Taylor's University and USP's APEC-LSIF Centers of Excellence (CoE) for Supply Chain Integrity:

Survey of CoE Trainees on Health Stakeholder Preparedness and Implementation of Track & Trace of Pharmaceuticals in the APEC Region

The onset of the COVID-19 pandemic and the impending arrival of COVID-19 vaccines have highlighted 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 in collaboration with Taylor's University launched a series of virtual training events between December 2020 and March 2021. Best practices were presented in establishing, expanding, and fortifying medical supply chains among industry professionals. To accompany the training, a Survey on the Preparedness and Extent of Implementation of Track & Trace of Pharmaceuticals was disseminated to participants, with the objective of gaining insights into the knowledge and perspectives of participants regarding supply chain issues.

Demographic Information of Survey Submitters

Out of the 400+ registrants to the series of webinars and trainings, nearly one half (191) submitted responses to the survey and the vast majority of the submitters were from APEC economies. Respondents were well balanced across the public sector (regulatory agencies were notably represented) and the private sector (multinationals, local manufacturers, and pharmaceutical distributors were all well-represented), as well as across age groups, with the largest group falling within the 30-50-year-old range. Most respondents were experienced in their fields, with over 40% of participants having at least a decade of experience, and over 60% holding at least 5 years of experience in their current sector of work.

# Respondents	Respondent Types[1]	Top Participating Economies
Total: 191 APEC: 168 Non-APEC: 23	**Public Sector** • Regulatory agency: 72 (37.7%) • Enforcement agency: 15 (7.9%) • Hospital: 2 (1%) • Procurement: 2 (1%) • Logistics: 15 (7.9%) **Private Sector** • Local pharmaceutical manufacturer: 22 (11.5%) • Multi-National Company: 29 (15.2%) • Importer of Generic medicines: 15 (7.9%) • Distributor of pharmaceuticals: 32 (16.8%) • Community pharmacy: 3 (1.6%) **Others**: 17 (8.5%)	**Malaysia:** 94 (49.2%) **Philippines:** 58 (30.4%) **Indonesia:** 9 (4.7%) **Singapore:** 9 (4.7%) **Chile:** 4 (2.1%) **Myanmar:** 4 (2.1%) **Papua New Guinea:** 3 (1.6%) **Thailand:** 5 (2.6%)

Participant Age	Number of Years in Current Sector of Work
20 – 30 years old: 37 (19.4%)	**<1 year**: 11 (5.8%)
31 – 40 years old: 56 (29.3%)	**1 – 5 years**: 58 (30.4%)
41 – 50 years old: 54 (28.3%)	**6 – 10 years**: 45 (23.6%)
51 – 60 years old: 36 (18.8%)	**11 – 15 years**: 23 (12%)
> 60 years old: 8 (4.2%)	**> 15 years**: 54 (28.3%)

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[1] Categories are not mutually exclusive; participants were allowed to choose more than one option.

Perspectives on the Implementation of Track & Trace

What modalities of T&T have been implemented in your economy?

Respondents indicated that the most widely implemented modalities of Track & Trace in their economies were 2D barcoding and QR codes, each of which was identified by over a third of the respondents as having been implemented in their respective economies. Other prominent modalities include radio frequency identification (RFID) and e-labelling. However, about a third of the respondents were unable to answer the question, indicating a significant lack of knowledge among participants regarding Track & Trace.

Modality	N (%)
2D barcode	78 (40.8%)
QR code	71 (37.2%)
Don't know/Not sure	64 (33.5%)
RFID	39 (20.4%)
e-labelling	23 (12%)
Others – Hologram	14 (7.3%)
Others – 1D barcode	2 (1%)

Implementation priorities for T&T of pharmaceuticals:

Respondents were asked to indicate their agreement or disagreement to a series of statements related to priorities for implementation of Track & Trace. In addition to sharing their views regarding specific process considerations (e.g., unit versus batch-level tracing, coverage of prescription versus all medicines), a majority of respondents (nearly 60%) shared the opinion that current Track & Trace measures implemented in their economies were insufficient.

Statement	Agree (N (%))	Disagree (N (%))	Don't know/ Not sure (N (%))
Individual unit tracing is not necessary and tracking at the batch level is sufficient.	61 (31.9%)	115 (60.2%)	15 (7.9%)
T&T should cover repacked medicines as well.	172 (90%)	9 (4.7%)	10 (5.2%)
T&T should be made mandatory only for prescription medicines.	56 (29.3%)	118 (61.8%)	17 (8.9%)
T&T should cover all medicines, including traditional medicines and health supplements.	151 (79.1%)	24 (12.6%)	16 (8.4%)
Current T&T measures implemented in your economy are sufficient.	28 (14.7%)	111 (58.1%)	52 (27.2%)

What are the hurdles for implementing T&T in your economy?

Given the concern about insufficient implementation, indicated above, it is evident that various implementation hurdles exist which pose substantial difficulty. The top hurdles identified by respondents were (1) financial obstacles, (2) lack of sufficient legislation, (3) concerns about confidentiality and data protection, and (4) lack of relevant expertise within regulatory agencies. This finding is telling because, although only 23.6% of respondents explicitly identified a lack of government

prioritization as a hurdle, the aforementioned issues all implicitly point towards the need for greater support from policymakers and regulatory leaders to implement Track & Trace. A substantial number of respondents were unable to answer this question, a finding consistent with the previously mentioned gap in knowledge on T&T matters.

Implementation Hurdles	N (%)
Financial	85 (44.5%)
Lack of sufficient legislation	65 (34%)
Concerns about confidentiality/information leakage of company data	53 (27.7%)
Lack of relevant expertise in the regulatory agency	53 (27.7%)
Lack of relevant expertise in industry	50 (26.2%)
Technology is not available	49 (25.7%)
Not a priority for the government/regulators	45 (23.6%)
Don't know/Not sure	41 (21.5%)
Resistance from the pharmaceutical industry	33 (17.3%)

In your opinion, implementation of T&T should include which of the following levels/points?

The manufacturer level and the distributor level were identified by the largest numbers of respondents as the stages within the supply chain where Track & Trace should be implemented.

Levels of Implementation	N (%)
Manufacturer	171 (89.5%)
Distributer	164 (85.9%)
Point of sale/supply (community pharmacy)	139 (72.8%)
Point of sale/supply (hospital)	136 (71.2%)
Point of sale/supply (general practitioner's clinic)	124 (64.9%)
Don't know/Not sure	6 (3.1%)

In your economy, who is (or likely to be) the prime mover for the implementation of T&T?

The vast majority of respondents indicated that regulatory agencies should be the main drivers to push Track & Trace initiatives. This response is well-aligned with the insight from previous questions that respondents believe that a lack of adequate legislation, lack of regulatory agency expertise, and limited data protection are important hurdles to implementation of Track & Trace.

Stakeholders	N (%)
Regulatory agency	138 (72.3%)
Enforcement agency (e.g., police, customs etc.)	20 (10.5%)
Don't know/Not sure	16 (8.4)
Private sector	13 (6.8%)
Others – Government, hospitals, quality assurance)	4 (2%)

In your opinion, should countries adopt the use of: (a) Global identification and serialization standards (adopted in a number of countries - e.g., GS1 standards and e-labelling); and (b) Local identification and serialization standards (developed and adopted in that economy only)?

Global identification and serialisation were identified by the vast majority of respondents as important measures to adopt, with local identification and serialization standards identified by a relatively small minority. It is worth noting that despite the clearly widespread support for such measures, implementation remains limited in practice. This is evident from the replies to the previous questions, in which only a minority of respondents stated that their economies had implemented measures such as QR codes. The discrepancy between respondents' expressed priorities and the measures that are actually in place further underscores the need for greater awareness on the issue and increased commitment from policymakers.

Measure to Adopt	N (%)
Global identification and serialization standards (adopted in a number of countries - e.g., GS1 standards and e-labelling)	149 (78%)
Local identification and serialization standards (developed and adopted in that economy only)	25 (13.1%)
Don't know/Not sure	17 (8.9%)

In your opinion, how long will it take for the industry in your economy to integrate a T&T system proposed by regulators?
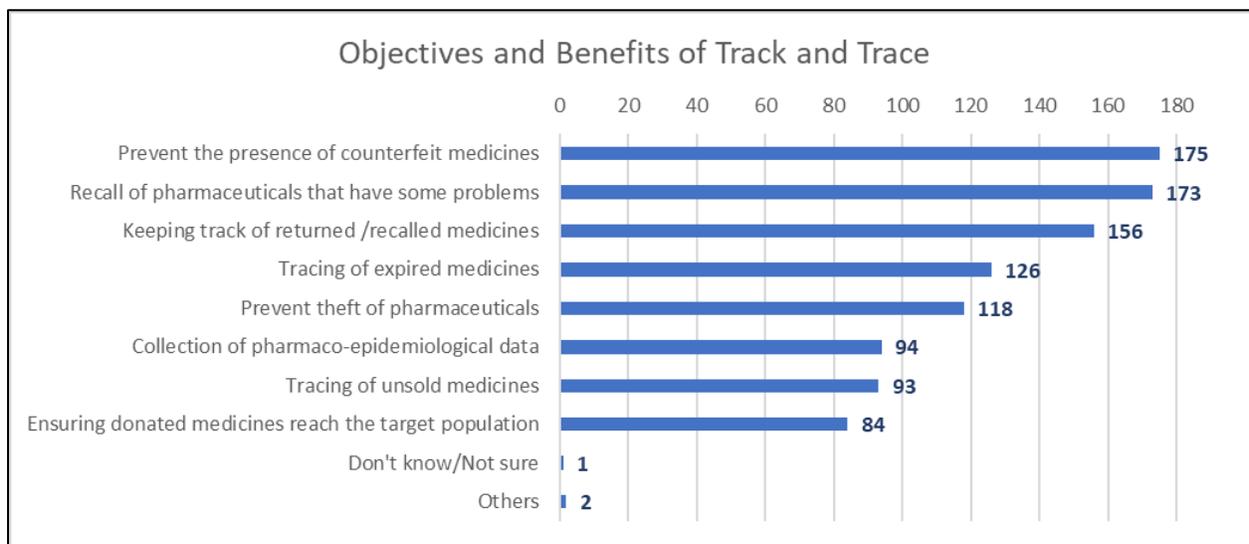
Nearly two thirds of respondents expect that integration of Track & Trace systems will take three years or more. This is to be expected, given responses to previous questions that indicate that there are currently limited implementation of Track & Trace modalities in many economies, as well as limited regulatory expertise and legislative frameworks.

Time Frame	N (%)
1 year	9 (4.7%)
2 years	34 (17.8%)
3 years	44 (23%)
More than 3 years	69 (36.1%)
Don't know/Not sure	35 (18.3%)

Perspectives on Stakeholders' Understanding of Track & Trace

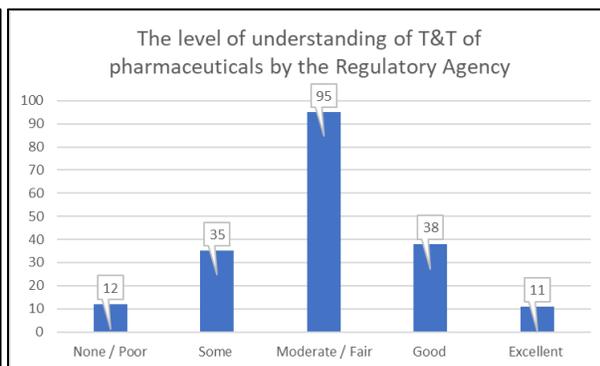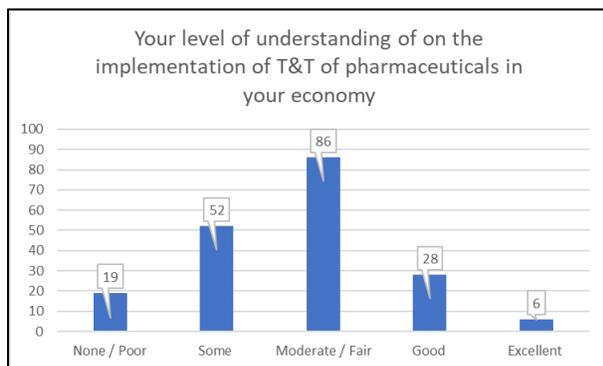**What are the objectives/benefits of Track & Trace?**

The vast majority of respondents saw the prevention of counterfeit medicines[2] as the principal objective of track and trace. Recalling medicines and keeping track of recalled medicines were also objectives that over 80% of respondents saw as important.
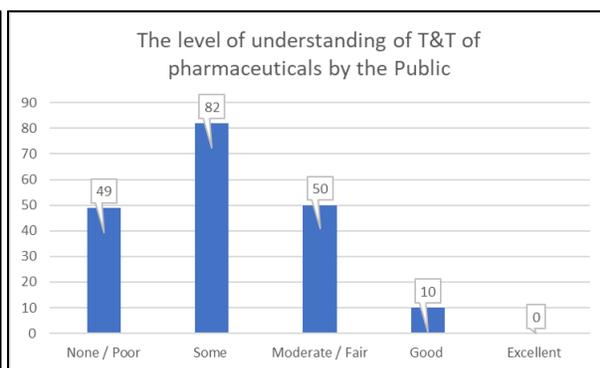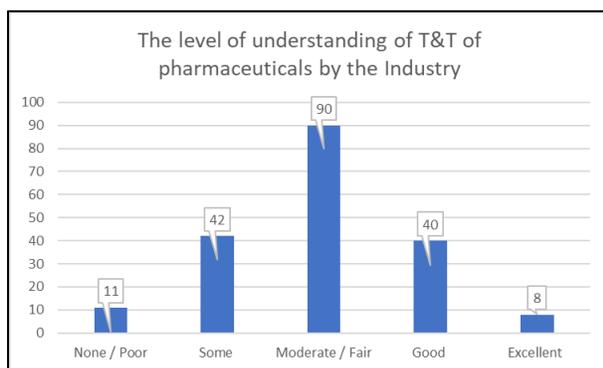

Objectives and Benefits of Track and Trace

Objective	Value
Prevent the presence of counterfeit medicines	175
Recall of pharmaceuticals that have some problems	173
Keeping track of returned /recalled medicines	156
Tracing of expired medicines	126
Prevent theft of pharmaceuticals	118
Collection of pharmaco-epidemiological data	94
Tracing of unsold medicines	93
Ensuring donated medicines reach the target population	84
Don't know/Not sure	1
Others	2

Understanding of the implementation of track and trace of pharmaceuticals:

Respondents were asked to evaluate their personal knowledge of the implementation of Track & trace of pharmaceuticals in their economy, as well as the knowledge levels of different stakeholders (regulatory agencies, industry, and the public) on the matter. Responses confirm the earlier findings that substantial knowledge gaps exist among respondents, and that there is room for improvement in the knowledge base of regulatory agencies, who will ultimately be charged with steering Track & Trace work.

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[2] "Counterfeit" in this context was intended to apply to *unregistered/unlicensed* and *falsified* medical products as well as to those falling under the category of *counterfeits*, as detailed in Appendix 3 of Document A70/23 from WHO's 70th World Health Assembly: https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1. Additionally, *diverted* genuine licensed products would also be included.

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Your level of understanding of on the implementation of T&T of pharmaceuticals in your economy

None / Poor: 19
Some: 52
Moderate / Fair: 86
Good: 28
Excellent: 6

The level of understanding of T&T of pharmaceuticals by the Regulatory Agency

None / Poor: 12
Some: 35
Moderate / Fair: 95
Good: 38
Excellent: 11

As shown above, less than one fifth of respondents claimed good or excellent levels of understanding, and little more than a quarter of respondents felt that regulatory agencies in their economies had good or excellent levels of understanding.

The level of understanding of T&T of pharmaceuticals by the Industry

None / Poor: 11
Some: 42
Moderate / Fair: 90
Good: 40
Excellent: 8

The level of understanding of T&T of pharmaceuticals by the Public

None / Poor: 49
Some: 82
Moderate / Fair: 50
Good: 10
Excellent: 0

The pharmaceutical industry is regarded somewhat more favorably in respondents' evaluations, with approximately one quarter of respondents evaluating their understanding of rTack & Trace as being good or excellent. Among the public, however, the evaluation unsurprisingly suggests that there is substantial room for improvement.

III. Key Conclusions

Given that a majority of respondents to the survey (60%) felt that current Track & Trace measures implemented in their economies were insufficient, there is certainly further work to be done by Taylor's University and USP's APEC-LSIF Centers of Excellence for Supply Chain Integrity, as well as other health and regulatory stakeholders in the APEC region.

An important starting point is to continue building awareness and understanding of Track & Trace implementation issues. The survey revealed a sizable knowledge gap, with approximately one third of respondents unable to answer questions on the implementation of modalities of Track & Trace in their respective economies. When asked to self-evaluate, less than one fifth of respondents claimed to have good or excellent levels of understanding of the implementation of Track & Trace, and about one fifth were unable to identify the hurdles to implementation that exist within their economies. These gaps represent a clear opportunity for increasing awareness among relevant stakeholders through follow-up

activities such as additional training, particularly training targeting and engaging regulators, who in the view of most respondents should hold the primary responsibility for advancing track and trace in the future.