Pharmaceutical Traceability Expert Task Group

Traceability Infrastructure Proposal

January 2020
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Executive Overview

This document describes the GS1 Canada Traceability Expert Group position, recommendations and framework for a Canadian pharmaceutical traceability framework and infrastructure to achieve standards-based pharmaceutical traceability1 in Canada.

The Canadian pharmacy sector has invested in pharmacy sector (shared) infrastructure which has enabled pharmaceutical stakeholders in Canada to realize significant supply chain optimization opportunities. The pharmacy sector recognizes that further investment will be needed to address current and future challenges.

The GS1 Canada Pharmacy Sector Board convened the Traceability Expert Group to explore current and future traceability requirements, determine capabilities needed and propose a future state information infrastructure.

A growing list of countries have legislated or regulated versions of traceability for pharmaceutical products within their jurisdiction. Traceability efforts usually include the unique identification (serialization) of each unit of sale, documentation and verification of the product as it travels through the supply chain or at least at the healthcare provider (dispensing) step.

The Traceability Expert Group examined traceability efforts in the European Union and in the United States to understand the capabilities that global supply chain stakeholders have developed to serve other markets. These efforts were triggered by counterfeit and otherwise adulterated drugs making their way into the legitimate supply chain and ultimately harming patients. Complex supply chains in these regions provide opportunities for nefarious characters to exercise their elicit trade undetected.

The Expert Group also explored a set of traceability use cases and developed an understanding of overall capabilities needed to support them. These capabilities helped determine infrastructure requirements for Canada.

After careful consideration of the traceability use cases and traceability activities globally, the Traceability Expert Group submits the following Traceability Position Statement, Traceability Concept Model and recommendations to the GS1 Canada Pharmacy Sector Board.

1 For the purposes of this document, the term “traceability” includes the traditional definition1 and also aspects of “permissioned visibility” where information about products, entities and locations is available for decision making on a permissioned basis.
GS1 Canada Traceability Expert Group Position Statement

The GS1 Traceability Expert Group, after careful consideration of pharmacy sector traceability needs, developed the following position statement.

Everything we do is with the patient in mind. We believe there are opportunities in healthcare supply chain to positively affect the health and wellbeing of patients while also improving the efficiency and effectiveness of healthcare system.

Canada has the unique opportunity to significantly enhance the current capabilities of the healthcare supply chain and clinical functions to address current and pending challenges.

The way the Canadian pharmacy sector can affect patient safety through standards-based traceability is:

- to fully leverage existing industry-led investment in place in Canada,
- to make ubiquitous the foundational elements of standardized product, entity and location identification,
- to ensure access to pharmacy sector shared information repositories to aid healthcare stakeholders in maintaining a high level of quality information throughout the pharmacy sector
- to remain on par with other pharmaceutical eco-systems (such as the US and European Union) through federal and provincial government action to harmonize product identification and barcoding policies with those of other leading healthcare jurisdictions

This foundation can then be reliably built upon to better connect stakeholders and achieve transformational improvements throughout the pharmacy sector through the application of the standardized traceability infrastructure described in this document.

We ask the pharmacy sector, regulators and GS1 Canada to endorse and implement these traceability recommendations, infrastructure and roadmaps.

Business Vision

Although product serialization and traceability are not currently legislated or regulated in Canada, the Traceability Expert Group believes that it is in the interest of Canadian citizens for Canada to remain on par with other pharmaceutical eco-systems such as the United States and the European Union. The Expert Group also believes that the Canadian pharmaceutical sector can leverage capabilities developed for other countries and regions to strengthen the Canadian supply chain. The team adopted the vision of “strengthening the Canadian Supply Chain: Creating an interconnected and agile supply chain and healthcare system... through an interoperable, flexible infrastructure” to point toward envisioning a pharmacy sector defined future supply chain.
Surveying the global advancements in visibility information sharing (including serializing product, verification and traceability of product), the team adopted a conceptual model of an interconnected information network available to all supply chain stakeholders.

This network provides the infrastructure framework for discovering, accessing and sharing information about the products, locations, transactions and visibility events that occur within the supply chain. Part of this vision is the thought that quality information should be accessed from the source of that information. For example, product information is available as the manufacturer has defined it, company, location, transaction and visibility information are sourced from the stakeholder who authored it. The vision also includes the use of shared repositories for use by multiple stakeholders (master data) and transaction and visibility event data held by the authoring stakeholder. Key to enabling this distributed information model is the capability to discover the location of needed data and how to electronically request and share the data.

Conceptually, the team envisions an infrastructure where transaction information flows between trading partners, information is discoverable and accessible from original sources, key pharmacy sector defined services are connected to and available within the network and stakeholders can exchange information in a permissioned, legible manner.

This infrastructure provides each stakeholder, at all levels of electronic system capability, the agency to participate in a legible eco-system.

A fundamental assumption of the vision is that Canada will leverage infrastructure developed to support other geographies, which includes:

- product identification using GTIN, lot # and Exp
- building on existing product identification infrastructure (GTIN registered to ECCnet and providing a cross reference to the Health Canada Drug Identification Number)
- interoperability of solutions (i.e. EMR)
- the need for real-time or near-real-time visibility to inventory
Traceability Use Cases

The Traceability Expert Group worked from an initial set of four use cases and added three as a result of exploring traceability and root causes for issues experienced in day to day operations. For the purposes of clarity, some of the individual use cases were broken down to individual components (such as Vaccine Traceability and Immunization Traceability) as the components represented different process flows.

Initial Traceability Use Cases:

1) Supply Chain Security and Efficiency
   i) Procure to pay, including Controlled Substances
   ii) Anti-Counterfeit and Diversion measures

2) Pharmacy / Hospital enhanced value
   i) Barcode Medication Administration (BCMA)
   ii) Analytics: Clinical Outcomes and Value-Based Procurement
   iii) Lot Based Product Recall

3) Vaccine and Immunization Traceability

4) Legalization, Regulation and Access to Cannabis (medical)

Use Cases added by the team:

5) Demand Forecasting (Vaccines and Pharmaceuticals)

6) Drug Shortage Mitigation

7) Medication Traceability (traceability to the patient)²

Of the traceability use cases that were provided, two were far ranging in scope (Vaccine Traceability and Cannabis Traceability), incorporating both foundational and transformational elements. The complexity of the remaining use cases was determined based on whether the interactions were between trading partners with established relationships (adjacent) or with trading partners that may not have an established relationship. Interactions between trading partners without an established relationship require transformational elements such as Discovery of information or services, and a means of authenticating the trading partner in question and rule guidance for granting authorization to information or services.

Use Case complexity

In order to better appreciate the complexity of the use cases, the following diagram plots each use case along two dimensions, whether the use case defines new or emerging electronic interactions between stakeholders and whether the infrastructure needs of the

² Added to emphasize healthcare provider manipulation and processing of medications
use case is foundational (supporting infrastructure exists) or transformational (new infrastructure is needed).

**Figure 2 - Understanding interaction complexity and grouping**

**Traceability Use Cases – Value and risk of not addressing**

The team assessed the value of each use case and the risk of not addressing each use case. This information is meant to be helpful to the Pharmacy Sector Board in assigning priority to
the use cases and in establishing individual working groups to address infrastructure, guidance and standards needs.

<table>
<thead>
<tr>
<th>Traceability Use Cases</th>
<th>Pharmacy Sector Value</th>
<th>Risk of Not Addressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Substances Procure to Pay</td>
<td>Increase efficiency, accurate orders, shipments and deliveries. Improved visibility to product movement which can support pharmacy sector responses to opioid crisis.</td>
<td>Higher cost of maintaining a level of rework due to inaccuracies within the supply chain due to order, shipping and delivery errors.</td>
</tr>
<tr>
<td>Anti-Counterfeit &amp; Diversion</td>
<td>Ensure safety of the Canadian supply chain. Additionally, traceability capability could be useful in tracing patient samples and personalized medication to the patient.</td>
<td>Efforts of other countries (US, EU, etc.) may cause Canada to be seen as unprotected and an opportunity for nefarious actors.</td>
</tr>
<tr>
<td>Barcode Medication Administration</td>
<td>Establishes accurate record for analytics, effective recalls and adverse event reporting. Includes all products that are administered, compounded or prepared. Improved patient outcomes through greater visibility of patient records across the clinical system.</td>
<td>Unacceptable amount of administration errors. Medication administration errors (for example: wrong medicine, wrong dose, etc.).</td>
</tr>
<tr>
<td>Lot Based Product Recall</td>
<td>Patient safety, through accurate and efficient removal of recalled product and prevention of administration to patients of recalled product.</td>
<td>Patient safety – recalled product dispensed or administered to patients inadvertently. Recalled product remains undetected in supply chain. Higher recall cost</td>
</tr>
<tr>
<td>Clinical Outcomes Analytics</td>
<td>Pharmacoeconomics, patient therapeutic and safety outcomes.</td>
<td>Patient safety and lack of enabling clinical scientific evidence for health outcomes</td>
</tr>
<tr>
<td>Value Based Procurement Analytics</td>
<td>Can increase patient access to new therapies. Provide solutions that best delivers needed output and reduce total cost of healthcare.</td>
<td>Continued focus on individual product cost rather than outcome. Risk poorer health outcomes and higher overall cost.</td>
</tr>
<tr>
<td>Vaccine Traceability</td>
<td>Increased vaccine availability to patients. Insight into location of vaccines to address localized shortages. Accurate movement of temperature sensitive product. Improved visibility to inventory enabling optimization of distribution and waste reduction.</td>
<td>Increased cost due to unnecessary high levels of safety stock kept throughout the supply chain. Potential for localized shortages.</td>
</tr>
<tr>
<td>Immunization Traceability</td>
<td>Patient safety, through accurate patient records. Less risk of miss-immunization. Also, an enabler for clinical outcome analytics, understanding of immunization program effectiveness.</td>
<td>Patient safety for at risk patient populations due to poor immunization coverage. Potential for patient harm due to inability to detect recalled, adulterated or damaged product administration.</td>
</tr>
<tr>
<td>Medication Traceability</td>
<td>Increased availability of medicines to patients. Patient safety through accurate recall and identification of expired product. Efficiencies throughout the supply chain due to accurate order to cash records. Accurate movement of temperature sensitive product. Improved visibility to inventory enabling optimization of distribution and waste reduction.</td>
<td>Inaccurate orders, shipments and deliveries. Inability to identify and remove damaged or adulterated product. Increased cost due to unnecessary high levels of safety stock kept throughout the supply chain. Potential for localized shortages.</td>
</tr>
<tr>
<td>Cannabis Traceability</td>
<td>Patient and consumer safety through accurate recall and identification of expired product. Efficiencies throughout the supply chain due to accurate order to cash records. Ensures accurate tax revenue. Increased visibility to inventory movement to ensure supply and understanding of product origin, reduce risk of introduction of illegal product.</td>
<td>Inaccurate orders, shipments and deliveries. Inability to identify and remove damaged or adulterated product. Potential loss of tax revenue.</td>
</tr>
<tr>
<td>Demand Forecasting</td>
<td>Patient safety through efficient use of inventories, reduction in shortages. Cost savings through accurate production planning and possible reduction in safety stock levels throughout the supply chain. Improve anticipation of returns.</td>
<td>Potential patient safety issues due to potential for shortages. High cost due to high safety stock levels.</td>
</tr>
<tr>
<td>Drug Shortage Mitigation</td>
<td>Proactively detect pending shortages, negotiate and direct movement of existing inventories to areas of shortages.</td>
<td>Remain reactionary to shortages. Risk to patient safety. High cost and inefficiencies of holding high safety stock inventories throughout the supply chain.</td>
</tr>
</tbody>
</table>

*Figure 3 – Use Cases, Value and Risk*
A Framework for Traceability Development

Figure 2 represents a framework for traceability support. It recognizes that the complexity of the use cases requires a foundation of existing and new Standards and Guidelines, access to shared data repositories and services, the development of individual digital business interaction guidances and industry governance to set access interaction rules.

Infrastruture Guiding Principles

The Traceability Expert Group recognizes that the traceability use cases provided, call for new interactions between stakeholders within the pharmacy sector. The following principals were adopted in order to ensure access by all stakeholders while maintaining quality checks and security mechanisms that are needed to manage the flow of information between and among stakeholders.

Providing the agency and access to all stakeholders – provide an infrastructure that allows stakeholders with all levels of technical capability to participate directly or through services (proxy).

Navigable infrastructure – provide mechanisms to allow stakeholders to navigate the infrastructure for complex use case needs (immunization analytics, clinical outcomes, recall, shortage management, forecasting).
Permissioned Visibility – allow for access to information sets based on pre-negotiated or as-negotiated permission agreements.

Establish a legible eco-system – utilizing standardized identifiers, data sets and information sharing protocols (EDI, EPCIS, GDSN, etc.)

Query-able, Structured Datasets – identify standardized datasets, transactions and events that can be shared, queried and accessed by stakeholders.

Increased cooperation between Stakeholders – provide an infrastructure that assumes cooperation across the public and private supply chains including best practices and standardized data exchange.

Increased access to original data – allows for registries, services and connections to information under the control and upkeep of the data source.

Conceptual Architectural Model

As the team explored and contrasted the needs of the use cases, it became apparent that most use cases share similar capabilities that could be transformational to supply chain stakeholders. Traditional transactions occur between healthcare collaborative partners. They authenticate, authorize and exchange information and messages. These “collaborative interactions” occur between pairs of healthcare partners up and down the supply chain on an hourly basis. From a pure traceability perspective (trace where a product goes / track where it came from), these business interactions can be linked together to provide a one-up / one-down traceability eco-system supported by well-established GS1 Standards such as EPCIS.

The use case set that the Traceability Expert Team was given includes the need for information sharing beyond the one-up / one-down trading partner pairs. These non-adjacent supply chain partner interactions require a new infrastructure framework for the pharmaceutical supply chain. One that is capable of digitally discovering needed information and services, authenticating and authorizing with the owner or holder of that information and lastly exchanging non-traditional data sets. Figure 10 – Transformational use cases are supported by a digitally interconnected network depicts an infrastructure where supply chain stakeholders have digital access to each other and to shared pharmacy sector information repositories and services.

We can see examples of this in the use cases of Analytics, Recall, Demand Forecasting, Drug Shortage Mitigation and others. These use cases require the capability to reach across the supply chain to companies and government agencies that are not established trading partners, develop the necessary trust in each other in order to establish an electronic connection and exchange information.

The Traceability Expert Group established a concept model for a traceability infrastructure that would interconnect all stakeholders and provide access to industry defined shared data repositories and services.

Figure 5 depicts a sample of stakeholders accessing shared data repositories and services.
To support the foundational and transformational use cases, we need to be able to find information repositories and services and negotiate access in real time.

Figure 5 - Pharmaceutical Sector Stakeholders accessing Industry defined Data Repositories and Services

The Concept Model (Figure 6) depicts stakeholders accessing shared data repositories and services. Stakeholders are also able to electronically interact with each other directly either through traditional transactions (such as procure to pay messages) or new interactions (such as analytics, forecasting and anti-counterfeit interactions).

The ability to access data and services across the pharmaceutical supply chain and clinical areas is central to many of the use cases. These use cases share a common pattern in that they depict stakeholders that normally do not interact with each other to securely digitally connect and exchange information. This requires a new way of digitally discovering each other, authenticating each other and accessing new information sets and services.

This concept model conforms to and supports the Infrastructure Guiding Principals outlined in the previous section.
In this vision, stakeholders are capable of:

1. discovering information and service sources (including other stakeholder’s systems) and services
2. connect to those information sources and services
3. authenticate that the source is legitimate
4. provide proof of the stakeholder’s identity and credentials that allow the information source or service to authenticate and authorize the stakeholder to access the information or service
5. engage in an agreed digital interaction (request/response) with the information source or service
6. Accomplish all the above securely, efficiently and privately

To achieve these transformational capabilities, the sector is recommended to explore, pilot and adopt:

1. A means to discover information sources and services such as:
   a. GS1 Digital Link
   b. Discovery registries
7. A means to authenticate and authorize information and services seekers and providers which may include:
   a. Identity
   b. Verifiable Credentials
   c. Pharmacy Sector approved digital interaction models

Centralized and Decentralized Components
The Concept Model includes centralized infrastructure such as shared, pharmacy sector defined and adopted repositories and services.

![Figure 7 – Centralized, shared, sector defined and adopted repositories and services](image)

The model also allows for decentralized, or individual repositories and services that stakeholders may make available on a permissioned basis.

![Figure 8 - Decentralized infrastructure components](image)
Figure 9 - Use Cases requiring new methods of access, permission and interaction

Fortunately, new uses of existing and developing standards and technologies are available to create transformational infrastructure components needed to link the entire supply chain, access information sources and realize transformational capabilities inherent in these new use cases.

Within GS1 and other Standards bodies (e.g. W3C, schema.org, etc.), it has been recognized that all interactions start with identity. Identity is central to Authentication\(^3\) of stakeholders in a digital environment and Authorization\(^4\) of those stakeholders to access needed data and services. These features help establish data sharing relationships between stakeholders. Figure 7 shows the use cases that can benefit from these new methods of providing transformational access and permission to services and information.

\(^3\) Authentication: confirmation of a stakeholder’s identity

\(^4\) Authorization: establishing a stakeholder’s credentials for access to a system or information
There are numerous efforts underway to establish a trust framework where supply chain partners who have need of information held by another stakeholder, registry or service can provide digital proof to enable the stakeholder, registry or service to authentication and authorization access to information. Most notably:

1. British Columbia⁵ is exploring the use of Decentralized Identifiers and Verifiable Claims to establish a means of authenticating companies doing business in British Columbia (have established a license). These Decentralized Identifiers are owned by the company doing business and can be used to establish an identity for interactions with other stakeholders, registries and services. These identifiers can be associate with established GLNs in order to connect traditional procure to pay relationships with the type of relationships needed for anti-counterfeit processes, analytics access, demand forecast signals, etc.

8. The Digital ID & Authentication Council of Canada has established a Pan-Canadian Trust Framework⁶. The Pan-Canadian Trust Framework ™ (PCTF) describes the roles and requirements to be agreed on by participating public and private sector organizations, to meet current and future Canadian innovation needs. PCTF documents and artefacts are intended to secure interoperability of public and private sector identity capabilities while prioritizing user-centred design, privacy, security, and convenience of use.

Concept Model Technical Vision

While the Business Vision outlines the “what” of the proposed infrastructure, the technical vision proposes the “how”. Over the years, information exchange infrastructures have been established, matured and changed rapidly as technology advances have been realized. Since the early 1970’s Electronic Data Interchange (EDI) serves as an example of standardized transaction formats for information exchange between enterprises. However, not all stakeholders are able to utilize complex exchange mechanisms or have structured processes in place to take advantage of the information they provide.

Since the development of the internet, enterprises have converged on more flexible, less complex architectures. While legacy systems and architectures will remain in play for some stakeholders, others may migrate to new architectures that provide simplicity and flexibility. Access to new sources of information provide new capabilities and new ways of doing business.

This technical vision leverages mature infrastructures such as product and location identification, master data repositories, application programming interfaces (APIs) and

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Pan-Canadian Trust Framework: (https://drive.google.com/a/gcdigital.canada.ca/file/d/1Xmjh8QJZKWmRkaTtE2f43ISntD7jE6DS/view?usp=sharing)

⁶ DIACC Pan-Canadian Trust Framework (https://diacc.ca/pan-canadian-trust-framework/)
pharmacy sector defined services for quality information. This includes the permeation throughout all operational, transactional and visibility systems of:

- Standardized identifiers:
  - Products
  - Entities
  - Locations
  - Shipments
  - Service Relations
- Master product registries enabling a trusted source of truth
- Standard data definitions
- Standard messaging formats
- Standard Barcoding and Labeling formats

These components along with emerging components such as discovery services, visibility event data sharing and decentralized identifiers (DID) allow us to establish an electronic infrastructure that will meet the business vision defined above.

The business vision of an interconnected supply chain requires that:

- products, companies and locations are uniquely identified
- foundational information is available to all in the form of master data registries
- services are available to manage critical processes such as recall
- data sources are discoverable and accessible by all stakeholders

The business vision is made possible through a multi-layered infrastructure which includes:

**Foundational Infrastructure Components:**

Foundational infrastructure components are crucial to improving the quality of information available to the supply chain stakeholders and enable further levels of automation leading to efficient practices. Transformational use cases and their needed infrastructure builds on top of the foundational infrastructure and are difficult if not impossible to achieve without foundational elements in place.

- Products identified and barcoded with traceability in mind
  - GS1 DataMatrix including:
    - GTIN
    - Serial Number
    - Lot Number
    - Expiration Date
- GS1-128 barcodes on logistics units labelled and identified with a Serial Shipping Container Code (SSCC)
- Product master data registry with standardized data attributes
- Company, location registries with standardized data attributes

**Operational Infrastructure Components:**

- Procure to Pay standardized transactions

**Traceability / Visibility Infrastructure Components:**

- Discovery Services (see appendix) as a means for stakeholders to electronically “find” each other for the purposes of requesting and sharing data
- Decentralized Identifiers (DID) Management (see appendix)
- API Specifications
- Increased use of accessible data formats (JSON, JSON-LD)
- Increased emphasis on quality data (original source, repositories, JSON-LD schema)
- Interconnected information network (Discovery, digital link, light weight messaging standard, repositories)
- Increase safety (recall service, data access and broadcast, best practices)
  - shortages, pandemic, disaster recovery
Recommendations

Supporting the traceability use cases fully will take time and effort on the part of sector stakeholders and GS1 Canada. The Concept Model includes foundational and transformational infrastructure components. As these infrastructure components are implemented and new capabilities are established, the roadmaps and interaction models will need to be revisited and revised.

The Traceability Expert Group recognizes the following:

1. adding Lot Number and Expiration Date to the barcode would provide an immediate benefit to patient health and sector stakeholders by providing the capability of:
   • Prevent dispensing and administering recalled product to patients
   • Increasing accuracy and reliability of health records through automation
   • Reducing waste by managing inventories by expiration date

2. although the Canadian drug supply is very safe, Canada must stay on par with other geographies in order to not become a target of nefarious actors. This includes serialization and traceability capabilities. Canada should not have anything less than other regions in the world.

3. Manufacturers serving other markets have or are developing serialization and traceability capability. Those manufactures would need to go through a process of label redesign and Health Canada approval to bring those capabilities to the Canadian market. Certain manufacturers produce product solely for the Canadian market and may not have developed serialization and traceability capabilities.

The Traceability Expert Group makes the following recommendations based on the analysis of the traceability use cases, global traceability activities, existing and future infrastructure developments.

Pharmacy sector-wide governance model recommendations

1. Develop a governance / oversight structure to achieve consensus on pharmacy sector Digital Interaction Models and pharmacy sector shared investments. GS1 Canada can provide the necessary support and neutral venue (antitrust adherence) to support a governance body.

Infrastructure Support recommendations

1. Full adaptation of the ECCnet Registry for all products, defining the entire packaging hierarchy down to unit dose.

2. Adoption of ECCnet product registry across the supply and clinical chain to eliminate duplication of product data and reduce the effort to keep that data current (Ex: Vaccine Identification Database).

3. Adoption of variable data in the label (human readable and barcode - GTIN, Lot & Exp Date) at all packaging levels.

4. Adherence to existing GS1 barcode standards.
5. Adoption of GS1 DataMatrix on lowest unit of sale and unit of use and sunsetting of the linear barcode with a clear transition period.

6. Fully deploy GTIN as product identifier and GLN as entity/location identifier in Procure to pay transactions (EDI).

7. Adopt and populate Global Location Number (GLN) registry (ECCnet Locations).

8. Complete current deployment of ECCnet Product Recall notification and extend across the healthcare supply chain.

9. Examine the feasibility to develop a community-based information discovery services to support authentication and authorization.

Use Case recommendations

1. Pharmacy Sector Board to establish priority of the traceability use cases.

2. GS1 Canada to establish working groups for each priority use case to develop a Digital Interaction Model per use case that defines:
   - Process flows
   - Information flows
   - Interaction rules
   - Standards enhancements
   - Implementation Guidelines

Product Bar coding and labelling recommendations

1. GS1 Canada’s Pharmacy Board, in collaboration with the pharmacy sector, to develop a draft pharmacy sector policy position for Health Canada on harmonizing with the position of global users and other countries who have deployed serialization, barcoding, labelling and traceability.

2. Pharmacy sector stakeholders across the healthcare supply chain to prepare for 2D barcode scanning as DataMatrix barcodes are implemented.

3. Canada pharmacy sector to implement barcoding, labeling and traceability capability and infrastructure in a phased approach.
Recommended Next Steps

In order to start the process of strategic investment in the foundational and transformational aspects of this infrastructure, the Traceability Expert Group recommends the following next steps:

1. GS1 Canada to survey the pharmacy sector stakeholders on their state of readiness for each use case.
2. GS1 Canada Pharmaceutical Board to Prioritize the use cases.
3. GS1 Canada and pharmacy sector to develop a draft pharmacy sector policy position for Health Canada on harmonizing with the position of global users and other countries who have deployed serialization, barcoding, labelling and traceability.
4. Pharmacy sector stakeholders across the healthcare supply chain to prepare for 2D barcode scanning as DataMatrix barcodes are implemented.
5. GS1 Canada to work with the pharmacy sector and establish work group(s) in accordance with Use Case prioritization to:
   - develop interaction models for each use case
   - prepare identification and labelling specifications for manufacturers
   - develop a guideline on unbarcoded product procedure (product data authentication)
   - accelerate sector wide GLN assignment and authentication
   - Fully populate ECCnet to include entire hierarchy down to unit dose (inclusive of use case attributes)
   - Explore and develop an information discovery service
   - Explore and develop infrastructure to support integrity of the network and stakeholders (authentication and authorization)
6. GS1 Canada to present a detailed plan and cost-recovery model, in accordance with industry prioritization.
The following material was created as part of the Traceability Expert Group exploration and may be helpful to future GS1 Canada Work Groups that address the specific use cases and shared infrastructure components.

**Pharmaceutical Barcoding Policy Harmonization – recommended timeline**

<table>
<thead>
<tr>
<th>Year</th>
<th>EU: GS1 DataMatrix and Human Readable (GTIN, Serial Number, Lot Number, Expiration Date, National # (opt))</th>
<th>Manufacturer: Product registration</th>
<th>Wholesaler: Risk-Based Product Verification</th>
<th>US: GS1 DataMatrix and Human Readable (GTIN, Serial Number, Lot Number Expiration Date, NDC embedded in GTIN)</th>
<th>Canada: Manufacturer, Wholesaler, Dispenser - Unit of sale Traceability</th>
<th>Dispenser - Unit of sale Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>2023: Canada: GS1 DataMatrix and Human Readable (GTIN, Serial Number, Lot Number, Expiration Date, DIN mapped to GTIN in Product Registry)</td>
<td>2019: EU: GS1 DataMatrix and Human Readable (GTIN, Serial Number, Lot Number, Expiration Date, National # (opt))</td>
<td>2025: Canada: GS1 DataMatrix and Human Readable (GTIN, Serial Number, Lot Number, Expiration Date)</td>
<td>2023: US: Manufacturer, Wholesaler, Dispenser - Unit of sale Traceability</td>
<td>2020 + Canada: Manufacturer, Wholesaler, Dispenser - Unit of sale Traceability</td>
<td>[Based on current threat and value analysis]</td>
</tr>
</tbody>
</table>
Proposed Roadmaps

In order to achieve the capabilities needed in the Traceability Use Case Set, certain foundational and strategic infrastructure investments are recommended. The use cases identified as having transformational infrastructure requirements (*Figure 6*), depend on the foundational roadmap elements being in place.

**Barcoding Labelling and Traceability Roadmap:**

**Pharmacy Sector Stakeholders**
- Prepare for 2D barcode scanning
- Multi-market manufacturers: Label changes to include DataMatrix, GTIN, Lot, Exp, Serial Number (Opt)
- Canadian only-market manufacturers: Label changes to include DataMatrix, GTIN, Lot, Exp

**GS1 Canada and Pharmacy Sector**
- Traceability Guidance
- Unbundled product guidance

**GS1 Canada**
- Stakeholder state of readiness survey
- State of Traceability and readiness survey

**Timeframes**
- 1 – 3 Years
- 3 – 5 Years
- +5 Years
Infrastructure Roadmaps:

Traceability Roadmap: Foundational Infrastructure Investment

<table>
<thead>
<tr>
<th>Stakeholder Actions and Value</th>
<th>1 - 3 Years</th>
<th>3 - 5 Years</th>
<th>+5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Registry Adoption</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Location Registry Adoption</td>
<td></td>
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Shared infrastructure Development

- Product Registry
- Location Registry

Standards / Guidelines Development

- GTIN Allocation Rules
- GLN Assignment Guideline
- GTIN/Serial/Exp Labeling Guideline
- SSCC Guideline

Use Case Digital Interaction Models as prioritized by the Pharmaceutical Sector Board

Key:
- Complete
- Manufacturer
- Dispenser
- Wholesaler
- Health CA/Provinces

Figure 10 - Foundational Infrastructure Roadmap
## Traceability Roadmap: Transformational Infrastructure Investments

<table>
<thead>
<tr>
<th>Stakeholder Actions and Value</th>
<th>Governance Participation</th>
<th>Industry Alignment on Digital Interactions</th>
<th>Recall Registry/Service Adoption</th>
<th>Targeted Recalls</th>
<th>Traceability Adoption</th>
<th>Shipment level Recall</th>
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<td>Traceability Adoption</td>
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<td>Cannabis Traceability</td>
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</table>

### Shared Infrastructure Development

- Product Registry
- Location Registry
- Recall Registry

### Standards / Guidelines Development

- Governance Structure
- Discovery
- Digital Link Guidance
- Identity/Authentication Authorization Model
- GLN / Identity Mapping Guidance

Use Case Digital Interaction Models as prioritised by the Pharmaceutical Sector Board

### Timeline

- **1 – 3 Years**
- **3 – 5 Years**
- **+5 Years**

---

**Figure 11 - Transformational Roadmap - Strategic Investments**
Exploration Method

The team embodied supply chain participants that are involved in the processes defined in the use case set. The goal of team discussions was to understand the use cases enough that a generalized architecture could be developed and assessed against the capability needs of the use cases.

Throughout the assessment, the team:

- Identified a set of infrastructure guiding principals
- Reviewed each traceability Use Case
- Identified capabilities required by each use case
- Identified Infrastructure needs
- Classified Infrastructure components (Foundational and Transformational)

Use Case drivers gave shape to functional abilities (referred to as capabilities here). The capabilities were used to derive an infrastructure that can support those capabilities and create new value for stakeholders.

The Expert Group considered where the infrastructure investment could be shared as a pharmacy sector solution. The Expert Group also considered that pharmacy sector capacity may already exist and be leveraged. For example:

- Data sharing standards already exist for basic supply chain functions and can be extended to support sharing of product movement details.
- Product master data management and sharing infrastructure and new product introduction processes exist in ECCnet.
- Pharmacy Sector classification schemes (SNOWMED, GMD) exist and are maintained and can be integrated into the Canadian infrastructure.
- Product recall services exist.
- Product serialization can be used where precise identification creates value (controlled substances, EMR records at the unit dose level).

Use Cases define interactions between supply chain stakeholders. From a systems perspective, each use case requires the development of process flows, information flows and sets of rules stakeholders agree to. We refer to this set of documentation as Digital Interaction Models. Each Digital Interaction Model defines the electronic interactions between stakeholder systems, external information repositories and services. Digital Interaction Models provide standards-based information exchange and Interaction Rules to
aid pharmacy sector stakeholders and solution providers in implementing interoperable systems.

The Expert Group found similarities across the use cases which confirmed that:

- Many capabilities are common to multiple use cases.
- Some infrastructure is foundational (such as product and location registries) and relevant to all use cases.
- Data quality is foundational to all use cases.
- Most use cases require new infrastructure components. These use cases and infrastructure components were defined as transformational in that they will provide a new level of value to patients and supply chain stakeholders.

Lastly, consideration was given to new developments in standards development (GS1, W3C\(^7\), etc.) that can be leveraged the transformational interactions.

\(^7\) W3C: World Wide Web Consortium
Significant Findings
The team had an initial set of assumptions going into the exploration. A majority were bore out by the exploration process and a few were challenged.

Initial assumptions confirmed

**The value of current pharmacy sector investment in Product ID, Location ID and Product Recall.**

These investments can accelerate improvement in patient safety measures through accurate and efficient identification of the drug and drug state (expired or recalled product) that may affect patients.

**The value of shared investment in pharmacy sector registries to support non-competitive business practices:**

Almost all use cases benefit from the use of shared registries such as product, entity and location registries. This fundamental infrastructure provides an efficient means of sharing critical data and to provide quality controls on that data. Their use can be extended to bring new value to a wider stakeholder group (eg. Vaccine supply managers at the provincial and regional levels) and extend recall across the value-chain. Registries will optimize cannabis supply chain functions through access to complete and quality product data helping the pharmacy sector to engender greater trust with healthcare professionals and ultimately patients.

**Foundational Standards are in place.**

The existing standards categorized in the GS1 System of Standards as Identify, Capture and Share are foundational to all the use cases examined.

**The needed infrastructure can be leveraged across the use cases.**

An example is “visibility to inventory movement” which can be leveraged by the Drug Shortage Mitigation use case as well as Demand Forecasting.

**Existing capabilities supporting the Vaccine Supply Chain**

As the team explored the use cases, it became apparent that the vaccine supply chain has several traceability infrastructure components in place that already provide much needed quality information throughout the supply chain.

- Vaccines are identified and barcoded with a GTIN, Lot Number and Expiration Date
- Vaccine barcodes are scanned at multiple places in the supply chain
  - For inventory purposes
  - For immunization records
- Vaccine and immunization analytics occur within Provincial vaccine schedules
Although the vaccine supply chain already has certain traceability infrastructure components in place, it does hold challenges:

- Multiplicity of product master data repositories
- Entity and Location Identifiers (GLN) not used in order to pay transactions
- Lack of product returns signal, leading to wasted product, possible localized shortages, increased cost to system

**Initial assumptions challenged**

Besides the initial set of use cases, the effort was begun with a few assumptions or hypothesis that were adjusted in discussions amongst the expert team.

**Counterfeit drugs in Canada:**

Much as in the EU, US and other countries, it was thought that the “Counterfeit and Diversion” use case would be a strong driver of traceability requirements within Canada. As reference material was examined and discussions took place within the expert team, a clearer understanding of the Canadian supply chain evolved. Two factors contributed to the reassessment of the “Counterfeit and Diversion” use case.

1. The Canadian drug supply chain is [thankfully] less complex than the EU or US supply chains. The Canadian drug supply chain does not have the proliferation of secondary wholesalers and the practice of extended movements of product among supply chain participants. Most drugs either pass directly from the manufacturer to the health care provider (hospital or retail) or pass through a single wholesaler. This lack of complex trades creates less opportunity for counterfeit drugs to enter the legitimate supply chain.

2. There are very few documented incidences of counterfeit product found in Canadian literature searches. This is backed up by the experience of expert team members.

While the Counterfeit use case isn’t as strong as first envisioned, the Expert Team believe that taking steps to further secure the Canadian supply chain is necessary to prevent criminals from perceiving Canada as a less protected opportunity.

**Leveraging capabilities developed for other countries**

The pharmaceutical supply chain is global. Many participants in the Canadian supply chain also operate in countries that require product serialization and traceability. The initial assumption was that global manufacturers and wholesalers could extend those capabilities to the Canadian market. While these capabilities can be leveraged, to do so, manufacturers of product destined for the Canadian market, must make label changes to accommodate new barcodes, submit the changes to Health Canada for approval and adjust production schedules in order to supply Canada with serialized product. The net result is that the capability can be leveraged, but the timeline will not be immediate as label changes are made.
However, the Expert Group concluded that a central model is appropriate for master data (product and entity/location). Decentralized data capture and sharing is the preferred model for transactional data (procure to pay and traceability events) and data discovery.
## Guiding Principles and Use Case Analysis

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<th>Guiding Principles Analysis - Use Cases</th>
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<th>Establish a legible ecosystem</th>
<th>Query-able, Structured Datasets</th>
<th>Increased cooperation between Stakeholders</th>
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<td>Fully deploy (all products, entire hierarchy down to unit dose) of ECCnet product registry to support current and added use cases</td>
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<td>Adoption of ECCnet product registry to replace Vaccine Identification Database (VIDS)</td>
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<td>Fully deploy GTIN as product identifier and GLN as entity/location identifier in Procure to pay transactions</td>
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<td>Populate (via supply chain mapping) and adopt the GLN registry</td>
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Additions to the Technical Infrastructure Recommendations

Product Identification and Barcoding

The Traceability Expert Group projects that manufacturers serving the Canadian market have the capability to identify and mark pharmaceutical products with a GS1 DataMatrix containing a GTIN, Serial Number, Lot Number and Expiration Date. Providing product so identified and marked will allow for support of new capabilities (see Figure 9 – Use Cases, Value and Risk) such as Recall, Anti-Counterfeit, immunization traceability and cannabis traceability.

However, due to labelling differences between Canadian bound products and other country bound products, most manufacturers will not move to a GS1 DataMatrix on their own. Adding a GS1 DataMatrix to a pharmaceutical product constitutes a label change (addition of the barcode and movement of other label elements to make space for the barcode) and must be approved by Health Canada.

Experience from the US and other regions show that guidance and education is needed to transition to the use of barcodes which include additional data elements. The transition period from labels containing just a linear barcode to labels containing both require training within the supply chain and within clinical environments regarding which barcode to scan.
For these reasons, it is recommended that the position statement reflect a move to the GS1 DataMatrix encoded with the four data attributes and guidance be developed to transition the pharmacy sector through the process.

**Infrastructure Architecture Recommendations**

The Traceability Expert Group projects that a decentralized approach toward visibility and traceability capability is the most feasible path for Canada. Although centralized systems are architecturally simpler than decentralized strategies, it is thought that decentralized components could be implemented in a phased approach within the supply chain for key interactions (recall, shortages, product verification) earlier than mobilizing the entire public and private supply chain towards a centralized approach.

**Patient Safety Strategy**

As the Canadian supply chain includes a small number of known stakeholders, patient safety checks (expiration check, recall check, verification check) may be an early win for Canadian patients prior to full traceability enablement.

**Solution Provider Recommendations**

During discussions within the Traceability Expert Group, the issue of solution provider role in implementing the final traceability infrastructure roadmap came up. In many cases, pharmacy sector stakeholders will experience implementation of the roadmap through updates to applications provided by solution providers.

The roadmap will provide insight into the timeframes in which each stakeholder type is projected to be able to implement and use traceability components. The roadmap should be
shared with solution providers that support stakeholders to enable them to plan changes to their applications.

**Clinician Acceptance Issues**

Many of the remaining use cases that the expert group will explore, rely on enhanced capabilities of downstream partners (healthcare providers). We will add to this section as workgroup teams address those use cases. However, we have already discussed issues that clinicians have identified. For any technology to be acceptable in the clinical setting, it must be simple to use, reliable and provide quality information.

- **The need for a single barcode on packaging:** Today, secondary packaging may carry many barcodes, serving different purposes. Clinicians may be confused by packaging that may include linear, DataMatrix and production purposed barcodes. Using a single DataMatrix barcode is critical to minimizing the potential for this confusion.

- **Systems may or may not be able to accept the information in all barcodes:** Over the course of the implementation roadmap, stakeholder systems must be upgraded to be able to read the standardized, GS1 DataMatrix barcode. Systems must be able to extract the data that they need from this barcode.

- **Barcode quality is an issue that affects clinicians trust in barcoding systems:** Poor quality, non-standard and multiple barcodes all lead to clinicians wasting precious time trying to access needed quality information and reliable quality checks. This is exacerbated by the pressures put upon the clinician to perform efficiently brought on by limited healthcare government budgets, healthcare provider cuts in wages and staff.
## Relationship between Use Cases and Foundational Infrastructure

### Foundational Components

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<tr>
<th>Traceability Use Cases</th>
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<th>SSCC</th>
<th>GLN</th>
<th>GS1N</th>
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### Identification

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<th>GS1 128 (GTIN &amp; Lot)</th>
<th>Mixed cases and pallets: GS1 128 (SSCC)</th>
<th>Product Master Data Management</th>
<th>Entity / Location Master Data Management</th>
<th>Standardized Order to Pay transactions using GS1 Identifiers</th>
<th>Traceability Events (EPCIS)</th>
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## Relationship between Use Cases and Transformational Infrastructure

### Transformational Components

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*Figure 14 - Use Cases and Foundational Infrastructure Components*

*Figure 15 - Use Cases and Transformational Infrastructure Component*