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ORGANISATION MONDIALE DU COMMERCE
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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 5: BEYOND VACCINES: MAPPING OTHER COVID-19 ESSENTIAL HEALTH TECHNOLOGIES AND TRADE

Questions for session 5:

- How can value chain mapping techniques be used to chart trade in other COVID-19 essential health technologies?
- What manufacturing, input and regulatory bottlenecks are these COVID-19 essential health technologies facing and why?

In his opening remarks, **Mr [Antony Taubman](#), Director, Intellectual Property, Government Procurement and Competition Division, WTO** emphasized the purpose of the session was to harvest insight on the wider spectrum of health technologies needed to contain the COVID-19 pandemic, including diagnostics, medical devices and therapeutics. He further noted the need for practical insights to build upon and thus help chart the way forward for cooperation.

Mr [Aaron Bernstein](#), Divisional Vice President, Procurement Technical Services, Abbott noted that one way to prepare for future pandemics is to adopt the guidance in the [100 Days Mission report](#) as presented to the G7. To help increase R&D, diagnostics could be incorporated into a business as usual healthcare approach rather than exclusively for hospital or laboratory use. A sustainable cycle of innovation taking place both during and in between pandemics would improve the potential to scale up production as required and would also help in the fight against AMR and non-communicable diseases. A common regulatory framework with clear specifications for diagnostics, including international assessment protocols and guiding principles alongside quality assurance processes, would reduce variability in diagnoses quality. Close cooperation between public and private actors, including unhindered access to samples and data, is needed for the surveillance of pandemic threats.

Mr [Carlos Eduardo Gouvêa](#), President, Latin American Alliance for the Development of In Vitro Diagnostics explained how an integrated system in which diagnostics are used may also in itself be an innovation. Diagnostic reagents, instruments and the IT network required to process results should be fully integrated because more and streamlined integration can reduce the time required to provide results, and ultimately therapies, to patients in need. To increase access, regulatory agencies and the framework in which diagnostics are used must be adaptable; for example, ANVISA modified existing emergency use authorization resolutions in order to register products with less delay, and pharmacies were authorized to carry on on-premises evaluations of rapid tests. A local consortium including medical societies, industry associations and public and private labs produced standardized protocols for assessing diagnostic results. ANVISA was thus able to carry out post marketing surveillance and manufacturers had sufficient feedback to improve their systems. A "One Health" integrated approach to human, animal and plant health and ecosystems will help prepare for future pandemics. Research on the impact of COVID-19 on non-communicable diseases underscores the necessity for an integrated response.

Ms [Tanya Vogt](#), Executive Officer, South African Medical Technology Industry Association noted that there is a lack of understanding of the medical devices sector and the quality requirements, and therefore WHO assistance regarding specifications was instrumental. There is an absolute need for coordination and sharing of best practices among regulators, including how to implement regulatory convergence, to prevent the duplication of rigorous testing, reduce the



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potential for corruption, avoid delays and avert uncertainty for suppliers. For example, SAMED collaborated with the African Union, organised business and the Ministry of Health to establish a procurement portal for PPE. Opening up the market without a high-quality regulatory framework increases the opportunity for sub-standard, falsified or counterfeit products and corruption; however, if regulators develop their own rigorous standards, require and conduct local testing and validation, this results in delays of access to market of critically required medical technology. International or harmonized regulatory standards for diagnostics and devices and the sharing of best practices and data can mitigate corruption, delays and uncertainty. Medical technology representatives play a critical role in areas of servicing, support and training and should be considered for vaccination early on as they often work in critical frontline patient facing settings. Ministries must engage industry associations prior to implementing import or export restrictions or other emergency policies to mitigate against unintended trade barriers and corruption.

Dr Trevor Gunn, Vice President for International Relations, Medtronic explained that health technology supply chains, such as those for devices such as ventilators, can be complex and implicate suppliers and producers across the globe – a delay in the shipment of a single component can bring an entire factory to a halt. It is therefore crucial to have multisource supply chains and for trade to flow freely and with minimal trade-restricting measures in order to avoid impediments to the movement of essential health products. Collaboration and partnerships involving training and knowledge transfer are required for successful device usage and adaptation in local or regional contexts. For instance, the Ventilator Training Alliance, created from partnerships of ventilator manufacturers, provides a platform of training and product resources for medical professionals, which can also be used to share content. Restrictions on the movement of workers had a negative impact on manufacturing and the support and usage of devices. Other challenges included sourcing from single suppliers, transport capacities and site access to provide technical support. The WTO can convene countries in emergency situations to share information and discuss pragmatic solutions. The WTO can also discourage unnecessary obstacles, often unintended, to trade, and can continue to promote transparency of trade measures and data.

Ms Hemal Shah, Director, IP & Trade Policy, Government Affairs & Policy, Gilead discussed how an early decision to put large scale production for their COVID-19 therapeutic Veklury (remdesivir) in place even before regulatory approval helped handling its resource- and time-intensive manufacturing process and ensuring an early arrival of important volumes on the market. Remdesivir's complex manufacturing process requires 25 chemical steps. A closely coordinated global supply chain as well as voluntary licensing agreements helped overcome the lack of specialized manufacturing capacities and enabled the fastest possible production of remdesivir. Cooperation included transfer of technology to enable real time sharing of know-how and donation of inputs to licensees. Collaboration and partnerships, including between public and private sectors, yield more closely coordinated global or regional production efforts, which ensures efficient allocation of inputs and distribution of products. Gilead's ability to produce large quantities and meet unanticipated spikes in global demand relied on multisourced supply chains. Such reliance underscores the need for countries to avoiding imposing trade restrictions. The main impediments to remdesivir access have been regulatory and administrative barriers – not IP barriers. Examples include slow regulatory approval processes, a lack of procurement processes and inadequate funding mechanisms.
