



Canadian Pharmaceutical Bar Coding Project



Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements

Input and technical support provided by:



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Foreword

The following national technical statement about voluntary bar coding of pharmaceuticals was developed under the direction of the national Implementation Committee (IC) for the Canadian Pharmaceutical Bar Coding Project. The 2-year project to develop this statement, described in a project proposal published in September 2008, was supported by funding from both not-for-profit and for-profit organizations that are committed to improving medication safety for all Canadian patients, while optimizing system efficiencies within the health care supply chain.

Related project documents, including the project proposal and this Statement, are available at the following web page.

<http://www.ismp-canada.org/barcoding/>

Phase I: National Stakeholder Roundtable (January 2008)

The need to adopt standards for processes related to automated identification of medications can be traced through the medical literature, which shows an overreliance on human checking methods. These legacy processes are now known to carry unacceptable rates of system errors. The need for a pan-Canadian standard for bar-coding of medications was documented in the Institute for Safe Medication Canada (ISMP Canada) and Canadian Patient Safety Institute (CPSI) Stakeholder Roundtable Proceedings, published in July 2008, which was based on broad input from the health industry. The reader is referred to those published proceedings for discussions related to these standards:

http://www.ismp-canada.org/download/BarCoding_Roundtable_Proceedings.pdf

Phase II

In phase II of the project, the Implementation Committee approved a national process to review and adopt a pan-Canadian bar coding standard for pharmaceuticals. It was envisioned that such a standard would provide a common basis for automated identification of medications at each stage of the medication process.

In April 2009, ISMP Canada and the CPSI jointly issued a statement endorsing the adoption of the GS1 global standard for automated identification of pharmaceuticals in Canada. In doing so, these 2 organizations recognized the importance of international integration of information about and identification standards for pharmaceutical products, represented by the existing global work previously established by GS1, a standard that has already been adopted by many Canadian and global manufacturers and other health-related organizations.

The bar code requirements set out in this technical statement are based on consensus reached during the original roundtable, held in January 2008, and the follow-up work of a national technical task force that held meetings in May and September 2009. Reporting to the Implementation Committee, the 34-member national technical task force, supported by GS1, consisted of members representing six identified Canadian health

sectors: pharmaceutical manufacturers, supply chain and group purchasing organizations, retail pharmacy professionals, institutional pharmacy professionals, integrated providers of health information technology, and professional practice and health quality organizations.

GS1's Canadian arm, GS1 Canada, a not-for-profit organization, worked with the Canadian Pharmaceutical Bar Coding Project and the project's technical task force to identify the requirements of users in each healthcare sector, to ensure that existing or planned GS1 global standards would meet identified needs for efficiency of the supply chain and patient safety.

The GS1 standards referenced in this technical statement are intended for use by all healthcare sectors represented in this process. Such broad use should result in pan-Canadian integration of automated identification of pharmaceutical products within a short period. It will also provide the basis for seamless transfer of medications from the manufacturer to the patient-dose level.

The existence of a global automated identification standard (coupled with advanced reduced-space bar code symbologies or radio frequency identification (RFID) chips) and the availability of reader technology connected to intelligent software have allowed the healthcare industry to advance safety practices. Adoption of a Canadian standard for automated identification of medications will inform integrated healthcare solution providers (HSPs) of future healthcare practice expectations, so that they can develop automated methods for identifying products and checking the safety of specific dosages within their proprietary patient care software modules. Such innovations by will, in turn, support healthcare providers by assuring that medications will be identified accurately and that they will have reliable access to standardized data from a common product database, thus providing the Canadian public with a more efficient and safer healthcare system.

This joint technical statement is written for both technical systems developers and front-line healthcare workers. It therefore includes explanations and examples of statements that might be unfamiliar to either of these audiences.

Phases III and IV

In phase III of this project, the joint technical statement will be communicated across all Canadian healthcare sectors, to encourage development of appropriate professional practice systems and a broad understanding of the benefits of bar coding by pharmaceutical manufacturers and of automated identification in general.

Subsequently, as part of phase IV of the project, healthcare sector compliance with the standards set out in the joint technical statement will be assessed, and issues related to safe pharmaceutical labelling practices will be addressed. The preferred practices for product labelling incorporating automated identification will be developed. And, in addition, standardized principles for "in-house" practices related to the bar-coding and labelling of medications will be needed, as such practices are increasingly being used within individual hospitals, retail pharmacies, and health regions. At present, there is no national standard for such practices in relation to repackaging of medications, compounded mixtures, or patient-specific doses.

Acknowledgements

In addition to the support of GS1 Canada and the organizations represented on both the Implementation Committee and the technical task force, ISMP Canada and the CPSI wish to recognize the foundational work of all the individuals who contributed to this work. The members of the Implementation Committee and its technical task force are listed below.

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Glossary of Terms and Abbreviations

Automated Identification (AI): A technology that allows a product to be automatically identified using readers of codes, such as bar codes, smart cards, biometrics, and RFID.

Automated Identification and Data Capture (AIDC): A technology that allows a product to be automatically identified using readers of codes, such as bar codes, smart cards, biometrics, and RFID, and that provides data about the identified product, usually from the code itself and/or from an associated product database.

Export Control Classification Number (ECCN): A commerce number used by the Bureau of Census for export control purposes; it denotes the country of final manufacturing.

Global Location Number (GLN): The identification key used by GS1 to identify physical locations or legal entities. The key comprises a company prefix, a location reference, and a check digit, all defined by GS1. (GS1 general specifications)

Global Trade Item Number (GTIN): The identification key used by GS1 to identify trade items. The key is comprised of a GS1- or UPC-defined company prefix, followed by an item reference number and a check digit. (GS1 general specifications)

GTIN Allocation Rules: Rules for assignment of GTINs, covering many common business situations relating to the introduction of new trade items that require a GTIN; used to identify any item that may be priced, ordered, or invoiced at any point in any supply chain; also used for products that have already been identified with a GTIN but that have undergone an attribute change requiring assignment of a new GTIN.

Global Data Synchronization Network (GDSN): Network built around the GS1 Global Registry. GDSN-certified data pools, combined with Global Product Classification, allow accurate and standardized product information to be shared between country and global databases, by means of common data elements.

Global Product Classification (GPC): A proprietary classification system of GS1 used by many industries to ensure that products are classified correctly and uniformly; gives buyers and sellers a common language for grouping products in the same way.

Radio-frequency Identification (RFID): A small implanted chip that allows information to be stored and retrieved by a compatible RFID reader.

Executive Summary

Foreword

The *Joint Technical Statement on Canadian Pharmaceutical Bar Coding and Product Database Requirements* is the result of collaborative efforts by representatives of Canadian healthcare sectors. The process of developing this statement was led by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), in partnership with GS1 Canada, under a 2-year project entitled the Canadian Pharmaceutical Bar Code Project.

The project itself, described in a proposal published in September 2008, is supported by funding from both not-for-profit and for-profit organizations that are committed to improving medication safety for all Canadian patients, while optimizing system efficiencies within the healthcare supply chain. It is being overseen by a national Implementation Committee comprising representatives of leading healthcare organizations.

The objectives of the project are consistent with efforts now under way in many global health jurisdictions. The project participants have endorsed existing GS1 global standards for the automated identification of pharmaceuticals, which are also being used increasingly around the world. A complete summary of the project, including the process used to develop the joint technical statement, is available on the ISMP Canada website:

<http://www.ismp-canada.org/barcoding/>

The existence of a global standard for automated identification, advanced reduced-space bar code symbologies, and Radio-frequency Identification (RFID) chips and the development of reader technology that can be connected to intelligent software have allowed the healthcare industry to begin the process of significantly advancing patient safety practices.

The adoption of a Canadian standard for automated identification of medications will give integrated healthcare solution providers the necessary expectations about future practice to allow them to develop automated methods for identifying products and checking the safety of specific dosages within their proprietary patient care software modules. Such innovations by these technology solution providers will, in turn, support healthcare practitioners (the end-users) by assuring that medications are identified accurately and that practitioners will have reliable access to standardized data from a common product database, thus providing the Canadian public with a more efficient and safer healthcare system.

This joint technical statement sets out a national technical methodology for cross-sector bar coding of pharmaceuticals (and automated identification) on the basis of which the innovations described above can be developed. It also includes compliance requirements and timelines for participating healthcare sectors.

Project Phases

The Canadian Pharmaceutical Bar Code Project originally consisted of 3 phases, but a fourth follow-up phase is now being proposed.

Phase I: National Stakeholder Roundtable (January 2008)

The need to adopt standards for automated identification of medications in Canada was initially discussed in a national forum. A 40-member roundtable confirmed that legacy (human) processes related to medications are known to carry unacceptable system error rates. Unanimous agreement was reached on the need to urgently adopt national standards.

Phase II: Creation of the Joint Technical Statement (2009)

In April 2009, after funding for the Canadian Pharmaceutical Bar Code Project had been secured and the project had been formally initiated, ISMP Canada and the CPSI jointly issued a statement endorsing the adoption of the GS1 global standard for automated identification of pharmaceuticals in Canada. In doing so, these 2 organizations recognized the importance of international integration of information about and identification standards for pharmaceutical products, represented by the existing global work previously established by GS1, and GS1 Canada.

Reporting to the project's Implementation Committee, the 34-member national technical task force consisted of representatives from 6 identified Canadian health sectors: pharmaceutical manufacturers, supply chain and group purchasing organizations, retail pharmacies, institutional pharmacies, integrated healthcare solution providers, and professional practice and health quality organizations. The technical task force received technical support from GS1's Canadian arm, GS1 Canada, a not-for-profit organization.

Phases III and IV: Dissemination of the Joint Technical Statement and Engagement of Stakeholders

In phase III (2010), the joint technical statement will be communicated across all Canadian healthcare sectors, to encourage development of appropriate expectations for professional practice and a broad understanding of the benefits, in terms of patient safety and efficiency of the supply chain, of bar coding by pharmaceutical manufacturers and of automated identification systems in general.

In phase IV (projected to take place in 2011), compliance with the standards set out in the joint technical statement will be assessed, and issues related to labelling and in-house repackaging (and bar coding) of pharmaceuticals will be addressed. Within this phase, we will also revisit the 2009 technical statement and update the technical requirements and compliance dates as necessary.

Summary of Contents of the Joint Technical Statement

The joint technical statement includes the technical compliance criteria for all Canadian healthcare sectors for included pharmaceuticals marketed within Canada. A summary of the key elements follows.

Section 1: Pharmaceutical Products to be Included

Key elements:

- Medications and related items to which this statement applies are listed, including all pharmaceuticals with a federal Drug Identification Number (DIN).

Section 2: Common National Standard for Automated Identification of Pharmaceuticals

Key elements:

- GS1 standards for automated identification should be applied.
- The GTIN (Global Trade Item Number), a unique global identifier, is a required “fixed” data element within the automated identification (bar code) symbology used.
- The bar code symbology must be GS1-compliant.
- The GTIN field length must accommodate a 14-character GTIN code.
- The bar code must also show the human-readable text form of the GTIN.
- Pharmaceutical manufacturers are responsible for validating the readability of their bar codes.

Section 3: Content of Bar Codes

Key elements:

- Required “fixed” data element will consist of the GTIN (up to 14 characters).
- “Variable” data elements (e.g., expiry date) are not required at this time, but they will likely be required in the future.
- Manufacturers may use RFID chips, but a compliant bar code must also be used until further notice.

Section 4: Pharmaceutical Packaging Levels, and the Placement and Content of Bar Codes

Key elements:

- Various packaging levels for medications are defined (i.e., pallet, case or shipper unit, secondary packaging, primary packaging, unit of use).
- The type, placement, and content of bar codes are outlined for each packaging level defined above.
- Reduced-space symbologies (e.g., 2-dimensional bar codes) are encouraged for pharmaceutical units with limited space on the label, such as ampoules or unit-dose tablet packages.

Section 5: Common Canadian Pharmaceutical Product Registry

Key elements:

- A common Canadian pharmaceutical product registry (CCPPR) will be identified and adopted in 2010.

- Each medication (or item for which a GTIN is required according to Section 1 of the joint technical statement) will have a corresponding data record in the CCPPR, with defined data elements describing the product. The CCPPR will force compliance with standardized data fields, units of measure, etc.
- In addition to the GTIN, the DIN must be included in the CCPPR.
- The Global Data Synchronization Network will be used to synchronize data exchange between GS1 (and other) global product registries.

Section 6: Bar Code Symbology

Key elements:

- GS1-compliant bar codes (or RFID) will be used.
- One-dimensional or 2-dimensional bar codes will be acceptable.
- End-user healthcare organizations (e.g., hospitals and retail pharmacies) should acquire only bar-code readers that are capable of reading both 1- and 2-dimensional GS1-compliant bar codes.
- Healthcare solution providers (including software developers) should develop functional software programs that can read, identify, and otherwise use manufacturers' bar codes to reduce patient harm, standardize documentation, and improve system efficiencies.

Section 7: Expectations of Professional Practice Organizations and End-Users

Key elements:

- Professional and regulatory bodies should develop professional practice recommendations that promote or require the increased use of automated identification in healthcare practices, such as bar code scanning at all levels of the medication-use process.
- End-user healthcare organizations (e.g., hospitals and retail pharmacies) should, in the coming years, acquire automated systems that will offer healthcare practitioners innovative methods of using scanned bar codes, reducing patient harm, and maintaining or improving system efficiencies.

Section 8: Timeline for Adoption of Standard by Health Sectors

Key elements:

- Timelines for compliance by various sectors are provided.
- By December 1, 2012, pharmaceutical manufacturers should be compliant with the requirement for fixed data elements (GTIN) for all products listed in Section 1.
- The inclusion of variable data elements (e.g., expiry dates and lot numbers) in product bar codes is recommended but not required by the deadline of December 1, 2012. It is expected that variable data will be required in the future, but this requirement will be reviewed in January 2011.
- Healthcare solution providers (e.g., vendors of automated systems and software) should develop methods for automated identification of products at **all** levels of the medication-use process, by a date to be determined in 2010.
- The readiness of end-users to acquire the necessary systems and a proposed timeframe will be reviewed and discussed by January 2011.

1. Pharmaceutical Products to be Bar Coded

- 1.1. All medications that have been assigned a Drug Identification Number (DIN) by Health Canada, whether prescription or non-prescription.
- 1.2. Products listed by Health Canada as natural products and neutraceuticals.
- 1.3. Medical or treatment kits that contain multiple medication products. Each such kit should have a GTIN for each medication contained within the kit, as well as a separate GTIN for the kit itself.
- 1.4. Any separate device packaged with a GTIN-bar coded medication that is inextricably related to the medication's dispensing, compounding, or dose administration.
- 1.5. Any powder that is commercially available for use as a therapeutic agent in humans.

2. Common National Standard for Pharmaceutical Automated Identification of Pharmaceuticals

- 2.1. The GS1 standard should be used, and this standard should be applied to products outlined in Section 1 across all private and public Canadian healthcare sectors, by means of the Global Trade Item Number (GTIN) and applicable GTIN Allocation rules.

- 1.1 The following items, among others, are specifically excluded from this statement:

- Medications with DIN numbers that have been previously removed for sale from the Canadian market, unless they are re-introduced for sale in Canada.
- Products available through the Special Access Programme that do not have Health Canada DINs
- Investigational New Drugs

2.1 The "GTIN gateway":

The GTIN is a unique identifier for pharmaceuticals and over-the-counter drugs. It is essentially a "simple code", without any product-specific information, but it provides a "gateway" through which standardized product data fields in a common central product database (or "repository") can be accessed.

For more information about GS1 standards,

GS1Canada

<http://www.gs1ca.org>

GTIN:

<http://www.gs1ca.org/page.asp?LSM=0&intNodeID=732&intPageID=273>

GTIN Allocation Rules:

http://www.gs1.org/docs/gsmc/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

2.2. For each defined medication-package level (defined in Section 4), all embedded required data elements should be encoded within a single bar code, in compliance with current GS1 standards for readable bar codes.

2.2 See also Section 4.3.3, which specifies an exception to the use of some UPC codes for retail pharmacy purposes (specifically, during a compliance transition period).

2.3. Bar codes used may be one-dimensional or two-dimensional.

2.3 Radio-frequency Identification (RFID) methods are not specifically addressed in this technical statement. This technology will be reviewed in the future. However, end-users in clinical practice are encouraged to monitor the development of scanning equipment capable of interpreting all variations of automated identification technology.

This technical statement does not recommend that end-users acquire RFID readers at this time.

2.4. Field lengths used for the GTIN must allow up to 14 characters.

2.4 The length of the GTIN may vary depending on the specific application and the environment of use, but it will never exceed 14 characters. The database field must be capable of accommodating a 14-character GTIN code. **It is recommended for Sectors planning for the GTIN data field that the GTIN be represented in software applications as 14 digits by right justifying and zero filling left, as appropriate.**

Note: Some confusion may exist between the scanned GTIN barcode field, and the final GTIN number stored in the software database. When scanned by a bar code reader the GS1-compliant bar-code GTIN is decoded as a 16 character field however the leading two-digit "application identifier" number (01) segment is **NOT** retained as part of the stored 14 character GTIN number.

Use of coding as specified by the National Drug Code (NDC) of the US Food and Drug Administration within a GS1-compliant system is acceptable, so long as it allows direct access to a specific product data record within the chosen common Canadian pharmaceutical product registry. The leading system character (3) within a GTIN-12 structure indicates that the NDC bar code is GS1-compliant. (See also Section 5.)

2.5. The product's bar code should also contain human-readable GTIN characters, except where the space on the product label does not allow for textual characters of reasonable size or due to regulatory standards set by Health Canada.

2.6. The placement of the bar code on the product package must not interfere with applicable regulatory standards for pharmaceutical labelling set by Health Canada.

2.6 Where necessary, pharmaceutical manufacturers should consult Health Canada to resolve any concerns related to labelling.

The National Health Service (NHS) in the United Kingdom has issued general guidance on pharmaceutical labelling, which may help pharmaceutical manufacturers to improve labelling practices.

<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=63053>

2.7. The bar code symbology selected should be capable, at a minimum, of encoding the fixed data elements outlined in Section 3.1 of this technical statement.

2.7 It is anticipated that when the automated identification standards are next reviewed, in January 2011, the inclusion of variable data elements, such as expiry date and lot number, will be recommended as part of the minimum standard.

2.8. The Common Canadian Pharmaceutical Product Registry (CCPPR) should be used by all pharmaceutical manufacturers and providers of healthcare information systems Providers. The registry should contain a corresponding data record for each product GTIN, using data provided by the pharmaceutical manufacturers. (See also Section 5.)

2.9. Pharmaceutical manufacturers are responsible for the following:

2.9.1. Assuring that product bar codes have been verified for readability.

2.9.1 Bar-code scan verification methods are discussed on the GS1 Canada website:

<http://www.gs1ca.org/page.asp?LSM=0&intNodeID0=665&intNodeID1=698&intNodeID2=705&intPageID=535>

2.9.2. Submitting accurate product data to the selected common Canadian pharmaceutical product registry. (See also Section 5.)

2.10. The GTIN should be added to all third-party clinical and product databases commonly used within Canada to facilitate future automated (direct) access to related product or clinical information.

3. Content of Bar Codes

3.1. The bar code should adhere to GS1 standards for formatting. In addition, depending on the level of packaging (see Section 4.3), the selected bar code should be ideally be capable of encoding the following data elements for the product:

- **Fixed data elements (required):**

- Global Trade Item Number (GTIN), allowing for up to 14 characters.

• **Variable data elements (desired):**

- Product Lot number
- Product Lot expiry date

Variable data elements

As of the publication date of this technical statement, the variable data elements are **not** required; however, it is anticipated that they will become required as part of a future Canadian requirement.

The GS1 global standard for bar-coding outlines the structure for incorporating both fixed and variable data elements into a single GS1-compliant bar code.

A planned review of variable elements is outlined in Section 8 of this document.

The GS1 website contains information on all Application Identifiers, their formats, and their varied purposes. Some of these identifiers relate to variable product data elements.

http://www.gs1.org/barcodes/technical/application_identifiers

Expiry date: (GS1 Application Identifier #17)

The GS1 application identifier data field #17 contains an expiry date. The expiry date determines the time limit for consumption or use of a product. Its meaning is determined from the context for the trade item (e.g., for pharmaceutical products, it indicates the possibility of an indirect health risk resulting from ineffectiveness or toxicity of the product after the specified date).

Lot number: (GS1 Application Identifier #10)

The application identifier data field #10 contains a batch or lot number. The batch or lot number associates an item with information that the manufacturer considers relevant for traceability of the trade item to which the element string is applied, and may allow improved product recall when necessary. The lot number data contained in the field may refer to the trade item itself or to any item contained in a kit.

Other variable elements likely to be considered in the future:

Serial number: (GS1 Application Identifier #21)

The application identifier data field #21 indicates that the GS1 application identifier data field contains a serial number. A serial number is assigned to a traceable entity for the lifetime of the entity. When combined with the item's GTIN, a serial number uniquely identifies an individual item.

It is expected that global jurisdictions will soon begin to develop detailed standards for serialization of some pharmaceuticals, but as of yet, these standards do not exist. Canada will monitor global recommendations in this area and will revisit the issue as required.

Country of final manufacturing (or “Country Origin Code”)

The country of final manufacturing may also be required at some future date as a variable element, but no clear global or Canadian regulatory direction exists.

4. Pharmaceutical Packaging Levels and the Placement and Content of Bar Codes

4.1. Bar codes should be used on **all** levels of packaging hierarchy described within the GS1 standard and in accordance with GS1's GTIN allocation rules and General Specifications.

4.1 For a given pharmaceutical product, the assigned GTIN varies slightly with each packaging level, as defined in the GS1 global standard. This GTIN variation for a given medication allows identification of both the item (medication) and the packaging unit in which it is contained (e.g. case, or each) when read by a bar code reader.

4.2. Definitions of Packaging Levels (GS1 Hierarchy)

The GS1 hierarchy of packaging should be used to determine requirements for the GTIN, and secondarily the placement of the bar code.

4.2 GS1 packaging hierarchy packaging is based on the GS1 application standard marking grids for automated identification

4.2.1. Pallet

Definition: A container that may contain one or more “cases” or “shipper units” of an identical item. It must not have any higher level (parent) packaging, nor be a mixed container of different items.

Example:

A pallet of identical units of a single product.

4.2.2. Case or Shipper Unit

Definition: Packaging unit that may contain one or more items in their “primary” and/or “secondary” packaging; represents the standard level of shipping unit, but may also have a pallet parent level.

Examples:

A case may contain medications packaged in single-unit or multiple-unit cartons.

A carton of one or more unpackaged bottles or multiple packs of blisters or syringes.

4.2.3. Secondary Packaging

Definition: Packaging that contains one or more single items in their “primary” packaging format; may consist of a single item or a group of items intended to be used together in a single therapy (a kit).

Examples:

A carton of one or more coded bottles or multiple packs of blisters or syringes.

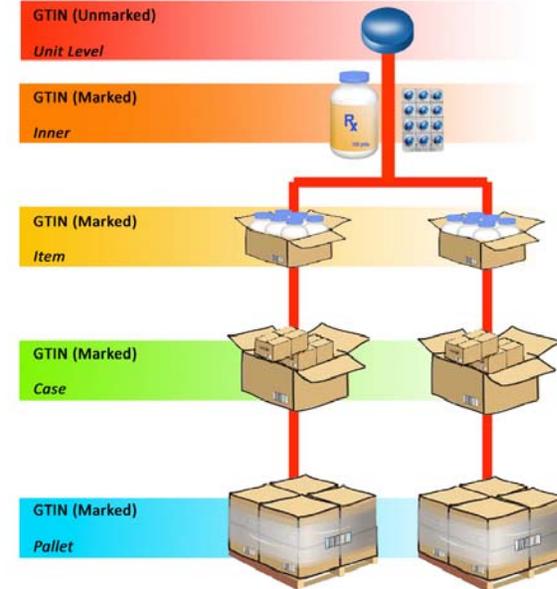
Single boxes, each containing a single inner primary package, such as a vial, ampoule, bottle, or tube.

4.2.4. Primary Packaging

Definition: Packaging for a traceable unit that may consist of a single item or a group of items intended to be used together in a single therapy (a kit); represents the lowest level of the hierarchy of items intended or labelled for individual use.

Examples:

Ampoules and vials.



4.2.4 Primary packaging has the product’s “inner label”, a term used by Health Canada.

Each pill in a perforated blister pack of 12 that allows the separation of one blister from the remaining blisters in the pack, a single separated unit-dose tablet, or a blister pack of 12 that does not allow separation of individual blisters.

Single bottles of 500 tablets or capsules.

Individual Infusion bags, tubes, bottles of liquid, etc.

Individual unit-of-use items (e.g., pre-filled syringes).

4.2.5. Individual Unit-of-Use Item without a Label

Definition: Packaging for a single unit-of-use item that is generally considered unidentifiable without the label bar code (or RFID chip) from the originating container (the primary packaging).

Example: A single unpackaged tablet or capsule, or a volume of liquid outside of its container.

4.2.5 It may be possible to encode an identifier directly on an individual unit-of-use item, without a label. This level is still under discussion at GS1 global.

4.3. Placement and Content of Bar Codes

Note:

The primary objective of this technical statement is to ensure that, at a minimum, the GTIN is encoded as a fixed data element within the single GS1 barcode at **all levels of packaging**.

The inclusion of the variable data elements listed in Section 3.1 at all levels of packaging is also desirable and such elements should be included in the bar code as soon as possible, most importantly at the primary and secondary packaging levels.

Recommendations and requirements for variable data will be the subject of a future review (see Section 8).

The content and placement of bar codes on packaging should conform with the following principles:

Ideally, variable data elements should be encoded at all GS1 packaging levels described in this section, however, for the purposes of patient safety, it was deemed most important that such data elements be encoded at the secondary and primary packaging levels as soon as possible.

4.3.1. **Pallet**

Type:

A single 1-dimensional or 2-dimensional GS1-compliant bar code. May also include an RFID tag but should not rely solely on the RFID for identification purposes.

Placement:

As per GS1 specifications.

Content:

Must include GTIN. May include additional elements.

4.3.2. **Case or Shipper Unit**

Type:

A single 1-dimensional or 2-dimensional GS1-compliant bar code. May also include an RFID tag but should not rely solely on the RFID for identification purposes.

Placement:

As per GS1 specifications.

Content:

GS1-compliant bar code, with GTIN at a minimum; inclusion of variable data is desirable (See Section 3).

4.3.3. **Secondary Packaging**

Type:

A single 1-dimensional or 2-dimensional GS1-compliant bar code. May also include an RFID tag but should not rely solely on the RFID for identification purposes.

Placement:

As per GS1 specifications.

Content:

GS1-compliant bar code, with GTIN at a minimum; inclusion of variable data is desirable (see Section 3).

4.3.1 Note: A bar code is required for a pallet only if the pallet constitutes a “tradable” unit of homogenous products. Pallets of mixed products are non-tradable units, and bar codes are therefore not required.

4.3.2 A bar code is required for a box (or case) only if it constitutes a “tradable” unit of homogenous products.

Boxes (or cases) of mixed products are non-tradable units, and bar codes are therefore not required.

4.3.3 and 4.3.4 (Secondary and Primary Packaging Sections)

Variable data elements: It is anticipated that, in 2011, bar codes capable of encoding variable data elements will become a requirement. (See Section 8.1.)

For Retail operators: An exception to the requirement for bar-coding of secondary packaging is made in relation to UPC codes currently in common use in retail practices, for which it is possible to encode only fixed data elements (e.g., the GTIN).

The Implementation Committee requests that the use of

4.3.4. Primary Packaging

Type:

A single GS1-compliant bar code. May also include an RFID tag but must not rely solely on the RFID for identification purposes.

Placement:

Although contrary to the recommendations of GS1, the preferred location is on the front of the unit of use, with human-readable text identifiers. This may not be possible in all cases. (See also Section 2.6.)

Content:

GS1-compliant bar code, capable of including both fixed and variable data elements. (See also Section 3.)

4.3.5. Individual Unit-of-Use Item without a Label

Type:

No recommendation at this time.

Placement:

No recommendation at this time.

Content:

No recommendations at this time.

current UPC codes be phased out. The above-noted exception for retail UPC codes is designed to allow the pharmaceutical manufacturers and retail pharmacies to transition their processes to the preferred standard of a single GS1-compliant bar code that is capable of encoding both fixed and variable data elements.

4.3.4. Non-standard methods of bar-code placement may be required for small units of use (e.g., unit-dose blisters or ampoules) in order to meet the required standards for labelling imposed by Health Canada. With this in mind, flexibility in both label types (e.g., use of flaps) and bar-code placement must be accepted.

Manufacturers may seek guidance from Health Canada to meet federal labelling requirements.

An objective of this technical statement is to encourage the encoding of variable data elements (e.g., lot number and expiry date) within a single barcode at all levels of packaging, especially where textual presentation of such variable data is currently required by federal regulation. Therefore, the use of reduced-space symbologies on small primary packages is encouraged where necessary.

5. Common Canadian Pharmaceutical Product Registry

5.1. A common Canadian pharmaceutical product registry (CCPPR) will be adopted. (See also section 2.8.)

5.1 A small working group of the technical task force will be established to select the CCPPR; the wording group will review the following aspects:

- necessary database elements, including current and future fixed and variable data fields
- database calculation fields
- methods and costs of uploading, downloading, and maintaining data
- integration of the CCPPR with other available clinical databases

5.1.1. Subject to Section 1 of this technical statement, all products with a GTIN will have a corresponding data record in the selected CCPPR.

5.1.2. Within the CCPPR, every listed product with a GTIN will contain within its record a corresponding Health Canada Drug Identification Number (DIN) for the purposes of cross-reference to other databases.

5.1.2 The CCPPR will be a product database and will not contain clinical information about the use of the products. Such clinical and other data will continue to be maintained in other databases, which may, in the future, be linked to the CCPPR, by means of the GTIN1-dimensional or 2-dimensional, within a relational database environment.

5.1.3. All products listed in the CCPPR will adhere to the rules of the Global Data Synchronization Network (GDSN) to ensure harmonization with global product registries.

5.1.4. The CCPPR selected should provide a method for identifying clinically-equivalent Canadian products; this method should be based on pre-designated database element comparisons.

5.1.4 Although it is possible to generate an approximate grouping of similar products within a CCPPR on the basis of similarities in designated data fields (attributes), it is fully understood that actual clinical equivalency can be determined and approved only by the expert clinical end-users and their organizations.

A separate Canadian and/or global working group will be needed to create strategies for determining clinical equivalency between products.

5.1.5. The CCPPR should consist of data elements that enable both product identification and mathematical calculation of part units and/or volumes when used in pharmaceutical compounding.

5.2. The CCPPR and the product data contained therein should be centrally maintained, using data uploaded directly from the pharmaceutical manufacturers.

5.3. Healthcare solution providers (HSPs) (or, “Health information technology providers”) should have direct access to the product data in the CCPPR, including product updates.

5.3.1. Product updates submitted by pharmaceutical manufacturers should be processed by the CCPPR agent within 2 business days and should be made available to Healthcare Solution Providers electronically within 1 (one) further business day.

6. Bar Code Symbology

6.1. A one-dimensional or two-dimensional GS1-compliant bar code symbology should be used for all defined package levels, capable of incorporating the elements described in Section 3 above.

5.1.5 The CCPPR working group of the technical task force will review this requirement.

Symbology issues:

The majority of healthcare stakeholders are now recommending a single automatic identification symbology that can contain the required fixed and variable data elements. The GS1 symbologies that meet this requirement include the following: GS1-128 (formerly UPC-128), GS1 Data Matrix, GS1 DataBar™, and EPC/RFID.

The following GS1 symbologies **cannot** capture variable data, such as lot number and expiry date: UPC-A, UPC-E, EAN13, and EAN 8.

The specific symbology chosen may be based on a number of factors, such as:

- size of product or area available for product labelling
- need for additional secondary information
- environment of use

Health Solution Providers should also anticipate the need for the capability to read both fixed and variable data elements and to make allowances for such capability in their software modules and related database structures, as required.

6.2. Healthcare solution providers (or, “Health information technology providers”) and institutional or retail end-users should obtain and use only bar code readers that are capable of reading the one- and two-dimensional GS1-compliant bar codes specified in this standard.

6.3. Healthcare Solution Providers should develop automated software functionality capable of reading all GS1-compliant bar code symbologies and using the encoded data elements (or data elements obtained from the CCPPR) in the functional end-user modules, at each stage of the medication-use process. Such modules should be made available according to the timelines specified in Section 8 of this technical statement.

7. Expectations of Professional Practice Organizations and End-Users

7.1. Best practice standards, policies, and associated audits should be issued by Canadian healthcare practice organizations, and such practice and system recommendations should be adopted by end-user organizations.

7.2. Individual end-user healthcare organizations in both the retail and public sectors, and their supporting contracting groups, should ensure that appropriate technology and relevant best practice standards are

expeditiously implemented according to the timelines specified in Section 8 of this technical statement by:

- 7.2.1. Creating strategic budgetary submissions for the acquisition of the necessary bar code-enabled software and hardware.
- 7.2.2. Purchasing only software and hardware that is capable of complying with automated identification at all levels of the medication-use process, including readers capable of reading all GS1-compliant one- and two-dimensional bar codes.

8. Timeline for Adoption of Standard by Health Sectors

8.1. The Global Trade Item Number (GTIN) should be present on all products defined in Section 1, at all packaging levels, by December 1, 2012.

- 8.1.1. Variable data described in Section 3.1 of this technical statement may be included in the bar code by the manufacturer at any time. A specific date when such variable data will be required on applicable packaging levels will be considered in January 2011.
- 8.1.2. Product serialization numbers may be included in the bar code by the manufacturer at any time. The need to set a specific date for inclusion of serialized product numbers will be monitored in light of requirements set by Canadian and other global jurisdictions and will be reviewed in January 2011.
- 8.1.3. Notwithstanding Sections 4.3.3 and 4.3.4 of this technical statement, RFID may be added to any level of defined packaging at any time. The required use of RFID will be reviewed in January 2011.

8.2. Healthcare solution providers (health technology providers) should offer the following minimal functionality:

- 8.2.1. By January 1, 2012, capability to read any GS1-compliant bar code, regardless of the number of characters in the GTIN, and to automatically identify the pharmaceutical within the medication-use processes outlined in section 8.2.3.

The database field used in software and database applications

A proposed requirement for encoding of serial numbers and country of final manufacturing will be reviewed after January 1, 2011, within the context of the review of all variable data.

Healthcare Solution Providers should be aware of the probable future need to read and store variable data (e.g., lot number and expiry date). Planned modifications to software for automated identification via bar-coding and related internal data files should incorporate the need for both fixed and variable data elements, according to the GS1 standard.

must be capable of accommodating a 14-character GTIN code. It is recommended that the GTIN be represented in software applications as 14 digits by right justifying and zero filling left, as appropriate

- 8.2.2. Participate in the CCPPR workgroup and establish, by January 2011, a timeline for functionality with regard to:
- accessing standardized pharmaceutical product data fields from the CCPPR
 - accepting and processing from the CCPPR all relevant any product data changes
 - ensuring full traceability (and associated documentation) of pharmaceutical events within software modules, as outlined in Section 8.2.3
 - relating multiple products (i.e., multiple GTINs) to other generically equivalent products, according to pre-designated CCPPR fields
 - Determine methods of using CCPPR data fields for calculation purposes.
- 8.2.3. By the timeline determined by the activities described in Section 8.2.2, provision of effective patient safety checks and related documentation throughout the medication-use process, including the following:
- purchasing and receipt of inventory
 - compounding or re-packaging in the pharmacy
 - verification of items dispensed
 - verification of ward stock or stocking of automated cabinets
 - point-of-care (Bar Code Medication Administration (BCMA) applications
- 8.3** A date to require the implementation of best practice clinical standards and associated audits will be discussed in January 2011.

National Implementation Committee



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Technical Task Force: Sectors and Representatives

Global Standards for Automated Identification and Public Health Information Systems



Pharmaceutical Manufacturers



Supply Chain and Group Purchasing Organizations (GPOs)



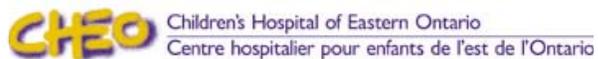
Providers of Health Information Technology



Retail Pharmacy Practice



Institutional Pharmacy Practice



Health Regulators and Professional Organizations



Funding Sponsors for the Canadian Pharmaceutical Bar Coding Project

