

Expert Opinion - Rajesh Jain

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VACCINES

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New benchmarks

Increased collaborations, skilled workers, and state-of-the-art manufacturing facilities continue to make India the leader in this segment

Vaccines continue to be important contributors of healthcare revenue across the globe. Global vaccines market has approximately tripled since 2000 and reached \$26 billion in 2010, making it one of the fastest growing sectors of the pharmaceutical industry with pediatric vaccines dominating the global vaccine market, pediatric proprietary vaccines and pediatric enhanced combinations being the growth engines. In addition, adolescent, adult, and travel vaccines are continuously assuming significance. Geographically, developing countries are emerging as the main hub for low-cost high-quality vaccines.

The key drivers of vaccine industry are cost effectiveness in combating diseases, greater appetite for vaccines from governments in the forecast period, technological advances in genetics and immunology and the launch of newer vaccines for treatment of range of diseases.

In 2010-11 the vaccines market in India was estimated at around \$350 million registering a growth of more than 22 percent over the previous year. It is estimated to gallop to over \$1 billion by 2017 and then race to

over \$1.7 billion by 2020.

Manufacturing and R&D trends

India has emerged as leading vaccine manufacturing hub, producing 60 percent of global vaccines and is largely becoming a premier location with skilled workers and state-of-the-art manufacturing facilities for producing affordable vaccines. There are increased collaborations to bring newer vaccines and combination vaccines to market. This is a significant change compared to few decades back when India was not considered a focus area by pharmaceutical companies.

At the same time, we are grappling with number of challenges at macro level. New vaccines, new markets and new production methods have to be embraced to ensure minimized costs and sustained growth. New technologies such as gene-based vaccines, VLPs, novel adjuvants and delivery systems represent promising approaches to future of India's vaccine industry.

Currently, at two percent penetration, the vaccines market is significantly under-penetrated, despite suffering from a high burden of deaths by vaccine preventable diseases. Universal Immunization Program (UIP) till 2007 covered only six vaccine preventable diseases.

Regulatory issues and business models

Introduction of newer vaccines such as Pneumococcal conjugate vaccine, Rota Virus vaccine and HPV are going to spur the growth of vaccine market in India. Key issue will be funding for phase III efficacy and safety trial. For example, the Rota virus safety trial will involve sample size in excess of 50,000. Who will fund? Who will take up the risk of failure? Will it get included in UIP? What will be the demand and forecast? Will there be long term agreements?

Apart from this, affordability is a major concern in India which needs to be addressed on priority by government and private organizations together. With nearly 470 million people living on less than \$1 (PPP) a day, developing medicine which is affordable to mass audience is biggest challenge in front of us. Government is setting up new schemes such as Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Program (BIPP) which have provided an additional impetus to innovation and encouraged new entrepreneurs in this business. However government's spend on public healthcare remains lowest among that of most of the nations on the planet. Government should invest in healthcare and make medicine free for all. It should also encourage private capital investment in the industry and provide policies and infrastructure to attract more investment. Government's corrective interventions are desperately needed in an industry.

- **Dr Rajesh Jain**, joint managing director, Panacea Biotec