

Uncovering Viable Markets In Global Health

While only a dozen new vaccines have been created in the past 75 years, the vaccine industry is on the rise again. With over \$10 billion in vaccine revenues annually, big pharma is reentering the vaccine market to tap into this growing opportunity. But can the value proposition for industrialized world vaccines apply to vaccines for neglected diseases of the developing world? A panel of biopharmaceutical industry representatives explored this question and discussed how to create value for industry investment in vaccines for global health.

When defining the value proposition for investment, companies examine several factors. "A key step in defining the value of an asset is through market segmentation," explained Thierry Darcis, vice president and general manager of ViroPharma Europe. "Companies try to understand and predict patterns of behavior. This is why forecasting is important." Product differentiation is also critical. "Differentiation makes your brand sustainable and this comes from the science," said Darcis. "It has to mean something to the customer – more safety, more efficacy. This will drive uptake."

But applying the model to neglected diseases reveals additional risks. "It's hard to predict human behavior," according to William Greene, general partner with MPM Capital, and even harder in unfamiliar markets with limited data.

One company that has taken on this challenge is GSK Biologicals. According to Kate Taylor, vice president of market access for GlaxoSmithKline Biologicals, "GSK has said we'll serve the developing world." One-third of their R&D pipeline now focuses on diseases of the developing world. But, she added, "you also have to make the business case for it."

Understanding how big a market needs to be before industry invests may depend on where you sit. For venture capitalists, according to Greene, "What's important is a return on investment." A product that sells \$75 million a year can be attrac-

tive while one that has an opportunity to sell \$2 billion a year can be unattractive. "We always think about it in terms of the risk and expense. Is there a return? Is there someone willing to pay for that product? We're agnostic as to whether that someone is a government, a non-profit, a traveler, a diplomat or a mother of a child in Africa, as long as someone is willing to pay for it."

Panelists noted that small biotechnology companies might be more inclined to pursue small markets than larger companies. "There's a need for small innovative companies to take these products forward," said Jeffrey Hackman, vice president of marketing at Emergent BioSolutions. "We know it's hard and that there are tons of hurdles. But we're willing to take that approach more readily than large pharmas."

But large manufacturers have also found value from pursuing smaller vaccine markets. With only a \$100-200 million annual market, two vaccines for Japanese Encephalitis (JE) have been developed by biotech companies and licensed by large pharmaceutical companies. Darcis, who helped make the investment decision in JE at Novartis explained, "The draw for us was that we were standing on the flu franchise and wanted to get another franchise. We needed a strong card. JE made sense. International market expansion made sense."

A critical factor for pursuing products with dual markets is tiered pricing. GSK, according to Darcis, started it two decades ago. They produced 1.1 billion vaccines – 80% of which went to the developing world. "Doing that relies on a system that respects tiered pricing," he explained. "But if other countries try to freeload on GAVI pricing, that's not sustainable."

The GAVI Alliance has made an important contribution to global health by building a market for vaccines in some of the world's poorest countries, while managing to keep costs low to ensure long term affordability and access. "The role of these partners makes a difference in the on-going viabil-

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ity of neglected diseases”, according to GSK’s Taylor. “Knowing that markets are willing to uptake those vaccines is compelling.”

Forecasting, an important tool for setting peak performance indicators, helps drive decision making. If you plan for a 50 percent uptake rate, but only get five percent, someone will ask why, explained Darcis. Good epidemiology is needed to get the estimates right, yet developing country data is frequently plagued by gaps. Companies use the best data they can find for developing and emerging markets, and are increasingly relying on public sector analysis to supplement their own. “It’s changed the way we do this,” said one panelist.

But all panelists recognized the difficult road ahead as new vaccines for diseases such as malaria, TB, cholera and HPV are developed and further crowd limited developing country markets. Ministers of Health need to be willing to make physical space for

new vaccines, as well as space in their health systems – including capacity building and training. And the markets need to be prepared years in advance so the health systems are being readied even as phase III trials begin.

According to panelists, we’re already facing these challenges today. In China, for example, there is the need and interest to pay for vaccines, according to Hackman, but the infrastructure is not there. GSK has encountered similar problems with their rotavirus vaccine. “We’re seeing a lack of uptake where there should be more,” said Darcis. “It’s not that [countries] don’t want to, it’s because they can’t.”

Biotech companies find it very hard to confront this issue because it’s taking them outside of their comfort area, since they are generally not in the business of delivering vaccines. However, Hackman noted, small companies are beginning to take the leap and help countries bridge that gap.