



28th March 2007

**The Project Officer
Labelling and Requirements for Medicines
C/- Joint Agency Establishment Group
Therapeutic Goods Administration
P O Box 100
Woden ACT 2606
Australia**

Dear Lyn

On behalf of GS1 New Zealand and GS1 Australia, we are pleased to provide a submission for the Presentation of the ANZTPA Unique Identifier on Medicine Labels as outlined in your letter dated February 26th, 2007.

Unique identification can occur at many different levels of the supply chain, at the transport unit, at the item level, and elsewhere. Such distinct entities are often handled by several parties; the sender, the receiver, one or more carriers, customs authorities, etc. Each of these parties must be able to identify and trace the item so that reference can be made to associated information such as configuration, maintenance history, address, order number, contents of the item, weight, sender, batch or lot numbers, etc. The information is often held on computer systems, and may be exchanged between parties involved in EDI and XML messages.¹

There are considerable benefits if the identity of the item is represented in bar code format, or other AIDC (Automatic Identification and Data Capture) media and attached to or made a constituent part of that which is being uniquely identified so that errors are minimised through the use of machines and not manual processes; one identity is able to be used by all parties and is interoperable; the identifier is unique within the class and cannot appear on any other item in the class during the lifetime of the item.²

This submission focuses specifically on the internationally accepted and applied unique identifier standard referred to as International Standards Organisation's (ISO) **Standard ISO/IEC 15459 Information technology – Unique identifiers parts 1 – 4**, where:

- Part 1: Unique identifiers for transport units
- Part 2: Registration procedures
- Part 3: Common Rules for unique identifiers
- Part 4: Unique identifiers for supply chain management

¹ ISO/IEC 15459-3:2006(E) pp:iv

² Ibid

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Standard ISO/IEC 15459 makes specific reference to and outlines instances and applications of unique identification disciplines throughout globally integrated supply chains using the GS1 System of unique identifiers. In doing so, it is clear that the intention of the Standard is to recommend an integrated, interoperable architecture throughout all industry verticals as well as interconnected global supply chains. Implicitly, using this industry standard as the basis for a licensing regime is entirely appropriate and complies with accepted world best practice¹.

Benefits to ANZTPA in adopting ISO/IEC 15459:2006

ISO/IEC 15459 provides an open global framework for constructing unique identifiers to support a wide range of business applications in all industry sectors. In addition to the proposals put forward by MEDSAFE and the Australian Department of Health, an ISO/IEC 15459 compliant unique identifier (ie: GS1 identifier):

- provides a '**global solution**' to the healthcare requirement. Healthcare is by nature a global sector, with supply chains that often cross borders. In a cross border trading environment, global solutions greatly reduce cost of compliance and enhance business interoperability.
- is designed to be read using **automatic identification technologies** (eg: AIDC - barcoding symbologies, RFID), thus minimising errors through cumbersome and often inaccurate manual processes.
- provides a **globally recognised structure** that is both published and supported, via the ISO network which includes SNZ (Standards New Zealand) and SA (Standards Australia), on a global scale.
- provides a single identity that is **interoperable** and can therefore be used by all parties in the transaction; each party can use the identity to look up its computer files to find the data associated with the item; the identifier is guaranteed globally unique and cannot appear on any other item of the class during the lifetime of the item.
- provides a platform to encode additional data such as Batch Numbers, Expiration Dates, Serial Numbers, etc. in bar code form.

The common rules for unique identifiers for item management are defined in ISO/IEC 15459:2006 and this further recommends that the Issuing Agency provides application guidance to individual issuers of unique identifiers. This could take the form of check-digit algorithms, selection of GS1 Application Identifiers and minimum print quality, for example. By endorsing a global standard, The Australia New Zealand Therapeutic Products Authority can point medical suppliers to **detailed application guidance** such as those offered by GS1 New Zealand and GS1 Australia. Application guidance and support routinely provided includes education about implementation of the GS1 System of standards, management programmes for the allocation of numbers, helpdesk (telephone and email support), check-digit calculators and frequently asked questions.

A full list of approved Issuing Agents is published by the Dutch Standard Organisation, and includes GS1. This is available from <http://www2.nen.nl/getfile?docName=196579>. GS1 New Zealand and GS1 Australia are therefore fully accredited via their associate membership of GS1 Global Office.

¹ The Council of Europe has recently released a report on safe medication practices – refer appendix.

The GS1 System

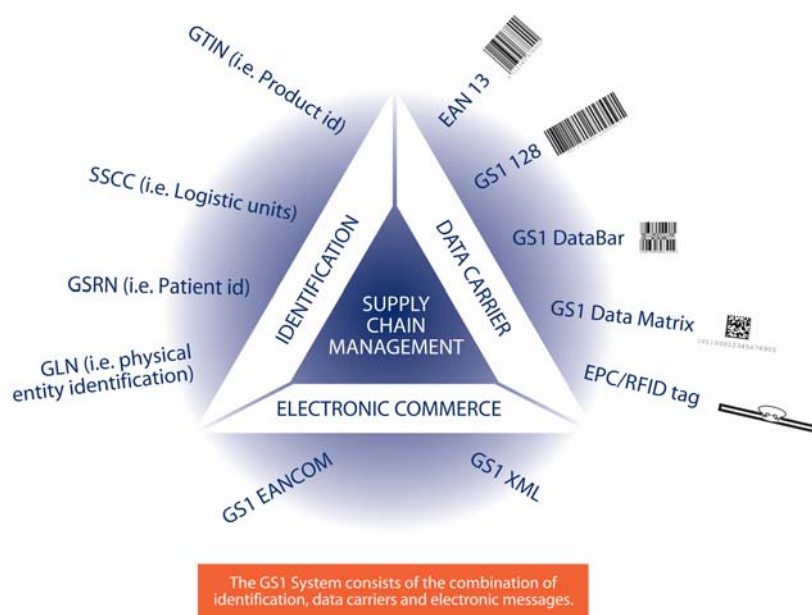
The GS1 (EAN•UCC) System is a set of open, non-proprietary standards enabling the efficient management of global, multi-industry supply chains. For healthcare, the system meets the requirements of all functions of the supply chain, from manufacturer to patient. The GS1 System is the most widely used set of identification standards throughout the world with over 1 million members in 104 countries generating billions of transactions daily.

The system consists of three distinct elements:

- A comprehensive set of **unique identifiers** (also known as Identification Keys) for products, shipping units, assets, locations, documents, people and services. Companies around the world use these unique identifiers in an unambiguous manner in demand & supply chains.
- A range of '**data carriers**' that symbolise these identifiers together with other information, such as batch number and expiry date (called 'Application Identifiers'). The most common sort of data carrier is a bar code but increasingly Radio Frequency Identification (RFID) tags will be used as data carriers. Different forms of bar codes are available for different applications - for very large items, such as a pallet, to very small items, such as a unit dose of a medicine. By scanning the bar code, information can be captured automatically and accurately. These data carriers are included in the GS1 BarCodes and GS1 EPCglobal categories below.
- A set of **electronic messages** for both master data e.g. product or price information, and transactional data – used for such transactions as orders; invoices and dispatch advice messages. These enable information to be communicated speedily and accurately between trading partners throughout the supply chain.

The GS1 System: Illustrated

The GS1 System can be illustrated as follows:



Through the application of standards – bar codes, unique identifiers, RFID tags, and electronic messages – all available within the GS1 System, the healthcare sector can:

- introduce more effective supply chain management and document referencing,
- implement systems for tracking and tracing products throughout the supply chain from manufacturer to patient, and
- use automatic data capture techniques; reduce errors from the supply chain making it more effective and more certain.

Products and Services – An Integrated System

The GS1 System is the foundation of a wide range of efficiency-building supply chain applications and solutions. Based on **GS1 Identification Keys**, a common recurring set of identification keys, the GS1 System is composed of four key product areas:



Global data and application standards for bar codes that use the globally recognised **GS1 Identification Keys** to automatically identify things such as trade items, locations, logistic units, and assets.



Global standards for electronic business messaging that allow rapid, efficient and accurate automatic electronic transmission of agreed business data between trading partners. Based on two components: GS1 EANCOM and **GS1 XML**.



The Global Data Synchronisation Network™ (GDSN™) is an automated, standards-based, global environment that enables secure and continuous data synchronisation, allowing all partners to have consistent item data in their systems at the same time. **Global Product Classification (GPC)** is a key component of GDSN , enabling effective category management.



A new global standards system that combines RFID (radio frequency identification) technology, existing communications network infrastructure and the Electronic Product Code (a number for uniquely identifying an item) to enable immediate and automatic identification and tracking of an item through the whole supply chain globally, resulting in improved efficiency and visibility of the supply chain.

GS1 also offers solutions integrating a number of GS1 products. **Traceability** is a robust solution for tracking and tracing items through the food supply chains. **Patient Safety** ensures prevention of medical errors and counterfeiting through the healthcare supply chain. **Conformance and Certification** is a programme to ensure integrity and equivalency of various certification and accreditation programmes for GS1 Bar codes and eCom messages worldwide.

GS1 Identifiers to ANZTPA

ISO/IEC 15459-4:2006 outlines a few examples of the numerous potential solutions within the GS1 suite of unique identifiers (Identification Keys), including the **global trade item number** - GTIN. When identifying items, this is the key that can be combined with GS1 application identifiers (AI's).

Definition of a GTIN

Global Trade Item Numbers (GTIN's) uniquely identify items that are traded (eg: Pharmaceuticals, Medical Devices, etc) in the supply chain. Integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other supply chain stakeholders. A change to one aspect, characteristic, variant or formulation of a trade item may mean this is considered a 'different' product/item and may therefore require the allocation of a new GTIN.

Brand owners who hold the specifications of a healthcare item must properly allocate and maintain their GTIN's to enable trading partners to distinguish products effectively for regulatory, supply chain and patient safety concerns.

The GTIN is commonly found on packaging, with surveys conducted in Australia finding that in 2003, 89 per cent of medicines packaging at unit of dispensing (the packaging level familiar to the consumer in FMCG environments) carried a GTIN represented in a GS1 bar code². This percentage is increasing annually and will soon reach 100% in Australia. In New Zealand the penetration of bar coding is lower – 46% on the unit of dispensing package.³ The GS1 Standards require that human readable interpretation is included on the product packaging. The consumer is familiar with the GTIN having seen this numbering structure not only on medicines but on almost all products traded through Point of Sale (POS) especially in the grocery channel throughout the world.

A unique GTIN is allocated to each different level of packaging allowing unique identification and traceability of this unit through the supply chain. This means that for each 'licensed' medicine, multiple GTIN's are able to be assigned.

Consumer familiarity with the GTIN makes this identifier very effective in the case of product recall. In fact, the GTIN is used during recall processes in other industry sectors, such as grocery, where there is significant product 'cross over' with medicines, in both New Zealand and Australia.

GS1 New Zealand and GS1 Australia therefore recommend that ANZTPA nominates the use of the GTIN as a mechanism for future recall processes.

² Refer: GS1 Australia

³ Refer: GS1 New Zealand - http://www.gs1nz.org/supplychain/documents/HealthAudit310805_002.pdf

Structure of a GTIN⁴

GTIN's are based on data structures (known as GTIN constructs) that guarantee global uniqueness when arranged in a standardised GTIN format.

Definitions

- **GS1 Company Prefix** – The first two or three digits N_1, N_2, N_3 constitute the GS1 Prefix allocated to each GS1 Member Organisation (eg: GS1 New Zealand/ GS1 Australia). The GS1 Company Number (ie: $N_4 - N_9$) that follows the GS1 Prefix is allocated by the Member Organisations. The GS1 Prefix and the Company Name form the GS1 Company Prefix. In general it comprises six to ten digits on the capacity needs of the company or organisation.
- **Item Reference** – The Item Reference is a non-significant number, which means that the individual digits in the number do not relate to any classification or convey any specific information. The simplest way to allocate Item Reference is sequentially, that is 000, 001, 002, 003 etc.
- **Check Digit** – The Check Digit is the last digit is a calculation of the preceding digits that is used to authenticate that the number is valid.

There are four ways to construct a GTIN:

GTIN-14 data structure

Indicator	GTIN of the items contained (without check digit)												Check Digit
N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}

GTIN-13 data structure

GS1 Company Prefix >												< Item Reference	Check Digit
N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	

GTIN-12 data structure

GS1 Company Prefix >											< Item Reference	Check Digit
N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	

GTIN-8 data structure (GTIN-8s are normally assigned one-by-one)

GS1-8 Prefix >							< Item Reference	Check Digit
N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	

⁴ http://www.gs1.org/hug/work_teams/gtin_allocation/GTIN_Allocation_DRAFT_v4.pdf

The following table summarises GTIN attributes:

Numbering Structures	GTIN Format													
	T ₁	T ₂	T ₃	T ₄	T ₅	T ₆	T ₇	T ₈	T ₉	T ₁₀	T ₁₁	T ₁₂	T ₁₃	T ₁₄
GTIN-14	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄
GTIN-13	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃
GTIN-12	0	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂
GTIN-8	0	0	0	0	0	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈

Global Document Type Identifier – GDTI

GS1 New Zealand and GS1 Australia recommend ANZTPA considers the use of the **Global Document Type Identifier** as the unique identifier for the license number for all medicines.

This identifier complies with ISO/IEC 15459:2006 and is structured in a similar way to the GTIN (with an optional serial component). The GDTI provides a globally unique identifier for documents and therefore provides a very functional license number solution also. It is used to access database information that is required for document control purposes. The GDTI is assigned for the life time of the document type.

It is important to note, that whilst the GDTI would be issued at ‘license level’ and therefore applicable to all packaging configurations of a licensed product, the GTIN would be different for each of those packaging configurations enabling traceability to these levels. The two numbers combined will prove a powerful combination for identification of medicines.

By omitting the serial component, the GDTI can be limited to 13-digits the same as the GTIN hence addressing ANZTPA’s concern about limited space on packaging. As the structure of the GDTI is common with the GTIN, it also familiar to consumers. However, to distinguish the GDTI from the GTIN, the Application Identifier (253) is required, whether the number is represented in human readable text and/or bar code form.

Most importantly the GDTI (like the GTIN) can be bar coded in many of the standard GS1 bar code symbologies⁵. Expressing the numeric data structure as a bar code provides clear benefits including automated document identification using AIDC (ie: scanning) technologies that enhance operational efficiency and accuracy. Bar code types include more traditional symbologies, as currently exist on the majority of medicines, and newer technologies such as GS1 DataBar™ (formerly known as RSS) and GS1 Data Matrix, which are designed for marking very small items eg: individual capsules or pills.

⁵ See Appendix for GS1 symbologies

The GDTI is constructed as follows:

GS1 Company Prefix > < Doc Type												Check Digit	Serial Number (optional)
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁ variable N ₁₇

Examples of symbologies are outlined in the appendix of this submission.

Summary

It has been concluded previously by the ANZTPA that the unique identifier is an important component of label information, particularly in product recalls and as a means of advising customers and health professionals that the medicine is licensed. To be of full benefit, ANZTPA has also recognised that consumers and others must be able to recognise the license number on the label, and for this reason standardisation of format is necessary.

Our submission has highlighted clearly that ANZTPA's prerequisite for an interoperable standardised numbering format for unique identification is met within ISO/IEC 15459:2006 and the GS1 System it cites. GS1's data formats are globally unique and accepted throughout the healthcare sector, are interoperable and are future-proofed to integrate with the other GS1 identifiers (eg: EPCglobal Radio Frequency Identification standards) used in global supply chains both now and into the future.

GS1 has 105 offices around the world, including throughout New Zealand and Australia. We have expert resources to assist ANZTPA in achieving its objectives. We certainly look forward to working closely with you.

Yours sincerely

Yours sincerely

Gary Hartley

Mark Fuller



General Manager – Sector Development
GS1 New Zealand

Chief Operating Officer
GS1 Australia

Appendix

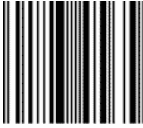

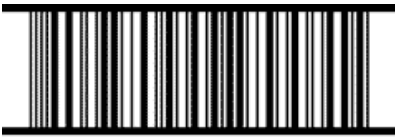



The Council of Europe Endorses GS1 Standards in improving patient safety throughout Europe.

The Council of Europe has released a report on safe medication practices on March 19, which you can find at: <http://www.gs1health.net/downloads/medication.safety.report.2007.pdf>

The reports highlights the following:

- Machine readable codes need to be standardised and considered together with other labeling information in the course of the marketing authorisation procedure of medicinal products in order to ensure patient safety and to prevent new risks.
- European medicine regulations should include requirements for machine readable codes. As an important element, the medicine regulations should require that pharmaceutical companies provide unit dose medicines with a bar code.
- With a view to full benefit for patient safety by this technology, it is recommended that the following changes are made to European medicines regulations: all medicinal products marketed in Europe should:
 - have an EAN-13 code bar containing the GTIN on the primary medicine container as a minimum requirement with an implementation period of two years (see Appendix 8);
 - have a data matrix bar code or RFID chip on both the primary container and unit dose with an implementation period of five years. The GTIN, batch number and expiry date should be encoded;
 - include a unique serial number for each packaging or container in addition to the data matrix and RFID chip with an implementation period of five years, if the medicine is at risk of being counterfeit.
- Pharmaceutical manufacturers should be allowed to market medicinal products with higher level technology and patient safety features, such as EAN-13 code bar containing GTIN, data matrix and RFID chip as soon as they wish but at the latest five years after the revision of the respective European regulations.
- The use of a machine readable code at dispensation should be recommended as a new professional standard by professional pharmacist associations across Europe.

GS1 Symbology

Standard Name	Symbology	Used for	Information Encoded
EAN-8	 0123 4565	Point of Sale (smaller items)	Product Identifier
EAN-13	 5 012345 678900	Point of Use	Product Identifier
EAN-14	 00012345678905	Carton Labelling	Product Identifier
EAN-128	 (00) 0 0123456 123456789 6	Point of use or carton labelling where additional information is required for traceability	Product Identifier, and other data, mainly batch code and expiry date
DataBar	 (01)00012345678905(21)12345678	Small Items, point of use as for EAN- 128 but for small items	Product Identifier, and other data, mainly batch code and expiry date
Data Matrix	 (01) 00012345678905	Small items, point of use as for DataBar but for very small items	Product Identifier, other data mainly batch and expiry date