Belgium

Baxter endorses GS1 Standards as a building block of brand integrity programme

ABSTRACT

Baxter International Inc. has endorsed and been a strong supporter of industry-wide, global adoption of the GS1 Standards for healthcare. Baxter believes that industry-wide adoption of these standards will improve patient safety and will drive increased efficiency and integrity within the healthcare system.

By **Philippe Majois,**
Baxter

Counterfeit and/or altered medical products pose growing risks to patient safety worldwide. Maintaining product integrity is complex and multifaceted, encompassing an array of supply chain, product design and packaging, and risk management strategies.

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Baxter believes that adoption of GS1 Standards for healthcare and serialisation of certain products will facilitate greater use of track-and-trace strategies and technologies that can help ensure that products are moved correctly and efficiently throughout the supply chain. Ultimately, adoption of these standards can help enable healthcare professionals to verify they are administering the right product to the right patient at the right time.

Baxter launched a formal, global product integrity programme in 2007 to safeguard the company's products from the threat of counterfeiting or adulteration. As part of this program, the company conducted a series of risk assessments, examining economic incentives, supply chain and product complexity and other factors. Based on those assessments, Baxter prioritised certain product lines and geographies for piloting and implementing various product integrity measures. The highest priority products and markets were earmarked for initial implementation of serialisation using GS1 Standards, which also comply with California Board of Pharmacy ePedigree requirements.

One Baxter facility in Belgium where biologic-derived therapies are produced has been bar coding and mass serialising for the last two years. The experience there has helped guide other Baxter product integrity efforts and points to the complexity involved in implementation.

A number of factors can influence the complexity of implementation, including the product itself, how it is manufactured, packaged and stored, and where it is manufactured and shipped. Implementation of GS1 and serialisation is not simply a matter of placing a bar code on a product. The implementation process involves a number of steps and requires the manufacturing capability to generate and print two dimensional dot matrices and the technology behind it to store, process and track data. The steps involved include: Upgrading packing lines to bar code (without serialisation) the unit of dose packaging level.

1. Upgrading packing lines to bar code and serialise the lowest sealable unit and the above packaging levels
2. Using GS1's Global Trade Item Number for product identification
3. Using GS1 DataMatrix bar codes for unit of dose and unit of sales packaging levels
4. Using a GS1-128 bar code on shipping case level

Baxter

About Baxter

Baxter develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide. Baxter's diverse product portfolio is manufactured in 27 countries and sold in more than 100 countries globally, and ranges in complexity from basic intravenous solutions to highly-specialised biologic derived therapies.

Baxter in Belgium – Production site in Lessines

5. Using a SSCC-18 bar code on pallet level
6. Including batch number and expiration date for all products, as well as potency for certain products
7. Continue to meet shifting or differing local bar code regulatory requirements, such as as having the National Drug Code (NDC) in a linear bar code in the US.

With this implemented, products can be scanned by warehouses, logistic partners, customers, nurses and patients for specific home care treatments at all levels of packaging.

Also adding complexity is the need to educate internal contributors/collaborators (for example Information Technology, Manufacturing, Supply Chain and Quality professionals across the organisation) and external stakeholders on GS1 Standards and the implications for systems, equipment and processes, including on such elements as:

- Working with GS1 on creation and allocation of GTIN to products
- Selection of system and equipment vendors
- Defining validation approach and demonstrating reliability of process
- Understanding the impact on labeling and packaging, particularly for Regulatory requirements or design
- Understanding the numerous operational impacts
- Understanding interactions between the enterprise level software and the plant equipment.

First and foremost for implementation, manufacturing capabilities need to be upgraded to incorporate printing and verification systems that are able to print bar codes and qualify them. This can require significant investment depending of number of packing lines, type of products, and packaging materials. Multiple sets of standards and requirements would drive unnecessary or redundant investment, extend timelines for implementation and create confusion and increased risk

for manufacturers, healthcare providers and patients. The continued adoption of GS1 Standards by additional countries will facilitate quicker adoption of a single global standard and spur the many supply chain and patient benefits envisioned with the creation of the GS1 Standard.

Preventing and overcoming the many threats to product integrity that exist today and will arise in the future requires a comprehensive approach that incorporates many elements. Industry-wide, global adoption of GS1 Standards and product serialisation is an important building block in those efforts. Baxter looks forward to expanding its implementation of those standards, furthering its product integrity efforts and driving greater security and efficiency in the delivery of our products to healthcare providers and patients around the world.

ABOUT THE AUTHOR

Philippe Majois is Packaging Technology Development Manager for Baxter's BioScience business. He has been with Baxter since 1998 and started as Packing Operation Manager. Since 2002, he has managed packaging design and technology development for biologic products within the company's BioScience business.

Brazil

Implementing GS1 DataMatrix at Moinhos de Vento Hospital: Ensuring drug traceability and patient safety

ABSTRACT

The Moinhos de Vento Hospital in Brazil implemented GS1 DataMatrix barcodes on medicines in 2011. The hospital aimed to enhance patient safety and reduce costs by more efficiently managing inventory and enabling traceability. Return on investment is expected within fifteen months, and could even be faster if more pharmaceutical suppliers print the GS1 DataMatrix on their unit dose packaging.

By **Joana Heydrich,**
Moinhos de Vento Hospital
(Brazil)

Quest for quality

HMV, the Moinhos de Vento Hospital, has been on a quest for quality in patient care since it was founded in 1927. The hospital manages the "Programa Excelência na Prática" (Excellence in Healthcare Programme), which involves ANAHP, Brazil's National Association of Private Hospitals, and the Institute for Healthcare Improvement (IHI) in the United States.

This continuous effort was recognised by the Brazilian Ministry of Health, electing the hospital as one of the most excellent hospitals in Brazil. HMV has also been certified four times by the Joint Commission International (JCI), a renowned organisation evaluating and accrediting hospitals worldwide.

Leveraging GS1 DataMatrix at HMV

The Brazilian Federal Law 11,903 instituted in January 2009 requires establishing a national system to control the supply of medicines. Any medicine manufactured, dispensed and sold in the country has to be tracked. ANVISA, the National Agency for Sanitary Surveillance in Brazil, will coordinate and adopt an identification system to be implemented gradually in the country. Pharmaceutical suppliers will have to comply with this system.

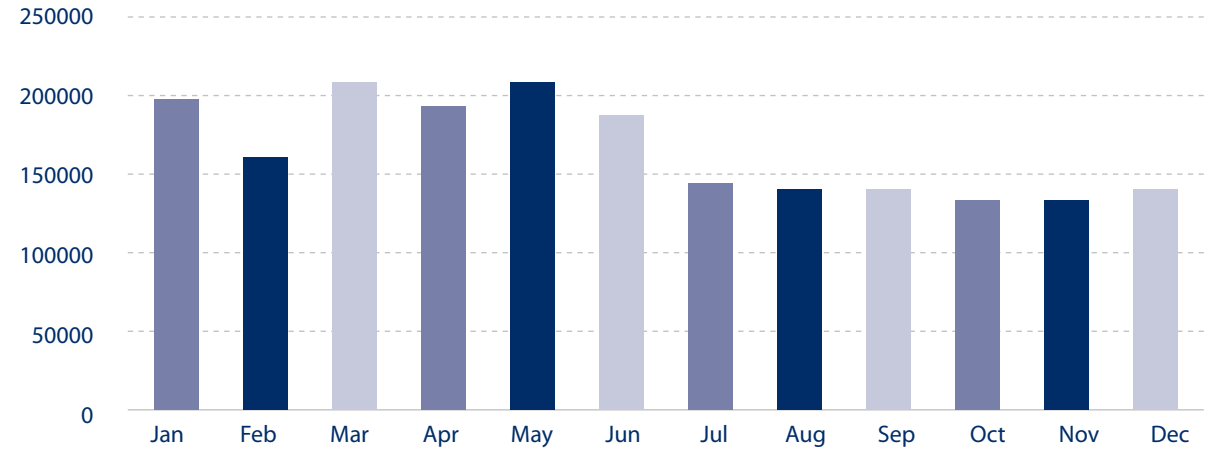
GS1 Brazil and ANAHP jointly promote the use of barcodes and identification standards in the healthcare supply chain, from production to the patient. A joint seminar in September 2010 brought suppliers and hospitals together to discuss the implementation and their benefits.

The conclusions from that seminar helped HMV to develop the hospital strategy to implement GS1 DataMatrix barcodes on medicines. This strategy was presented to the hospital's board and subsequently approved.

"The main goals of the project are to enhance patient safety and ensure inventory control."

The main goals of the project are to enhance patient safety and ensure inventory control. This can be achieved by ensuring the traceability of medicines inside the hospital, in particular the ability to track and trace medicines from receiving to dispensing, and report on the process in detail. Technology, in particular barcoding, needs to be implemented to enable this. The hospital would like to work with its suppliers to have GS1 DataMatrix barcodes printed on the packaging, avoiding unnecessary rework by the hospital and increasing the traceability in the whole chain.

Figure 1: **Internal labelling of medicines at HMV in 2011**



The main benefits for HMV to implement this traceability system and leveraging GS1 DataMatrix include:

- ensuring traceability of medicines from receiving to dispensing;
- reducing operating costs by eliminating internal labelling as suppliers leverage a global standard;
- saving time during receiving and internal identification;
- reducing waste by monitoring expiry dates of medicines;
- optimising human resources by eliminating internal identification and focusing on core activities;
- performing registry safety;
- reducing errors by automating the process and eliminating human errors; and
- reducing waste by eliminating internal labelling.

Internal identification and labelling of medicines

Every medicine that is distributed and dispensed in the hospital receives an internal label with information about the product, its batch number and expiry date, in addition to the barcode printed on the label. This label serves as an entry in the computer system used in the hospital to ensure the traceability of that medicine.

The labelling process is sometimes manual, sometimes automated, but always carried out by pharmaceutical professionals with full-time supervision of the responsible pharmacist. This process is one of the most important steps in the medicine supply chain in the hospital – not only for financial control, as it guarantees the correct charge of the medicine in the patient account – but also for process safety.

This labelling process not only brings on unnecessary work, but also increases cost and the risk of errors in the medicine supply chain. In June 2011, four suppliers (Eurofarma, B. Braun Brasil, Isofarma Industrial Farmacêutica Ltda and Baxter Brasil) started supplying their products printed with GS1 DataMatrix. As shown in Figure 1, the monthly average of manual, internal labelling decreased almost 28%, averaging 137,043 units per month as of June 2011 instead of 189,476 units prior.

This has saved a lot of work for the hospital and is a much safer process for the patient. The product information comes directly from the supplier and remains unchanged throughout the process.

The project allowed the hospital to save approximately R$1,250 (€~500) per month in supplies (labels, ink, etc.) and R$4,900 (~€1,900) per month in labour costs in the second half of 2011.

	Monthly average labelling	Average monthly cost - supplies	Average monthly cost – labour
Before	189,476 medicines	R$ 4,500	R$ 7,000
After	137,043 medicines	R$ 3,270	R$ 2,100

Investing in equipment and people

To be able to read two-dimensional (2D) barcodes in the hospital, it was necessary to replace all the previously used scanners and data collectors. HMV invested R$72,765 (~€21,000) in scanners and data collectors. Forty-two fixed data readers were replaced in all locations where medicines are dispensed, and three handheld data scanners were replaced in the central warehouse and pharmacy for increased mobility.

Description	Quantity	Location	Unit Value R$	Total Value R$
Fixed Data Scanner	42	All	896	37,623
Handheld Data Scanner	3	Central Warehouse and Obstetric Care Unit	766	2,298
Data Collectors	11	Central Warehouse and Pharmacy	2,730	**30,030**
Batteries	11	Central Warehouse and Pharmacy	255	2,805
Total	67	-		72,765

Examples of data scanners

The computer system used at HMV was already prepared to understand the data scanned from GS1 DataMatrix barcodes. For this phase, it was only necessary to do tests before the implementation to ensure system reliability. Using standardised solutions is a great advantage in these kinds of projects.

Training of hospital staff was essential for the project in order to be successful. In total, 118 co-workers have been trained in eighteen different satellite stocks in the hospital, from the Central Warehouse, to Oncology, to ICU, and so on. The responsible pharmacist conducted training in their area.

"Training of hospital staff was essential for the project in order to be successful."

To make sure all hospital staff was and remained engaged in the project, HMV's marketing department helped to promote the use and benefits of the GS1 DataMatrix for drug traceability. A marketing campaign – "Datamatrix – Segurança para todos (Security for everyone) – was set up, including a poster used throughout the hospital and e-cards sent via email to hospital staff.

From planning to reality in less than eight months

The project was successfully concluded and according to plan. Eight months after the project's kick-off, the GS1 DataMatrix started to capture information for medicines from Eurofarma and B.Braun.

The project was done through a truly multidisciplinary approach, engaging and integrating multiple hospital departments, including procurement, information technology, marketing, corporate education, and decentralised storages. Without this multidisciplinary approach, there is no doubt that the project would not have achieved so much in such a short period of time.

Nº	Activities	Sep/10	Oct/10	Nov/10	Dec/10	Jan/11	Feb/11	Mar/11	Apr/11	May/11
1	Participation in the ANAHP/GS1 Event									
2	A study of equipment needs									
3	Project work-up at HMV									
4	Project presentation to the board									
5	Supply quotation									
6	Analysis and approval of the equipment									
7	Equipment purchase and receipt									
8	Equipment installation									
9	Adjustments in the internal system - software (Screen for the Supplier and Product Register)									
10	Team training in the inventory									
11	Full functioning of the Project									

Conclusion – "Segurança para todos"

Return on investment in new equipment will be achieved by HMV in less than fifteen months. With only four suppliers, HMV could reduce 30% of its internal labelling efforts. More pharmaceutical suppliers participating in the GS1 DataMatrix project will enable the hospital to realise more savings.

Enhancing patient safety was the most important goal of HMV. Although difficult to measure, the automation of the dispensing process through the usage of the GS1 DataMatrix reduces the risk of medication errors by eliminating the human intervention to capture product identification and information.

"Return on investment in new equipment will be achieved by HMV in less than fifteen months."

HVM was one of the winners of the 14th edition of Brazil's automation prize, "*Simplifying business and lives*" (November 2011).

When it comes to their tasks, better trained and motivated staff members perform better, catching the attention of the clients and forming loyalty to the HVM brand – generating a positive spiral and better results for everyone.

For more information about this case study, contact Roberto Matsubayashi at:
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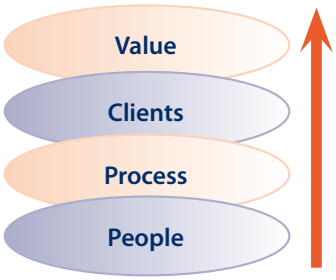

Positive spiral of the Balanced Score Card. Source: Adapted Model - Kaplan and Norton.

About the Moinhos de Vento Hospital

HMV is a 376-bed hospital in Brazil and was founded in 1927 as Hospital Alemão (German Hospital). The hospital campus has four modern buildings that are fully integrated, with a hospital, two clinics and an Institute for Research and Education. HMV is renowned for its quality in patient care and is the only hospital in South Brazil to be accredited by the Joint Commission International. HMV provides comprehensive assistance, which includes personalised and integral assistance by a multidisciplinary team, searching for not only the physical wellbeing, but also the spiritual and psyche wellbeing.

ABOUT THE AUTHOR

Joana Heydrich, Responsible Pharmacist at the Moinhos de Vento Hospital in Brazil, joined the hospital in 2008 as Technical Pharmacist in charge of the materials processes and medicine. She leads the team at the Central Warehouse and is responsible for the performance of the whole process of receiving, registering and distributing all supplies. She is also a member of the Standardisation Committee of Hospital Medical Device (Comitê de Padronização de Materiais Médicos Hospitalares) and the HMV Medicine Committee (Comitê de Medicamentos do HMV). She managed the HMV's GS1 DataMatrix project.

Ms. Heydrich holds a post graduate degree in Pharmaceutical Sciences from the Universidade Federal do Rio Grande do Sul. Currently, she is pursuing her MBA in Health Management (Gestão da Saúde) at Fundação Getulio Vargas in a partnership with HMV.