Biological E. Limited

Celebrating Life Every Day

Developing Country Vaccine Manufacturers – Access to Immunization

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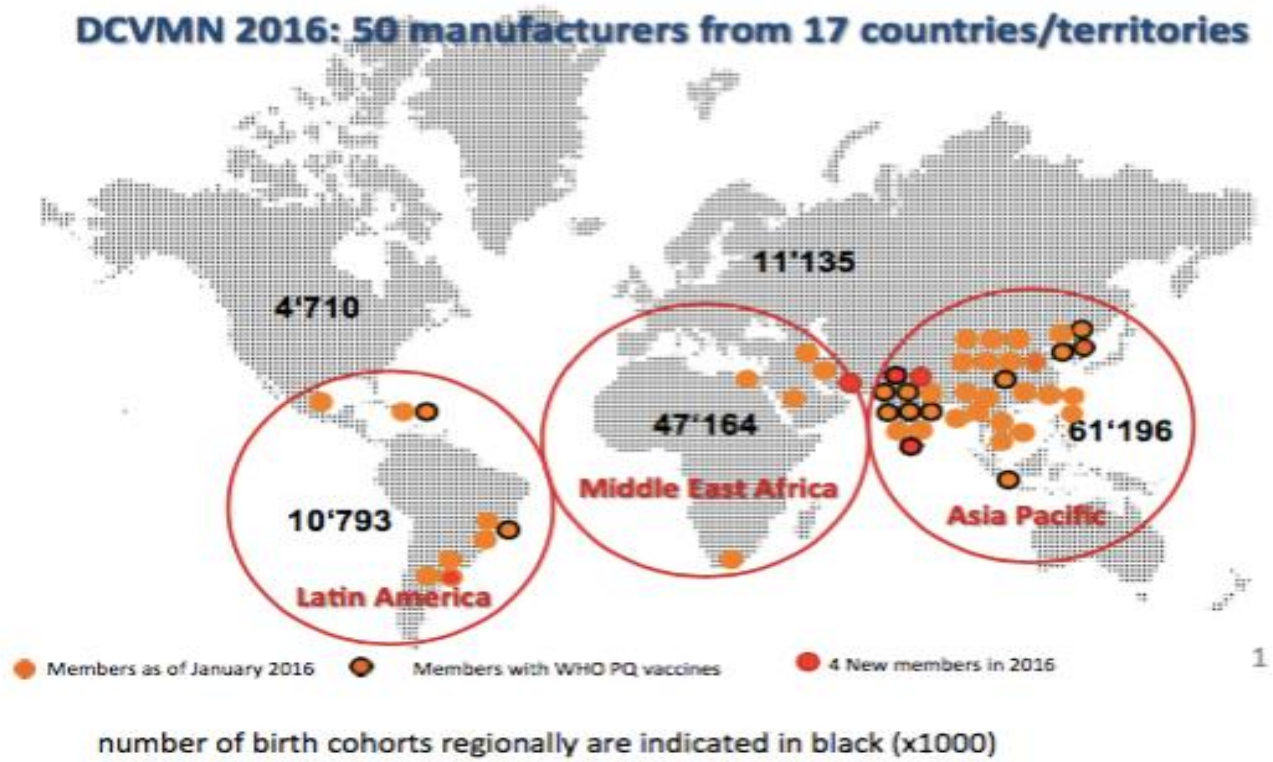
DCVMN Overview

DCVMN was established in the year 2000, sharing the vision of protecting all people against known and emerging infectious diseases, with the mission of increasing the quality and availability of vaccines affordable to all

Objective

To provide a consistent and sustainable supply of quality vaccines at an affordable price to developing countries



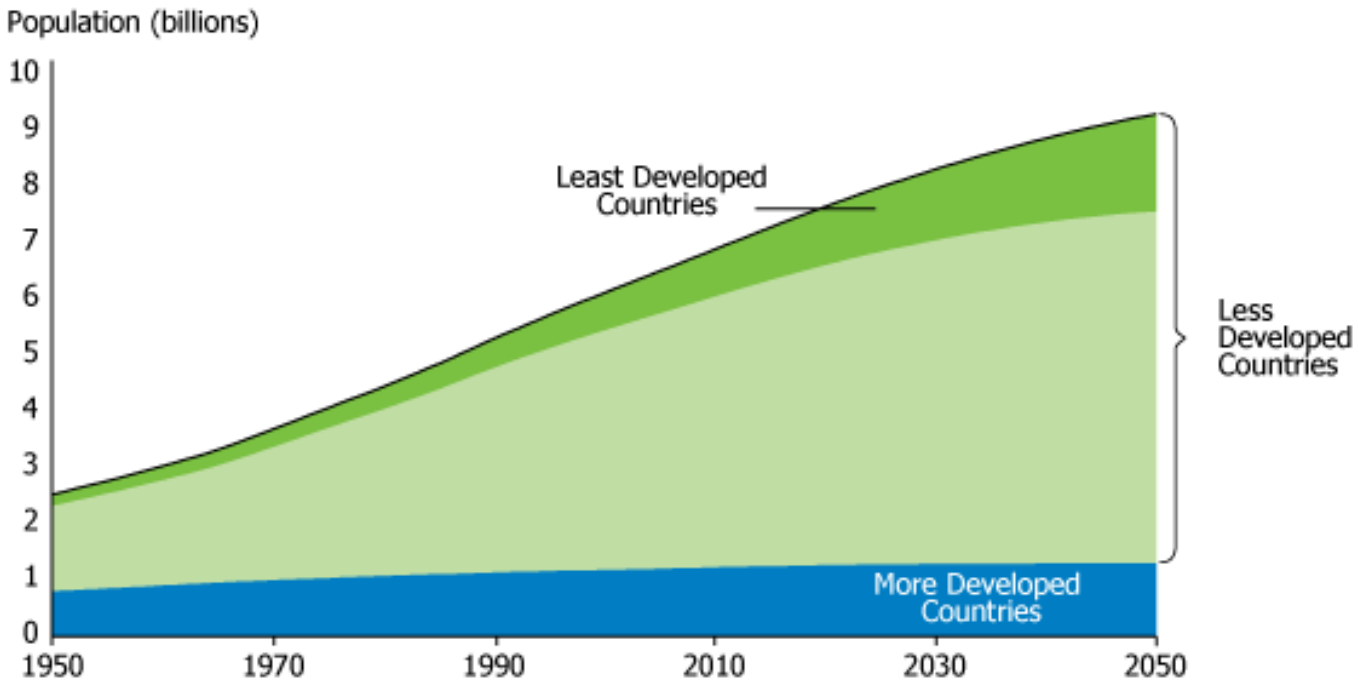
Ancillary Objectives

- To form a voluntary public health driven alliance of vaccine manufactures from developing countries
- To strive for an International recognition such that developing country vaccine manufactures have an essential role in assuring the availability of quality vaccines for national immunization programs
- To encourage continuation of Research and Development efforts to meet the emerging vaccine needs in the developing world.
- Foster the development of members of the network to attain the status of WHO pre-qualification
- Foster collaboration and communication amongst members of the network and actively participate in the international vaccine community to accomplish network specified goal.

Developing Countries plays a major role in driving the demand for immunization as well as in supplying the affordable vaccines to the 84% of world population

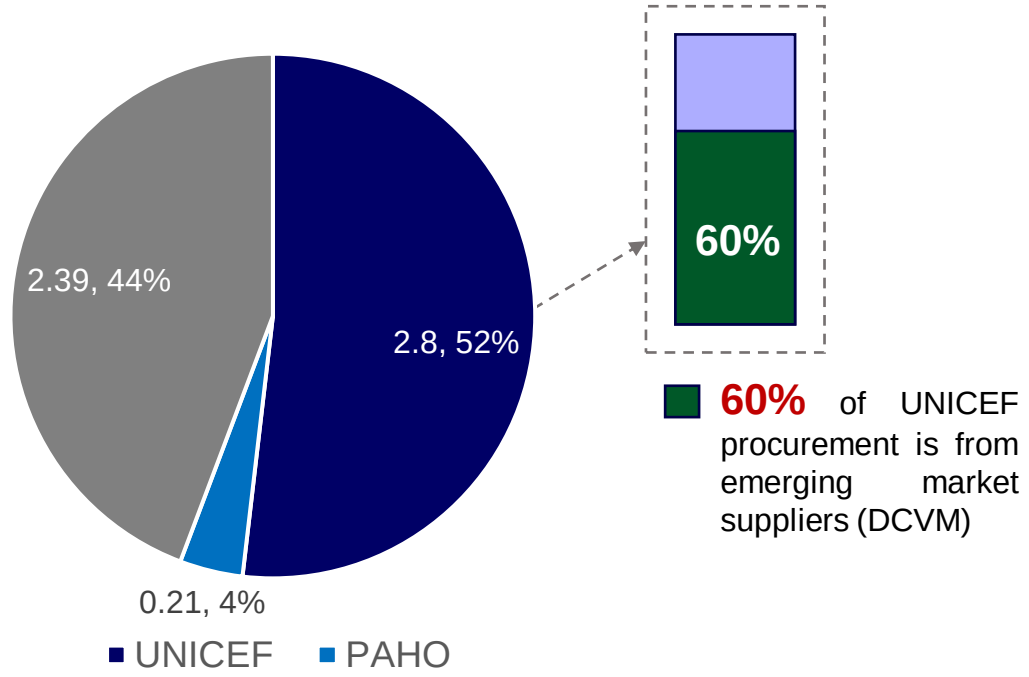
Global Population Distribution

84% of the global population is present in Less developed countries



Vaccine Share by Volume (Billion Doses)

60% of the UNICEF vaccine procurement is from Developing Country Vaccine Manufacturers



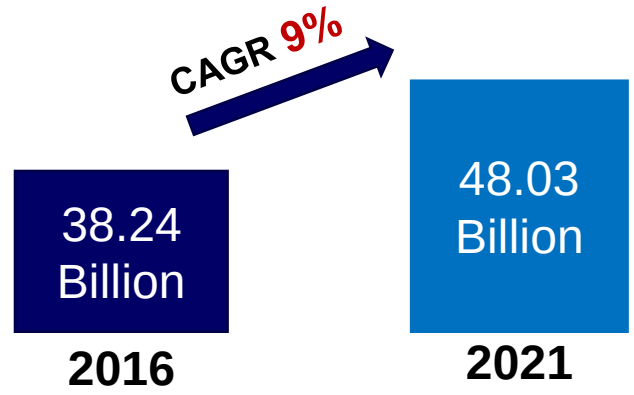
Source : Internal Research

Even though the DCVMs plays a huge role in the vaccine market, the market value they have access to is miniscule due to the restrictions in entering High Income Countries

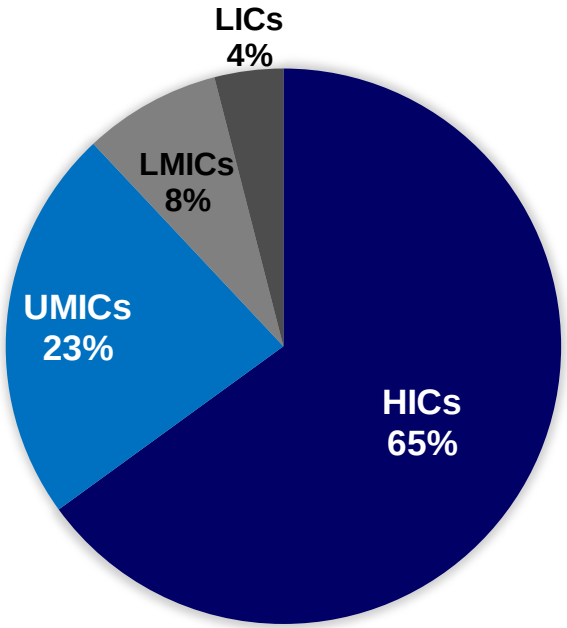
38.24 Billion

Current Vaccine Global Market Size Globally

- 65% of market in High Income Countries
- Unicef & PAHO procurement accounts to 6% only
- DCVM lacks access to HICs



Segment wise Market Size (by value)



HICs

- USA
- UK
- Japan
- Germany

UMICs

- Brazil
- China
- Mexico
- Argentina
- Thailand

LMICs

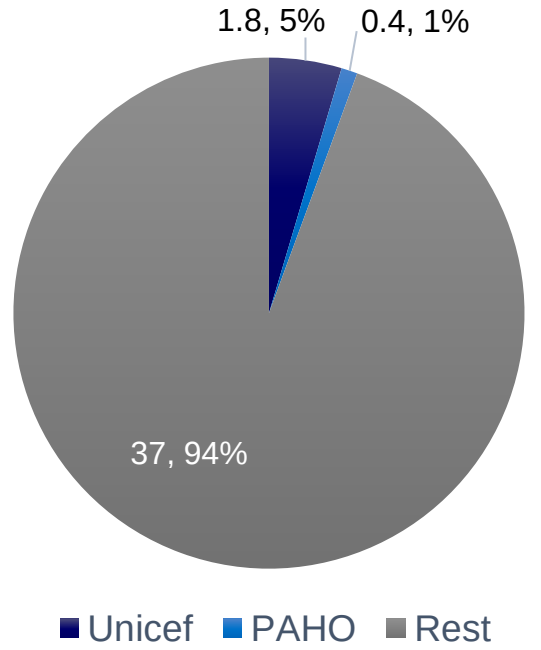
- India
- Philippines
- Indonesia
- Egypt
- Nigeria
- Pakistan

LICs

- Ethiopia
- Bangladesh
- Uganda
- Kenya
- Afghanistan
- Cambodia

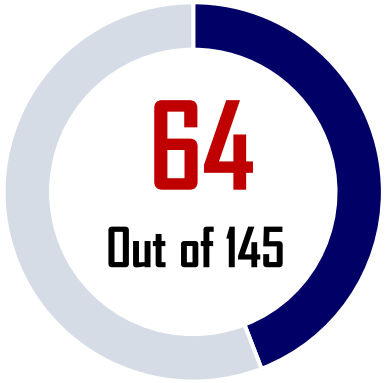
HIC: High Income Countries; UMIC: Upper Middle Income Countries; LMIC: Lower Middle Income Countries; LIC: Low Income Countries

Vaccine Share by Value (USD Billion)



Source : Global vaccine Market Presentation, PATH ; Research and Markets Report

DCVM and Affordable Vaccines



64 out of 145 WHO Pre-Qualified vaccines are from Developing Countries Vaccine manufacturers

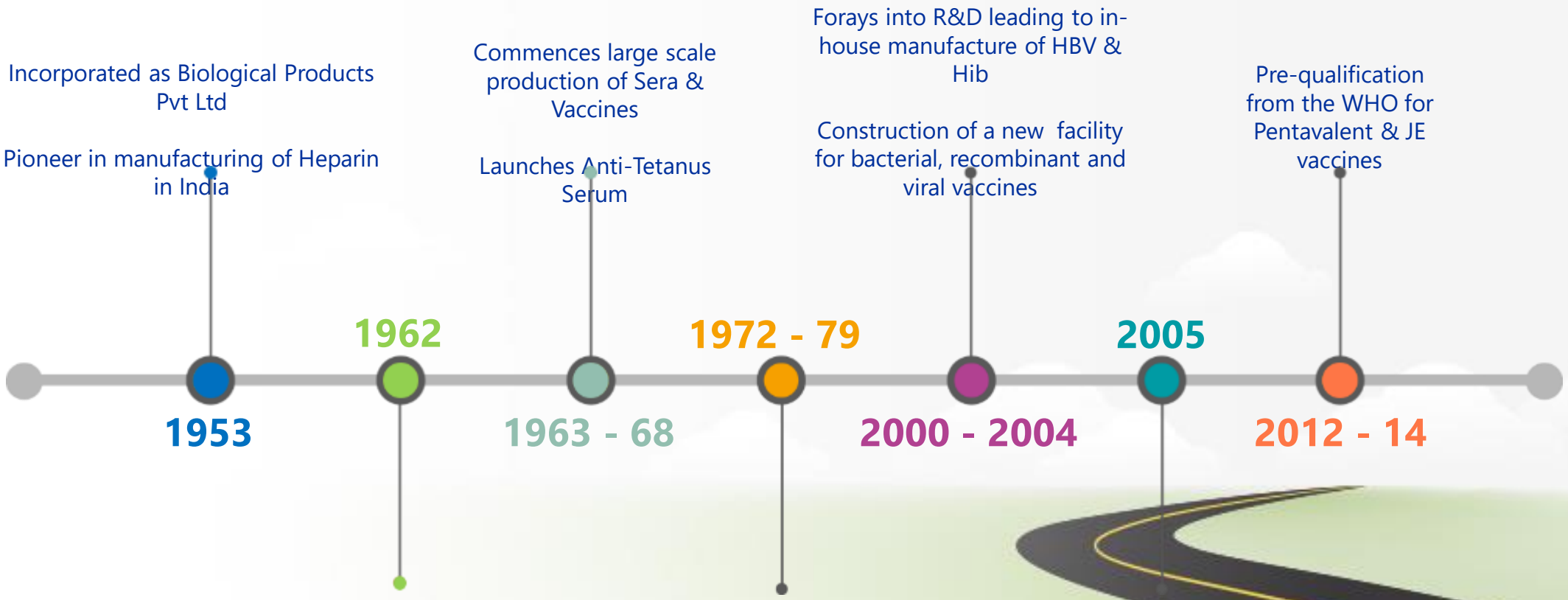
DCVM Success Stories

- **ManAfrivac**
- **Pentavalent**
- **Tetanus**
- **Japanese Encephalitis**
- **Oral Polio Vaccine**
- **Oral Cholera Vaccine**
- **Novel Rota and Typhoid Conjugate vaccines**

Novel Vaccines against **Diarrhea** disease

Introduction to BE

MILESTONES



Bio E: A Unique Combination of Capabilities

Exceptional Track Record

- Vaccine manufacturing experience since 1968
- Strong tradition of supporting public health programs
- In the last decade BE supplied more than **1.2 billion doses** of vaccines towards the immunisation needs of India
- Total number of doses supplied to the public and private market exceeds 2.5 billion

Quality Manufacturing

- Extensive development, scale-up and manufacturing capabilities
- Validated quality systems for global supply
- cGMP, Global standards of Quality and Safety
  - WHO pre-qualified
  - Capabilities and systems for Global compliance (USFDA, EMEA etc)

Technical Excellence

- Proven in-house development capability (HBV, HIB, DTP-HBV, DTP-HBV-HIB & JE)
- Strong, established capabilities in preclinical, clinical development and process science
  - Science-driven development and partnering in discovery research
  - Internationally experienced and accomplished R&D leadership team from firms like Wyeth, Novartis, Merck and GSK
  - R&D investments leading to an exciting early stage product pipeline

Engineering expertise

- In-house efficient and effective engineering capabilities
- Executed multiple projects successfully
- Expertise in large capacities, bulk, fill- finish, upscaling and downscaling

Business Risks

Demand Predictability

Since the fixed costs involved are high, any sudden changes in demand can adversely impact the business

Pricing Pressure and Long term Sustainability

Any sudden drop in prices would increase the investment gestation periods and can make the investments unviable

Regulatory Complexity

Differing regulatory requirements in countries creates additional operational complexity

Limited Markets for certain products

Certain vaccines are relevant in few regions only and hence it is difficult to achieve the scales for required cost efficiencies

Unattractive financials for pandemic vaccines

Developing vaccines to fight epidemic breakouts in financially unviable unless stockpiling is done or any other financial assistance is provided

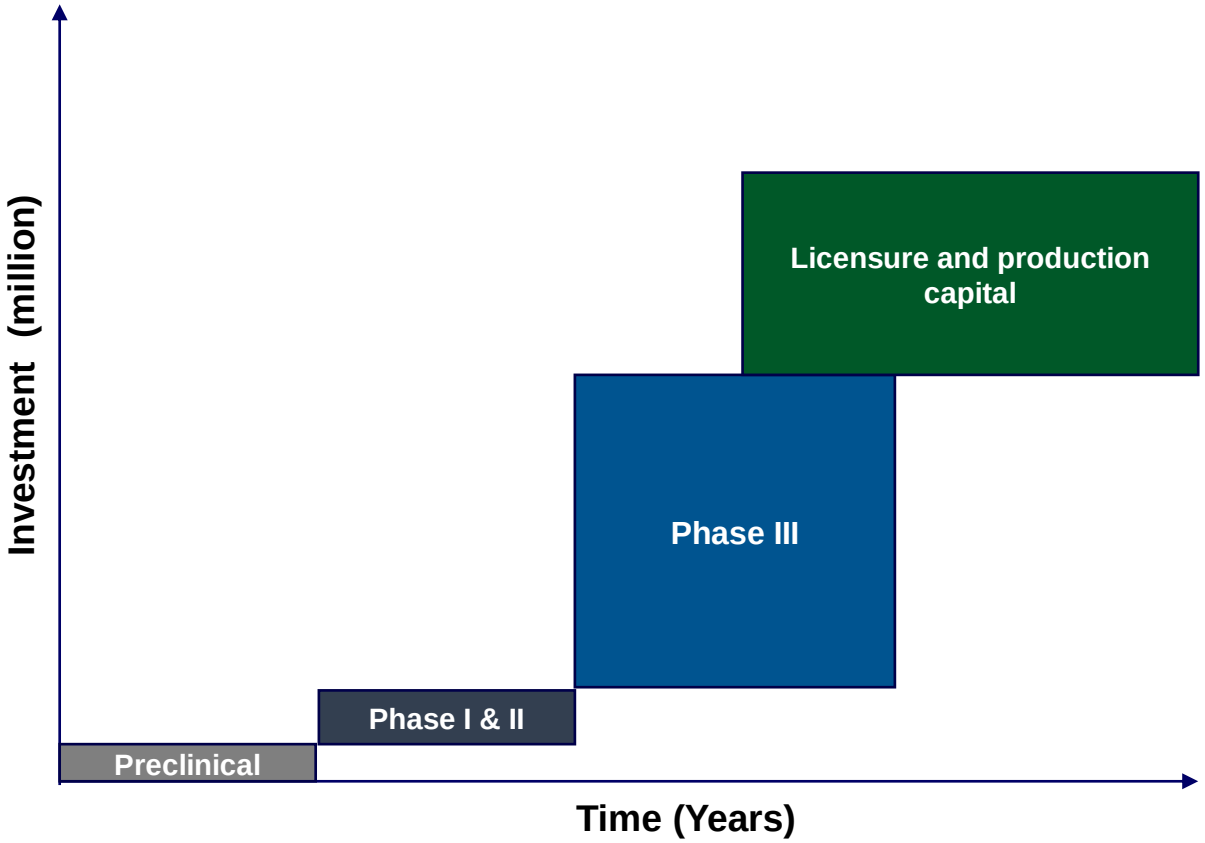
Procurement Mechanisms

Unhealthy, non standardized procurement mechanisms in certain markets promotes monopolies

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

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



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

The complex manufacturing process in vaccines ensures that the operations costs can also be significantly high and it is all the more important to have a long term visibility of the demand

7.5
Months

The long and complex manufacturing process of LPV takes 7.5 months to complete on an average – including downstream, upstream and fill-finish

104

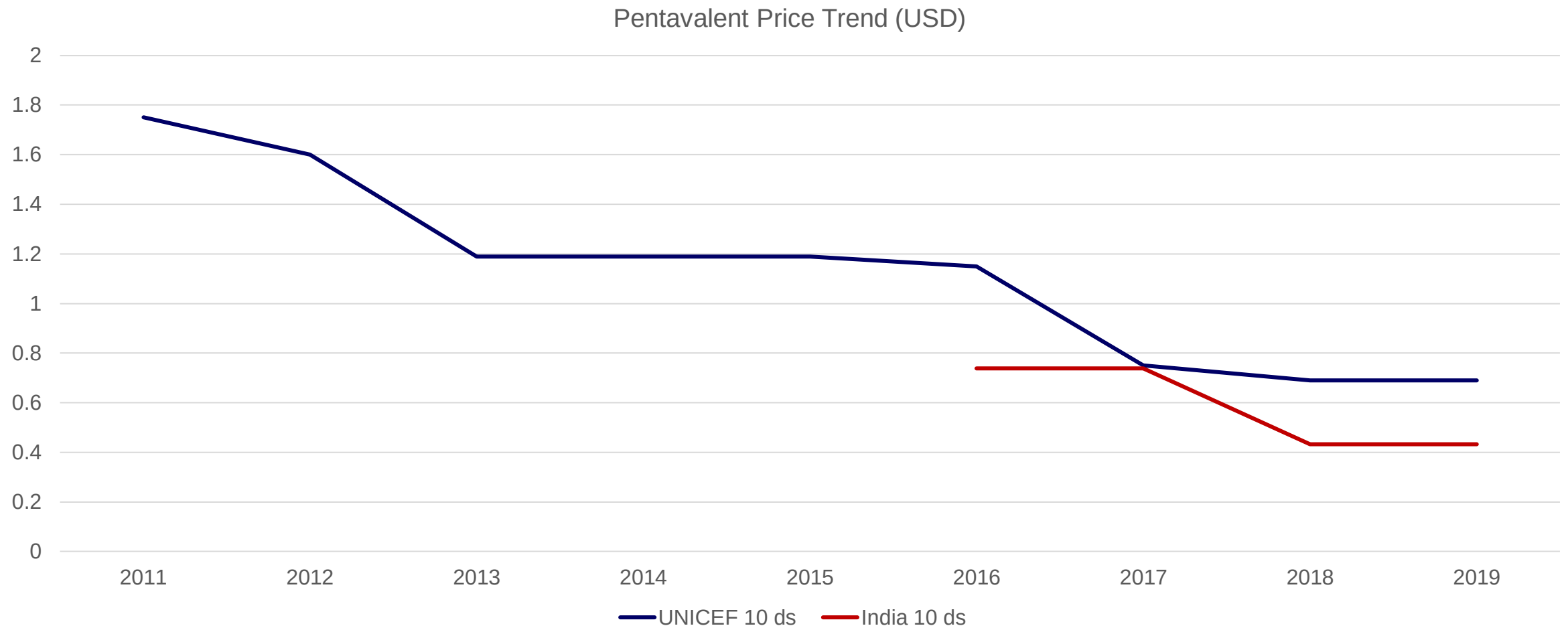
Number of analytical interventions for Pentavalent vaccine at various stages in 7.5 months of manufacturing

Implications of long manufacturing lead time

- **Long term planning**
- **Inventory vs hold time**
- **Costs in case of high COGs intermediates**
- **Time cost of failure**

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



Challenges and Way Ahead

“In the global effort for the affordable access to Immunization, Vaccine Manufacturers in the developing markets plays a key role and it is important that the commercial operations of such manufacturers remain sustainable”

Sustainability of manufacturer’s financial health

- Pricing Stability
- Capacity utilization-Overheads recovery
- Optimal competition per vaccine

Development lead times reduction to help broaden the portfolio

- R&D lead times
- Regulatory lead times-Both National & Supra National

Channel suitability innovation

- Thermostable vaccines
- CTC Compliant Vaccines
- Variant’s for retail market suitability

Progression in value chain-Partnering in Early stage screening of novel candidates to bring velocity in broadening unmet needs

Investment & expertise in development of Vibrant retail Preventive healthcare Culture -Vaccines

- Cross licencing culture between vaccine companies


Biological E. Limited
Celebrating Life Every Day
COMMITTED TO PROVIDING ACCESS TO AFFORDABLE HEALTHCARE
THANK YOU