials
5. Abundant skilled manpower and scientists
6. Huge demand in the local market
7. Blockbuster potential of new vaccines

Key challenges for the vaccine market

1. Price point pressure: The model of low cost high volume business has created margin pressure for some vaccines to their manufacturers.

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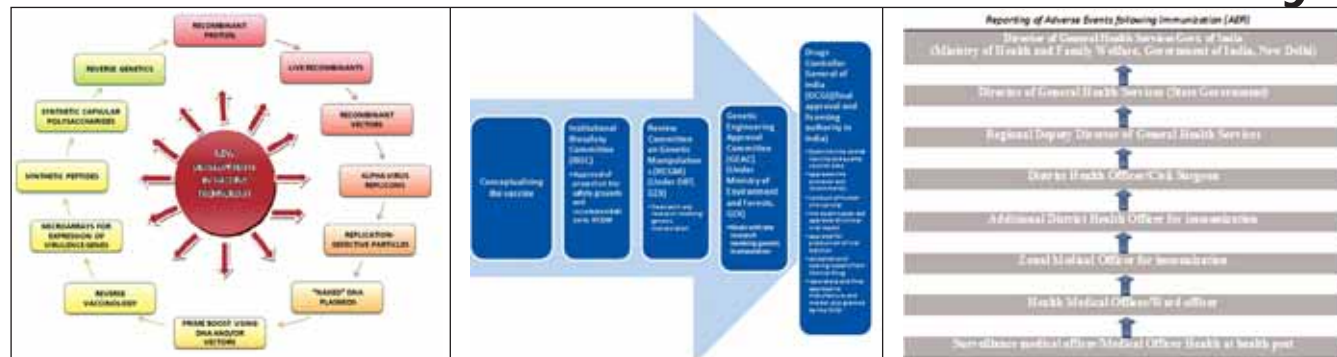
Competition to increase with traditional cos entry

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- The supply chain: Vaccines have to be strictly monitored for specific temperature which adds to the costing woes of the manufacturer.
- Clear regulatory guidelines are still under development in India.

Developments in vaccine technology

There have been vast developments in the vaccine technology. The acellular purified fractions have replaced the conventional pertussis vaccine eliminating the side-effects during vaccination. The replacement of toxoids in the place of non-pathogenic and immunogenic mutants of tetanus and diphtheria toxins is a landmark development. The recombinant technology is now used to prepare vaccines. Conjugated vaccines have been developed to reduce the number of injections. Human recom-



binant antibodies are used for treating terminal tetanus and rabies.

Unmet needs

Medical survival is very poor for lung cancer patients. Vaccines are looked upon to provide a cost effective and low toxic therapies. A number research works are in progress for developing vaccines for breast cancer.

Many clinical trials are in progress for cancer treatment vaccines which include bladder cancer, brain tumours, breast cancer, cervical cancer, hodgkin lym-

phoma, kidney cancer, melanoma, multiple myeloma, leukaemia, lung cancer, non-hodgkin lymphoma, pancreatic cancer, prostate cancer and solid Tumours. Clinical trials for cervical cancer and solid tumours are in progress for the development of preventive vaccines.

The increased incidence in the rate of diabetes has strong collateral effects with incidence of influenza as diabetics are more prone to this disease. The need for addressing this demand is in the increasing trend.

Vaccines safety reporting-

India scenario:

The Indian Council for Medical research (ICMR) has provided all the guidelines and has prescribed the rules of conduct for clinical trials from Phases I to IV and for studies on combination vaccines. The ethical issues are addressed by these guidelines.

The ICMR set up new guidelines in 2006 which included conducting clinical research of vaccines in human subjects. All vaccine trials are expected to be carried out in accordance to these guidelines and were earmarked under,

- Phase I-IV studies
- Bridging studies
- Combination vaccines
- Vaccines administered simultaneously with a combination vaccine

Vaccine Pharmacovigilance in India:

The centres for Adverse Drug Reaction (ADR) monitoring and Adverse Events Following Immunization (AEFI) monitoring perform the role of Pharmacovigilance for vaccines. At present only the health-care workers can report to the ADRs.

Futuristic landscape

The rapid growth of the vaccine market would lead to increased competition and would resemble the pharmaceutical market. There would be a distinct first mover advantage for companies launching their vaccines early in the market with funding from various government agencies. Competition in the market is set to increase with the entry of more traditional companies. India must develop its own national strategies to meet its vaccination needs within its budgetary constraints. ◆

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