GLOBAL VACCINE SUPPLY:  
THE CHANGING ROLE OF SUPPLIERS

A study by WHO/World Bank for GAVI with Boston Consulting Group

DCVMN Meeting 2005
Julie Milstien
Context of Study

Follow on from 2002 study by Mercer

Study intended to explore the evolving manufacturer base with a particular emphasis on Emerging Suppliers (ESs)

Intended Uses of the Study

Inform the GAVI Board and provide recommendations to strengthen the supply base

Provide input into ongoing development of GAVI’s supply strategy, for DTP combination products in the first instance
Project Goals

Help ensure sufficient, reliable, and affordable supply of priority vaccines for the developing world by:

- Developing a picture of the evolving supply of GAVI relevant vaccines
- Identifying the constraints facing suppliers in vaccine development and production
- Identifying mechanisms to ensure sustainable supply of new priority products
- Reduce uncertainty about the economics and capabilities of vaccine manufacturers
- Establish where interventions could be useful
- Develop a set of programmatic, policy and investment options for GAVI partners to consider
# Project Participants

## Project Leadership

<table>
<thead>
<tr>
<th>WHO/World Bank</th>
<th>BCG</th>
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<tbody>
<tr>
<td>Michel Zaffran</td>
<td>Dave Matheson</td>
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<tr>
<td>Amie Batson</td>
<td>Wendy Woods</td>
</tr>
<tr>
<td>Alastair West</td>
<td>Charles-André Brouwers</td>
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<td>Jeremy Bender</td>
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## Working Team

<table>
<thead>
<tr>
<th>WHO</th>
<th>WHO consultant</th>
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<tbody>
<tr>
<td>Miloud Kaddar</td>
<td>Julie Milstien</td>
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<tr>
<td>Alejandro Costa</td>
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<td>Diana Chang Blanc</td>
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<tr>
<th>BCG</th>
<th>USAID</th>
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<tr>
<td>Maggie Cheng</td>
<td>Susan McKinney</td>
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<td>Matt Diver</td>
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</tbody>
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## External Stakeholder Advisory Board (ESAB)

- Jon Andrus, PAHO/FCH
- Debbie Atherly, Rotavirus ADIP
- Lew Barker, Aeras Global TB Vaccine Foundation
- Jean-Marie Okwo-Bele, WHO
- Shawn Gilchrist, Sanofi-Pasteur / Jackie Keith, Wyeth
- Robert Hecht / Holly Wong, IAVI
- Julie Jacobson, Japanese Encephalitis Program
- Suresh Jadhav, Dev. Country Vaccine Manuf. Network
- Marc Laforce, Meningitis Vaccine Program
- Steve Landry and Gargee Ghosh, Gates Foundation
- Julian Lob-Levyt / Ivone Rizzo, GAVI-VF
- Melinda Moree, Malaria Vaccine Initiative
- Monique Mrazek, IFC
- Angeline Nanni, Pneumo ADIP
Project Scope: Manufacturers

1. Emerging suppliers

- Brazil
  - Panacea Biotec
  - Shantha Biotechnics
  - Bharat Biotech
  - Biological E (BE)
  - Serum Inst. of India

- Indonesia
  - Bio-Manguinhos
  - Butantan Institute

- Mexico
  - Birmex
  - CIGB
  - Instituto Finlay

- Cuba

- China
  - Chengdu
  - Shanghai (SIBP)
  - Sinovac
  - Shenzhen AVP
  - Shenzhen Kangtai

- S. Korea
  - Berna Green Cross (Berna)
  - LG Life Sciences (LG)

- India

2. Multinational suppliers

- Berna Biotech
- Chiron
- GSK
- Merck
- Wyeth
- Sanofi-Pasteur
# Project Scope: Vaccines

<table>
<thead>
<tr>
<th>Global</th>
<th>Regional</th>
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<tbody>
<tr>
<td><strong>Accessible technologies</strong></td>
<td>MMR</td>
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<tr>
<td>Combination vaccines (DTP +/- Hib, Hep B)</td>
<td>Rabies</td>
</tr>
<tr>
<td><strong>Newer technologies</strong></td>
<td>JE</td>
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<tr>
<td>Rotavirus vaccines</td>
<td>Meningitis A-containing conjugates</td>
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<tr>
<td>Pneumococcal conjugate vaccines</td>
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<tr>
<td><strong>Undeveloped technologies</strong></td>
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<td>HIV</td>
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<td>Malaria</td>
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<td>TB</td>
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Manufacturers are a highly heterogeneous group……

Examples of differences include:

- Remit – e.g. public verses private
- Aspirations
- Political context
- Access to financing
- Appetite for risk
- Capabilities in different stages of development
- Product portfolio
- Breadth of pipeline
- Magnitude of capacity
- Ability to attract viable partners
- Cost structures
The relative importance to GAVI of different suppliers can be mapped by assessing two key parameters:

1. Relative supplier focus on GAVI market:
   - Higher focus & lower/medium capability
   - Lower focus & lower/medium capability

2. Relative capability to supply vaccines of interest to GAVI:
   - Higher focus & higher capability
   - Lower focus & higher capability

- 83% of public agency sales
The supply situation is vaccine specific

<table>
<thead>
<tr>
<th>“Mature” products with accessible technologies</th>
<th>“Late stage” development products with some technical risks</th>
<th>“Early stage” technologies with large technical uncertainties and risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple companies, including emerging suppliers, have the capabilities needed to produce these vaccines</td>
<td>Currently available from MNCs, with emerging suppliers facing some barriers to development or production that limit current capability</td>
<td>Significant scientific challenge, demand uncertainty, and some capability gaps have limited emerging supplier investments to date; some MNCs are in active development</td>
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<tr>
<td><strong>Includes:</strong></td>
<td><strong>Includes:</strong></td>
<td><strong>Includes:</strong></td>
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<tr>
<td>• DTP-containing combinations</td>
<td>• Pneumococcal conjugate vaccines</td>
<td>• Malaria</td>
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<tr>
<td>• MR / MMR</td>
<td>• Rotavirus</td>
<td>• HIV / AIDS</td>
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<td>• Rabies</td>
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<td>• TB</td>
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<td>• JE</td>
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Product pipelines for the different diseases

<table>
<thead>
<tr>
<th>Has plans, has not started</th>
<th>Early product development</th>
<th>Process development</th>
<th>Clinical trials</th>
<th>Licensing/ regulatory</th>
<th>Production, sales and marketing</th>
</tr>
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<tbody>
<tr>
<td>DTP- HepB</td>
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<td>DTP-HepB +Hib</td>
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<td>MR/ MMR</td>
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<td>Rabies</td>
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<td>JE</td>
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<td>Mening. A conj.</td>
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<td>Pneumo conj.</td>
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<tr>
<td>Rotavirus</td>
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<td>Malaria(1)</td>
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<td>HIV(2)</td>
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<td>TB</td>
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Additional projects by suppliers outside this study

Emerging supplier project
Multinational project
For DTP Combination Vaccines a number of ESs have late stage programs

It is possible that as many as three ESs will have prequalified DTP-Hep B + Hib by end 2006. Since the market size is uncertain, this could be an issue for GAVI in procurement.
Different companies face different barriers and constraints.

Examples of some mentioned:

- Demand uncertainty
- Lack of guaranteed off-take
- Access to capital (mainly issue for public sector entities)
- Limited expertise in intellectual property
- Access to seed stocks
Academic and research partnerships are the largest source of technology partnerships for ESs
Potential deficits in IP capabilities for ESs

- IP currently not viewed as a barrier
  - emerging suppliers believe they have freedom to operate with existing products

- However, some suppliers believe evaluating and managing IP will be important for certain pipeline products
  - suppliers will need to be more sophisticated with IP management in the future
  - many currently lack dedicated IP departments and/or sufficient IP expertise
One major constraint mentioned by a number of ESs was uncertainty about the prequalification process.

Emerging supplier prequalification experience and potential GAVI-relevant vaccines in pipeline

(1) Supplier currently has no prequalified vaccines but had six products prequalified in 2003

Source: WHO; Company Interviews
Key Findings

- Numerous manufacturers positioning themselves to supply vaccines for GAVI; for combination vaccines procurement strategy will be priority issue
- Economics of GAVI market attractive to many ESs, but demand uncertainties and certain technical issues of concern
- MNC focus requires greater demand certainty and sustained and reasonable returns
- Unique factors influence supply and demand for each disease
- Consistency in supply strategy and processes important for credibility of GAVI market
- Re-examine Hib vaccine experience for consequences of well-intended but poorly implemented actions
- GAVI actions now and in the near future will strongly impact supply situation for the long term; manufacturers are wary of activities by GAVI that will unlevel playing field
Recommendations for GAVI

- Time lag for production decisions → GAVI’s intent must be communicated early
- To influence supplier investments, must address risk
- Early signals on priorities can shape market early
- Implement supply strategies based on data and objectives
- Resolve specific supplier bottlenecks in transparent manner
- GAVI’s handling of pentavalent and quadravalent combinations (DTP-HepB-Hib) will have a significant impact on GAVI’s credibility going forward