"Bridging the Gap: Vaccine Industry Perspectives on Meeting India's Immunisation Needs."

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National Disease Modelling Consortium (NDMC)

Women's Collective Forum (WCF) 10 March 2025 IIT Bombay, Mumbai

SII's priorities are aligned to NDMC focused disease area



4 Key Critical Dimensions to

Bridging Immunization / Vaccine Access Gaps

1: Vaccines Save Lives 50 Years of EPI Success

2: Affordable Access of Vaccines

- for Immunization Programs

3: Continued Development of Vaccines for Non Vaccine Preventable Diseases of today

> 4: Last Mile Delivery of Vaccine -Reaching Vaccines to Community

1:Vaccines Save Lives 50 Years of EPI Success

Immunization is a success story, saving millions of lives every year

<u>New Study on 50 years of the Expanded Programme on Immunization and its Contribution</u>

- In the modelling study, Since 1974, vaccination has averted 154 million deaths, including 146 million among children younger than 5 years of whom 101 million were infants younger than 1 year. For every death averted, 66 years of full health were gained on average, translating to 10-2 billion years of full health gained.
- Many new vaccines introduced PCV, ROTA, HPV, TCV, Cholera and Meningitis
- New vaccine to protect against Malaria, Dengue and Ebola
- Promising one being RSV, <u>Tuberculosis</u>, Universal Influenza

Important challenges

- Benefits of immunization **unevenly shared**
- Each year **20 million** infants don't receive full course of basic vaccines
- Of these over 13 million receive no vaccine through NIP "Zero dose children"
- Most Important Sustainability of immunization program specially in Middle Income Countries for newer antigens remains a challenge

The cause of low vaccine use must be understood and addressed

"Adequate predictable supplies of appropriate, affordable vaccine of assured quality must be available at service delivery – WHO"

https://cdn.who.int/media/docs/default-source/immunization/strategy/ia2030/ia2030-draft-4-wha_b8850379-1fce-4847-bfd1-5d2c9d9e32f8.pdf?sfvrsn=5389656e_69&download=true

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11140691/

2: Affordable Access of Vaccines - for Immunization Programs

- Over 116 manufacturers supplying vaccines to WHO members states in 2023
- Supply dependent on fewer than 10 manufacturers with <u>broad portfolio</u>, <u>global reach</u>, and a <u>diversity of</u> <u>deployable technology</u>
- For individual vaccines often *only 2 or 3 suppliers* provide more *than 80% supply*
- Manufacturing concentration leads to <u>market health issues</u>, <u>regional supply insecurity</u> for high impact vaccines
- Coordinated procurement and financing mechanisms for lower income settings have reduced gaps
- Challenge still remains in Middle Income Countries for new vaccine introduction/coverage
- India achieved a unique distinction of self sufficiency for its immunization programs

A shared understanding for equitable access to vaccines - Global vaccine market report 2024 WHO*

* https://cdn.who.int/media/docs/default-source/immunization/mi4a/who_global_vaccine_market_report_2024_vdraft.pdf?sfvrsn=d7bffd94_5&download=true

SII delivered <u>affordable vaccines with broadest portfolio</u> to countries needing it most (> 170 countries) <u>Vaccine doses share @ 22%</u> and value share @ 2% - Saving precious lives

Share of market of volume by manufacturer in 2023

7 Bn doses

Share of market by financial value in 2023

77 Bn USD



* https://cdn.who.int/media/docs/default-source/immunization/mi4a/who_global_vaccine_market_report_2024_vdraft.pdf?sfvrsn=d7bffd94_5&download=true

Vaccine volumes (doses) and financial value (US\$) during 2023 by WHO procurement mechanism and country income group

India is leading the world with 42% of doses share in self-procuring category



Annual Number of Doses

Financial value in USD

* https://cdn.who.int/media/docs/default-source/immunization/mi4a/who_global_vaccine_market_report_2024_vdraft.pdf?sfvrsn=d7bffd94_5&download=true

Emerging vaccine manufacturers are innovating for next decade* Total of 77 WHO PQ vaccine from 15 manufacturers bridging the affordability and access gap

- SII has achieved the distinction of broadest WHO PQ vaccine portfolio (unique products)
- Vision of starting WHO PQ process as early 1990
- And consistently adding WHO PQ products virtually every year since 2000
- And broad number of technology types used

Manufacturer/Year	1994	1995	1996	1997	1999	2000	2001	2003	2004	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	PQ	
																								Vaccines	
Bharat/India																			1		2	1		4	
BioE/India													1		1	2	1	2		1		1	1	10	
BioM/Brazil							1				1													2	
Cadila HC/ India																							1	1	
CNBG/China																	1				1			2	
EuBiologics/Korea																			1		1			2	
GrrenCross/ Korea														1	1	1				1	1			5	
Grren Signal/India																			1					1	
Haffkine/India										1			1	1										3	
LG Chem/Korea			1													1				1				2	\frown
Panacea/India																	1					1		2	As on
Biofarma/Indonesia				2	2		1	1	2	1			1	1	1			1	1				1	15	2025
Serum Institute/India	1	3				1		2	1	2		1		3		1	1	2	1	1		2	1	23	29
Sinovac/China																					1				
SK biosciences/Korea																							3	3	
Total 15	1	3	1	2	2	1	2	3	3	4	1	1	3	6	3	5	4	5	5	4	6	5	7	77	
PQ Vaccine	10						23								44										

Challenges to Immunization Agenda Globally and in India - Zero dose children

Gavi defines zero-dose children as those who lack the first dose of diphtheria-tetanus-pertussis containing vaccine (DTP1)

- Currently, the program provides free immunization against 12 diseases and around 600 million doses are administered to children every year under UPI in India.
- As a percentage of total population of India,
 Zero Dose children account for 1.6 Mio Children
- Zero dose child population of the World is 14.5 Mio Children.
- India is better placed due to Mission Indradanush Campaign.

*WHO and UNICEF estimates of national immunisation coverage (WUENIC)

10 countries accounted for 55% of children without a measles vaccine. 3 of these are also among 10 countries with lowest MCV1 coverage.

The countries with most "measles zero dose" children is a mix of those with large birth cohorts, weak health systems, or both. New in this list in 2023 are countries afflicted by conflict, like Sudan, Yemen, and Afghanistan.

Additionally, some smaller countries have even lower coverage.

World Health Unicef

WHENIC 2023



of vaccinated and unvaccinated children

No meas es vaccine

3: Continued Development of Vaccines for Non Vaccine Preventable Diseases of today

Vaccine Development – Long Lead time with Many Risks Before its uptake.



ttp://www.nature.com/news/2008/080611/full/453840a.html

www.lancet.com Vol 387 May 7, 2016

Five actions for accelerating vaccine innovation beyond a crisis

1. Expanding R&D and manufacturing partnerships: New collaboration models

- 2. <u>Enhancing commercial viability</u> through global funding: New sources for vaccine development
- 3. Boosting vaccination rates: New ecosystem partnerships to create commercial demand
- 4. Investing in flexible manufacturing capabilities: New funding and incentives to derisk vaccine production
- 5. Advancing global regulatory alignment and regulator-innovator collaboration: Lessons from the COVID-19 pandemic

Impact and effort matrix showing	HIGH	Quicker wins	Major advancements						
actions stakeholders can take to	Ĩ	1. Expanding R&D and manufacturing partnerships	2. Enhancing commercial viability through global funding						
advance vaccine innovation			3. Boosting vaccination rates						
			4. Investing in flexible manufacturing capabilities						
	Potential								
	impact	Additional areas to explore	Deprioritized						
		5. Advancing global regulatory alignment and regulator–innovator collaboration	Large investment for low return						
	÷								
	LOW	Level of requirements	ired → HIGH						

Investments in new delivery technologies that have the potential to increase people's willingness to get vaccinated. For example, vaccine microarray patches (VMAPs) and vaccine pills, which can potentially increase vaccine adoption, will need to overcome significant hurdles to widespread availability, including production at commercial scale.

Evolvement of Indian Regulatory System

- □ The <u>regulatory system in India</u> for the new drug/vaccine development and approval has <u>evolved significantly in</u> <u>recent years</u>.
- □ The <u>change has been gradual but steady</u>; key changes are;
 - □ Implementation of e-submission platforms
 - SUGAM online platform for;
 - ✓ Clinical Trial Application
 - ✓ Marketing Authorization modules
 - ✓ Post Approval Changes Quality
 - ✓ Post Approval Changes Clinical Trial
 - ✓ Registration and import of Drug Substance and Drug Product
 - ONDLS online platform for submission and approval / endorsement of mfg license (Form-28D)
 - NSWS online platform for Form CT-10 (test & analysis) and Form CT-16 (import)
 - Revision of Regulatory Guidance documents for Industry i.e. NDCT Rules, 2019; PAC Guidance, GMP, PV, GDP guidelines.....

In 2024, Indian NRA (CDSCO) was assessed/audited & granted ML-3 by the WHO and committed to raised the bars and stringency in benchmarking criteria i.e. ML-4.





CDSCO-Central Drugs Standard Control Organization ; IBSC- Institutional Biosafety Committee; RCGM-Review Committee on Genetic Manipulation ; CBER-Center for Biologics Evaluation and Research

Confidential & Proprietary Information

4:Vaccine Manufacturing and Distribution at Serum Institute

Vaccine Manufacturing & Distribution Supply Chain



Supply Milestones and Activities	Activity Timelines	Activity Responsibility & Description
Receipt of PO with Delivery Schedule		GOI / MOHFW / CMSS issues Purchase orders based on Tender awards with detailed consignee delivery schedule (Quantities and timelines)
Vaccine DP Fill Finish Manufacturing	90 Days	Serum initiates manufacturing of Vaccine batches based on delivery schedule and PO Terms (remaining shelf life). On Average it takes ~90 days for most vaccine batches to be filled, Labelled & Packed and QC & QA cleared
Tendering and Inspection of Vaccine Batches	7 – 10 Days	 GOI / MOHFW / CMSS Inspecting Authority visits Serum to inspect the tendered vaccine batches . This process takes about 7 – 10 days from Serum intimation, based on Inspecting Authority Availability
National Control (CDL) Release of vaccine batches	35 Days	CDL (GOI) Receives the samples from Serum after inspection for each tendered vaccine batch. It takes ~35 Days for release and receipt of CDL certificate
Dispatch and supply of Vaccines by Road / Air to Consignee Points	4 – 7 Days	Serum supplies the vaccine batches to the consignee points (based on their readiness) within 4-7 days of receipt of CDL release & according to quantity to be supplies as per Delivery schedule
	Total: ~140 Days	

Preparing for next pandemic – Global responsibility



Pandemic Preparedness Facility - Manjari Site

- Serum has built World's largest pandemic preparedness facility with the capacity between 5 to 10 billion doses in time of crises for India and beyond.
- Individual manufacturing suits capable of handling technologies like,
- ✓ mRNA, Vectored vaccines
- ✓ Live Attenuated Viruses
- ✓ Inactivated Viruses
- ✓ Recombinant proteins (using bacterial, yeast, mammalian and insect cell lines.

Collaborating with CEPI for their **100 days Mission** to develop and deploy vaccine within 100 days of new pandemic pathogen emerging.

"It is our endeavour to make quality vaccines more affordable around the world because we firmly believe that health should be the right of every child."

Dr. Cyrus S. Poonawalla

Chairman and Managing Director

Mr Adar C. Poonawalla

CEO