

Taylor's University and USP's APEC-LSIF Centers of Excellence for Supply Chain Integrity Hosts Webinars and Training Session

December 2020-March 2021

Executive Summary

Beginning in December 2020, United States Pharmacopeia (USP) and Taylor's University Training Centers of Excellence (CoE) for Global Supply Chain Integrity in collaboration with the APEC Life Sciences Innovation Forum (LSIF) and Ministry of Health Malaysia, convened a series of webinars culminating in a two-day training session on global supply chain integrity. The onset of the COVID-19 pandemic and the impending arrival of COVID-19 vaccines highlight the importance of fortifying vulnerable medical supply chains with a proper understanding of Track & Trace and Storage & Transportation of medical products. In response to this need, USP and Taylor's University launched this training series to present and educate on best practices in establishing, expanding, and fortifying medical supply chains among industry professionals. During the series, a *Survey on the Preparedness and Extent of Implementation of Track and Trace of Pharmaceuticals* was disseminated to participants. A total of 191 respondents took part in the survey. They represented 14 of the 21 APEC economies and included 95 government officials, 22 local pharmaceutical manufacturers, 25 distributors of pharmaceuticals, and other key professionals working in the global pharmaceutical supply chain.

The issues examined during the series included the following:

1st Webinar: *Increasing Transparency: Global Data Standardization*

During the first webinar, experts discussed the importance of increasing transparency and raising quality standards in the medical supply chain, upstream and downstream, to ensure the quality and safety of medicines patients can trust. Anthony Tann of USP discussed the importance of standardizing data across supply chains, emphasizing that increasing supply chain transparency will only be meaningful if the data is standardized. Goh Chiang Fein of GS1 Malaysia Berhad provided an overview of the ways in which companies can leverage Track & Trace using global standards to properly identify both where products have been and where they are now. Such careful oversight and data sharing strengthen medical supply chains by increasing visibility and transparency and ultimately preventing breakdowns such as what was seen during the COVID-19 pandemic.

2nd Webinar: *Quality Management in Drug Storage and Transportation*

The second webinar offered a technical explanation of the recently updated [USP-NF Chapter 1079 on Good Storage and Distribution Practices for Drug Products](#). The discussion, led by technical experts from USP, FURP/UNIP, and Cardinal Health, explored the revised rationale for writing chapter 1079 with a focus on quality management and risk management to ensure drug

products are handled safely when moving from the supplier, through the supply chain, and to the patient. A strong quality management system manages product environment, risk, distribution, storage, and documentation to ensure that drug products progress through the supply chain safely.

3rd Webinar: *Track & Trace Technology: Serialization*

The third webinar presented a practical, detailed discussion of the technology available to Track & Trace medical products through the supply chain, including serialization and EZTracker. Volker Ditcher of WIPOTEC-OCS described how serialization protects products through the assignment of unique serial numbers that can be tracked as a product moves through the supply chain and later traced by the patient back to its origin. Serialization offers companies quick and organized access to product-related data to increase transparency and consumer safety. Daniel Laverick of Zuellig Pharma went further to detail how technology such as EZTracker can be leveraged to empower patients, increase patient trust in doctors, raise doctor credibility, and protect manufacturer brand integrity. Traceability is often hampered by problems in information exchange between parties. EZTracker offers a threefold solution through information sharing via blockchain technology, tagging products with an identifiable digital ID, and a mobile application which scans products to inform patients whether the product was imported by an authorized distributor.

Main event: *2-Day Training on Global Guidance on Supply Chains*

The 2-day event was launched by Datin Dr. Faridah Aryani binti Md. Yusof of the Ministry of Health Malaysia, with a keynote presentation by Anita Sands of WHO. The training sessions emphasized the importance of establishing strong and resilient patient-centric medical supply chains in compliance with new regulation put forth by US FDA and the Malaysian Ministry of Health to Track & Trace medical products through the supply chain. These regulations and standards provide patients with confidence that the medical products they consume are legitimate, safe, and trustworthy.

Guest speakers also discussed how digital advancement can eventually put digital information at the fingertips of patients, doctors, nurses, and other medical professionals to deliver the best possible treatment immediately. Three areas were identified to begin this digital transformation: 1) zero touch release and last mile traceability, to ensure product quality at unit-level tracking; 2) home delivery of medications to patients; and 3) electronic patients leaflets (i.e., e-labeling).

The training included a session on the [APEC Supply Chain Security Toolkit](#) along with WHO guidance on traceability of medical products. The Toolkit addresses the areas of vulnerability in the medical product supply chain and contains recommended best practices and tools to prevent and detect substandard and falsified medical products before they reach consumers. It also provides tools to respond to incidents involving substandard and falsified medical products.



Malaysia's plan to roll out Track & Trace was discussed together with other areas such as online purchase and the view of community pharmacists on Track & Trace. A complete view of the European Track & Trace system was presented along with results from a satisfaction and usage survey answered by 448 Spanish community pharmacists who have used the system for two years.

Additional Background & Resources

Webinars

- [9 December 2020 – Increasing Transparency in the Medicines Supply Chain and Overview of Track & Trace using the Global Standard](#)
 - Anthony Tann, General Manager and Senior Director of APAC USP
 - Goh Chiang Fein, CEO of GS1 Malaysia Berhad
- [27 January 2021 – Overview and Trends on Storage and Transportation of Drug Products](#)
 - Desmond Hunt, PhD, Principal Scientist at U.S. Pharmacopeia
 - Glauca Karime Braga, PhD, Quality Auditor at FURP and Professor at UNIP
 - Chris Anderson, Quality Director at Cardinal Health
- [24 February 24 2021 – The Technology for Implementation of Track and Trace](#)
 - Volker Ditcher, Director of Global Sales Track & Trace of WIPOTEC-OCS
 - Daniel Laverick, Head of SAP & IT Solutions at Zuellig Pharma

APEC-LSIF COE 2021 2-Day Training

- [March 11 – The Supply Chain Security Roadmap and Toolkit, WHO guidance, Traceability of Medical Products, and a Deep Dive in GDP](#)
 - Datin Dr. Faridah Aryani binti Md. Yusof, Ministry of Health Malaysia
 - Eunah Kostal, U.S. Food & Drug Administration
 - Anita Sands, World Health Organization
 - Desmond Hunt, PhD, U.S. Pharmacopeia
 - Chris Anderson, Cardinal Health
 - Robert Seevers, Pearl Pathways
- [March 12 – Track & Trace: Pharmaceuticals, Malaysia's Roll Out Plan, and What It Means for the Community Pharmacist](#)
 - Abha Kundi, US FDA
 - Mohd Azuwan bin Mohd Zubir, Ministry of Health Malaysia
 - Ramesh Raj, Pharmaceutical Security Institute
 - Jaime Acosta-Gómez, Community Pharmacist
 - Dr. Sannie Chong, Roche

Further Reading:

- [USP-NF Chapter 1079 on Good Storage and Distribution Practices for Drug Products](#)
- [APEC Supply Chain Security Toolkit for Medical Products](#)
- [World Health Organization Policy Paper on Traceability of Medical Products](#)
- [APEC LSIF Regulatory Harmonization Steering Committee Website](#)
- [Taylor's University APEC-LSIF Centre of Excellence Website](#)