

Roadmap to the Implementation of GS1 DataMatrix Barcodes on Pharmaceuticals in Canada

February 2022



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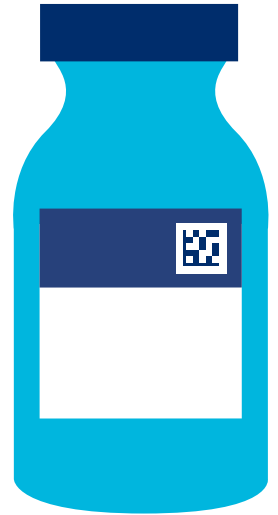
Canada is advancing action to align with the global movement for the adoption of 2D barcodes (GS1 DataMatrix) on pharmaceuticals. Patient safety, best practices in dispensing to patient record workflow, along with improvements to supply chain traceability capabilities are the strategic imperatives driving this movement.

GS1 Canada's Pharmacy Board has approved the pharmaceutical barcoding adoption roadmap detailing readiness expectations of relative stakeholders - manufacturers, distributors and pharmacies.

All categories of pharmaceuticals are included – prescription drugs, behind-the-counter, over-the-counter (OTC), and natural product (NPN).

This roadmap guides the 2025 deadline for system-wide capabilities in Canada to scan, store and process the GS1 DataMatrix barcode that contain the Global Trade Item Number (GTIN – the number below the barcode), lot number, and expiry date (serial number is optional).

The approval also directed a corresponding action plan that includes community engagement and taking a collaborative approach to request that Health Canada introduces regulations to harmonize pharmaceutical barcoding requirements in alignment with regulators around the globe.



Background – Why Now?

Concerns for safety have given rise to the urgent and strategic request for greater supply chain visibility capabilities enabled through global standards, including barcodes. With the reality that medical errors are the third leading cause of death in North Americaⁱ, combined with the COVID-19 crisis exposing the vulnerabilities linked to significant lack of visibility in the supply chain and resulting challenges with drug shortages, the pharmacy community is advancing a pharmaceutical barcoding implementation action plan and a corresponding government relations strategy.

Global leaders of pharmaceutical manufacturing, including the United States, European Union, and India, all have regulations to align globally, with specific deadlines to deliver critical data such as the GTIN, lot number and expiry date within one globally-standardized barcode at the saleable unit, the GS1 DataMatrix. Considering more than half of Canadian pharmaceutical production is exported and over 78% of the Canadian pharmaceutical market is supplied by imports from the US and EUⁱⁱ, Canada is in a strong position to benefit from manufacturer readiness in a significant way.

Canada's goal is that only one GS1 DataMatrix barcode will be on pharmaceutical products at both the primary and secondary packaging level. This level of barcode readiness will enable:

- Reduction in medical errors and improvements in patient care outcomes
- Traceability capabilities for each product right down to bedside scanning and to the patient record
- Lot-based product recalls to the inventory and patient-level
- Elimination of risk and resources dedicated to barcode re-labelling at the primary and secondary packaging level

- Forecasting data to mitigate shortages
- Predictive analytics for clinical outcomes and value-based procurement
- Visibility into the supply chain for inventory management
- Reduction of waste and costs
- Prevention of fraudulent or poor-quality product entering Canada's supply chain

The recommended Adoption Roadmap for Pharmaceutical Barcoding in Canada was approved by the GS1 Pharmacy Board with the following conditions understood:

- To support data synchronization to the patient record, all pharmaceuticals must have a GTIN assigned to the unit of use packaging hierarchy level and, where feasible, marked with a barcode (e.g.: inner blister packs). Unit of use packaging trends and related needs to be identified by the Pharmacy Deployment Committee.
- Barcodes on primary packaging are not to be subject to serialization, only GTIN, lot number and expiry date.
- To support the transition period for distributors and pharmacies, two barcodes are recommended at the saleable unit (linear & DataMatrix); except for products whereby a barcode does not exist today or where there is small usable space, a GS1 DataMatrix should be used. It is recognized that the transition to a single GS1 DataMatrix barcode for Behind-the-Counter (BTC), Over-the-Counter (OTCs), and Natural Health Products (NHPs) will align with the global movement for consumer goods, and in alignment with the Global 2D Migration program.
- Medical devices sold at the retail level will also align with the Global 2D Migration program movement for consumer goods. Discussions about the global movement towards 2D barcodes for consumer goods and foods are underway, and readiness timelines are expected to extend beyond 2025. Canadian timelines will be established through GS1 Canada's community management process. Should manufacturers of BTCs, OTCs, NHPs, and medical devices wish to voluntarily adopt GS1 DataMatrix in advance of the pending global timelines, then manufacturers are encouraged to prioritize those products with the potential to be dispensed due to a prescription (for example, some shampoos, OTCs and diabetes test strips can be prescribed and dispensed or administered while in hospital or Long-Term Care).
- The roadmap and related readiness timelines will continue to be assessed through sector and barcoding scorecarding and audits. Any recommended adjustments will be brought forward to the Pharmacy Work Group and Healthcare Pharmacy Board. If interested in joining GS1 committees, email healthcare@gs1ca.org.

Roadmap Requirements by Stakeholder

Manufacturers

Shall:

- Affix a GS1 DataMatrix barcode to primary and secondary packaging
- Permanently assign a unique GTIN to each packaging level
- Assign, and where feasible mark a GTIN to the Unit of Use level
- Affix a GS1-128 at the case level and accept the addition of an optional GS1 DataMatrix, Both barcode symbologies must contain the same GTIN
- Barcodes include static and variable data as noted below:

Static Data:

- GTIN

Variable Data:

- Lot Number
- Expiration Date
- **Serial Number (optional)***

What do Manufacturers need to do to determine if they are prepared?

- Assess printing software - conformance to ISO / IEC 16022 standard and [GS1 General Specifications](#).
- Assess if packaging material is suitable to carry a barcode
- Verify if GTINs are:
 - Allocated according to the GS1 Healthcare GTIN Allocation Rules
 - Properly **formatted** so GS1 DataMatrix is created using the GTIN-12 or GTIN-13 in 14-digit format (using leading zero(s))

Implementation Timeline: **December 31, 2021 to 2023****

**Including serialized data is optional, however it is recommended that manufacturers who include serialized data in barcodes to meet regulatory requirements for other countries, should consider including serialized data in the barcodes destined for Canada.*

***It is recognized that the transition to a single GS1 DataMatrix barcode for Behind-the-Counter (BTC), Over-the-Counter (OTCs), and Natural Health Products (NHPs) will align with the global movement for consumer goods, and in alignment with the Global 2D Migration program.*

Additionally, medical devices sold at the retail level will also align with the Global 2D Migration program movement for consumer goods.

Discussions about the global movement towards 2D barcodes for consumer goods and foods are underway, and readiness timelines are expected to extend beyond 2025. Canadian timelines will be established through GS1 Canada's community management process. Should manufacturers of BTCs, OTCs, NHPs, and medical devices wish to voluntarily adopt GS1 DataMatrix in advance of the pending global timelines, then manufacturers are encouraged to prioritize those products with the potential to be dispensed due to a prescription (for example, some shampoos, OTCs and diabetes test strips can be prescribed and dispensed or administered while in hospital or Long-Term Care).

Additionally, manufacturers are encouraged to follow the GS1 DataMatrix Roadmap for product samples. Samples which have the potential to be recalled or to be dispensed in a clinic or hospital setting require traceability, therefore, benefit from effective barcoding.

To support the transition period for distributors and pharmacies, two barcodes are recommended to be included at the saleable (linear and GS1 DataMatrix), except for products whereby a barcode does not exist today or where there is small usable space, a GS1 DataMatrix should be used.

Distributors

Shall be able to scan, store and process into legacy ERP, ordering and distribution systems:

- A GS1 DataMatrix for the primary and secondary packaging
- Unique GTINs at each packaging level
- GTINs at the Unit of Use level
- GS1-128 at the case level
- Barcodes include static and variable data as noted below:

Static Data:

- GTIN

Variable Data:

- Lot Number
- Expiration Date
- Serial Number (optional)*

Implementation Timeline: December 31, 2023

Pharmacies

Shall be able to scan, store and process into legacy ERP, PPMs, EMRs:

- A GS1 DataMatrix for the primary and secondary packaging
- Unique GTINs at each packaging level
- GTINs at the Unit of Use level
- GS1-128 at the case level
- Barcodes include static and variable data as noted below:

Static Data:

- GTIN

Variable Data:

- Lot Number
- Expiration Date
- Serial Number (optional)*

Implementation Timeline: December 31, 2025

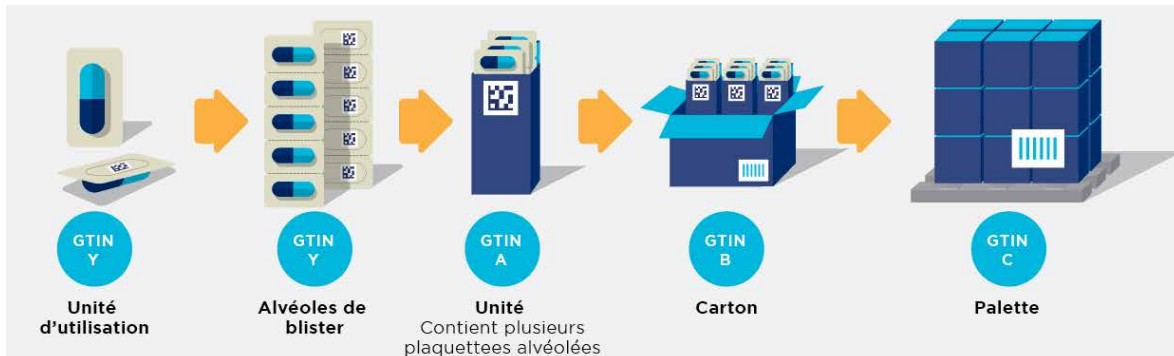
What do distributors need to do to determine if they are prepared?

- Assess scanning equipment - confirming camera-ready barcode scanning equipment is in place to read both linear and 2D barcodes.
- Verify if databases and systems are:
 - Properly **configured** so the 14-digit GTIN can be stored in a 14-character data field
 - Can ingest/store lot number and expiry date (to enable lot-based recalls and stock rotation)
- Plan for future: establish a plan to scan and store serialized data in your internal systems

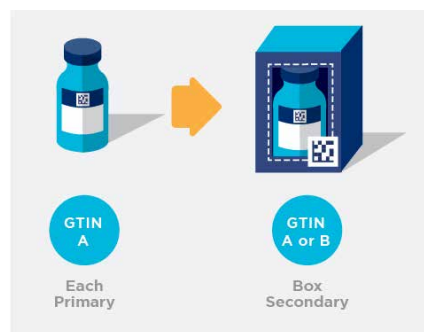
What do pharmacies need to do to determine if they are prepared?

- Assess scanning equipment - confirming camera-ready barcode scanning equipment is in place to read both linear and 2D barcodes.
- Verify if databases and systems are:
 - Properly **formatted** so the 14-digit GTIN can be stored in a 14-character data field
 - Are capable of ingesting/storing lot number and expiry date (key to lot-based recalls and stock rotation)
- Plan for the future: establish a plan to scan and store serialized data in your internal systems.

Barcoding at all packaging levels



Primary & Secondary Packaging



Guidance documents

1. [GS1 DataMatrix: A tool to improve patient safety through visibility in the supply chain](#)
2. [GS1 DataMatrix Guideline: Overview and technical introduction to the use of GS1 DataMatrix](#)
3. [GS1 Automatic Identification Data Capture Healthcare Implementation Guideline](#)
4. [GS1 General Specifications](#) (a deep dive on technical specifications)

ⁱ Makary MA, Daniel M. Medical error—the third leading cause of death in the US. *BMJ*. 2016;353:i2139

ⁱⁱ Statistics Canada, Industry Canada Trade data online