Submission of comments on 'ICMRA Recommendations on Common Technical Denominators for Track and Trace (T&T) Systems to Allow for Interoperability'.

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Comments received from:

Name of organisation or individual
1. Brian Rezach (bdr@omedia.com) on behalf of the Association for Accessible Medicines (AAM)
2. Angelique Berg (angelique@capdm.ca) on behalf of the Canadian Association for Pharmacy Distribution Management (CAPDM)
3. John Willenbrock (jwillenbrock@cganet.com) on behalf of the Compressed Gas Association's (CGA)
4. Nasir Hussain (nasir.hussain2@gilead.com) on behalf of Gilead Sciences Ireland UC (Gilead)
5. Sérgio Cavalheiro Filho (s.cavalheiro_filho@ifpma.org) on behalf of International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
6. Suzette Kox (Skox@igbamedicines.org) on behalf of International Generic and Biosimilar Medicines Association (IGBA)
7. Lama Abi Khaled (labikhaled@imc-mnc.ca) on behalf of Innovative Medicines Canada (IMC)
8. George Craigie (George.Craigie@McKesson.ca) on behalf of McKesson Canada
9. Alissa McCaffrey (alissa.mccaffrey@leavittpartners.com) on behalf of The Alliance For Global Pharmaceutical Serialization (RxGPS)
10. Saja M. Alhabardi on behalf of Saudi Food & Drug Authority (SFDA)

Conventions

Comments were grouped into one of categories as outlined below:

Category	Description
Accepted	The comment has been incorporated as proposed into the current version of the T&T recommendation.
Under Review	The intent is to address the comment in the current version of the T&T recommendation, however the WG may determine that the comment should be deferred.
Deferred	This could be included in future versions of the T&T recommendation if the scope of the project is expanded.
Denied	It was determined that the comment was either not applicable or not Accepted.
Noted	It was determined that the comment will not be addressed directly in the T&T recommendation. Examples include jurisdictional implementation aspects where they align with the ICMRS T&T recommendations or jurisdictional considerations that have no impact on other jurisdictions or on the implementation of the ICMRA T&T recommendation.
Covered	It was determined that the comment is already covered in the current T&T recommendation.
Removed	This section or topic was removed from the T&T recommendations.

1. General comments

ID	Stakeholder name	General comments	Outcome
1.	Angelique Berg	Distinct callout for general comments: A distinctive callout is that the ICMRA Recommendations do not include the Global Location Number (GLN), a critical component to traceability capabilities (what went where). The GLN must be considered in future efforts of the ICMRA.	**Deferred** The GLN aspect may be included in future versions of the T&T recommendations.

ID	Stakeholder name	General comments	Outcome
2.	John Willenbrock	**Medical gases are local, not global.** We applaud ICMRA and the participating regulating agencies for addressing the concerns for traditional pharmaceuticals manufactured, distributed, and used worldwide; however, medical gases are not manufactured and distributed globally, but locally. Medical gases are originally manufactured in bulk form and either distributed directly for use in hospitals or distributed to secondary manufacturers who fill those gases into dispensing containers which are then distributed and used locally. Medical gases are generally distributed no more than a few hundred kilometres from their original point of manufacture through a managed distribution system due to the physical properties of medical gases and their supply chain. For example, bulk oxygen is produced by taking atmospheric air and, through an air liquefaction and distillation process, separating it into its component parts. Because of the very cold nature of this process, oxygen stored at -183 degrees C, these components will vaporize completely over time and therefore can only be distributed a limited distance. Product is placed into customer's storage tanks and the new cryogenic product from the transport is commingled with the product in the customer's storage tank that also vents. The medical gas container filling operations are also limited in their distribution sphere due to the weight of the medical gas high pressure and liquid containers. These containers, generally owned by the filling company, are distributed locally to various customers, including hospitals, physicians, and home care firms, and tightly controlled. The containers, once empty, are returned to the filling company for refill. Medical gas containers are unlike any other in the pharmaceutical industry and are already uniquely controlled.	**Covered** While it is correct that an objective of T&T is to enable global information exchange there are other objectives these include the ability to have supply chain visibility and reporting at a global, domestic, and regional level. Therefore, we feel that while this comment is accurate it does not change the objectives or scope of the recommendations as this version of T&T recommendation excludes Medical Gases.

3.	John Willenbrock	**Medical gas production and distribution model does not fit the ICMRA T&T proposal** Again, using bulk oxygen as an example, the cryogenically distilled oxygen is continually produced into large bulk storage where it is commingled with previously cryogenically distilled oxygen. Although this production is assigned batch numbers for documentation purposes, the continuous process does not permit discreet sub-batches of the product to be segregated or identified. Portions of the commingled product is then withdrawn from the storage tanks and placed into cryogenic transports where it is again commingled with the residual product in the transport and assigned a lot for documentation and traceability purposes. The bulk product in the transport is then delivered and placed into customer's storage tanks where the comingled cryogenic product from the transport is commingled with the product in the customer's storage tank. Information as to the lot placed into the customer's storage tank is communicated to the customer but the "lot" is dependent on the percentage of residual product in the storage container and the percentage of "new" product added. Multiple customers are normally served from one transport, including industrial customers, medical customers, or cylinder filling operations that in turn fill both industrial and medical high pressure and liquid refillable containers. Although lot identification is provided for traceability throughout the bulk manufacturing, distribution, and storage tank filling process, the ICMRA model for a T&T system that could be communicated in the manner proposed is not workable because of the constant commingling that occurs. Reusable medical high pressure and liquid gas containers are lot numbered at each fill and strictly controlled through the managed local distribution chain as discussed above. The lot size for high pressure medical gases is very limited, generally less than one hundred that are filled at one time, therefore lot size compared to other pharmaceuticals is minuscule. Unless filled at the ultimate consumer, each liquid container filled is designated its own lot number, and even for filling at the customer site there is traceability to the product being used for filling traceable to the individual patient for who it is filled. To assign a unique barcode or product identifier that would allow for interoperability as described by the ICMRA T&T system would not be cost effective and would provide no additional traceability above what the industry currently uses for controlling distribution.	**Deferred** This comment raises several valid concerns and does merit a review on how to address all use cases where the "product" production and filling process is additive rather than starting from a clean slate. This issue may be addressed in future versions of the T&T recommendation, as the current version does not address the scenario detailed in the comment nor other cases of similar nature.

ID	Stakeholder name	General comments	Outcome
4.	John Willenbrock	**Medical gases already meet the benefit goals identified by ICMRA as part of the T&T system** In its recommendations, ICMRA indicated that their proposals emphasized that interoperability of T&T systems would help to protect public health by improving information sharing in case of quality defects, reducing shortages, contributing to the fight against falsified medicines and supporting pharmacovigilance activities. Our comments address why a T&T system will not assist in the "information sharing" areas cited above. • Quality – In North America, both Health Canada and the U.S. Food and Drug Administration (FDA) recognize that medical gas manufacturing and distribution is low risk. Due to their local nature, medical gases are not the subject of global recalls. The current traceability systems have proven sufficient for the rarely occurring local recalls. • Shortages – We have worked with Health Canada and FDA during the COVID-19 pandemic and have successfully mitigated medical gas shortages where they were initially identified as potential stress points and we do not believe a T&T system recommended by the ICRMA would provide any improved mitigation measures. Due to their properties, method of manufacture, and distribution model, there is very limited ability to move medical gases from areas with surplus to areas of higher demand. • Falsification – Medical gases, based on their properties, method of manufacture, and distribution model, are not subject to diversion or intentional adulteration for fraud or other nefarious purposes. Medical gases that are provided in reusable containers, typically owned and distributed by the company filling them, are not subject to potential diversion. • Pharmacovigilance – Medical gases have been safely used by the medical community for well over a century, and their efficacy is not questioned. CGA has communicated the need to modify pharmacovigilance reporting requirements both in Canada and the US and would recommend they be reconsidered worldwide as well.	**Deferred** It is recommended to establish a dialog with CGA to determine how to incorporate the aspects to the additive manufacturing processes into the T&T recommendations, potentially as an Annex that delineates the general aspects Covered in the main document and the restrictions/deviations applicable to additive processes in the Annex. The comment needs to be addressed as there are differences between additive and clean slate manufacturing processes.

ID	Stakeholder name	General comments	Outcome
5.	Sérgio Cavalheiro Filho	IFPMA welcomes the guidance provided by ICMRA in this document. Overall, the document is very well drafted and in line with majority of the regulations, consolidating the most robust features of each regulation. Below we make a few considerations that may be useful to keep in mind when drafting the further iterations of this document: 1. Potential disruptions in the supply chain following "system blockages/alerts" linked with wrong status of items before executing a transaction are not addressed in this guidance. These interruptions can have huge and costly effects for patients and for regulators and industry to handle these exceptions. 2. The "use cases" presented constructed and presented in a useful format. However, in many ways, some of these case studies could be constructed in a way closer to real-life examples. Detailed suggestions can be found in our specific comments. 3. Tracing products outside of national jurisdictions opens significant privacy and legal concerns. Increasing access to traceability data also adds additional risks/opportunities for bad actors to infiltrate systems with potential exponentially larger impact, so any proposed system would need robust privacy, security and access measures included. 4. The guidance does not address a possible opening of the data to the end user (patient or doctor) via an open App. Further considerations about this are mentioned in our specific comments. **5.** Chapter 6 on "Considerations on possible system architectures" contains no recommendations but considerations, which does not seem not aligned with the title of the document "recommendations on …".	**Deferred** 1. The use cases where not meant to be exhaustive rather they were intended to be illustrative, however based on the feedback received it is possible that future versions of the T&T recommendation expand on the use case set and include the example identified in the comment. **Deferred** 2. As per above the use cases were intended to be illustrative, however a future version of the T&T recommendation may include both illustrative and real-life examples. **Deferred** 3. This is a valid concern and an area that may be strengthened in a future version of the T&T recommendations. **Deferred** 4. This was considered and deemed out of scope, it may be revisited in the future. **Deferred** 5. The observation is correct, this may be addressed in a future version of the T&T recommendation.

ID	Stakeholder name	General comments	Outcome
6.	Suzette Kox	IGBA acknowledges the ICMRA draft recommendations on common technical denominators for track and trace systems to allow for interoperability and thanks for the opportunity to share our thoughts on these recommendations. We fully support the implementation of interoperable systems for medicines around the world which will contribute protecting public health by improving information sharing in case of quality defects, reducing shortages, helping to fight falsified medicines and supporting pharmacovigilance activities. However, we would like to stress that stakeholders (regulators, authorities) should not invent new standards and use and implement directly what is already up and running in regulated countries. This standardization will be by far the best starting point for the future interoperability.	**Noted** The intent is to ensure we fully leverage existing standards and approaches where they meet the objectives, if there is a gap the intent is to work with the standards body to address the gap and only if that approach fails would a new standard be considered.
7.	Lama Abi Khaled	That said, health agencies need to consider the issue that needs to be addressed by the proposed implementation of a T&T system. Consideration of the costs, not only for the industry but also for the health agency, to achieve the implementation of any T&T system must need to be factored into the decision as well.	**Noted** Agreed cost in the context of T&T is the Total Cost of Ownership (TCO) this includes all parties including the Health Agency, Point of Dispensing, etc.

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8.	Lama Abi Khaled	Existing or simpler solutions should first be considered before implementing any T&T system. The intended purpose of serialization is to address the issue of falsified medicines in some countries. This serious concern may not be prevalent in a jurisdiction like Canada to warrant implementation of a T&T system that extends beyond the existing tracking solutions and this should be considered in the final recommendation of a common technical denominator for an interoperable T&T system.	**Noted** While alternatives should be considered an analysis of these is required to ensure the objectives of the T&T recommendations are met. It is up to each jurisdiction to ensure the solution they implement meets their local as well the broader requirements in an effective and efficient manner. However, the comment is accurate, the reason for T&T differs amongst the jurisdictions and therefore so does the implementation focus.
9.	George Craigie	One element that is key to implementation of Track and Trace systems and recommended by the GS1 Canada Pharmaceutical Traceability Expert Group is the use of the Global Location Number (GLN). This does not seem to be included in the ICMRA recommendations. The GLN should be considered in future efforts of the ICMRA.	**Deferred** This might be addressed in a future version of the T&T recommendation.
10.	George Craigie	The Canadian Pharmaceutical Traceability Infrastructure roadmap supports the ICMRA recommendations on the common technical denominators for track and trace systems to allow for interoperability. The Canadian roadmap has additional recommendations on entity and location identification using GLN, the use of a national registry (ECCnet Registry) to support product hierarchy and using specific standards such as GTIN and GS1 Data Matrix.	**Deferred** This might be addressed in a future version of the T&T recommendation.
11.	George Craigie	We encourage Health Canada to engage the community via the GS1 Canada Pharmaceutical Traceability Expert Group on the best approach for a national deployment of the traceability infrastructure.	**Noted** Health Canada is a ICMRA member.

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12.	Alissa McCaffrey	**Recommendations for Implementation** **1. Adoption and implementation of any traceability or track and trace system should be phased in over time, starting simple and achieving benefits before considering additional functionalities**. While RxGPS agrees that there are many potential benefits of interoperability as highlighted by the draft paper, we believe it is up to each individual market to determine the goals of a system for serialization and whether traceability is the right approach for their market. As stated in the first RxGPS principle for serialization, "Any country mandating serialization or traceability should clearly identify the goals and purposes of the mandate." Once the goals have been identified, RxGPS supports a stepwise approach to implementing serialization, verification, and/or traceability, that evaluates the costs and benefits of each successive phase of implementation. Global regulators seeking additional guidance on the core components of a serialization model may refer to the RxGPS "Model Regulation."	**Deferred** The recommendation is to use a phased and incremental approach to the T&T capabilities. This might be addressed in a future version of the T&T recommendation.
13.	Alissa McCaffrey	**Recommendations for Implementation** **2. Global markets should adhere to clear and consistent packaging level terminology.** Figure 14 in the draft paper utilizes packaging level terminology that is not aligned with the standard units of trade across the pharmaceutical industry. A lack of consistent terminology within and across markets has led to significant confusion and has resulted in situations where product barcodes are misplaced, repetitive, etc. For example, global manufacturers serialize at the level of the saleable unit (*i.e.*, the smallest unit of a finished product intended by the manufacturer for sale to the dispenser). Given that the definition of the saleable unit is at the discretion of the manufacturer, the saleable unit is not always a "secondary package" or a "primary package." Therefore, we believe that a component of global interoperability should be alignment around utilizing trade terminology to better align regulatory language with pharmaceutical practices and provide additional clarity and consistency for trading partner, especially those who buy and sell product in multiple markets. RxGPS has outlined a proposal for such a construct in our "Packaging Levels Position Statement."	**Deferred** This aspect will need to be addressed, this includes both clarification and standardization. However, it is important to note that due to jurisdictional differences there are limits on the degree of harmonization and some degree of mapping and inconsistencies will likely remain, the intent is to minimize these.

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14.	Alissa McCaffrey	**Recommendations for Implementation** **3. Global markets should leverage a globally standard unit identifier.** RxGPS supports the ICMRA recommendations in the draft paper around use of the ISO/IEC data matrix and the standard four data elements and believes that consistency in the unit identifier is critical to both harmonization of global requirements and future interoperability. Our position is further described in the RxGPS "Position Statement on Unit Identifier." Please note that critical to the RxGPS position is the serialization of the smallest unit of product intended to be sold to a dispenser (*i.e.*, the saleable unit), as noted above.	**Deferred** Clarifications on how to apply the serialization might be addressed in a future version of the T&T recommendation.
15.	Alissa McCaffrey	**Interoperability Challenges for Continued Exploration** **1. The ICMRA paper should note data sharing and reporting considerations for various models.** The success of a product tracing system for pharmaceutical supply chain security hinges on secure and interoperable data sharing and data reporting across the entire pharmaceutical supply chain. However, there is no single or uniform solution that will work across all systems and between markets. The foundational decisions made by regulators and industry around how to construct a system for using serialization have important implications for how serialized data are shared and communicated. For example, markets pursuing a traceability or track and trace system will experience a drastic increase in data capture obligations, data volumes, and the complexity of data connections needed when compared to a point-of-dispense verification model. Additionally, data sharing and reporting considerations will vary depending on the chosen data architecture (*i.e.*, centralized database/repository or distributed, company-owned databases). We believe that a discussion of data sharing and reporting is missing from the ICMRA paper. For additional insight on data sharing and reporting considerations, please see the RxGPS "Primer on Data Sharing and Reporting."	**Deferred** The topics of integration, data exchange, data sharing and reporting might be expanded upon in a future version of the T&T recommendation.

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16.	Alissa McCaffrey	**Interoperability Challenges for Continued Exploration** **2. The ICMRA paper should explore and discuss the challenge of balancing global interoperability and data integrity.** Preservation of the integrity of serialized data is essential to the functioning of any system for serialization, verification, or traceability. Any time the commissioned data are transmitted to another database, or when serialization data are derived from another source such as scanning of packages, there are risks for data errors. Data errors, data mismatches, or missing data can lead to false product alerts for legitimate product and potentially result in delays for patient access or destruction of legitimate product. As such, data integrity is a challenge even within individual markets. Any systems for global interoperability involving multiple markets would thereby increase the complexities of data sharing and reporting and increase the challenge of maintaining data integrity. We believe that a discussion of the data integrity implications of the various models discussed is the draft paper is critical to include in the ICMRA paper.	**Deferred** This topic might be addressed in a future version of the T&T recommendation.
17.	Alissa McCaffrey	**Interoperability Challenges for Continued Exploration** **3. The ICMRA paper should explore and discuss alerts and the handling of data errors.** As noted above, data errors can lead to false product alerts for legitimate product. One key challenge for any system for utilizing serialization is the implementation of systems and processes for identifying, understanding, and resolving data errors to prevent good, valid product from being unnecessarily held in the supply chain, unable to reach patients. We suggest that ICMRA identify data errors as a potential challenge of systems and processes for interoperability and work to incorporate any common solutions and best practices into future recommendations. Further, as previously highlighted, the challenge of resolving data errors increases in complexity when multiple markets are involved. In addition to single market challenges, resolving errors across markets could introduce concerns around a single point of failure for multiple markets, prioritization of the process for resolving errors, etc.	**Deferred** This topic might be addressed in a future version of the T&T recommendation.

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18.	Alissa McCaffrey	**Interoperability Challenges for Continued Exploration** **4. The ICMRA paper should acknowledge the risks associated with "mobile verification" and patient level verification.** Lines 682-706 of the draft paper discuss the potential for use of mobile phones as code verification scanners. We do not believe this section adequately addresses the risks associated with mobile verification, patient level verification (a common use case for mobile verification), or primary package serialization (a required pre-condition of patient level verification). Patient level verification can create significant security concerns, and the process of serializing primary packaging is extremely complex and costly. Additionally, patient-level verification can create significant security concerns because authentication by patients would necessitate a database that is accessible by any person in a country. Patient level verification would also require serialization or additional labelling at the primary package level. There are many different configurations for primary packaging, and the operational impact of encoding many of those configurations would be significant. Further information on the challenges of patient level verification is available in the RxGPS "Patient Level Verification Position Statement."	**Removed** This section was removed from the T&T recommendations.
19.	Alissa McCaffrey	RxGPS suggests use of the term "suspicious" or "suspect" product rather than "falsified product." The systems discussed will more accurately identify product that is suspicious or at risk of being determined to be falsified, but absent further investigation, a system for verification, for example, would not be able to be relied upon to identify falsified product.	**Deferred** During the drafting of the current version this aspect was debated, and the current definition agreed upon. This might be addressed in a future version of the T&T recommendation.

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20.	Saja M. Alhabardi	It should be clearly stated that the serial number (SN) must be randomized and never to be used again. Some stakeholders will take the literal meaning of SN "serial number". Serializing their product like (001,002,003) which defeat the purpose of tracking making it much easier for counterfeiter to guess these numbers. Others might reuse the same SN for the same GTIN rendering the detection of falsified product difficult.	**Covered** The requirement is that the composite ID is globally unique.
21.	Saja M. Alhabardi	The regulatory body in a country's that is going to implement full T&T system that track each single box of drug should mandate aggregation. It would be virtually impossible to fully track the drug unite along the supply chain without aggregation. Moreover, it will cause a delay in the project if it has not been mandated at the beginning.	**Deferred** This aspect might be addressed in a future version of the T&T recommendation.
22.	Saja M. Alhabardi	The bundle level aggregation should be optional for any case scenario as some manufacturers will use thin film of plastic to group the drug unit. It is difficult to print the barcoded label on such thin film of plastic "unique for each bundle". We found that the best-balanced way to adopt aggregation (for manufacturers and warehouses operations) is to be written on carton "shipper case" and pallets. Other levels should be optional.	**Deferred** Clarifications on how to apply the serialization might be addressed in a future version of the T&T recommendation.
23.	Saja M. Alhabardi	All stakeholders (manufacturers, warehouses, hospitals, Pharmacies, importers…etc.) must have a unique GLN from GS1 to register in T&T system.	**Deferred** This might be addressed in a future version of the T&T recommendation.
24.	Saja M. Alhabardi	All stakeholders should integrate with the system through SOAP-XML web services.	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation.

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25.	Saja M. Alhabardi	We suggest exchanging recalled drug information between regulators from different countries through a central international data repository. The World Health Organization (WHO) or any international organizations that are willing and able to maintain it can create this repository. GS1 is also a good candidate if most countries will utilize GTIN as the product identifier. Then regulatory bodies in every country can access and update the recall information or query the status of any product to update their local system given that all countries are using the same identifier on their products, namely GTIN & batch number. Such system should only contain recalled or falsified products information. This would help countries to insure the quality of products even if they do not implement a T&T system.	**Covered** The use of a global T&T repository model is one of the main objectives of T&T and is fully aligned with the recommendations.

2. Specific comments on text

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
1.	Page 23	Brian Rezach	"Recommendation 1: Use numeric product identifiers: Product identification should ideally be based on numeric identifiers, instead of alphabetic ones. As countries use different alphabets the inclusion of letters within product identification can lead to interoperability issues between systems." While AAM members indicated that they understood the groups position on adopting numeric-only identifiers to uniquely identified products, they cautioned that for high volume global manufacturers, this could present issues with availability of enough serial number combinations for several years of global unit volume. Further a numerical-only code may present challenges involving serialization, data exchange and verification for those manufacturers who depend on different contract manufacturing organizations in their ecosystem. Our members, which include some global manufacturers, appreciate the diversity of language among different markets, we also understand that an alphanumeric identifier is used in most of the world's markets. As work continues on this vital topic, AAM urges for some flexibility that would allow for alphanumeric codes to be used.	**Deny** There is no practical limit to the number of available product identifiers.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
2.	62	Suzette Kox	**Comment:** Spelling error in "Verification Route Service". **Proposed change (if any):** Replace by "Verification Router Service"	**Accepted** Thank you for highlighting this error, it has been corrected.
3.	134	Suzette Kox	**Comment:** Confusing wording. **Proposed change (if any):** Replace by "For the purpose of this document, all the product traceability systems and product tracking systems will be gathered under "T&T Systems", covering the following main possibilities:"	**Accepted** The wording has been globally updated
4.	138	Sérgio Cavalheiro Filho	**Comment**: The phrase "end to end" commonly refers to a full track and trace system, which would be a duplicate of line 135. The phrase" point of dispense verification" should be used to label the type of system being described by this definition. **Proposed change**: "~~End-to-end systems~~ **Point of dispense verification** (systems which allow verification of the product…	**Accepted** The change has been incorporated.
5.	138	Alissa McCaffrey	RxGPS suggests a change from the "end-to-end" terminology to "point of dispense verification" or "end user verification."	**Accepted** The change has been incorporated.
6.	147	Suzette Kox	**Comment:** Incomplete statement, current coverage may be interpreted broader than it really is. **Proposed change (if any):** Add "and primarily the prescription drugs" at the end of the sentence.	**Accepted** Thank you for highlighting this issue, it has been corrected.

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7.	153	John Willenbrock	**Comment**: Scope to exclude medicinal gases **Proposed change (if any)**: The scope of this document does not include medical gas products.	**Deferred** As per the general comment, the recommendations must be enhanced to address additive manufacturing including medicinal gases. Until the recommendations are updated medicinal gases should be excluded.
8.	197	Sérgio Cavalheiro Filho	**Comment**: Add clarification via header, to identify categories of interoperability (as this section is referred to later in the paper). **Proposed change**: Add overall header "Categories of Interoperability" prior to line 198.	**Accepted** This aspect has been corrected as per the proposal.

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9.	203-204	Suzette Kox	**Comment:** Clarify that it is easier, but it is not easy. If you want to include further details, you can refer to the second & third paragraphs. In case the proposal below may appear too long/detailed for this chapter #3, an alternative proper location could be chapter #5. **Proposed change (if any):** Easier to implement, compared to transactional integration, but not "easy". It also presupposes that reportable changes that occur at other levels are reported back to a system so that the proper information is known at one master system. This system could be a Marketing Authorization Holder (MAH) originator system or a centralized system (i.e., EMVS). Push implementation is harder than pull implementation because reportable changes must be known, and it will have to trigger changes through multiple partner levels. Pull implementation depends on whether the entire industry community can connect to the master system for direct query, or it would need to go up through all the partners that are between the master system that holds the data and the request originator. A centralized system (i.e., EMVS) would be easier to have all the request originators directly connected whereas separate systems (i.e., MAH originator systems) would be more trouble to do all direct connections.	**Accepted** A clarification on the complexity aspect has been included, however the proposed change was denied as it relates to an implementation approach.
10.	215	Alissa McCaffrey	RxGPS suggests limiting the scope of interoperability among verification and traceability systems, at least initially, to finished product.	**Noted** The implementation is incremental, the scope and timelines are determined independently by each jurisdiction.

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11.	220	Suzette Kox	**Comment:** It was found in the industry that doing precise identification at the batch level is not a good concept, given the size of some of the batches. Even though it is more difficult to perform sellable unit serialization, it is nevertheless more precise and allows for better tracking with multiple shipments of the same batch. **Proposed change (if any):** We recommend to add at the end of row #221: "Note that the industries' experience now shows that identification at sellable unit level would be a better concept as it would enable a better tracking with multiple shipments of the same batch."	**Deferred** The para refers to the 2017 paper, however the comment aligns with several others. Clarifications on how to apply the serialization might be addressed in a future version of the T&T recommendation.
12.	226	Sérgio Cavalheiro Filho	**Comment**: The International Common Product Identifier (ICPI) would impose a significant change on the industry. It appears as though the ICPI would be an additional master data element required for every GTIN. The format of what this ICPI would look like is unclear, and current systems do not have a data field for this value. An even more challenging interpretation of this paragraph suggests the ICPI would be a 5th data element for the 2D Data Matrix barcode. While the intent of the proposed value is understood, this short paragraph feels like a very casual reference to something that would trigger a substantial amount of effort across the entire industry. **Proposed change**: Clarify the intent and applications for developing an International "Common Product Identifier" (ICPI). Specifically, provide detail on why and how the ICPI would differ from using a GTIN, and provide examples and benefits of its use. We prefer that the ICPI concept be deleted, or at a minimum embedded in global GS1 standards, using a GTIN (Global Trade Identifier Number).	**Accepted** The document has been updated to clarify the role of the ICPI.

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13.	226	Alissa McCaffrey	The International Common Product Identifier (ICPI) would involve substantial change and investment of time and resources for the pharmaceutical industry. We recommend further discussion of the complexities of an ICPI, including recognition of the implementation challenges.	**Deferred** While the ICPI is required, it is acknowledged that at this time it is a concept and additional work on the standard and its application are required. This might be addressed in a future version of the T&T recommendation.
14.	226 to 228	Suzette Kox	**Comment:** Challenging to imagine a 'Common Product Identifier' from a global perspective. There will always be differences in unique product identifiers across jurisdictions (for instance. Sequential vs. randomized serial numbers). **Proposed change (if any):** Replace by or add "As much as possible the known and already commonly used International Common Product Identifier shall be selected rather than developing new ones"	**Deferred** While the ICPI is required, it is acknowledged that at this time it is a concept and additional work on the standard and its application are required. This might be addressed in a future version of the T&T recommendation.
15.	242	Sérgio Cavalheiro Filho	**Comment**: Proposed text is recommended to clarify "equivalency identification". **Proposed change**: "…commissioning/decommissioning or products, **drug** equivalence identification, information exchange…"	**Denied** Equivalency identification is not limited to drugs but can include all components including products.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
16.	245	Sérgio Cavalheiro Filho	**Comment**: Tracing products outside of national jurisdictions opens significant privacy and legal concerns. Proposed text clarifies the scope of product tracing is addressed within national/regional jurisdictions. **Proposed change**: "Enhanced Traceability **within national or regional jurisdiction**: regulators knowing where the product has been before reaching their jurisdiction…"	**Denied** The scope as proposed is appropriate, however the text has been updated to clarify the intention.
17.	264 to 268	Suzette Kox	**Comment:** Additional benefits are enabled like control of storage requirements fullfilment. But interoperability alone is not sufficient to bring those benefits. **Proposed change (if any):** Replace "bring" by "enable" on row #264. Add bullet point "control of storage requirements fulfilment" after row #268.	**Accepted** This wording has been modified as per the proposal. **Deferred** The additional bullet and related use case might be added to a future version of the T&T recommendation.
18.	265	Alissa McCaffrey	RxGPS suggests use of the term "suspicious" or "suspect" product rather than "falsified product." The systems discussed will more accurately identify product that is suspicious or at risk of being determined to be falsified, but absent further investigation, a system for verification, for example, would not be able to be relied upon to identify falsified product.	**Deferred** During the drafting of the current version this aspect was debated, and the current definition agreed upon. This might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
19.	268	Sérgio Cavalheiro Filho	**Comment**: It is not clear how the proposed interoperability would reduce medicine shortages unless full track and trace was implemented globally. To reduce shortages some amount of knowledge of the drugs' current location and dispense events would be required. We recommend removing this bullet. **Proposed change**: ~~Reduce shortage of medicines.~~	**Accepted** The document was updated to clarify the intent.
20.	274	Nasir Hussain	**Comment**: Technical Enablers standards section: - Utilization of GS1 standards is the industry's current standard and should be included. **Proposed change (if any):** Include GS1 standards	**Denied** The EPCIS & CBV standards are GS1 standards however we are identifying them using their ISO references.
21.	274	Nasir Hussain	**Comment**: Technical Enablers – Interconnected T&T system: - A centralized system with the appropriate governance and buy-in from government agencies to utilize, is the best path forward to achieving a global or regional track and trace system and interoperability. UNICEF has also initiated a track and trace project to track and trace COVID 19 vaccines. **Proposed change (if any):** It would be ideal of all interested parties can come together and align on approach, system architecture and governance.	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
22.	274	Sérgio Cavalheiro Filho	**Comment**: Text proposed for removal between brackets is already included in the barriers **Proposed change (if any):** Interconnected T&T system ~~(currently not existing)~~	**Accepted** This has been updated as per the proposal.
23.	274	Sérgio Cavalheiro Filho	**Comment**: Under General Implementation Considerations, "Procedural Enablers", 2nd bullet, add clarification around "allow controlled access to data in non-local T&T databases" **Proposed change**: Consider adding verbiage to reflect use of verifiable digital identity credentials, authorized trade partner/user credentialling systems.	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation.
24.	274	Sérgio Cavalheiro Filho	**Comment**: Under "Implementation Considerations", "Barriers", bullets 1 and 2, we recommend the following edits for clarification/readability: **Proposed change for bullet 1**: "Technical barriers **<u>such</u>** as establishing interconnected T&T systems globally is technically **<u>challenging</u>** ~~not easy~~ and **<u>requires</u>** ~~needs~~ economical and human resources". **Proposed change for bullet 2:** "Procedural barriers **<u>such</u>** as…"	**Accepted** This aspect has been updated to clarify the intent.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
25.	274	Sérgio Cavalheiro Filho	Comment: We recommend including the following bullet under "Barriers" for completeness: Proposed change: Add the following bullet point, • **<u>Legal/Regulatory barriers wherein different jurisdictions require differing content on labels and in electronically readable data carriers (e.g. NTIN vs. GTIN, NHRN)</u>**	**Accepted** The document has been updated to address this aspect.
26.	274	Suzette Kox	**Comment:** In section "Barriers", Please add information barrier from a point of view of a customer not wanting to share distribution data. **Proposed change (if any):** Add in the "Barriers" section: "Information barriers, where some members of the supply chainconsider purchasing, distribution, and status information that would have to be included in data sharing as private business confidential data."	**Accepted** The document has been updated to address this aspect.
27.	276	Nasir Hussain	**Comments**: In Interoperability applied to section, following should be mentioned: - Should be applied at an individual saleable unit using the unique serial number and the 4 data elements as defined by GS1	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
28.	276	Sérgio Cavalheiro Filho	**Comment**: The expiry date of the original batch is only needed when there is a suspected falsification of the expiry date. **Proposed change**: "Required as part of exchanged information in case falsification carries valid batch ID ~~or~~ **but** an expiry date other than the expiry date of the original batch."	**Accepted** This aspect will be updated as per the proposal.
29.	276	Sérgio Cavalheiro Filho	**Comment**: For "Use case 1" - Would such a real time information sharing really be an improvement? Falsification cases requires investigations at the concerned country level and with manufacturers. An early alert created and shared with other regulators before confirmation of falsification may result in inefficient, redundant and time-consuming interactions between stakeholders. A minimum set of information should be available prior to widely sharing an alert. Ideally, sharing should be possible after a falsification was proven.	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
30.	276	Sérgio Cavalheiro Filho	**Comment**: In the "Use Case 1: Accelerated Alerting…" table, we recommend the following edits for clarification/readability. Additionally, in the "Benefits" section (Bullet 2), "stopping in real time the dispensing of packs of the suspect falsified products which has entered the global legal supply chain" would require both a full traceability model to be globally adopted and at minimum a point of dispense verification model in all jurisdictions. As such, we recommend rewording the second bullet. **Proposed change for bullet 1**: "As a patient, I don't want to **receive or have inadvertent access to** ~~get in contact with~~ falsified products" **Proposed change for bullet 2**: "~~It would be possible to start~~ **Supports** investigation, regulatory and risk management action**s** in a timely **manner,** ~~way~~ ~~with the further option of stopping in real time~~ **and may allow prevention** of the dispensing of **falsified product packs** of ~~the~~ suspect falsified products in 'point of dispense' verification models (where used)."	**Accepted** Bullet 1 has been updated as per the proposal. **Accepted** Bullet 2 has been updated to reflect the proposal.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
31.	276	Sérgio Cavalheiro Filho	**Comment**: In "Interoperability Classification", "Interoperability applied to" - is this suggesting falsification of a single pack warrants global communication? If so, the volume of alerts could lead to higher priority items being overlooked as regulators sift through the data. **Proposed change**: Revise to clarify the approach for alerting; possibly bracket single markets or regional areas for alerts, to avoid overloading communication systems with non-relevant alerts.	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation.
32.	276	Sérgio Cavalheiro Filho	**Comment**: In "Interoperability Classification – Type of Interoperability": Systems for tracing products in non-approved markets opens risks/concerns and tacitly permits parallel trade across markets where may not be legally/regulatorily permitted. **Proposed change**: Clarify the intent. Is ICMRA proposing tracing non-registered/non-approved products and dispensation in non-approved markets, or is this only applicable to markets with "shared packs"?	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
33.	276	Sérgio Cavalheiro Filho	**Comment**: in "Implementation Considerations", under "Barriers" (second bullet), we recommend the following changes for clarity/readability. Additionally, we recommend including a third bullet in this section for completeness. **Proposed change for bullet 2:** • Falsification of presentation**s** of a product in one country **may not indicate** ~~usually does not allow to conclude that~~ that presentations in other countries are equally affected by the falsification. **[Additional bullet to be added]:** • **Establishing a means of recording the transformation of one product code/batch into another product code/batch (to support action on Scenario 2).**	**Denied** The intent of the T&T recommendation is to express probability. **Deferred** Implementation aspects might be included in a future version of the T&T recommendation.
34.	276	Suzette Kox	**Comment:** In section "Barriers": Depending on the models and regulations, the legal responsibilities of stakeholders are not the same. Interoperability may be limited from a legal/governance perspective. **Proposed change (if any):** Add at the end of the section "Barriers": "Depending on the models and regulations, the legal responsibilities of stakeholders are not the same. Interoperability may be limited from a legal/governance perspective."	**Accepted** This aspect has been updated in the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
35.	276	Suzette Kox	**Comment:** In section "Interoperability applied to": Tracking/tracing based on batch may not work when trying to deal with dispensing in multiple jurisdictions. Products have been designed/labelled so that they can be sold into multiple jurisdictions so this will not work at this level. **Proposed change (if any):** In section "Barriers" add: "Due to the possibility of having the same batch numbers across different organizations & jurisdictions, the use of product identifiers is necessary. However, product identifier structure and format is not the same across jurisdictions, which can complicate the identification of what product and batch is actually meant."	**Denied** This aspect is implicit to the use case.
36.	278	Suzette Kox	**Comment:** in section "Use Case Description", the wording "As a supplier" may be confusing. **Proposed change (if any):** Replace "supplier" by "Supply Chain actor"	**Accepted** The terminology has been updated.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
37.	278	Nasir Hussain	**Comment**: In Use case Description, following should also be mentioned as a use case for supplier/manufacturer: - A supplier / manufacturer is also interested in the end to end supply chain. This should be visible to all legitimate supply chain participants. The participants and access to the system will need to be closely managed through a verification of the "authorized trading partners". The Partnership for DSCSA Governance group is establishing a good model that could be leveraged and expanded to verify global authorized trading partners **Proposed change (if any):** Consider inclusion of the above use case	**Deferred** The topics of integration, data exchange, data sharing and reporting might be addressed in a future version of the T&T recommendation. **Deferred** The use case might be addressed in a future version of the T&T recommendation, but will be affected by data exchange, data sharing, data ownership and regulatory aspects.
38.	278	Nasir Hussain	**Comment**: In Interoperability Classification, following should be added to Interoperability applied to line item - Should be applied at an individual saleable unit using the unique serial number and the 4 data elements as defined by GS1 **Proposed change (if any):** Add above wording	**Deferred** Clarifications on how to apply the serialization might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
39.	278	Sérgio Cavalheiro Filho	**Comment**: In "Use Case Description". The first bullet, traceability information to support investigating falsification incidents, requires full track and trace. There are very few countries that have implemented full track and trace today. The first step to providing this type of information to investigators is not global interoperability, it is development of domestic solutions first. The increased burden to scan every hop in the supply chain is significant, which is why verification models such as the EU do not include this activity. As for the second bullet, what would interoperability bring in this context? A supplier would need to wait for a confirmation from the concerned manufacturer before implementing any necessary measure. **Proposed change**: Add clarification or a statement indicating that development of domestic solutions has to proceed the proposed global interoperability. Scanning at every hop or transfer can be burdensome; propose the use of the EU model.	**Deferred** The recommendation is both to use a phased and incremental approach to the T&T capabilities, however based on the comment this aspect is not clear in the current version of the T&T recommendations and might be addressed in a future version of the T&T recommendation. **Deferred** In terms of the recommended model, the jurisdictions must balance the options and select the most suitable one. The selection criteria might be addressed in a future version of the T&T recommendation.
40.	278	Sérgio Cavalheiro Filho	**Comment**: The graph for Use Case 2 appears to indicate that this use case is high effort and low importance. That suggests it is a poor choice to be the second use case presented. It will be difficult for companies to be able to address the situations outlined in this use case, given the cost vs. benefit (high effort and low importance). **Proposed change**: Remove the chart or remove this Use Case entirely. High effort/low importance use cases may have a negative impact on the overall intended objective.	**Denied** The order of the use cases is random and not based on priority. **Denied** A review of the usage of the charts was performed and deemed to add value.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
41.	278	Sérgio Cavalheiro Filho	**Comment**: In "Implementation Considerations". The 3rd bullet in the "Technical Enablers" references tracking a U.S. pack in the EU system. From a regulatory perspective it would be illegal for the U.S. pack to be in the EU system today. Just the presence of a product in the wrong country should be enough to trigger red flags. It is unclear why the systems of countries that do not share medicines should be connected. **Proposed change**: Remove this bullet. This bullet supports arguments around tracking parallel trade, not falsified medicines.	**Denied** This is allowed by specific Regulators
42.	280	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 3", "Use Case Description", first bullet, for patient verification it is unclear how common this scenario is. For the U.S. it does not seem like a practical use case, but maybe in other parts of the world crossing borders to buy medicine is more common. **Proposed change**: Delete bullet or revise	**Denied** While this may not be the norm the use case is common enough to warrant inclusion.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
43.	280	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 3", "Use Case Description", is traceability the key to suppliers buying valid medicines from foreign countries? This type of approach was attempted by India for exports and did not appear to generate much value and often caused confusion in destination market due to conflicting product coding requirements in source market vs. destination market. Are there other mechanisms that suppliers should be implementing to ensure they are purchasing from legitimate suppliers? **Proposed change**: Delete bullet or revise.	**Under Review** The use case will be reviewed by the working group.
44.	280	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 3", "Implementation Considerations", Technical Enablers" and "Barriers", we propose the following additional text for completeness. **Proposed Change:** "Technical Enablers": add 5th bullet: • **Global Authorized Trade Partner/User Credentialling System** "Barriers: add 2nd bullet: • **Building and implementing a global ATP/User Credentialling System**	**Denied** While the comment is correct, directionally we are not repeating the implementation aspect for all identified barriers.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
45.	280	Sérgio Cavalheiro Filho	**Comment**: Under "Type of Interoperability" classify this as "Information Exchange" rather than "Transactional interoperability". This classification would then agree with the example for the definition of "Information Exchange" in lines 198-204, which specifically cite "request… to retrieve the status of a pack". **Proposed change**: "~~Transactional Interoperability~~ **Information Exchange** to verify individual product packs across jurisdictions"	**Accepted** This aspect has been updated as per the proposal.
46.	280	Suzette Kox	**Comment:** In "Alternatives" section, missing bracket at the end of "Stand-alone (e.g., Brand owner) verification apps (these would be less effective than national/regional systems" **Proposed change (if any):** Add the bracket. "Stand-alone (e.g., Brand owner) verification apps (these would be less effective than national/regional systems)"	**Accepted** This aspect has been updated as per the proposal.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
47.	280	Suzette Kox	**Comment:** Ref. to section "Alernatives", item "Stand-alone (e.g., Brand owner) verification apps (these would be less effective than national/regional systems": Why is the brand owner verification system noted as less effective than a national system? If a patient is doing this, it should not make much difference to the effort the patient expends (i.e. no connection setup/automatic transfer) and the brand owner does not have to setup to transfer to a national system. A national system better, it is not clear why they indicate it is less effective. **Proposed change (if any):** Remove "(these would be less effective than national/regional systems"	**Accepted** The preference was clarified.
48.	282	Sérgio Cavalheiro Filho	**Comment**: Suggest revise wording or first bullet. Proposed change: "…dispensing of a ~~defective~~ **recalled** product to be stopped…"	**Accepted** This aspect has be updated as per the proposal.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
49.	282	Sérgio Cavalheiro Filho	**Comment**: Lack of awareness of current location within some jurisdictions (e.g. EU FMD) prevents timely automatic recall as product transfers between supply chain participants (e.g. wholesalers, distributors, third party logistics providers). Timely detection may not occur in these jurisdictions until product is scanned at point of dispense. **Proposed change**: In the second bullet under "Use Case Description", include an additional barrier reflecting the above comment, i.e., the system throws a "recalled" flag at time of dispense.	**Denied** The current scope does not address implementation aspects..
50.	282	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 4", "Interoperability Classification", it is not clear how a Common Global Data Carrier facilitates recalls. As manufacturers we certainly prefer common use of the 2D across all countries. However, if a given country chooses something else, their domestic systems would be built around that unique data carrier. If a recall were initiated, the local regulators would have the tools in place to scan their domestic product. In addition, recall of a batch in one market does not necessarily require recall in other market (depending on the reason for recall and production model). **Proposed change**: We propose adding to the section on technical enablers: "**The use of a common 2D data carrier for secondary packaging across all countries is preferred. However, if a given country does not align, their domestic system should be built around that unique data carrier."**	**Denied** The current scope does not address implementation aspects.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
51.	282	Suzette Kox	**Comment:** In section "Interoperability Classification", is the triggering to another jurisdiction wanted/needed in all cases? What if the recall in one jurisdiction is something specific to that jurisdiction that does not affect others? Could be something like the raw ingredients included a supplier that has not been approved in one jurisdiction but has been approved in others. **Proposed change (if any):** In section "Procedural enablers", add "The triggering of multiple recalls within several countries shall be subject to approval/governance and regulatory considerations, and not be fully automatic"	**Noted** The text "if allowed by procedures in place in the receiving jurisdiction." addresses the issue highlighted in the comment. Recalls are indeed subject to governance and only automated when appropriate and approved.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
52.	283	Suzette Kox	**Comment:** In section "Benefits", currently there are no regulations for component tracking of product (only finished goods), so this would be a significant effort to find the requirements / specifications, and to implement. Is this needed or should the MAH simply do the current function and notify on finished goods issues. Easier at this point for the MAH to identify the finished goods that have the implicated substance and notify based on the finished goods units. Major new effort to do substances and link them into the finished goods. And would companies (particularly brand) cooperate in giving out what is a list of ingredients for their products ? **Proposed change (if any):** Add a "Barriers" section like for other use cases and put "From a technical perspective, it remains easier for the MAH to identify the finished goods that have the implicated substance and notify based on the finished goods units. Disclosing the list of ingredients may be a major intellectual property/confidentiality obstacle as well."	**Denied** The long-term intent is to leverage the IDMP PhPID (General Implementation Consideration (line 274)) to enable this capability, additionally the intent is to enable T&T to be used at the component and not solely at the finished product level, however it is a major effort and a departure from the current practice of only addressing finished products.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
53.	283	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 5: Support Pharmacovigilance", "Use Case Description", the wording in the first bullet states, "As a patient, I want to avoid product for which a safety issue has been identified or is under investigation." The second bullet then discusses PV issues and reporting of adverse events. However, there may be additional reporting requirements that need to be considered and should be addressed in this bullet. **Proposed change**: "As a regulator (…) I also want to have access to traceability information to support pharmacovigilance and to improve the level of reporting of adverse events globally. **Additionally, there may be other reporting requirements that need to be considered. For example, a company's U.S. Regulatory Affairs organization may have to be consulted regarding U.S. pharma product safety systems/communications/alerting, Field Alerts or Product Recalls, etc."**	**Deferred** There are indeed many other aspects involved in supporting pharmacovigilance as it is an extremely broad topic, this use case might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
54.	283	Sérgio Cavalheiro Filho	**Comment**: In Use Case 5 "Benefits" section, the possibility to exchange information on the items of concern seems a very theoretical and remote benefit. Incorporating data on medicinal product components in the track and trace systems in an interoperable way is not envisaged to date. In addition, these statements do not take into account markets (e.g. U.S.) where packs are often not given directly to patients (e.g. pills supplied in separate prescription bottle prepared by dispenser vs. manufactured trade pack). **Proposed change**: At the end of the second bullet, add "…**except in markets where packs are often not given directly to patients (e.g., U.S.)**"	**Deferred** The use case might be enhanced in a future version of the T&T recommendations; however, it should be Noted that pharmacovigilance is not limited to finished products but applies to all levels including the discrete components and parties.
55.	283	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 5", "Implementation Considerations", the bullet under "Technical Enablers" appears to propose a system beyond just the GTIN. As an example, drug ABC in Argentina will have GTIN 1 and drug ABC in Brazil will have GTIN 2. This is necessary because the packaging will require different languages. The reference to "linkages among individual GTIN numbers" implies that an additional data element is requested to indicate that GTIN 1 and GTIN 2 are the same drug. While there may be some value in this, by itself this proposal alone would require a substantial global industry effort to implement. **Proposed change**: Remove the reference to "~~linkages among individual GTIN numbers~~" from this bullet.	**Denied** The observation is correct, it does imply a method such as the IDMP PhPID to relate discrete GTIN's

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
56.	285	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 6", "Benefits", the technical requirements of identifying product in one country that could relieve a shortage in another country is only one piece of the puzzle. There are a number of political and regulatory hurdles to implementing a solution for sharing medicines across borders. **Proposed change**: Either delete or include potential drawbacks/considerations as described above.	**Deferred** The barrier section might be enhanced in a future version of the T&T recommendation to highlight additional barriers.
57.	285	Sérgio Cavalheiro Filho	**Comment**: The footnote stating that "…T&T systems however could be used for traceability of other aspects such as active substances, excipients, manufacturers etc." would add significant additional complexity to proposed global traceability models. **Proposed change**: Remove this footnote, as this expansion of scope would add significant and additional complexity to proposed global traceability models implied throughout the document. We would not advise to pursue this via level of effort/cost/complexity vs. finished goods traceability models.	**Denied** The footnote accurately identifies long term T&T objectives.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
58.	285	Sérgio Cavalheiro Filho	**Comment**: It may not be limited to own/other jurisdiction. There may be instances where there is a drug shortage although products are or have been available in the own jurisdiction, but products are "diverted" through nonregular or illicit flows. Interoperability of T&T systems can provide increased transparency of goods flows which will allow regulators to take right measures to increase product availability. **Proposed change**: On the first bullet point under "Benefits" suggest to change to: "Interoperability of T&T systems ~~could allow regulators to identify real time the availability of the same product or alternative products in other jurisdictions~~ **will provide increased transparency to regulators on illicit flows and non-regular product diversion, allowing them to take preventive measures that can increase product availability"**	**Under Review** The comment may result in an additional bullet and will be reviewed by the working group.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
59.	285	Sérgio Cavalheiro Filho	**Comment**: In "Use Case 6", "Implementation Considerations", Technical Enablers" and "Barriers", we propose the following additional text for completeness. **Proposed change**: "Technical Enablers": add 3rd bullet: • **Global Authorized Trade Partner/User Credentialling System** "Barriers": add 5th bullet: • **Building and implementing a global ATP/User Credentialling System for access to information regarding shortages**	**Denied** While the comment is correct, directionally we are not repeating the implementation aspect for all identified barriers.
60.	285	Sérgio Cavalheiro Filho	**Comment**: Procedural enablers should clarify ownership of data and access rights for MAH **Proposed change (if any)**: Add bullet point: "**Clarify rules regarding ownership of data and access rights for MAH"**	**Deferred** An additional bullet might be added to the use case relating to the ownership and access rights to the data in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
61.	285	Suzette Kox	**Comment:** In section "Benefits", no method currently built in to do real time inventory on T&T systems. With no records back regarding the dispense / decommission and not all products recorded when shipped it is not a good inventory list even if you query for active serial numbers. **Proposed change (if any):** In section "Barriers", add: "Currently regulators may not have all the capabilities to view inventories of product. This would only work if the dispense/decommission actions were updated accurately into the regulatory reporting system."	**Deferred** An additional bullet might be added to the use case relating to the barrier in a future version of the T&T recommendation.
62.	285	Suzette Kox	**Comment:** ref to "[2] identification of the same or similar (e.g. same active substance) products in interconnected systems", same comment as last use case, will companies cooperate in giving a list of ingredients for their products? It might be easier to have a list of which companies are registered with a product and search on that. **Proposed change (if any):** In section "Barriers", add "Disclosing the list of ingredients may be a major intellectual property/confidentiality obstacle, that my prevent the suggested identification of the same or similar (e.g. same active substance) products in interconnected systems."	**Denied** The long-term intent is to leverage the IDMP PhPID (General Implementation Consideration (line 274)) to enable this capability, additionally the intent is to enable T&T to be used at the component and not solely at the finished product level, however it is a major effort and a departure from the current practice of only addressing finished products.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
63.	340-342	Sérgio Cavalheiro Filho	**Comment**: Section "A. Product Identification": Regarding the statement "…the unit of sale or use, i.e., the pack which is dispensed to the patient in its market designation(s)", in many countries the unit of sale is not dispensed to the patient. In the U.S. pills are commonly distributed in amber vials by the pharmacy. In low-income countries saleable cartons may be opened and product distributed as blister strips. **Proposed change**: "In the context of this document, the product being tracked and traced is a pharmaceutical pack. This is usually defined as the unit of sale or use, i.e., the pack which is dispensed to the patient in its market destinations. **Note, however, in many countries (U.S. and others) the package for the unit of sale is not dispensed to the patient.**"	**Accepted** This aspect has been clarified.
64.	354	Sérgio Cavalheiro Filho	**Comment**: We recommend using short and internationally recognized identifiers to be used for the human readable	**Denied** Aspects are covered in the existing recommendations and the human legibility aspects are not included in the scope of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
65.	354	Suzette Kox	**Comment:** We understand the groups position on adopting numeric-only identifiers to uniquely identified products, but caution that for high volume global manufacturers, this could present issues with availability of enough serial number combinations for several years of global unit volume. Further a numerical-only code may present challenges involving serialization, data exchange and verification for those manufacturers who depend on different contract manufacturing organizations in their ecosystem. Our members, which include some global manufacturers, appreciate the diversity of language among different markets, we also understand that an alphanumeric identifier is used in most of the world's markets. As work continues on this vital topic, we urges for some flexibility that would allow for alphanumeric codes to be used. **Proposed change (if any):** Add "Note that numeric product identifiers may be problematic in some business situations, of high volumes for instance, and it is not recommended at all to make it a mandatory requirement"	**Denied** The identifiers referred to are product identifiers, not package identifiers and therefore the use is appropriate.
66.	Line 355 (Recommendation 1)	Alissa McCaffrey	RxGPS believes that limiting product identification to numeric identifiers could present constraints in the number of available identifiers, particularly for large companies that rely on contract manufacturing organizations (CMOs).	**Denied** The identifiers referred to are product identifiers, not package identifiers and therefore the use is appropriate.
67.	357	Angelique Berg	Canada has adopted the GS1 Global Trade Item Number (GTIN) as the standard for product identification. Any other standards would become disruptive to our supply chain.	**Noted** Health Canada is a ICMRA member.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
68.	357	George Craigie	**Comment:** In Canada, we have adopted the GTIN (GS1 standards) as the standard for product identification. Any other standards would become disruptive to our supply chain.	**Noted** Health Canada is a ICMRA member.
69.	374	Sérgio Cavalheiro Filho	**Comment**: A unique serial number alone does not guarantee authenticity. The serial number is just one component of protecting the supply chain and verifying the drug. **Proposed change**: "…this in turn allows for the authenticity of an individual product's **serial number** to be checked as no two products will ever have the same identifying number."	**Accepted** The para has been updated as per the comment.
70.	385	Angelique Berg	We support the use of ISO/IEC data matrix outlined in Recommendation 5 (Line 432) and recommend to use the GS1 DataMatrix which aligns with the community adoption roadmap in Canada that includes variable data for GTIN, Lot, Expiry Date as mandatory and Serialization as optional. These 4 data elements from the Canadian community adoption roadmap aligns with Recommendation 3 (Line 385). Introducing other potential barcode carriers would disrupt the supply chain. The Canadian community is advancing system-wide capabilities to scan and ingest one GS1 DataMatrix barcode on pharmaceuticals by 2025. This goal recognizes the need for a suitable barcode symbology that can fit a large amount of data within small pharmaceutical packaging sizes. It is also critical for patient safety; by having one barcode, clinicians will know which barcode to scan.	**Noted** This is fully aligned with the T&T recommendation..

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
71.	385	Sérgio Cavalheiro Filho	**Comment**: Under "Recommendation 3: Use the four data elements", the example graphic showing a 2D barcode and 4 data elements, including "PC". **Proposed change**: In addition to "PC", we recommend adding "**GTIN**" as well, or included as an alternative graphic.	**Denied** A clarification on the graphics was added to the scope section.
72.	385	George Craigie	**Comment**: We support the use of ISO/IEC data matrix outlined in Recommendation 5 (Line 432) and recommend to use the GS1 Data Matrix which aligns with the community adoption roadmap in Canada that includes variable data for GTIN, Lot, Expiry Date as mandatory and Serialization as optional. These 4 data elements from the Canadian community adoption roadmap aligns with Recommendation 3 (Line 385). Introducing other potential barcode carriers would disrupt the supply chain. The Canadian community seeks to have system-wide capabilities to scan and ingest one GS1 DataMatrix barcode on pharmaceuticals by 2025. This goal recognizes the need for a suitable barcode symbology that can fit a large amount of data within small pharmaceutical packaging sizes. It is also critical for patient safety; by having one barcode, clinicians will know which barcode to scan.	**Noted** This is fully aligned with the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
73.	396	Sérgio Cavalheiro Filho	**Comment**: Add a statement acknowledging that aggregation allows for inferring, but not actually knowing, the units contained within a package. **Proposed change**: Add text at the end of line 396 stating the following: "**It should be noted that the process of aggregation is not infallible, when scanning to look up the associated items, we can infer, but not necessarily know the units contained therein.**"	**Deferred** This might be addressed in a future version of the T&T recommendation.
74.	408	Sérgio Cavalheiro Filho	**Comment**: In Recommendation 4, aggregation must be mandated if the traceability model is full track and trace. The physical movement of product will be crippled if each saleable unit must be scanned at every single hop in the supply chain **Proposed change**: "Aggregation should be ~~**allowed but not**~~ **mandated**."	**Deferred** This might be addressed in a future version of the T&T recommendation.
75.	408	Sérgio Cavalheiro Filho	**Comment**: Complying with recommendation 4 would require a centralized data governance to manage evolutions to the standards. **Proposed change**: Add to the recommendation: **"Rules for structure need to be technically specified and ideally implemented in a central system**".	**Denied** Recommendation 4 does not propose implementation aspects, the architecture is separate from the objectives identified in this recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
76.	409	Angelique Berg	Recommendations 4 and 12 discuss the identification and barcoding of packaging levels. In Canada, the community adoption roadmap recommends the use of GS1-128 barcodes on logistic units labelled and identified with a Serial Shipping Container Code (SSCC), with the GS1 DataMatrix as an optional addition. Canada, uses ECCnet Registry as the national registry that support aggregation outlined in the ICMRA recommendations. ECCnet Registry enables the identification of product with a GTIN by packaging hierarchy and globally standardize attributes that describe the product which include the national Drug Identification Number (DIN). There are various loading options into ECCnet Registry, including the Global Data Synchronization Network (GDSN).	**Noted** This is fully aligned with the T&T recommendation.
77.	409	George Craigie	**Comment**: Recommendation 4 and 12 discuss the identification and barcoding of packaging levels. In Canada, the community adoption roadmap recommends the use of GS1-128 barcodes on logistic units labelled and identified with a Serial Shipping Container Code (SSCC), with the GS1 DataMatrix as an optional addition. In Canada, we use ECCnet Registry as the national registry that support aggregation outlined in the ICMRA recommendations. The ECCnet Registry enables the identification of product with a GTIN by packaging hierarchy and globally standardize attributes that describe the product which include the national Drug Identification Number (DIN).	**Noted** This is fully aligned with the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
78.	414	Nasir Hussain	**Comment**: Majority of manufacturers have only invested in qualifying the 2D Data Matrix. All other options will be a barrier to entry and increase both the time and cost for implementation. 1D / Linear barcodes are still used to meet some countries requirements however the proposal should be limited to these two options. **Proposed change (if any):** Utilization of 2D Data Matrix	**Accepted** Figure 4 has been revised..
79.	417	Sérgio Cavalheiro Filho	**Comment**: Figure 4 shows a 2D DataMatrix and a QR Code, but the text below could be confusing. **Proposed change**: Update the text to describe each illustration separately, i.e., "2D DataMatrix" (under the 2D DataMatrix) and "QR Code" (under the QR code).	**Accepted** Figure 4 has been revised.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
80.	432	Angelique Berg	We support the use of ISO/IEC data matrix outlined in Recommendation 5 (Line 432) and recommend to use the GS1 DataMatrix which aligns with the community adoption roadmap in Canada that includes variable data for GTIN, Lot, Expiry Date as mandatory and Serialization as optional. These 4 data elements from the Canadian community adoption roadmap aligns with Recommendation 3 (Line 385). Introducing other potential barcode carriers would disrupt the supply chain. The Canadian community is advancing system-wide capabilities to scan and ingest one GS1 DataMatrix barcode on pharmaceuticals by 2025. This goal recognizes the need for a suitable barcode symbology that can fit a large amount of data within small pharmaceutical packaging sizes. It is also critical for patient safety; by having one barcode, clinicians will know which barcode to scan.	**Noted** This is fully aligned with the T&T recommendation.
81.	432	Sérgio Cavalheiro Filho	**Comment**: In Recommendation 6, if significant costs are added to the manufacturers it is likely that some, if not all, of those costs may be passed down to the patients. **Proposed change**: "Scratch-off mechanisms add significant costs for manufacturers ~~and do not significantly increase the overall security of the system~~ **which are frequently passed down to the customers. Despite the increased costs the scratch-off mechanisms do not significantly increase the overall security of the system.**"	**Under Review** The wording of recommendation 6 will be reviewed by the working group.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
82.	432	George Craigie	**Comment**: We support the use of ISO/IEC data matrix outlined in Recommendation 5 (Line 432) and recommend to use the GS1 Data Matrix which aligns with the community adoption roadmap in Canada that includes variable data for GTIN, Lot, Expiry Date as mandatory and Serialization as optional. These 4 data elements from the Canadian community adoption roadmap aligns with Recommendation 3 (Line 385). Introducing other potential barcode carriers would disrupt the supply chain. The Canadian community seeks to have system-wide capabilities to scan and ingest one GS1 DataMatrix barcode on pharmaceuticals by 2025. This goal recognizes the need for a suitable barcode symbology that can fit a large amount of data within small pharmaceutical packaging sizes. It is also critical for patient safety; by having one barcode, clinicians will know which barcode to scan.	**Deferred** This might be addressed in a future version of the T&T recommendation.
83.	438	Suzette Kox	**Comment:** We would recommend to use the GS1 Application Indicators (AIs) to determine the data, and to not mandate the order of the data in the barcode. **Proposed change (if any):** Add "Use the GS1 Application Indicators (AIs) to determine the data, and do not mandate the order of the data in the barcode."	**Deferred** This might be addressed in a future version of the T&T recommendation.
84.	458	Sérgio Cavalheiro Filho	**Comment**: Recommendation 6 seems to be the wrong reference. Recommendation 7 seems more suitable.	**Accepted** The reference has been updated as per the comment.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
85.	469	Sérgio Cavalheiro Filho	**Comment**: Recommendation 7 seems to be the wrong reference. Recommendation 6 seems more suitable.	**Noted** A clarification was provided, this is a typo and a duplicate of the comment regarding line 458.
86.	469	Nasir Hussain	**Comment**: Majority of manufactures only apply the barcodes at the "saleable units". This excludes the primary package in most situations. We recommend against applying this at the primary package as this is both time and cost prohibitive. In many situations, the amount of space to print this makes this impossible to achieve a quality barcode that can be read by a scanner or to even put on the package. **Proposed change (if any):** Exclusion of primary packaging serialization requirements	**Accepted** Figure 7 has been updated.

87.	469	Sérgio Cavalheiro Filho	**Comment**: Serialization of primary packaging is shown in the illustration fig 7 and fig 14. It should be mentioned that serialization of primary packaging is not usually possible with current installed medicines packaging equipment. Furthermore, significant number of current primary packaging are not suitable for being printed with serialization feature (especially if datamatrix and human readable must be associated (recommendation 9). Therefore, serializing primary packaging would be huge effort in term of technical innovation, packaging line changes and packaging material changes (size increase). No regulation is imposing primary packaging serialization (some country regulators had to renounce for these reasons). There are 2 points to consider in order to deal with this topic: 1) Tamper evidence of sales unit (typically secondary packaging) should be impose as an additional anti-counterfeiting, as it is in some regulation like EU one. To be added as a commendation. 2) Serialization of primary packaging should be required only when primary packaging is also the sales unit packaging as registered to the Health Authorities. In other words, the first packaging to be serialized must be the sales unit, in combination with Tamper evidence. **Proposed change (if any):** Modify fig 7 and 14 showing first level of serialization at "sales unit" level and not "primary packaging" – this could be done with a bottle or blister to avoid a misleading picture. Add following recommendations: **Tamper evidence must be always required together with serialization of a packaging. This should apply to any packaging, primary, secondary or tertiary; The lower level / first level of serialization should be the sales unit, most common one**	**Accepted** Figure 7 has been updated. **Denied** Tamper evidence is not an T&T issue.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
			being secondary packaging, by exception primary packaging when it is the sales unit packaging.	
88.	473	Angelique Berg	Recommendations 4 and 12 discuss the identification and barcoding of packaging levels. In Canada, the community adoption roadmap recommends the use of GS1-128 barcodes on logistic units labelled and identified with a Serial Shipping Container Code (SSCC), with the GS1 DataMatrix as an optional addition. Canada, uses ECCnet Registry as the national registry that support aggregation outlined in the ICMRA recommendations. ECCnet Registry enables the identification of product with a GTIN by packaging hierarchy and globally standardize attributes that describe the product which include the national Drug Identification Number (DIN). There are various loading options into ECCnet Registry, including the Global Data Synchronization Network (GDSN).	**Noted** This is fully aligned with the T&T recommendation..

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
89.	473	Suzette Kox	**Comment:** For ease of use, if it is homogeneous, if you want to aggregate, and you want to specify all levels of aggregation, it would be better to have all of the data (lot, expiry, GTIN, serial number) on each level (Saleable unit, bundle, shipper). The diagram that is shown only has a linear barcode at bundle and case. A linear barcode is not sufficient at carrying the amount of data for all four fields specified above. **Proposed change (if any):** In "Recommendation 12", at the end of the first paragraph, add: "Practicalities to be taken into account: Diagram above shows linear barcode at bundle and case. If these are to be aggregated, they should be serialized with the four data fields if homogeneous, and that does not fit well on a linear barcode. If a mixed case, then SSCC in a linear code works."	**Noted** This is fully aligned with the T&T recommendation.
90.	473	George Craigie	**Comment**: Recommendation 4 and 12 discuss the identification and barcoding of packaging levels. In Canada, the community adoption roadmap recommends the use of GS1-128 barcodes on logistic units labelled and identified with a Serial Shipping Container Code (SSCC), with the GS1 DataMatrix as an optional addition. In Canada, we use ECCnet Registry as the national registry that support aggregation outlined in the ICMRA recommendations. The ECCnet Registry enables the identification of product with a GTIN by packaging hierarchy and globally standardize attributes that describe the product which include the national Drug Identification Number (DIN).	**Noted** This is fully aligned with the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
91.	483	Sérgio Cavalheiro Filho	**Comment**: The data exchange systems of national T&T systems are interoperable if they are designed that way. The EU is the best example of this. Regional partnerships and agreements likely provide the best opportunity for interoperability. **Proposed change**: "~~Indeed, because the data exchange specifications of the national T&T systems are not interoperable, the national databases cannot be directly cross-referenced.~~ **If designed as such, data exchange specifications of national T&T systems are interoperable. However, in some cases the data exchange specification of the national T&T systems may not be interoperable, and if that is the case the national database cannot be directly cross-referenced**."	**Accepted** The refence has been updated.
92.	487	Sérgio Cavalheiro Filho	**Comment**: Phrase mentions "recommendations below", but it's not clear which recommendation it's referring to. **Proposed change (if any):** "Below ~~are recommendations~~ **are considerations** focusing on the data model and data exchange elements needed to ensure the interoperability of T&T systems".	**Accepted** The refence has been updated.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
93.	489	Sérgio Cavalheiro Filho	**Comment**: While the technical aspects of creating an interoperable data exchange must be considered, the technical aspects are likely not the biggest challenge. The political challenges of obtaining agreement for countries to share data are significant and would need to be resolved before beginning the technical implementation. **Proposed change**: Add the following text to the end of line 489: "**Regional partners, such as the member countries of the EU, recognize that the physical flow of product goes beyond any one country's borders. It is critical that the geographical coverage of the T&T system aligns with the physical movement of the drugs.**"	**Denied** The addition does not add clarity.
94.	514	Sérgio Cavalheiro Filho	**Comment**: Add an element on complexity of granularity and that T&T events need to mirror real life supply chain events **Proposed change (if any):** "Collecting traceability data, especially at small unit level (e.g. packs) requires significant time and resources and generates costs. **In a T&T architecture the complexity rises by the granularity of transactions and their pre-requisites. If an event needs complex pre-requisites blocking situations can occur. Logical steps should be foreseen to mirror events take place in the physical world, e.g. taking an item from a pallet without de-aggregation pallet and case first**."	**Deferred** This might be addressed in a future version of the T&T recommendation.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
95.	516	Sérgio Cavalheiro Filho	**Comment**: Regarding who can access databases for verification purposes, we recommend consideration of a gaited implementation of users. **Proposed change**: "…"who do we want to be able to verify the authenticity and origin of the medicine?" **Regarding who can access databases for verification purposes, during system design, one may possibly propose a gaited implementation of user access levels, i.e., first phase access for credentialled authorized trading partners (ATPs); second phase for authorized providers/networks; final phase for patient populations. One would also need to consider the system's ability to handle the volume of scans as each phase ramps up**."	**Deferred** This might be addressed in a future version of the T&T recommendation.
96.	545	Sérgio Cavalheiro Filho	**Comment**: Russia and the USA are poor examples to include for full track and trace. The U.S. system is not operational, and statutorily is not required until November 2023. Russia's system has had numerous challenges with the initial rollout. Argentina and Turkey would be better examples, since these countries have had systems in place for a decade. **Proposed change**: Examples of this kind of systems already in place include ~~Russia and the USA~~ **Argentina and Turkey**."	**Accepted** The examples were updated.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
97.	545	Alissa McCaffrey	The US and Russia should not be cited as example of fully implemented full track and trace systems. The US system has not yet been fully implemented (deadline is November 27, 2023), and the Russian system is experiencing many challenges in the initial rollout of the systems for storing and transmitting serialization data. Argentina or Turkey may be better examples to consider.	**Accepted** The examples were updated.
98.	566	Angelique Berg	We encourage Health Canada to be engaged in the community via the GS1 Canada Pharmaceutical Traceability Expert Group on the best approach for a national deployment, and to establish a firm position for Canada.	**Noted** Health Canada is a ICMRA member.
99.	566	George Craigie	The Pharmaceutical Traceability Expert Group in Canada projects that the decentralized approach toward visibility and traceability capability at the transactional level is the most feasible path for Canada due to its ability to implement in a phased approach quicker. It should be noted that the systems that support additional details such as master data attributes for product and entity/location, a central model is appropriate. We would encourage Health Canada to be engaged in the community via the GS1 Canada Pharmaceutical Traceability Expert Group on the best approach for a national deployment. A recommendation of the GS1 Canada Traceability Expert Group is community engagement with Health Canada to establish a clear position for Canada.	**Noted** Health Canada is a ICMRA member.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
100.	573	Sérgio Cavalheiro Filho	Comment: In the descriptions of the "3 main available types of architecture", include some pros/cons to each architecture model (e.g. single point of failure/compromise vs. data access/controls, etc.).	**Accepted** A reference was included.
101.	578	Sérgio Cavalheiro Filho	**Comment**: • Brazil should not be included. While the intent in Brazil is to build a centralized system, as of January 2021 ANVISA has yet to release the final technical specs for their system and there are many questions around how the system will function. • EU is a hybrid model of both centralized and distributed components. Serial data is distributed to the various interconnected national repositories while master data is stored in the central database (EU Hub). Intermarket queries are another example of the distributed nature of the EU model. **Proposed change**: Remove EU and Brazil from this list.	**Denied** The examples are deemed valid..
102.	578	Alissa McCaffrey	This line cites the EU, Russia, and Brazil as centralized systems. To-date, Brazil has not released the full technical guidance for its system. Further, the EU is not a fully centralized system, but a hybrid system with centralized and distributed components.	**Denied** The examples are deemed valid..

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
103.	593	Sérgio Cavalheiro Filho	**Comment**: The model being described in this paragraph (semi-centralized model) is an e-pedigree system such as the California model in the U.S. in the early 2000s. The semi-centralized model includes multiple databases that are available for posting traceability data rather than a single, fully centralized database. **Proposed change**: Consider using definition Dirk Rodgers outlines on the RxTrace website: https://www.rxtrace.com/2011/05/the-viability-of-global-track-trace-models.html/.	**Deferred** The architecture and implementation options might be addressed in future version of the T&T recommendation.
104.	593	Alissa McCaffrey	The definition of semi-centralized does not describe a semi-centralized system. The current definition describes a pedigree system akin to the California model proposed in the US in the early 2000s. RxGPS supports a definition of semi-centralized as a model that using multiple "central" databases for posting traceability data (as opposed to one centralized database or fully distributed databases).	**Deferred** The architecture and implementation options might be addressed in future version of the T&T recommendation.
105.	611	Angelique Berg	We agree with the consideration related to data access rights that the permission to access data collected and generated by traceability systems must be clearly defined. That is also a key design principle and considerations for the Canadian Pharmaceutical Traceability Infrastructure Proposal established by GS1 Canada's Pharmaceutical Traceability Expert Group.	**Noted** The architecture and implementation options might be addressed in future version of the T&T recommendation this could include ownership, access, and security aspects.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
106.	611	George Craigie	We agree with the consideration related to data access rights that the permission to access data collected and generated by traceability systems must be clearly defined. That is also a key design principle and considerations for the Canadian Pharmaceutical Traceability Infrastructure proposal.	**Noted** The architecture and implementation options might be addressed in a future version of the T&T recommendation and could include ownership, access, and security aspects.
107.	621	Sérgio Cavalheiro Filho	**Comment**: Consider including information that discusses the pros and cons of the difference traceability models from a cyber security perspective. **Proposed change**: Include the addition of a matrix of models with pros and cons based on cyber security levels.	**Deferred** The architecture and implementation options might be addressed in a future version of the T&T recommendation and could include ownership, access, and security aspects.
108.	637-638	Sérgio Cavalheiro Filho	**Comment**: While specifying a standard data structure, such as EPCIS, is important, it alone is insufficient. **Proposed change**: "…trace platforms can cope with multiple file formats**. However, EPCIS has numerous optional fields and there are still integration costs and effort required to share data via EPCIS between any 2 partners.**"	**Deferred** The architecture and implementation options might be addressed in future version of the T&T recommendation and could include ownership, access, and security aspects.
109.	647	Sérgio Cavalheiro Filho	**Comment**: In Figure 13, in "Data Formats" there is an entry for "Fixed" while all other items refer to a specific technical format/file type. Clarify the meaning of "Fixed" in this figure and section of the document.	**Accepted** The figure has been updated.

110.	651	Sérgio Cavalheiro Filho	**Comment**: Generally restricting data access from all end users (so all population) may be an excessively impediment in the long run. To a certain extent, having this information available is the "final objective" of T&T and will be probably be a strong expectation in the future, not only for medicines but all purchased goods. It could be envisaged that healthcare professionals should have access to the data base with "upload" "modify" or "read" capability depending on their function, based on specific monitored connection tools and access. A separate tool and access in "read only" mode could be envisaged to open authentication to anyone. In this configuration, multiple access events to a single code must be appropriately monitored. **Proposed change (if any):** The quality and security of a traceability system depends on reliable and robust processes, this include ensuring that **any access to the data base is secured with best available standards and data reading versus data modification / upload is clearly** monitored ~~only authorized users can upload data~~. Add as a recommendation**: Access to the data base for data management (upload, modify, verify) should be done by a tool and access fully secured and dedicated to professional health care of the official supply chain, controlled by regulation. Such an access can not be anonymized and must be auditable.** Add as a recommendation: **An open access to the data base must be limited to "read only" by sequence of 1 serial number only, done with a specific tool not suitable for any "upload" or "modification". Multi verification events**	**Deferred** The architecture and implementation options might be addressed in a future version of the T&T recommendation and could include ownership, access, and security aspects.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
			must be monitored. The "feedback message" at verification by an open tool (mobile app) must be agreed with regulatory authorities and must take in consideration that what is checked is a packaging not a medicine.	
111.	667	Angelique Berg	We strongly agree with the position on data hierarchy. In Canada's Pharmacy community, we have adopted the GTIN and ECCnet Registry that support product hierarchy data structure. This digital capability has not been scaled in Canada, primarily the government registration process or healthcare providers are still adopting. We need government influence on adopting this digital capability in these areas. The aggregation or data hierarchy topics are critical to patient safety and promote barcode scanning at the point of care level to include into the patient health records. Having full product hierarchy information is a critical component for precision recall and shortage mitigation.	**Noted** The architecture and implementation options might be addressed in a future version of the T&T recommendation and could include ownership, access, and security aspects.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
112.	667	George Craigie	**Comment**: We strongly agree with the position on data hierarchy. In Canada's Pharmacy community, we have adopted the GTIN and ECCnet Registry that support product hierarchy data structure. The aggregation or data hierarchy topics are critical to patient safety and promote barcode scanning at the point of care level to include into the patient health records. Having full product hierarchy information is a critical component for precision recall and shortage mitigation.	**Noted** The architecture and implementation options might be addressed in a future version of the T&T recommendation and could include ownership, access, and security aspects.
113.	675	Sérgio Cavalheiro Filho	**Comment**: Include some details on different kinds of errors - e.g., discrepancy management -- and associated risks/impact (auto vs. manual aggregation, cascading impact of errors, etc.). Aggregation data accessibility is also a concern as some systems are not setup to share aggregation data with downstream partners (e.g. Brazil SNCM requires separate data exchange between trade partners while Turkey's system is designed such that trade partners can download aggregation data from central database).	**Deferred** The architecture and implementation options might be addressed in a future version of the T&T recommendation and could include ownership, access, and security aspects.
114.	677	Sérgio Cavalheiro Filho	**Comment**: It is not feasible to fully track product movement at a secondary pack level without aggregation. **Proposed change**: "**Aggregation is an essential component to tracing as scanning each individual unit has a detrimental impact to the movement of goods through the supply chain**".	**Accepted** The wording has been updated.

115.	679	Sérgio Cavalheiro Filho	**Comment**: Serialization of primary packaging is shown in the illustration fig 7 and fig 14. It should be mentioned that serialization of primary packaging is not usually possible with current installed medicines packaging equipment. Furthermore, significant number of current primary packaging are not suitable for being printed with serialization feature (especially if datamatrix and human readable must be associated (recommendation 9). Therefore, serializing primary packaging would be huge effort in term of technical innovation, packaging line changes and packaging material changes (size increase). No regulation is imposing primary packaging serialization (some country regulators had to renounce for these reasons). There are 2 points to consider in order to deal with this topic: 1) Tamper evidence of sales unit (typically secondary packaging) should be impose as an additional anti-counterfeiting, as it is in some regulation like EU one. To be added as a commendation. 2) Serialization of primary packaging should be required only when primary packaging is also the sales unit packaging as registered to the Health Authorities. In other words, the first packaging to be serialized must be the sales unit, in combination with Tamper evidence. **Proposed change (if any):** Modify fig 7 and 14 showing first level of serialization at "sales unit" level and not "primary packaging" – this could be done with a bottle or blister to avoid a misleading picture. Add following recommendations: **Tamper evidence must be always required together with serialization of a packaging. This should apply to any packaging, primary, secondary or tertiary; The lower level / first level of serialization should be the sales unit, most common one**	**Denied** Tamper evidence is not an T&T issue.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
			being secondary packaging, by exception primary packaging when it is the sales unit packaging.	
116.	680	Sérgio Cavalheiro Filho	**Comment**: There is nothing in the text of the document that Figure 14. Figure 14 is also a copy of Figure 7 **Proposed change**: Delete figure 14.	**Denied** The figures illustrate different issues and are both required.
117.	689-692	Sérgio Cavalheiro Filho	**Comment**: Patient verification is a difficult area to navigate. If a patient receives a negative verification or is confused by the response it can be difficult for the patient to know how to respond. In a general recommendation document such as this it is not clear that this would be a good area to discuss. **Proposed change**: Delete lines 689 through 692.	**Removed** This section was removed from the T&T recommendations.
118.	693	Angelique Berg	We agree with the consideration related to the importance of data access and data authentication to achieve the balance of sharing information to the right audience without compromising on the security and prevent exploitation of the information within a track and trace system. In Canada, the Pharmaceutical Traceability Expert Group has identified a next step to explore and develop an information discovery service such as GS1 Digital Link to address the potential challenges of access to information across multiple systems and exploitation by counterfeiters.	**Removed** This section was removed from the T&T recommendations.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
119.	693	George Craigie	We agree with the consideration related to the importance of data access and data authentication to achieve the balance of sharing information to the right audience without compromising on the security and prevent exploitation of the information within a track and trace system.	**Removed** This section was removed from the T&T recommendations.
120.	693-702	Sérgio Cavalheiro Filho	Comment: The concept of e-leaflets and the use of QR codes is a significant topic with a broad reach of involvement from regulators, manufacturers, standards groups, patient advocates and more. The title and scope of this paper centers around traceability. The e-leaflet topic cannot be adequately discussed in a short paragraph such as this. It would be preferrable to remove this paragraph and allow the e-leaflet discussion to be discussed in a separate document. Proposed change: Delete lines 693 through 702.	**Removed** This section was removed from the T&T recommendations.
121.	698	Angelique Berg	We agree with the consideration related to the importance of data access and data authentication to achieve the balance of sharing information to the right audience without compromising on the security and prevent exploitation of the information within a track and trace system. In Canada, the Pharmaceutical Traceability Expert Group has identified a next step to explore and develop an information discovery service such as GS1 Digital Link to address the potential challenges of access to information across multiple systems and exploitation by counterfeiters.	**Removed** This section was removed from the T&T recommendations.

ID	Line number(s) of text	Stakeholder name	Comments	Outcome
122.	698	George Craigie	We agree with the consideration related to the importance of data access and data authentication to achieve the balance of sharing information to the right audience without compromising on the security and prevent exploitation of the information within a track and trace system.	**Removed** This section was removed from the T&T recommendations.
123.	705-706	Sérgio Cavalheiro Filho	**Comment**: SMS-based systems often rely on manual data entry which is prone to user/human error. This could lead to false alerts as experienced in the EU with manual data entry by end users performing verification/decommissioning. **Proposed change**: "However, it may be necessary to allow for SMS-based methods in some countries where mobile-internet or smartphone availability is low. **Note that SMS-based systems often rely on manual data entry which is prone to user/human error**."	**Removed** This section was removed from the T&T recommendations.