

CEPI

The case for globally distributed vaccine manufacturing – *CEPI perspective*

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This presentation addresses:

- 1 To what extent what CEPI is doing in manufacturing has been informed by the recent covid pandemic?
- 2 What are the critical challenges to local manufacturing sustainability and how CEPI thinks these challenges can be overcome?
- 3 What is CEPI doing to build local manufacturing capacity for advancing outbreak preparedness and response, and reducing system inequities?
- 4 How is CEPI collaborating with the ecosystem partners to make local manufacturing sustainable?

CEPI is a global partnership – launched in Davos (2017)

CEPI 2.0

Vision statement

A world in which epidemics and pandemics are no longer a threat to humanity

Mission statement

Accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need



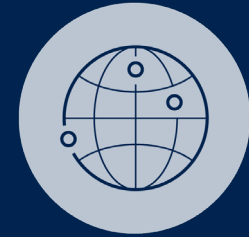
Prepare

for known epidemic and pandemic threats



Transform

the response to the next novel threat



Connect

to enhance and expand global collaboration

100
day
aspiration

To develop a safe and effective vaccine in 100 days from the moment that a pathogen is sequenced and/or the need for a vaccine is recognised to initial availability for use.

1

In the acute phase of the pandemic, the equitable delivery of COVID-19 vaccines proved to be a manufacturing and supply chain challenge

TIMELY, EQUITABLE ACCESS CHALLENGE

Vaccine manufacturers and suppliers of key inputs needed to **scale-up** an announced cumulative supply target of up to 14 billion doses by the end of 2021 (at least **three times the pre-COVID19 annual global supply** for all vaccines).

However, **shortages in most critical input supplies** were identified by COVID-19 vaccine manufacturers.

CEPI RESPONSE

CEPI established the **COVAX Manufacturing and Supply Chain Taskforce** to facilitate production of COVID-19 vaccine doses, promoting equitable access to vaccines in the context of COVAX.

The Taskforce has been successfully **debottlenecking supply of critical raw materials and consumables** that were constraining vaccine production.

A lesson learned from COVID-19: globally disbursed local vaccine manufacturing capacity is a key enabler of equitable access



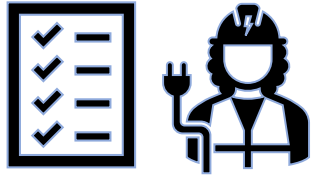
As recently observed during the COVID-19 pandemic, to be ready for emerging infections needs **geo-diversified vaccine manufacturing and supply** through inter epi-/pandemic periods, particularly in under-served regions

Closing the global vaccine equity gap: equitably distributed manufacturing

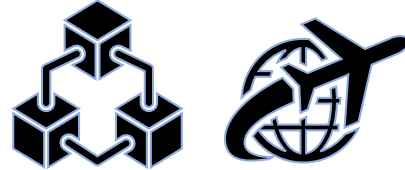
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[https://doi.org/10.1016/S0140-6736\(22\)00793-0](https://doi.org/10.1016/S0140-6736(22)00793-0)

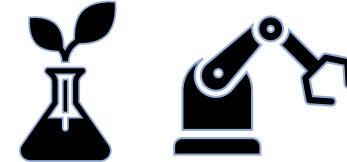
2 To achieve equitably distributed vaccine manufacturing capacity, the world needs:



A surrounding ecosystem to support sustainable manufacturing, including regulatory readiness and trained, skilled workforce



A transparent and robust supply chain that can produce unhindered production in a crisis & worldwide availability of raw materials



Technical innovations to contribute to easier, less expensive, faster vaccine manufacturing with a lighter footprint & platform technologies



Sustainable financing and business models to ensure long-term viability (at individual facility and national/ regional levels)



Policy measures to enable effective transfer of manufacturing technology to LMIC manufacturers

3 CEPI is on a mission to build vaccine manufacturing capacity closer to outbreaks

A globally distributed network would enable rapid access to vaccine doses in LMIC regions

It could also allow for vaccine production to take place closer to the source of an outbreak

Facilitates promotion of vaccine uptake



#100DaysMission

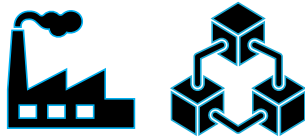
CEPI Vaccine Manufacturing Facility Partner Network

- CEPI is establishing a ***Preferred Partner Manufacturing Facility Network***, focusing on the **Global South**.
- The Network will comprise of a **portfolio of well-established players** (pandemic surge, outbreak response, reversal of Covid-19 vaccine dose needs) and **newer facilities**. These facilities will **receive funding and specialist support from CEPI** to create or sustain their capabilities for **regional vaccine production**.
- In return, the CEPI **framework agreements** will have **clauses to enable equitable access** to the production facilities, and to **maintain oversight of critical aspects** such as **Quality Assurance** and **new process platform technology introduction** that are key to readiness to accept tech transfers or respond in emergencies.
- CEPI will also work with CEPI-funded vaccine developers, where appropriate, to encourage them to **tech transfer** to these CDMOs.



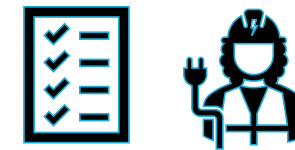
CEPI Vaccine Manufacturing Facility Partner Network

Two manufacturing partner framework agreements in place for pandemic preparedness and response activities, with a further **4-6** planned for **facilities in the Global South in 2023/4.**



Aspen, South Africa

- Co-funding with BMGF to preserve Aspen's viral vector fill & finish capabilities, for improving access to vaccines in Africa
- Improve sustainable manufacturing capacity for suspension vaccines for future epidemics and pandemics
- Support technology transfer from SII to Aspen to manufacture routine vaccines
- To f/f-supply Pneumococcal, Rotavirus, Polyvalent Meningococcal, Hexavalent vaccines in Africa

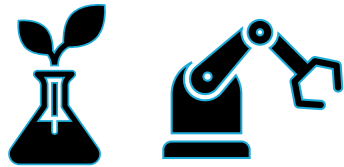


Institute Pasteur Dakar, Senegal

- 10-year partnership to boost manufacturing of affordable vaccines for the Global South
- Equip the DS manufacturing capability to produce outbreak vaccines
- Expanding capacity to produce vaccines across multiple technologies
- Launch a bioprocess lab to accelerate vaccine production and reduce costs
- Invest in workforce training and development
- Develop IPD's Quality Management System
- Reserve capacity to rapidly supply vaccines to Global South countries during disease outbreaks

CEPI CMC Innovations and Marketplace Activities

In addition to the Partner Network, CEPI is also investing in **innovative technologies** to advance manufacturability and use in LMIC settings, and is further **expanding the COVAX Market Place** to include non-covid pathogens.



CfP Innovative technologies to improve vaccine thermostability

3rd round evaluation in progress. Two agreements signed so far:

- *20Med*– Stabilised mRNA (polymeric nanoparticles)
- *Vaxxas Pty* – High density micro-array patches



Evolution of the COVAX Market Place, and establishment of a Supply Chain Services group

- Matchmaking between manufacturers and raw materials/consumables suppliers to support CEPI's portfolio and outbreak response efforts
- Market place has been leveraged for by the US Department of State* (LOE2 GAP clearing house is endorsed at the UN General Assembly Sep'22)

*US State Dept. launched a global supply chain clearing house at UNGA (23Sep'22) see: [International Public Health and Medical Supply Chain Clearinghouse](#)

CEPI is engaging with diverse stakeholders to assess DCVMN technical capabilities, capacities and aspirations



Sustainable vaccine manufacturing in low- and middle-Income countries

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Highlights

- Developing country vaccine manufacturers have diverse capabilities to develop, produce, and supply vaccines for local and global use.
- Manufacturers report strategic plans to acquire new technologies, expand capacities and develop novel vaccines.
- Partnerships and funding support are critical to sustainable vaccine manufacturing in LMICs.
- Regulatory challenges and price competition are key impediments to manufacturer viability.

CEPI will continue to work within the broader ecosystem to deliver opportunities identified in the CEPI 2021 vaccine manufacturing landscaping survey

Obstacles	Opportunities
Limited or no vaccine R&D within region	Establish in region training centers to address imbalance of vaccine R&D and support training in vaccine manufacture spanning GMP, QC and QA release as a minimum
Limited or no local vaccine manufacturing experience	Implement technology and knowhow/knowledge transfers, international training programs, and establishing vaccine manufacturing capacity/capability
Limited end-to-end capability and capacity	Support with technology and knowhow/knowledge transfers
Weak regulatory environment	Implement stringent quality standards and getting WHO pre-qualification
Requirement to coordinate and deliver vaccine manufacturing capacity/capability programs	Nurture regional vaccine manufacturing collaborative partnerships / associations to deliver
Barriers to the cross-border movement of vaccines and inputs	Regional and WTO measures to reduce the unnecessary use of formal and <i>de facto</i> export restrictions, promote supply chain transparency, and facilitate border clearance and import/export permissions



The World Economic Forum launched the **Regionalised Vaccine Manufacturing Collaborative (RVMC)** at its Annual Meeting in Davos in May 2022, with CEPI and the US National Academy of Medicine as co-chairs.

- The goal is increasing vaccine access for LMICs through successful & sustainable establishment of a versatile global manufacturing network capable of producing during non-/pandemic times

*See details at [Survey launched by CEPI to track multinational vaccine manufacturing capacity for use in future epidemics and pandemics](#) (19May'21)

*See data at [Vaccine production efforts across key regions mapped in first-of-its-kind study to prepare for future pandemics](#) (27Oct'21)

For geo-diversified vaccine manufacturing and supply, the world needs all stakeholders to play an active role

CEPI is only one actor in the global health security ecosystem. We need all stakeholders from **public, private, non-governmental sectors and civil society** to work together to have:

- ✓ Agility to meet surge demands
- ✓ Platform and innovative technologies
- ✓ Consumables & raw materials available worldwide
- ✓ Trained, skilled workforce around the world
- ✓ Suitable and sustainable business models (or procurement systems)
- ✓ Robust supply chains that can produce in a crisis

Q&A

CEPI