Supplement B

Canadian Pharmaceutical Bar Coding Project

Minimum Software Safety Functionality Checklist

From the
Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements
(Version II)

February 24, 2012

Purpose

This document is second of two supplements to the *Joint Technical Statement on Pharmaceutical Automated Identification and Database Requirements (Version II)*. Its purpose is to provide additional guidance on software and automation functionality related to the use of pharmaceutical package bar codes in medication practices. It is intended primarily for use by solution (technology) providers when planning developmental improvements to their current systems. It will also find application for Group Purchasing Organizations (*GPOs*) or end-user organizations when assessing new or upgraded systems, to assure the maximum possible functionality, for patient safety and related health record documents.

Foreword

A voluntary technical statement for bar coding of commercial pharmaceutical products within Canadian health practices was developed as part of the Canadian Pharmaceutical Bar Coding Project (the *Project*). The collaborative *Project* was supported by funding from both not-for-profit and for-profit organizations committed to improving medication safety for all Canadian patients, while optimizing system efficiencies within the health care supply chain. The *Project* involved representative organizations from six Canadian health care sectors.

Following release of the initial *Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements* (Version I), January 2010) end-user clinicians and support organizations requested that the *Project* conduct a survey of software functionality needs related to ***Automated Identification*** of pharmaceutical products, including safety checks, ability to calculate dose quantities, and documentation.

This document is the result of the end-user survey. The functionality requirements are presented in several sections, related to sequential steps described within the medication process.

This objective of the document is to allow both solution providers and their healthcare customers (including those responsible to assessing new or upgraded systems) to converge on essential patient safety functions of an automated system, thus allowing such systems to evolve in the most efficient and safe manner possible.

Disclaimer

Glossary of Terms and Abbreviations for Supplement B

Terms and abbreviations defined in this supplement are utilized within this statement and are meant to provide the reader with a meaning in the context of this document only. Some of these terms may also be defined within externally-approved technical standards, but 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 product descriptors (data elements) are located and can be accessed (through subscription) by organizations requiring such data. The term is not used in relation to a specific database, nor does it indicate a specific database structure. The project will select 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 database structure (also known as a data pool or registry) selected by this project as the preferred ***CCPPR. It is used to register products to which a ***GTIN*** has been assigned. It complies with ***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 database are owned by the manufacturer, but are pre-checked by GS1 Canada for consistency with global and/or ***ECCnet Registry*** (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 **GTINs**, 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.

Ref. No.	Status	Recommended Software Safety Functionality Safety Functionality	Description

B1. Overall Software Functionality

B.1.1	Required	Interprets GS1 Codes and Bar Code Data Elements	System software can read GS1 standard bar codes and can extract, interpret and document a product's ***GTIN***, lot Number and expiry date, at the following packaging levels: Shipping Case, ***Secondary Package*** and ***Primary Package***.
B.1.2	Required	Bar code Readers	System has associated bar code readers with the ability to scan and interpret both one-dimensional (linear) and two-dimensional GS1-compliant bar codes, which may include fixed and variable data elements. RFID chip readers are optional at this time.
B.1.3	CRITICAL: Required	User-defined Product Interchangeability	System allows a user to determine therapeutic equivalency (interchangeability) between various manufacturers' products and, thereby, their associated ***GTINs***, at the above packaging levels.
B.1.4	Required	Use of Standard Product Data Description Elements from GS1 ***ECCnet Registry*** Data pool	Local system inventory file(s) is (are) populated with standard product descriptors from the GS1 ***ECCnet Registry***. Such product descriptors will include the alternate product identification codes (e.g., DIN) and drug classification systems (e.g., AHFS classifications) itemized below.
B.1.5	Required	Cross-referencing to Alternate National and Group Purchasing Organization (*GPO*) Product Codes	System has an *Inventory Module* that contains cross-references between the ***GTIN,*** the *Drug Identification Number* (*DIN*) or *National Product Number* (*NPN*). The system uses ***GTIN*** to cross-link to *GPO* contracted item code for correct item purchasing and costing information.
B.1.6	Required	Cross-referencing to Alternate User-defined (*Local*) Product Codes	System allows user to input and utilize local site-specific codes, and enables cross-referencing of the local product codes to the ***GTIN***, as well as other product ***GTIN***s which are deemed to be therapeutically equivalent by User. (See also B.1.3)

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.1.7	Required	Use of American Hospital Formulary Service (AHFS) Drug Classification and World Health Organization Identification Codes	System inventory file(s) to have a data field that contains the AHFS drug classification system code for each medication. As above, the number should be obtained from the ***ECCnet Registry*** initially, however should allow user modification thereafter.
B.1.8	Required	Linking of ***GTIN*** to Standard Product Descriptor Data Elements in Inventory File. (See also B.1.4)	System links a scanned product's ***GTIN*** number to standard product descriptors, and utilizes that data when printing or displaying the product scanned. Such instances include, but are not limited to: - Prescription order entry - Prescription label printing - Dose identification - Medication Management forms - Purchasing functions (purchase orders, receiving, etc.)
B.1.9	Required	Point-of-Sale, or Point-of-Transfer Stock Movement	Where a Point-of-Sale (or Point-of-Transfer) of product is needed, the system will both scan the product bar code and link to the Point-of-Sale (or Point-of-Transfer) module for the transaction, including inventory adjustments, pricing, and, if needed, billing.
B.1.10	Required	Minimize the Use of Codes on Paper Reports or Labels: Avoiding Possible Patient Safety Work-arounds	The use of printed bar codes on health record documents should be limited to avoid or lessen the potential for user work-arounds (i.e., worker non-compliance with patient safety processes). The system should force users to scan only actual drug/dose containers and patients, when performing critical medication safety checks, such as verifying the correct drug/dose or correct patient ID. In other words, the printing of ***GTIN***, prescription, or patient bar codes on health record forms (e.g., Medication Administration Records, prescription labels, etc.) may inadvertently allow non-approved worker "work arounds". It may facilitate a worker bypassing a critical safety checks by scanning a document, rather than the actual drug, dose or patient. Therefore, only ACTUAL drug/dose containers or *ACTUAL* patient wrist bands should be scannable.

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.1.11	Optional	Inventory File Links to NDC	The system should allow cross-reference to NDC codes.
B.1.12	Optional	Linkages to External Databases	***GTIN*** should facilitate the ability to link to external databases, such as clinical data sources, online drug information, product monographs, patient education material, h*igh resolution product Images*, Health Canada information and warnings, AHFS, WHO databases, etc. Such external data sources may be within an institution's intranet, or, if allowed, outside internet sites.
B.1.13	Optional	Database Mining	System should allow site management to report on user bar code scanning and documentation activities; such as user-over-rides of warnings, omitted or late doses, non-administered doses, etc.

B2. Supply Chain Warehouse

Out of Project Scope

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**

B3. Contracting and Purchasing (Purchasing & Receiving Stock)

B.3.1	Required	Cross-Referencing Clinically Equivalent Product Codes for Purchasing (See also B.1.3 and B.1.4)	Inventory module records contain cross-references between ***GTIN*** and DIN or NPN. Also, the system needs to provide links to contract number(s) from *GPOs* for correct item purchasing. The system should also facilitate the purchaser selection of therapeutically equivalent products, in cases of manufacturer back orders, etc.
B.3.2	Required	Use of Bar codes on Purchasing Documents or Electronic Systems	System allows bar codes to be printed on paper purchase orders, or used within mobile/electronic devices, such that the users can utilize the codes for associated inventory functions. However, it is important that the bar code printed on the purchase order not be the ***GTIN*** itself, as this might inadvertently allow a bypass of inventory safety checks by allowing the worker to scan the paper code, instead of the product and shelf locations. The reader is referred also to the GS1 *Global Document Type Identifier* standard for additional information.
B.3.3	Required	Automated Purchasing Functions	The system allows purchasing by bar code scanning of shelf or item to assure correct item ordered, with the appropriate purchasing documentation completed. Allows user entry of purchasing quantity. Please note that the shelf location may allow storage of more than one therapeutically equivalent brands (e.g., different brands of a common antibiotic of the same strength and form). In such cases, the shelf bar code may link to a number of equivalent products, each with its own ***GTIN***. (See B.1.3)

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.3.4	Required	Quarantined Stock	User is warned to quarantine stock prior to release of the product for use, if any of the following conditions occurs upon receipt of product: - No bar code to read on product - Bar code is unreadable - Item scanned is not in the inventory system, or - Product is on a user-defined "mandatory quarantine" list
B.3.5	Required	Automated Receiving Functions	Update Quantity on-Hand. Notify User if Qty is less than purchase order quantity, and creates a “Back-order” document.
B.3.6	Required	Automated Receiving Functions: Received Stock Placement	Placement of received stock in the correct Storage location(s) is verified by scanning shelf/bin locations and items.
B.3.7	Required	High Alert Notification	Designated "High Alert" medications (from an internal user-defined list) will trigger an audio and visual warning to staff when: - Received item is scanned, and - When product is placed upon the shelf at the time of shelf bar code scanning
B.3.8	Optional	Product Safety Problem Reporting	Electronic reporting to ISMP Canada, vendor and GPO (if required) for any product with dangerous labelling, packaging, or look-alike concerns.
B.3.9	Optional	Drug Shortage Notification	Upon receipt (scanning) of a drug which is on a user-defined "short supply" list, the receiver is notified and can access a notification list within the order, to inform listed persons that a supply has now arrived.
B.3.10	Optional	Auxiliary Product Labels	Allow production of auxiliary bar coded inventory labels at time of receiving, such as: - shelf labels, or - smaller primary packaging labels (for non bar coded items)

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B4. Local Inventory Storage and Transfers			
B.4.1	Required	Stock Selection	Whether paper-based or electronic/mobile system, the user is forced to verify stock and quantity, based on bar code scanning of ACTUAL product, not the bin/shelf location. (See also B.1.10)
B.4.2	Required	Replenishing Stock Location(s) for Manual and Automated Storage Systems	Placement of stock onto/into the correct storage location(s) is verified by scanning both the shelf/bin/drawer locations and the actual drug product, using either the product's primary or secondary package GTIN. (See also B.1.3)
B.4.3	Required	Replenishing Automated Technology Stock	While re-stocking of automation (re-packager cassettes/canisters, compounder pump channel vials, etc), the user is forced to verify that correct product is placed on the correct location (canister location, or compounder spike). The system should scan and verify both the product and the location before validating the correct product/location. (See also B.1.3)
B.4.4	Required	High Alert Warning	Scanning a designated "High Alert" medications using an internal user-defined list, will trigger an audio and visual warning to staff when received item is scanned.
B.4.5	Required	Printing Bin Labels, or Transport Labels	System allows printing of shelf/bin or transport labels with bar codes that relate to acceptable ***GTIN***s and standard product data elements. (See also B.1.3)
B.4.6	Required	Point-of-Sale, or Point-of-Transfer Stock Movement	See B.1.9

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.4.7	Required	Returned Medications	System should force the scanning of returned medication, and prompt user to verify whether the product is re-usable or not. The system should makes appropriate inventory changes and, if the product is re-shelved, will checks the location of the product upon re-shelving. (See also B.4.2). If the return item is to be wasted, the system appropriately documents the wastage, quantity, cost, etc.
B.4.8	Optional	Look-alike Sound-alike (LASA) Warning	Look-alike or around-alike warning when a designated item is scanned based on an internal User-defined list of products.

B5. Medication Compounding Process

B.5.1	Required	Automated (Coded) Standard Recipes	For both printed and electronic/mobile systems: All recipes will have both product and ingredient bar codes. The ingredients, when scanned, are verified against the standard recipe. This includes oral or topical, parenteral nutrition, bulk compounded products (oral or parenteral), and individual multi-ingredient prescriptions. (See also B.1.3)
B.5.2	Required	Forced Ingredient Scan and Documentation	The system will create a bar code label with the NEW product code, textual description, Expiry Date, Lot No., and document the completion of the compounding process in a compounding log function.
B.5.3	Required	Replenishing Automated Compounding Technology	See B.4.3

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.5.4	Required	Replenishing Parenteral Robots or Similar Multi-channel Compounders	For Parenteral Compounding Technologies: Automation forces ***GTIN*** verification to ensure correct product is placed in the correct location/channel. (See also B.1.3)
B.5.5	Required	User-made (Compounded) Ingredient for Multi-channel Compounder Channel.	Where the user must create a user-made bulk solution for an automated compounder channel, the system will print an acceptable bar coded label with human readable text, to be affixed to the solution container, and usable within the bar code verification function, B.5.4.
B.5.6	Required	High Alert Warning	Any designated "High Alert" medications (from an internal user-defined list) will trigger an audio and visual warning to user when received item is scanned as part of the compounding function. (See 8.5.1 and 8.5.4)
B6. Medication Dispensing Process			
B.6.1	Required	Order Entry: Correct Medication ***GTIN*** is Selected by User.	During the prescription (medication) order entry process, the system lists the acceptable therapeutically equivalent ***GTIN***(s). If multiple ***GTINs*** are possible, then the institutional recommendation is highlighted. (See also B.1.3)
B.6.2	Required	Patient Container Labels	A bar code is placed on all dispensed labels, regardless of dose form or route, to allow bedside dose safety scanning (Point-of-Care) scanning. Label must have adequate single bar code to allow the verification of the following at dose administration: Correct patient, correct drug, correct dose, and correct time. (See also B.1.10)

Ref. No.	Status	Recommended Software Safety Functionality Safety Functionality	Description
B.6.3	Required	Dispensed Medication Verification	Verification of correct medication dispensed, based on entered Rx (label code). System will scan the ACTUAL drug selected and determine the quantity dispensed. (See also B.1.3) Note: The system should also warn the user if recalled Lot number, or out-of-date product is selected, based on an internal list of "Do Not Use" products, lot numbers or expiry dates.
B.6.4	Required	Refills for Patient-Specific Refills	All refill lists (e.g. Unit-dose fill lists, or retail refill labels), whether in printed or electronic/mobile format, will contain bar codes which include both patient ID bar code and drug item. The system should forces the user to scan ACTUAL product, and determines correct quantity. (See B.1.10)
B.6.5	Required	Correct Patient Drawer or Rx Container	Correct patient container/bin verification. When stocking a patient's pre-labelled drawer or prescription container, the patient drawer/bin/container bar code (using Medical record number, or equivalent) should be verified against the printed or electronic fill list patient ID.
B.6.6	Optional	Relational Database link to Clinical Information	Order Entry process allows access to secondary clinical information associated with the ***GTIN*** used, usually through a clinical database.

B7. Patient Care Area Supply

B.7.1	Required	Stocking Remote Patient Care Area	See B.4.1
B.7.2	Required	Replenishing Stock Location(s), including Manual and Automated Storage Systems	See B.4.2

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.7.3	Required	Point-of-Sale (Point-of-Transfer)	See B.1.9
B.7.4	Required	High Alert Warning	Designated "High Alert" medications (from an internal user-defined list) will trigger an audio and visual warning to staff when received item is scanned for any reason.
B.7.5	Optional	Look-alike Sound-alike (LASA) Warning	Look-alike or sound-alike warning will sound when item is scanned, based on an internal User-defined list of products.
B.7.6	Optional	Relational Database External Linkages	The ***GTIN*** links to allowable clinical data, drug information, product monographs, patient education material, high resolution product images, warnings, etc. (See also B.1.12)

B8. Patient Care Area Healthcare provider (e.g. RN) Drug Selection

B.8.1	Required	Stock Removal Validation	When RN removes product from an automated storage system, the system requires User Identification, Stock confirmation and, if possible, patient ID selection.
B.8.2	Required	High Alert Warning	Designated "High Alert" Medications (from an internal user-defined list) will trigger an audio and visual warning to staff when received item is scanned.
B.8.3	Required	Active Patient Prescription Validation	If Patient ID is available in an automated storage system and it is linked to the active medication profile, the system should validate that chosen medication is an active prescription. (See also B.1.3)
B.8.4	Optional	Look-alike Sound-alike (LASA) Warning	Look-alike or Sound-alike warning when item scanned based on an internal User-defined list of products.

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.8.5	Optional	Relational Database External Linkages	The ***GTIN*** links to allowable clinical data, drug information, product monographs, patient education material, high resolution product images, warnings, etc. (See also B.1.12)
B.8.6	Optional	Kit Assembly	For procedural medications chosen and assembled by an individual as a "kit", the system utilizes bar codes on the standard list, which allows individual to verify that the correct medication is collected for the procedure.

B9. RN or Care-giver Dose Administration

B.9.1	Required	Bar Code Medication Administration (*BCMA*): Correct Patient, Drug, Dose and Time	*BCMA*: All administered doses are scanned for right drug, right dose, right date/time and right patient, and performs a patient allergy status check. (See also B.1.3)
B.9.2	Required	Bar Code Medication Administration: Parenteral Pump Programming	All smart pumps using drug libraries, allow scanning of commercial and internally-produced container labels, using ***GTIN*** bar code scan to identify and match to the correct drug and concentration within drug library. (See also B.1.3)
B.9.3	Required	High Alert Warning	Designated "High Alert" medications (from an internal user-defined list) will trigger an audio and visual warning to staff when received item is scanned.
B.9.4	Required	Validate Active Prescription for Patient	If Patient ID is available and linked to an active medication profile, the system should validate that chosen medication is an active Rx. (See also B.1.3)

Ref. No.	Status	Recommended Software Safety Functionality	
		Safety Functionality	**Description**
B.9.5	Required	Medication Reconciliation (Transfer or Discharge)	A printed or electronic discharge or transfer medication reconciliation form should be available if requested by the user. The form should include the ***GTIN*** of the medication product the patient was receiving, such that an outside agency can scan and verify the actual commercial product the patient was receiving and/or determine a therapeutically equivalent product.
B.9.6	Optional	Look-alike Sound-alike (LASA) Warning	Look-alike or sound-alike warning when item is scanned, based on an internal User-defined list of products.
B.9.7	Optional	Relational Database External Linkages	The ***GTIN*** links to allowable clinical data, drug information, product monographs, patient education material, high resolution product images, warnings, etc. (See also B.1.12)
B.9.10	Optional	Late or Omitted Patient Doses, or Monitoring reminders	System software should prompt the user if a dose is late or omitted. If over-ridden, the system may also prompt for a "reason" from a pre-defined list. The system may also prompt the user to monitor selected (user-defined) clinical medication safety parameters at regular intervals, should the site define standard monitoring for medications and develop an internal list of such monitoring requirements.