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*Celebrating Life Every Day*

# The Global Vaccine and Immunization Research Forum

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March 28, 2023

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**Mahima Datla**

Managing Director,

*Biological E. Limited*



# Suppliers Table



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#	Product	Current Suppliers	Max. suppliers	Current no.of suppliers	Product Status
1	DTP-HepB-Hib	Biological E. Limited, SII, Panacea, LG Chem	7(2015)	4	
2	Td	Biological E. Limited, SII, PT Biofarma, BulBio-NCIPD	5(2020)	4	
3	DTP	Biological E. Limited, SII	5(2005)	2	
4	Hep B	SII, LG Life Sciences	7(2006)	2	
5	IPV	LG Chem, Sanofi, Bilthoven , AJ Vaccine, Shantha Biotechnics	5(2021)	5	

- TCV no clarity on demand quantity. For example, for the 3 year period of 2022-25, the demand projected was 150mn doses but only 40mn doses is being tendered

DCVMN Suppliers

Supply exceeds demand

Room for Capacity, Needs Planning

No information from UNICEF on Supply Requirement

Continued...



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# Suppliers Table

#	Product	Suppliers	Max. suppliers	Current no.of suppliers	Product Status
6	Rota Virus	Bharat Biotech, SII, GSK	4 (2019)	3	
7	Rabies	SII	2 (2014)	1	
8	OCV	EuBiologics Co., Shantha Biotechnics	2 (2018)	2	
9	OPV	Sanofi, SII, Bio Farma, Bharat Biotech, Panacea, GSK, Haffkine, Beijing Bio-Institute Biological	7 (2012)	8	
10	PCV	SII, Pfizer, GSK	3 (2020)	3	
11	YFV	Bio-Manguinhos (Brazil), Sanofi, Institut Pasteur de Dakar (Senegal), FSUE of Chumakov (Russia)	4(2010)	4	

- MR: For major period of its history, there was only one supplier

DCVMN Suppliers

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# Business Risks



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Demand  
Predictability



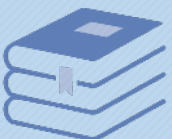
Limited Markets for  
certain products



Pricing Pressure and  
Long term Sustainability



Unattractive financials  
for pandemic vaccines



Regulatory  
Complexity



Procurement  
Mechanisms



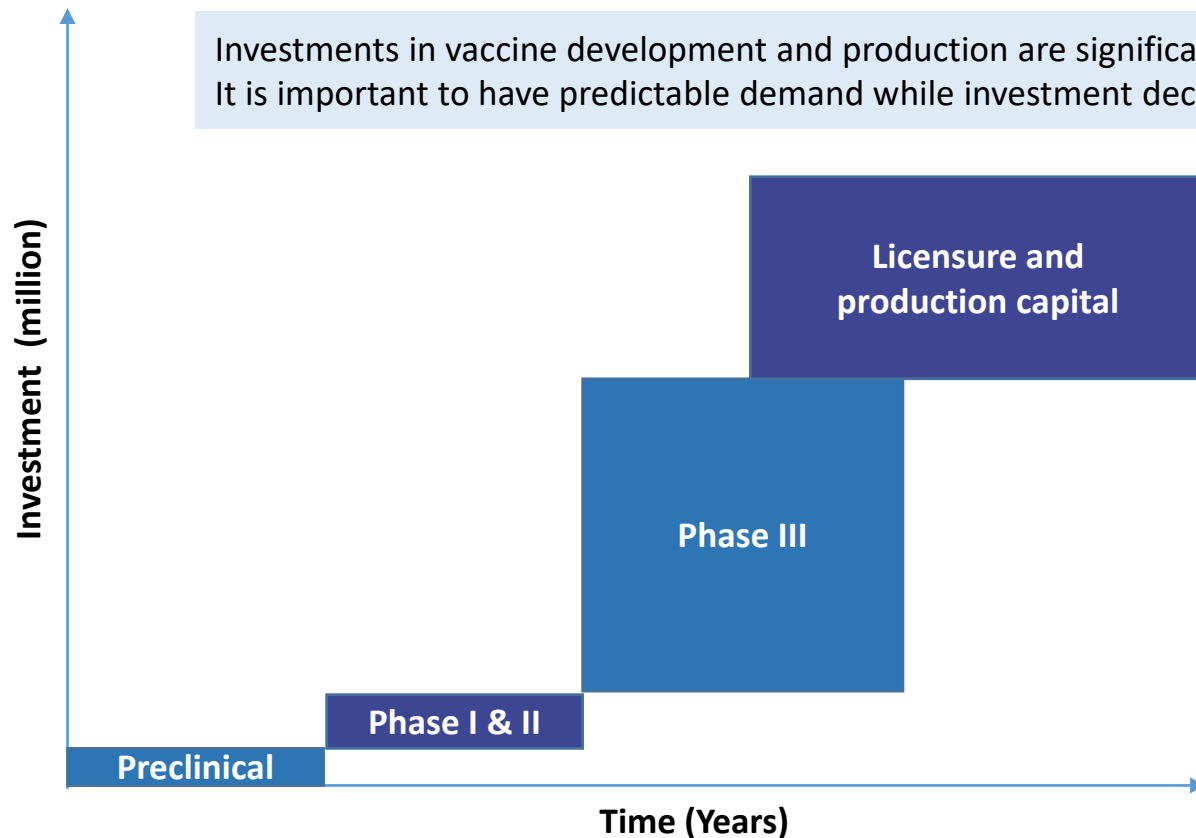
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# Long Lead Times & High Investments

## Investment in vaccine development & commercialization

Investments in vaccine development and production are significant. It is important to have predictable demand while investment decisions are made.



- Vaccine development requires significant investment in capital assets
- Investment gestation periods are typically around 5-7 years

## Major Fixed cost heads

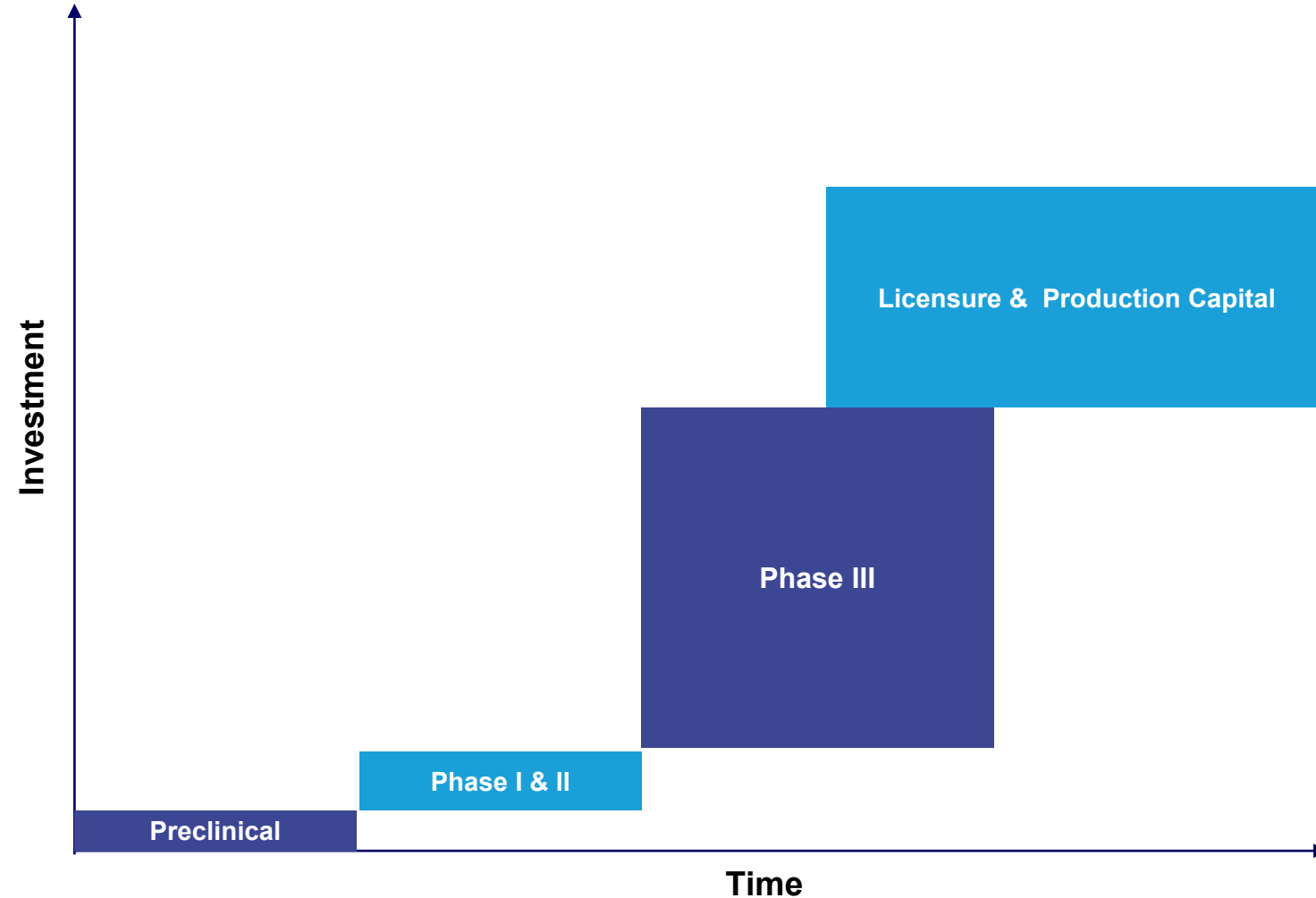
- ✓ **Development**
  - R&D
  - Process development and scale up
  - Clinical development
    - Most of the financial commitments are made even before Phase 3 trials
- ✓ **Facility and equipment**
- ✓ **Quality**
- ✓ **Energy**
- ✓ **People**

# Complex Development Process: Cost & Time



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Significant Investment- Importance of Predictable demand for Investment Decisions



7.5

Months

Time taken for commercial manufacture of one LPV Vial



104

#. of Analytical interventions for LPV at various stages

## IMPLICATIONS

- Long term planning
- Inventory vs Hold time
- High COGs
- Time cost of failure



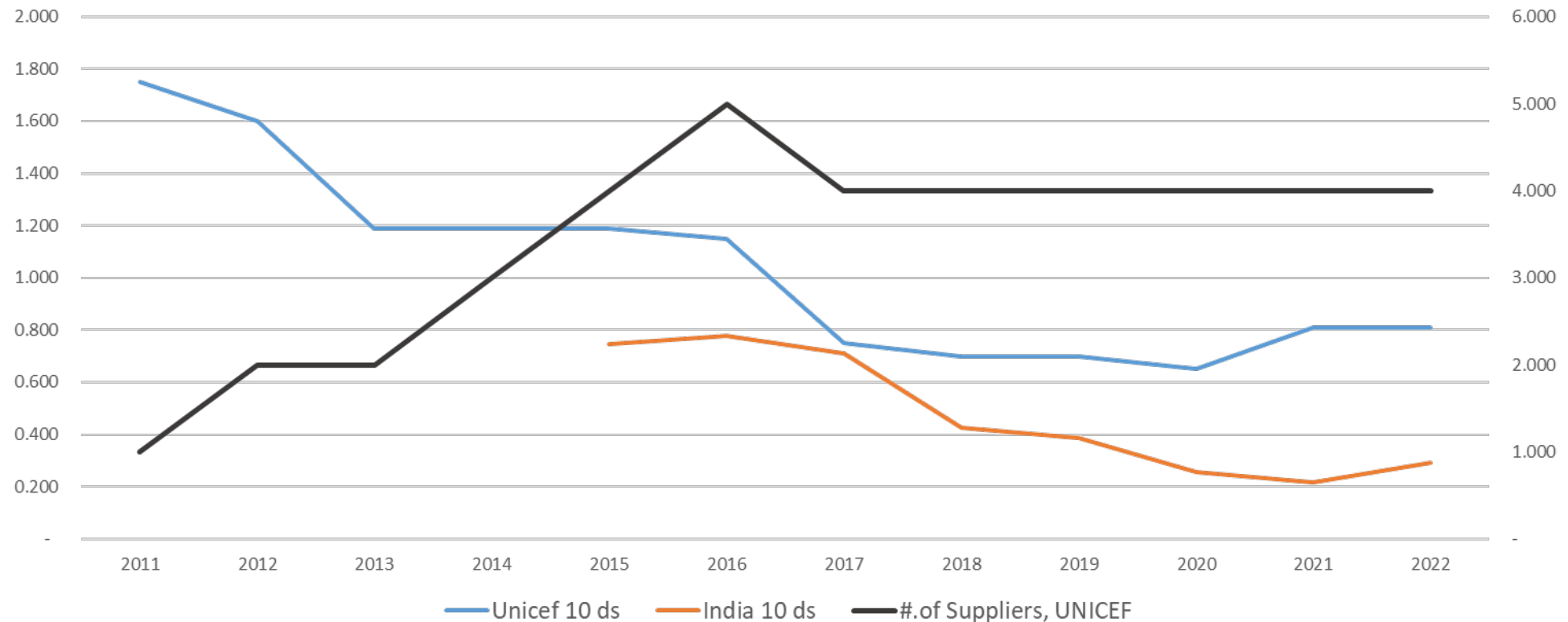
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# LPV price reduction trend

*The price of pentavalent vaccine reduced steadily (-16% annually) and has currently reached a level where it might not be commercially sustainable for some of the manufacturers to remain in the market*

LPV Price Trend (USD)



# Challenges



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Competitive  
Prices

High Capacity

Substantial Assets  
Large Manpower

Some Binary  
Markets

Loss in Market  
Share

Asset  
under-utilization  
Excess Manpower

Strain on Price,  
R & D  
Investment





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# Capacity Usage Vs Supplier Margin Impact

## ***Assumptions & Key Variables :***

- *Market Size = 100 Mds*

## ***Build Facility @ 60% of Market Demand***

- *5 Scenarios Presented with different order quantities for simulation purpose*
- *Conservatively, we have not incorporated any R&D costs*
- *Conservatively, we have taken a 10-year depreciation of assets (straight-line depreciation)*
- *Fixed costs –overheads (manpower, utility, quality, depreciation etc) is about 13.8mn\$*



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# Capacity Usage Vs COGS Impact

	Market Size (Mds)	100	100	100	100	100
<b>Market Dynamics</b>	Award Qty (%)	60%	40%	20%	13%	10%
	Award Qty (Mds)	60	40	20	13	10
	Mfg Capacity Utilization (%)	100%	66.7%	33.3%	22.2%	16.7%
<b>Cost</b>	Fixed Cost	\$ 0.23	\$ 0.34	\$ 0.69	\$ 1.03	\$ 1.38
	Variable Cost	\$ 0.17	\$ 0.17	\$ 0.17	\$ 0.17	\$ 0.17
	Total Cost	\$ 0.40	\$ 0.51	\$ 0.86	\$ 1.20	\$ 1.54

# Managing Risks



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Diversify Product Risk



Diversify Customer/Market Risk



Diversify Capacity Risk

# Distributed Manufacturing



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Pool Procurement



Regulatory Harmonization



Geo Political Treaties

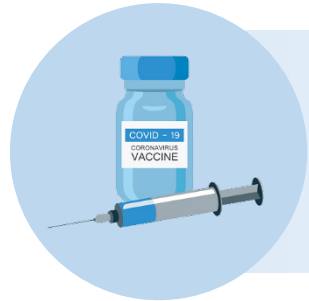


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THANK YOU





- 7.5 billion doses of COVID-19 vaccine
- 60% of global volume



- 60+ Products
- 78 WHO prequalified vaccine presentations



- 43 vaccine manufacturers from 15 countries
- 17 pre-qualified by WHO



- Meningitis-A for Africa
- First Hexavalent vaccine



- Indigenously developed affordable vaccines. Eg. JE, Rota, PCV, Cholera, MR & Typhoid Conjugate
- Improved accessibility -Strengthens National immunization programs