



The Global Language of Business

GS1 Healthcare

Public Policy Discussion Papers







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GS1 Data Matrix implementation (2011)

Purpose

This document discusses GS1 Data Matrix implementation in the Healthcare sector in order to address the growing demands of increased data needs and facilitate increased patient safety.

This document provides clear direction and encourages actions for the Healthcare sector to meet the non-binding goal sets by the GS1 Healthcare community of implementation by 2015 of GS1 Data Matrix on regulated Healthcare products where the current needs are not being met by other GS1 Data Carriers.

Background

Pharmaceutical and medical device identification and marking have very specific needs. Some of these needs are being met, and will continue to be met, through the use of 'traditional' linear bar codes. However, for applications where they are not (e.g. increased amount of data, direct part marking, error detection and correction), GS1 Healthcare has adopted the use of GS1 Data Matrix as the data carrier (bar code symbol) solution.

This document is also recognizing the challenges linked to the implementation of this new technology.

Recommendation

GS1 Healthcare recommends to:

- Begin or expand implementations of GS1 Data Matrix
- To ensure that the infrastructure is in place (e.g. printing and scanning systems)
- To bring awareness to the industry of the need to consider practical challenges and to move forward as quickly as practical

Position Statement

To meet the growing demands of increased data needs and facilitate increased patient safety, the healthcare community is in the position to be the leader in GS1 Data Matrix implementation. To demonstrate support of this leadership position, the GS1 Healthcare community has set a goal of 2015 for implementation of GS1 Data Matrix printing on, and scanning of, regulated Healthcare Trade Items where the current needs are not being met by other GS1 Data Carriers. While not a binding mandate, the community feels strongly in setting a clear direction to further galvanize the industry and encourage action over and above the many active implementations that exist today.

Global standards for automatic identification provide an opportunity to make the healthcare supply chain safer as well as more efficient and accurate. Healthcare regulators and trading partners have realized that a global, standardised identification system from product manufacture to patient treatment is imperative to comply with the increasing need for product traceability around the world.

The GS1 System, globally endorsed by the healthcare community, is the most widely used trade item identification system worldwide with more than 5 billion transactions per day. Built on a foundation of identification keys (such as the Global Trade Item Number or GTIN) and attributes (such as batch/lot numbers, expiry date, etc.) it is uniquely suited to meet the needs of the global healthcare industry.

Pharmaceutical and medical device identification & marking have very specific needs, including:

- Encoding large amounts of variable or dynamic data (Lot Number, Expiration Date, Serial Number, etc.) at high production speeds
- Direct part marking (e.g. marking on surgical instruments, etc.)

- Efficient marking of irregular packaging for many medical products
- Global legal and regulatory requirements that dictate the placement of data in a bar code symbol
- Traceability requirements for both pharmaceuticals and medical devices

Some of these needs are being met, and will continue to be met, through the use of 'traditional' linear bar codes, such as GS1-128 or GS1 DataBar. However, for applications where they are not, GS1 Healthcare has adopted the use of GS1 Data Matrix as the data carrier (bar code symbol) solution.

Data Matrix is a 2-dimensional (2D) bar code symbology that efficiently meets all of the above needs by:

- Allowing the encoding and marking of a greater amount of data within a smaller space
- Enabling direct part marking of trade items where labels may not be practical (small medical / surgical instruments)
- Providing error detection and correction capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label

As with the implementation of any forward looking technology, there can be challenges that must be recognised.

For GS1 Data Matrix, these could include:

- Upgrades to scanner systems: to read the GS1 Data Matrix symbology, camera-based bar code scanners are required. Linear technology based bar code scanners cannot read 2D bar codes, however camera-based bar code scanners can read both linear as well as 2D bar codes and users should be prepared to see both of these types of bar code symbols (see the GS1 Healthcare position statement on 2D camera based scanners)
- Updates to printing systems: to print GS1 Data Matrix, particularly on-line, direct to packaging, within production
- Environments, printing systems may need software / hardware updates or replacement
- Updates to IT infrastructure systems: to ensure that dynamic, variable attribute data (Lot/Batch, Expiry Date, Serial Number, etc.) is available for encoding in a "real time" packaging environment as well as ensuring

that the underlying systems can support the additional data where this is not already implemented.

Recognising all of these needs, as well as the potential challenges of implementation, GS1 Healthcare and its global members strongly support the implementation of 2D capable scanners and the adoption of GS1 Data Matrix. A global implementation will not be accomplished without time and effort. The use of the Data Matrix can facilitate increased automation of data capture in any country without creating trade barriers that could otherwise potentially impact patient care and safety. Where Data Matrix can enhance or solve data capture issues, we need to begin or expand implementation and ensure that the infrastructure is in place as we move to the use of 2D Symbols (like GS1 Data Matrix) through the investment in 2D capable scanners. To bring awareness to the industry of the need to consider these practical challenges and to move forward as quickly as practical, GS1 Healthcare urges that new investments in printing and scanning systems throughout the global healthcare market include compliancy to GS1 Data Matrix.



Implementation in hospitals hindered by bar code symbol issues (2012)

Purpose

In this document, the Healthcare Provider Advisory Council (HPAC) members have been exploring the opportunities and challenges of implementing GS1 standards to improve various care-giving processes and, ultimately, patient safety.

This document describes the different issues faced both for pharmaceuticals and medical device products and presents the “providers request”.

Background

Issues with bar code symbols have emerged as a broad, reoccurring and major challenge, or ‘pain point’, during implementation projects. The issues include:

- No bar code symbol present
- Poor quality bar code symbols
- Placement of the bar code symbol
- More than one bar code symbol
- Non-standard bar code symbols

Recommendation

The GS1 Healthcare Provider Advisory Council (HPAC) issues this ‘Call to Action’ to all upstream stakeholders and Regulators around the world to:

- Adopt ONE global standard: The GS1 System of Standards
- Immediately address the issues covered above: no bar code symbol present, poor quality bar code symbols, placement of the bar code symbol, more than one bar code symbol, non-standard bar code symbol, bar code symbology, etc.

Position paper

Towards the end of 2011, GS1 Healthcare established the Healthcare Provider Advisory Council (HPAC) to be the forum for sharing and discussing the practical realities of implementation of GS1 Standards in the care giving environment in regards to the impact on clinical care and patient interaction. The membership of HPAC consists of thought leaders and early adopters (clinical and non-clinical) of GS1 Healthcare Standards from the global clinical provider environment (e.g. hospitals, retail and hospital pharmacies, clinics, care homes, etc.) and staff from GS1 Member Organisations (MOs). Through regular monthly conference calls and occasional face-to-face meetings (e.g. at GS1 Healthcare Global Conferences) HPAC members have been exploring the opportunities and challenges of implementing GS1 Standards to improve various care-giving processes and, ultimately, patient safety.

Issues with bar code symbols have emerged as a broad, reoccurring and major challenge, or ‘pain point’, during implementation projects. On both pharmaceuticals and medical device products (products), the issues include:

- No bar code symbol present
- Poor quality bar code symbols
- Placement of the bar code symbol
- More than one bar code symbol
- Non-standard bar code symbols

Bar code symbology

All of the above present various challenges and definitely pose a barrier to widespread adoption and implementation in the provider environment. Thus, the proven benefits – enhancement of patient safety and support of clinical processes – could be severely limited or, at worse, not be realised.

No bar code symbol present

Lack of a bar code symbol (Figure 1) on products means that the provider has to have a minimum of two separate processes: one manual, for the products without a bar code symbol, and one automatic, for those products with a bar code symbol. This scenario is counterproductive, particularly as it is likely, for example, that it is the manual process, with its inherent errors, that they are aiming to replace by implementation of GS1 Standards. Indeed, it adds unnecessary complexity. Alternatively, whilst this situation persists, providers who want to progress the implementation of GS1 Standards may, and are, employing the necessary resources and equipment and implementing new processes to generate and place bar codes on products. In the view of most, however, this is not a viable alternative, due to the complexity and cost of the task and the risk of errors that might endanger patients.



Figure 1

Example of a suppository with no bar code. The provider has to create and place a 'flag' bar code label on each item.

Providers request that all products received carry a GS1 Data Carrier in the form of a bar code symbol, either on the package containing the product (primary package) or, for some medical devices (e.g. surgical instruments), directly marked on the item itself (Direct Part Marking (DPM)).

Poor quality bar code symbols

This is a known issue with bar code symbols in a number of industries in which they are used and can occur for numerous reasons, e.g. the type of material the bar code symbol is printed upon (substrate) or the type of printing used (e.g. thermal transfer, ink jet, etc.). But, for whatever reason, if the bar code symbol is of poor quality

this can result in problems in reading it when it is scanned.

Providers request bar code symbols that, at least, meet the published minimum quality criteria found in the GS1 General Specifications and associated ISO standards, whether they are printed on the primary package or, for some medical devices (e.g. surgical instruments), in DPM.

Note: Many GS1 member organisations (MOs) offer bar code symbol print quality verification services.

Placement of bar code symbols

There are products used in the provider environment that can pose particular challenges when a bar code symbol is applied (e.g. vials, syringes, ampoules, nebulizers, etc.), (Figure 2), but sub-optimal placement and orientation of the symbol can present particular scanning problems. For example: a) placing a label containing a linear bar code symbol horizontally around a vial renders the bar code symbol unreadable due to the curvature of the vial; in this case by placing the bar code label vertically along the vial the curvature would be minimised thus significantly improving its readability; b) a bar code symbol is usually placed at the bottom of the primary package that contains a tube, and in some cases a bar code symbol is also placed on the tube itself. In the care-giving environment the outer, primary packaging is discarded and the tube itself is what is dispensed. As the contents of the tube are administered at regular intervals over a period of time by the caregiver/nurse, the end of the tube is rolled up to force the contents to the top, which then hides the bar code. Placing the bar code at the top of the tube would overcome this issue.



Figure 2

An example of a linear bar code placed on a curve of a small bottle – this medication is packaged in 15 and 30ml quantity which is equivalent to the patient's dose. Care givers have difficulty scanning due to the placement of the bar code on the curve of the bottle.

Providers request upstream stakeholders (e.g. Brand Owners, manufacturers, suppliers, repackagers, etc.) to consider the scanning constraints of downstream stakeholders, particularly in regards to the practical application in the provider environment, and that bar code symbols are placed so their readability is increased or assured.

More than one bar code symbol

Many countries have been developing regulations for identification of products using bar code standards; and, although there has been good progress towards ONE global standard being regulated and adopted (i.e. the GS1 System of Standards), there are still countries with local requirements and/or proprietary bar code systems. Providers appreciate the compliance challenges faced by upstream stakeholders whose products are sold in multiple markets that may result in more than one bar code symbol being applied to packaging (e.g. see Figure 3 (Peda)), but having more than one symbol on a product creates challenges in the care-giving environment, for example: the time taken to identify which symbol to scan, the impact of the wrong symbol being scanned, the ability of the scanner to scan and decode only one symbol when in close proximity to another, etc., these have potential to impact patient safety!



Figure 3

The ideal situation would be for all regulators from around the world to coalesce around ONE global standard, thus negating the need to apply more than one bar code symbol to product packaging. Until that situation is achieved, **Providers request** upstream stakeholders to consider the scanning constraints of downstream stakeholders (hospitals, hospital pharmacies, care homes,

clinics, etc.) and that only ONE bar code symbol is placed on product packaging (see 'Bar code symbology' below). In the case where this is not possible due to extenuating circumstances, multiple bar code symbol guidance, such as that in the GS1 General Specification, should be followed.

Non-standard bar code symbol

Similar to the situation outlined in the previous issue ('More than one bar code symbol') the ideal situation of ONE global standard being regulated and adopted is yet to be achieved and therefore, there are countries using proprietary or category (e.g. medical device) specific bar code systems (Figure 4). This can result in similar issues to those previously stated, e.g. delays in scanning, but may also create problems of data capture into the provider's information systems that have been developed to comply with a global standard (See Position Paper: "Implementation of GS1 Standards based processes in hospitals is hindered by lack of interoperability of information technology systems").



Figure 4

Example of a nebulizer with a linear bar code that is non-standard. It's placed on a clear background, causing potential issues with scanning. The image also shows a flag label added by the provider to overcome these issues.

Providers request upstream stakeholders to consider the scanning constraints of downstream stakeholders, particularly in the provider environment, and that only GS1 compliant bar code symbols are printed either on the primary package or, for some medical devices (e.g. surgical instruments), in DPM.

Bar code symbology

The familiar symbology (format) of bar codes, particularly in the retail environment, is that of the '1D' or 'linear' type, vertical black lines and white spaces (Figure 5), but over recent years another generation of bar code symbology is being increasingly used, the "two-dimensional (2D) or "matrix" type symbology, e.g. GS1 Data Matrix (Figure 3).

**Figure 5 and 6**

These two symbologies contain the same data.

A position statement¹ issued by GS1 Healthcare in October 2009, relating to Camera-Based bar code scanners, states: "Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:

- A large amount of data (product ID, Batch/Lot Number, Expiry Date, Serial Number, ...) to be stored in a small space
- Variable information (such as unique identification number at unit dose level) to be marked at high production rates
- Direct part marking (e.g. surgical instruments and implants)
- Bar code [symbols] that cannot be scanned not only impact supply chain efficiency, but more importantly, patient safety
- The above requirements may not always be achieved with the 'traditional' linear bar code symbols, but a solution is available: GS1 Data Matrix"

Today, current GS1 standard implementation projects or those in planning will include provision for purchasing camera-based scanners, which scan both types of symbologies; negating the need for both symbologies being placed on product packaging (see "More than one bar code symbol" above). Therefore, providers are or will be able to accept and scan GS1 Data Matrix symbologies.

Providers request upstream stakeholders (when printing one bar code symbol as requested above), to select the GS1 Data Matrix symbol, the preferred symbology if there is a need to:

- Hold a large amount of data on small space (e.g. Global Trade Item Number (GTIN), Lot/Batch No., Expiry Date, Serial No., etc.)

- Note: In the Netherlands the Federation of University Hospitals, The general Hospitals and the Hospital Pharmacists) has stated that they want GS1 bar codes on their products, preferably, not necessarily, a GS1 Data Matrix, including GTIN, Expiry Date, Batch Number and/or Serial Number.
- Include variable information, e.g. Serial Number
- Direct Part Mark (DPM) an item, e.g. a medical device such as a surgical instrument
- If these constraints are not present, then the traditional GS1 linear/1-dimensional bar code is acceptable.

Historical context

Providers understand the numerous reasons that upstream stakeholders have established and continue the approaches outlined above. A common argument is that upstream stakeholders who have implemented GS1 Standards have realised the efficiency benefits but the use of the bar code stops at the doors of the provider. But the situation is changing! Indeed, it has been changing over the last 5-7 years due to a number of drivers:

- Patient Safety: numerous reports related to medical errors and, for example, how bar code standards reduce mistakes at administration of drugs diminishes with 42% (Poon et al, 2010¹)
- Regulatory: Over a number of years Regulators have been publishing regulations focused on upstream healthcare stakeholders such as manufacturers. Now there are examples of regulators or governing bodies expanding their focus to the healthcare provider community, e.g. in May 2012 in the Foreword to NHS procurement: Raising our game², Sir David Nicholson, NHS Chief Executive demanded all trusts take action to implement GS1 in NHS Procurement
- Efficiency: as a route to improving their procurement processes and systems, some providers are now entering GS1 Standards compliance as a criteria in tenders

¹ Effect of Bar-Code Technology on the Safety of Medication Administration, The New England Journal of Medicine <http://www.nejm.org/doi/full/10.1056/NEJMsa0907115>

² <http://www.sci-ware.com/documents//NHS%20Procurement%20raising%20our%20game.pdf>

- There is increasing evidence that the situation is changing by the number of case studies published related to the implementation of GS1 Standards and the benefits realised. Many of these have been captured and published over the last four years in the GS1 Reference Books, 2009-2010, 2010-2011, 2011-2012, 2012-2013 (New)³. BUT, the growth in implementation has, in parallel, increased the occurrence of the bar code symbol issues covered in this paper and these could pose a barrier to widespread adoption and implementation in the provider environment. Thus, the proven benefits to patient safety, and the other drivers mentioned above, could be severely limited or, at worse, not realised.

Conclusion

Bar code symbol issues have hindered successful implementation of GS1 standards and could pose a barrier to widespread adoption and implementation in the care-giving environment. Receiving pharmaceuticals and medical devices that carry GS1 standards-based, quality bar code symbols on the packaging or in DPM are fundamental to enable their adoption and use in hospitals, hospital pharmacies, care homes, clinics with the primary objective of improving Patient Safety. They are also foundational to enabling and improving other key processes such as procurement, inventory management, internal deliveries, dispensing, tracking, tracing, recalls, etc. and ultimately realising GS1 Members Vision for Traceability in Healthcare:

“Full, end-to-end, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from point of production to point of use”⁴

To eventually achieve this long-term Vision, ALL stakeholders involved in healthcare globally would be required to collaborate and work together to implement GS1 Standards-based systems and processes.

Call to action

The GS1 Healthcare Provider Advisory Council (HPAC) issue this ‘Call to Action’ to all upstream stakeholders and Regulators around the world to:

- Adopt ONE global standard: The GS1 System of Standards
- Immediately address the issues covered above: no bar code symbol present, poor quality bar code symbols, placement of the bar code symbol, more than one bar code symbol, non-standard bar code symbol, bar code symbology, etc.⁵



3 GS1 Reference Books <http://www.gs1.org/healthcare/library#publications>

4 GS1 Members Vision for Traceability in Healthcare <http://www.gs1.org/traceability-healthcare>

5 http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

Mobile Authentication Services (MAS) in healthcare (2013)

Purpose

This document acknowledges that the use of Mobile Authentication Services (MAS) solutions has been seen in some countries as a good first step in providing patients with the means to verify the authenticity of the medicinal products they have received.

It also explains that the strength and robustness of these solutions has not been demonstrated and consequently proposes alternative solutions such as the adoption of global standards.

Background

The LMICs have been widely reported to be a major source or recipient of falsified pharmaceuticals. Numbers of solution providers have therefore developed proprietary SMS solutions that have been adopted by a few pharmaceutical manufacturers and wholesalers, almost exclusively for those products destined for Low-medium income countries (LMIC).

But while these solutions may be suitable for specific drugs in specific countries, they are not scalable on the broader, regional or even global level as they are often proprietary and not standards-based.

Recommendation

This document concludes that it may be ill-advised for regulators to mandate the use of SMS technology for product verification purposes without a strict regulatory framework, which would ensure that in determined cases such a solution could be implemented to prevent product falsification.

It encourages regulators to support global standards as a tool to fight product falsification, and look at future-proofed concepts.

Discussion paper

In the last 20 years there has been a significant growth of mobile communication devices, such as mobile/cell phones, tablet computers and personal digital assistants (PDAs); for 'smart' mobile/cell phones in particular there has been exponential and continually expanding development and availability of usually free and downloadable applications or 'Apps'.

An emerging healthcare application involves the use of **Mobile Authentication Services (MAS)** to verify information found on pharmaceutical product packaging with data held in a database. Specifically, a manufacturer may apply a number onto a product's package (e.g. a blister card, a tube, etc.) which the patient/consumer can send to a designated mobile short message services (SMS) number (also printed on the primary package) (Figure 1) and an SMS message is returned confirming if the number associated with that product is verified, or not.



Figure 1

Use of SMS solutions in healthcare and their potential benefits to increase patient safety can be viewed as promising. A number of solution providers have developed proprietary SMS solutions that have been adopted by a few pharmaceutical manufacturers and wholesalers, almost exclusively for those products destined for Low-medium income countries (LMIC)¹. The LMICs have been widely reported to be a major source or recipient of falsified pharmaceuticals.

¹ World Health Organisation (WHO) terminology

Reducing and/or detecting falsified medicines are therefore a key driver for deployment and use of MAS solutions. But while these solutions may be suitable for specific drugs in specific countries, they are not scalable on the broader, regional or even global level as they are often proprietary and not standards-based.

In general, for pharmaceutical manufacturers, SMS solutions represent one of several possible technologies that can strengthen the likelihood that only genuine products will reach patients. And, given the technological framework in LMICs is often less mature, the use of MAS solutions has been seen in some of these countries as a good first step in providing patients/consumers with the means to verify the medicinal products they have received.

However, based on limited adoption to date of SMS applications in healthcare, the strength and robustness of these solutions have not been demonstrated. Consequently, it may be ill-advised for any regulator or government to mandate the use of SMS technology for product verification purposes without a strict regulatory framework, which would ensure that in determined cases such a solution could be implemented to prevent product falsification.

In addition, on a practical level, manufacturers and others remain technically challenged with applying these codes to the various types of primary or secondary packaging and an appropriate and sufficient print quality of the number applied to the packaging is critical to ensure the consumer can accurately read and send the correct number to the SMS service.

Also, with SMS solutions, as opposed to using a smart phone app to scan a bar code, the opportunity for human data entry error is high, even with legible numbers. The image in Figure 1 shows how difficult it can be to read the number on a blister pack due to creasing or wear, increasing the likelihood that an incorrect number is entered, e.g. a 3 instead of an 8 or a 5 instead of a 6; resulting in an invalid number being sent and not receiving an SMS response, receiving a response for a valid number on a different product or a response indicating that the number cannot be verified, which may indicate the product is counterfeit when it isn't.

Concerns with defeating SMS Solutions

A regulation or mandate that requires adoption of a single, proprietary solution could be significantly compromised when the technology is defeated, successfully copied or mimicked by a falsifier. When this occurs, as is common with brand protection technologies, the regulation or mandate intended to secure the supply chain becomes the means by which falsifiers can proliferate their fraud and endanger patients' lives; manufacturers utilize a range of technological solutions as it is unlikely that a single technological solution would be successful in fighting counterfeiting.

Importantly, the responsibility for confirming a product is genuine or not, should not be solely with the patient and not based entirely on verification of a number. Responsibility for ensuring the integrity of the product and supply chain rests with all supply chain stakeholders. Solutions, in which the first patient to verify a valid number receives a message, e.g. 'this is a genuine product', particularly in the situation where the number has been copied and the product is falsified, give the patient a false sense of security. In reality, in some cases of suspected falsification, the only practical solution is to return the suspect product to the manufacturer to determine its authenticity based on forensic testing.

Regulations – Falsified medicinal product

The issue of falsified pharmaceuticals is one important driver of regulations in force or emerging from around the world, predominantly led by developed countries. These regulators are introducing various tools in order to prevent falsified pharmaceuticals from entering the supply chain and reaching patients/consumers.

To this end, in 2010 the US FDA released a 'Guidance for Industry' intended to provide a common and comprehensive framework on the development of package-level standardized numerical identifiers (SNIs) for prescription drugs². In this Guidance, the FDA is explicitly referring to GS1 Standards; the use of Global

² <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm>

The European Union (EU) defines 'Falsified medicinal product' as

"Any medicinal product with a false representation of:

- a) *its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;*
- b) *its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or*
- c) *its history, including the records and documents relating to the distribution channels used.*

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."

Trade Item Numbers (GTINs) for the product identification, as a measure to secure the drug supply chain and to guarantee international interoperability. Due to the wide variety of packaging, the FDA is leaving options open for encoding the SNIs into machine-readable forms of data carriers but is proposing the use of 2D bar codes and radio-frequency identification (RFID).

More recently, the European Union's Directive on falsified medicines has been adopted³. In order to fight against falsified medicines, the European regulator is requiring safety features, which are defined further as a unique identifier and anti-tampering solutions on the medicines packaging. The European Commission is currently working on drafting the detailed rules for the implementation of this Directive and is considering the use of linear bar codes, 2D bar codes and RFID tags as possible data carriers.

³ http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm

The need for a comprehensive/ holistic approach

Requirements for a protection system are only effective if they are part of a larger system that assists in identifying falsified products. Brand Owners, World Customs, GS1, etc., have international experience in different protection technologies and are willing to support the development of new requirements to improve their effectiveness. However, single proprietary solutions, defined by solution providers, may lead to uncompetitive markets, strong dependencies, reduced supply chain efficiency and hinder the cross border movement of product and information.

Global standards

There is some variability in the emerging regulations regarding serialisation, in terms of serialised identification, unique identifiers, linear and 2D data-carriers and data registries, but ultimately the aim is, to ensure patient safety, increase efficiency across healthcare supply chains, protect manufacturer's brands, and eventually to establish full end-to-end traceability⁴ of these products from finished goods to the patient.

A common and recurring theme in these regulations is for compliant systems and processes to be based on global standards, increasingly the GS1 system of standards. This approach is supported by a recent white paper by McKinsey & Company: "Strength in Unity: The promise of global standards in Healthcare"⁵.

The McKinsey report concludes: "...Our research also suggests that these benefits would be put at risk if the industry continues to try to manage the complexity of multiple standards rather than aligning around one. Global healthcare leaders have a window of opportunity now to work together to align around a single set of global standards and to collaborate to drive adoption of the practices

⁴ Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration (taken from GS1 Global Traceability Standard for Healthcare (GTS) http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf)

⁵ http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

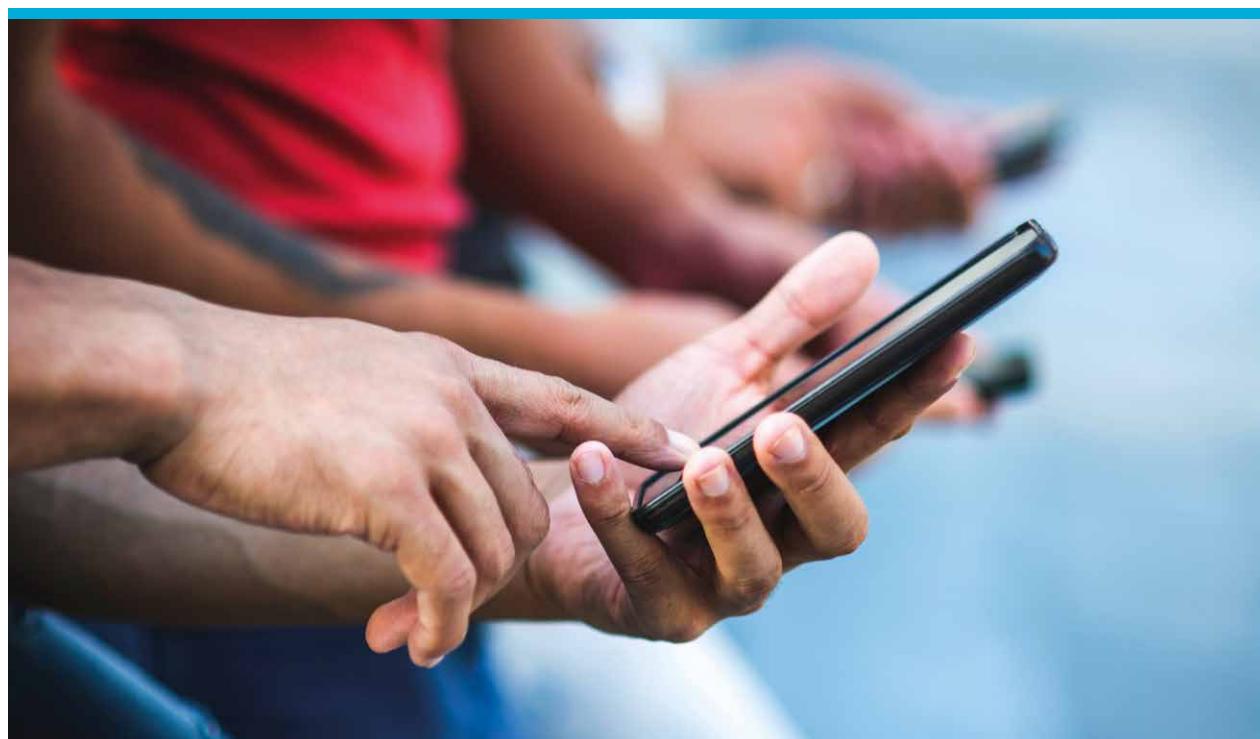
enabled by these standards..." However, today there continues to be divergence from this; in this context, the emerging MAS solutions are proprietary to the solution provider; as the number of proprietary solutions grow so does the complexity and cost for the pharmaceutical manufacturers if they are required to adopt different solutions for different markets.

Due to regulations, like those in Turkey, Korea, France, Japan, US and Europe, manufacturers globally are adopting and implementing GS1 Standards, in particular the Global Trade Item Number (GTIN) as the product identifier. And, increasingly the need to capture related data attributes (e.g. Expiry Date, Lot/Batch Number, Serial Number) is driving the adoption of a 2D bar code: GS1 Data Matrix, which also has the advantage of requiring less space on a label compared to the usual linear bar code. While there can be significant costs associated with implementations, these would be even higher if these companies had to implement regulations advocating local and/or proprietary solutions for the numerous markets that they trade with across the globe.

Conclusion / Recommendations - regulators

GS1 Healthcare recommends that a holistic 'proof of concept' should be developed and published, in regards to the use of SMS technology, which addresses the issues surrounding falsified medicines. This work should involve industry stakeholders from all healthcare sectors and take into consideration the technical capabilities and infrastructure in a given market. For example, there may be widespread use of mobile/cell phones in a particular region but not 'smart phones' and there may be a high prevalence of medicines falsification. Implementing a 'point of dispense' authentication model or a track-and-trace system, including consumer verification, may not be an achievable solution in these markets; effective and practical alternatives are needed to enhance patient safety.

GS1 Healthcare also recommends regulators refrain from specifically mandating the proprietary solutions within their domains and that further study on the effectiveness and relevant strengths and weaknesses of these solutions be conducted. In addition, GS1 Healthcare encourages regulators to support global standards as a tool to fight product falsification, and look at future-proofed concepts.



Facilitating the implementation of the EU Falsified Medicines Directive with GS1 standards (2014)

Purpose

This document aims at presenting the current status of Implementation of GS1 Standards for pharmaceutical traceability in the EU as well as the different options leading to a harmonised implementation of the EU Falsified Medicines Directive (FMD) using global standards and moving away from national coding systems.

Background

There is currently a need for national numbers for specific purposes in some countries. However, there is also a need for a harmonised approach to be developed across Europe, using global standards to efficiently address the issues surrounding falsified medicines and to enable cross-border traceability.

As the pharmaceutical industry becomes more global, managing the labelling and packaging in as many as 28 countries in Europe becomes more and more challenging for manufacturers. In order to facilitate the development of a harmonized system for pharmaceuticals identification, GS1 has created a standard allowing national numbers to be utilized within the GS1 Standards. Including the national number in an Application Identifier allows holding a GTIN and national number in the same bar code so that both can be captured with a single scan.

Recommendation

The overview of the implementation of GS1 Standards provided in this Discussion Paper emphasises that the large majority of EU Member States are using GS1 GTIN or GS1 NTIN today, and are therefore able to implement the requirements of the FMD within a short time frame when the database to hold the information on the safety feature is prepared. Utilising a GS1 GTIN in all the EU countries would enable increased patient safety levels and improved supply chain efficiency.

Discussion paper

The EU has a strong legal framework for the licensing, manufacturing and distribution of medicines. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including the legitimate sale via the internet.

In July 2011, the EU strengthened the protection of patients by adopting a new Directive on falsified medicines (FMD)¹.

The ultimate goal of this Directive is to prevent falsified medicines entering the legal supply chain and reaching patients. It introduces harmonised safety features and strengthens control measures across Europe.

In particular, the FMD is including requirements that medicinal products subject to prescription shall bear safety features. A mandatory authenticity feature will be printed on or attached to the outer packaging of the medicines.

While the modalities are still to be defined, the assumption is that this feature will be entered or checked into a database by the manufacturer, and checked out when dispensed by a pharmacy. The Delegated Acts will provide more detailed requirements on this capability when they are published during 2014. The requirements will have to be implemented by healthcare supply chain actors in the EU Member States by 2017².

¹ [http://eur-lex.europa.eu/LexUriServ/LexUriServ.
do?uri=OJ:L:2011:174:0074:0087:en:pdf](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:en:pdf)

² Apart from MS with existing measures (BE, GR, IT), for which the deadline will be 2023

**The European Union (EU) defines
'Falsified medicinal product' as**

"Any medicinal product with a false representation of:

- a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;*
- b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or*
- c) its history, including the records and documents relating to the distribution channels used.*

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."



GS1 traceability standards in healthcare

GS1 Traceability Standards provide a complete set of standards for implementing traceability to enable full actionable visibility of pharmaceuticals and medical devices from point-of-production to point-of-sale, point of dispense or point-of-care and to ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.

GS1 Standards are ISO-compliant³ and likewise ISO standards are a mainstay of the references within GS1 documents.

As background, the GS1 Global Trade Item Number (GTIN) is the foundation of the GS1 System (formerly EAN/UCC System). The GS1 GTIN encoded in a GS1 Data Matrix together with an Expiry Date, a Lot/Batch Number and a Serial Number, provides the basis for unambiguous identification of pharmaceutical products globally and enables traceability at pack level.

In some countries due to history, national numbers (such as national reimbursement numbers) have been embedded into the structure of a GS1 GTIN which then became a GS1 National Trade Identification Number (NTIN). As NTIN's are allocated from the GTIN number pool they can be used by any market which uses GTINs but only one will be able to utilise the embedded national number. The GS1 NTIN can also be encoded in a GS1 Data Matrix with an expiry date, a lot/batch number and a serial number.

³ http://www.gs1.org/docs/gs1_iso_brochure.pdf

Implementation of GS1 standards for pharmaceutical traceability in the EU

EU Member State	GS1 Standards		National	Note
	GTIN	NTIN		
Austria		✓		
Belgium			✓	Could move to using GS1 Standards through one of the methods described later in this paper
Bulgaria	✓			
Croatia	✓			
Cyprus	✓			
Czech Republic	✓			
Denmark	✓	✓		GTIN is the preferred option but NTIN are accepted
Estonia	✓			
Finland	✓	✓		GTIN is the preferred option but NTIN are accepted
France		✓		
Greece		✓		
Germany		✓	✓	GS1 NTIN is in place for Germany and would allow the PZN to be captured in a GS1 Data Matrix
Hungary	✓			
Ireland	✓			
Italy			✓	Could move to using GS1 Standards through one of the methods described later in this paper
Latvia	✓			
Lithuania	✓			
Luxembourg	✓	✓	✓	Belgium national number is also used in Luxembourg
Malta	✓			
Netherlands	✓			
Poland	✓	✓		
Portugal			✓	Could move to using GS1 Standards through one of the methods described later in this paper
Romania	✓			
Slovakia	✓			
Slovenia		✓		
Spain		✓		
Sweden	✓	✓		GTIN is the preferred option but NTIN are accepted
United Kingdom	✓			

Conclusion

There is currently a need for national numbers for specific purposes in some countries. However, there is also a need for a harmonised approach to be developed across Europe, using global standards to efficiently address the issues surrounding falsified medicines and to enable cross-border traceability. To place both these on the pack would require two separate bar codes, one for the national number and the other for the GTIN; this is confusing and, error prone, it requires large amount of space on packs.

As the pharmaceutical industry becomes more global, managing the labelling and packaging in as many as 28 countries in Europe becomes more and more challenging for manufacturers. Utilising a GS1 GTIN in the different EU countries would make it possible to supply multi-country packages.

In addition, the overview of the implementation of GS1 Standards provided in this Discussion Paper emphasises that the large majority of EU Member States are using GS1 GTIN or GS1 NTIN today, and are therefore able to implement the requirements of the FMD within a short time frame when the database to hold the information on the safety feature is prepared.

In order to facilitate the development of a harmonized system for pharmaceuticals identification, GS1 has created a standard allowing national numbers to be utilised within the GS1 Standards. Including the national number in an Application Identifier allows holding a GTIN and national number in the same bar code so that both can be captured with a single scan.

The following list of options has been developed with the Healthcare sector in order to move from the use of national number in a particular country toward the use of global identification numbers⁴ :

GTINs (Global Trade Item Number) for supply chain and reimbursement purposes (Option 1). This is the most effective way to ensure traceability beyond the countries.



In case of an existing system of NHRNs (National Health Reimbursement Numbers), GTINs can be cross-referenced to the NHRN in a database (Option 2).

GTIN and NHRN can also both be encoded in one bar code (Option 3), but that is less optimal than the first and second option as it requires larger bar codes and adds complexity for cross-border trade and interoperability. This is recommended as a migration path to Options 1 or 2 and would require the creation of an NHRN application identifier for the specific national number (following a GS1 established process).

The NHRN can also be embedded in the GTIN, creating a NTIN (National Trade Item Number) (Option 4), but this is sub-optimal as by definition, it prohibits reciprocity of packaging because the country using them typically does not permit GTINs or NTINs from other countries, so traceability across borders is more difficult and multi-country packaging more restricted.

⁴ For more information : http://www.gs1.org/docs/healthcare/20100819_GTIN-NTIN-NHRN_Option_Evaluation.pdf

Use of GS1 Data Matrix in healthcare and a comparison to GS1 QR Code (2014)

Purpose

The purpose of this paper is to facilitate discussions on the similarities and differences between GS1 Data Matrix and GS1 QR Code data carriers, their use in “business to consumer” (B2C) applications, and the Global GS1 Healthcare preference for the use of GS1 Data Matrix in the healthcare sector.

Background

While regulatory bodies drive the implementation of GS1 Data Matrix for the fight against counterfeit healthcare products and for better control of the supply chain, QR code is primarily found on packages as a link to marketing information about a product. Applying two or more bar code symbols on the same package or label is not recommended by GS1 Healthcare and its community.

Recommendation

GS1 Community strongly supports the implementation and use of GS1 Data Matrix as the only recommended data carrier. As per GS1 Standards, GS1 Data Matrix is the only permitted GS1 2D matrix bar code carrier for the healthcare sector.

To help bring awareness of the positive effects with the use of GS1 Data Matrix as the only 2D data carrier for the healthcare supply chain, GS1 Healthcare encourages any new investments and education in the areas of printing and scanning using GS1 Data Matrix for mobile apps.

Discussion paper

Regulatory requirements – GS1 Data Matrix as a preferred option

The unique identification of medicinal products is a key objective of regulations around the world. More and more regulators are requiring the use of unique identifiers to be encoded into machine-readable forms (also called data carriers). Increasingly, regulators are recommending or requiring GS1 Data Matrix as that data carrier.

For example, GS1 Data Matrix was widely used on the secondary packaging in successful drug traceability pilots in Austria, Brazil, Colombia, Serbia, Switzerland and the United States (U.S.), and on primary packaging in Belgium. Its use on pharmaceutical products is already specified by regulators in Argentina, France, India, Jordan, Korea, Saudi Arabia, Turkey, Ukraine and the U.S. It is also recommended for use on vaccines in Canada.

Healthcare industry practices – the drive for one bar code symbol: GS1 Data Matrix

While regulatory bodies drive the implementation of GS1 Data Matrix for the fight against counterfeit healthcare products and for better control of the supply chain, QR code is primarily found on packages as a link to marketing information about a product. Applying two or more bar code symbols on the same package or label is not recommended by GS1 Healthcare and its community.

Multiple bar code symbols on a single item can lead to potentially dangerous confusion for the user. Likewise, it can lead to scanning and reading performance issues as the caregiver/pharmacist might find it difficult to identify which bar code should be or has been scanned or read. The GS1 Healthcare Provider Advisory

Council (HPAC) developed a position paper highlighting issues with bar codes symbols, which are hindering the implementation process in hospitals.¹

In addition, using multiple symbols takes up valuable package and label space, which could lead to quality issues or other practical manufacturing inefficiencies. When a packaging line must print the bar code and variable information dynamically and in multiple places on an item, two or more printing systems and verification systems may have to be installed and maintained. This leads to more equipment, more costs and more risk of errors.

Although the application of dynamic information in bar code symbols is relatively new to healthcare applications, Data Matrix was developed and in use in global industrial applications before QR code. GS1 Data Matrix already has an installed base and background knowledge for use in these types of packaging applications. GS1 Data Matrix is widely used in the healthcare sector, based upon the “industrial” practices in other sectors.

However, consumers are not informed on the benefits of this two-dimensional (2D) bar code and often cannot distinguish it from QR code. The creation and scanning of GS1 Data Matrix have been improved and optimised to better meet the needs of the supply chain, and to enable consumers to easily scan one with a smart phone.

In light of this, it is important to acknowledge all the work accomplished over the past years by the industry to maintain the Data Matrix and improve its printing quality, given that all these efforts can also be applied to the B2C needs. If the industry moved to QR code in place of Data Matrix, all the previous achievements would be wasted and little value realised as QR code does not bring any added benefits.

Data Matrix and QR Code: similar technical capabilities

In comparing the data carriers ISO/IEC Data Matrix (known in the GS1 System as GS1 Data Matrix) and ISO/IEC QR code (known in the GS1 System as GS1 QR Code) from a technical point of view (e.g. amount of data to be encoded, high-level technical capabilities of 2D bar codes, error prevention and detection), there is no significant practical advantage to use one versus the other. Both data carriers are 2D bar code symbologies that can encode large amounts of data in small areas and employ “error detection” and “error correction”. Potentially the only unique benefit in the use of QR code over Data Matrix is a higher efficiency when encoding (Japanese) Kanji characters. However, given that today’s international business language is English, the relevance of this technical advantage is minimal.

Over the last few years, there has been a significant growth of free and downloadable applications (referred to as ‘apps’) on smart phones and mobile communication devices that allow the consumer to remotely access information about a particular item or product. Both GS1 Data Matrix and GS1 QR Code can facilitate connectivity to product information with these types of apps. Previously, B2C apps were limited to scanning QR codes. Nowadays, new apps are developed which can scan Data Matrix as well, giving greater user flexibility.

In the future, through GS1’s increased collaboration with the Open Mobile Alliance (OMA), apps will be able to access product information via the GS1 Global Trade Item Number (GTIN), a trusted URL through the generic bar code symbologies noted, and the 2D bar code carrier (i.e. GS1 Data Matrix, GS1 QR Code). This will enable additional information in the GS1 Application Identifiers (Al)s associated with the GTIN and encoded in the data carrier. For example, when scanning a GS1 Data Matrix on a pharmaceutical packaging, the user will be able to identify the GTIN of the trade item and any relevant encoded Als, such as Expiration Date, Lot/Batch Number and/or Serial Number. It could potentially provide access to the product’s Electronic Information for Use (EIFU), patient leaflet, or maybe even to an instructional online video.

¹ http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf

GS1 Healthcare current activities on GS1 Data Matrix and apps

- GS1 works on enabling smart phones to read both GS1 Data Matrix and GS1 QR Code bar code symbols
- GS1 has developed a healthcare demo app to demonstrate the B2C capabilities of GS1 Data Matrix



QR Code

Recommendations and conclusions

Considering all the aspects of this discussion, GS1 Healthcare and its global members continue to strongly support the implementation and use of GS1 Data Matrix as the only recommended data carrier. As per GS1 Standards, GS1 Data Matrix is the only permitted GS1 2D matrix bar code carrier for the healthcare sector.

To help bring awareness of the positive effects with the use of GS1 Data Matrix as the only 2D data carrier for the healthcare supply chain, GS1 Healthcare encourages any new investments and education in the areas of printing and scanning using GS1 Data Matrix for mobile apps.



Data Matrix

Multi-market packs for pharmaceutical products (2014)

Purpose

This paper has been written to help demonstrate ways in which GS1 bar codes can be used to minimise the need for multiple bar codes to appear on product packaging while still enabling products to be supplied to multiple countries. This can be more challenging where a country has a requirement to identify a trade item using the GS1 Global Trade Item Number (GTIN) and also requires national/country specific data to facilitate other processes such as reimbursement.

Background

Pharmaceutical product packs are increasingly carrying more data within a bar code to facilitate safer and more efficient use. The actual design of a pack will be influenced by regulatory, legal, commercial and technical requirements/ constraints.

The situation is further complicated as countries have differing regulatory and data requirements and furthermore products can be supplied to more than one country using the same packaging. The use of packs supplied to multiple countries (multi-market packs) exist to ensure the availability of products and optimisation of the supply chain.

Recommendation

This paper is not intended to provide guidance on which countries can take a common product pack, however it does give examples that can be followed and will maximise the opportunities to share common packs based on the data held within the bar code, therefore limiting the need to apply multiple bar codes.

The examples focus on using the GTIN as the primary identifier of a trade item and how this can be used either alone or in combination with an additional field for the National Healthcare Reimbursement Number (NHRN) data field in various combinations to satisfy the needs of multiple countries.

The example also demonstrate the flexibility of the GS1 Standards in being able to encode multiple data items in the same GS1 Data Matrix in order to fulfil the needs of users in many countries.

Discussion paper

This paper is not intended to provide guidance on which countries can take a common product pack, however it does give examples that can be followed and will maximise the opportunities to share common packs based on the data held within the bar code, therefore limiting the need to apply multiple bar codes.

There are some limitations to be aware of in the context of this paper. When bar codes are encoded with variable data relating to production batches or even between individual packs, the bar code cannot be included in the packaging artwork but instead has to be applied as part of the production and packaging processes. There are many technologies available to apply bar codes to packaging, each with different technical capabilities. Some technologies may not have the capability of applying bar codes at the size, quality, or speed required or perhaps be able to handle the data required. While it may not be possible for all manufacturers to achieve the desired outcomes described in the examples provided below, due to individual capabilities, technical constraints have been considered when providing examples. The authors have been careful not to provide examples that are technically impossible to accomplish or impractical.

This paper does not suggest that packs have to be used in multiple countries; this is down to manufacturers to determine. The examples in this paper focus on the two following Application Identifier (AI) data fields:

- Global Trade Item Number (GTIN)
- National Healthcare Reimbursement Number (NHRN)

The paper does not provide for other identifiers that may also be required by regulators, legislators and business practice such as expiry (use by) date, lot/batch number and/or serial number.

This paper is not intended to be prescriptive regarding which countries should or should not take a multi-market pack and addresses the issue from the perspective of the GS1 Data Matrix bar code symbology² and the data encoded in it. There may be other reasons why two or more countries are unable to share a common pack, many of these are in addition to the issues covered in the scope of this paper, and should be considered separately.

The examples provided are all based on the use of the GS1 Data Matrix bar code and not a one dimensional linear bar code. The GS1 Data Matrix bar code is endorsed as the preferred data carrier for use in global Healthcare given the ubiquity of use worldwide, the enhanced data encoding and the benefits provided by the smaller bar code size.

The principles outlined in this paper can be applied to any situation where a pharmaceutical pack is used in more than one country, and is not intended to apply to any specific country or group of countries.

Note: Regulatory requirements may prohibit the implementation of examples given in this paper.

The ability to implement a given example may also be limited by the technology being used to apply and manage the application of bar codes or by physical constraints such as pack size or configuration. This paper does not attempt to explain how the examples are technically achieved, e.g. which GS1 Data Matrix module size to use, printing technology, etc.

In addition to regulatory, legal or technical constraints that may limit the ability to use a multi-market pack there is another important factor to take into account; consideration should be given to the way in which a computer system collects and processes the data captured from the GS1 Data Matrix bar code when assessing if a multi-market pack can be

used. The data encoded in the GS1 Data Matrix bar code is defined using Application Identifiers (AI's) e.g. (01) for GTIN, (10) for batch, etc. As such, computer systems should be able to determine what data is required and what data can be ignored in a data string. If computer systems are not configured to function in this manner it may prevent a GS1 Data Matrix bar code being used that contains unexpected data fields.

Background

Pharmaceutical product packs are increasingly carrying more data within a bar code to facilitate safer and more efficient use. These bar codes can hold national specific data as well as data that is variable in nature, data that changes from batch to batch or even between individual packs within a batch. There are many factors driving the demand for more data to be held in a machine readable format such as: the need to unambiguously identify the product, the need for electronic capture of product identification, batch and expiry information in medical records, unique product authentication to help address counterfeit and falsified products, the management of product reimbursement and linking patients and users of the product to electronic off pack/label sources of information.

The situation is further complicated as countries have differing regulatory and data requirements and furthermore products can be supplied to more than one country using the same packaging. The use of packs supplied to multiple countries (multi-market packs) exist to ensure the availability of products and optimisation of the supply chain. There are many situations where supply can be more challenging, especially in situations where: (1) products have relatively low volumes, e.g. the product is used as part of a specific regime, the disease is rare or patients are a small population and (2) demand is highly variable such as in a pandemic. Multi-market packs have to meet the requirements of all the countries in which they are supplied, not only in terms of language requirements and regulated indications but also the types of bar code symbologies and data encoded.

The increased demand for national specific product data, variable production data held in bar codes and products being used in multiple

² Some countries do not currently use a GS1 Data Matrix bar code as their current requirements are met through the use of a linear bar code. These countries fall outside the scope of this paper.

countries, has resulted, in some circumstances, to products having to display more than one bar code on the packaging to fulfil all the localised requirements. While it may be possible to apply more than one bar code to a pack, it is not recommended as this often leads to issues including:

- Confusion from users over which bar code to scan for what purpose
- Slower processing of the product during handling, dispensing and use
- Accidental scanning of the wrong bar code due to the close proximity of the bar codes
- Scanning the wrong bar code for the required purpose
- Lack of space on the packaging to apply all the required content, compromising other elements of the pack design

These issues can cause resistance to the use of bar codes, slowing down the level of adoption, increasing risk of error and foregoing the desired benefits of enhanced supply chain efficiencies and improved patient safety outcomes. In October 2012 Healthcare Providers working with GS1 Healthcare published the Position Paper “Implementation in hospitals hindered by bar code symbol issues”³ which captures these issues and requests industry to address them.

A single bar code on a product pack that contains all the data required by users is the ideal solution. GS1 global standards provide the functional capability for more than one country to share a pack using the same bar code; this has been the situation in the global retail sector for many years. This environment can also be achieved in global Healthcare, due to the way the standards have been designed be the user community.

Scenarios and examples

Single country pack

We will consider a very simple scenario, before covering more complex multi-market examples. Assume a country only requires a GTIN to support all local Healthcare processes (logistics, reimbursement, etc.) and the pack is only supplied to a single country, then the GS1 Data Matrix only needs to hold a GTIN.



Figure 1.0

A single pack with a GTIN (09504000059101) encoded in the GS1 Data Matrix

The pack is only supplied to a single country (represented by the blue country circle).

The examples using the following colour coding:

Countries using GTIN shown in blue

Countries also using NHRN shown in purple

Countries using an NTIN are shown in green.

Multi-market pack

The multi-market pack examples that follow illustrate situations where up to four countries share the same pack. This does not mean that the number of countries using a pack is limited to four; it could be more or less than four and is limited only by the factors outlined above (e.g. technical, regulatory, etc.).



Figure 1.1

Multi-country use of same pack

³ http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf

Expanding on the first example, it is possible that many countries, using GTIN as the primary identifier could also take the pack outlined in Figure 1.0 (assuming that all regulatory and legal requirements are met).

In this example four countries use the same pack and scan the same GTIN.

In some countries the registration and/or reimbursement of products is controlled through a proprietary number, an NHRN as mentioned previously, issued and managed by the national authority or an issuing organisation. Countries that have such numbers often require them to appear on the packaging and may also require them to be held in a bar code. It is GS1's recommendation that the GTIN is held within the GS1 Data Matrix and the NHRN is cross-referenced within a database, however where this is not possible the GTIN and NHRN can be encoded within the GS1 Data Matrix bar code. Data processing protocols within a specific country will either use the GTIN or the NHRN as appropriate.



Figure 2.0

GTIN and NHRN on same pack.

This figure highlights that the NHRN must always appear in addition to the GTIN. In this situation the GS1 Data Matrix bar code will contain both Application Identifier data fields.



Figure 2.1

GTIN and NHRN on same pack.

As a pack with an NHRN in the GS1 Data Matrix will also hold a GTIN, it is possible for other countries to also take this pack using the GTIN and ignoring the NHRN data when processing the data.¹⁸

The NHRN Application Identifier is issued to an entity, e.g. country or jurisdiction, through a defined application and assessment process involving the local GS1 Member Organisation, each country/ jurisdiction is therefore allocated, when deemed necessary, their own specific NHRN AI.



Figure 2.2

Several countries using their own NHRN can share the same pack

As each country/ jurisdiction would have its own NHRN, more than one NHRN can be encoded into a single GS1 Data Matrix using different Application Identifiers, as illustrated in Figure 2.2. Other countries which only require a GTIN can also take this pack.

4 Whilst a GTIN may be allocated by a particular GS1 Member Organisation (MO) e.g. GS1 UK, the GTIN is global and can be used in all GTIN countries. The country, in which the GTIN is used, does not have to be the same as the country in which the GTIN was issued. Due to the global nature of supply chains, a pack's GTINs is frequently used in several countries on route to its final destination.

Despite the GS1 Standards permitting the use of more than one NHRN being encoded into a GS1 Data Matrix, it does increase the amount of data being encoded. Technical constraints and process efficiencies will need to be carefully considered as the volume of data in the GS1 Data Matrix bar code increases.

In some instances a country will have a national method of product identification (a proprietary number), but will use the GTIN Application Identifier data field to hold this number. When this occurs the identifier is known as a National Trade Item Number (NTIN) to distinguish it from a GTIN. An NTIN is only used where all other alternatives e.g. the use of an NHRN, have been discounted. In these circumstances the local GS1 Member Organisation will allocate a range of numbers from the GTIN number pool to the local organisation which manages the country/jurisdiction numbers.

The example in figure 3.0 illustrates a scenario in which a country requires an NTIN and takes a pack which is not shared with another country.



Figure 3.0
The National Trade Item Number (NTIN)



Figure 3.1
GTIN countries and an NTIN country sharing a single pack²
As an NTIN is allocated from the GTIN number pool and held in the (01) Application Identifier data field, it can be used by a GTIN market, allowing the use of the pack across one NTIN country and multiple GTIN countries.
A GS1 Data Matrix bar code must only contain a single (01) data field, therefore two or more NTIN countries cannot share a pack.¹⁹

The examples above provide a basic framework for describing how to construct a multi-market pack using a single GS1 Data Matrix bar code. The following table summarises the multi-market scenarios.

Pack illustration – example only

In reality, countries are likely to require additional data to be encoded into the GS1 Data Matrix bar code. The following diagram, Figure 4.0, illustrates how a pack might look and is based on the example shown in Figure 2.1. In this example the GS1 Data Matrix contains six data elements, i.e. GTIN, Expiry Date, Batch/ Lot Number, Serial Number, National Health Reimbursement Number (NHRN) and URL. Each country will make use of the data relevant to their local processes and requirements.

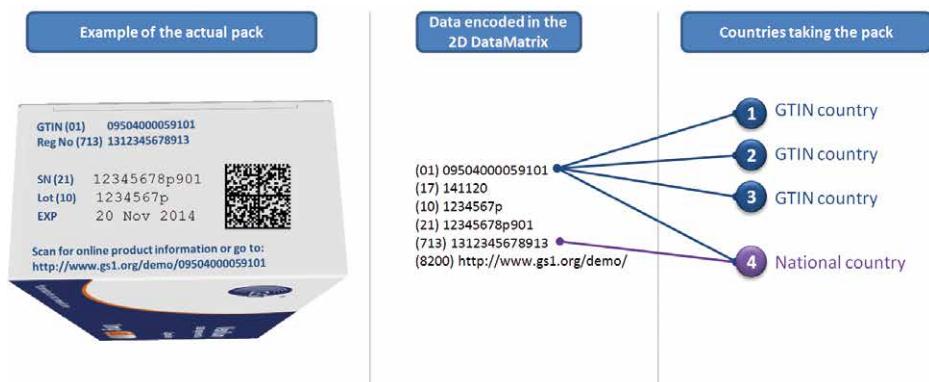
Note: The order that the data is shown on the product packaging and the order in which it is encoded in the GS1 Data Matrix bar code is not necessarily the same. The example in Figure 4.0 is not meant to imply an order in which to encode the data in the bar code, however encoding fixed length fields first followed by variable length fields is generally recommended as this minimises the size of the GS1 Data Matrix bar code.

The actual design of a pack will be influenced by regulatory, legal, commercial and technical requirements/ constraints. The above example is for illustrative purposes only and not prescriptive of what must appear on a multi-market pack. It does however demonstrate the flexibility of the GS1 Standards in being able to encode multiple data items in the same GS1 Data Matrix in order to fulfil the needs of users in many countries.⁵

⁵ As GTINs are granted to a responsible entity such as a manufacturer, part of the number identifies this company. As NTINs are not granted in this way it is not possible to directly identify which company is accountable for the product. This needs to be a factor in deciding if a GTIN country can take a pack with an NTIN encoded in the (01) Application Identifier.

Table 1.0 Possible pack scenarios

Figure number	Fields in GS1 Data Matrix		Market types which can take this pack		
	Primary key	Other fields	GTIN countries	NHRN 1 country	NHRN n country
1.0 & 1.1	(01) Containing a GTIN		→	GTIN countries	
2.0 & 2.1	(01) Containing a GTIN	NHRN 1	→	GTIN countries	NHRN 1 country
2.2	(01) Containing a GTIN	NHRN 1	→	GTIN countries	NHRN 1 country
3	(01) Containing a GTIN		→	NTIN country	
3.1	(01) Containing a GTIN		→	GTIN countries	NTIN country

**Figure 4.0**

Pack example - GTIN and NHRN on the same pack with additional data fields

Terminology

AI	Abbreviation for “Application Identifier”
Application Identifier	The field of two or more digits at the beginning of an Element String that uniquely defines its format and meaning
Global Trade Item Number (GTIN)	The GS1 Identification Key used to identify trade items. The key comprises a GS1 Company Prefix, an Item Reference and Check Digit
GS1 member organisations	A member of GS1 that is responsible for administering the GS1 System in its country (or assigned area). This task includes, but is not restricted to, ensuring brand owners make correct use of the GS1 System, have access to education, training, promotion and implementation support and have access to play an active role in GSMP
GTIN	Abbreviation for “Global Trade Item Number”
MO	Abbreviation for “GS1 Member Organisation”
Multi-market pack	A product which is designed to be supplied and used in more than one country
National Healthcare Reimbursement Number (NHRN)	National and/or regional identification numbers used on pharmaceutical and/or medical devices where required by national or regional regulatory organisations for product registration purposes and/or for the management of Healthcare provider reimbursement
National Trade Item Number (NTIN)	A coding scheme, administered in the Healthcare sector by a national organisation for which a GS1 Prefix has been issued to permit its uniqueness within the GTIN pool but without assurance of full compatibility with GTIN functionality. The result is a product identification number assigned by a third party (not the brand owner or manufacturer). Example: the CIP (Club Inter Pharmaceutique) in France administered by the French Health Products Safety Agency (AFSSAPS).
NHRN	Abbreviation for “National Healthcare Reimbursement Number”
NTIN	Abbreviation for “National Trade Item Number”

The information and views set out in the Public Policy Discussion Papers are those of the GS1 Healthcare members and do not necessarily reflect the sole opinion of GS1 AISBL. Neither GS1 nor any person acting on its behalf may be held responsible for the use which may be made of the information contained therein.

**For more information please visit:
www.gs1.org/healthcare/position-papers**

About GS1

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders, including manufacturers, distributors, healthcare providers' solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies. GS1 Healthcare members include over 60 leading Healthcare organisations worldwide.

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