Combined GS1 Healthcare and GS1 Healthcare User Group – Australasia

Response to the TGA Paper: Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods

1 Executive Summary

GS1 is a global, neutral, not-for-profit standards organisation dedicated to the design and implementation of global standards and solutions to improve efficiency and visibility in supply and demand chains. There are 111 GS1 member organisations world-wide, each dedicated to assisting industry to implement the GS1 System. The GS1 System is the most widely used system of identification (numbering), data carrier (bar code) and automatic data capture and sharing (EDI) standards throughout the world. It is recognised by organisations such as the International Organisation for Standardisation (ISO), the American National Standards Institute (ANSI) and the European Committee for Standardisation (CEN).

The GS1 Healthcare[1] user group was created to drive the development and adoption of GS1 standards and solutions to meet the needs of the global Healthcare industry. There are currently over 300 participants in GS1 Healthcare, representing over 150 companies, including thirty of the forty largest global manufacturers. The work of GS1 Healthcare allows the sector to drive towards the effective utilisation and development of global standards with the primary focus on automatic identification to improve patient safety and supply chain efficiencies.

The GS1 Healthcare User Group – Australasia[2] is the Australian and New Zealand local user group of GS1 Healthcare.

It is the strong recommendation of the stakeholders of this submission that the National Product Catalogue (NPC) should be a foundational mechanism by which inclusion of a product in the new-to-market risk communication scheme is communicated to healthcare trading partners. The stakeholders commend the TGA for identifying the opportunity to leverage the NPC in this way and including this as an option in the consultation paper.

This approach would leverage data already being provided by suppliers to the NPC and remove the work effort involved for suppliers to provide the same information via an additional mechanism. The global standards underpinning the NPC contain existing functionality by which a particular item can be indicated as being subject to a regulatory scheme. This functionality could be deployed in the NPC in line with global best practice.

In addition, use of the NPC would leverage the unique identification provided by the GTIN (Global Trade Item Number), which is the primary product identifier both in the NPC and also as part of the product bar code. Use of the GTIN provides unambiguous identification of the different product variants and package configurations of a medicine or medical device. The GTIN links the product data in databases to the physical product, so is an essential part of a new-to-market risk communication

[1] Refer: www.gs1.org/healthcare/
[2] Refer: http://www.gs1au.org/industry/healthcare/australasia/

scheme, assisting to eliminate any confusion regarding identification of the products subject to the scheme.

The stakeholders to this submission believe it is important that any policy or recommendation released be in line with that undertaken in other countries to ensure global interoperability, thus minimising the cost impost on the supply chain and ensuring effective medicine or medical device identification and traceability.

It is the recommendation of the stakeholders to this submission that any outcomes relating to this consultation fall in line with the work already completed by GS1 Healthcare, the National E-Health Transition Authority, and Australian healthcare stakeholders.

The stakeholders recognise that a collaborative approach is both necessary and desirable. As such, we emphasise our commitment to working with the Therapeutic Goods Administration relating to changes to pre-market assessment requirements for medical devices, incorporating globally standardised GS1 identification, bar coding and product data that will benefit all Healthcare stakeholders across Australia.

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2 Background to this Submission

At the request of industry, GS1 Australia, the global GS1 Healthcare User Group and GS1 Healthcare User Group Australasia have coordinated this submission on behalf of the organisations referenced in Section 3.

In preparing this submission, the stakeholders have emphasised their wish to work collaboratively with the Therapeutic Goods Administration (TGA) to aid the development of a standardised approach evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods incorporating globally standardised identification, data capture practices (leveraging GS1 data carriers) and product data provision (leveraging the National Product Catalogue in Australia. This submission is deliberately and specifically limited to the above via provision of background information.

The overall aim of the stakeholders is to take into account work already underway within the sector and ultimately benefit the complete Healthcare supply chain.

We invite the TGA to make use of the combined knowledge and expertise of the stakeholders in arriving at an optimal solution.

3 Stakeholders

The following organisations have all provided input to this submission.

- GS1 Healthcare http://www.gs1.org/healthcare/
- GS1 Healthcare Public Policy Work Team
- Leadership team of the GS1 Healthcare User Group Australasia http://www.gs1au.org/industry/healthcare/australasia/, including:
    - Clifford Hallam Healthcare (CH2)
    - The National E-Health Transition Authority (NEHTA)
    - SA Health
    - Terumo Australia

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5 Background to stakeholders

5.1 Who is GS1?

GS1 is a global, neutral, not-for-profit federated organisation dedicated to the design and implementation of global standards and solutions to improve efficiency and visibility in supply and demand chains. GS1, its national member organisations and partnerships connect companies with standards-based solutions that are open, consensus-based and universally endorsed. From bar codes, electronic messaging, data synchronisation, radio frequency identification, to business process automation standards, GS1 is the trusted source to deliver innovative standards, services and solutions to address the most pressing supply chain challenges facing businesses today. GS1 is a fully integrated global organisation, with 111 Member Organisations serving nearly two million companies in 145 countries.

5.2 What is GS1 Healthcare?

Globally, GS1 supports the Healthcare community through its GS1 Healthcare initiative. GS1 Healthcare is a voluntary, global user community bringing together all Healthcare stakeholders, including: pharmaceutical and medical device manufacturers, wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistics and solution providers, governmental and regulatory bodies and associations.

GS1 Healthcare was established to drive the development of GS1 standards and solutions to meet the needs of the global Healthcare industry. The work of GS1 Healthcare allows the sector to drive the effective utilisation and development of global standards with the primary focus on automatic identification to improve patient safety and supply chain efficiency.

The objectives of GS1 Healthcare are to:

- Work with key partners in the global Healthcare supply chain to develop and optimise the use of global standards to enhance accurate and fast movement of goods from manufacturer to distributor to Healthcare providers (such as hospitals or retail pharmacies).
- Facilitate awareness in the Healthcare sector of new technologies and methods of doing e-business.
- Provide advice and recommendations to GS1 on issues and opportunities in the Healthcare sector.
- Promote best practice implementation of the GS1 System in the Healthcare industry.
- Promote the implementation of GS1 voluntary, global business standards throughout the Healthcare sector.

There are currently over 300 participants in GS1 Healthcare, representing over 150 companies, including thirty of the forty largest global manufacturers. The group was formed in association with leading industry groups and associations and benefits from the active participation from all key supply chain roles (i.e., manufacturers, distributors, retailers, and hospitals/providers)[3] .

The GS1 Healthcare Leadership Team comprises industry tri-chairs Abbott, Alcon Labs and Covidien, as well as industry members Axway, 3M, Baxter, B.Braun, Bayer, BD, Cardinal Health, Fresenius, GHX, GSK, Johnson & Johnson, McKesson, Medtronic, Novation, Pfizer, Premier, and Zimmer.

[3] Refer: http://www.gs1.org/sectors/healthcare/

GS1 Healthcare actively collaborates with the Joint Initiative Council (JIC), formed to enable common and timely standards in health informatics. The JIC comprises CEN, CDISC, GS1 Healthcare, HL7, IHTSDO, IHE and ISO.[4]

5.3 What is the GS1 Healthcare User Group – Australasia?

The GS1 Healthcare User Group – Australasia, is the Australian and New Zealand local user group of GS1 Healthcare, the GS1 global Healthcare user group. This local group comprises over 100 representatives from Healthcare organisations operating in the Australian and New Zealand markets, who wish to ensure they have the opportunity to input to the work being undertaken by GS1 Healthcare for the benefit of the global Healthcare community[5].

5.4 What is the GS1 System?

The GS1 System is the most widely used system of identification (numbering) and data carrier (bar code), automatic data capture and sharing (EDI) standards throughout the world. Over 1.5 million users across 145 countries and more than 24 industry sectors have adopted the GS1 System. It is recognised by organisations such as the International Organisation for Standardisation (ISO), the American National Standards Institute (ANSI) and the European Committee for Standardisation (CEN).

At its most fundamental level, the GS1 System is an integrated suite of global standards that provides for accurate identification and communication of information regarding products, assets, services, locations, relationships and documents based on the concepts of Identify | Capture | Share, as detailed in Figure 1.

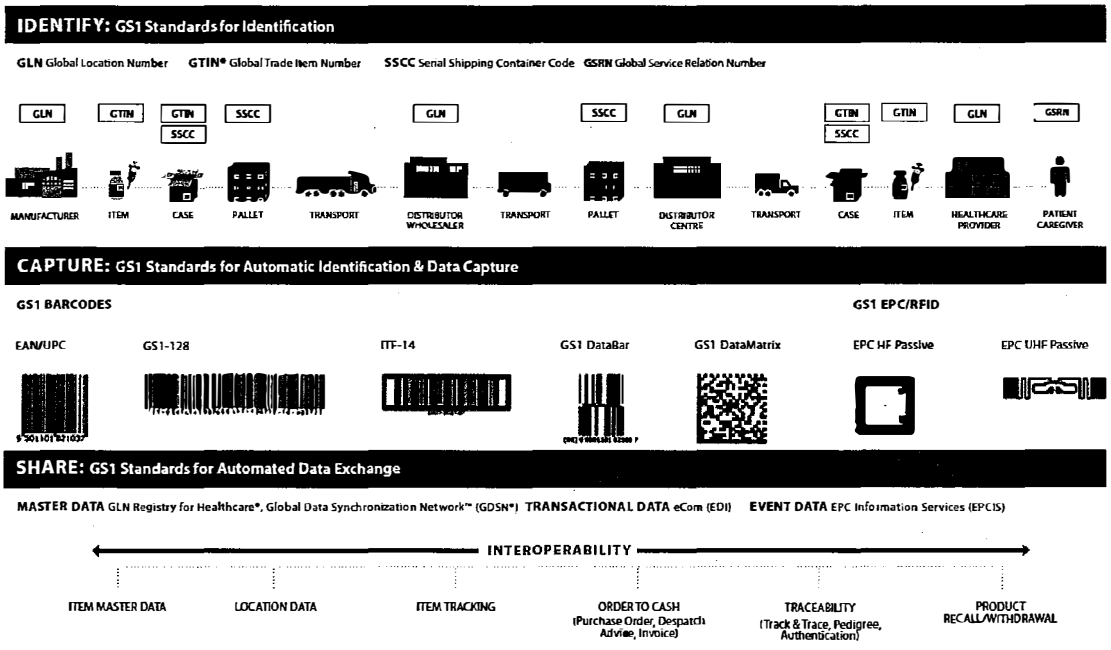


Figure 1: Concepts of the GS1 standards

Using GS1 identification numbers, companies around the world are able to globally and uniquely identify physical items like trade items, assets, logistic units, shipments, physical

[4] Refer: http://www.jointinitiativecouncil.org/

[5] Refer: http://www.gs1au.org/industry/healthcare/australasia/

locations and documents, as well as logical items like corporations or a service relationship between provider and recipient.

When this identification system is combined with GS1 data carriers, electronic business messages, data synchronisation via the National Product Catalogue (NPC) as well as the Global Data Synchronisation Network (GDSN) worldwide, the connection is made between these physical or logical items providing the information the supply chain needs.

The GS1 System is:

- **Open:** the GS1 standards development process is user-driven which permits full interoperability and compatibility and ensures end users are not locked into proprietary often inflexible solutions.

- **Global:** Healthcare is by nature a global sector, with supply chains that often cross national borders. On the other hand, Healthcare is also very much local. The GS1 standards development process ensures that local needs are incorporated into global standards.

- **Proven:** the GS1 System has been used for over 30 years in different industry sectors all over the world ensuring its robustness and reliability, including built-in security and privacy (e.g. identification numbers are non-significant - they identify an item but contain no information about it).

It is widely accepted that the use of GS1 standards improves patient safety and reduces costs in the global Healthcare supply chain. Use of GS1 standards enables traceability and promotes a safe and secure supply chain by providing greater visibility, accuracy and efficiency for the benefit of all parties involved. Preventing medical errors, enabling traceability & recall and combating counterfeiting are top-of-mind concerns facing the Healthcare sector, and GS1 standards are helping to solve these issues.

5.5 The Business Case for Global Standards

McKinsey & Company has released a report highlighting the cost savings and patient safety benefits of adopting a single global supply chain standard in Healthcare. McKinsey interviewed more than 80 Healthcare leaders across the world and examined more than 25 cases of standards-enabled improvement. This report, called: "Strength in unity: The promise of global standards in healthcare" is the first of its kind to quantify the benefits of a single global standard for Healthcare supply chains.[6]

Report findings:

- The research has revealed "that implementing global standards across the entire healthcare supply chain could save 22-43,000 lives and avert 0.7 to 1.4 million patient disabilities."
- Addressing counterfeit drugs, a major and ever growing problem for public health and industry, the report concludes that "rolling-out standards based systems could prevent tens of billions of dollars' worth of counterfeit drugs from entering the legitimate supply chain".
- At the same time, it states that "global standards could enable substantial safety benefits and enable healthcare cost reduction of $40-100 billion". Once adopted, global standards benefits will span over all the supply chain stakeholders from manufacturers to patients.
- "The healthcare industry faces a potentially costly patchwork of requirements. Over the long term this patchwork could become unworkable. The adoption of a single set

[6] Refer to: http://www.gs1au.org/industry/healthcare/GS1-Healthcare-Conference-Business-LiNK-ed-2-article.asp

of global standards will cost significantly less than two and far less than three or more".

The report concludes that the potential benefits enabled by global standards in Healthcare supply chains "could be significantly larger than anticipated, as proven by the lessons learned from the CPG/retail industry, when GS1 standards were widely adopted". End-to-end supply chain visibility could create new opportunities in mobile health, improve treatment compliance, avoid drug interactions and more.

6 Existing implementation of GS1 standards in Australia

6.1 Identification of medicines and medical devices

Within the GS1 System, the GTIN (Global Trade Item Number) is used to identify the different product variants and package configurations of a medicine or medical device. A change to one aspect, characteristic or variant of a medicine or medical device may require the allocation of a new GTIN.

GS1 Healthcare has produced a guide to GTIN allocation for Healthcare items[7]. This guide clearly outlines requirement and guidelines for identification of medicines or medical devices and provides a comprehensive reference to organisations responsible for GTIN allocation.

Integrity of the GTIN throughout a medicine's or medical device's lifetime is key to maintaining accurate identification of these products by manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other supply chain stakeholders, irrespective of their country or region. To ensure this integrity and unambiguous product identification, it is global GS1 policy and Australian local industry best practice (via a NEHTA industry best-practice communiqué) that GTINs should not be re-used for any regulated healthcare trade items (including all high-risk medical devices).[8]

GTINs are allocated to all medicines and medical devices, at all levels of product packaging (including primary packaging), and loaded into the NPC (refer Section 6.3). Therefore the majority of medical devices in the Australian markets already have GTINs allocated. Major organisations such as, Abbott, B.Braun/Aesculap, Cook Medical, Fresenius Kabi, Johnson & Johnson, Terumo and many others, use GTINs as the identifier for their medical devices.

The stakeholders to this submission wish to emphasise that the unique identification provided by the GTIN (Global Trade Item Number) which is used both in the National Product Catalogue (see section 6.3), and also as part of product bar codes (see section 6.2), to unambiguously identify the different product variants and package configurations of a medicine or medical device is essential as part of a new-to-market risk communication scheme.

6.2 Bar coding medicines and medical devices

The GS1 System currently includes five bar code formats, providing flexibility for trading partners in selecting the best bar code for their application. Each of the GS1 symbologies or formats has a common and global standard method by which information (e.g., GTIN plus additional information, if applicable) can be encoded. This ensures that GS1 standards function on the premise that the best way to determine the right bar code for a product is to have a user driven, global process (where bar code selections are based on considerations

[7] Refer: http://www.gs1.org/gtinrules/index.php/p=static/t=healthcare.

[8] Refer: http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare and http://www.gs1au.org/assets/documents/industry/healthcare/GS1-Australia-Healthcare-NEHTA-GTIN-Re-Use-Statement.pdf

such as those highlighted above). The GS1 System provides guidelines for selection, structure and placement to assist this decision.

The recent NEHTA Supply Chain Reform Group Product Identification and Data Capture Technology Statement recommends use of GS1 standards for bar coding healthcare products in line with the GS1 standards[9].

Audits undertaken by GS1 Australia indicate the level of GS1 bar coding of medicines and medical devices in the sector is steadily increasing. The last audit in mid-2011 indicated that more than 60% of medical devices and consumables (audited as a single category) carried at a minimum a GS1 GTIN in a bar code on all levels of product packaging, including primary packaging. Likewise 95% of medicines at secondary packaging level carried a GS1 GTIN in a GS1 bar code. Supplier organisations such as those mentioned in Section 6.1 all have GTINs bar coded on their products. This increase in bar coding is being driven by suppliers (both local and international) adopting best practice supply chain processes within their organisations, or alternatively by international regulations.

The stakeholders to this submission emphasise that linking the GTIN in the product bar code, to the same GTIN used to identify the product in the NPC will ensure clear identification of products subject to the new-to-market risk communication scheme.

6.3 The National Product Catalogue

The primary purpose of the National Product Catalogue (NPC) in Australia is to provide, for the first time, a nationally centralised and standardised data repository for all medicines, medical devices and medical consumables supplied to the public health system. Major private healthcare providers are also using the NPC for this purpose The NPC is used for the storage, management and distribution of product data between suppliers and trading partners.

In Australia, suppliers are able to supply their product data once, to a centralised point, and distribute this to the health system and the 1,300+ public and private hospitals in the sector (AIHW, 2010). As well as its use in Australia's public Healthcare sector, the NPC is also being implemented in the private Healthcare sector, with data recipients including Ramsay Healthcare, Clifford Hallam Healthcare, Symbion Pharmacy Services and St Vincent's Health Australia[10]. Pricing data can also be loaded and visible only to trading partners. Healthcare suppliers make significant efforts to ensure that accurate product data is maintained. The NPC is the most advanced implementation of its kind in Healthcare around the world, currently containing more than 286, 000 GTIN records and growing steadily.

The NPC in Australia is GS1 standards-compliant, build on the GS1 Global Data Synchronisation Network (GDSN) standards. The primary item identifier used in Australia's NPC is the GTIN (the identifier also included in medicine or medical device bar codes). This provides the key for matching NPC data with data recipient and data provider systems allowing accurate and complete data to be recorded against each GTIN. Therefore, when the bar code is scanned, the 'look- up' is to an accurate database.

There is existing functionality within GDSN to allow reference of an item to a given regulatory scheme. This functionality could be deployed within the NPC for Australia, with a new code in the field code list indicating the particular data being transmitted is included in the Australian new-to-market risk communication scheme.

[9] Refer: http://www.gs1au.org/assets/documents/industry/healthcare/Supply-Chain-Reference-Group-Product-Identification-Data-Capture-Technology-Statement.pdf

[10] Refer to: http://www.gs1au.org/services/gs1net/industry/npc/useful_contacts.asp

Once the final requirements for the new-to-market risk communication scheme are determined, both GS1 Australia and NEHTA would work with the TGA to ensure the mapping of required data to the NPC is in line with global best practice.

On this basis, the stakeholders to this submission believe the National Product Catalogue (NPC) should be a foundational mechanism by which inclusion of a product in the new-to-market risk communication scheme is communicated to healthcare trading partners.

7 Other Considerations

7.1 Support for Industry

A significant part of GS1 Australia's charter in is to provide support in various forms for companies, including education & training, implementation assistance and industry user groups. GS1 Australia provides telephone/web-based Healthcare-specific training as well as industry education seminars. In addition, GS1 provides multi-industry training, telephone and email-based support to industry. Therefore, any recommendation made by the TGA to require use of GS1 identifiers, bar codes or the NPC for healthcare would be fully supported by GS1 Australia via our various industry programmes.

Much of this training is complementary with subscription to GS1 in both Australia while some is charged on a cost recovery basis. As not-for-profit organisations, GS1 Australia works on cost recovery for fee-based services.

The network of 111 GS1 member organisations offers similar support (to that provided by GS1 Australia) to their local markets. Multi-national companies, or organisations importing product from overseas would find that their head offices / suppliers would have the information they need to implement any recommendations or policy issued.

7.2 International regulatory practice / Harmonisation with other countries

As mentioned in Section 6.2, other countries and regions have existing or developing regulations relating to use of the GS1 System for identification and bar coding of medicine or medical devices. Product data synchronisation using GS1 standards is also undertaken in other countries including the US, and key European markets. GS1 Healthcare maintains a register of information of all of the current regulations and, should the TGA be interested, can provide further information for your reference.

In addition, GS1 Healthcare actively works with regulators across the globe to educate and advise users about industry endorsement of the GS1 System. GS1 Healthcare sees its role being to help educate regulators about what members of the sector see as best practice for identification, bar coding and product data exchange, to ensure that any policy developed is undertaken in a collaborative manner reflecting a global approach.

The stakeholders to this submission believe it is important that any policy or recommendation released in Australia be in line with that undertaken in other countries to ensure global interoperability, thus minimising the cost impost on the supply chain and ensuring effective medicine or medical device identification and traceability.

7.3 Industry Developed Guidelines and Standards

Today, an extensive set of standards and guidelines exist for identification and bar coding of Healthcare items using the GS1 System. GS1 Healthcare has worked in a cross-functional, global team of over 90 members to define a tiered approach to identification and bar coding

of Healthcare items, with the amount of data carried in the bar code appropriate to the intended use of the product. In addition, the GS1 Global Traceability Standard for Healthcare has been created by industry, as have a range of position papers and technical documents.[11]

The recommendations of the stakeholders to this submission that any outcomes relating to medicine or medical device identification, bar coding or provision of product data, fall in line with the work already completed by GS1 Healthcare, NEHTA and Australian healthcare stakeholders.

8 Conclusion

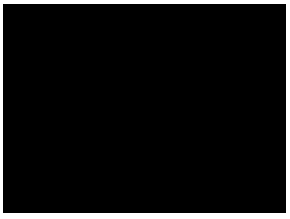
The stakeholders to this submission are very pleased that the TGA has released this consultation paper, and are keen to support the TGA throughout the information gathering and decision making process. The GS1 standards are well suited to meet the specific needs of Healthcare for identification, bar coding and master data provision, and are the predominant standards within the medical devices sector.

The NPC is a foundational mechanism to:
(1) Communicate products included in the new-to-market risk communication scheme, and
(2) Provide clear and unambiguous identification of those products via the GTIN, which is also encoded in the product bar code, thus linking the product data with the physical product.

This approach eliminates the potential for confusion and misidentification.

Throughout its decision making process, the stakeholders to this submission recommend the TGA reference the position and recommendations of industry, existing work of other Government organisations, e.g. NEHTA, and also the policies and recommendations from other countries across the world, many of whom are moving to implementation of the GS1 System.

The leadership of the GS1 Healthcare User Group – Australasia would be pleased to meet with representatives of the TGA to further discuss this submission, and any related questions. Please contact Tania Snioch, Industry Manager – Healthcare, at GS1 Australia (contact details at the beginning of this document) to arrange further discussions.



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[11] Refer to: http://www.gs1.org/healthcare/standards