Vaccine Advance-Purchase Agreements for Low-Income Countries: Practical Issues

Ernst R. Berndt & John A. Hurvitz
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Covington & Burling
Deaths from Infectious Diseases

- 4.3 million deaths per year
- 6+ million deaths from AIDS, TB, malaria

Vaccines in use today:
- Measles
- Tetanus
- Pertussis
- HepB
- Hib
- Rota
- Pneumo

Vaccines on horizon:
- HIV
- Malaria
- TB

Vaccines in the distance:
Diverging Causes of Death

Least developed:
- Communicable disease: 56%
- Non-communicable disease: 33%
- Injuries: 11%

Industrialized:
- Non-communicable disease: 85%
- Communicable disease: 6%
- Injuries: 9%
Paying for Pharmaceutical R&D

- R&D spending for developing countries is 7-10% of total
- Overall, private dollars are single most important source for pharma R&D
- For products for developing countries, private investment is very low
## The Challenge

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<th>The goals</th>
<th>The constraints</th>
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<td>Better health through:</td>
<td>Developing country markets are too small</td>
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<td>• Faster development of new vaccines</td>
<td>Vaccine purchasing is unpredictable and prices are low</td>
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<td>• More access to existing and new vaccines</td>
<td>Vaccine priorities are diverging between north &amp; south</td>
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Solutions

- **Buying products today**
  - GAVI/VF (and IFFIm)
    - Creates more visible market for existing products
    - Strengthens delivery systems
- **Prepare for future products**
  - ADIPs and UNICEF
    - Better demand forecasting and creation
    - Negotiation of supply commitments
- **Invest public resources in R&D**
  - Product-development public-private partnerships
  - “Enterprise” and initiatives to promote greater scientific collaboration

**Missing:** market for future products
Advance Market Commitment for Early-Stage Products

- ex ante specification for vaccine
  - efficacy, duration, target population, presentation
- sponsors make a legally binding commitment
- underwriting a guaranteed price
- for a max number of treatments
  - based on demand – no demand, no payout
  - procured through normal channels
- providing a return to suppliers
  - taking into consideration opportunity cost of capital, and alternative markets
- in exchange for affordable price afterwards
IAC established
• Rules of competition fixed
• Product specifications set
• Guarantee terms set
  • price per treatment =
    Maximum Guaranteed
    Amount / max number of
    treatments procured

Companies sign on → binding contract
Periodic reports
  • Work with IAC on waivers, etc.
  • Apply to IAC for approval

First Vaccine Approved

Price guarantee
• Manufacturing capacity
  • Vaccines delivered
  • Adverse event reporting etc
  • Superior vaccine purchased

Suppliers provide vaccine to Eligible Countries long-term at agreed lower price

Commitment exhausted

Timeline

Framework Agreement Announced
Framework Agreement
• Companies sign on → binding contract
• Periodic reports
  • Work with IAC on waivers, etc.
  • Apply to IAC for approval

First Vaccine Approved
Guarantee Agreement

Superior Vaccine Approved

Commitment exhausted
A Market not a Prize

- No quantity guarantee
- Incentives for innovation
- Allows less exhaustive specifications
  - Lower risk for donors
- Some demand risk with manufacturers
  - Removes risks of certain market failures
  - Incentives to develop optimal products
- Allows developing countries to choose
  - Co-payment helps ensure efficient procurement and distribution
- Advance Market Commitment
Two-Stage Pricing

- Guaranteed first stage price
- Guaranteed long run price
- Marginal cost

$Xbn

- Sponsor tops up price paid by developing countries
- Sponsor makes payments for maximum number of treatments
Choice of Price and Quantity

- Higher price = bigger incentive to develop quickly
- Lower price for more treatments = bigger incentive for second entrants

$3bn in NPV revenues
Late-Stage Vaccine Candidates

- Market uncertainty may still affect investment decisions
  - Process and plant capacity
  - Specifications and presentations
  - Development and approval
- Negotiated bilateral agreements rather than open framework agreement
  - Allows donors to influence specific activities of known Developers for known products
  - Single agreement
- Benefits
  - Accelerate availability of, and access to, new vaccines, modified as necessary, to meet specific needs of developing countries
  - Ensure continuity of supply at affordable prices
  - Enhance credibility of advance market commitments