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## HOW HAS INDIA MASTERED THE LOCAL PRODUCTION OF VACCINES ?

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# DEMOGRAPHIC & ECONOMIC LANDSCAPE : INDIA

- **A nation of ~ 1.4 billion people, ~ 26 million birth cohort,**
- diverse disease burden, communicable and non-communicable diseases,
- Prevalence of Neglected Tropical Diseases (NTDs), hygiene and sanitation-related health issues
- **A large unified market across National Govt, State Govts, Private Markets,**

## **Developments:**

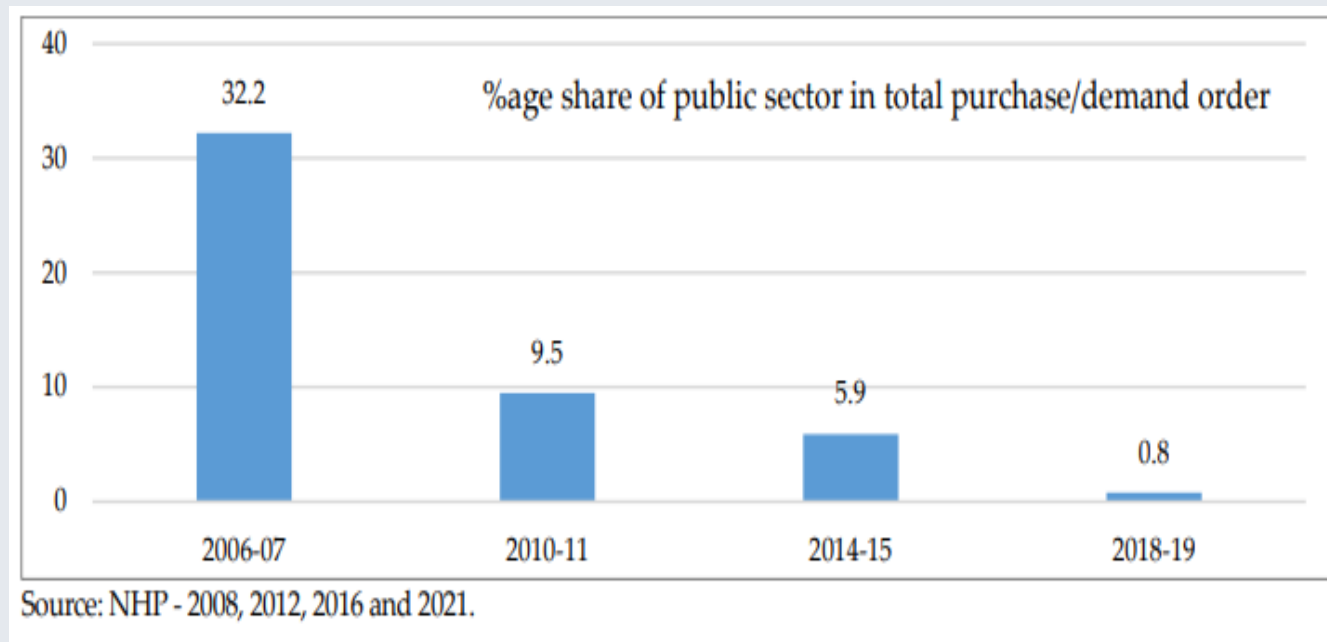
- India: Emerging as a global powerhouse in vaccine production
- **$\frac{2}{3}$  of India's vaccine production - exported globally, especially LIC's and MIC's,**
- **$\frac{1}{3}$  distributed domestically through the Universal Immunization Program (UIP) ~ 12 vaccine-preventable diseases**
- **Total ~ 15-20 Vaccines procurement by UIP, State Governments and Private Markets**

# VACCINE DEVELOPMENT IN INDIA:

- **~1000 AD: Written records of inoculation practiced in India, China, Turkey, and Africa**
- **1802: First doses of smallpox vaccine arrived in India. It was imported from Great Britain until the 1850s**
- **Late 1800s: 15 vaccination centers established across India**
- **1897: Dr. Haffkine developed India's first plague vaccine**
- **1904-1907: Central Research Institute (Kasauli) and Pasteur Institute (Coonoor) established**
- **1907: PII produced an anti-rabies vaccine; by 1957, an influenza vaccine**
- **1970: India's first indigenous oral polio vaccine (OPV) developed**

# IMPLEMENTATION STRATEGY OF VACCINES IN INDIA:

- **1978:** Expanded Program for Immunization launched by the Government of India (GoI)
- **1985:** Universal Immunization Program (UIP) began – enhancing domestic procurement & supply
- The enormous vaccine demand - largely met by the public sector & imports.
- **2008:** Suspension of three public sector vaccine units; Private sector took over ~95% of the demand for vaccines.



# GLOBAL LEADERSHIP :

- India – **the largest** number of **WHO-prequalified vaccines** globally (~50)
- Indian Vaccine Manufacturing Association (**IVMA**) – Sustainable Industry
- Developing Countries Vaccine Manufacturers Network (**DCVMN**) – **Healthy Industry**
  
- India supplies **70% of the efficacious and affordable life-saving** vaccines to LIC's and MIC's,
- saving millions of lives and \$ billions
- **Cost savings from Indian Vaccines resulting in more vaccinations with the same budget**
- COVID-19 Pandemic: India's vaccine prowess highlighted with the '**Vaccine Maitri**' initiative.

# HOW HAS INDIA MASTERED THE LOCAL PRODUCTION OF VACCINES?

## End-to-end structure & comprehensive Vaccine Ecosystem

1. Policy Initiatives
2. Scientific Advancements and Research
3. Domestic & International Collaborations
4. Production Capabilities and Infrastructure
5. Regulatory Framework and Intellectual Property
6. Human Resources and Skill Development
7. Adequate Funding & Financing Innovation
8. Robust RM, PM & Equipment ecosystem
9. Stable Local Procurement and Distribution
10. Political and Social Stability

**Comprehensive Ecosystem**



**Sustainable Industry**

# COMPREHENSIVE VACCINE ECOSYSTEM

## Supportive Policy Initiatives –

- **Early Government investments** in public health infrastructure (Primary and Community Health Centers) and immunization programs laid the foundation for indigenous vaccine development
- **Govt of India** has allocated **~\$ 11 billion**
- **State Govt Health Budgets ~ \$ 20 Billion**
  
- **National Health Missions:** The National Rural Health Mission and the National Health Policy emphasized vaccine accessibility and affordability, creating demand for vaccines development manufacturing
- **Biopharma Mission, Make in India** - favourable ecosystem, easing the path for local production and doing biologicals in India

# COMPREHENSIVE VACCINE ECOSYSTEM

## Broad Scientific & Technology Landscape – India

- Since 1900's, DST, DSIR, CSIR, DBT, ICMR, ICAR, IVRI, etc etc ... ~ 500 research institutes / centers
- State-of-the-art research labs, fostering basic science, applied and translational research
- **Investment in Technological Innovations** by Indian vaccine manufacturers.
  - mRNA, DNA, viral vector, subunit vaccines, live attenuated, rDNA, inactivated, etc
  - Injectable, oral, intra-nasal, intra-dermal, subcutaneous, etc
- **Public-Private Partnerships:** Collaborative efforts between government agencies, research institutions, and private companies have accelerated vaccine development and production



# COMPREHENSIVE VACCINE ECOSYSTEM

## Strategic Manufacturing Capabilities -

- India invested in building **large-scale vaccine production** facilities to meet domestic and global demand
- **Low-cost, high-volume, safe and effective vaccine production** gave it a competitive advantage, enabling it to supply affordable vaccines
- Estimated current capacity > 10 billion doses annually
- Indian manufacturers **catered to under-served and emerging markets**, mastering production processes for vaccines such as OCV, TCV, HPV, PCV, ORV, etc often neglected by HIC manufacturers
- **Efficient Supply Chain and Cold Storage Capabilities** : well positioned for global distribution

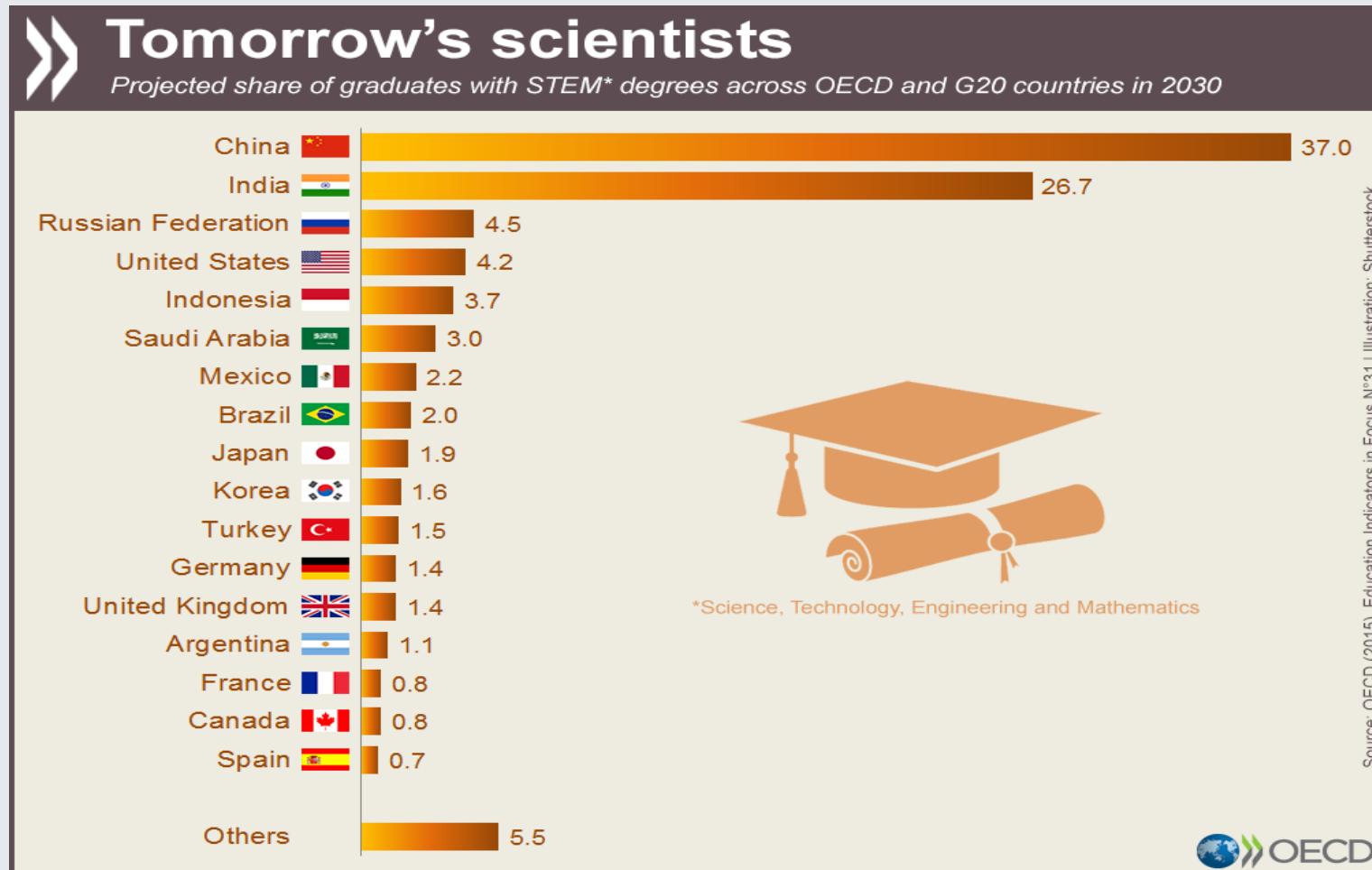
# COMPREHENSIVE VACCINE ECOSYSTEM

## Quality Standards and Regulatory Compliance -

- Indian manufacturers adopted WHO-PQ standards since 1990s
- Certain vaccines approved by SRA's, USFDA, ANVISA, KFDA, PICS, EMA, SAPHRA, TGA, etc.
- **Central Drugs Standard Control Organization (CDSCO)** : regulates licensing, regulation, and compliance in vaccine production – ML-3 standards. Has fast-track approval processes during public health emergencies.
- **CDTL's : Batch testing and release for vaccines**
- **State FDA's and DCA's** : regulate licensing, regulation, and compliance
- **Quality Control Monitoring and Regular Audits-** compliance for raw material sourcing, facility standards, production processes, and packaging.

# COMPREHENSIVE VACCINE ECOSYSTEM

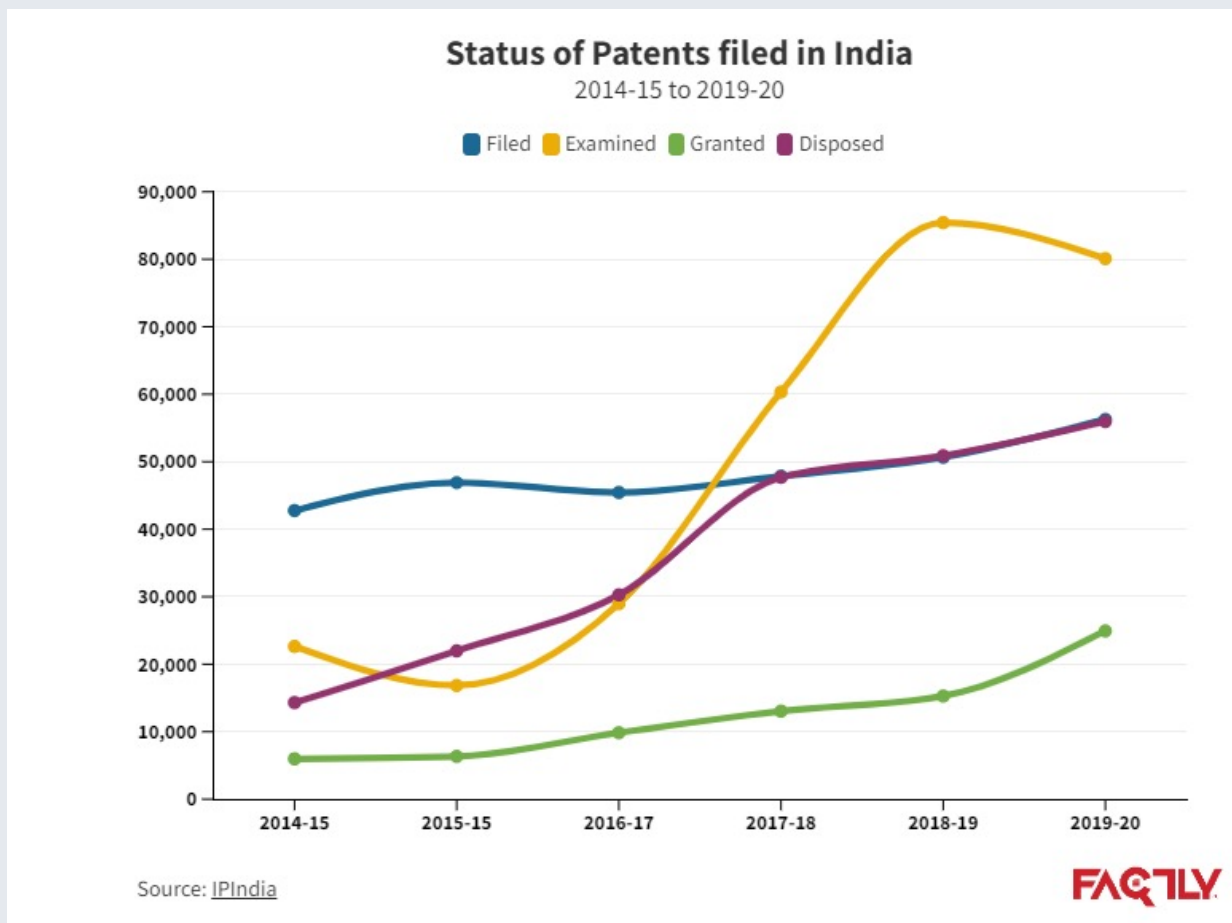
## Skilled Human Resources and Capacity Building



- India's strong base of skilled scientists, researchers, and healthcare professionals - ease to innovate and localize production processes.
- **Affordable** scientific and technical workforce enabled Indian companies to operate at a reduced cost and channel the returns for future innovation

# COMPREHENSIVE VACCINE ECOSYSTEM

## Innovation & Intellectual Property



This surge in patent activity is driving economic growth and fostering a culture of innovation and creativity among STEM youth and the broader population.

The younger generation is losing “Fear of Failure”  
Resulting in entrepreneurship, startups, novel product development for India and the world,

# COMPREHENSIVE VACCINE ECOSYSTEM

## Adequate Financing & Funding for Innovation

### Financing :

- Equity – Private Equity, IPO's, etc
- Debt – Lending Institutions, Indian and global,

### Innovation Funding :

- Grants : DST, DBT, ICMR, Pharma Fund, BIRAC, etc
- Low cost debt for Commercial Manufacturing : TDB, DBT-SBIR, etc

Global collaborations and partnerships, R&D, product development, commercial scale manufacturing fostering innovation

# COMPREHENSIVE VACCINE ECOSYSTEM

## **RM, PM, & Equipment Ecosystem**

- Robust supply chain ecosystem for Raw Materials, Packing Materials, consumables, Manufacturing Equipment, Clean Room Infrastructure, Design & Construction, etc
- PLI Scheme by GOI : To further localize RM, PM, Consumables, equipment etc

## **Stable Local Procurement & Distribution**

- National Govt procurement for UIP
- State, City and Municipal Corporations
- SOE's and Large private corporations
- Private markets

## **Political & Social Stability**

- Product development ~ 7 - 20 years
- Global Regulatory approvals ~ 2 - 5 years
- Facility development ~ 3 - 5 years
  
- Industry needs ~ 20 – 30 years for Sustainability
- A stable political and social environment a must



# THANK YOU

