



GLOBAL VACCINE SUPPLY: THE CHANGING ROLE OF SUPPLIERS

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

**DCVMN Meeting 2005
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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



Reduce uncertainty about the economics and capabilities of vaccine manufacturers

Identifying the constraints facing suppliers in vaccine development and production



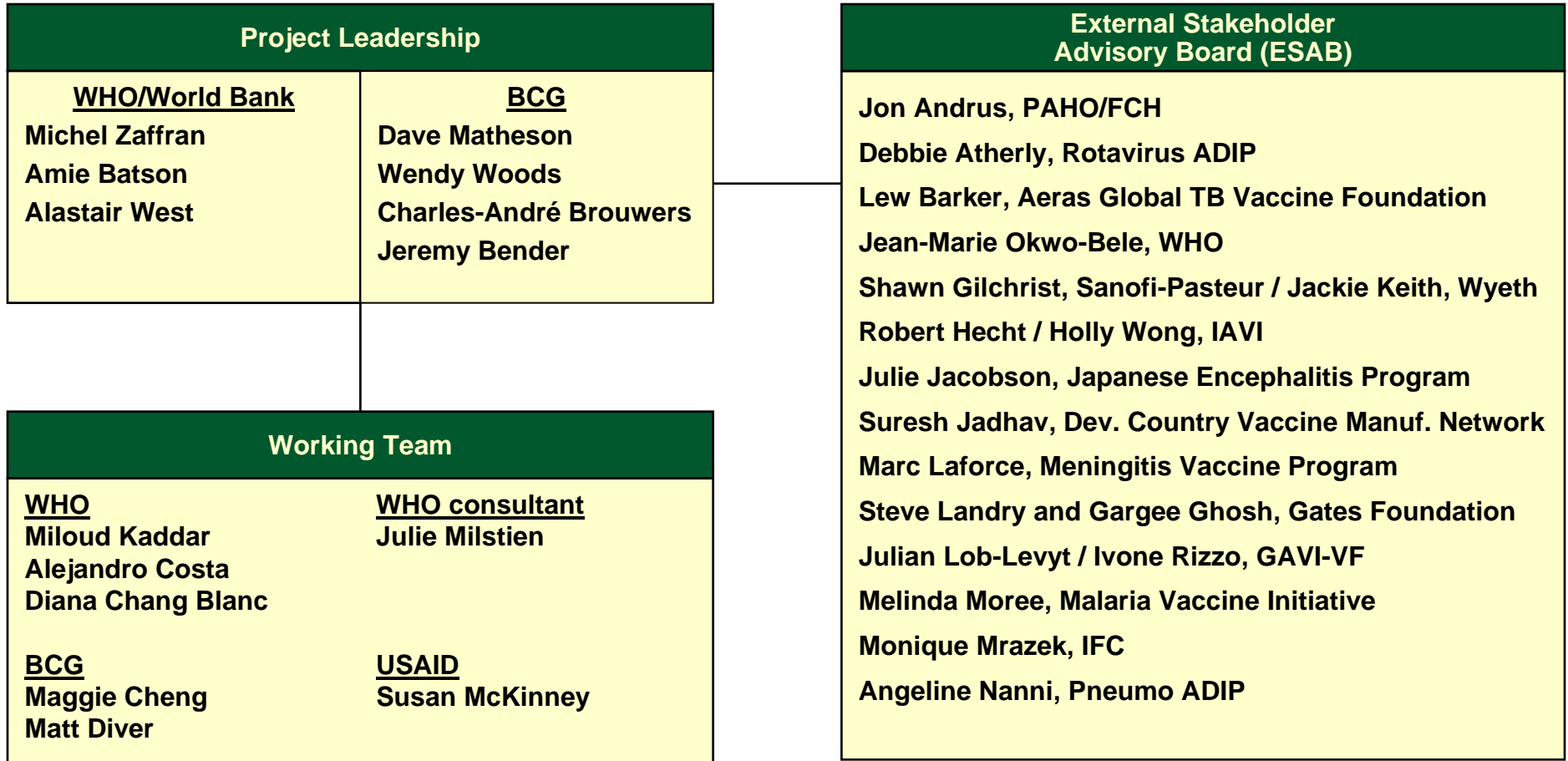
Establish where interventions could be useful

Identifying mechanisms to ensure sustainable supply of new priority products



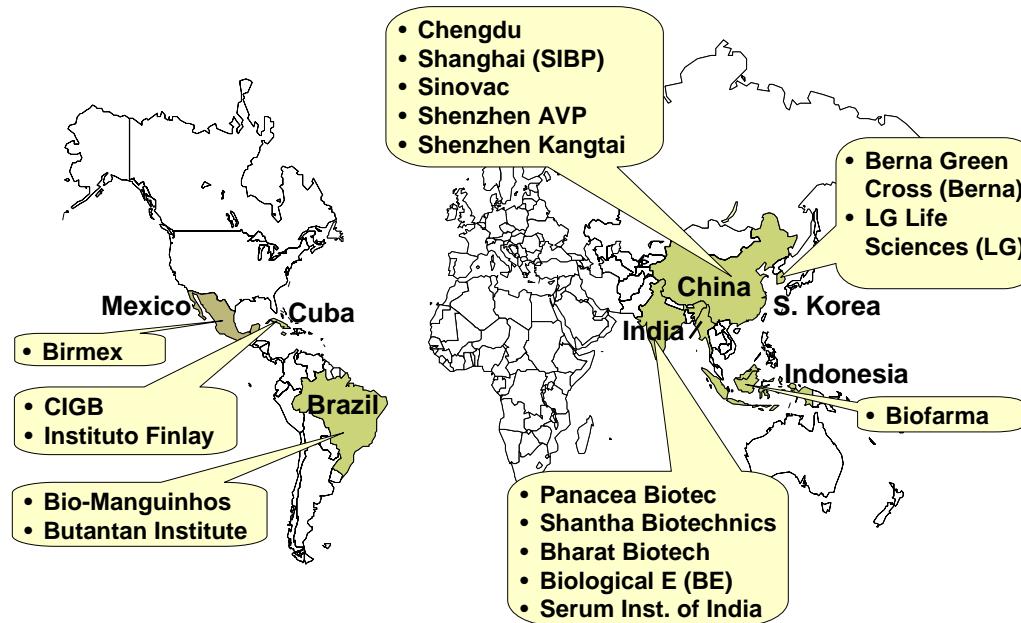
Develop a set of programmatic, policy and investment options for GAVI partners to consider

Project Participants



Project Scope: Manufacturers

1 Emerging suppliers



2 Multinational suppliers

Berna Biotech

Chiron

GSK

Merck

Wyeth

Sanofi-Pasteur

Project Scope: Vaccines

Global
<u>Accessible technologies</u> Combination vaccines (DTP +/- Hib, Hep B)
<u>Newer technologies</u> Rotavirus vaccines Pneumococcal conjugate vaccines
<u>Undeveloped technologies</u> HIV Malaria TB

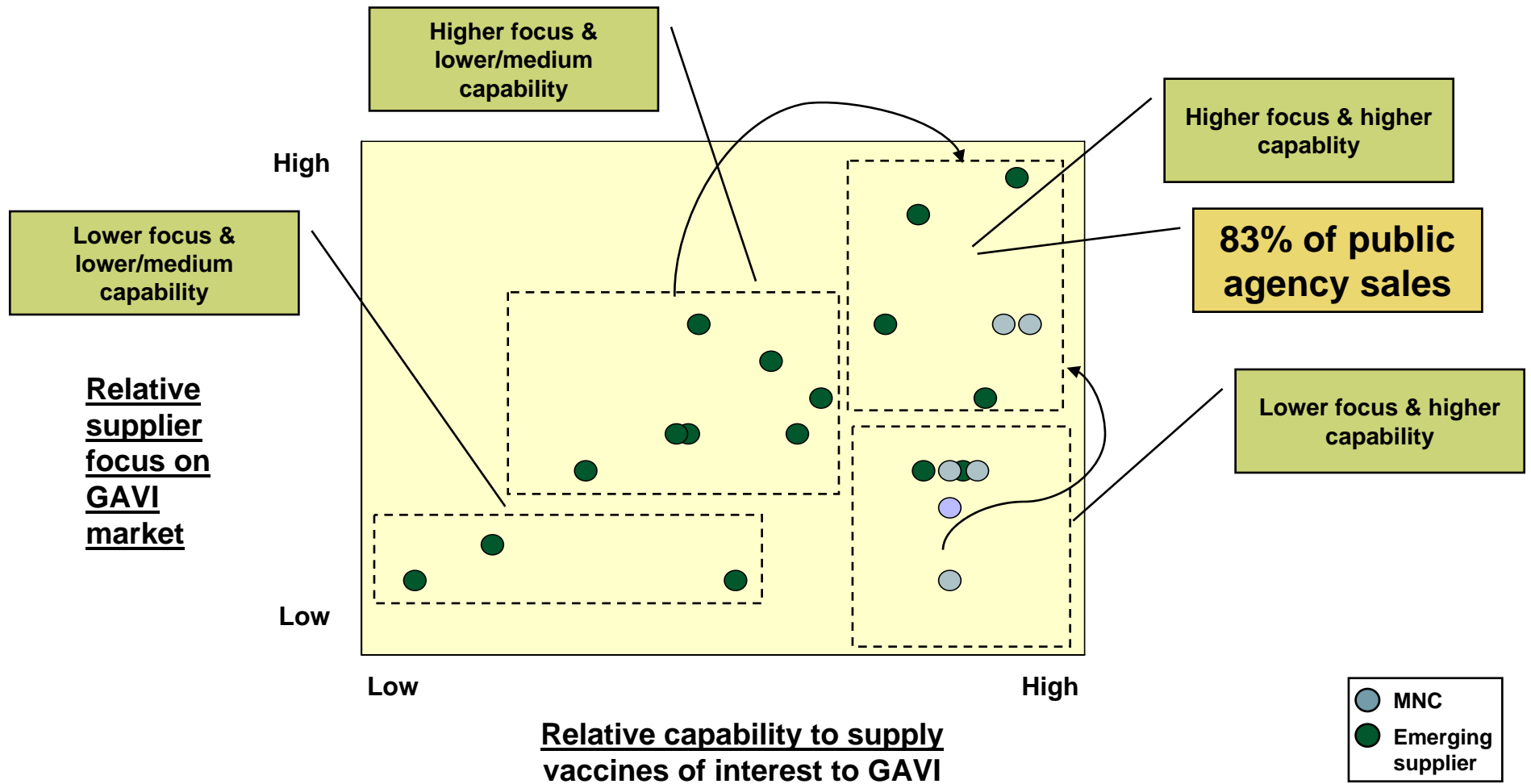
Regional
MMR
Rabies
JE
Meningitis A-containing conjugates

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



The supply situation is vaccine specific

“Mature” products with accessible technologies

Multiple companies, including emerging suppliers, have the capabilities needed to produce these vaccines

Includes:

- DTP-containing combinations
- MR / MMR
- Rabies
- JE
- Meningococcal vaccines

“Late stage” development products with some technical risks

Currently available from MNCs, with emerging suppliers facing some barriers to development or production that limit current capability

Includes:

- Pneumococcal conjugate vaccines
- Rotavirus

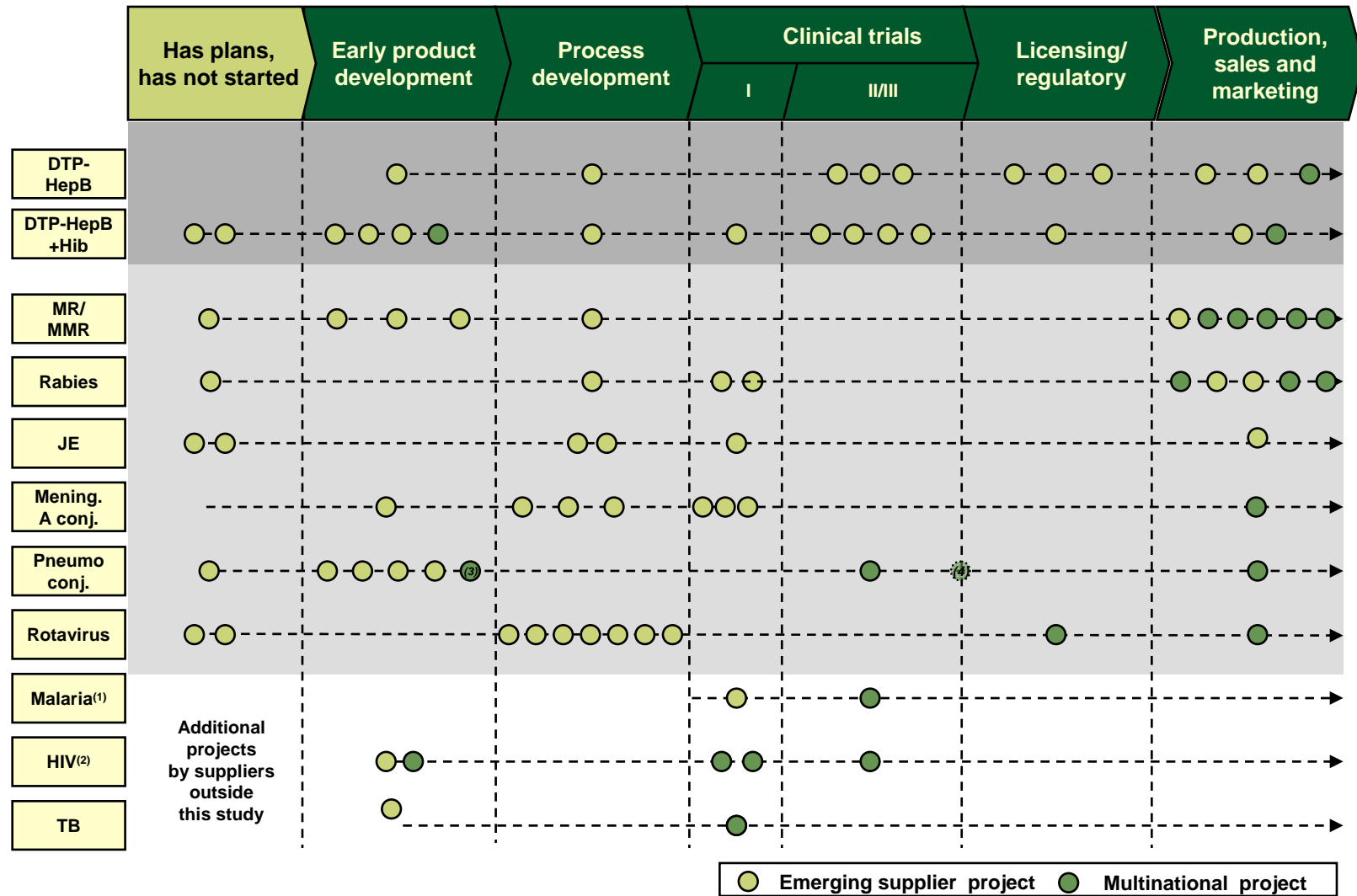
“Early stage” technologies with large technical uncertainties and risks

Significant scientific challenge, demand uncertainty, and some capability gaps have limited emerging supplier investments to date; some MNCs are in active development

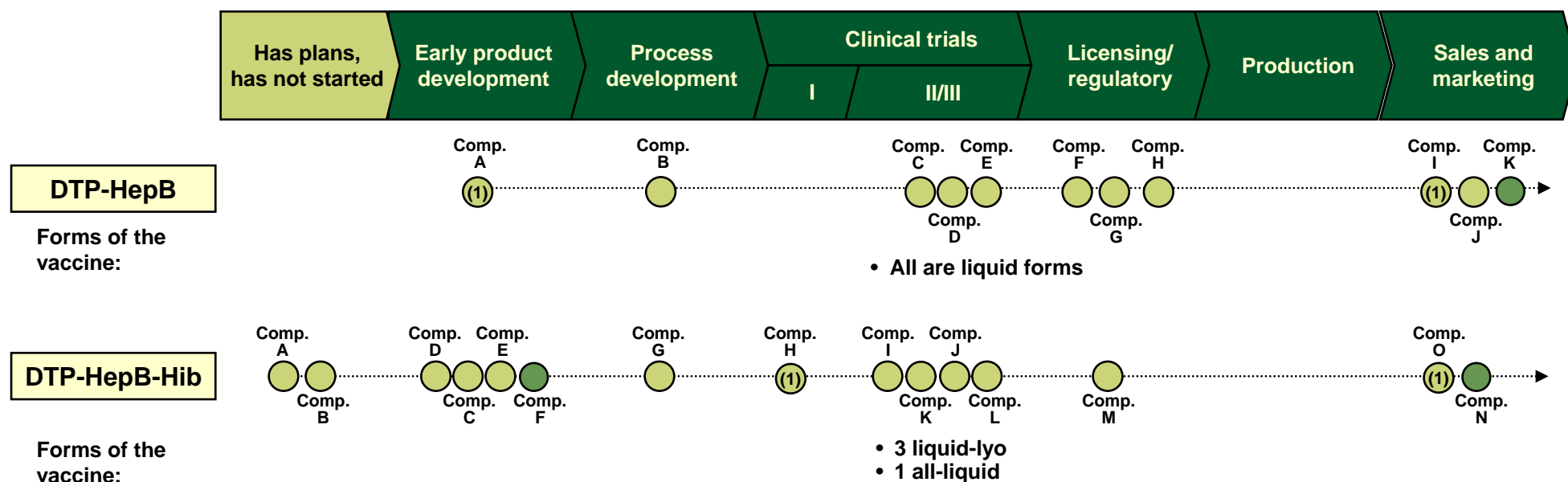
Includes:

- Malaria
- HIV / AIDS
- TB

Product pipelines for the different diseases

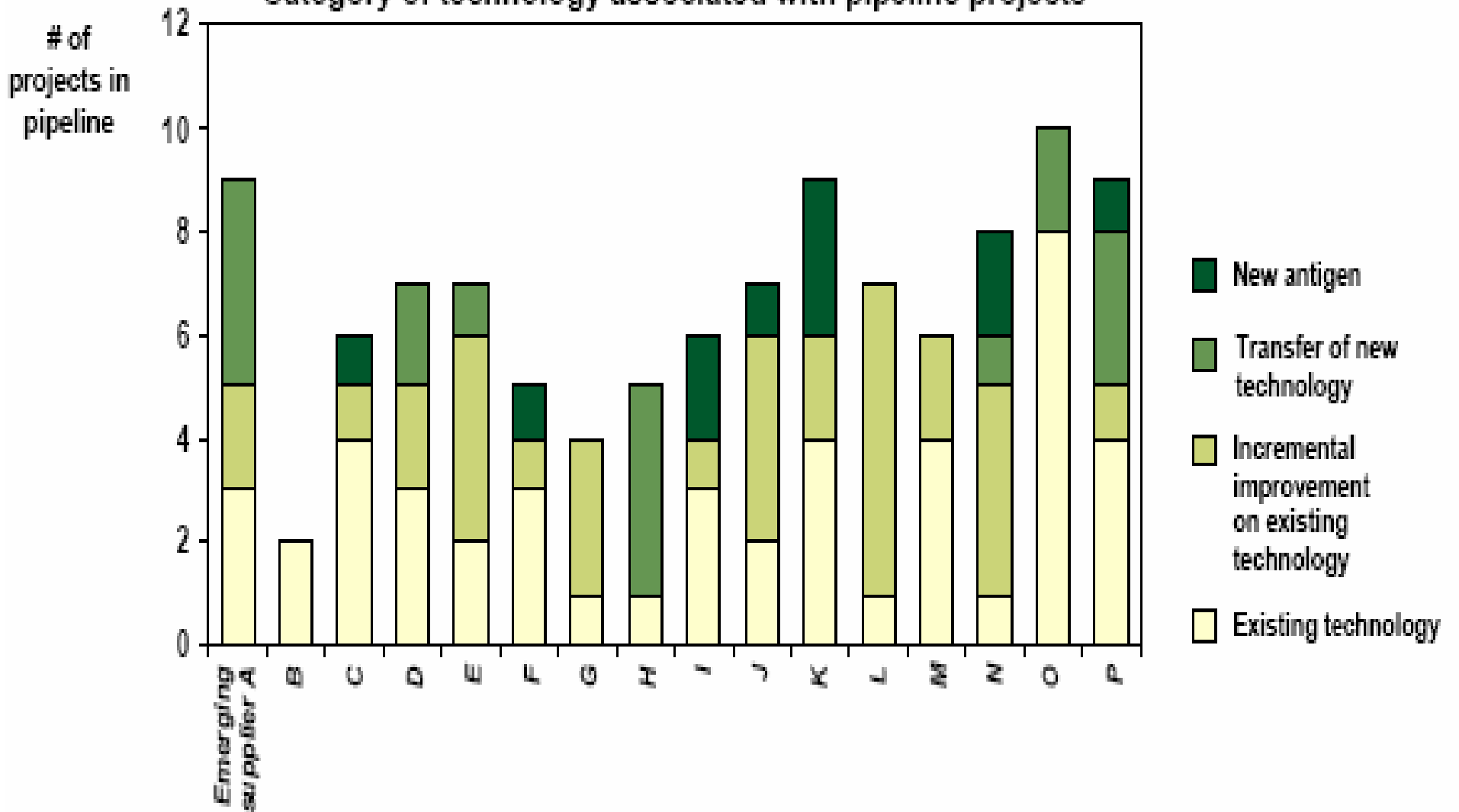


For DTP Combination Vaccines a number of ESs have late stage programs



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.

Category of technology associated with pipeline projects



Different companies face different barriers and constraints.

Examples of some mentioned:

- **Demand uncertainty**

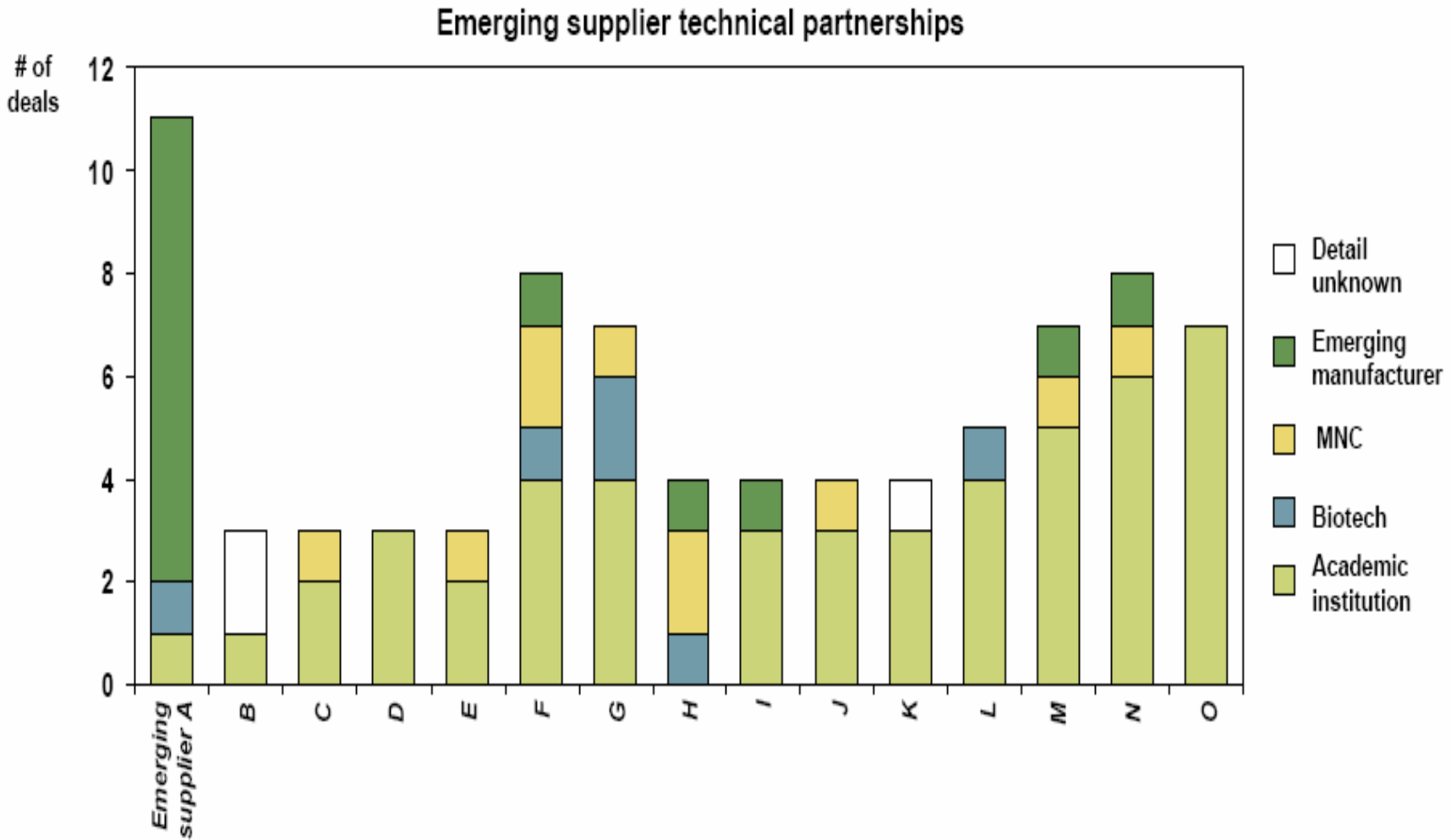
- **Lack of guaranteed off-take**

- **Access to capital (mainly issue for public sector entities)**

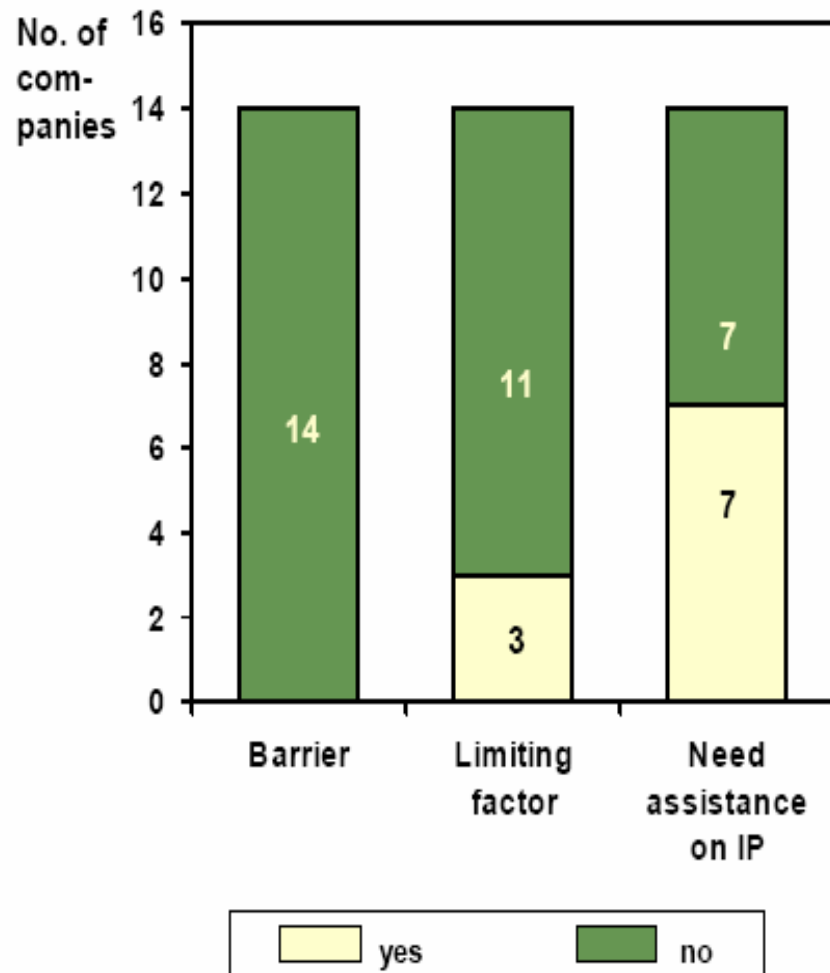
- **Limited expertise in intellectual property**

- **Access to seed stocks**

Academic and research partnerships are the largest source of technology partnerships for ESs



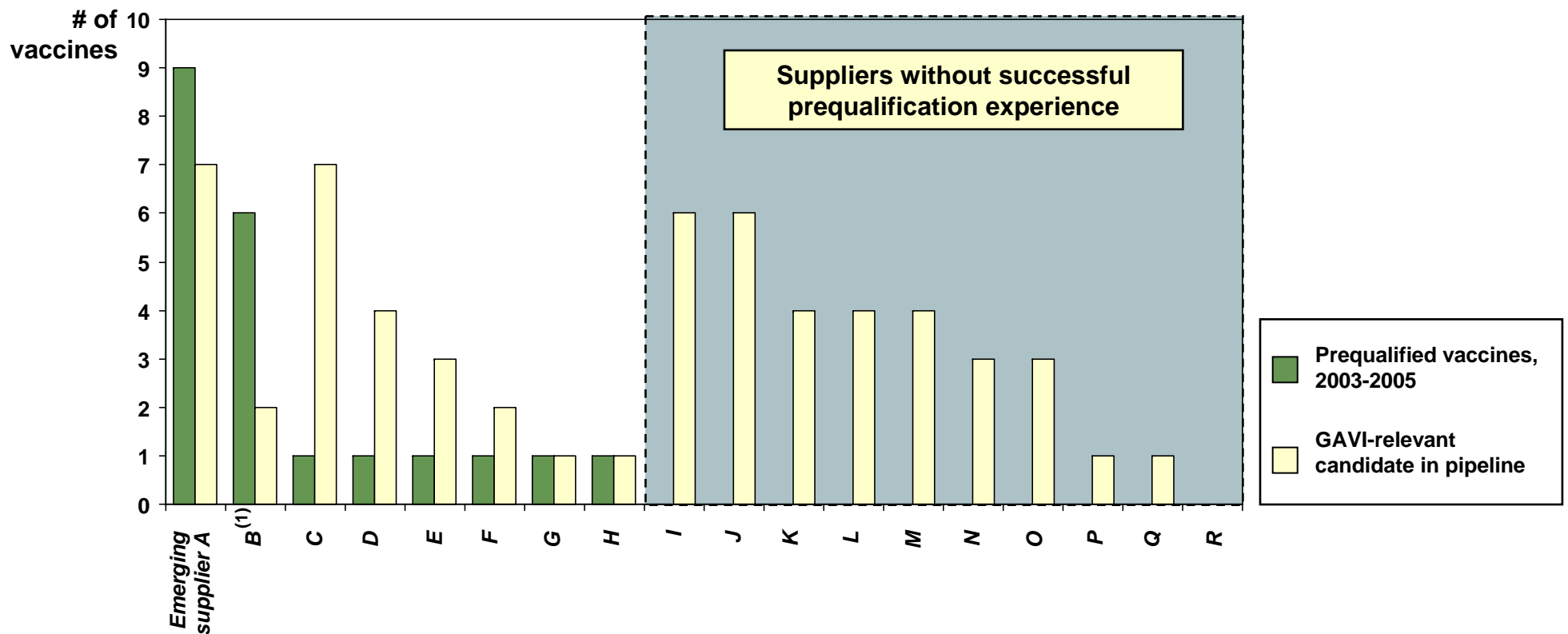
Potential deficits in IP capabilities for ESs



- 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

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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**