GS1 Australia

The Global Language of Business

30 April 2018

[redacted]
Director, Technical and Safety Improvement Section
Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Therapeutic Goods Administration consultation on the management and communication of medicine shortages

Dear [redacted]

Thank you for the opportunity to provide industry feedback on the Government's management of medicine shortages in Australia consultation paper ("the consultation paper").

GS1[i] works with all stakeholders in the healthcare supply chain and we are acutely aware of the impact of medicine shortages to both consumers and health professionals. Within a global context, there is increasing complexities surrounding medicine shortages. To pro-actively combat this, system leadership is required to drive improved medicine traceability / track and trace (herein "traceability"), greater utilisation of technology for interoperability and predictive analytics / artificial intelligence.

We work broadly with the Commonwealth Department of Health on a range of initiatives which includes changes to medicine labelling (inclusion of GS1 unique identifier now a requirement of revised labelling and packing regulations[ii]), the current work of the PBS Taskforce on improving medicine traceability for high cost medicines, unique product identification, and recall management processes.

In reviewing the consultation paper, our industry expertise centres on global standards and accordingly our feedback is focussed on the "*proposed timing and content of mandatory reports and product details on the medicine watchlist*".

The World Health Organisation through the World Health Assembly has provided leadership on traceability[iii] confirming that Australia is not unique in requirements, and the importance of aligning with global standards as the direction being widely adopted. The use of GS1 unique identifiers for traceability is currently in place / underway in countries such as Argentina, Brazil, Canada, Columbia, Denmark, Japan, Russian, the USA[iv] and the UK[v,vi].

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Supporting this global direction, McKinsey highlighted in their 2012 report[vii] that the adoption of global standards could save the global Healthcare industry $40-100B (USD). In the UK, Dan Poulter, Parliamentary Under Secretary of State for Health is quoted as saying "we have now mandated the use of GS1 and PEPPOL standards by amending the NHS standard contract to require compliance with the NHS eProcurement Strategy"[viii]. This strategy is now known widely known as the Scan4Safety[ix] program which through the adoption of global standards is targeted to saves lives and up to $1B (GBP) over the next 7 years.

Unique identification is at the core of effective traceability of medicines, enabling both the identification of the specific product, and the points within the supply chain it has passed through, including those involved in how they are dispensed or consumed. The GS1 unique identifiers, Global Trade Item Number (GTIN) and Global Location Number (GLN), and standards for capturing and sharing data, are core enablers of this process. Both the GTIN and GLN are effectively 'unique key's' to enabling interoperability between the wide range of stakeholders and systems used. The GTIN is the unique identifier represented as a barcode embedded in almost all medicines packages, not only in Australia, but also around the world.

In reviewing the consultation paper there are three key areas which with minor amendments, we believe would provide *significant* benefits to the Australian Healthcare industry. These are:

1. Inclusion of Global Trade Item Number (GTIN) in mandatory reporting obligations.
2. Inclusion of Global Location Number (GLN) as the 'Manufacturer' and/or 'Distributor' identifier.
3. Inclusion of GTIN, GLN and trade name in the 'Medicine Watch List'.

The benefits are common between these areas and include:

- Consistency with other medicine supply chain related data and organisational processes being utilised within the Australian industry.
- Faster analysis of medicine supply chains as stakeholders will be able to utilise technology to search for products e.g. scanning medicine barcodes into pharmacy / inventory systems.
- Reduction in wasted pharmacist's time undertaking preliminary analysis so 'downstream' stakeholders can undertake product analysis.
- Utilisation of an unambiguous common language for all stakeholders in the medicine supply chain. The use of the GTIN (represented as a barcode on the box) enables both health professionals and consumers to visually identify the correct product quickly (both product and the correct unit of measure).
- Global analysis / monitoring, as the GTIN is a globally unique product identifier. As we utilise the GTIN globally to monitor medicine shortages, interoperability between countries monitoring systems will become more seamless.

- Greater utilisation of analytics to provide a foundation for artificial intelligence / predictive analytics, as the GTIN ensures interoperability between systems, and other datasets e.g. Australian Medicines Terminology (AMT) / SNOMED CT.
- GLN enables unambiguous business to business identification of the correct trading partners not readily available through other business identifiers (e.g. ABN).

Australia is well progressed in the use of the GS1 standards for the medicine supply chain, with the GTIN specifically being used to uniquely identify 97-98%[x] of medicines in our domestic market. As noted above, the GTIN is represented as a barcode (linear or 2D) and often also includes other key medicine attributes such as batch, expiry or serialised product information. Within a global medicine supply chain, harmonisation of common standards is important to ensure industry impacts and associated regulatory costs are appropriately managed, and we can leverage these foundations to ensure increased visibility and monitoring capability.

The inclusion in the TGA's medicine labelling requirements, and many State's and Territory's conditions of contracts for the use of GS1 standards, has already paved the way for broader regulatory adoption of GS1 standards. We believe the inclusion of these requirements in the TGA's medicine shortages requirements would be a minor change, and position Australia well to improve our response times and industry collaboration on medicines shortages.

We would appreciate the opportunity to discuss this further as our ultimate goal is to support an improved and interoperable medicine supply chain, in which our standards are already a core pillar. We are able to support your timelines and provide additional assistance in drafting specific wording for documentation as required.

Thank-you again, for the opportunity to provide our insights on this important area of work.

For further information on our submission please contact Paul Broadbridge, Director Government (Healthcare) [redacted] or email [redacted]

Regards,

[redacted]

GS1 Australia

[i] GS1 is a neutral, not-for-profit organisation that develops and maintains the most widely used global standards for efficient business communication. We are best known for the barcode, named by the BBC as one of "the 50 things that made the world economy". GS1 standards and services improve patient safety, enable traceability and support efficiencies of supply chains across physical and digital channels in the healthcare sector. With local Member Organisations in 112 countries, 1.5 million user companies and 6 billion transactions every day, GS1 standards create a common language that supports systems and processes in 25 sectors. In Australia GS1 represent 18,000 organisations across a wide range of industry sectors.

[ii] Therapeutic Goods Administration Labelling and Packaging Overview https://www.tga.gov.au/labelling-packaging. TG091 specifically requires the use of the GTIN as the "Machine Readable Code"

[iii] World Health Organisation "Existing Technologies and Track and Trace Models in use and to be developed by Member States" http://www.who.int/medicines/regulation/ssffc/mechanism/A69_41-en9-28.pdf?ua=1

[iv] World Health Organisation "Existing Technologies and Track and Trace Models in use and to be developed by Member States Country Overview" November 2017 Updated Table of Country Experiences http://www.who.int/medicines/regulation/ssffc/mechanism/country-experience-table_updated-nov2017.pdf?ua=1

[v] European Commission Falsified Medicines Directive https://ec.europa.eu/health/human-use/falsified_medicines_en

[vi] Operational productivity and performance in English NHS acute hospitals: Unwarranted variations - An independent report for the Department of Health by Lord Carter of Coles https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf

[vii] McKinsey & Company, October 2012, Strength in Unity "the Promise of global standards in Healthcare", P45 https://www.mckinsey.com/~/media/mckinsey/industries/healthcare%20systems%20and%20services/our%20insights/strengthening%20health%20cares%20supply%20chain%20a%20five%20step%20plan/strength%20in%20unity%20the%20promise%20of%20global%20standards%20in%20health%20care.ashx

[viii] World Health Innovation Network Case Study on the National Health Service, England titled "The Impact of Supply Chain Transformation in Health Systems" https://issuu.com/worldhealthinnovationnetwork/docs/final_for_release_nhs_case_feb_14_8

[ix] https://www.scan4safety.nhs.uk/

[x] This is based on survey's conducted by the GS1 Australia Healthcare team in pharmacies in multiple States in 2017/2018