

News release

Meeting discusses COVID-19 vaccine manufacturing bottlenecks that must be urgently tackled for C19 vaccine output to reach its full potential

9 March 2021: Chatham House, in collaboration with <u>COVAX</u>, <u>IFPMA</u>, <u>DVCMN</u>, and <u>BIO</u>, convened a Global COVID-19 Vaccine Supply Chain & Manufacturing Summit on 8th and 9th March. The unprecedented scaling up of vaccine manufacturing, from zero to billions of doses in record time, has led to shortages that are impacting the entire vaccine supply chain. Open dialogue among manufacturers, suppliers, international organizations and governments is urgently needed to address these shortages so that they do not interrupt vaccine manufacturing. The meeting aimed to kick start the dialogue to identify, understand, and discuss potential solutions for these supply chain challenges. Held under the <u>Chatham House Rule</u>, the meeting provided the opportunity for frank, open and problem-solving discussions while respecting anti-trust rules.

A discussion document¹ was prepared to help inform participants, giving an overview of the current landscape of COVID-19 vaccine manufacturing and emerging supply chain challenges. Vaccine manufacturers, and suppliers of vaccine components, are part of a global supply chain that is scaling up from zero to billions of doses in record time and tripling previous annual vaccine output. As founding partners of COVAX, vaccine manufacturers are playing their part in achieving fair and equitable access to vaccines. COVID-19 is an exceptional crisis of global magnitude with several unforeseen and shifting challenges and complexities.

Vaccine manufacturing processes (upstream, downstream, fill-and-finish) are highly complex and involve cutting-edge science and technologies. Effective manufacturing capacity expansion needs to overcome major challenges, including but not limited to the need for highly specialised equipment, qualified and trained personnel, difficult and time-consuming technology transfers, and, not least, managing complex international supply chains frequently involving more than 100 components.

Vaccine manufacturers and upstream suppliers are increasingly reporting shortages of raw and packaging materials, critical consumables, and equipment. Over time such shortages, if left unaddressed, will lead to shortages of vaccines and impact delivery commitments. Such shortages will also impact the ability to manufacture other lifesaving vaccines and biologics. Preventing bottlenecks in the system requires among others: addressing export restrictions, immediate easing and facilitation of access to raw materials and upstream supplies; regulatory prioritization of validation of supply, batch release and achieving greater visibility on vaccines demand forecasts to enable upstream suppliers to do better supply planning.

All stakeholders agreed there is a need to expand capacity and in a way that promotes equitable access and leaves no one behind. Other approaches were discussed including:

- 1. Free flow of goods and workforce;
- 2. Continue technology transfer and manufacturing partnerships between innovators and manufacturers to scale up and scale out COVID19 vaccine capacity;
- 3. Better demand forecasting and inventory management of raw materials and critical consumables;
- 4. Support from the highest political level is needed;
- 5. Value of regulatory harmonization and streamlining to accelerate manufacturing capacity and supply;
- 6. Better production, demand and supply, forecast and visibility;
- 7. Give consideration to the potential impacts of COVID-19 production on non-COVID products.

¹ Landscape Discussion Paper, Appendix.



Richard Hatchett, CEO, Coalition for Epidemic Preparedness Innovations (CEPI): "Over the last two days, stakeholders from across the spectrum, from upstream suppliers to vaccine manufacturers, multilateral organizations, governments, and representatives of nongovernmental organizations and civil society, have had a frank and vigorous discussion about the challenges we face. What is clear is that our industry partners have risen to the occasion in developing safe and effective vaccines but now are struggling to ensure they have all the materials they need to deliver them. We must urgently work together to prevent these shortages from slowing the delivery of the vaccines we need in order to end the pandemic".

Thomas Cueni, DG, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA): "Let's put the current challenge in perspective: pre-Covid-19 global vaccine manufacturing capacity was 3.5 bn doses per year, 5bn if you include seasonal flu shots. This year for Covid-19 vaccines alone, manufacturers have scaled up new capacity from zero to 10bn. Doubling world vaccine capacity of what is a very complex process in a matter of months; thanks to unprecedented industry commitment and collaboration. We should not be surprised if there are bumps along the road, in the manufacturing process itself as well as strains on the whole supply chain; starting with hundreds of raw materials needed to make vaccines. It will inevitably lead to bottlenecks that will urgently need to be addressed. We are deeply aware that we are not only in a war against the virus, but also in a war against time, because we know that no one is safe until everyone is safe. During the Summit discussions there was a clear desire to to leave no stone untouched to address inefficiencies and increase manufacturing capacities. I'm confident we will see new players coming in with their manufacturing know-how and capacities".

Dr Seth Berkley, CEO, Gavi, the Vaccine Alliance: "Through unprecedented partnership, COVAX is now rolling out vaccines to many countries that otherwise would not have had access to doses. Manufacturing has played a key role in helping us begin to close the vaccination divide and continued collaboration will be vital if we are to achieve the global capacity needed to end the pandemic. Today's Summit represents an important step in building the global consensus needed to solve the bottlenecks and supply constraints that stand in our way".

Dr Soumya Swaminathan Chief Scientist, World Health Organization (WHO): "We need to explore both short term and medium term solutions to address the problem of inequity in vaccine availability. While removing roadblocks in supply chains can enable companies to ensure they can meet their commitments to supply doses now, a longer term more sustainable approach will be to enable technology transfer to manufacturing sites in LMICs that have the capacity. This will allow the strengthening of regional health security and enable the use of new platforms to develop vaccines for COVID and other infectious diseases".

Dr Michelle McMurry-Heath, President and CEO, Biotechnology Innovation Organization (BIO): "The technical and logistical complexities of the task before us will require vaccine manufacturers, suppliers, governments, multilateral organizations and non-governmental organizations to work together in new and creative ways to find solutions to our shared challenges. We must invest across all of the ecosystem to ensure that there is not only manufacturing capacity but also increasing amounts of the vital production supplies needed for that capacity".

Mr Sai D.Prasad, President, Developing Countries Vaccine Manufacturers' Network (DCVMN): "COVID-19 can be conquered only through equal participation of innovators and manufacturers. Developing country vaccine manufacturers and industry at large have lead through innovation and large scale manufacturing. With rapid capacity expansion and new manufacturing partnerships, global access of COVID-19 vaccines will become a global reality in the months to come, in all countries. Global products, local manufacturing, and leave no one behind".

Media contacts: media@globalc19mfgsummit.org

Chatham House	IFPMA	BIO	DCVMN	CEPI
Stuart Coles	Abigail Jones	Scott Frotman	Rajinder Suri	Rachel Grant
pressoffice@chathamhous	a.jones@ifpma.	sfrotman@bio.	r.suri@dcvmn.	Rachel.grant@cepi.
e.org	org	org	net	net

About Chatham House

The mission of Chatham House is to be a world-leading source of independent analysis, informed debate and influential ideas on how to build a prosperous and secure world for all. Chatham House was founded in 1920 and is based in St James's Square, London.

About IFPMA

IFPMA represents the research-based pharmaceutical companies and associations across the globe. IFPMA collaborates with the United Nations and other organisations to contribute to industry expertise in helping the global health community find solutions that improve global health. IFPMA is a founding partner of the Access to COVID-19 Tools (<u>ACT) Accelerator</u> of which the COVID-19 Vaccine Global Access Facility (<u>COVAX</u>) is a key pillar. IFPMA members are fully committed to the goal of COVAX to accelerate development, production, and equitable access to safe, effective, and affordable COVID-19 vaccines.

About BIO

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

About DCVMN

Developing Countries Vaccine Manufacturers' Network (DCVMN) is a voluntary public health-driven alliance of vaccine manufacturers from developing countries, firmly engaged in research, development, manufacturing and supply of high-quality vaccines that are accessible to protect people against known and emerging infectious diseases globally.

About CEPI

CEPI is an innovative global partnership between public, private, philanthropic, and civil society organisations launched in Davos in 2017 to develop vaccines to stop future epidemics. Our mission is to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks.