vaccine to the market—including a late-entry emerging supplier.

- *Cost of goods*: The COGs will determine whether a supplier makes a profit or a loss on each dose sold at the AMC price and in the post-AMC supply and price period. Some of the likely pneumococcal vaccine suppliers will have lower COGs initially. For others, the AMC may motivate process improvements and/or partnership deals to bring COGs in line with AMC prices. Estimates of the likely COGs incurred by each firm now and after 10 years of production are very inexact and must be treated particularly carefully as they are one of the key drivers of any AMC model.
- *Competition*: The licensed heptavalent vaccine (Prevnar) has been used in industrial countries to vaccinate more than 30 million children. Capacity is, however, inadequate for global supply and the vaccine is not considered suitable for widespread introduction in developing countries on the basis of the serotypes of *Streptococcus pneumoniae* circulating in those countries. Two vaccines that extend protection for populations in both developing and industrial countries by adding more serotypes may be licensed by 2009 to 2010. From the 20-plus candidates at different stages of development, other vaccines, including from emerging manufacturers, may come to the market in the following 5 to 10 years.

The AMC must therefore have sufficient funding, and operate for long enough, to purchase vaccine from multiple suppliers, thus providing incentives for these companies to develop, license, and produce the vaccine. Competition is a core objective of the AMC donors as it increases the likelihood of long-term sustainable supply at more affordable prices. Creating an AMC to support competition involves trade-offs, since an AMC with a high price would provide significant returns to the first firm to enter an AMC agreement but would be depleted too quickly for further suppliers to enter the market. A lower price would allow the AMC to operate for longer, providing more time for companies to develop the vaccine, establish capacity, and benefit from the AMC, but potentially delaying earliest availability.

The final decisions on the AMC terms will be based on the most robust estimates available. Sensitivity analyses will be run around key assumptions and estimates about the future, for example, slower or faster development of demand, COGs being higher or lower than estimated, and delays in licensing and introduction to the market. If, despite all the efforts to identify appropriate terms the AMC does not provide adequate incentives to obtain the desired investments from industry, the IAC will be responsible for reassessing the AMC and recommending any significant changes to the terms.

Recommended AMC and Post-AMC Terms

The recommended size of the AMC is $1.5 billion. The price per dose is to be determined but is estimated to be within the range of $5 to $9 per dose, with developing countries responsible for a small copayment per dose. The first purchases are anticipated to begin in 2009 or 2010 and to last for six to nine years. Once the AMC is depleted, each participating supplier will be contractually obligated to continue to supply the vaccine at a pre-agreed price for a set period.

The terms governing the supply and price of pneumococcal vaccines after the AMC is depleted are as important as those in force during the operating life of the AMC. This reflects the long-term objectives of donors, governments, and industry. The requirements for post-AMC volumes and price are still being determined with the goal of establishing a sustainable supply and demand equilibrium.

Expected Impact of the AMC

The broad AMC terms currently under consideration are expected to support purchases from the first three firms to reach the market with an eligible pneumococcal vaccine. The AMC is expected and will be judged by whether the following public health and market goals are achieved (22): *Public health goals to help prevent 5.4 million deaths between 2010 and 2030* are as follows:

- Accelerated introduction of pneumococcal vaccine in low-income countries beginning in 2010, reducing the historical 15-year delay in the introduction of new vaccines between low- and high-income markets.
- Sustained supply of affordable pneumococcal vaccines in the long term as measured by adequate supply to meet low-income country demand at prices between the AMC price and estimated marginal costs of production.

Market goals to assure supply at affordable prices to meet demand are as follows:

- Investments by two or more multinational firms in production capacity to meet the increasing demand from the low-income countries;
- One or more emerging vaccine manufacturers to develop, license, and produce an eligible pneumococcal vaccine in the next 10 years;
- Competition among manufacturers for the developing country market.
- Investment in new technologies for new and more efficient vaccine production and potentially second-generation technologies (e.g., protein vaccines) tailored to developing country markets.

Next Steps

The first AMC pilot is in final development and should be launched in late 2008. Experts and stakeholders from the public and private sector have vetted the concept and the more detailed mechanics proposed for the pilot for pneumococcal vaccines. They have agreed that the AMC can help address the market failures that are inhibiting rapid development, scale-up, and introduction of these vaccines. As this chapter goes to print, six donors, the Governments of Italy, the United Kingdom, Canada, Russia, and Norway and the Gates Foundation have guaranteed $1.5 billion for a pneumococcal AMC. The World Bank and GAVI have agreed to provide fiduciary and operational support, respectively. An IAC has been established and members selected through a competitive process. The target product profile for pneumococcal vaccines has been agreed. Donors are defining the final AMC and post-AMC terms. The agreed terms, processes, roles, and responsibilities will then be codified and launched in a signed AMC framework agreement.

Once established, the AMC for pneumococcal vaccines will provide a new tool to help prevent unnecessary pneumococcal deaths in the poorest countries of the world. Importantly, it will also allow a rapid assessment of the value and impact of the AMC mechanism. Donors are already looking to the future