WORLD TRADE ORGANIZATION
ORGANISATION MONDIALE DU COMMERCE
ORGANIZACIÓN MUNDIAL DEL COMERCIO

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

**TUESDAY, 29 JUNE 2021, 10.00 – 18.00 (CET)**

## SUMMARY SESSION 4: PROMOTING TRANSPARENCY AND CONVERGENCE IN THE REGULATORY LANDSCAPE

### Questions for Session 4

- What approaches are being used to expedite the regulatory processes needed to get new manufacturing capacity up and running?
- How can we cooperate internationally to quickly and safely manufacture, approve and disseminate needed vaccines, therapeutics and diagnostics?
- How can transparency in the regulatory approval process be strengthened?
- How do we increase regulatory cooperation and capacity building for better future pandemic preparedness?

**Mr Aik Hoe Lim, Director at the Trade and Environment Division of the WTO,** underlined the key role of regulatory authorities for vaccines supply chains and their ability to ensure the safety, quality, and efficiency of vaccines. However, divergent regulatory approaches can create challenges for dissemination and access. He highlighted the TBT Agreement as a tool to facilitate trade by addressing regulatory barriers and promoting harmonization to international standards, and the work of TBT Committee on these issues.

**Dr June Raine, Chief Executive at the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK,** explained how the UK expedited their emergency authorization process through a range of regulatory flexibilities, including very early engagement with developers, rapid approval of clinical trials (phases undertaken in parallel in real time), rolling review of vaccine and therapeutics dossiers (shorten approval time), and agile inspections (including remote). The aim was to shorten the approval of vaccines from several years to under a year. To mitigate the risk of working under expedited processes, transparency and openness were strengthened (e.g. sharing data nationally with experts and explaining the process and findings at public briefings) and independent expert advice was gathered in real time. International convergence and collaboration are vital to improving our response to COVID-19, and preparedness for any future pandemic. Arrangements such as ICMRA[1], ICH[2], IMDRF[3] were mentioned in this respect. The G7 100 Days Mission report sets outs proposals for an international network of clinical trials to accelerate development of vaccines, diagnostics and therapeutics, and calls for a common regulatory frameworks for diagnostics. Regulatory convergence and transparency can help remove unintended barriers created by regulators that slow access.

**Dr Rogério Gaspar, Director at the Regulation and Prequalification Department of the World Health Organization** recalled the WHO prequalification program, WHO Emergency Use Listing, WHO clinical guidelines and the reliance concept as mechanisms to expedite the regulatory processes for vaccines and diagnostics. The WHO undertook joint assessment and inspection work with EMA on COVID-19 vaccines, which ensured the effective use of time and resources. To support low and middle-income countries to efficiently authorize emergency use of vaccines, a special procedure was put in place to share regulatory dossiers under confidentiality agreements and to promote the use of reliance. These special arrangements and reliance allowed 101 countries to successfully authorize the AstraZeneca vaccine in record time (less than 15 days). In terms of

[1] International Coalition of Medicines Regulatory Authorities
[2] The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
[3] International Medical Device Regulators Forum

preparedness, developing international guidelines and reference standards are of critical importance, as are normative guidelines for technical assistance. Three WHO and ICMRA joint statements were highlighted: on enhancing regulatory alignment on COVID-19 medicines and vaccines[4]; on the need for the pharmaceutical industry to increase transparency and data integrity by providing wider access to clinical data for all new medicines and vaccines (including for the 50% of clinical trials that are unreported because of negative outcome)[5]; and informing healthcare professionals and the public that regulators have not cut the corner, but took robust a scientific approach to determine safety, efficacy and quality of COVID-19 vaccines and how safety is closely and continually monitored even after approval [6]. Key to overcome bottlenecks and other challenges is to continue working together, by coordinating and collaborating to speed up and facilitate global access to safe, effective and quality health products.

**Dr Yashiro Fujiwara, Chief Executive at the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan** highlighted the ICMRA response to the pandemic, including global collaboration to facilitate and expedite the development and evaluation of COVID-19 diagnostics, therapeutics and vaccines. ICMRA is holding frequent teleconferences and workshops to allow regulators to collaborate and share the most updated COVID-19 information. PMDA has developed principles to accelerate the evaluation of COVID-19 vaccines.[7] Transparency is a key instrument for efficient vaccines development. In that regard, he mentioned the availability of COVID-19 related information on the PMDA website, such as Chief Executive's Statements in English on COVID-19 related information. PMDA is helping enhance the capacity of other regulators to review products and implement post-market measures, through Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs. Regulatory convergence, collaboration and transparency are vital for addressing the COVID-19 pandemic. Information sharing and good communication will allow regulatory convergence.

**Mrs Delese Mimi Darko, Chief Executive Officer at Food and Drugs Authority (FDA) of Ghana** described the immediate actions taken by Ghana after the declaration of the pandemic. A Presidential COVID-19 Taskforce was established, and it activated an Emergency Use and Authorization (EUA) guideline, which was developed during the Ebola crisis. An internal system was set up for authorizing COVID-19 medical products, which allowed medical products and clinical trials to be evaluated on average in 15 days, and if the products or clinical trials had already been approved by stricter authorities, the timeline was cut to 10 days. The Presidential COVID-19 Taskforce coordinates the multi sectoral efforts at managing the pandemic. This included support to regulatory agency who worked with local industry to develop standards for PPE, face masks and hand sanitizers.

The FDA approved vaccines using both its EUA guideline (Covishield and Sputnik V), and reliance and WHO Emergency Use Listing (J&J; Pfizer and Moderna were soon to be approved). The FDA is responsible for inspecting consignments and formally releasing every batch of shipments received from COVAX. Transparency was essential to Ghana's rapid response. Information was disseminated online on guidelines and timelines, frequently asked questions on FDA processes, and a list of registered COVID-19 products (updated every 24 hours). A joint committee on safety was established to monitor adverse events, and Ghana joined the AU Nepad 3S Project which monitors safety and adverse events across four countries (Ghana, South Africa, Ethiopia and Nigeria).

**Mr Rajinder Kumar Suri, Chief Executive Officer at Developing Countries Vaccine Manufacturers' Network (DCVMN),** highlighted the work done by EMA to provide scientific advice to developers and manufactures to speed up development of COVID-19 vaccines, the fast-track authorization by the US FDA, as well as the important work of ICRMA and WHO. National regulatory authorities (NRAs) also took important steps, such the Indian NRA which allowed for restricted emergency use of foreign produced vaccines with emergency use authorization by US FDA, EMA, UK

[4] WHO-ICMRA joint statement on the need for improved global regulatory alignment on COVID-19 medicines and vaccines (November 2020)
[5] Transparency and data integrity International Coalition of Medicines Regulatory Authorities (ICMRA) and WHO (May 2021)
[6] Statement for Health care professionals: How COVID-19 vaccines are regulated for safety and effectiveness (June 2021)
[7] https://www.pmda.go.jp/files/000237021.pdf and https://www.pmda.go.jp/files/000240416.pdf

MHRA, PMDA Japan and/or EUL by WHO, under the condition of a post approval parallel bridging trial.

Considering the rapid development of COVID-19 vaccines, several regulatory challenges were identified. In the first instance, differences between countries in terms of regulatory frameworks, procedures and timelines adds complexity for manufacturers. The fast development of vaccines has led to additional challenges and burdens for manufacturers following the initial authorization, such as gathering data and optimizing processes, including in the management of COVID-19 variants. NRAs have not established accelerated pathways for post approval changes to Emergency Use Authorized vaccines, which could hinder availability due to delays in approval. Regulatory collaboration can lead to dependencies and delays, as the local NRA may require small bridging clinical trials to be approved by the reference NRA. There is uncertainty about regular registration of vaccines and variations once the Emergency Use Authorizations expire. Global regulatory collaboration, collaborative review and reliance practices should be adopted more broadly, as these practices have yielded positive results.

**Mr Alistair West, Coordinator for the African Union's Business Plan at UNIDO,** emphasized the importance of a strong regulatory environment for scaling up manufacturing of vaccines in the global south. Substantial investment was needed for new productive capacities and to upgrade existing facilities, as well as for building and retaining human capital. He highlighted the need for further harmonization of markets, which supports regulators and facilitates trade. This should be based on strong standards and conformity assessment procedures, that would enable different nations to engage in pharmaceutical value chains. New vaccine manufacturing facilities will need to be viable and based on market demand. The international community's experience in applying advance market commitments and other market shaping and risk production issues, could be applied with technical initiatives to help ramp up vaccines manufacturing capacity in the global south.

**Ms Raj Long, Independent Expert Advisor on Regulation and Access** said the pandemic has been both phenomenally disruptive and immensely opportunistic as an accelerator. The stronger collaboration between all regulators, on the national and international level, was a vital behaviour that we should learn from for future pandemics. Beyond collaboration, we need to build transparency by design, for all parties including regulators and manufacturers. Agile and informed regulatory decision making during the pandemic was made possible by transparency.

Scalable manufacturing is vital for overcoming vaccine nationalism and the access problems faced in this pandemic. The WTO has a key role to play in the whole ecosystem needed for scalable manufacturing, from the operation of supply chains, imports and exports, facilitating trade, and supporting local manufacturers through technology transfer. Inequity of vaccine supply needs to be tackled by looking at this whole ecosystem – to ensure that countries with less resources have a fair shot at equitable access – and be better prepared for the next pandemic.

In closing, **Aik Hoe Lim**, emphasized the synergy between trade facilitation and regulatory convergence, and the key role of transparency in both. Agile, expedited, and collaborative regulatory approaches rely on transparency by all parties. There are various existing cooperation arrangements (WHO mechanisms, ICRMA, ICH, IMDRF), so we don't need to reinvent the wheel, but rather use them better to accelerate convergence and improve preparedness. The regulatory dimension should be considered in the context of whole ecosystem needed for scaling up vaccine manufacturing. In this regard, strengthening regulatory frameworks goes hand in hand with ramping up vaccine manufacturing in developing countries.