Global Vaccine Supply: the Changing Role of Suppliers

Project summary

The goal of the study is to develop a picture of the evolving vaccine supply system for current and potential GAVI priority vaccines over the short, middle and long term.

The following outputs will be delivered by the study:

- A detailed understanding of the current supply situation
- Actual or potential constraints that could inhibit vaccine supply
- A vision of the future roles of emerging manufacturers, established manufacturers and likely interrelationships
- Priority actions for consideration by GAVI partners
- A suggested process to facilitate ongoing monitoring and the appropriate responses

The study is divided into three phases:

1. Setup - during the 4-week setup phase the study team defined the scope and focus of the project and planned the data gathering and logistics for country visits and manufacturer interviews.

2. Research - during the 12-week research phase, which ended June 10, teams led by WHO and including representatives from other GAVI partners and The Boston Consulting Group visited 7 countries (Mexico, India, China, Korea, Indonesia, Cuba, and Brazil) and interviewed a total of 18 emerging vaccine suppliers. In parallel, BCG has been conducting interviews with the major multinational vaccine manufacturers, with four of the six consulted to date, and interviews of the remaining two to be complete by July 18.

   The team has collected comprehensive data from suppliers on their strategies and plans, product pipelines, R&D and production capabilities, economics and financial performance, and on their intentions to supply vaccines to GAVI and to other export markets.

3. Synthesis and recommendations – This phase started on 11th June and will continue until August 5th. Initial activities have focused on validating and processing the large quantities of data collected to allow for more flexible subsequent analyses.

   During the rest of this phase the team will conduct more detailed analyses aimed at understanding the complexities of the evolving supply environment and identifying areas of future uncertainty. This analysis will enable the team to develop a range of suggestions of possible GAVI actions and an understanding of the trade-offs and wider ramifications that these proposed initiatives will entail.

Through all three phases, the core team has been working with an External Stakeholder Advisory Board (ESAB) that is comprised of PPPs, ADIPs and other relevant organizations.

Initial key findings

Though the project team has only just begun the synthetic part of the effort, several initial key findings have emerged from the study. These are provided here as a preview of the topics that will be presented to the GAVI Board in July.

1. The vaccine manufacturing base in developing countries has changed significantly over the last decade. Many of the weakest production facilities, often supplying 10% of vaccines needed by national immunization programs, have shut down. Many emerging manufacturers are now positioning themselves to be global suppliers of GAVI-priority vaccines. In fact, thirteen of the eighteen emerging suppliers visited during the study are looking to sell at least one vaccine internationally. Some have also made innovative improvements in vaccine production processes. As these emerging manufacturers expand their portfolios, the total number of pre-qualified suppliers for GAVI priority vaccines is likely to broaden.

2. The supply picture and role of emerging manufacturers varies depending on the relative maturity of the product/technology. Products can be divided into three primary groups:

- "Mature" products with accessible technologies
- "Late stage development" products with some technical risks
- "Early stage technologies"/products with large technical uncertainties and risks

(a) Mature products with accessible technologies (DTP combos, MR/MMR, rabies, JE, and meningococcal conjugate vaccines)

Multiple suppliers have the development and production capabilities required to supply these vaccines. Emerging suppliers are particularly focused on DTP-containing combination vaccines, where they are investing in capacity and working to improve production yields and lower costs. Within the eighteen emerging suppliers visited there are twelve DTP-combination vaccine projects in late-stage development (Phase II clinical trials or later).

(b) Late stage technologies with some technical risks (Pneumococcal conjugate and rotavirus vaccines)

Initial products to be licensed will be or have been developed by the multinational manufacturers. However, there remains uncertainty as to the level of investments that will be made to supply the less developed world markets. Emerging manufacturers do face some barriers to development or production of some of these vaccines including technical know-how (*e.g.* conjugation technologies for pneumococcal conjugate vaccines) and demand uncertainty. Nevertheless, a number of these companies expressed an interest in these products and have projects at early stages.

(c) Early stage technologies/products with large scientific, technical, and financial uncertainties and risks (malaria, HIV/AIDS and TB vaccines)

There remains substantial uncertainty with regard to the demand picture for vaccines for these diseases that predominantly impact less developed countries. This factor plus capability limitations has meant that the majority of emerging manufacturers have displayed limited interest in developing products for these diseases. There are exceptions to the capability limitations, with a number of manufacturers having cutting edge research capabilities. Furthermore, it appears that a number of public private partnerships working in these fields have actively been seeking to engage emerging manufacturers.

3. Emerging suppliers have made substantial investments in production capacity for DTP-containing combination vaccines. By 2007, the installed capacity available to produce these vaccines could significantly exceed currently anticipated GAVI demand and, possibly, global demand. However, annual production volumes will be a function of demand and the prices in the different markets each supplier enters (*e.g.* domestic, middle income country, and GAVI markets).

4. Therefore any accurate forecast of the supply available to GAVI at any specific price will require a thorough understanding of demand for these products in each of these markets. The current global demand projections for priority vaccines are incomplete and weak, and a comprehensive understanding of the evolution of the supply picture for each vaccine will require more reliable forecasts. Demand needs to be considered globally, and forecasts should include not only GAVI countries but also PAHO and other middle income or low middle income, self-procuring countries. More accurate projections of the timing and volume of national uptake based on an understanding of country priorities and sensitivity to price would help GAVI to identify and mitigate risks to supply. Furthermore, consistent communication concerning demand, and other key issues, is critical to the suppliers and the efficiency of the overall system.

5. Differentiation among products and presentations within a specific vaccine category is increasing. This differentiation includes differences in presentation (*e.g.* one vial fully liquid vs. two vial liquid-lyophilized pentavalent) and differences in the immunizing antigen(s) (*e.g.* composition of meningococcal and pneumococcal conjugate vaccines, live attenuated vs. inactivated JE vaccine). The differentiated nature of newer vaccines will necessitate changes to the procurement process if vaccine quality and other benefits from innovation are to be rewarded. Differentiation does, however, cut against the operation of certain scale economies in production, so GAVI must be careful to support only those innovations that add substantial value to market segments, and to recognize the implicit costs of doing so.