Pandemic Planning: Vaccine Development and Production Issues

Aventis Pasteur

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Pandemic Preparedness

- Overview of Influenza Vaccine Production
- Pandemic Event: Implications for Industry
- Lessons and Recommendations to Improve Pandemic Planning
Overview:
Aventis Pasteur Influenza Vaccine Production

- Aventis Pasteur is one of the world’s leading vaccine manufacturers
- Aventis Pasteur globally accounts for approximately 50% of world’s influenza supply
- In 2003-2004 season, Aventis Pasteur shipped more than 43 million influenza vaccine doses in US
- Entered agreements with NIAID to conduct R&D on inactivated SARS vaccine and Avian Influenza
Aventis Pasteur: Efforts in Pandemic Preparedness

- Aventis Pasteur entered into agreement with NIAID to produce influenza vaccine based on a potential pandemic strain
  - Producing two pilot H5NI lots of 8000 doses
- Aventis Pasteur expanding operations and will complete a new formulation and filling plant (2006-2007)
- Cell Culture work progressing with Crucell
- Continuing to review internal Pandemic planning
Manufacturing of Influenza Vaccine

- Influenza vaccine manufacturing performed in US and France (only US manufacturing site for inactivated influenza vaccine)
- Production is based on multi-tiered process with extensive QA/QC
- Combination of internal/external factors affect production
- Realistic vaccine production timelines important
Manufacturing Timeline Overview for One Lot

Assumptions:
- Availability of potency testing reagents
- Approved packaging components (labels, package inserts)
Increasing Inter-Pandemic Influenza Vaccine Demand is essential for Public Health

- Optimal solution is to build inter-pandemic demand
- Predictable/steady demand essential for adequate supply
- Key is how to expand influenza immunization rates:
  - Healthy People 2010 goal is 185 million Americans
  - Only 75-80 million Americans immunized annually
  - Only 38% of health care workers
- US public needs to make preparedness a habit
Preparing for 2004-2005 Influenza Season and Beyond

- Pre-Bookings Drive Annual Supply
- Allows manufacturers to forecast demand
- Pre-Book Vaccine Orders for 2004-05 began Dec. 1st 2003
- Planning Early Assists all stakeholders
  - 90-100 million doses of trivalent vaccine

*Figures internal estimates/Also depends on strain yields
Pandemic Event: Implications for Vaccine Industry

- Egg-based production only proven and rigorously tested method
- Shift toward greater influenza vaccine production reduces other vaccine availability
- Critical to ensure flock protection/reserve eggs
- Consider use of adjuvants
- Indemnification is essential for industry participation
Pandemic Event:
Implications for Vaccine Industry

Assumptions:

- Limited advance notice/timing between waves
- In US, industry required to provide approximately 300 million doses of monovalent vaccine
- Production/filling requirements rapidly expanded
- Additional materials for production (e.g., syringes, vials) would be required to expand industry surge capacity
- CBER surge capacity in influenza testing important
Pandemic Event: Implications for Vaccine Industry

Assumptions

- Private sector has expertise in order processing, storage, distribution and shipment
- Overhaul of distribution unnecessary
- Distribution remains primarily in private sector
  - In US, 85% of influenza vaccine sold, distributed and administered in private market
  - Build on current system
The Influenza Vaccine Market is Increasingly a Private Purchase System
Public - Private Demand

- Estimated 83-87 million total doses
Pandemic Event: Implications for Vaccine Industry

Assumptions (cont’d)

- Worldwide surveillance/detection needs to be enhanced and information quickly relayed to private industry

- Federal agencies should determine policy regarding exports of vaccine during Pandemic

- Plans for internal/external industry communications need to be formulated
Key Lessons for Pandemic Planning

➢ Demand Drives Supply:
  - Industry can optimize influenza production if demand is stable and predictable
  - Develop sustainable initiatives to drive demand

➢ Industry Expertise:
  - Manufacturers expertise should be utilized at earliest stage of policy process
Key Lessons for Pandemic Planning

➢ **RFPs:**
  - RFP deliverables should realistically reflect Pandemic requirements
  - Ensure clear and effective coordination in US government of various RFPs

➢ **Build Upon Existing Private-Public Distribution:**
  - Improve upon system
Key Lessons for Pandemic Planning:

- Identify High Risk Groups: Determine who needs to be immunized early
  - Health Care Workers, First Responders, Police
- Extend Immunization Season
Key Lessons for Pandemic Planning

- Counter Outbreaks: Sending influenza vaccine overseas to stem small, virulent outbreaks

- Established Firms: Companies with track record of influenza vaccine production should be involved in development
Strategic Reserves: Immediately develop shared-risk reserves for unanticipated demand/outbreaks on an annual basis.

Stockpiles: Establish stockpiles of routinely used vaccines.