Canadian Pharmaceutical Bar Coding Project

**Joint Technical Statement
(Version II)**

on
**Pharmaceutical Automated Identification
and Product Database Requirements**

Input and technical support provided by:

GS1
Canada

February 24, 2012

(This version replaces Version I, dated January 15, 2010)

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May 18, 2011 (DBWG and TTF Changes)	Modification of JTS Version I
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Foreword

This document is an updated technical statement, Version II, and replaces Version I (dated January 15, 2010).

The following updated national joint technical statement about voluntary bar coding of commercial pharmaceuticals was developed in partnership by the Institute for Safe Medication Practices (Canada) (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), as the Canadian Pharmaceutical Bar Coding Project, under the direction of a national *Implementation Committee* (IC). All statements have been obtained by consensus agreement from the project's multi-sector *Technical Task Force* (TTF), followed by the review and approval by the IC.

The objectives of the Canadian Pharmaceutical Bar Coding Project included the development of this national consensus on pharmaceutical **Automated Identification**, described in a project proposal published in September 2008. The project continues to be 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 updated 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/Bar coding_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 two 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 Canada, 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 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

During phase III of this project, the joint technical statement has been communicated across all Canadian healthcare sectors, to encourage development of appropriate healthcare software and automated practice systems, and to promulgate a broad understanding of the safety benefits of bar coding by pharmaceutical manufacturers and aligned *Automated Identification* practices.

The project's national approach to a cohesive approach to automated medication practices, and a national standard, has received multiple endorsements from leading healthcare practice organizations. Such endorsements can be viewed on the project web pages.

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

As part of phase IV of the project, other related labelling practices will be examined in collaboration. The preferred practices for product labelling incorporating *Automated Identification* will be developed.

Finally, 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 repacking 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 updated statement. The members of the Implementation Committee and its technical task force are listed below.

Disclaimer

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Funding Sponsors for the Canadian Pharmaceutical Bar Coding Project

The following organizations have provided financial support to the Canadian Pharmaceutical Bar Coding Project:

Contents

Glossary of Terms and Abbreviations for the JTS version II

Terms and abbreviations defined in this section are utilized within this technical statement and meant to provide the reader with a meaning in the context of this document. Some of these terms may also be defined within externally-approved technical standards. The reader should not assume the defined terms hereunder necessarily fully reflect the meaning within such standards.

Bold Italicised words, abbreviations, and phrases used in this document, whether in singular or plural form, denote terms defined in this glossary.

Automated Identification (**AI**): For the purposes of this document only, **AI** refers to any technology that allows a product to be automatically identified with readers (scanners) of codes, including bar codes, smart cards, biometrics, and **RFID**. In other documents, the abbreviation **AI** may alternatively refer to "Application Indicator", a term also used in **Automated Identification** code character strings.

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

Common Canadian Pharmaceutical Product Registry (**CCPPR**): For the purposes of this document, **CCPPR** represents the project's concept of a central Canadian database, or "*data pool*", in which pharmaceutical products approved by Health Canada are registered. The related product descriptors, or "*data elements*", are stored and can be accessed (through subscription) by organizations requiring such data. The **CCPPR** term is not used in relation to a specific database, nor does it indicate a specific database structure. The project has selected a preferred specific database for this process.

Community Management Process (**CMP**): A term used to describe a process undertaken by a GS1 member country (e.g., Canada) to consider the addition of new business processes or data elements by the country-specific standards organization (e.g., GS1 Canada), using a "'change request" from its local membership. After review, should such processes be accepted within the country-specific standards organization (e.g., GS1 Canada), the change may be submitted internationally for global review (see **GSMP**, below).

ECCnet Registry: The GS1 Canada–owned product registry structure (also known as a "*data pool*", selected by this project as the preferred **CCPPR**. It is used to register products to which a **GTIN** has been assigned.   It complies with global **GDSN** standards, but may also contain additional data elements for Canada only, if approved by the **CMP** described within this document. Data residing in this registry are owned by the manufacturer, but are pre-checked by GS1 Canada for consistency with global and/or ECCnet (GS1 Canada) standards. The **ECCnet Registry** contains a wide range of products, including non-health products, but, for the purposes of this document, this term refers only to those pharmaceutical products defined in Section 1.

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

Global Location Number (*GLN*): Though not used within this document, this identification key used by GS1 standard 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 for *AIDC*)

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

Global Standards Management Process (*GSMP*): A GS1 standard global process by which each member country may request the inclusion of additional business processes in the global *AIDC* standard to better accommodate business practices, including health-related practices. Such changes, if accepted by one member country (e.g., Canada), may then be referred for international review and, if approved at that level, become part of the global GS1 *AIDC* standards. The local member country review is referred to as a "*Community Management Process*". Although usually used to describe a change in practice or process, this document also uses the term *GSMP* to describe potential changes in database elements, if considered for global change (through the *GDSN* standard).

Global Trade Item Number (*GTIN*): The identification key used by GS1 to identify trade items. The key comprises a GS1- or UPC-defined company prefix, followed by an item reference number and a check digit. Longer forms also include a packaging hierarchy number. (GS1 general specifications for *AIDC*)

GTIN Allocation Rules: Rules for assignment of *GTIN*s, covering many common business situations related 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 to which a *GTIN* has already been assigned but that have undergone an attribute change requiring assignment of a new *GTIN*.

Radio-frequency Identification (*RFID*): An *AIDC* process by which a small implanted chip, that emits a radio-frequency signal, is implanted in a product's package or label, thus allowing information to be stored and retrieved by a compatible *RFID* reader.

Executive Summary

This updated *Joint Technical Statement on Canadian Pharmaceutical Bar Coding and Product Database Requirements (Version II)* is the result of continuing collaborative efforts by representatives of Canadian healthcare sectors. The process of developing this statement continues to be 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 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 comprised of 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 GS1 global *Automated Identification* standards for 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 scanning 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 single Canadian standard for *Automated Identification* of medications will provide integrated healthcare solution providers with the necessary expectations about future practices, thereby allowing them to develop software which incorporates automated methods for identifying products and checking the safety of dosages. Such innovations will, in turn, support healthcare practitioners (the end-users) by assuring 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 updated joint technical statement represents the next step in establishing safer product identification and documentation. It sets out a national technical methodology for cross-sector bar coding of commercial pharmaceuticals (and *Automated Identification* practice*s*) on the basis of which the innovations described above can be developed. It includes compliance requirements and timelines for participating healthcare sectors. Version I (January 2010) recommended the adoption of the GS1 global AI (bar code) standard and use of the *Global Trade Item Number* (*GTIN*) by December 2012, while this updated version (Version II) now additionally

recommends the inclusion of both Lot Number and Expiry Date within the bar code by December 2017, and establishes a "minimum software safety functionality" standard for end-user software used in patient care.

Project Phases
The Canadian Pharmaceutical Bar Code Project originally consisted of 3 phases, but a fourth follow-up phase was 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 was communicated across all Canadian healthcare sectors, including many practice organizations. The objective was to encourage development of appropriate expectations for professional practices 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. Several key formal endorsements were received, and can be viewed on our project web pages.

In phase IV the joint technical statement was updated, and issues related to packaging and labelling will be addressed, with further dissemination efforts.

Summary of Contents of the Joint Technical Statement (Version II)

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, with key Version II changes highlighted in blue font.

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), or other designations (e.g. Natural Product Number (NPN)).

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 single *Automated Identification* (bar code) symbology used.
- A one-dimensional or two-dimensional bar code may be used; preference is given to two-dimensional formats.
- The bar code symbology must be GS1-compliant.
- The *GTIN* field length must accommodate a 14-character *GTIN* code.
- The bar code should also show the human-readable text form of the *GTIN,* where package/label space permits.
- 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 (i.e., expiry date and lot number) are recommended by December 2017
- Retail pharmacy products are allowed to contain both a UPC and a second GS1-compliant bar code for an interim time period, to fully allow retail software practices to evolve to a single non-UPC bar code.
- 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.
- Guidelines for Pharmaceutical Manufacturers for Bar Code Placement are provided in Supplement A.

Section 5: Common Canadian Pharmaceutical Product Registry

Key elements:

- The concept of a preferred *Common Canadian Pharmaceutical Product Registry* (*CCPPR*) was re-confirmed.
- The preferred *CCPPR* was identified as the GS1 Canada database, *ECCnet Registry*.
- 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* (*GDSN*) may be used to synchronize data exchange between GS1 global product registries.

Section 6: Bar Code Symbology

Key elements:

- GS1-compliant bar code symbologies (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.
- Healthcare solution providers and end-users should adhere to an appended (Supplement B) checklist of "Minimum Software Safety Functionality.

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.
- Healthcare solution Providers should develop software development plans to adhere to the "*Minimum Software Safety Functionality*" outlined in Supplement B.

Section 8: Timeline for Adoption of Standard by Health Sectors

Key elements:

- Timelines for compliance by various sectors are provided.
- By <u>December 1, 2012</u>, pharmaceutical manufacturers should be compliant with the requirement for fixed data elements (*GTIN*) for all product categories listed in Section 1.
- By <u>December 1, 2017</u>, pharmaceutical manufacturers should be compliant with the requirement for expiry date and lot numbers within the GS1-compliant barcode.
- Healthcare solution providers (e.g., vendors of automated systems and software) should commit to a technology <u>development timeline</u> for the *Automated Identification* of pharmaceutical products at *all* levels of the medication-use process, and for compliance with the "Minimum Software Safety Functionality" (Supplement B) by <u>March 1, 2013</u>.
- The readiness of end-users to acquire the necessary systems and a proposed timeframe will be reviewed and discussed within Phase IV of the project

1. Pharmaceutical Products to be Bar Coded

1.1. Medications to which Health Canada has assigned a Drug Identification Number (DIN), whether prescription or non-prescription, except all vaccine products.

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 reintroduced for sale in Canada.
- Products available through the Special Access Programme that do not have Health Canada DINs.
- Investigational New Drugs.
- Vaccine products with a DIN. Refer to Public Health Agency of Canada project (Automated Identification of Vaccine Products).

1.2. Products that are listed by Health Canada as natural health products (NHPs) and that have been assigned a Natural Product Number (NPN) or a Homeopathic Medicine Number (DIN-HM).

1.3. Medical or treatment kits that contain multiple medication products. Each such kit should have a *Global Trade Item Number* (*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 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 *GTIN* and applicable *GTIN Allocation Rules.*

2.1. The "*GTIN* gateway"

The *GTIN* is a unique identifier for pharmaceuticals and over-the-counter medications. It is essentially a "simple code", or "key", without any product-specific information, providing a "gateway" through which standardized product data fields in a 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/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

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

2.2.1. During a transitional period ending on December 1, 2017, products used primarily within retail pharmacy environments should carry two separate bar codes.

2.2.1 The UPC (Universal Product Code) is incapable of encoding variable data elements, which are required by December 1, 2017. Although a single bar code containing all data elements is recommended by this statement, retail pharmacy operations may require a formal transitional period during which both a UPC code (required for point-of-sale purposes) and the eventual single bar code appear on the product label.

Canadian Pharmaceutical Bar Code Technical Statement Component	Discussion of Component
	This issue is currently also under review by the global GS1 group. Should the global group agree upon international time frames different from those contained in this document, the date specified herein will be reviewed.
	It is further recommended that one of these codes be a one-dimensional linear bar code UPC code and the other a two-dimensional bar code (GS1 DataMatrix) to provide greater visual differentiation between the two bar codes, as an aid to healthcare providers. *Refer also to Sections 4.3.3, 4.3.4, and 6 for additional information.*
2.3. Bar codes may be one-dimensional or two-dimensional. The preference for two-dimensional GS1 DataMatrix codes should be considered. (See also Sections 6.1, 6.2 and 8.2.4)	2.3 Radio-frequency Identification (RFID methods are not specifically addressed in this technical statement. This technology will be reviewed in 2013. However, end-users in clinical practice are encouraged to monitor the development of scanning equipment capable of interpreting all types of *Automated Identification (AI)* technology.
	This technical statement does not recommend that end-users acquire *RFID* readers at this time.
2.4. Database field lengths for the *GTIN* should 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 <u>database</u> field must be capable of accommodating a 14-character *GTIN* code. **For sectors that are already planning for the *GTIN* data field, it is recommended that the *GTIN* be represented in software applications as 14 digits, with right justification and zero filling on the left, as appropriate.**
	Some confusion may exist between the bar coded *GTIN* that is scanned and the final *GTIN* code stored in the software database. When scanned by a bar code reader, the GS1-compliant bar coded *GTIN* is decoded as a 16-character field; however, the leading 2-digit Application Identifier (01) is *not* retained as part of the stored 14-character *GTIN*.

To avoid potential confusion between US and Canadian products, it is recommended that pharmaceutical manufacturers *not* use the National Drug Code (NDC) of the US Food and Drug Administration within a GS1-compliant system, because different labelling and/or active ingredient may be required in Canada. In such circumstances the Canadian version should be considered a different product.

If the NDC is used, it is acceptable, so long as it allows direct access to a specific product data record within the chosen *Common Canadian Pharmaceutical Product Registry.* If the leading system character within a *GTIN*-12 structure is 3, the NDC bar code is GS1-compliant. (See also Section 5)

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

A human-readable lot number and expiry date are <u>not</u> required within the bar code; however, they must be present elsewhere on the product label and packaging as per Health Canada requirements.

2.5 Where space on the label is constrained, the manufacturer should also refer to the GS1 General Specifications for guidance on the human-readable component of the bar code.

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.

2.7. The bar code symbology selected should be capable, at a minimum, of encoding the data elements outlined in Section 3.1 of this technical statement, which are based on GS1 global standards.

2.8. The *Common Canadian Pharmaceutical Product Registry (CCPPR)* should be used by all pharmaceutical manufacturers and providers of healthcare information systems. The registry should contain a corresponding data

record for each product **GTIN**, using data provided by the pharmaceutical manufacturers. (See Section 5)

2.9. Pharmaceutical manufacturers and commercial product repackagers are responsible for the following:

2.9.1. Assuring that product bar codes have been validated for readability. At a minimum, bar code readability should minimally conform to ISO standard 1.5 (ANSI Grade C), but ISO standard 2.0 (ANSI Grade B) equivalency or better is preferred.

2.9.1 Verification of bar code readability, or "grading", is important to ensure high reliability of operational scanning. The verification standard varies with the type of bar code symbology used. Pharmaceutical manufacturers should consult with GS1 Canada for the most appropriate ISO verification standard.

Methods of verifying bar code scanning are outlined 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 Section 5.1)

2.10. The **GTIN** should be added to all third-party clinical and product databases used in Canada, to facilitate future direct (rapid) access by health practitioners to clinical or product information.

3. Content of Bar Codes

3.1. Depending on the level of packaging (see Section 4.3), the selected bar code symbology should be capable of encoding the following data elements for the product, by the dates listed (see also Sections 8.1.1 and 8.1.2). In addition, the bar code should adhere to GS1 formatting standards and use of 'Application Identifiers' within the barcode.

- **Required:** Fixed data element.

  - *Global Trade Item Number (GTIN*), with allowance for up to 14 characters, and specific to packaging level.

    Where: All packaging levels

    When: December 31, 2012

- **Required:** Variable data elements:

  - **Product lot number**

    Where: All packaging levels, except pallets

    When: December 1, 2017

  - **Product lot expiry date**

    Where: All packaging levels, except pallets

    When: December 1, 2017

3.1. 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.

The GS1 website also provides 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

Lot number:
(GS1 Application Identifier 10)
Application Identifier data field "10" contains the batch or lot number, which associates the item with information that the manufacturer considers relevant for traceability of the trade item to which the lot number is applied. This, in turn, may allow more efficient product recall when necessary. The lot number contained within the field may refer to the trade item itself or to any item contained in a kit.

Expiry date (Discussion):
(GS1 Application Identifier 17)
Application Identifier data field 17 contains the expiry date, which 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).

- **Optional:** Variable data elements:

  - **Serialized item numbers**

    Serial numbers (Discussion): Health jurisdictions in Europe, Asia, and North America are investigating serialization of pharmaceutical products at both the primary and secondary packaging levels. Some jurisdictions have begun to specify that serialization will be required in the future. It is probable that Canada will also consider this requirement in the future for pharmaceutical products. The recommended use of serial numbers for will be reviewed again in 2013.

    Pharmaceutical manufacturers and technology providers undertaking system improvements should anticipate the requirement for serialization.

    Serial number:
    (GS1 Application Identifier 21)
    Application Identifier data field 21 contains the unique item serial number, which is assigned to the traceable entity for its lifetime. When combined with the item's *GTIN*, the serial number uniquely identifies the individual item.

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

4.1. Bar codes should be used on *all* levels of the packaging hierarchy described within the GS1 standard and should be 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 variation in *GTIN* for a given medication allows identification of *both* the item (medication) and the specific 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, placement of the bar code.

4.2 The GS1 packaging hierarchy is based on the marking grids for *Automated Identification* specified in the GS1 application standard.
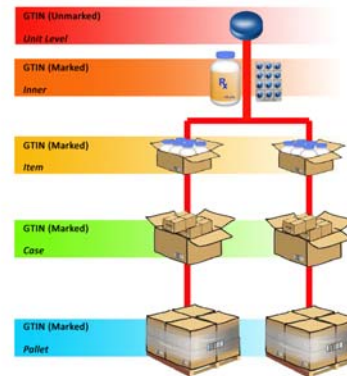

4.2.1. Pallet
Definition: A container that contains one or more "cases" or "shipper units" of an identical item. It must not have any higher-level (parent) packaging, nor should it contain a mixture of different items.

4.2.1. Example:
A pallet of identical units of a single product.

4.2.2. Case or Shipper Unit
Definition: Packaging unit that contains one or more items in their "primary" and/or "secondary" packaging (see below); and represents the standard level of shipping unit, but may also have a parent (e.g. pallet) level.

4.2.2. Examples:
A case containing medications packaged in single-unit or multiple-unit cartons.
A carton of one or more unpackaged bottles or multiple packs of blisters or syringes.

Canadian Pharmaceutical Bar Code Technical Statement Component	Discussion of Component
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).	4.2.3. 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 consists 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.	4.2.4 The primary packaging has the product's "inner label", a term used by Health Canada. Examples: Ampoules and vials. 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, or bottles of liquid. Other individual unit-of-use items (e.g., prefilled 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* tag from the originating container (the primary packaging).	4.2.5 It may be possible to encode an identifier directly on an individual unit-of-use item, without a label. This packaging level is still under discussion by the global GS1 group. Example: A single unpackaged tablet or capsule, or a volume of liquid outside of its container.
4.3. Placement and Content of Bar Codes The inclusion of the fixed and variable data elements listed in Section 3.1 at all levels of packaging is desirable, and such elements should be included in the bar code as soon as possible, most importantly at the primary and secondary packaging levels. The placement and content of bar codes on packaging should conform with the following principles:	4.3. 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 primary and secondary packaging levels as soon as possible.

4.3.1. **Pallet**

Type:
A single one-dimensional or two-dimensional GS1-compliant bar code. May also include an *RFID* tag but should not rely solely on the *RFID* tag for identification purposes.

Placement:
As per GS1 specifications.

Content:
Must include *GTIN*. May include additional elements.

4.3.1 A bar code is required for a pallet only if the pallet constitutes a "tradable" unit of homogeneous products. Pallets of mixed products are non-tradable units for which bar codes are not required.

4.3.2. **Case or Shipper Unit**

Type:
A single one-dimensional or two-dimensional GS1-compliant bar code. May also include an *RFID* tag but should not rely solely on the *RFID* tag for identification purposes.

Placement:
As per GS1 specifications.

Content:
GS1-compliant bar code, with, at a minimum, *GTIN*, lot number, and expiry date (See Section 3)

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

Boxes (or cases) of mixed products are non-tradable units for which bar codes are not required.

4.3.3. **Secondary Packaging**

Type:
A single one-dimensional or two-dimensional GS1-compliant bar code. May also include an *RFID* tag but should not rely solely on the *RFID* tag for identification purposes.

Placement:
As per GS1 specifications.

Content:
GS1-compliant bar code, with, at a minimum, *GTIN*,

For both Sections 4.3.3. and 4.3.4. :

The Technical Task Force and Implementation Committee request that the reliance on current UPC codes be phased out by all health care sectors over the upcoming years, to facilitate the incorporation of additional important bar code information within the bar code itself, and to remain consistent with global pharmaceutical *AI* practice direction.

An exception to the requirement for bar coding of packaging is made for retail pharmacy operators in relation to UPC codes, currently in common use within retail practice

lot number, and expiry date. (See also Section 3.)	environments. With UPC codes, it reasonably possible to encode *only* fixed data elements (e.g., the GTIN).

This exception for retail UPC codes is designed to provide pharmaceutical manufacturers and retail pharmacy operators sufficient time to transition their automated processes to the preferred standard of a single GS1-compliant bar code that is capable of encoding both fixed and variable data elements. (*See also Section 2.2.1*)

4.3.4. Primary Packaging

Type:
A single one-dimensional or two-dimensional GS1-compliant bar code. The package may also include an *RFID* tag but must not rely solely on the *RFID* tag 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, with, at a minimum, *GTIN*, lot number, and expiry date. (See Section 3)

4.3.4. As per note 4.3.3 above, plus:

Nonstandard placement of bar codes may be required for small units of use (e.g., unit-dose blisters or ampoules) to meet labelling and packaging requirements imposed by Health Canada. With this in mind, flexibility in terms of both label types (e.g., use of flaps) and placement of the bar code must be considered.

Manufacturers may seek guidance from Health Canada to meet federal labelling and packaging 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 bar code at all levels of packaging, especially where textual presentation of such variable data is currently required by federal regulation. Therefore, the use of two-dimensional (reduced-space) symbologies such as DataMatrix bar codes, especially on small primary packages, is strongly encouraged.

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 recommendation at this time.

5. Common Canadian Pharmaceutical Product Registry

The GS1 Canada pharmaceutical product descriptor data pool, *ECCnet Registry*, should be utilized where possible as the *Common Canadian Pharmaceutical Product Registry (CCPPR)* for product data descriptors associated with bar code software applications.

The *CCPPR* represents a project concept of a central data pool (*database*) of commercial pharmaceutical product descriptors for Canada. *ECCnet Registry* is the primary data pool that has been selected by this project, by consensus of the Technical Task Force and Implementation Committee members.

Other global *GDSN*-compliant product data pools exist, which may currently be used by pharmaceutical vendors with strong global sales. Where possible, the use of ECCnet Registry is preferred for products used within Canada. The reader is referred to sections 5.2.1 and 5.2.2 for recommendations.

5.1.1. Subject to Section 1 of this technical statement, all products with a *GTIN* should have a corresponding data record in the *ECCnet Registry*.

5.1.2. Within the *ECCnet Registry*, 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 the Health Canada Drug Product Database and other databases.

5.1.2 *ECCnet Registry* is a product registry that does not contain clinical information about the use of the products listed. Such clinical and other data will continue to be maintained within other databases, which may, in the future, be linked to *ECCnet Registry* by means of a relational database environment, using *GTIN* code as the linking key.

5.1.3. The *ECCnet Registry* adheres to the rules of the *Global Data Synchronization Network (GDSN)* to ensure harmonization with other global *GDSN* registries.

5.1.4. GS1 Canada will work with Canadian healthcare sectors to advance requests to modify the *ECCnet Registry* (e.g., data elements) as a means of improving patient safety. This process will be managed through the existing GS1 Canada *Community Management Process* (*CMP*). Where applicable, advanced to the *Global Standards Management Process* (*GSMP*). (See also Section 6.4)

5.1.5. Current and future *ECCnet Registry* data elements identified by industry should support software functionality that enables product identification and mathematical calculation of part units and/or volumes when used in pharmaceutical compounding and/or patient dosing.

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

5.2.1. Pharmaceutical manufacturers with existing pharmaceutical product data in an alternative *GDSN* data pool may also supply these data through a data feed to the *ECCnet Registry.*

5.2.1 Once entered into the *ECCnet Registry*, these submitted data will be subject to Canadian data integrity protocols and Canadian data requirements.

5.2.2. Pharmaceutical manufacturers that do not currently house product data in a *GDSN*-compliant data pool should store their pharmaceutical product information in the *ECCnet Registry*.

5.3. Healthcare solution providers (also known as health information technology providers) should provide their clients with access to the standardized product descriptor data within the *ECCnet Registry*, including updates to product descriptors. *ECCnet Registry* standardized product data should preferentially be used to build inventory product databases for end-users (clients).

5.3 Methods of transferring data from the *ECCnet Registry* to end-user organizations should continue to be based on a GS1 Canada cost-recovery model with a contractual arrangement between the end-user organization (or its agent) and GS1 Canada. Such arrangements should continue to be assessed for their overall cost impact on the respective healthcare system.

Local institutions may be required to include additional product data fields or new products entries in their local inventory databases.

Some end-users may independently wish set up a local database structure to align with the *ECCnet Registry* fields.

5.3.1. All product data records should contain Health Canada's *Drug Identification Number (DIN), the Global Trade Item Number (GTIN)*, American Hospital

Formulary Service (AHFS) code(s), and any alternative classification system that may be used by Health Canada, for the purpose of database record cross-referencing.

5.3.2. Different models exist for transfer of data from the *ECCnet Registry* to end-user organizations. GS1 Canada, healthcare solution providers (health information technology providers), and/or drug reference data providers are encouraged to consider these models when planning for data transfer to the end-user sector.

5.3.2 The use of standardized data by end-user organizations will improve the quality of medication-related documentation.

The project's Database Working Group discussed three models of data transfer that would assist in the efficient transfer of standardized data between the *ECCnet Registry* and end-user organizations. Two of these models would involve a third-party agency acting as a conduit for the *CCPPR* data.

All three models would provide end-user organizations with standardized product data, on the basis of a cost-recovery funding model, under a signed contractual subscriber arrangement with GS1 Canada.

The following three models were discussed:

- **Individual (End-User) Subscriber Model**
  An individual (end-user) organization subscribes directly to the *ECCnet Registry* and uses the data solely for internal purposes.

- **Third-Party Subscriber Model: One-to-One**
  An end-user organization engages a third-party software or data provider, which would subscribe to the *ECCnet Registry* on direct behalf of the organization.

- **Third-Party Subscriber Model: One-to-Many**
  As above, except the third-party organization would subscribe to the *ECCnet Registry* on behalf of multiple end-user organizations, under agreement with GS1 Canada.

5.3.3. Product updates submitted by pharmaceutical manufacturers should be processed by GS1 Canada within two business days and should be made available to healthcare solution providers electronically within one further business day.

5.4. By agreeing to the use of *ECCnet Registry* product data, or any other product data source, the end-user organization acknowledges certain responsibilities, including the following:

5.4.1. Validation of both the accuracy and use of any data received.

5.4.2. Confirmation of the local approved therapeutic use for each product, including, but not limited to, therapeutic interchangeability of products with different *GTIN*s or Drug Identification Numbers (DIN).

5.4 While every effort should be made by pharmaceutical manufacturers and GS1 Canada to ensure the accuracy of *ECCnet Registry* data, only end-user organizations are responsible for confirming the accuracy presentation of the data, defining appropriate use of the data, and, importantly, determining therapeutic usage (including product interchangeability) for patients or clients under their care.

6. Bar Code Symbologies and Uses

Symbology issues:

The majority of healthcare stakeholders are now recommending a single *Automated Identification* symbology capable of containing the required fixed and variable data elements. The GS1 bar code symbologies that meet this requirement include the following: GS1-128 (formerly UPC-128), GS1-DataMatrix, GS1-DataBar, and EPC/RFID.

From time to time, the GS1global standard will be reviewed for the possibility of adding new or altered bar code under the GS1global *AIDC* standard.   One such current example is the "QR" 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.

The use of two-dimensional reduced-space (e.g. DataMatrix) codes should be considered by pharmaceutical manufacturers and commercial repackagers of products. Refer also to Section 2.3

6.1 The full range of GS1 bar code symbologies and their data-carrying capabilities can be found on the GS1 global website, or through consultation with GS1 Canada.

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

The choice of specific symbology by a pharmaceutical manufacturer for a given product packaging level may be based on a variety of factors, such as the following:

- size of package area available for labelling

- need for additional information within a bar code

- products probable environment of use

Two-Dimensional Bar Code Symbology:

Two-dimensional reduced-space bar codes, such as the GS1 DataMatrix symbology, have the advantage of allowing longer character strings while maintaining a compact size. Their use is recommended preferentially by this project for consideration by pharmaceutical manufacturers.

Canadian Pharmaceutical Bar Code Technical Statement Component	Discussion of Component
	A growing global requirement for additional encoded bar code data elements, such as the serial number of the item, is anticipated. The additional characters required by these data elements may exceed, or nearly exceed, the maximum character limits of common linear (one-dimensional) bar codes. **"QR" Code Symbology:** The two-dimensional "QR" bar code symbology is currently under review by GS1 global. At this time, this symbology has *not* been approved within the GS1 standards. Until this symbology is formally approved, pharmaceutical vendors should continue to investigate approved two-dimensional codes (e.g., GS1 DataMatrix). For additional information as to the status of "QR" code symbology, please contact GS1 Canada.
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 reliably capable of reading the one- and two-dimensional GS1-compliant bar codes specified in this standard.	6.2 Optical or "camera-ready" scanners are now capable of reading both one-dimensional and two-dimensional bar codes. Their price points have dropped significantly in recent years. Care should be taken to choose readers that demonstrate consistent reliability in reading two-dimensional bar codes.
6.3. Healthcare solution providers (or health information technology providers) should develop automated and software system functionality capable of reading (scanning) all GS1-compliant bar code symbologies. Systems should use a product's bar code–encoded data elements and should access the product descriptor data elements from the *ECCnet Registry*. Such software functionality should also be aligned with the "*Minimum Software Safety Functionality*" checklist (See also Section 5.1.4. and Supplement B.)	6.3 Appendix B of this document provides an important checklist of the minimum safety and documentation functionality of medication software, aligned with each stage of the medication-use chain. The checklist was developed solely from the perspective of *AIDC* for medications. It does not attempt to define other clinical safety functionality. The reader is also advised to consult other professional practice organizations for additional medication practice-related requirements.
6.4. End-users should review the software safety functionality of systems under consideration to determine which are	

consistent with the safety functionality outlined within Supplement B.

Such system functionality should be made available by healthcare solution providers according to the timelines specified in Section 8.2 of this technical statement.

6.5. Healthcare solution providers and/or drug reference data providers should actively engage with GS1Canada to ensure that all required *ECCnet Registry* data elements are aligned and compatible with both their internal inventory database structure and their software functionality.   (See also Sections 5.1.4 and 5.1.5)

6.5 GS1 Canada utilizes its global associations to ensure that many identified Canadian healthcare needs are reviewed by global standards maintenance groups (*GSMP*) and that approved changes are considered for inclusion within global *AIDC* standards.

The GS1Canada *Community Management Process* (*CMP*) should be used to request utilized for requested changes to the data structure of the *ECCnet Registry* or to health business processes. Approved modifications will often be recommended globally, according to the *GSMP* process.

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 the following means:

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 stages of the medication-use process, including readers (scanners) capable of reading all GS1-compliant one- and two-dimensional bar codes. (See Supplement B, Minimum Software Safety Functionality)

8. Timeline for Adoption of Standards by Health Sectors

8.1. Pursuant to the preceding sections, GS1-compliant bar code elements should be present on pharmaceutical product packages as follows:

8.1 The requirements within section 8.1 are intended for both pharmaceutical manufacturers and commercial repackaging services.

Organizations performing in-house repackaging (i.e., not intended for resale or under for-profit re-packaging repackaging service contracts) may also wish to voluntarily comply with this statement, through local registration with GS1 Canada.

Dates for compliance are also consistent with global direction, through the GS1 Sunrise date recommendations. The reader is directed to the GS1 global website for more detail.

8.1.1. *Global Trade Item Number (GTIN) o*n all products defined in Section 1, at all packaging levels, **by December 1, 2012**, for all products produced after this date

8.1.2. Lot number and expiry date, at the primary, secondary, and case packaging levels, **by December 1, 2017,** for all products produced after this date.

8.1.2. The 2017 date was selected by the project technical task force to give pharmaceutical manufacturers time to research, acquire, and allow a reasonable business replacement cycle for appropriate packaging systems. This date also allows for the depletion of stock manufactured before this date having bar codes that do not contain expiry date and lot number.

8.1.3. Product serial numbers remain optional.

8.1.3 A proposed requirement for encoding serial numbers will be reviewed in 2013, in light of *AIDC* advances and requirements within other global jurisdictions.

8.1.4. The use of *RFID* remains optional.

8.1.4 The required use of *RFID* will be reviewed in 2013.

8.2. By March 1, 2013 , and pursuant to sections 6.1 through 6.4 , healthcare solution providers (or health information

technology providers) should establish a developmental timeline of not longer than three years from that date to offer the following minimal functionality:

8.2.1. Capability of reading all GS1-compliant bar codes, including the following required data elements:
   ▪ *GTIN*
   ▪ Lot number
   ▪ Expiry date
	8.2.1 Healthcare solution providers (or health information technology providers) should also be aware of the probable future need to read and store transactions related to serialized medication items, known as "Track and Trace". Please consult with GS1 Canada for additional information and functionality requirements.

8.2.2. **Minimum Software Safety Functionality** compliant with the functionality outlined in Supplement B of this statement.

8.2.3. Capability of accessing and using *ECCnet Registry* data elements.

8.2.4. Use of camera-ready bar code scanners capable of scanning all GS1-compliant bar codes.

Supplements to this Statement

A. *Guidelines for Placement of Bar Codes on Pharmaceutical Labels for Primary Packaging*	Separate Document Supplement A
B. *Minimum Software Safety Functionality Checklist*	Separate Document Supplement B

Technical Task Force: Sectors and Representatives

Global Standards for Automated Identification and Public Health Information Systems

Pharmaceutical Manufacturers

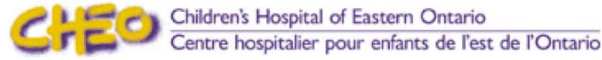**Supply Chain and Group Purchasing Organizations (GPOs)**

Providers of Health Information Technology

Retail Pharmacy Practice

Institutional Pharmacy Practice

Health Regulators and Professional Organizations