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Recipient Org and Address

Date

RE: Updated Joint Technical Statement on Pharmaceutical Automated Identification and Database Requirements (JTS) Released (2012)

We are pleased to provide you with an update to our project, the Canadian Pharmaceutical Bar Coding Project, co-facilitated by ISMP Canada and the Canadian Patient Safety Institute. The appended document is our project's most important document: *The Joint Technical Statement on Pharmaceutical Automated Identification and Database Requirements (Version II; 2012) (**JTS**)*.

The project is a national effort to develop a common multi-sector consensus on the role of automated identification (bar coding) of medications at all levels of the medication chain. By adopting a common approach, it will lead to increased patient safety through the avoidance of preventable medication errors, while increasing business (supply chain) efficiencies of our pharmaceutical industry. The recommendations contained within the national statement (*JTS*) arise from the project's many representatives from six Canadian healthcare sectors.

Careful global attention continues to be paid to the expanding role of medication bar coding within healthcare practice. These advancements yield multiple system benefits, including improved patient health outcomes through increased patient safety and improved documentation, plus a variety of health system efficiencies such as avoidance of the significant cost of preventable errors, improved patient access, and tighter inventory control.

The attached *JTS* (ver II; 2012) has been updated from its original version (ver I; 2010). It is designed to:

- Reflect the rapidly evolving global technical standards surrounding medication automated identification (bar coding), and
- Translate technical bar code standards into the practice needs of Canadian healthcare providers, by providing a simplified multi-sector (common) roadmap to achieve safer Canadian medication practices.

The attached technical statement consolidates not only pharmaceutical manufacturer needs and efforts in bar coding, but also aligned patient safety and documentation concepts. The statement also addresses centralized pharmaceutical product data sources, aligned automated (software) systems development and, most importantly therefore, the continued effort to integrate these improvements into safer patient care practices throughout in Canada, both within institutional and community care environments.

Appended to this letter is a synopsis of key updates found within JTS (ver II; 2012).

It is our hope this letter and the attached *JTS* document will assist your organization in developing familiarity with this important national endeavour. We encourage your organization to consider its future implications to your members' practices. We would be grateful if you would forward a communication to your members in the form you feel may best meet their information needs.

Your organization's support will result in a continual growth in the national understanding of the next generation of health systems for Canadian patients.

Please contact us if you have any comments, suggestions, or questions.

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

Yours sincerely,

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cc.
David U, President and Chief Executive Officer, ISMP Canada
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Letter Attachments:
1. Joint Technical Statement on Pharmaceutical Automated Identification and Database Requirements (Version II; 2012) (**JTS**).
2. Supplement A: Guidance for Placement of Bar Codes on Pharmaceutical Labels for Primary Packaging
3. Supplement B: Minimum Software Safety Functionality Checklist

Appendix:
Synopsis of the Canadian Pharmaceutical Bar Coding Project's Joint Technical Statement on Pharmaceutical Automated Identification and Database Requirements (Version II; 2012) (JTS)

- **Revised Glossary of Terms**
- **Bar Code Contents and Types in Practice**
  - Retail pharmacy planning for bar codes (2.2.1)
  - Comment on Canadian versus U.S. GTIN requirements (2.4)
  - Bar code readability requirements (2.9.1)
  - Addition of 14-digit GTIN and Health Canada Drug Identification Number (DIN) to all product and system databases (2.10)
  - Dates for additional variable data elements within GS1-compliant bar codes (3.1)
    - GTIN (previously required by December 2012)
    - Lot Number (by December 2017) (new)
    - Expiry Date (by December 2017) (new)
  - Planned review of serial numbers on pharmaceutical products (2013) (3.1)
- **Requirements at Various Product Packaging Levels**
  - Revised requirements for bar code data elements at various packaging level (4)
- **Centralized Product Database Source**
  - Selection of ECCnet Registry as the preferred Common Canadian Pharmaceutical Product Registry (CCPPR) (5.1)
  - GS1 Canada methods of advancement of Canadian business and practice needs (5.1.4)
  - Pharmaceutical Manufacturer use of ECCnet Registry for product data (5.2.1 and 5.2.2)
  - Defined data transfer models: From ECCnet to End-user practice environments (5.3.2)
  - End-user responsibilities related to data received from central data sources (5.4)
- **Bar Code Types (Symbologies)**
  - Promotion of the two-dimensional (GS1-Datamatrix) symbology for smaller items (6.1)
- **Automation Software Functionality**
  - Recommended compliance with Minimum Software Safety Functionality (*MSSF*) for automated Solution Providers (6.3; Appendix B)
  - Solution Provider development plan and timeline by January 2013 (6.3, 8)
  - Collaboration between End Users and Solution Provider Planning (6.5)
  - Recommended end user fiscal planning for system acquisition (7.2.1)
  - End user purchasing compliance with the *MSSF* when assessing systems (6.4 and 7.2.2)

Appendix (continued): JTS Version II Key Updates (continued)

- **Timelines for Compliance**
  - Manufacturer: (8.1)
    - GS1-compliant bar coded GTIN (December 2012)
    - GS1-compliant bar coded Lot Number and Expiry Date (December 2017)
  - Solution Provider Functionality: development plan and timeline (January 2013) (8.2)
- **Appendices**
  - Bar Code Placement Guidelines for Pharmaceutical Manufacturers (Appendix A)
  - Minimum Software Safety Functionality (*MSSF*) Checklist (Appendix B)