Supplement A

Canadian Pharmaceutical Bar Coding Project

Guidance for Placement of Bar Codes on Pharmaceutical Labels for Primary Packaging

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

February 24, 2012

Revision Date Log	***Modifications***
October 13, 2010 (Rev 1)	Original Draft for Internal ISMP Discussion
TTF DRAFT	Version 7
IC DRAFT	Version 8
Final Draft Project Executive	Version 10

Purpose

This document is the first of supplements to the *Joint Technical Statement on Pharmaceutical* ***Automated Identification*** *and Database Requirements (version II)*. Its purpose is to provide additional guidance on the placement of bar codes on commercial pharmaceutical labels or packaging material for ***Primary Packaging*** only. It is intended primarily for use by pharmaceutical manufacturers, health care sectors, and commercial repackaging agents; however, it will be useful to end-user organizations or their group purchasing organization as part of their contractual product assessments. This guidance builds on work completed within the context of the Canadian Pharmaceutical Bar Coding Project, as well as work completed by the GS1 global organization.

Foreword

A voluntary technical statement for bar coding of pharmaceutical products in the Canadian context was developed as part of the Canadian Pharmaceutical Bar Coding Project (hereafter referred to as the ***Project***). This collaborative ***Project*** was supported by funding from both not-for-profit and for-profit organizations committed to improving medication safety for all Canadians, 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 Joint Technical Statement on Pharmaceutical ***Automated Identification*** and Product Database Requirements (version I, January 2010), industry sectors requested additional guidance about its interpretation and implementation, especially with regard to bar code symbologies, labelling, and packaging. Readers are directed to GS1 Canada support services for detailed technical advice related to bar code symbologies. This supplement provides guidance on the design and placement of bar codes on ***Primary Packaging*** for pharmaceutical products. Other collaborative efforts involving ISMP Canada will offer further guidance related to a broader range of labelling and packaging considerations.

The printed bar code is the critical link to successful ***Automated Identification and data capture (AIDC).*** The design and placement of the bar code must ensure efficient and accurate reading. However, ***AIDC*** will be used in combination with human-readable text, which also provides essential product identifiers and information. Therefore, the addition of a bar code must not compromise the clarity and safety of human identification methods.

- The information in this document is presented in three sections:
- Established regulations, standards, and guidelines affecting labelling of pharmaceutical products
- General principles for the design and placement of bar codes
- Dosage form–specific guidelines for the design and placement of bar codes

This document is not intended to be comprehensive. Rather, it is designed as a supplemental resource for those engaged in the design or review of pharmaceutical product labelling that includes bar codes. Furthermore, it is not intended to replace or restate the details of the Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements or to supplant any federal (e.g., Health Canada) regulations related to labelling or packaging.

Disclaimer

Contents

Glossary of Supplemental Terms and Abbreviations

The terms and definitions used within this *Supplement A* are in addition to those listed in the main body of the ***JTS*** (version II) document. The defined terms below, as with the main body of this Statement, are used in the context of this document only. The definitions therefore may or may not directly match nomenclature defined within other formal standards, or the pharmaceutical industry itself.

Capitalization and **bolding** of words, abbreviations, and phrases used in this Supplement, whether in singular or plural form, denotes terms defined in this Glossary of Supplemental Terms and Abbreviations.

***GS1-DataBar*:** One of a GS1-compliant family of linear (one-dimensional) bar codes, which were formerly referred to as an **RSS** (Reduced Space Symbology) or **RSS-14** code. Allows both fixed and variable data, but imposes some limitations in terms of both number of embedded characters and size of print (footprint), which must be relatively large. Bar codes in this family can also incorporate a composite code; using both a linear (one-dimensional) portion which can contain the **Global Trade Item Number (*GTIN*)**, and a matrix (two-dimensional) portion of the same bar code. In composite codes, the linear portion can be read by a linear scanner; and all of the data can be read by a two-dimensional scanner.

***GS1-DataMatrix*:** A GS1-compliant two-dimensional code used primarily for packages or labels requiring a small bar code size (footprint). Allows both fixed and variable data elements, allows a greater number of embedded characters, and has ECC200 auto-correction (redundancy) to increase reading reliability. Requires an imaging (camera) scanner; and may not be readable by older models of two-dimensional cameras.

JTS: Latest version of the *Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements*, available on the ***Project*** web pages, hosted by ISMP Canada.

Machine-Readable Code: Though not used within this document, this term may be used in related discussions. It refers any data carrier that allows ***Automated Identification*** by a reader (scanner); includes ***Radio-Frequency Identification (RFID)*** tags, bar codes, and other data carriers.

Primary Packaging*:** 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); and which represents the lowest level of packaging hierarchy of items intended or labelled for individual use. Depending on the intent of the packaging, such packaging may also be referred to as "Unit-of-Use* Packaging**", which usually refers to the package that touches the drug product itself.

Examples:

- Ampoules and vials.
- Each solid separable **Unit of Use** (e.g., tablet or capsule) found in a perforated blister pack having multiple Units of Use, which allows separation of a single unit from the remaining blisters in the pack.
- Each solid unit (e.g., tablet or capsule) found in a single individual ***Unit-of-Use*** package, such as a unit-dose tablets

- A single blister pack that does *not* allow separation of individual ***Unit-of-Use*** doses
- Single bottles of multiple tablets or capsules, such as a bottle of 100 or 500 units
- Individual infusion bags, tubes, or bottles of liquid
- Individual ***Unit-of-Use*** items (e.g., prefilled syringes)

See also ***Secondary Packaging***.

Project: Canadian Pharmaceutical Bar Coding Project, led jointly by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). Information and related documents can be found on the ***Project*** web pages, hosted by ISMP Canada.

RSS or RSS-14*:** A ***GS1-DataBar "Reduced Space Symbology" symbology. ***RSS-14*** has a 14-character length.

Secondary Packaging: 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). May or may not represent the manufacturer's purchasing unit.

Examples:

- A box of 10 vials
- A box of 10 sleeves of multiple dose (perforated) blisters, each of 12 tablets
- An outer container holding a single vial, bottle, or tube

See also ***Primary Packaging***.

Unit Dose: For the purpose of this document, an individual ***Unit-of-Use*** package that may have been customized for a dose required for a specific patient; and may or may not be a commercially available ***Unit-of-Use*** package.

See also ***Unit-of-Use***.

Unit-of-Use*:** A form of ***Primary Packaging in which the medication product is a *single-unit package* containing one discrete dosage form, such as one tablet or capsule, a volume of liquid representing a usual single dose, or a volume of topical product intended for a single use. May also refer to a package that contains multiple dosage forms intended to be given as a *single* dose. This term does *not* refer to a perforated or segmented package designed to contain and dispense *multiple doses*, such as multiple dose blister packs or birth control tablet compact.

See also ***Unit Dose***.

Section 1

Established Regulations, Standards, and Guidelines Affecting Labelling of Pharmaceutical Products

The guidance contained herein is intended neither to contradict nor to supplant Health Canada regulations for marketed pharmaceutical products. The design of any label must meet all current federal labelling and packaging regulations and related requirements.

To accommodate bar codes, it may be necessary to alter the layout or size of a label or package. Companies are encouraged to consider, within reason, alternative label sizes or modified container formats. For example, the use of flags for container labels (i.e., fold out extensions) may create a larger label "footprint" to accommodate both the required product information and the bar code.

Table A.1.1 lists selected relevant Canadian guidance and regulatory documents.

Table A.1.1 Existing Canadian Guidance and Regulatory Documents (as of 2011)

Document	Content
Government of Canada (2006). Food and Drug Regulations, C.R.C., c.870. Ottawa **Health Canada,** **Health Products and Foods Branch** *http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/*	Health Canada's Food and Drug Regulations (Current to February 2012).
Government of Canada.. Drugs and Health Products: Labelling Requirements Checklist **Health Canada,** **Health Products and Foods Branch** *http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/label-list-etiquet-eng.php*	A manufacturer checklist for labelling of products approved by Health Canada with Natural Product Numbers (NPNs or DIN-HM), arising from the Natural Health Products Regulations.

Document	Content
Draft Guidance Document (for consultation): Labelling of Pharmaceutical Drugs for Human Use **Health Canada,** **Health Products and Foods Branch** July 2010 http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/consultation/drug-medic/draft_ebauche_label_guide-eng.pdf	General labelling requirements Label information Product claims and content of text Additional Considerations for Specific Product Types
Canadian Standards Association International 1999. Labelling of Drug Ampoules, Vials and Pre-filled Syringes. **(Vol.CAN/CSAZ-264.2. Etobicoke, ON: CSA International)**	Labelling guidelines for parenteral dose formats.
Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements December 2011 (Version II) http://www.ismp-canada.org/barcoding/download/CanPharmBarcode_JointTechnicalStatement.pdf	Products to be identified using bar codes Use of a common National Pharmaceutical ***Automated Identification*** Standard: GS1 global Required content of bar codes Packaging and placement of bar codes **Common Canadian Pharmaceutical Product Registry** GS1 bar code symbologies Expectations of professional practice organizations and end-users Timeline for adoption of standard by health sectors
GS1 Canada Bar Code Guidance Technical guidance regarding the creation, readability, validation, and implementation of bar codes is found in the *GS1 General Specifications Guideline,* which is available through GS1 member organizations.	The *GS1 General Specifications Guideline* is a technical resource and implementation guideline which is updated annually; please ensure the most up-to-date version of the guideline is used.

Section 2
General Principles for Design and Placement of Bar Codes on Primary Packaging

Accurate ***Automated Identification*** (AI) of a pharmaceutical product using a bar code depends on a large number of interrelated factors. More specifically, the following factors, among others, contribute to the successful interpretation of a scanned code: code symbology used, placement of the label, paper quality, appearance of background, clarity and/or fading of the printing, curvature of the container or label, and proximity of competing label features. It is therefore essential that any design or bar codes consider the relevant issues outlined in this document.

1. Multiple independent assessments of the label design plan
2. Statistical validation of code readability by means of the validation process recommended by GS1 Canada
3. Broad stakeholder input
4. Field-testing and confirmation

Table 2.1 provides guidance related to various aspects of planning the placement of bar codes for ***Primary Packaging***. ***Secondary Packaging*** may also be important for patient safety but will usually have sufficient area to allow full compliance with Canadian regulations and guidelines for bar coding. Nonetheless, the reader is encouraged to also consult Table 2.1 for issues that may assist in the planning of ***Secondary Packaging***.

Table A.2.1 Specific Guidance for *Primary Packaging* (Labels or Packages)

Element	Discussion
Primary Packaging packages (***Unit-of-Use***)	Any product that, under usual circumstances, is likely to be separated from a larger package before administration must be individually labelled with all required information, including a bar code.
Label size	If the usable surface area on a label is small, the requirement for inclusion of specific information on the label presents major challenges. On small products, label size can be increased by using a tag or flag that extends beyond the limits of the product itself. Alternatively, or in addition, a reduced-space ***GS1-DataBar*** (***RSS-14***) symbology or ***GS1-DataMatrix*** (two-dimensional) symbology may be used.

Element	Discussion
	Several symbology options exist. Pharmaceutical manufacturers should consult with GS1 Canada to discuss available bar code options, and the benefits of each compliant symbology.
Label surface	The surface should be opaque and minimally reflective. The chosen material should be of high quality. It should allow clear printing (visualization) of information. Refer to formal bar code reading validation testing, and associated recommendations, for assessment of conformance.
Print quality	The print quality of the label should be such that barcode lines (or dots) are clear and visually distinct, with high contrast against the field background of the bar code. The printed code should be resistant to fading and the effects of cleaning solutions routinely used in clinical or dispensing practices.
Selectivity (percent correct readings)	According to the applicable ISO validation test limits, the bar code will identify the correct product when it is read by at least four different commonly used bar code readers, or as per the GS1 Canada approved validation method.
Specificity (percent incorrect readings)	Attempted scanning of the bar code will always fail (i.e., be unreadable) rather than interpreting the bar code incorrectly as the wrong product.
Readability	The size and location of the area of contrast (i.e., white space) on container surfaces is integral to the fidelity of a drug identification system that relies on bar codes. The contrast space surrounding a bar code should be adjusted for optimal readability.
Overwrap	(See also Section 3: Overwrap) ***Primary Packaging*** with partial or full overwrap (e.g., cellophane wrapping) should have an identical bar code

Element	Discussion
	on the outer wrap. This packaging practice will eliminate the need to unwrap the product for scanning purposes during usual operational processing of the product. If a bar coded overwrap is not reasonably possible, then the primary package bar code should be readable through the overwrap, without removal of the overwrap. Under no circumstance should it be necessary to remove the overwrap to scan the bar code. The above requirement may change in the future should additional validation of reading through shrink-wrap emerge. (Consult GS1 Canada GTIN Allocation Rules for additional information.)
Placement relative to other bar codes on the package	The ***JTS*** specifies that a single bar code is preferred over multiple bar codes. However, if multiple package codes are necessary during periods of transition to single GS1-compliant bar codes, the GS1-compliant code *intended for the management of a patient's medications* should be physically separated from any other code intended for supply chain or point-of-sale operations.
Placement relative to primary product identifiers	The bar code intended for the management of a patient's medication should appear on the same side of the product as the primary human-readable product identifiers, if possible.
Placement relative to other information	A band of clear space ("quiet zone") should surround the bar code, but the size of the zone may vary by bar code symbology. Consult technical documents to determine the minimum space for the chosen symbology.
Font size	Manufacturers should consult Health Canada regulations for suitable font sizes. Font sizes of 10-12 point should be a goal during design.

Element	Discussion
	It is further recommended that all numbers and bar codes be surrounded by a clear space ("quiet zone") with a minimum width of 1 mm.
Design Input from stakeholders	If a company is designing package and/or label for a new or unique item, obtaining design input from stakeholders will increase the likelihood of safe product use. Health system partners can assist manufacturers and packagers with field testing. Once marketed, a product's bar code readability, or errors related to reading it, should be directly reported by stakeholders (end-users) to both the Pharmaceutical Manufacturer (or commercial re-packager) and GS1 Canada.
Readability testing (validation)	Refer to ISO bar code validation (readability) methods, and consult with GS1 Canada for specific tests. At a minimum, validation should ensure an ISO 1.5 (ANSI grade C) readability, but ISO 2.0 (ANSI grade B) readability or better is preferred. Test methods will vary with the type of bar code. Pharmaceutical manufacturers should retain quality control logs of validation testing. If manufacturers perform these readability tests in-house, the testing apparatus and the methodology should be reviewed regularly to ensure compliance with the standard. Details of ISO specifications and calibrated test cards are available through GS1 Canada. Among the most important design concepts is the importance of field-testing bar codes on the actual package in real practice environments or in a high-fidelity simulated environment. Such field trials should encompass variations in practice environments, scanning equipment, light sources, storage, cleaning, and product handling.

Element	Discussion
	The use of It is advisable to involve human factors engineers in designing the field-testing conditions.
Readability over life of product	According to the principles of safe medication practice, it is generally recommended that a single product item not be used for multiple doses. However, any product that may be used for multiple doses should be labelled so as to ensure that the extended use of the product will not interfere with readability of the product's bar code.
Curvature	A bar code should not be placed on a curved surface, unless such placement is absolutely unavoidable. If a bar code on a product label is curved because of curvature of the product package or because of rolling of the label (as may occur with flag or tag labels), then a two-dimensional bar code (***GS1-DataMatrix***) is recommended, because of its square shape and small size. If a linear bar code is used in this situation, it should be aligned along the axis of least curvature. Published technical specifications for the bar code symbologies provide more details on the amount of curvature that can be accommodated while maintaining good readability. The reader is also referred to the GS1 General Specifications Guideline document (see Table 1.1).

Section 3
Dosage Form–Specific Guidelines for Design and Placement of Bar Codes

Various dosage forms (packaging formats) are used within healthcare practice. The ***Global Trade Item Number*** (***GTIN***) system is based on a packaging hierarchy, such that each ***GTIN*** is unique to a particular product and its respective package level or volume. From an ***Automated Identification*** (AI) perspective, the use of a variety of packaging formats, such as small ***Unit-of-Use*** formats or over-pouching, for medications can become problematic in clinical practice.

Table 3.1 provides additional guidance related to various options for pharmaceutical packaging.

Table A.3.1 Dosage Form–Specific Guidelines

Element	Discussion
Large-volume parenteral and irrigation products (e.g., bags or bottles with volume greater than 100 mL)	Bar codes on labels for intravenous (IV) products should be oriented with the human-readable (textual) information visible to and readable by a person of average height when the product is hung from a standard height IV pole. Also, the container's key text and bar code should be located so that both of the following two conditions are simultaneously met: a) For *unmodified* product: The bar code and description should be placed so that it will ***not*** be obscured by the addition of patient-specific labels who receive the *exact and unmodified* contents of the container; and, b) For *modified* container contents: The bar code and description of the contents of the bag should be placed so that they ***can be*** overlaid by a patient-specific or batch production label when necessary.
Small-volume parenteral products (e.g., bags or bottles with volume of 25 to 100 mL)	Where such containers' contents may be modified; such as the removal of content, or the addition of another agent, the container's key text and bar code should be located so that both of the following two conditions are simultaneously met:

Element	Discussion
	a) For <u>*unmodified*</u> product: The bar code and description should be placed so that it will ***<u>not</u>*** be obscured by the addition of patient-specific labels who receive the <u>*exact and unmodified*</u> contents of the container; and, b) For <u>*modified*</u> container contents: The bar code and description of the contents of the bag should be placed so that they ***<u>can be</u>*** overlaid by a patient-specific or batch production label when necessary.
Vials for sterile powders and liquids (e.g., vials with volume of 5 to 100 mL)	Either ***GS1-DataBar*** (linear) or ***GS1-DataMatrix*** (two-dimensional) bar codes may be used; however, the latter is recommended and should be implemented wherever possible. If a ***GS1-DataBar*** (linear) bar code is used, it should be orientated along the package axis with the least amount of curvature. According to the principles of safe medication practice, it is generally recommended that a single product container *not* be used for multiple doses. However, any product that may potentially be used in that manner (e.g., insulin) should ideally carry auxiliary peel-off or tear-off bar coded labels for labelling dose syringes removed from the original container for individual patients. The bar codes on such labels should be the same bar code used on the original primary package container.
Ampoules or small vials (e.g., volume less than 5 mL)	Given the curvature of small-radius containers, use of label flags may be considered, preferably along with a ***GS1-DataMatrix*** (two-dimensional) bar code. Potential problems with tearing or dislodgement of label flags during automated processing may be of concern, so design and operational (field) testing should be applied.

Element	Discussion
Prefilled syringes or cartridges (e.g., multiple volumes and systems)	The product should be labelled on the drug-containing portion of the syringe barrel or cartridge. This stipulation also applies if the syringe or cartridge requires assembly before activation or use, as for syringes containing dextrose or sodium bicarbonate. The bar coded label should not interfere with the operation of the unit or, in the case of a syringe that is placed into a pump or other automated device, the operation of that device.
Respiratory therapy nebules	If it is not possible to apply glued paper labels (with or without flaps) directly onto the ***Primary Packaging***, individually wrapped **Unit-Dose** products are preferred as the safest alternative.
Spray products (canisters)	Placement of the bar code toward the bottom of the product is preferred.
Kits	Bar codes for kits may be placed in any convenient space that has an opaque background, so long as that location is both easily observable and readable by an automated reader. Each item within the kit that is to be administered to the patient (including diluent, drug, flavouring, and pigment) should be separately and distinctly labelled and have an individual bar code to reflect its content, and to be positively identified. For example, a glucagon emergency kit should include a container of diluent with a bar coded label and text that reads “sterile water for injection” and a vial of powdered glucagon with a bar coded label that also reads “glucagon”. Where such parts are both integral to the pharmaceutical integrity of the dose, such as a specialized diluent for a powder, additional efforts should be made to inform the healthcare worker, and package the drugs in a manner that indicates the interdependence.

Element	Discussion
	Medical devices integral to the administration of one or more components of the kit should also be bar coded and labelled.
Bulk bottles (e.g., tablets, capsules, liquids)	Bar codes should generally be placed toward the middle or the bottom of the container. Placement of **one-dimensional** bar codes on containers for liquids should not require that the container be turned sideways for reading the text label or scanning the barcode. If possible, the bar code should be placed on the same surface as the primary human-readable text. Containers for liquids should incorporate a pouring side to catch drips, to minimize the potential for spilled liquid to obscure the bar code or the human-readable text. And, in any event, the product label and printing should be tested to reduce the possibility of smearing of the printed text or bar code.
Multiple-use topical products (e.g., creams, ointments, gels, powders)	The bar code for a multiple-use topical product should be placed near the point where the product is expressed, poured, or shaken from the container, to ensure that it is not hidden by collapsed or rolled packaging material.
Ophthalmic and otic products (e.g., dropper bottles)	The same **symbology** recommendations apply as for ampoules or smaller vials. Use of ***GS1-DataMatrix*** (two-dimensional) bar codes should be considered. If a ***GS1-DataBar*** (linear) bar code is used, it should be oriented along the package axis with the least amount of curvature.
Overwrap materials	(See also Section 2: Overwrap) ***Primary Packaging*** with partial or full overwrap (e.g., cellophane wrapping) should have an identical duplicate bar code on the outer wrap. This packaging practice will eliminate the need to unwrap the product for scanning purposes during usual operational processing of the product.

Element	Discussion
	If a bar coded overwrap is not reasonably possible, then the primary package bar code should be readable through the overwrap, without removal of the overwrap. Under no circumstance should it be necessary to remove the overwrap to scan the bar code. The above requirement may change in the future should additional validation of reading through shrink-wrap emerge. (Consult GS1 Canada GTIN Allocation Rules for additional information.)
Small ***Unit-of-Use*** (**Unit-Dose**) packages (e.g., tablets, capsules, liquids, ointments, powders, eye drops, ear drops, rings, pledgets, wipes)	***GS1-DataMatrix*** (two-dimensional) bar codes should be considered. If ***GS1-DataBar*** (linear) bar codes are used, the codes should be placed horizontally under or over the human-readable text on the Unit-Dose package. Oddly shaped items (e.g., vaginal rings, suppositories) should be packaged individually in oversized, flat packaging to accommodate the bar code and other required information and to ensure readability.
Blister package ***Unit-of-Use*** items <u>without</u> perforations (e.g., 7-day dose packs, Z-packs)	Blister packages for medications intended for self-administration (e.g., dose packs, compliance packs, cycle packs, contraceptives) that do *not* allow separation of Unit-Dose packages should have an outer sleeve or plastic box or compact labelled with a bar code and human-readable text. The label may be placed on the front or rear exterior of the package in a location that is easy to read. If the **Primary Package** containing the medication has a cardboard exterior shell (such as a residential care blister card) and/or is designed to be placed into a reusable shell, an additional identical bar code identifying the **Primary Package** should be placed in a location that will be readable during the product's lifespan of use by the patient or healthcare worker.