

# Immunity creators

**Donors commit billions, while manufacturers lower prices of life-saving vaccines at a conference held by Global Alliance for Vaccines and Immunisation**

**R**ight from the beginning of this year, there has not been a single dull moment for the vaccine industry in India. First, the Bill and Melinda Gates Foundation announced funding for two Indian firms – Serum Institute of India and Bharat Biotech – to develop and sell vaccines for pneumonia and diarrhoea that kill thousands of children every year, at less than half the current market price.

More recently, donors committed \$4.3 billion at the first pledging conference held by the Global Alliance for Vaccines and Immunisation (GAVI). The phenomenal response handsomely exceeds the initial target of \$3.7 billion set by GAVI, a Geneva-based public-private partnership aimed at improving health in the world's poorest countries. The funding will help immunise more than 250 million of the world's poorest children against life-threatening diseases by 2015 and prevent more than 4 million premature deaths! Alongside the donors, the vaccine manufacturers pledged to lower prices of a range of life-saving vaccines, including a two-thirds reduction on the rotavirus vaccine, which combats the leading cause of diarrhoea deaths.

In what way these developments are likely to impact the market remains to be seen. "To enable GAVI to deliver on its market shaping strategy, GAVI must give due consideration to the economic realities that shape the vaccine market. An efficient match of supply with demand requires



*Vaccines: preventing disease early in life*



Schwalbe: emphasis on strong advocacy support

more intense and targeted competition, the entrance of new suppliers, increased bargaining power for purchasers, strong advocacy support to immunisation and stronger health systems to support vaccine uptake. The pricing announcements underline some of these key aspects in operation, for example, the entrance of India-based suppliers of new rotavirus vaccine in the medium-term will increase competition and will support price reductions,” explains Nina Schwalbe, managing director, policy & performance, GAVI.

Point taken. There’s no denying that GAVI’s market-shaping strategy has worked. Through its Advance Market Commitment, the price of pneumococcal vaccine has already come down. However, the price offers announced earlier in the month by vaccine manufacturers concern other types of vaccines, including rotavirus, HPV and pentavalent, which do not fall under the Advanced Market Commitment (AMC) funding scheme.

GAVI’s business model has ensured good returns. “Subject to the outcome of the tender process, the rotavirus vaccine could be purchased at a price as low as \$2.50 (\$5 per course); a price this low could

save about \$500 million up to 2020 or about \$140 million through 2015. These savings are based on the difference between the \$2.50 and GAVI’s current assumption of future prices (rather than the difference between the \$2.50 and current prices). Should other vaccines be developed by new market entrants such as Bharat Biotech, which has announced a price of \$1 per dose (\$3 per course), this would yield for further saving from 2015 onwards,” adds Schwalbe.

**Profitable business**

GAVI employs the principle of lowest sustainable pricing so that multiple manufacturers get an incentive to develop and supply products for GAVI countries. GAVI, its procurement partners (UNICEF and PAHO Revolving Fund), and other Alliance members such as the Bill & Melinda Gates Foundation work in partnership with industry to ensure this balance is struck as part of GAVI’s market shaping strategy. The Alliance also claims to actively engage in a range of push-and-pull funding mechanisms to ensure that new suppliers enter the market in the medium- to long-term. The price reduction is, however, unlikely to affect the manufacturers’ bottomline

because the high volumes purchased through GAVI funding should enable them to benefit from economies of scale.

But to what extent will the competition dynamics between the established multinational firms based in the US and Europe, and the emerging suppliers based in developing countries change as a result of the price cut? “Though Indian vaccine companies will always remain competitive when it comes to tenders for the UNICEF and GAVI, the price reduction by GSK and Merck will still keep them in the competition. With this bid for price reduction for such tenders, the companies are now on a cost plus basis, rather than on margins business. They are now relying on the volumes that will make their prices viable.

“This can be seen in the statement of Merck Inc, which states that the further price reduction to \$3.5 will occur only after the sale of the first batch of 30 million doses at \$5 for rotavirus. The prices for these vaccines in the US and EU markets will however remain the same, and continue to bring in profits to these

**GESTURES OF A DIFFERENT KIND**

- ♦ **Glaxo-SmithKline** announced that it will sell its **£8** a dose rotavirus vaccine for less than **£3** a dose to low-income countries through GAVI. It’s almost a **67 per cent** reduction on the lowest price available today.
- ♦ Pune-based **Serum Institute** lowered its price to **\$1.75** per dose for its pentavalent vaccines, while Panacea Biotech lowered its prices by up to **15 per cent**.
- ♦ **Merck** has announced it would offer GAVI the HPV vaccine at a reduced price of **\$5** per dose, a **67 per cent** reduction in the current public price.
- ♦ **Sanofi Pasteur** will extend the GAVI prices to its pentavalent vaccine besides the yellow fever and the rotavirus vaccines being developed by its subsidiary Shantha.

Source: GAVI



Ella: making a real contribution

companies,” feels Dipta Chaudhury, senior consultant, pharma & biotech practice, South Asia & the Middle East, Frost & Sullivan, a business research and consulting firm.

Providing quality vaccines at significantly lower costs gives Indian vaccine manufacturers a definite edge. Besides, the world is also clearly looking at India as the source of a lot of important innovations. Consider the indigenously developed rotavirus diarrhoea vaccine for instance which Bharat Biotech will offer at a dollar. “We’ll be there by 2014,” says Krishna Ella, chairman and managing director, Bharat Biotech. The journey hasn’t been easy for him though. “I got into the programme nine years ago. Everyone laughed at me. People asked me if I’d gone crazy. There was criticism in my own company against me.”

But for Ella, it was a conscious decision. “While I had 50-60 research papers to satisfy my ego, I wanted to make some real contribution to the community as a scientist,” says Ella. “As a technocrat entrepreneur, I wanted to do something about the fact that 600,000 children are dying globally due to rotavirus... 200,000

of them in India alone. The number could even be double. Unfortunately, in India, doctors can’t even identify rotavirus. In India, we do not value life. In US, about 100 children die each year from rotavirus. They want to avoid hospitalisation because they know it will lead to other children getting infected. Vaccination there is compulsory,” he adds.

**Adequate funding**

The programme is also credited for first of its kind efficacy trial in India, costing nearly ₹250 crore. Despite the challenges, when he got the offer to license out the molecule during phase two, he decided against it. There were intense technological barriers too which, thanks to the \$30 million funding from the Gates Foundation and support from the department of biotechnology, Ella was able to tide over.

“I don’t want to be greedy. If I price the vaccine at \$10, how will India’s GDP afford it? For Zimbabwe, it



Barollier: too early to judge

might be 60-70 cents because, at the end of the day, you have to match the GDP of the country,” says Ella. He is at present using the rest of his portfolio consisting among other vaccines for polio, rabies, hepatitis B and typhoid, to offset the rotavirus programme.

Multinationals like Sanofi do not wish to be left behind. “It is too early to know how these announcements will impact market dynamics. Sanofi Pasteur’s price guarantee is part of the company’s long time commitment to ensure through tiered pricing that all countries, including developing countries, have access to life saving vaccines,” said Pascal Barollier – vice-president, external & scientific communications, Sanofi Pasteur.

At the GAVI international meet in London, Cyrus S. Poonawalla, chairman and managing director, Serum Institute of India (SII), appealed to big pharma companies and suppliers to

**ELOQUENT NUMBERS**

**\$34 billion:**  
The global vaccine market is expected to register revenues in excess of \$34 billion by 2012. With a projected CAGR of over 13 per cent during 2009-12, vaccines make a rapidly growing segment of the global pharmaceutical market.

**5 million:**  
The number of future deaths averted as a result of GAVI support provided since year 2000.

**24.1 million:**  
Number of babies who are not vaccinated against common diseases.

**530,000:**  
The number of lives Rotavirus disease claims each year.

**\$4.6 billion:**  
The top 11 vaccines in India at present make it a \$1.1 billion market and is estimated to become \$4.6 billion by 2017.



Source: Oxfam, GAVI, Frost & Sullivan



Bill Gates, David Cameroon (UK Prime Minister) and Cyrus Poonawala

follow the principle of 'philanthropic pricing policy'. "I make a personal pledge on behalf of Serum Institute that we recognise our moral responsibility to keep vaccines as affordable as possible for the underprivileged children. I would also urge other big pharma companies and suppliers to follow the same philanthropic policy on pricing," he said. SII offered GAVI its pentavalent vaccine (5-in-1) at \$1.75, which was earlier purchased by GAVI at more than \$3 per dose.

"This is the most affordable vaccine offered by any manufacturer in the world," he added.

#### Badly designed

However, as earlier pointed out by Ella, there are several challenges that Indian manufacturers need to overcome. "As pointed out in the conference, the Serum Institute would have already had an anti-pneumonia product in the market at \$2. Unfortunately, patents on the grounds of

technology to produce the vaccine blocked its way. Serum Institute had to reinvent the whole process and lost a few years. That's a critical issue – will the Indian companies in future get to quickly access the technology they need to reach the market? But vested interests are preventing Indian companies from getting quickly on the market," says Daniel Berman, deputy director, Campaign for access to essential medicines, Médecins Sans Frontières (Doctors Without Borders).

Berman is vocal about other issues as well. He questions the \$225 million subsidy that both Pfizer and GSK have received from Advance Market Commitment at GAVI. "The mechanism has been badly designed," he argues. "They don't need the subsidy. I would say they were not being honest about the cost of development and production. I say that because the cost according to Indian companies to make a vaccine manufacturing plant is \$30-50 million. Big pharma is claiming it cost them \$250-400 million. They are exaggerating their cost as a way to keep up the prices. GAVI and the donors are not taking advantage of the capacity of India to produce high quality-low price products."

He also urges the big pharma companies and emerging companies to come off the GAVI board to avoid the prevalent conflict of interest. "Unfortunately, donors have been giving a bit of unfair advantage to their own companies."

Recently, when UNICEF decided to make the prices it pays to vaccine manufacturers public, it became more than evident that Indian companies were offering dramatically low prices. "It's not been a competitive market. We saw that Johnson & Johnson's division Crucell and Glaxo have been charging significantly higher price for the Penta vaccine.... If prices of Indian vaccines continue to be competitive, and formulations adaptable to the needs of developing countries, then Indian manufacturers will have significant part of market," says Berman.

A positive note indeed.

♦ KIRAN YADAV