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Indian Vaccine sector: opportunities and challenges

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Indian Vaccine majors: Opportunities to explore, potential to transform

Recently, Panacea Biotec, India' s second largest producer of vaccines, bagged an order worth Rs 187.61 crore from the Indian government for the supply of 345 million doses of trivalent oral polio vaccine (tOPV) and bivalent oral polio vaccine (bOPV). The same has to be supplied between December 2012 and May 2013. The order is to meet the requirements of national immunization days (NIDs) and supplementary national immunization days (SNIDs). The deals are an indication that the Indian government has stepped up its dependency on the Indian companies.

The policymakers in fact have always been worried about the lack of vaccination alternatives and the high prices from the multinationals. Yet, the vaccine market at two percent penetration as McKinsey report puts it, is significantly under-penetrated. It estimates the Indian vaccine market at around $900 million and it is poised to grow to $4.6-billion revenue by 2017. With the opportunities wide open, the vaccine manufacturers are aiming to consolidate their positions.

Local companies play epochal role

The model that most Indian vaccine makers follow is similar to what domestic generic drug companies have been doing for a long time. Indian vaccines, alike the Indian generic medicines are also being projected as low-cost alternatives to high-priced vaccines produced by global majors.

Every year, the rotavirus causes fatal diarrhoea that kills around 500,000 children under five years. Among the key companies, the vaccines that are currently undergoing phase III clinical trials for safety and efficacy in 8,000 children and, along with vaccines from Serum Institute of India and Shantha Biotechnics, are expected to hit the market in 2015. These vaccines will bring the price of vaccinating a child to $3, down from the current $7.5 per dose. Bharat Biotech had announced that it will price rotavac, India's first indigenously developed rotavirus vaccine at $1 per dose. According to Dr Krishna Ella, chairman of Bharat Biotech, "When this company had initiated the development of Rotavac a decade ago, a promise was made that the vaccine, as and when approved, will be priced below $1 a dose for global supplies." Dr Ella feels that the competition will always be helpful in reducing the prices further.

Serum Institute of India, one of the country's leading vaccine producers, claims that two of every three children immunized in the world is vaccinated by a vaccine, which is manufactured by the company. The company's products, used in 140 countries, are known for their low cost. Last year, Serum Institute lowered the price of its pentavalent vaccine to $1.75 per dose, the lowest price available globally.

Panacea Biotec has committed to lower its prices of vaccines by up to 15 percent. The company introduced EnivacHB (hepatitis B) in 1997. The superior manufacturing process lead to better immunogenicity proven in clinical trials. The unique prefilled syringe ready-to-use device (ENivac HB Safety) ensured safe injection practices advocated by World Health Organization (WHO). The EasyFive (pentavalent vaccine - DTP-HIB-HepB) was introduced by the company in 2005. The first fully liquid (wP) pentavalent vaccine was introduced in 2007. Dr Rajesh Jain, joint managing director, Panacea Biotec, says, "We have utilized the unique Easy-Track mobile sms service to remind the parents for timely immunization of the child and also Easy-Vaccination mobile and web-based service to educate the customers about vaccination online."

Major hurdles faced by vaccine industry

- Technological capacity and access to know-how
- Lack of generic pathway for vaccines
- High capital investment in manufacturing infrastructure with lack of demand
- Gap in the need and accessibility of vaccines
- Need to add new vaccines in Expanded Program on Immunization (EPI)
- High cost of R&D, long and complex clinical trials result in longer time to licensure
- Entry barriers to emerging suppliers in competition

Many believe that companies might not be able to offer affordable vaccines owing to high investments in R&D, the dual pricing might be one of the solutions. "I suggest dual pricing policy and control over price when government is buying it. For people, who can afford it, can take them," says Dr Shirshendu Mukherjee, senior strategic advisor, Wellcome Trust. At present, HPV vaccine is priced between Rs 6,000 to Rs 7,000 per dosage. Shortly one can see the companies putting efforts to develop HPV vaccines by Indian companies.

The growing involvement of the Indian companies is also forcing the global players to come up with a local strategy. In fact, the affordable vaccines from India is forcing the big multinationals to go for reduction in prices. For example, the prices of basic pediatric vaccines have been reduced significantly over the years to match the budgetary constraints. Earlier, the recombinant vaccines against hepatitis B by GlaxoSmithKline (GSK) and Merck were the first to be sold in India at $40 a dose. After patent expiry of the innovator vaccine, and with the entry of low-cost manufacturers, prices were reduced to $1 per dose. For the pentavalent vaccine (DTP-HepB-Hib), the prices offered to the United Nations Children's Fund (UNICEF) and the Pan American Health Organization (PAHO) were dropped by 50 percent during last five years from approximately $4 per dose.

GSK has announced its rotavirus vaccines at $2.50 per dose or $5 to fully immunize a child in response to a current tender administered by UNICEF. The offer is a 67 percent reduction in the current lowest available public price. Merck also announced reducing HPV vaccine prices from the current $15 per dose to $5 per dose, a 67 percent reduction in the current public price. The decision came after Serum Institute of India and Panacea Biotec lowered the prices of their pentavalent vaccine that protects against five potentially fatal infections such as Hib (Haemophilus influenzae type b), diphtheria, pertussis (whopping cough), tetanus, hepatitis B, rotavirus and cervical cancer.

The report by Global Health Strategies Initiatives (GHSI), an international non-profit organization working to improve health in developing countries, puts India as the largest producer of low-cost drugs and vaccines. With India producing 60 percent of the world's vaccines and accounting for 60-80 percent of the annual United Nations vaccine purchases, several Indian vaccine manufacturers have been granted the WHO prequalifications approval for quality.

To make vaccines available in developing world countries, immunization programs are driven and funded by governments and UN agencies like WHO, the Global Alliance for Vaccines and Immunization (GAVI Alliance), Pan American Health Organization (PAHO), PATH with funding from donors like Department for International Development (DFID, UK), Japan International Cooperation Agency (JICA, Japan), Rotary Foundation, Rock Feller Foundation, and Bill and Mellinda Gates Foundation.

Talking about the government role, Dr TS Rao, senior advisor, Department of Biotechnology (DBT) opined, "National immunization program of the government is the best example of policy makers regulating the prices directly, so that the vaccines should reach the masses at affordable cost. Government has to look at various options to make the vaccines affordable. For example, the polio vaccine was made available to masses at negligible price through the public programs. Without compromising the quality of vaccines, we have to work towards achieving the affordability. Healthy competition is a necessity for the companies and at the same time the government too has social responsibility."

Dr Mukherjee, agreeing with Dr Rao, feels that Indian funding agencies are big pillars who have played a vital supportive role. "The Hep B vaccine is now available at approximately Rs 15 per dosage while outside of India its price is about Rs 70 per dosage. Earlier, a MNC used to sell it at Rs 400 per dosage. But after Technology Development Board (TDB) funded Shantha Biotechnics' vaccine program, the price came down substantially. Then other companies such as Panacea Biotec, Wokhardt, Bharat Biotech and Serum Institute of India too launched their products at affordable price. This describes the success story of how India had funding agencies as big pillars in developing vaccines," explained Dr Mukherjee.

Although WHO estimates that the basic immunization coverage has improved substantially in recent decades (from about 20 percent in 1980 to about 80 percent in 2007), there are about 26 million children (roughly 1 in 5 born per year), who still needs to be immunized. Wider use of available vaccines could further avoid about two million deaths annually.

The new vaccines need to be added to the immunization schedule, but these are prohibitively expensive. Vaccines like rotavirus, pneumococcal, meningococcal, and HPV are already available in developed world but still out of reach in the developing countries. Since both governments and United Nations agencies have limited funds, there is always a pressure on decreasing the price of vaccines to improve the access.

It is being hoped that the emergence of new-generation vaccines will see India's vaccine market transition from being a publicly-funded initiative to a private business, where vaccines will be prescribed by private practitioners across the country.