GAVI

THE GLOBAL ALLIANCE FOR VACCINES & IMMUNIZATION

Partnering with The Vaccine Fund

GLOBAL VACCINE SUPPLY: THE CHANGING ROLE OF SUPPLIERS

Update to GAVI Board

July 19, 2005

THE BOSTON CONSULTING GROUP

PROJECT GOALS AND APPROACH

Goals	Approach and team

Help ensure sufficient, reliable, and affordable supply of priority vaccines for the developing world by:
• **Developing a picture of the evolving supply, including pipeline, of GAVI priority 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 successful**
• **Identifying mechanisms to ensure sustainable supply of new priority products**
  - **develop a set of programmatic, policy and investment options for GAVI partners to consider**
	<u>Approach and status</u>
	Project is in the middle of the final phase, synthesis
	• **Phase I: Setup (4 weeks)**
	• **Phase II: Field visits to 18 manufacturers in 7 countries (12 weeks)**
	• **Phase III: Synthesis (8 weeks)**
	
	<u>Team</u>
	• **Overall project led by Boston Consulting Group, World Bank and WHO**
	• **Field visits led by WHO consultants**
	• **Input and guidance provided by External Stakeholder Advisory Board**
	  - **members from PPPs, industry, and other GAVI partners**

WHY IS THIS STUDY IMPORTANT FOR GAVI?

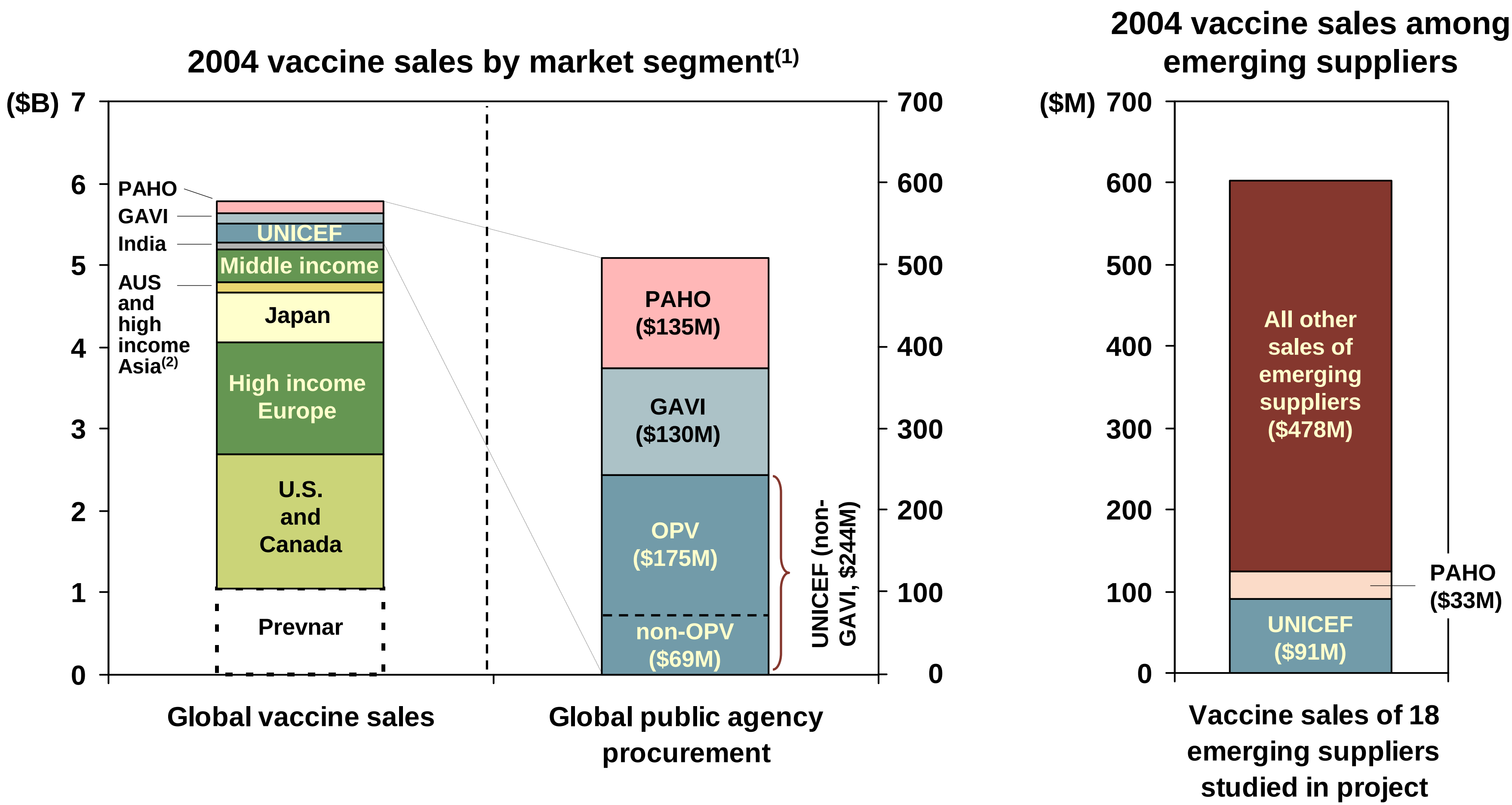
Several supply desiderata with inherent trade-offs	Many constraints in historical supply picture	Some important changes under way
Many competent suppliers Price levels as low as is consistent with a healthy supply sector Continued stream of innovation that allows new vaccines to be developed ...	Few choices among suppliers Relatively low levels of supply security Higher prices than would be sustainable Innovation, but less than what is needed	Capability of both emerging and traditional suppliers to develop and manufacture priority vaccines is increasing Emerging companies more responsive and sensitive to the GAVI market and messages

IMPORTANCE OF EMERGING SUPPLIERS TO GLOBAL SUPPLY HAS GROWN

Category	Historical		Current
Product range	**Narrow (one product beyond EPI)(1)**	→	**Expansive (multiple suppliers with >5 vaccine products)**
Emerging supplier vaccine revenues	**<$400 million(1,3)**	→	**>$600 million(2)**
Vaccine supply to UNICEF(2)	**$35 million in 2002**	→	**$90 million in 2004**
R&D pipeline	**"Limited R&D resources for emerging suppliers"(3)**	→	**58 GAVI-priority candidates(2)**

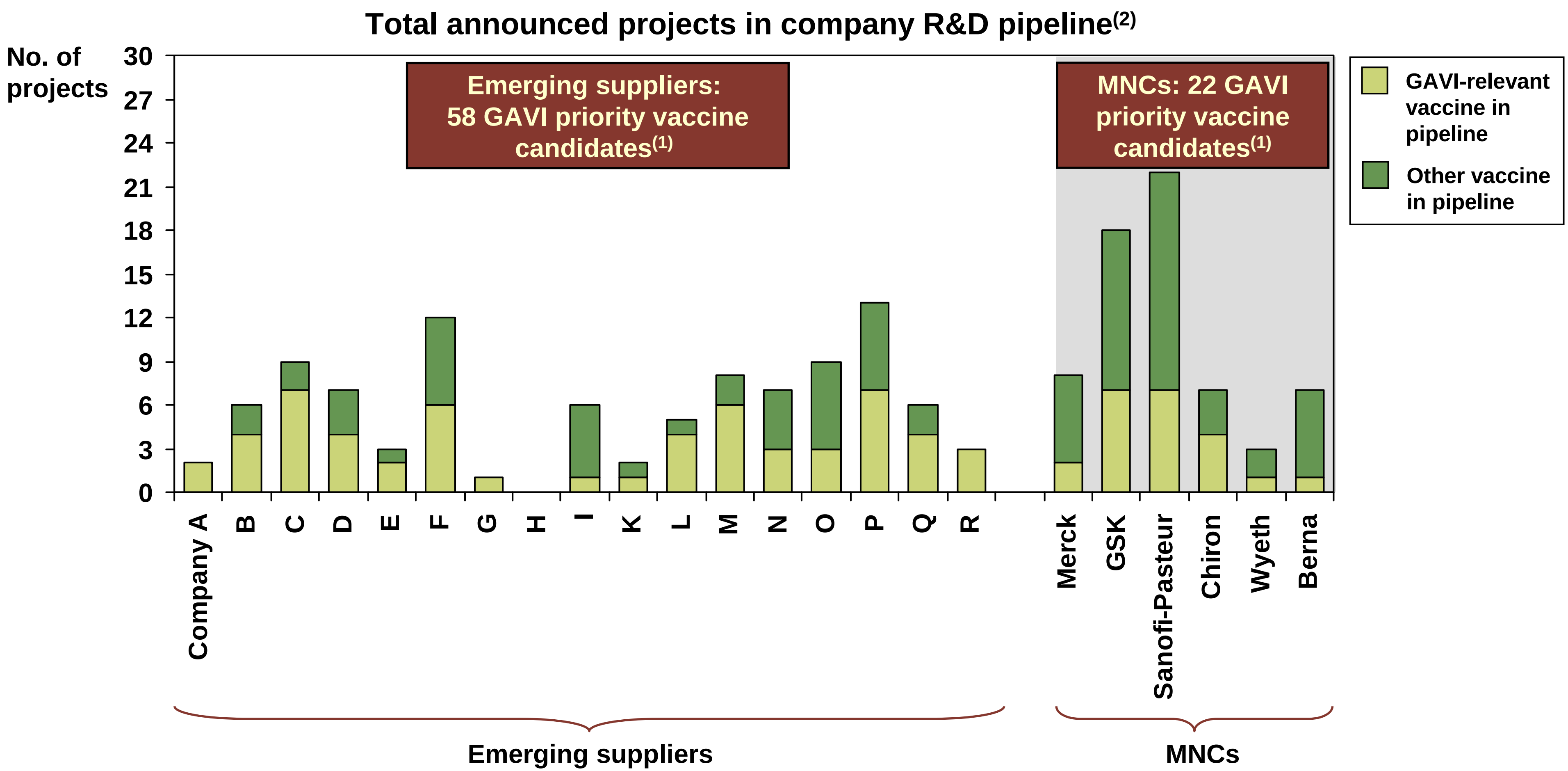
(1) Includes entire non-OECD/MNC base
(2) Includes 18 emerging suppliers surveyed: Berna Green Cross, Bharat, Biofarma, Biological E, Bio-Manguinhos, Birmex, Butantan, Chengdu, CIGB, Finlay Institute, LG, Panacea, Serum Institute, Shantha Biotech, Shenzen A-P, Shenzen Kangtai, SIBP, Sinovac
(3) 2002 Mercer study
Source: Mercer Consulting (2002); Company interviews; UNICEF; BCG analysis

THE GLOBAL PUBLIC MARKET IS CRITICALLY IMPORTANT TO MANY OF THE EMERGING SUPPLIERS



(1) Includes all vaccine segments (pediatric and adult prophylactic, travel, and therapeutic vaccines)
(2) South Korea, Taiwan, Singapore, Hong Kong
Note: Vaccine procurement for UNICEF/GAVI includes vaccine doses and excludes procurement services / other overhead
Source: UNICEF Supply Division Annual Reports (2000-2004); IMS Health Incorporated

EMERGING SUPPLIERS AND MNCS ARE POSITIONING THEMSELVES TO BE GLOBAL SUPPLIERS OF GAVI-PRIORITY VACCINES

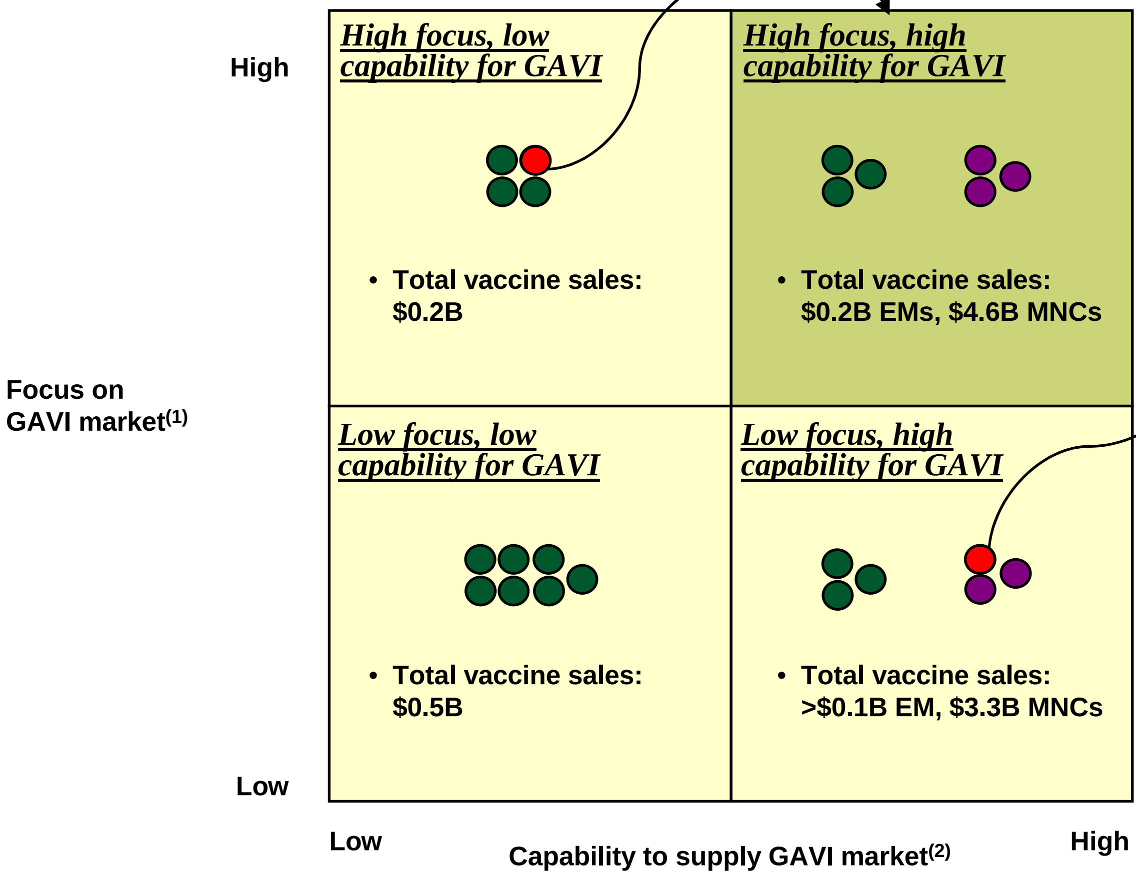


(1) Includes pipeline products company intends to pre-qualify that are either current or likely future GAVI priorities (HIV, malaria, etc.)
(2) Pre-clinical development through registration
Note: Berna Green Cross pipeline incorporated into Berna pipeline
Source: Company interviews and annual reports; Evaluate Pharma; BCG analysis

ILLUSTRATIVE

SUPPLIERS DIFFER IN CAPABILITIES AND FOCUS ON GAVI MARKET

Levers to increase capability to supply GAVI market would target here, *e.g.,*
- **Technical assistance for prequalification**



MNC
Emerging supplier

Levers to increase interest/orientation towards GAVI market would target here, *e.g.,*
- **Upfront subsidies**
- **Guaranteed price/ volume contracts**

Supplier that can be influenced by potential GAVI actions:
RED SHADINGS ARE CURRENTLY ILLUSTRATIVE

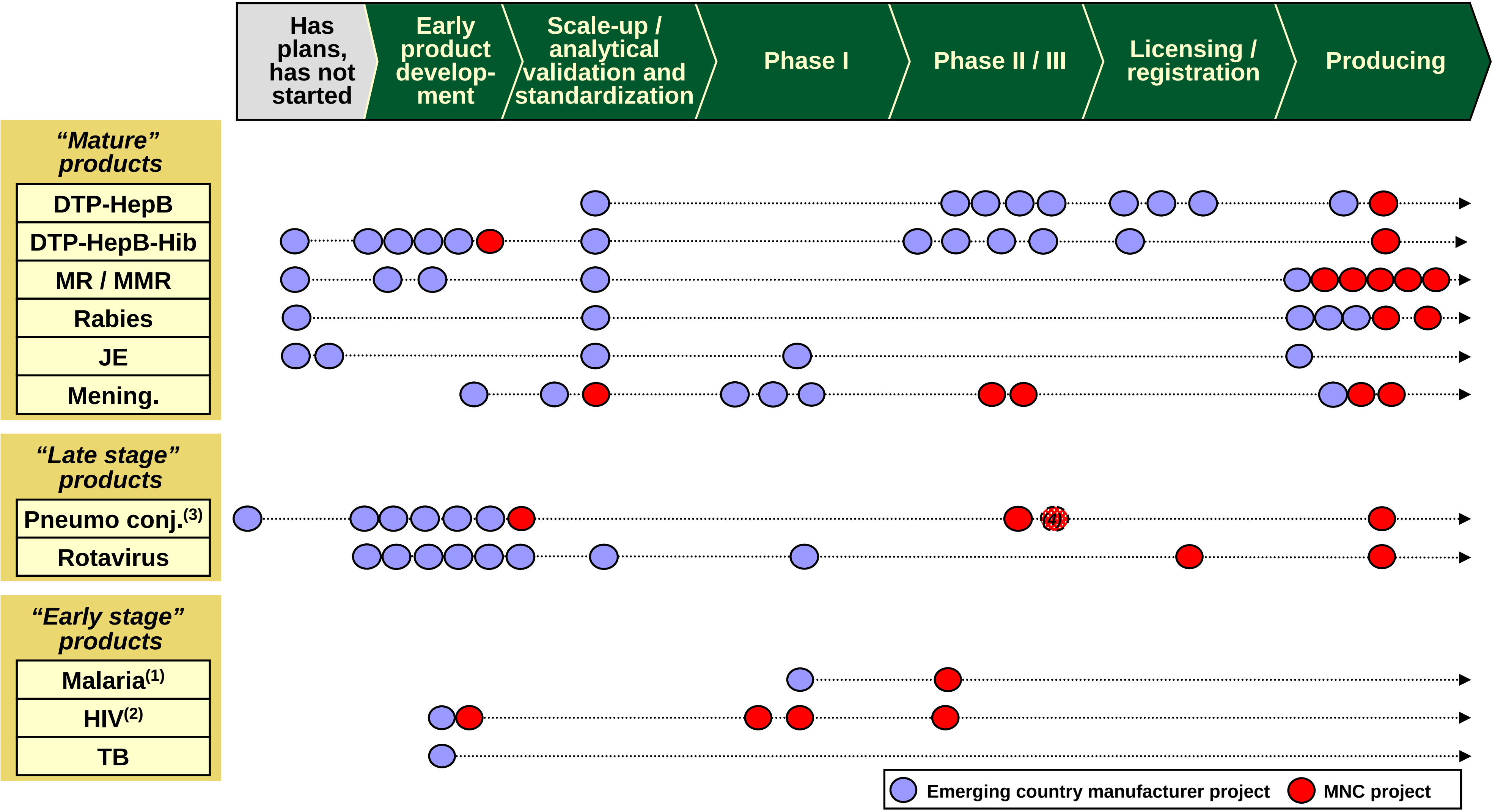
Important factor for GAVI is extent to which suppliers can be influenced— how they move and can be moved in and out of different segments

(1) Criteria include: % and # of pipeline products focused on GAVI priority vaccines, % of current vaccine sales that come from GAVI/UNICEF procurement; investments and preparations for pre-qualification; flexibility to pursue and invest in non-domestic markets. (2) Criteria include technical and production capabilities
Note: 6 total MNCs includes Berna (which includes Berna Green Cross), Chiron, GSK, Merck, Sanofi-Pasteur, and Wyeth
Source: Company interviews; BCG and study team analysis

SUPPLY PICTURE ALSO VARIES BY RELATIVE MATURITY OF THE PRODUCT / TECHNOLOGY

"Mature" products with accessible technologies	"Late stage" development products with some technical risks	"Early stage" technologies with large technical uncertainties and risks
Multiple companies, including emerging suppliers, have the capabilities needed to produce these vaccines Includes: • DTP-containing combinations • MR / MMR • Rabies • JE • Meningococcal conjugate vaccines	Currently available from MNCs, with emerging suppliers facing some barriers to development or production Includes: • Pneumococcal conjugate vaccines • Rotavirus	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

POTENTIAL PARTICIPATION OF EMERGING SUPPLIERS AND MULTINATIONALS VARY BY PRODUCT SEGMENT



(1) Over 80 candidates in pipeline at companies not in this study; (2) Additional projects exist outside of the suppliers in this study; (3) ~20 additional projects in early R&D exist in academic settings, most of which are pneumo protein vaccine candidates; (4) Includes two projects with uncertain development paths that have already been through PIII testing
Note: Order of bubbles within a single phase does not imply one manufacturer is further ahead in that phase than another; Includes only those projects for which emerging country manufacturers plan to seek WHO pre-qualification to contribute to the global public market

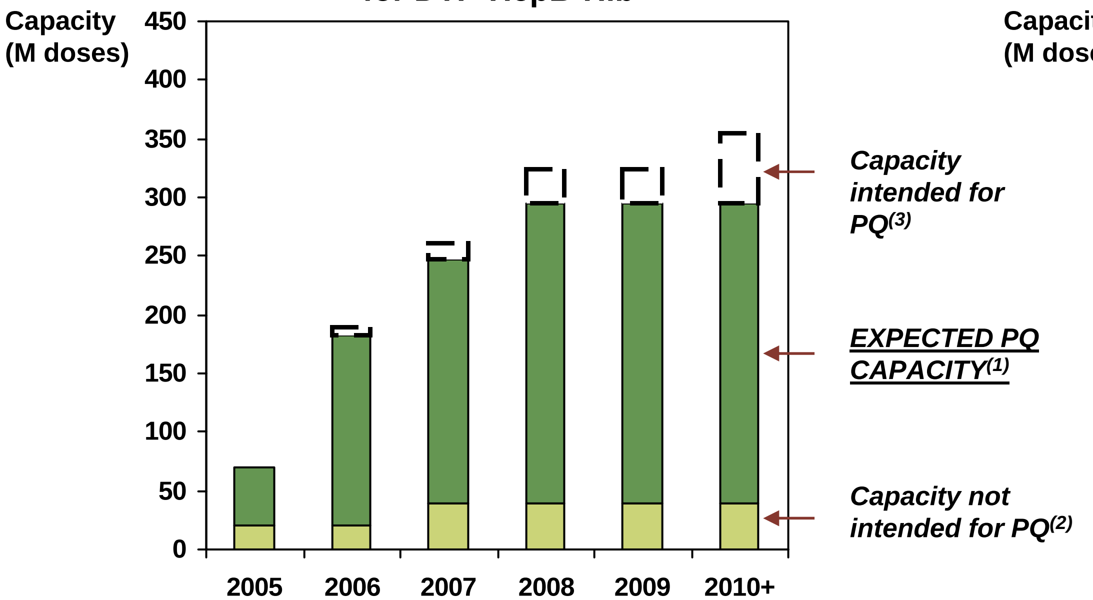
INCREASING DIFFERENTIATION OF PRODUCTS PRESENTS CHALLENGES

Examples of the non-commodity nature of GAVI-priority vaccines	Key issues this differentiation presents
Differences in presentation, e.g., • Pentavalent: One vial fully-liquid versus two vial liquid-lyophilized Differences in production composition, • Different adjuvants • Serotypes of meningococcal and pneumococcal conjugate vaccines • Live attenuated versus inactivated JE vaccine	How to recognize differences in vaccine quality and other product benefits in the procurement process How to support innovation while at the same time ensuring low cost through manufacturing scale economies How to ensure that the products supplied to each GAVI country have the appropriate presentation and product composition over time

CAPACITY FOR PRODUCTION OF DTP-CONTAINING COMBINATION VACCINES PROJECTED TO BE SIGNIFICANT

Actual Production Will Depend on Multiple Factors

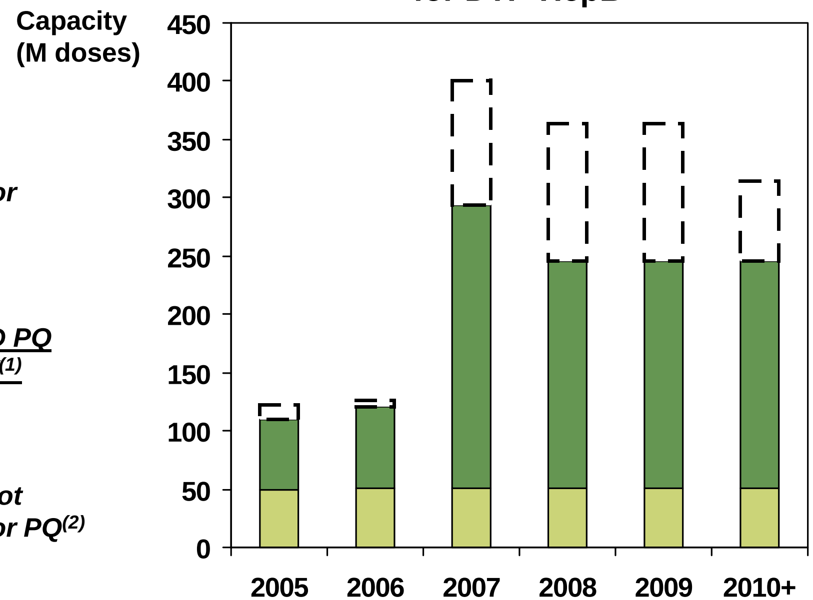
Projected production capacity available by end of year for DTP-HepB-Hib



Number of suppliers

	2005	2006	2007	2008	2009	2010+
	1	4	5	5	5	5
	1	1	2	2	2	2
	0	1	2	3	3	5

Projected production capacity available by end of year for DTP-HepB



Number of suppliers

	2005	2006	2007	2008	2009	2010+
	1	4	5	5	5	5
	1	1	1	1	1	1
	1	1	4	5	5	5

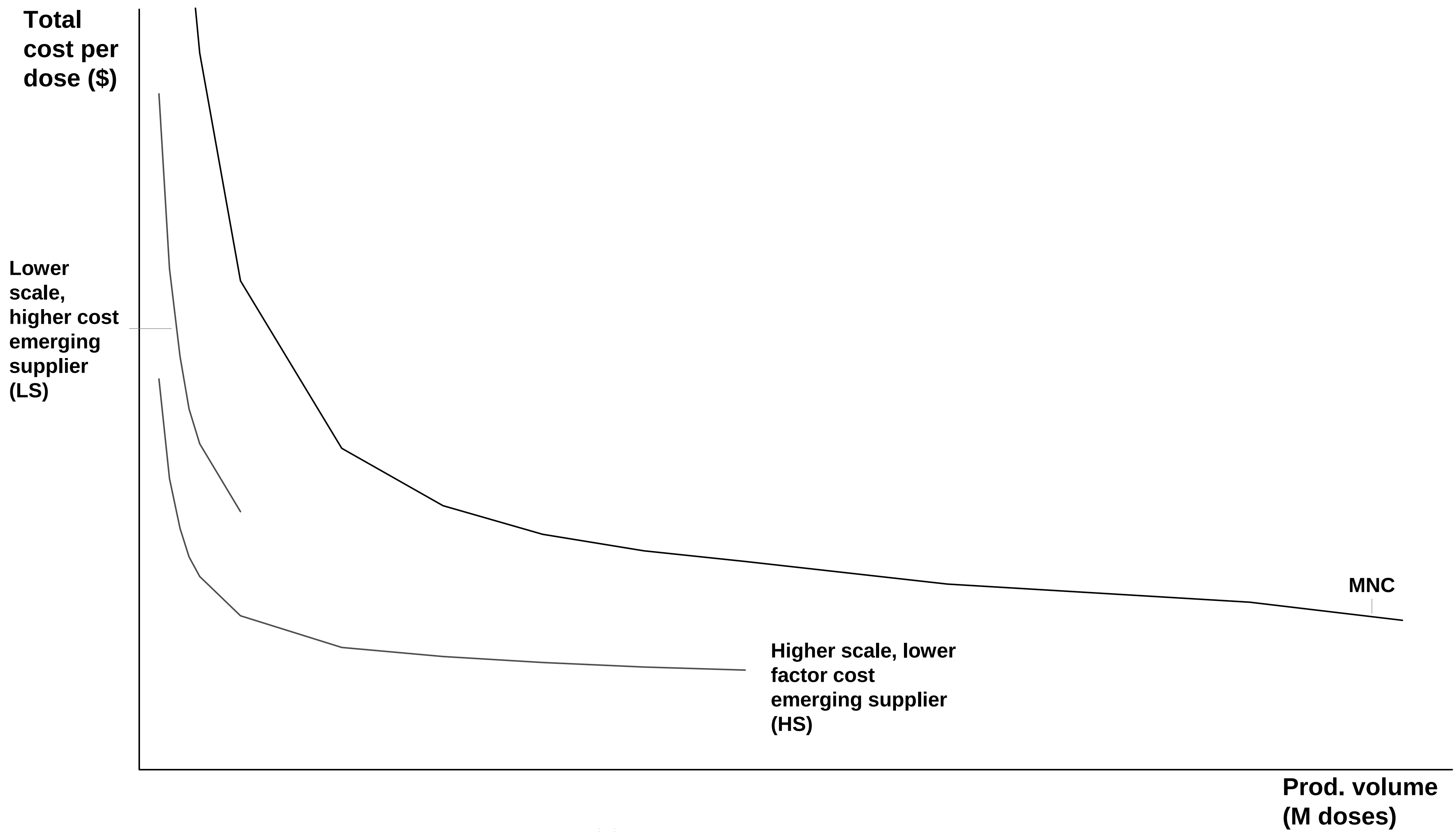
(1) Includes capacity the study team projects to be pre-qualified based on assessments by a technically experienced team of the capabilities of suppliers interviewed
(2) Includes capacity that suppliers have stated will be used for domestic sales and will not be pre-qualified; (3) Capacity for which suppliers intend to seek PQ, but for which study team believes there is significant uncertainty about whether or not capacity will pre-qualified and/or available for production

Note: DTP-combination capacities are additive and non-overlapping; capacity for pentavalent includes different presentations

Source: Company visits; Project Team assessment

Illustrative

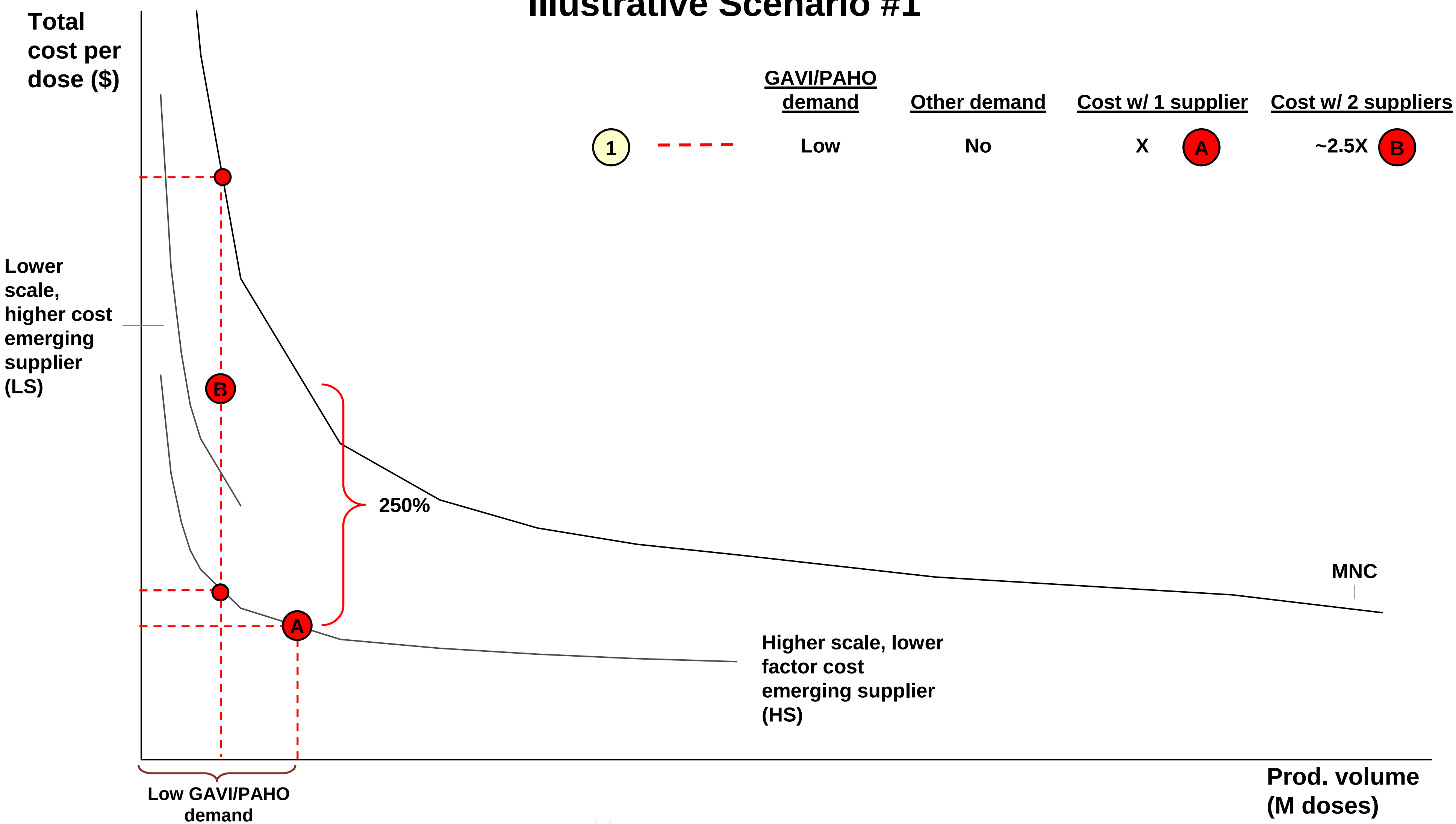
A COMPREHENSIVE UNDERSTANDING OF DEMAND IS NEEDED TO MANAGE SUPPLY WELL



Illustrative

A COMPREHENSIVE UNDERSTANDING OF DEMAND IS NEEDED TO MANAGE SUPPLY WELL

Illustrative Scenario #1

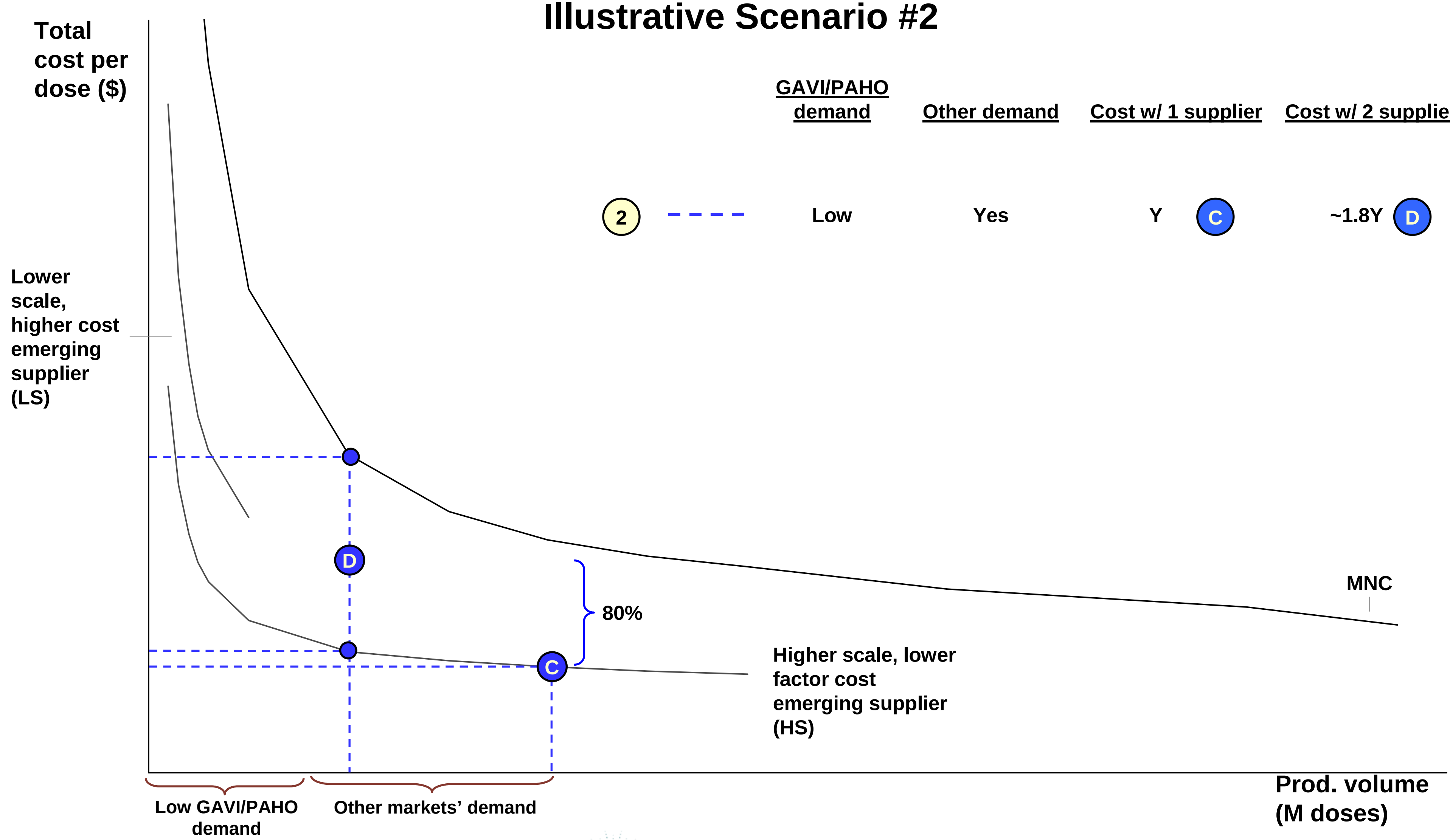


Illustrative

A COMPREHENSIVE UNDERSTANDING OF DEMAND IS NEEDED TO MANAGE SUPPLY WELL

Illustrative Scenario #2

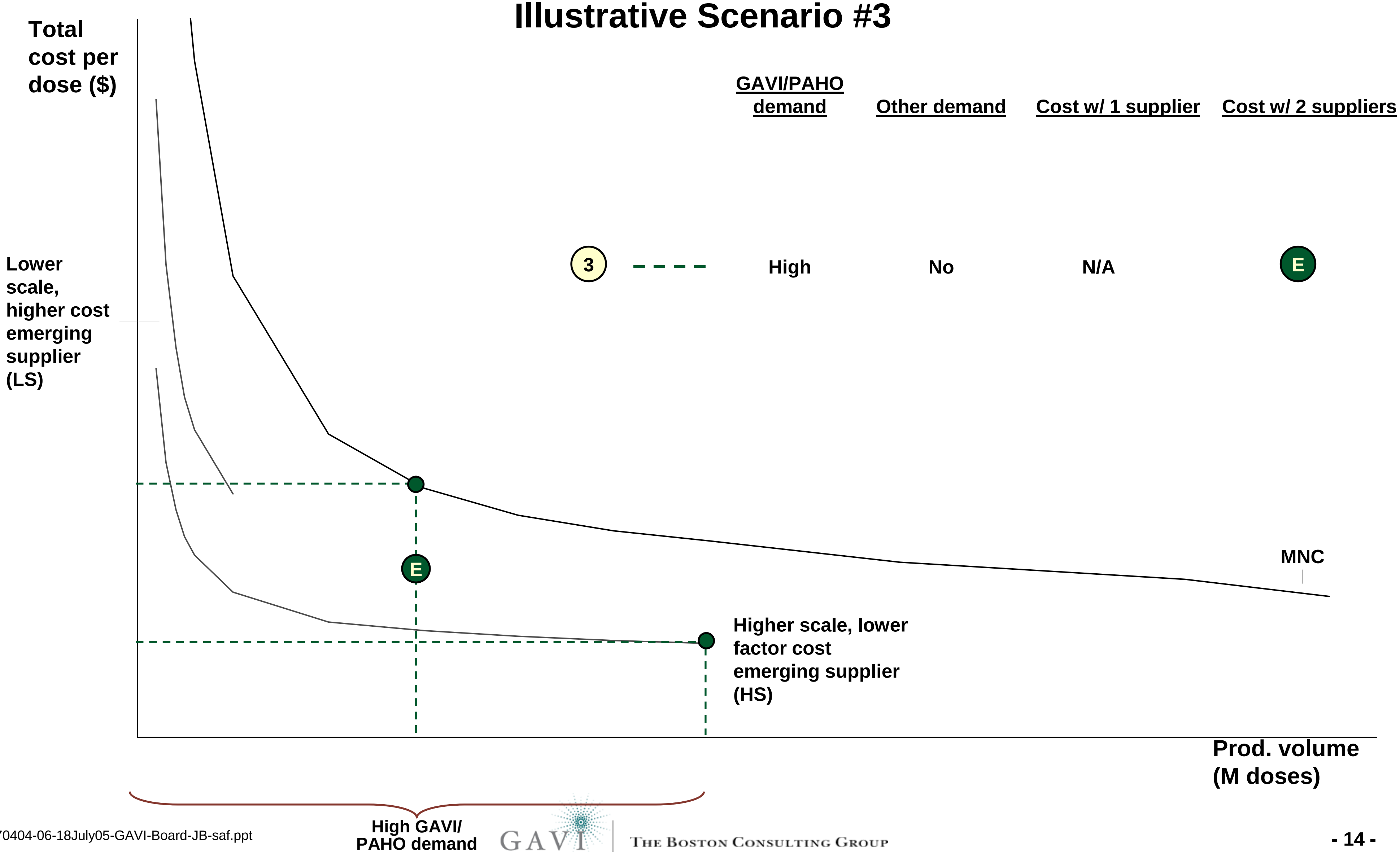
		GAVI/PAHO demand	Other demand	Cost w/ 1 supplier	Cost w/ 2 suppliers
2	- - - -	Low	Yes	Y C	~1.8Y D



Illustrative

A COMPREHENSIVE UNDERSTANDING OF DEMAND IS NEEDED TO MANAGE SUPPLY WELL

Illustrative Scenario #3



CONCLUSIONS

GAVI is likely to have more opportunities than it has in the past

- **More vaccines**
- **A broader supplier base, some of which may rely on GAVI for survival**

This opportunity brings certain challenges

- **How to manage procurement of increasingly differentiated products**
- **Trade-offs between cost and innovation and between cost and security of supply (through multiple suppliers)**

These shifts will require GAVI to

- **Prioritize a broader portfolio**
- **Communicate clearly and transparently with a broader and more diverse set of suppliers**
- **Improve the reliability of demand assessments for priority vaccines**