Brief 15: The Vaccine Market – Vaccine Production and the Market

What does the vaccine manufacturing landscape look like?

The global vaccine market is expected to increase by more than 100%, from US$24 billion in 2009 to US$56 billion in 2016.[1] Multinational vaccine companies historically have conducted much of the innovation, research, and development in the field of vaccine production. They have used significant revenues, global size, and deeper expertise to fund the development of new technologies for vaccine development – an expensive and relatively time-consuming process. Biotechnology companies have also had a role in vaccine development – particularly in the early stages during discovery, though these firms lack the capacity to bring a vaccine to market.

Local manufacturers in low- and middle-income countries, primarily in Latin America and Asia, have supplied traditional EPI vaccines to countries for many years. These suppliers produce vaccines using relatively simple technology and are able to do so without significant research and capital investment.

In recent years, a few local manufacturers have begun to export their products to other low-income countries and international agencies, such as PAHO and UNICEF. As many of them remain state-owned, they are obligated to supply domestic needs first and can export only the remainder of their supply. Well-known examples of state-owned vaccine producers are Brazil's BioManguinhos (the biologics arm of Fiocruz) and Butantan, Indonesia's Biofarma, Mexico's Birmex, and Cuba's Finlay Institute. While initially focusing on production of existing vaccines, many manufacturers are considering greater research and development investments as they look to develop new vaccines. In order for local manufacturers to supply their products internationally through regional and international organizations, they must become prequalified with the WHO.

In addition to state-owned firms, a number of private manufacturers, particularly in India, have expanded and now supply a significant proportion of traditional EPI vaccines purchased by UNICEF for distribution worldwide.

How is vaccine cost linked to price?

There are two broad types of vaccine costs: manufacturing costs; and research and development costs. Often, the focus is on the cost of production, with an assumption that the cost of the vaccine should be close to the cost of production. However, this ignores the research and development costs.

For many of the newest vaccines, manufacturers will invest many years and several hundreds of millions of dollars. For vaccines that have both an industrialized country and

[1] http://centerforvaccineethicsandpolicy.wordpress.com/2010/01/17/global-vaccines-revenues-projected-to-more-than-double-by-2016/

developing country market, research and development costs are often borne through higher priced sales to wealthier countries, in line with tiered pricing. (See Brief 14: The Vaccine Market – Tiered Vaccine Pricing.) In addition, research costs are often subsidized by governments and other organizations through subsidies, rebates, and tax exemptions to local firms.

In addition, manufacturers often price vaccines without a link to the cost of production, focusing instead on what the market will bear and setting prices in line with the avoided costs of treatment. This is particularly the case in wealthy countries. For example, a pneumococcal vaccine can prevent substantial expenses from treatment of pneumonia and this is often considered by manufacturers in developing a pricing strategy. The cost of producing a given vaccine is closely guarded by manufacturers and, in the case of new vaccines, the cost is rarely known by the public sector. Moreover, early in the production of a new vaccine, when there is often only one manufacturer, the public sector has limited leverage. Thus, vaccine prices often begin at very high levels.

Vaccine manufacturing has significant economies of scale, meaning that producing a bigger volume reduces the price per dose. For example, even if a manufacturing plant is producing at only 20% of its capacity, it still has to pay the operating costs of the plant and those costs are divided over fewer doses, therefore driving up the cost per dose.

The costs of producing a vaccine can therefore vary enormously. For instance, a polio vaccine that is developed from a relatively simple technology, has a high global demand, and is produced by multiple suppliers will have a much lower unit price per dose than a multivalent conjugate vaccine, like pneumococcal, that requires a complex manufacturing technology, and is produced globally in smaller quantities. However, it is worth noting that over time, costs generally drop as efficiencies are found in production, and as manufacturing plants increasingly operate at full capacity.

Types of costs relevant for national immunization programs

Variable costs have a steady unit cost and could include such items as vials. Every dose of vaccine increases cost. A larger volume means a higher total cost.

Semi-fixed costs have a consistent batch (generally a size of several thousand doses) cost regardless of dose number. So, if a manufacturer is able to produce a bigger batch size, the cost per dose will drop.

Fixed costs are the biggest proportion of production costs. These costs are independent of volume and so, as the number of doses produced goes up, unit costs go down. In general, this means that a larger scale of production is cheaper.

Most vaccine production costs are either fixed (60%) or semi-fixed (25%) with the remainder (15%) being variable.

What does this mean for newer vaccines?

High fixed costs and increasingly complex production techniques make it difficult for new manufacturers to enter the market. In addition, these new vaccines are simply more complex, making it possible that they may never reach the low prices at which traditional vaccines are set in developing countries. To date, new vaccines have come to the market at a high price, reflecting the complexity of the technology and the limited supply (often there is a single supplier initially). Then over time, the technology becomes cheaper and efficiencies are found in production that maximize yield and lower costs. Additional manufacturers enter the market, driving up supply level and increasing competition to lower costs.

With newer vaccines this may be a slower process. A case in point is DTP combination vaccines. Initially, GAVI expected prices of this vaccine to drop quickly. But producing the pentavalent (DTP-HepB-Hib) vaccine used widely by GAVI required conjugation technology for which many emerging manufacturers lacked expertise. For several years, only a single manufacturer produced the vaccine. While a second manufacturer entered the market in 2006, real price reductions did not emerge until additional manufacturers entered the market. Now – after almost ten years – the price of pentavalent is beginning to drop.

There are a series of steps that can be taken to ameliorate this situation. First of all, manufacturers who are first to market with new vaccines can be encouraged to define transparent pricing criteria for various markets from the outset. International organizations are advocating for this approach with manufacturers. In addition, efforts can be taken to support emerging manufacturers through technology transfer and advice on intellectual property and regulatory issues. Organizations such as PATH and other product development partnerships are making efforts to partner with manufacturers to increase supply and reduce prices. In some cases, support to manufacturers from public sector organizations comes with specific requirements regarding a price ceiling for the product that is eventually developed.

Further Reading

Oxfam International and MSF. "Giving Developing Countries the Best Shot: An Overview of Vaccine Access and R&D." April 2010.
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