Pharmacy Practice Management Systems Supplemental Requirements

on Traceability and Bulk Preparation Labelling to Support NAPRA's "Model Standards of Practice for Canadian Pharmacists" and "Model Standards for Pharmacy Compounding"

NAPRA ANORP

National Association of Pharmacy Regulatory Authorities ®
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Pharmacy Practice Management Systems Supplemental Requirements on Traceability and Bulk Preparation Labelling to Support NAPRA's "*Model Standards of Practice for Canadian Pharmacists"* and *"Model Standards for Pharmacy Compounding"*

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Executive Summary

Information management systems used by pharmacy professionals (referred to in this document as pharmacy practice management systems or PPMS) support the delivery of patient care including the dispensing of drugs in accordance with Canadian regulations and standards. They must also do much more, in that the ability to record, display, store, and exchange patient-specific information in a manner that optimizes workflow within pharmacy teams is critical. PPMS must also facilitate information exchange with external systems such as electronic health record systems and drug information systems.

Pharmacy regulatory authorities have a responsibility to consider the minimum requirements of systems used by pharmacy professionals in their delivery of quality care and services. In 2013, the Council of Pharmacy Registrars of Canada (CPRC), an advisory committee of the National Association of Pharmacy Regulatory Authorities (NAPRA), established a working group for this purpose to be informed by the "Model Standards of Practice for Canadian Pharmacists"[1] developed by NAPRA and the Pan-Canadian Drug Messaging Standard[2] developed by Canada Health Infoway. This work culminated in a set of requirements regarding the functionality required by PPMS in order for pharmacists and pharmacy technicians to comply with their respective standards of practice. The requirements were approved by NAPRA's Board of Directors in 2013 as the "Pharmacy Practice Management Systems: Requirements to Support NAPRA's 'Model Standards of Practice for Canadian Pharmacists'".

While the initial requirements for the PPMS document were under development, ongoing discussion took place in several venues regarding labelling requirements for drugs. At that time, detailed labelling requirements were beyond the scope of the aforementioned requirements. However, the discussion regarding labelling requirements was revisited, specifically the case of labels printed for drugs prepared or repackaged in bulk[3] and in maintaining detailed records on these bulk preparations. The discussion ultimately gave rise to the notion to prepare a supplemental document to address these specific requirements. These requirements include information in both human-readable and machine-readable formats. The requirements address specific public safety issues involving the need to trace drugs by product identifier, lot or batch number, and expiry date. It must be possible to rapidly determine whether those drugs have been dispensed to patients and if so, to whom. Machine-readable data allows systems to collect data, populate records, check for accuracy, and advise of potential errors before the drug is administered. The requirements ensure that traceability can be accomplished for pre-packaged drugs as well as for drugs that have been compounded or re-packaged in bulk by a pharmacy professional.

This supplemental document also aligns with specific recommendations of the Thiessen Report[4], a report that was issued in Ontario as a result of the oncological under-dosing incident that took place in four Ontario hospitals and one New Brunswick hospital in early 2013.[5] That report recommends that the Ontario College of Pharmacists (OCP) and by extension, NAPRA, "stipulate specialized electronic material records and label requirements for non-sterile and sterile product preparation within a licensed pharmacy." As these requirements relate to PPMS, the idea was to augment the original 35 requirements with three additional ones on labelling and record keeping for bulk preparations to ensure their traceability (see Section 3 on page 8).

[1] Available at: http://www.napra.ca/Content_Files/Files/Model_Standards_of_Prac_for_Cdn_Pharm_March09_Final_b.pdf

[2] Canada Health Infoway, *Canadian Electronic Drug Messaging (CeRx)*. Available at: http://www.infoway.ca

[3] The requirements are written to include drugs that are packaged with dosing devices, but the general topic of medical devices (other than those pre-loaded with drugs) is outside the scope of these supplementary requirements.

[4] Thiessen, J. (2013). *A Review of the Oncology Under-Dosing Incident*, Ontario Ministry of Health and Long-term Care. Available at: http://www.health.gov.on.ca/en/public/programs/cancer/drugsupply/docs/report_thiessen_oncology_under-dosing.pdf

[5] The incident was also the subject of an ISMP Canada safety bulletin (Vol. 13, No. 7, August 2013). See http://ismp-canada.org/ISMPCSafetyBulletins.htm

The proposed supplemental requirements address technical, functional, and administrative requirements of PPMS and are listed in Section 3. Together with the original 35 requirements published in 2013, these requirements, when met, will ensure that PPMS are designed and used in ways that ensure the traceability of pharmaceutical products and the safety and efficacy of e-prescriptions and related electronic pharmacy records.

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1. Introduction

Information management systems used by pharmacy professionals (referred to in this document as pharmacy practice management systems or PPMS) must support the delivery of patient care, including the dispensing of drugs in accordance with federal/provincial/territorial regulations and standards. System ability to record, display, store, and exchange patient-specific information in a manner that optimizes workflow within pharmacy teams is critical, as is the ability to exchange information with other systems such as provincial health record systems and drug information systems.[6] Effective systems should be integrated and interoperable. Systems must be developed using nationally recognized data and technical standards to facilitate both information exchange with external systems such as federal/provincial/territorial electronic health records, and processes such as electronic prescribing and the traceability of pharmaceutical products. They must also be designed to support the privacy and security of the personal health information recorded and stored within, and transmitted to and from the systems.

The National Association of Pharmacy Regulatory Authorities (NAPRA) is an association of the provincial and territorial organizations responsible for the governance of pharmacists, pharmacy technicians (in some jurisdictions) and pharmacies. NAPRA provides a forum through which these provincial and territorial authorities cooperate in developing standards and programs that can be applied commonly across Canada (i.e., the national "Model Standards of Practice for Canadian Pharmacists"). The Council of Pharmacy Registrars of Canada (CPRC) functions as an advisory committee of NAPRA, and includes the Registrars from each jurisdiction who are responsible for regulating the practice of pharmacy and the operation of pharmacies. In 2012, a working group formed from among the Registrars and subject matter specialists from other pharmacy regulatory authorities to develop requirements for pharmacy practice management systems used by pharmacy professionals across Canada. The "Model Standards of Practice for Canadian Pharmacists"[7] developed by NAPRA and the pan-Canadian Drug Messaging Standard (CeRx and MR2009)[8] developed by Canada Health Infoway informed the working group's discussions. In total, 35 requirements were presented to NAPRA's Board of Directors and approved in 2013.[9]

The purpose of the 35 requirements found in the PPMS is to instruct pharmacy professionals, pharmacy managers, pharmacy owners, pharmacy practice management system vendors, and developers of federal/provincial/territorial electronic health records about the minimum functionality required by systems used in pharmacy practice in order for pharmacists and pharmacy technicians to comply with their respective standards of practice. The requirements do not contemplate inventory control, business management, or other functions that can optimize practices but have not been identified as requirements in the standards of practice. The requirements are intended to direct the development and deployment of information management systems that enable patient care services within pharmacy practice and as such should be read by anyone involved in the acquisition or use of PPMS. They are intended to be considered minimum requirements for a PPMS: vendor software (alone or in combination with other software, systems, and services) must meet all the requirements and perform all the mandatory functions described in the 2013 NAPRA document before such software can be considered compliant with, and supportive of, NAPRA standards of professional practice and hence suitable for deployment.

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[6] It is understood that not all pharmacists and pharmacy technicians work in environments where they have access to full-blown PPMS, nor are all PPMS effectually interfaced to EHR systems. While this document's scope is limited to PPMS requirements, these requirements will only impact patient care to the extent that they are implemented in systems that pharmacists and pharmacy technicians actually use in their daily work.

[7] NAPRA, (March 2009). *Model Standards of Practice for Canadian Pharmacists* available at: http://www.napra.ca/Content_Files/Files/Model_Standards_of_Prac_for_Cdn_Pharm_March09_Final_b.pdf

[8] Canada Health Infoway, *Canadian Electronic Drug Messaging (CeRx)*. Available at: http://www.infoway.ca

[9] NAPRA, (November 2013). *Pharmacy Practice Management Systems: Requirements to Support NAPRA Standards of Practice.* Available at: http://napra.ca/pages/Practice_Resources/ppms.aspx

During the time that the PPMS requirements were under development, ongoing discussion took place in several venues regarding labelling requirements for dispensed drugs. Because this work on labelling was already underway, detailed labelling requirements were left out of scope of the aforementioned requirements. This supplemental document addresses this omission in the case of drugs prepared or repackaged in bulk[10] and proposes minimum requirements that PPMS must meet in printing labels and in maintaining detailed records on these bulk preparations to support their traceability. These supplemental requirements include information in both human-readable[11] and machine-readable formats.

The requirements in this supplemental document address specific public safety issues involving the need to trace drugs by product identifier, lot or batch number and expiry date. It must be possible to rapidly determine whether those drugs have been dispensed to patients and if so, to whom (as addressed by the original 35 requirements). The supplemental requirements also address the need to accommodate drug administration systems where these are used to automate the capture of essential label information at the time of drug administration; for example, by allowing a nurse in a hospital or long-term care facility to scan a bar code on a drug label so that automated systems can populate records, check for accuracy, and advise of potential errors before the drug is administered. These requirements ensure that traceability can be accomplished for pre-packaged drugs as well as for drugs that have been compounded or repackaged in bulk by a pharmacy professional.

As with the original 35 requirements found in the PPMS document published by NAPRA, it is not anticipated that provincial or territorial pharmacy regulatory authorities will be involved in the process of conformance testing of or record-keeping capabilities. Some national organizations, such as Canada Health Infoway, currently provide pre-implementation certification testing for some aspects of electronic health record (EHR) and electronic medical record (EMR) software (e.g., EMR systems, consumer health applications, diagnostic imaging systems, and most importantly from the perspective of this report, drug information systems).[12] As well, some jurisdictions provide province-wide certification services (e.g., eHealth Ontario sets criteria for EMR certification testing and the testing is then carried out by OntarioMD).[13] The GS1 Canada bar code verification service also offers a neutral third party conformance report of applied bar codes, based on global standards.[14]

[10] The requirements are written to include drugs that are packaged with dosing devices, but the general topic of medical devices (other than those pre-loaded with drugs) is outside the scope of these supplementary requirements.

[11] Human-readable refers to words intended to be read by a patient, healthcare provider, or other patient caregiver.

[12] For a description of certification services provided by Canada Health Infoway, see https://www.infoway- inforoute.ca/index.php/programs-services/certification-services

[13] For a description of certification services provided by OntarioMD, see https://www.ontariomd.ca/portal/server.pt/community/emr_offerings/offering_details/

[14] For further information on GS1 barcode testing, see http://www.gs1ca.org/pages/n/Services/IV_Bar_Code_Scan.asp

2. Background

This supplemental document was developed in response to the need for further clarity on the requirements for supporting traceability. It also aligns with specific recommendations of the Thiessen Report, a report issued in Ontario as a result of an oncological under-dosing incident that took place in four Ontario hospitals and one New Brunswick hospital in early 2013.[15] This report recommended that the Ontario College of Pharmacists (OCP) and by extension, NAPRA, "stipulate specialized electronic material records and label requirements for non-sterile and sterile product preparation within a licensed pharmacy." As these requirements can only be effectively implemented through PPMS, they are best addressed by augmenting the original 35 requirements with additional requirements on labelling and record keeping for preparations compounded or repackaged in bulk by a pharmacy professional (i.e., with the requirements in Section 3 of this supplement). While the impetus for this re-examination originated with the OCP, the issues of drug traceability discussed in the current document are of national concern, have been discussed by national stakeholders, and are addressed here in a Canada-wide context.

Traceability

Traceability provides the capacity to immediately determine which patients received a given drug product, given a unique product identifier for the drug and optionally, the manufacturer's lot or batch number and expiry date. Traceability is a major concern of those involved in patient safety. The need for traceability extends to all dispensed drugs, whether for sterile or non-sterile product preparation. It also extends to all drugs whether packaged by a pharmaceutical manufacturer, or compounded or repackaged in bulk by a pharmacy professional. To achieve traceability, it must be possible to locate a specific drug or specific lot of a drug or specific expiry date of a drug at any point in the pharmaceutical supply chain.

Traceability allows drugs to be effectively recalled and to rapidly locate patients who have been dispensed recalled drugs. This requires every formulation of a drug dispensed to a patient to be traceable back to its manufacturer or preparer by product name, lot number, and expiry date. This in turn requires each drug product to have several data fields on its labelling:

a) an unambiguous and unique identifier for the pharmaceutical manufacturer (or the pharmacy in the case of products that are routinely compounded or repackaged in bulk by a pharmacy professional);

b) an unambiguous and unique product identifier for the specific drug formulation and (where applicable) the intended patient; and

c) an unambiguous and unique lot or batch number for the production lot or batch of the drug or bulk preparation.

Additional information on traceability is contained in Appendix III.

[15] Thiessen, J. (2013). *A Review of the Oncology Under-Dosing Incident*, Ontario Ministry of Health and Long-term Care. Available at: http://www.health.gov.on.ca/en/public/programs/cancer/drugsupply/docs/report_thiessen_oncology_under-dosing.pdf

Drug Identification

Commercially available pharmacy products are uniquely identified by means of a Global Trade Item Number (GTIN). This is an identifier for trade items developed by the GS1 organization and used to look up product information in a registry (often by inputting the number via a bar code scanner pointed at an actual product). Each GTIN is assigned by a manufacturer, reseller, or other entity in the product's supply chain. The GTIN is unique to a given product and for pharmacy products, is also unique to the dose and packaging. Additionally, it is unique to the packaging and labelling of the product. For example, a drug intended for both adult and paediatric use – but packaged differently for each – would have two GTINs: one for the adult product package and one for the paediatric package. In this way, a GTIN is more fine-grained than the Health Canada Drug Identification Number (DIN): one DIN may correspond to several GTINs, but where a single medication is packaged and identified by a GTIN, that configuration will correspond to a unique DIN.

GTINs are familiar to consumers as the Universal Product Code (UPC) code, a bar coding of the 12 digit GTIN on the package of a specific product.

Information on GTINs in use in Canada is contained in a database called ECCnet Registry.[16] The structure of ECCnet Registry is maintained by GS1 Canada (a not-for-profit organization tasked with maintaining barcode information for Canada) and each GTIN record for a pharmaceutical product can contain over 40 fields of data, including manufacturer, brand name, active ingredients, units of measure, usage instructions, temperature warnings, and many others. Web-based tools allow ECCnet Registry records to be looked up online for any GTIN identified product.

GTINs are assigned to pharmaceutical products by the pharmaceutical manufacturer. Pharmacies can also apply for a GTIN company prefix and then assign their own unique GTINs (the barcoding for which can also include batch or lot numbers) to products compounded or repackaged in bulk.[17] Licencing for pharmacies to obtain their own GTIN company prefix is provided on a cost-recovery basis by GS1 Canada.

Several important differences exist between GTINs and DINs:

a) use of the DIN is mandatory, but does not allow the exact identification of products provided by the GTIN.

b) use of the GTIN is voluntary, but widespread.

c) ECCnet Registry is not available for free consultation. Electronic access to ECCnet is provided by GS1 Canada on a cost-recovery basis.

See Appendix I for further discussion of drug identification.

Bar Coding

Data described above needs to be printed in machine-readable format to facilitate reliable data capture and to allow pharmacy professionals and other healthcare providers to act quickly in the event of a product recall. The reliable and error-free capture of data on drug products is an essential component of patient safety efforts, especially in hospitals and long-term care facilities, as it greatly helps care providers to ensure that the right medication is dispensed to the right patient. A standardized bar coding methodology can capture all of the information described above and make it decipherable by a suitable bar code reader so that it can be immediately captured for data entry purposes by a pharmacy professional or by a healthcare provider administering the drug in a hospital,

[16] GTINs must be allocated according to the rules set out in the GTIN allocation rules for healthcare. See http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

[17] See Appendix II

clinic or nursing home. Like all such encoding methodologies, effective use of bar coding requires that information be accurately encoded at the time the bar codes are created. Bar coding methodologies contain built-in integrity checking mechanisms to ensure that bar codes are accurately read.

In 2012-2013, the Canadian Pharmaceutical Bar Coding Project[18] looked at two uses of pharmacy bar coding:

a) **on commercial products**: The Bar Coding Project consulted with several Canadian healthcare sectors and GS1 Canada to promote voluntary national compliance of pharmaceutical manufacturers and technology providers with recognized forms of automated data capture. The project advocated that, as of December 2012, commercial pharmaceuticals used in Canada have predictable and readable bar codes at every level of packaging based on GS1 standards and that these bar codes should be readable by the bar code readers used at community and institutional facilities. The project also advocated that the same bar code be useable at each stage of the medication and prescription processes: purchasing, internal pharmacy dispensing operations, stock transfers, and where applicable, dose administration at the patient bedside.

b) **on in-house modified products**: Non-commercial medication packages and labels are created within institutional pharmacies or community-based pharmacies (e.g., those serving nursing homes) for repackaged and/or compounded medication doses, followed by package labelling and subsequent dispensing. These medication manipulations become necessary when bulk commercial products are modified into dose packages (e.g., unit-dose blisters, multiple drug blister packs, or 30-day monitored dosage cards). The products also include sterile bags or vials of reconstituted solutions or aliquots of commercially prepared solutions or mixture such as ointments, oral solutions or parenteral mixtures compounded from several ingredients. These altered medication formats may be produced in bulk (i.e., batches) ahead of their need and hence, they have the same labelling requirements as commercial products in terms of patient safety and support for product traceability.

Based on commercial and in-house uses of bar codes described above, the Project considered three types of medication dose bar codes:

1) **Commercial dose bar codes**: The dose bar code symbology complies with GS1 standards and, at a minimum, contains the product's GTIN. These are the bar codes already found on many manufactured pharmaceuticals in Canada.

2) **In-house pre-prepared "batched" dose bar codes**: The bar code symbology is chosen by the facility and, at minimum, contains the local unique inventory ID code. The Project advocates use of GS1-standard bar code symbologies[19] that "include essential information within the code, using GS1 standard data elements such as: the product inventory ID (minimally) (i.e., GS1 GTIN or other similar unique ID codes), lot number, [and] expiry date".[20]

3) **In-house "patient-specific" dose bar codes**: The bar code uses a specialized patient-specific and prescription-specific number code scheme to identify a prescription-correct dose unit. The Project advocates that the bar code "include the following data elements necessary for the system to

[18] Institute for Safe Medication Practices Canada, *Canadian Pharmaceutical Bar Coding Project: Medication Bar Code System Implementation Planning: A Resource Guide* (September, 2013). Available at: http://www.ismp-canada.org/barcoding/download/ResourceGuide/BarCodingResourceGuideFINAL.pdf

[19] The Project recommends the use of 1D or preferably 2D bar codes; see Appendix II on page 24 for an explanation of these types of bar code.

[20] Ibid. Page 127. Note that for bulk preparations, the preferred term is beyond use date, not expiry date, as used in the ISMP quotation.

> obtain the correct EHR prescription data elements from the active EHR prescription record for verification: unique patient ID or medical record number, unique patient visit number, [and] unique prescription number."[21]

While the primary focus of these supplemental requirements focus on item 2 above, bar codes as described in item 1 are also covered by Requirement 38 below. Item 3 is not explored in this document.

Printing multiple barcodes on a single label is not best practice: it necessitates scanning each barcode individually. This process needlessly takes time and it confuses the user as to which barcode to scan and in which sequence the scans should be done. Various data fields can be combined into a single bar code and there is a standard methodology for doing so. This methodology allows various data fields to be prefixed with a unique code (e.g., 01 for GTIN, 10 for lot or batch number, 17 for expiry date) and then combined into a single string that can be encoded by a single bar code (e.g., a Datamatrix or Databar bar code).

Further information on bar coding, bar code methodologies and bar code symbology can be found in Appendix II on page 24.

[21] Ibid. Page 127. The EHR referred to is not necessarily a provincial or territorial EHR as envisioned by Canada Health Infoway and may refer instead to a local or regional EMR implementation.

3. Supplemental Requirements on Traceability and Bulk Preparation Labelling

These requirements are technical in nature: they address the minimum requirements for record-keeping to support traceability, for label printing by PPMS for the routine preparation of drugs compounded or repackaged in bulk. These requirements have been carefully reviewed to ensure their applicability to both community-based pharmacies and to hospital pharmacies. As they are functional in nature, they apply to all dispensing environments (community, hospital, and long-term care).

Note on compounding or repackaging in bulk: A clear distinction is drawn in the text that follows between patient-specific compounding or repackaging of drugs and bulk compounding or repackaging of drugs. The original 35 PPMS requirements already support record-keeping requirements for patient-specific compounding or repackaging (i.e., the compounding or repackaging of products to fill specific prescriptions for specific patients). The three supplemental requirements below address the compounding or re-packaging of products in bulk (i.e., not for a specific patient) and the attendant functional capabilities required of PPMS to provide record keeping and label printing capabilities that support traceability of bulk preparations.

While bulk (sometimes referred to as batch) compounding is well defined (see Health Canada, *Policy on Manufacturing and Compounding Drug Products in Canada* in the References section), bulk-repackaging merits further clarification. In contradistinction to patient-specific repackaging (e.g., the preparation of adherence packages for a given patient), an example of bulk repackaging might involve the preparation of hundreds or thousands of adherence packages wherein each combined drugs taken from the packaging provided by the manufacturer or repackaging of oral dosage forms into unit dose or unit of use packaging.

Note on numbering: To maintain consistency with the existing 35 requirements for PPMS, the requirements that will be found in this supplemental document below begin with Requirement 36.

Requirement 36: Traceability and Record-Keeping for Bulk Preparations

Every PPMS must provide authorized users with the capability to create, access, and update records of drugs that have been compounded or repackaged in bulk by pharmacy professionals including:

a) a Global Trade Identification Number (GTIN), batch number, batch preparation date, and beyond use date that, in combination, are unique for the bulk preparation,

b) lot numbers and expiry dates of all components used to prepare the product (active ingredients, excipients, storage/transfer devices, etc.) and, where applicable, lot numbers of dosing devices, and

c) the identity of the pharmacy professional(s) who prepared the batch.

This functionality must provide users with the ability to report on records by GTIN, batch number, beyond use date and/or identity of the pharmacy professional(s) who prepared the batch.

[Note: when a record is created, accessed or updated, its generation is an auditable event as discussed in Requirement 30: Auditable Events and Audit Information Recorded.]

[Note: when a bulk preparation involves constituent ingredients that each have varying expiry dates, the beyond use date of the bulk preparation should be assigned conservatively according to established standards. Further discussion is available in USP 795; see References.]

[Note: for 36 a) to be satisfied, each pharmacy providing bulk preparations will need to be uniquely identified, and for this the pharmacy will need to obtain a unique GTIN that is included in the bar code. See the previous discussion of GTINs in Section 2: Drug Identification.]

Rationale

As discussed above, drugs cannot be effectively recalled if they cannot be traced through each stage of the pharmaceutical supply chain from initial manufacture to patient consumption. For drugs that have been compounded or repackaged in bulk by pharmacy professionals, traceability requires that the constituent ingredients be traceable by unique product number (identified here via the GTIN), batch and expiry dates; as any of these constituent ingredients can be the subject of a drug recall.

Note that, during dispensing, pharmacies link ingredients back to their source supply via lot numbers, etc. that are recorded during the processing of the prescription, thus making them traceable in terms of the formulation record at the pharmacy. As such, it should not be onerous for pharmaceutical ingredients and excipients to be tracked. This record keeping allows the recall of any ingredient to also allow recall of the dispensed prescriptions that used such recalled ingredients (whether active pharmaceutical ingredient or excipient).

See also Requirement 9: Comprehensive Medication Profile, Requirement 10: Comprehensiveness of Clinical Records, and Requirement 22: Safety and Quality.

Requirement 37: Traceability and Bulk Preparation Labelling

In the case of pharmacy professionals compounding or repackaging drugs in bulk, every PPMS must provide authorized users with the capability to print a preparation label for primary packaging such that:

a) the bulk preparation is identified by brand name, non-proprietary name or both, as appropriate, printed in human-readable form;

b) the bulk preparation is uniquely identified by a combination of Global Trade Identification Number (GTIN), lot number, and beyond use date printed in machine-readable and human-readable form;

c) a list of active ingredients is printed in human-readable form, showing the amount of each ingredient present and the net contents (in dosage units, mass, or volume);

d) where applicable, the notation "sterile" is printed in human-readable form; and

e) in the case of injectable preparations intended,

   1) for single dose use only (e.g., entire bag infusion), the notation "use for single dose only" is printed in human-readable form along with total dose;

   2) for multiple dose use, the notation "use for multiple doses" is printed in human-readable form along with total dose, total volume and concentration (e.g., grams per millimetre);

[Note: the GS1 DataMatrix two-dimensional bar code symbology satisfies all of the machine-readability specifications in 36 b) above in a single bar code. This type of bar code is already recommended for use on the primary packaging of all vaccines sold in Canada.[22] The machine-readability requirements are also met by the GS1-128 linear (i.e., one-dimensional) bar coding symbology in a single bar code. This type of bar code is a permissible alternative to the use of the GS1 DataMatrix symbology on secondary packaging of vaccines sold in Canada (though GS1 DataMatrix symbology can be exclusively used on both types of vaccine packaging).[23] In any event, the specification of one barcode standard over another is outside the scope of this document. What is important is that vendors and pharmacies not have to support multiple, competing formats. Among the candidate coding tech-

[22] Government of Canada. *Bar Code Standards for Vaccine Products in Canada (Update 2014-2015)*). Available at: http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-bar-codes-vaccination-codes-barres/index-eng.php

[23] Ibid.

nologies that meet the functional requirements above, the best choice will be dictated by a combination of technology and market forces.]

[Note: Printing multiple barcodes on a single label is strongly discouraged: it necessitates scanning each barcode individually; needlessly taking extra time and confusing the user as to which barcode of several to scan in which sequence.]

Rationale

Drugs cannot be effectively recalled if they cannot be traced through each stage of the pharmaceutical supply chain from initial manufacture to patient consumption. Traceability requires all of the following:

- unique product numbers on products indexed to comprehensive records of manufacture and compounding, contents, active ingredients, dosage and all other relevant data needed for the proper use of the product;
- batch/lot numbers and beyond use dates (and unique serial numbers where available); and
- machine-readable labelling of these data to allow accurate and automated data capture (the volume of numbers otherwise overwhelms even diligent efforts to input such data manually with any degree of sustained accuracy).

Without this information, there is no traceability and auditability to the patient level. The information is also required for the healthcare provider to act as a final check.

Pharmaceutical manufacturers already provide bar coded GTIN, lot and expiry on secondary and sometimes primary packaging of manufactured pharmaceuticals. Pharmacy professionals need a similar ability to provide the same level of unique product numbering when they compound or repackage products in bulk and a similar ability to produce machine-readable labelling for such products compounded or repackaged in bulk. This information, contained in the bar code, must also be human readable, if for no other reason than that it acts as a reliable backup in cases where a bar code reader is unavailable.

See also Requirement 22: Safety and Quality.

Requirement 38: Automated Data Input from Barcode Labels

Every PPMS must provide authorized users with the capability to read GS1 bar codes on product, dispensing or preparation labels on primary packaging, and automatically input data fields into relevant records, including:

a) machine-readable Global Trade Identification Number (GTIN), identifying the product, lot or batch number, expiry, and where available, product serial number; and

b) where appropriate, machine-readable patient identifier(s).

[Note: As with other aspects of the PPMS, these data input tools need not be embedded in a single, monolithic PPMS software program. The functionality of these data input tools may be provided by a PPMS that combines software packages, tools and hardware devices into a coherent system.]

[Note: patient identifiers referred to in 38 b) may be explicit or inferred from some other machine-readable identifier such as a prescription or transaction number.]

Rationale

Pharmacy professionals must be able to read bar codes on products to facilitate accurate automated data input. They should also be able to read the bar codes on their own dispensed products when needed to ensure accuracy and prevent mistakes in packaging.

See also Requirement 22: Safety and Quality.

4. Interpretation

The requirements above are to be read in the context of the original 35 requirements found in the original (core) PPMS document. Readers should refer to the NAPRA "Model Standards of Practice for Canadian Pharmacists" for further insight on the information that needs to be recorded into fields and datasets that are required to support pharmacy practice. The "Model Standards for Pharmacy Compounding" also serves as a reference.

5. Effective Date

The original 35 requirements came into effect on January 1, 2016. It is proposed that these supplementary requirements come into effect January 1, 2019.

The use of GTINs is dependent upon continued uptake by the manufacturers of pharmaceuticals and effective traceability requires their use of tools such as the ECCnet Registry to publish essential information relating the GTIN back to an ECCnet Registry record containing information on an identifiable drug or bulk compound. Pharmaceutical manufacturers are encouraged to expand their current use of GTINs and their use of tools such as the ECCnet Registry, as well as to ensure the accuracy, timeliness and completeness of the information they input in such registries.

6. Future Opportunities

Some international healthcare jurisdictions are contemplating the future use of drug product serial numbers: i.e., drugs will not only have lot numbers, but a serial number unique to each vial or unit of medication. Serialization will create a continuous documentation of a drug from the manufacturer, through warehousing, shipping companies, pharmacies and hospitals, to the patient. Its use will assist in global efforts to combat counterfeit drugs. It should be noted that initial serialization efforts are typically limited to the level of cases of products or secondary packages though the ultimate goal is serialization of primary packages.

The future use and application of drug product serial numbers is under review by ISMP Canada, following review of global regulation in this area.

A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the dates of those transactions and the names and addresses of all parties to them. Some international healthcare jurisdictions (in particular, some US states) are enacting laws requiring an "ePedigree" – an electronic document containing required information that is submitted using a product's serial number to a database that tracks such products and ensures that distributed products are not counterfeit, misbranded or diverted (stolen). Such laws are intended to increase public confidence that medications are effective and authentic. Combined with serial numbers, such endeavours could ultimately allow pharmaceutical products to be tracked through the entire pharmaceutical supply chain from raw materials to finished form of drug products received by patients. The success of such endeavours has yet to be established.

7. References

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8. Terms and Definitions

Term	Definition	Reference
1D bar code (GS1 DataBar symbology)	A one-dimensional or linear bar code that consists of printed vertical lines of varying thickness arranged into a horizontal bar. One-dimension bar codes typically have error detection features. GS1 DataBars are much smaller than Universal Product Code (UPC) linear bar codes and are therefore appropriate for small packages such as vaccines. They can carry additional information such as serial numbers, lot numbers and expiry dates.	Public Health Agency of Canada: http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-bar-codes-vaccination-codes-barres/index-eng.php
2D bar code (GS1 DataMatrix symbology)	A two-dimensional bar code that consists of printed squares or dots, spiralling outwards from the centre of the symbol. Two-dimensional bar codes have error detection features and may include error correction features. The main advantage of the 2D bar codes is the ability to provide a significant amount of information on a very small surface (for example on a vial or pre-filled syringe). In addition, they are easier to read on curved surfaces and are more resilient especially when handled multiple times and still maintain high scanning efficiency.	Public Health Agency of Canada: http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-bar-codes-vaccination-codes-barres/index-eng.php
AIDC	See *Automated Identification and Data Capture*	
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, and RFID chips, and that subsequently provides data about the identified product, usually obtained from within the code itself and/or from an associated product descriptor database (e.g., ECCnet Registry).	ISMP Canada (adapted from GS1) https://www.ismp-canada.org/barcoding/download/JTSv2/SupplB-MinFunctionality.pdf
Beyond use date	Date after which a compounded preparation shall not to be used and is determined from the date when the preparation is compounded. By contrast, the term "expiry date" is used for constituent ingredients of a compound or bulk preparation.	United States Pharmacopeial Convention (USP 795)

Term	Definition	Reference
Compounding	Health Canada's Policy on Manufacturing and Compounding Drug Products in Canada "POL-0051" sets out 14 criteria that distinguish compounding as an activity. See section 5.1 of http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php The document also distinguishes between compounding and manufacturing.	Health Canada
Council of Pharmacy Registrars of Canada	A council consisting of provincial and territorial registrars of pharmacy regulatory authorities.	Council of Pharmacy Registrars of Canada http://napra.ca/pages/About/CouncilofPharmacyRegistrarsofCanada.aspx
CPRC	Council of Pharmacy Registrars of Canada	
DIN	See *Drug Identification Number*	
DIS	See *Drug Information System*	
Dispensing	Dispensing means, with respect to a drug, any one or more of the following: 1. Evaluating a prescription for a drug 2. Assessing the patient and the patient's health history and medication record 3. Packaging and labelling of a drug 4. Providing a drug to or for a person pursuant to a prescription.	NAPRA "Model Standards of Practice for Canadian Pharmacists" http://napra.ca/Content_Files/Files/Model_Standards_of_Prac_for_Cdn_Pharm_March09_Final_b.pdf
Drug Identification Number	A Drug Identification Number (DIN) is a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.	Health Canada http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/dinfs_fd-eng.php

Term	Definition	Reference
Drug Information System (DIS)	An EHR system and/or collection of services that offers real-time access to patient medication profiles, as well as comprehensive drug information and an interactive database to assist pharmacists and physicians in identifying potential adverse drug interactions and events. It is also the jurisdictional repository that receives and manages medication prescriptions and dispensation events.	Canada Health Infoway E-Prescribing Harmonization Project, *ePrescribing Reference Specification*
Drug pedigree	A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the dates of those transactions and the names and addresses of all parties to them. See also *Electronic Pedigree.*	U.S. Food and Drug Administration. See http://www.fda.gov/OHRMS/DOCKETS/98fr/06-9211.htm
ECCnet Registry	A GS1 Canada–owned product descriptor database (also known as a data registry). It is used to register products to which a GTIN has been assigned. It may also contain additional data elements for use in Canada only (e.g., DIN in the case of a pharmaceutical). Data residing in this registry are owned by the manufacturer, but are prechecked by GS1 Canada for consistency with global and/or ECCnet Registry (GS1 Canada) standards via an automated process (GS1 Canada does not alter data). The ECCnet Registry contains a wide range of products, including non-health products, as well as pharmaceutical products and medical devices.	GS1 Canada http://www.gs1ca.org/pages/n/Services/GS1Canada_ECCnet_Registry.asp
EHR	See *Electronic Health Record*	
Electronic Health Record (EHR)	An Electronic Health Record (EHR) provides each individual in Canada with a secure and private lifetime record of their key health history and care within the health system. The record is available electronically to authorized health care providers and the individual anywhere, anytime in support of high quality care.	Canada Health Infoway, *EHRS Blueprint Version 2*, 2006, page 326
Electronic Medical Record (EMR)	A general term describing computer-based patient record systems. It is sometimes extended to include other functions like order entry for medications and tests, amongst other common functions.	Canada Health Infoway, Canadian Electronic Drug Messaging (CeRx)

Term	Definition	Reference
Electronic Pedigree	An electronic document that provides data on the history of a particular batch of a drug, including all data and information required by one or more pedigree laws along with the necessary certifications. It satisfies the requirement for a *drug pedigree* (see definition above) while using a convenient electronic form.	EPC Global, as adapted from Pedigree Ratified Standard, version 1.0: http://www.gs1.org/sites/default/files/docs/epc/pedigree_1_0-standard-20070105.pdf
Electronic pharmacy record (EphR)	A general term describing computer-based patient records used in the practice of pharmacy. The EphR is the record created in the PPMS including information about a patient, care decisions made by pharmacy professionals, and services provided by pharmacy professionals (record of care), as required by NAPRA standards of professional practice.	ISMP Canada https://www.ismp-canada.org/barcoding/download/JTSv2/SupplB-MinFunctionality.pdf
EMPI	See *Enterprise Master Patient Index*	
EMR	See *Electronic Medical Record*	
Enterprise Master Patient Index (EMPI)	An Enterprise Master Patient Index (EMPI) or Client Registry is a system which coordinates client identification across multiple systems, namely by collecting and storing identifications (IDs) and person-identifying demographic information from source system (track new persons, track changes to existing persons). These systems also take on several other tasks and responsibilities associated with client ID management.	Canada Health Infoway, *Electronic Health Record Blueprint*, version 2, 2006
ePedigree	See *Electronic Pedigree*	
EphR	See *Electronic Pharmacy Record*	

Term	Definition	Reference
Global Trade Item Number (GTIN)	An identifier for trade items developed by GS1 and used to look up product information in a database (often by inputting the number via a bar code scanner pointed at an actual product). Each GTIN is assigned by a manufacturer, reseller, or other entity in the product's supply chain. The uniqueness and universality of the identifier is useful in establishing which product in one database corresponds to which product in another database, especially across organizational boundaries. GTINs may be 8, 12, 13 or 14 digits long, and each of these 4 numbering structures is constructed in a similar fashion, combining a company prefix, item reference and a calculated check digit. GTIN-14 adds another component, the indicator digit, which can be 1-8 and refers to packaging level. The 12 digit GTIN is familiar to consumers, as it is encoded by the Universal Product Code (UPC) bar code. GTINs are assigned to pharmaceutical products by the pharmaceutical manufacturer and to medical devices by the medical device manufacturer. Pharmacies can also apply for a GTIN company prefix and then assign their own unique GTINs to compounded or repackaged pharmaceutical products produced in bulk.	GS1 http://www.gs1.org/
GS1	A neutral, not-for-profit, international organization that develops and maintains standards for supply and demand chains across multiple sectors. GS1 has local Member Organizations in over 110 countries, including Canada. GS1 works with communities of trading partners, industry organizations, governments and technology providers and responds to their business needs through the adoption and implementation of global standards. GS1 Canada has representatives from a wide variety of industrial sectors, including healthcare.	GS1 Canada http://www.gs1ca.org/pages/n/Aboutus/index.asp
GTIN	See *Global Trade Item Number*	
ISMP Canada	Institute for Safe Medication Practices Canada	http://www.ismpcanada.org/index.htm
NAPRA	National Association of Pharmacy Regulatory Authorities	
Pharmacy licensee	Licensed clinical pharmacist that is granted a licence to operate a pharmacy. This person may also be referred to as the pharmacy manager.	Alberta College of Pharmacists

Term	Definition	Reference
Pharmacy Practice Management System (PPMS)	An electronic system that supports the provision of pharmacy patient care as defined through NAPRA standards of professional practice. A PPMS facilitates the recording, use and disclosure of electronic pharmacy records and reporting on these records. Note: PPMS capabilities need not be embedded in a single, monolithic software program. PPMS functionality may be provided by a combination of software packages, tools and information technology (IT) services that together function as a coherent system.	
Pharmacy professional	An individual registered with, and regulated by, a provincial or territorial pharmacy regulatory authority.	
PPMS	See *Pharmacy Practice Management System*	
Practice management system	Generic term used to reference a management system.	Canada Health Infoway, *Electronic Health Record Solution (EHRS) Blueprint,* version 2, 2006
Primary packaging	Primary packaging materials are those that are in direct contact with the pharmaceutical product. By contrast, secondary packaging materials are not in direct contact with the product (e.g., cardboard boxes).	WHO http://apps.who.int/medicinedocs/documents/s19638en/s19638en.pdf
Sterile	Free from viable microorganisms.	Good manufacturing practices (GMP) guidelines; 2009 edition, version 2; Ottawa, Health Canada, Health Products and Food Branch Inspectorate; 2009.
User	Person, device, program, or computer system that uses a computer system for the purpose of data processing and information exchange.	Canada Health Infoway, *Electronic Health Record Blueprint*, version 2, 2006

Term	Definition	Reference
User authorization	The permission to perform certain operations or use certain methods or services.	Canada Health Infoway, *Electronic Health Record Blueprint*, version 2, 2006
Vaccine Identification Database System (VIDS)	A single, web-based repository of comprehensive information on all vaccines licensed for use in Canada. VIDS is the link between the bar code and the information required to populate the client health record. When a health care worker scans the bar code on a vaccine product, the link to VIDS allows the population of the information on that specific vaccine product into the client health record.	Public Health Agency of Canada http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-bar-codes-vaccination-codes-barres/index-eng.php
VIDS	See *Vaccine Identification Database System*	

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Appendix I: Unique Identification of Drug Products and Preparations

Commercially available pharmaceutical products are uniquely identified by means of a Global Trade Item Number (GTIN). This is an identifier for trade items developed by the GS1 organization and used to look up product information in a database (often by inputting the number via a bar code scanner pointed at an actual product). Each GTIN is assigned by a manufacturer, reseller, or other entity in the product's supply chain. The GTIN is unique to a given product. For pharmacy products, it is also unique to the dosage and to the packaging and labelling of the product. For example, a drug intended for both adult and paediatric use – but packaged differently for each – would have two GTINs: one for the adult product package and one for the paediatric package. In this way, a GTIN is more fine-grained than the Health Canada Drug Identification Number (DIN): one DIN may correspond to several GTINs, but each GTIN for a drug product commercially available in Canada corresponds to a unique DIN.

GTINs may be 8, 12, 13 or 14 digits long, and each of these numbering structures is constructed in a similar fashion, combining a company prefix, item reference and a calculated check digit. GTIN-14 adds another component, the indicator digit, which can be 1-8 and refers to packaging level. The 12 digit GTIN is familiar to consumers as Universal Product Code (UPC) that is present as a UPC-A bar code on most commercially available products.

The 14-character length GTIN contains the following elements:

- product packaging level digit (e.g., pallet, case, secondary product package, primary product package)
- company identifier,
- company's product category,
- company's internal product number, and
- a final "check digit" to ensure the GTIN is read properly: the check digit is computed from the other digits in the GTIN. Such check digits are a common feature of credit card numbers, health numbers, and other numbering schemes used for unique identifiers.

GTINs can be combined with lot or batch numbers and expiry dates to create a serialized GTIN: a single structured string containing all three data elements.

Information on GTINs in use in Canada is contained in a registry called ECCnet[24]. The structure of the ECCnet Registry is maintained by GS1 Canada and each GTIN record for a pharmaceutical product contains over 40 fields of data, including manufacturer, brand name, DIN, active ingredients, units of measure, usage instructions, temperature warnings, and many others, provided the information is published by the data owner. Web-based tools allow ECCnet Registry records to be looked up online for any GTIN identified product, provided the data owner has published the information in the registry.

GTINs are assigned to pharmaceutical products by the pharmaceutical manufacturer. Pharmacies can also apply for a GTIN company prefix and then create and assign their own unique GTINs to compounded or repackaged pharmaceutical products produced in bulk. The pharmacy creates a matching record in the ECCnet data registry for each GTIN that contains all the relevant information (DIN, ingredients, packaging size, dose, etc.)

[24] Information on ECCnet is available at: http://www.gs1ca.org/pages/n/Services/GS1Canada_ECCnet_Registry.asp

Appendix II: Machine Readable Symbologies

Data printed in machine-readable format allows pharmacists and healthcare providers to readily ascertain what drug, lot and expiry date pertain to pharmacy products and to act quickly in the event of a product recall. In order to facilitate reliable data capture, these data also need to be printed in machine-readable format. The reliable and error-free capture of data on drug products is an essential component of patient safety efforts, especially in hospitals and long-term care facilities, to ensure that the right medication is dispensed to the right patient. A standardized bar coding methodology is required that can capture all of the above information and make it available to a suitable bar code reader so that it can be immediately captured for data entry purposes by a pharmacy professional or by a healthcare provider administering the drug in a hospital, clinic or nursing home.

Various data fields can be combined into a single bar code and there is a standard for doing so. Automated Identification and Data Capture (AIDC) codes allow various data field to be prefixed with a unique code (e.g., 01 for GTIN, 10 for lot or batch number, 17 for expiry date) and then combined into a single string that can be printed in a single bar code, provided the bar code format can accommodate strings of that length.

Bar codes and their data contents may vary depending on the type of dose to be dispensed:

- commercially based products where the secondary (and sometimes primary) package is bar coded;
- patient-specific bulk or pre-packaged dispensed doses where, especially in hospital pharmacies, bar coding the primary package facilitates safe administration of the drug (assuming the bar codes can be read by bar code reading hardware that is affixed to dispensing carts and wirelessly connected to hospital systems); and
- patient-specific customized doses.

There are several standardized bar code symbologies in widespread use but a few in particular are widely used in healthcare.

1. A 2D bar code (GS1 DataMatrix symbology) consists of printed squares or dots, spiralling outwards from the centre of the symbol. 2D bar codes allow a significant amount of information to be encoded on a very small surface (e.g., on a pre-filled syringe). They are also easier to read on curved surfaces.

   The following is an example of a DataMatrix (2D bar code): [25]

   (01) 0 9501101 53000 3
   (17) 140704
   (10) AB-123

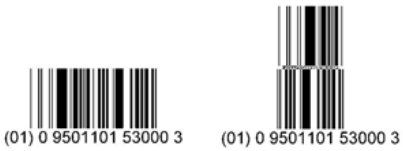
   This example contains the following encoded information:

   - GTIN (01): 09501101530003
   - Expiry (17): 2014-07-04, and
   - Lot number (10): AB-123

[25] These bar code examples are taken from Government of Canada. *Bar Code Standards for Vaccine Products in Canada (Update 2014 -2015).* Available at: http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-bar-codes-vaccination-codes-barres/index-eng.php

2. The GS1 DataBar is a family of bar code symbols that can be linear or 2D. The GS1 DataBar can carry additional information such as serial numbers, lot numbers and expiry dates. Linear DataBars can be stacked to create a 2D bar code. GS1 DataBar enables GTIN identification on hard-to-mark products. GS1 DataBar symbols are already approved for global use on healthcare items that do not cross point of sale.

   The following is an example of a GS1 DataBar (2D bar code):



3. The GTIN-128 code (linear) bar code structure is a 1D barcode that can encode up to a fourteen data digit structure consisting of a packaging indicator, a company reference (company ID + product ID and a check digit value to ensure data integrity).

   Example of a GS1-128 (linear bar code)

   This example contains the following encoded information:

   - GTIN (01): 40697177000322
   - Expiry date (17): 2015-09-25.

Use of multiple bar codes on a single level of packaging (e.g., primary package) is strongly discouraged, as it may confuse users and lead to degraded system functionality.

Best practice also limits the use of printed bar codes for pharmaceutical products on health record documents to avoid or lessen the potential for user workarounds that do not comply with patient safety processes. The system should require users to scan only actual drug/dose containers and patient bracelets when performing medication safety checks, such as verifying the correct drug/dose or correct patient ID. Otherwise, it may facilitate a worker bypassing critical safety checks by scanning a document, rather than the actual drug, dose or patient. As a consequence, only actual drug/dose containers or actual patient wristbands should be able to be scanned.

Appendix III: Pharmaceutical Traceability

Traceability is a business process that enables pharmacy organizations to identify the direct source and direct recipient of a pharmaceutical product as its moves from its initial point of creation through to its final use or disposal. The ability for a pharmacist or pharmacy technician to understand the journey that a product has taken from its point of creation to its final use is an important component of safe and effective medication management.

Implementing a traceability system within a pharmacy supply chain requires that all parties involved are able to link a physical flow of products with the flow of information about them. An effective traceability program enables any party involved in that journey to trace the product forward (from creation to use) or backward (from use to creation).

- Forward traceability is the ability to discover the places to which a product was delivered, its inclusion as an ingredient in subsequent products, and its administration to a patient.
- Backward traceability is the ability to discover the origin of a product administered to a patient, the ingredients from which the product was made, and the origins of those ingredients.

All entities participating in the product's journey must collect, record, and share product data in a manner that allows discovery between parties in an interoperable manner.

Traceability requires globally unique product identification

As discussed in Section 2, products are identified by their manufacturer using a globally unique Global Trade Item Number (GTIN). This includes all levels of a product hierarchy (unit of use, unit of sale, cases, etc.) and each are identified using a GTIN. The GTIN serves as the primary product identifier.

There is a specific set of rules that manufacturers adhere to in assigning GTINs to their products. For further information, see *Healthcare GTIN Allocation Rules GS1 Issue 9.0* (December 2015) available at http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

Traceability requires secondary identification of individual product lots or batches

Individual instances of a product (e.g., bulk preparations) are identified such that their manufacturing characteristics are discoverable. For a bulk preparation, a production lot number or batch number serves as a reference to a set of preparations that have:

- a common preparer (pharmacist or pharmacy technician),
- a common preparation location (pharmacy), and
- common ingredients.

The lot number also identifies a set of attributes associated with a set of preparations, such as beyond use date. Whereas the GTIN (primary identifier) identifies a product, the lot or batch number (secondary identifier) identifies a set of preparations.

Traceability data must be provided (exchanged) throughout its journey from inception to final use. This data must be provided throughout the information flow (e.g. invoices, receiving advice) and on product labelling. Common to all these documents is a need to convey:

- the GTIN number
- the production batch or lot number, and
- the lot expiry date or preparation beyond use date.

In the case of bulk preparations, a package label includes sufficient information in both human-readable and machine-readable form to properly identify the preparation. Machine-readable data includes at least the primary (GTIN) and secondary (lot or batch) identifiers and may include additional attributes such as the expiry date or beyond use date and the intended patient (where applicable). All other attributes must be accessible online based on these primary and secondary identifiers.

Human-readable data includes machine-readable data as well as descriptive text necessary for proper administration (product name, active ingredient, strength, expiry date or beyond use date, patient name, etc.)