GS1 Healthcare - Discussion paper on multi-market packs for pharmaceutical products

Purpose

This GS1 Healthcare 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.

The examples, outlined below, 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.

Note: There are many technical terms used within this paper, the definition of these terms can be found in the Glossary of the GS1 General Specifications and in a terminology table at the end of this paper.

Scope

This paper focuses on Healthcare and specifically pharmaceutical products.

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 DataMatrix bar code symbology[1]

[1] Some countries do not currently use a GS1 DataMatrix 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.

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 DataMatrix bar code and not a one dimensional linear bar code. The GS1 DataMatrix 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 DataMatrix 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 DataMatrix bar code when assessing if a multi-market pack can be used. The data encoded in the GS1 DataMatrix 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 DataMatrix 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.

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The increased demand for national specific product data, variable production data held in bar codes and products being used in multiple 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"[2] 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 DataMatrix only needs to hold a GTIN.

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**
Counties also using NHRN shown in **purple**
Countries using an NTIN are shown in **green**.

Figure 1.0
A single pack with a GTIN (09504000059101) encoded in the GS1 DataMatrix

[2] http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf

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.).

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.

Figure 1.1
Multi-country use of same pack

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 DataMatrix 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 DataMatrix bar code. Data processing protocols within a specific country will either use the GTIN or the NHRN as appropriate.

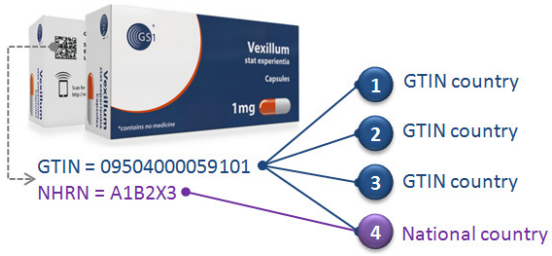
This figure highlights that the NHRN must always appear in addition to the GTIN. In this situation the GS1 DataMatrix bar code will contain both Application Identifier data fields.

Figure 2.0
GTIN and NHRN on same pack.

As a pack with an NHRN in the GS1 DataMatrix 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.[3]

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.

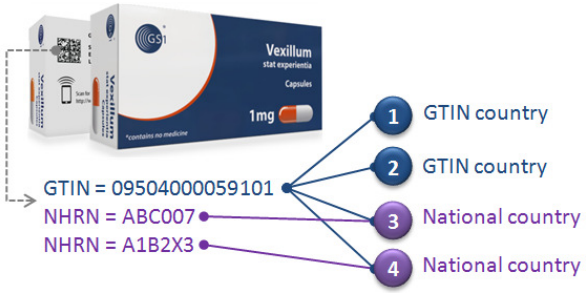
Figure 2.1
GTIN and NHRN on the same pack



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

Despite the GS1 standards permitting the use of more than one NHRN being encoded into a GS1 DataMatrix, 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 DataMatrix bar code increases.

Figure 2.2
Several countries using their own NHRN can share the same pack



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.

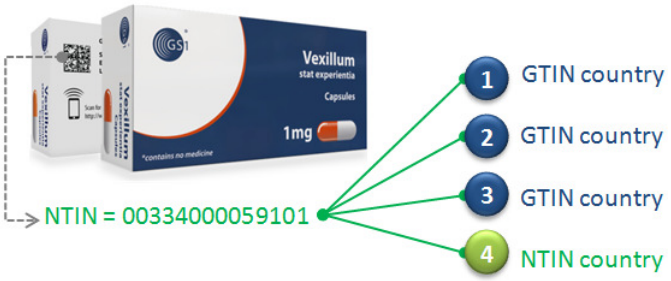
Figure 3.0
The National Trade Item Number (NTIN)

[3] 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.

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 DataMatrix bar code must only contain a single (01) data field, therefore two or more NTIN countries cannot share a pack.

Figure 3.1
GTIN countries and an NTIN country sharing a single pack[4]



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

Table 1.0
Possible pack scenarios

Figure number	Fields in GS1 DataMatrix			Market types which can take this pack		
	Primary key	Other fields				
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	NHRN n	GTIN countries	NHRN 1 country	NHRN n country
3	(01) Containing an NTIN			NTIN country		
3.1	(01) Containing an NTIN			GTIN countries	NTIN country	

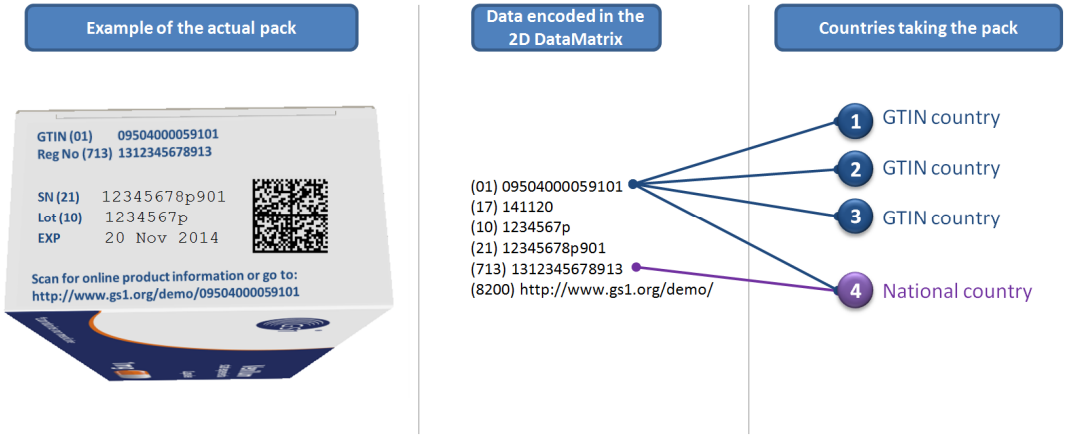
[4] As GTINs are granted to a responsible entity such as a manufacturer, part of the number identifies this company. As NTINs are not granted in this way it is not possible to directly identify which company is accountable for the product. This needs to be a factor in deciding if a GTIN country can take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

Pack illustration – example only

In reality, countries are likely to require additional data to be encoded into the GS1 DataMatrix 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 DataMatrix 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.

Figure 4.0

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



Note: The order that the data is shown on the product packaging and the order in which it is encoded in the GS1 DataMatrix 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 DataMatrix 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 DataMatrix in order to fulfil the needs of users in many countries.

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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 Organisation	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"

Reference and contacts

- Discussion Paper Product Identification in Healthcare — http://www.gs1.org/docs/healthcare/20100819_GTIN-NTIN-NHRN_Option_Evaluation.pdf
- Position Paper (II), Healthcare Provider Advisory Council, Implementation in hospitals hindered by bar code symbol issues — http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf
- GS1 General Specifications — http://www.gs1.org/genspecs

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About GS1 Healthcare

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. For more information about GS1 Healthcare, please visit www.gs1.org/healthcare.