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## COVID-19 VACCINE SUPPLY CHAIN AND REGULATORY TRANSPARENCY TECHNICAL SYMPOSIUM

## TUESDAY, 29 JUNE 2021, 10.00 - 18.00 (CET)

## SUMMARY SESSION 2: MAPPING VACCINE MANUFACTURING AND TRADE, 10:15 - 11:30

## **Questions for Session 2:**

- What are the latest projections on COVID-19 vaccine manufacturing output?
- What can supply chain mapping exercises tell us about vaccine manufacturing production and related value chains?
- Vaccine producers are experiencing bottlenecks in their supply chains. Which types of problems are being experienced and what can policy makers do to address them?

In his **opening remarks**, **Dr Robert Koopman**, **WTO Chief Economist**, highlighted the rapid contraction and gradual pick-up in merchandise trade caused by the COVID-19 pandemic. This recovery was gathering pace, but supply chain bottlenecks were still visible, notably affecting inputs, final goods and some services across global supply chains. He highlighted that the objectives of the session were threefold: i) to discuss the latest projections on COVID-19 vaccine manufacturing output; ii) to explore vaccine manufacturing production though supply chain mapping exercise; and iii) to highlight the main types of bottlenecks and recommendations on how to address them.

**Mr** Rasmus Bach Hansen, **CEO & Founder, Airfinity**, provided an overview of the latest vaccine production. He noted that over 3.3 billion doses had already been produced in 2021, of which 1.1 billion had been manufactured over the past month and 314 million over the last week. He highlighted that four vaccines had achieved significant scaling-up in production: Sinovac, Pfizer, Sinopharm and AstraZenecca. Growth in the supply of other COVID-19 vaccines had been more measured. Looking ahead, vaccine production could exceed 11 billion in 2021, as more vaccines come through the pipeline. (Observed production also tended to exceed Airfinity's projections). He noted that there were 83 different production sites, located mostly in Europe and the United States. Close to 70% of the forecasted production was expected to come from vaccine manufacturers' own productions sites. At the same time, contract development and manufacturing organization production sites are more numerous than in-house production facilities for COVID-19 vaccines. He also pointed to high market concentration of suppliers of sub-components, with most of the suppliers of bioreactors, glass vials, and syringes being located in the United States. A push in manufacturing of input components could have an important effect on alleviating supply chain shortages. His presentation can be viewed on this hyperlink.

Dr Matthew Downham, Sustainable Manufacturing Lead, Coalition for Epidemic Preparedness Innovations, provided a brief overview of the role of CEPI in accelerating development of vaccines against emerging infectious diseases and enabling equitable access to these vaccines. He highlighted CEPI's collaboration with COVAX manufacturing task force. He also pointed to the workstream on improving input supply availability which aimed at launching marketplace for critical input supplies; facilitating free flow of critical supplies for vaccine manufacturing; and expanding mid-term available input supply capacity. Having provided several examples of country-specific challenges, he highlighted the importance of ensuring greater trade facilitation, addressing technical barriers to trade and export restrictions on critical input supplies. He also stressed the need to support rapid creation of bilateral agreements to ease import-export of input supplies on key routes. While the input supply shortage solutions had been restricted by limited interchangeability of supplies, the importance of standardization of supplies as well as the matchmaking between manufactures could be used to facilitate interchangeability of supplies. In closing, he stressed the importance of international travel exemptions for vaccine workers and prioritizing their vaccination to travel.



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Ms Giulia del Brenna, Head of Unit for Strategy and Regulation: Single Market and Industrial Policy, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, (DG Grow) and European Commission Task Force for the Industrial Scale-up of COVID-19 vaccine production, recalled that COVID-19 vaccine had been authorized in the European Union in late 2020 and that the EU had set an early target to vaccinate over 70% of its population by the end of 2021. She also recalled that on average it took ten years to develop vaccines and only after an approval by the regulatory authorities would companies then embark on production. In the COVID-19 context, the EU had intervened with advance purchase agreements prior to vaccine authorization. Since February 2021 a special task force had also been working on scaling up industrial production across four streams: mapping, prioritizing, synchronising, and matchmaking. As a result of mapping of critical inputs, a number of problems with disposables had been identified - and not necessarily where problems had been expected. Supplies were tight for plastic caps for vials. She also highlighted the EU's experience in organizing a matchmaking in March 2021 with the participation of over 300 companies – an event that had helped address market information problems. In closing, she stressed the importance of mapping the entire supply chain; identified that partnerships played a critical role; and noted that public policy actions should be supporting the scaling up of manufacturing.

**Mr** <u>Andrew Wilson</u>, **Global Policy Director**, **International Chamber of Commerce**, identified the scaling up of vaccines manufacturing as a critical economic challenge. He stressed that the inefficiencies in medical supply chains had hindered the global response to COVID-19 and an effective coordinated international global response was required to end the pandemic. He recalled ICC's views about establishing a clearing house that could collect and publish aggregate data in non-commercially sensitive way could also serve a longer-term purpose for building a more resilient economy, he noted. He referenced examples from the automotive and agricultural sectors that could useful here, as well as the potential tools that artificial intelligence could offer as well as third-party data providers. He noted that the Agricultural Market Information System could serve as a useful analogue in this area. In closing, he encouraged the WTO, WHO and other partners to accelerate work in this area considering the long-term vision of establishing medical supply chains that would allow to combat future pandemics with efficacy and efficiency.

**Mr** <u>Hongvi Wang</u>, *Vice-President, International Business, CanSino Biologics Inc*, provided an update on China's progress in vaccine rollout, noting that more than 1.3 billion doses had already been administered, with nearly 18 million doses administered per day over the last 20 days alone. China's vaccine capacity is expected to exceed 7 billion doses by the end of 2021. He noted that China had provided 350 million vaccines to the international community, including through vaccine aid projects in nearly 80 countries, and vaccine exports to approximately 40 countries. China would also provide 10 million vaccine doses to the COVAX implementation plan. He gave an overview on his company's COVID-19 vaccine production footprint, with randomized community trials being conducted in China, Pakistan, Mexico, Russia, Chile and Argentina. He also informed that CanSino had recently launched new production plants in Tianjin and Shanghai, with an annual expect production capacity of 500 million to 600 million doses per year. He pointed to examples of transfer of technology that CanSino was involved in with companies in Pakistan and Mexico to ensure local manufacturing of vaccines. He also made some recommendations for supply chain efficiency based on organizational best practices, including a comprehensive inventory of all the raw materials.

**Ms** Laetitia Bigger, Vaccines Policy Director, International Federation of Pharmaceutical Manufacturers and Associations, noted that over 3 billion COVID-19 vaccines had been supplied globally by June 2021, with producers on track to manufacture an estimated 10 to 12 billion by the year end. Biotechs, large pharmaceutical companies, and contract manufacturing organizations were working together, with over 300 agreements, in both developed and developing countries today. To date, some 89 million vaccines had been shipped through COVAX to 133 economies, but the pace of COVAX deliveries has been affected. Countries, that had supported R&D and manufacturing scale-up at risk to a much-needed global scale, but reserved supply in excess of domestic requirements, and most recently the tragic Indian epidemiological situation and related export restrictions. In response, IFPMA launched a 5-step plan to call on manufacturers, governments, and non - governmental organizations to work together to further address vaccine inequities. A copy of her presentation can be viewed on this <u>hyperlink</u>.



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**Ms** Elsie Soto, Vice-President, Supply Chain, Emerging Markets, Pfizer, noted that Pfizer had concluded agreements to supply COVID-19 vaccines to 122 countries and pledged to provide 2 billion doses to lower-middle income countries over the next 18 months. She also recalled that Pfizer had pledged 500 million doses to the United States at a not for profit price for the COVAX and the African Union. She noted Pfizer's success in scaling-up manufacturing: some 3 billion doses would be produced before the end of 2021. The scale-up relied on two production networks: one in Europe and one in the US. In Pfizer's manufacturing facilities, the formulation capacity had been tripled, the bag sizes had been doubled and new finish lines had been added. In addition, new suppliers within the existing networks had been validated and average production time had been nearly halved to 60 days. She made a strong call for a predictable policy environment which would enable viable and competitive manufacturing.

In Pfizer's view, the scarcity of inputs was the main barrier to COVID-19 vaccine manufacturing upscaling. She opined that the progress made to date in addressing the COVID-19 pandemic would not have been possible without a predictable system of IP rules established by TRIPS Agreement. She welcomed the Trade and Health Initiative put forward by some WTO members. She stressed that WTO rules had helped to scale up the vaccine manufacturing which had been very dependent on global supply chains and the swift transit of goods. The Pfizer's COVID-19 vaccine supply chain relied on 280 components sourced from 19 different countries. She acknowledged that the application of export restrictions had impacted Pfizer's operations and called for such measures to be transparent, proportionate, targeted, and temporary. In closing, she stressed the importance of trade facilitation and called for removal of tariffs on essential medical supplies.

**Mr** <u>Rajiv Gandhi</u>, **CEO & Managing Director, Hester Biosciences**, introduced the Hester BioSciences Group recalling that it was predominantly an animal vaccination manufacturer with operations in South Asia and Africa. In response to the pandemic, it become involved in COVID-19 vaccine manufacturing efforts. These included manufacturing inactivated antigens for Bharath Biotech, an Indian vaccine producer. He pointed to shortages of machinery and inputs as major bottlenecks for capacity expansion. He recommended that future investment in vaccine production units should be designed with modularity in mind to ensure flexibility so as to be able to rapidly expand manufacture of either animal or human vaccines. In his view this could be done safely through measures that included by designing different blocks within the vaccine manufacturing and by creating plant laboratories that comply with BSL3 (Bio-safety hazard level 3) safety requirements. In closing, he cited another important factor that needed to be considered in brining on new capacity and called for further simplification and harmonization of country-level vaccine registrations.

Mr Carel du Marchie Sarvaas, Executive Director, Health for Animals, gave an overview of Health for Animals, which represents approximately 85% of global producers of animal health products, including vaccines. He described the animal health vaccine supply sector, noting that it was smaller, more fragmented and operated on a lower price structure than its human health vaccine market counterpart. Production standards, required by law, were the same as those in human health; so production facilities were, at least theoretically, interchangeable. There had been growth in demand for animal vaccines partly driven by increased focus on prevention of animal diseases as a more cost-efficient alternative to treatment. During this crisis, animal health vaccine producers had had discussions with several governments on pivoting animal health facilities to produce human COVID vaccines. Ultimately, it was deemed more appropriate that animal health vaccine production facilities should continue to produce animal vaccines given the continued risk from zoonoses. He cautioned that a global vision for disease prevention should not focus on humans alone, but also integrate animal-borne infections. Some 60% of all diseases were zoonotic by nature. Cutting animal vaccine production to produce human vaccines could create unintended public health consequences, he stated. In closing, he noted that the existing obstacles related cross-border animal vaccine trade restrictions had to be reduced.