GS1 Brasil

The Global Language of Business

Proposal for EPCIS System Implementation to control drugs in pharmaceutical sector in Brazil

10/2015, Version 01

Contributors

Name	Organization	E-mail
Patrícia Amaral	GS1 Brasil	patricia.amaral@gs1br.org
Marcus Vinicius dos Santos	GS1 Brasil	marcus.santos@gs1br.org
Luiz Costa	RFID CoE (Center of Excellence) Flextronics Institute of Technology–FIT	luiz.costa@fit-tecnologia.org.br

Abstract — Considering GS1, a multi-sectoral non-profit global organization for managing information that facilitate the marketing of items in supply chain and communication between companies different parts through the supply chain.. The healthcare scenario today requires traceability, shows a specific need. Thus, GS1 intends to assist this sector in this matter / issue with a global communication standard between health supply chain companies using EPCIS (Eletrocnic Product Code Information Service).

Keywords—RFID; GS1; EPCIS

Introduction

The EPC Information Services (EPCIS) is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers. The goal of EPCIS is to enable disparate applications to create and share visibility event data, both within and across enterprises. Ultimately, this sharing is aimed at enabling users to gain a shared view of physical or digital objects within a relevant business context.

Based on the need to use a international standard to exchange information with all the supply-chain partners, GS1 Brazil developed a proposal of how to comply with the law. This Paper aims to present the best identification and codification best practices for secondary packaging (cartridge) and tertiary (transport) and how this information will be traced on the national Brazilian System (ANVISA), like is showed on figure 1 at right.

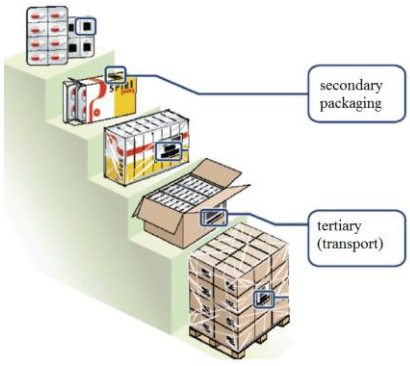

Fig. 1. Secondary and tertiary packaging system.

Application to the ANVISA RDC 54/2013

The Resolution RDC No. 54 provides the implementation of the national drug control system and the mechanisms and procedures for tracking drugs in the chain of pharmaceuticals and other measures.

Expected benefits:

- Technical support for proper application of the codes in secondary and tertiary packaging.
- Direction to ensure quality printing of codes.

For the purposes of this guideline, the RDC 54/2013 can be viewed as a two-milestone implementation over three years:

- The first milestone, at December 10th 2015, defines that all supply chain participants get involved in a pilot exercise of at least 3 (three) batches of pharmaceutical products serialized and tracked with complete traceability technology implemented . The traceability information required for these batches involve the end-to-end movement of goods, from the manufacturing plant, including transaction between subsidiaries, until the sales or administration point , that can be understood as a hospital, drug store, physician handling free samples, and others. The responsibility to report the traceability information to Anvisa resides with the Industry and an alignment of assumptions and approach is required with all other supply chain participants to make this pilot phase happen.
- The second milestone of the RDC 54/2013, ending at December 10th 2016, requires that all supply chain participants have already in place the processes and technology to support the serialization and traceability of all pharmaceutical products with sanitary register in ANVISA and commercialized in Brazil. All movement of goods need to be registered by all these participants, including subsidiaries, within their information systems, and is responsibility of the Industry to consolidate all this information and attend the Anvisa expectation around the reporting requirements. Anvisa defines the Datamatrix as the mechanism to identify serialized pharmaceutical products and leaves with the Industry the responsibility to create, own and maintain a traceability solution that will connect all the supply chain participants in a specific IT solution.

Use of GS1 Standards

Secondary Packaging – GTIN Identification

- The GTIN (Global Trade Item Number) is a number that identifies goods and services uniquely. It consists of the GS1 company prefix, an item reference and a check digit. Despite the GTIN not mandatory, their use ensures interoperability in supply chain and adherence to international markets. When a GTIN is assigned, the owner of the brand / registration must link this

identification number to item characteristics, such as description, weight, dimensions, the active ingredient, etc. in its database. The GTIN most commonly used for identification of drugs is GTIN-13 (with 13 digits).

Fig. 2. GTIN13 - Structure.

Secondary Packaging – GS1 Data Matrix

- The GS1 DataMatrix is a two-dimensional symbology that can encode, with the use of Application Identifiers (AI), a series of information such as product identification (GTIN), expiry date, lot, serial number, etc. The RDC 54/2013 determines that the Datamatrix code minimally the following data that make up the IUM (Drug Identification Single):
  - I - the drug registration number at Anvisa;
  - II - Serial number;
  - III - Expiry Date;
  - IV - Lot Number.
- The number of positions in the RDC 54/2013 mentioned range according to the table below. Note that GS1 standard in some cases, has a larger capacity position.

Fig. 3. Data Matrix- Structure.

Tertiary Packaging – Serial shipping container code: SSCC

- The SSCC is a standard voluntary que establishes a system of identification que can be used by all parties in the supply chain, from the manufacturer to the carrier, distributor and retailer, to track the distribution of products. It is an 18-digit number que Allows exclusive and serialized identification of logistical / transport units.
  When combined with shipment information provided in advance by electronic means (ASN, eCom, etc.), the SSCC will support applications such as

shipping/receiving, inventory update, selection, reconciliation of purchased orders, product traceability, etc.
The SSCC is particularly suitable for identifying transport packaging including that which is mixed and / or contains serialized items, allowing the merchandise that is packed to be identified and thus enabling checking and control.

Fig. 4. SSCC - Structure.

These are the most important standards to be used for screening drugs using the EPCIS development platform (it is important to note that any global standardization of GS1 can be used for communication between links in drugs chain).

EPCIS Standard

EPCIS is GS1 Standard that defines a way to enable disparate applications to create and share visibility event data, both within and across enterprises. Ultimately, this sharing is aimed at enabling users to gain a shared view of physical or digital objects within a relevant business context.

The EPCIS standard was originally conceived as part of a broader effort to enhance collaboration between trading partners by sharing of detailed information about physical or digital objects. The name EPCIS reflects the origins of this effort in the development of the Electronic Product Code (EPC). It should be noted, however, that EPCIS does not require the use of Electronic Product Codes, nor of Radio-Frequency Identification (RFID) data carriers, and as of EPCIS 1.1 does not even require instance-level identification (for which the Electronic Product Code was originally designed). The EPCIS standard applies to all situations in which visibility event data is to be captured and shared, and the presence of "EPC" within the name is of historical significance only.

Additionally, the EPCIS has in its structure, four key elements:

- EPCIS Capture Interface, understand the business context in which the capture of EPCIS information occurs. That is, an EPCIS capture is able to provide a context of the highest level of business for the captured GS1 data.
- EPCIS Accessing Applications, can be any application that accesses EPCIS. Generally, this application is responsible for performing a business process. The application access can stay outside the company.
- EPCIS-Enabled Repository, records EPCIS events generated by one or more EPCIS capture applications and makes them available for further research using EPCIS accessing applications.

- EPCIS Query Interface, provide a standard way for internal and external systems to request business events from repositories and other sources of EPCIS data using a simple, parameter-driven query language.

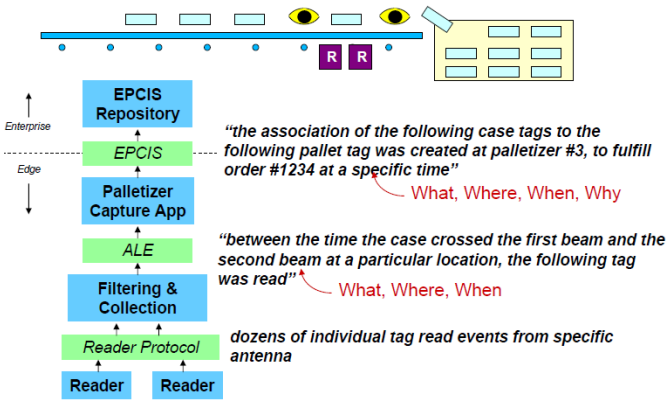

Fig. 5. Data Capture example.

Product Identification that can be captured may come in the form of:

- Passive RFID Tag –UHF Gen 2, HF
- Barcodes –Linear, Data Matrix
- Active RFID Tag
- Human Readable Number

Finally, EPCIS provides the critical foundation for the visibility needed to improve business processes, comply with regulations, and increase consumer and patient safety. At the same time, its flexibility and extensibility are geared to support both current and future needs of trading partners across multiple industries, regardless of data carrier.

Work Development

Anvisa expects from the pharmaceutical supply chain participants the evidences that they were able to deliver what is expected from the 2 (two) different milestones as described above.

Both milestones consider serialization and traceability capabilities, in this way differing from other countries like US where serialization and traceability are handled separately from an implementation timing perspective.

Another important aspect of the transition between the pharmaceutical market current state in Brazil and supply chains with serialization and traceability capabilities is to consider a smooth and clear approach with final customers. Communication for example needs to be planned in advance for a scenario where products non-serialized

will co-exist with serialized ones, clear rules on how to correctly identify a counterfeit and diverted product.

The figure below shows the storage processes and logistics distribution of pharmaceutical drugs:

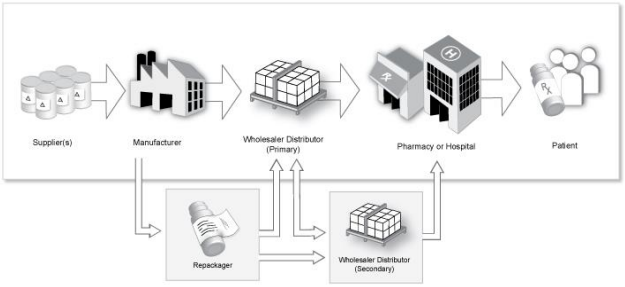

Fig. 6. Data Capture example.

Global standards such as EPCIS could allow applications and processes across the industry to support the Five Sure, improving patient safety and supply chain efficiency:

- Traceability of medicines: Partners supply chain can use integrated barcodes with EPCIS system to control all drugs throughout the supply chain, according to their risk category and in the case of some products, full traceability of medical supplies could improve the processing of recalls and facilitate inventory management.
- Drug receiving authentication: distributors, pharmacies and hospitals could use the EPCIS system to track and confront all medicines with manufacturers' data and possibly elsewhere in the supply chain, making it much more difficult for counterfeit and damaged goods arrived to the patients.
- Collaborative inventory management: dispensing points, distributors and manufacturers could easily exchange information on use of health products and medicines, location and availability of products. Program planning and forecasting stocks could analyze data to optimize inventory levels, improve the availability of medical supplies and medicines throughout the supply chain, and ensure availability of medical products in critical moments of treatment.
- Transaction automation: The processes and systems may be automated, removing most of the insert, validation and data correction today made manually. The administration of medicaments and the use of medical devices could be captured by reading the bar code and automatically fed in logistical systems.

Conclusion

With the proposed implementation of the EPCIS system in health, concludes in this article that this standard meets ace regulations along the National Agency of Sanitary Surveillance (ANVISA).
After implementing this system, the following benefits are estimated:

- Reducing product waste due to obsolescence;
- Reducing the cost of data management;
- Improving the accuracy of transactions;

In a conservative approach, it is estimated that the costs in the health sector could be reduced by $ 40-100 billion worldwide, mainly through the reduction of medication errors cost (US $ 9-58 billion), cost of improvement of inventory management (financing, processing, reduced obsolescence cost at $ 30-42 billion) and reducing data management costs ($ 1-2 billion).

Acknowledgment

The authors would like to thank GS1 Brasil for attention with this work.

References

[1] EPC Information Services (EPCIS) Version 1.1 Specification, GS1 Standard Document Version 1.1, May 2014
[2] EPCglobal inc. avaiable ar: www.epcglobalinc.org
[3] Brazilian Medicine Traceability using GS1 EPCIS, draft, GS1 Brasil
[4] GS1 RFID Bar Code Interoperability, GS1 Guideline, Issue #1 August 2012.
[5] RDC N° 54, ANVISA, 10 December, 2013