Australian Government
Department of Health
Therapeutic Goods Administration

Better healthcare:

a vision for use of data matrix codes and medicines traceability

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TGA Health Safety Regulation

Contents

The vision

The Australian Government is committed to improving our healthcare services, putting patients first and modernising to achieve better efficiencies and improved effectiveness.

Today's consumers are knowledgeable and increasingly using sophisticated technology on their health journey. Australians have said that they want more information about the medicines they take and better support in managing their health.

Health professionals want better electronic systems to improve patient safety - systems that are integrated and efficient to allow better automation and give them information at their fingertips.

Australia has reached a critical point in the digitisation of our health care system and we need to invest in digital infrastructure that ensures interoperability of systems both locally and globally. The ability to track medicines through the supply chain, and bring together fragmented health data, will unlock the value of this important information.

Easier access to better medicine information will reduce medication errors and adverse events. This information needs to be immediately accessible using commonplace scanning technology – read directly from a medicine or searchable within a secure data repository.

While Australia currently has neither requirements nor infrastructure to facilitate medicine tracking, other countries are already adopting this technology. Australia has a role to play in developing secure interconnected systems to allow us to collaborate with international partners. Sharing common information will improve our existing safety systems and medicine supply chains, ensuring our access to the most relevant, up to date information.

Introduction

The benefits of a digital environment can only be fully realised by automating the translation of physical information into digital data. Manual identification and upload of data as a medicine moves through the supply chain introduces risk of operator error, compromising accuracy and safety. Machine-readable codes allow scanning of a medicine for identification with automatic upload into electronic systems. Linking these electronic systems would achieve further efficiencies and wider benefits.

Australian GPs use software programs to prescribe medicines and pharmacies use various systems to track inventory. A comprehensive, interoperable system would give visibility of the entire lifecycle of a medicine. These 'track and trace' systems have many benefits:

- reduced medication errors by ensuring the correct medicine is dispensed to the patient
- automated recording and transfer of data in electronic systems
- ability to identify whether a product is authentic by tracking medicines through the supply chain
- increased ability to target specific medicines involved in a recall in the event of a medicine safety problem
- detailed visibility of stock quantities and locations, allowing better management of potential medicine shortages

A fundamental component needed to achieve these benefits is unique identification of the medicines. This can be at product level (to distinguish one type of medicine from another) or in more detail to include production information (such as a batch number or individual unit identifiers). These identifiers must be accessible, able to be scanned and verified easily. Compared to other machine-readable codes, two dimensional data matrix codes can carry more

information in a smaller size, are robust and easily read. While overseas markets have implemented different variants of track and trace systems, the majority rely on data matrix codes.

Australia must participate in this growing global transformation and implement robust, consistent systems that allow international trade and facilitate interoperability. The type of information used for identification, and how it is presented, must be agreed and applied consistently within and across markets. This interoperability relies on standardised information; consequently, the Therapeutic Goods Administration (TGA) is developing a standard for data matrix codes used on Australian medicines setting out the information that must be encoded and its format.

TGA's role is defined by responsibilities outlined in the *Therapeutic Goods Act (1989)*; that is, to support the quality, safety, efficacy and timely availability of therapeutic goods in Australia. TGA does not regulate the flow of information in health systems or the broader diversity of stakeholders in the medicine supply chain. The new standard is the first necessary step in establishing requirements that support all systems relying on the codes. Its introduction will occur independently from the broader considerations needed before Australia determines which track and trace system is appropriate for our medicine supply chain.

Objectives

Use of standardised data matrix codes will provide better availability of important medicine data to improve patient-centred care.

Data matrix codes that uniquely identify each medicine, consolidated by data that records the movement of the medicines through the supply chain, forms the basis of a track and trace system. The codes also allow multiple digital applications within e-health systems to upload electronic data directly from the physical goods. In the future, established use of the codes and

associated data could be a new avenue for consumer- and patient- access to accurate, timely information about medicines.

Widespread use of data matrix codes has the potential to generate a large volume of important medicine data. These data, captured and shared appropriately, could be analysed to provide a better understanding of how medicines are used; where and how problems arise; and identify anomalies within big data that are not yet obvious. Consolidation of what are currently disparate data sets will allow real-time and predictive data analysis, generating powerful information to help strengthen the public health system with the potential for great advancements in individual patient safety.

Any future track and trace system in Australia must be globally aligned, using common fundamental components to ensure interoperability. The new TGA standard for data matrix codes must therefore incorporate globally agreed data elements to allow international as well as national data links.

Benefits

Medicine traceability

The TGA standard for data matrix codes will provide consistency for early adopters. This is the first step towards a long-term goal of a system for medicine traceability and authentication.

A number of overseas markets have implemented track and trace systems, each developed to address local concerns with medicine supply. Systems vary in the number of points within the supply chain that verification must occur; and in the way data are consolidated and stored.

In the European Union, the focus is on minimising substandard or falsified medicines in the supply chain. A 'point of dispense' verification system relying on data matrix codes has been mandated for most prescription medicines and some over-the-counter medicines. This simplified system does not capture a complete picture of the movement of goods in supply – serialisation must occur at the point of manufacture but verification is mandated only at the time the medicine is dispensed. The EU system relies on a central hub for the uploading of product data from manufacturers and the transmission of data to separate national databases for verification.

In the USA, steps are being taken to build an electronic, interoperable system to identify and trace certain prescription drugs under the Drug Supply Chain Security Act. This system relies on supply chain partners sharing information, with each entity responsible for data verification and passing all accumulated data to the next partner. In this way, a full history is generated but there is no central repository for the data.

Many other countries are implementing systems, either simplified or a full track and trace model. Notably, the two approaches are not incompatible. Implementation can commence with point of dispense verification and then move to a more comprehensive data flow as systems mature.

However, the risk with these independent approaches is a lack of interoperability, adversely affecting global supply chains. The identification, capture and sharing of information about a medicine and its movement throughout the supply chain must be in a globally recognised format and language.

Under a globally recognised system, medicines and locations are uniquely identified.

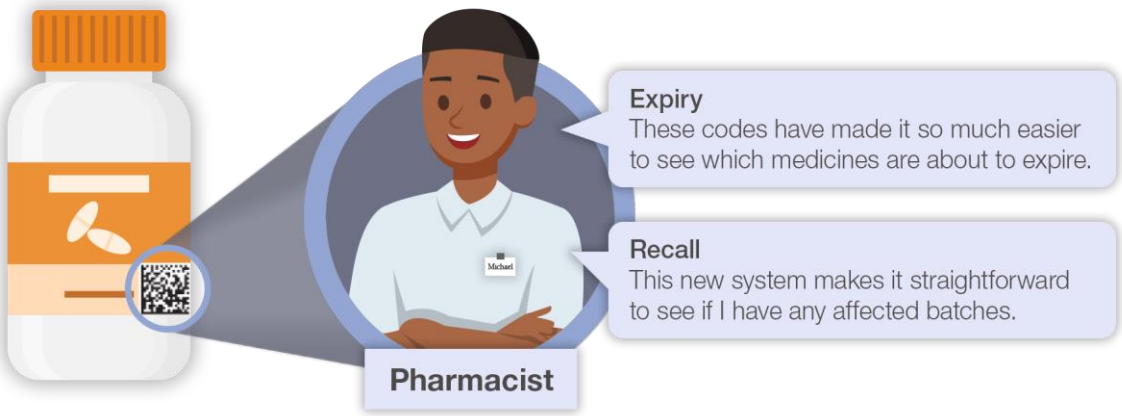
Medicines are identified as 'trade packs' and assigned a Global Trade Item Number (GTIN). This differentiates medicines by their name, active ingredients, strength, dosage, pack size and packaging details (class level identification).

Product identifiers combined with production information further uniquely identifies goods. Batch and expiry details provide an additional level of identification, but apply to multiple units or packs. A unique serial number assigned to a specific unit (e.g. one carton) allows tracking of each one through the supply chain (instance-level identification).

Use of the GTIN, and associated global standards, is mandated in Australia's medicine labelling requirements. The new standard for data matrix codes similarly relies on GTINs and a globally adopted approach to serialisation.

Depending on the model chosen, a track and trace system for medicines in the Australian supply chain could provide the following benefits:

- Visibility of product status (e.g. recalled, expired)
- Reduced risk of substandard, falsified and counterfeit medicines entering the legitimate supply chain and being dispensed to patients
- Improved pharmacovigilance and monitoring of treatment outcomes
- Efficient and targeted recall management
- Real-time visibility of product numbers and locations in the supply chain, which may assist during medicine shortages and also help prevent them
- Coordinated strategic management of shortages, with all stakeholders easily identifiable
- Improved inventory management, including both forwards and reverse logistics
- Efficient payment and payment monitoring
- Robust reimbursement processes
- Assurance of authenticity, increasing trust and confidence in Australian medicines.



Supporting electronic health systems

As Australian health systems transition to digital technology, use of data matrix codes could potentially provide the following benefits:

Closed loop medication management

- Improved patient safety by using the code to verify the identity and status of the medicine (e.g. recalled or expired) when it is being dispensed.
- Targeted recalls and transparency for patients through the recording of medications in local electronic health systems, such as patient administration charts, and national electronic health systems including My Health Record, as part of our commitment to Quality Use of Medicines.
- Improved safety and monetary savings through better inventory management and tracking high value and high risk medicines, such as Schedule 8 items, in hospital systems.

Adverse events reporting

- Simplifying the capture of critical medicine information by scanning the code into adverse event reports
- Expanding the level of detail beyond that captured in existing linear codes.

Inventory management

- Efficient inventory management for distributors, retailers and dispensaries with electronic coding of batch details and expiry dates.

Consumer information

As health systems and technology solutions mature, data matrix codes can be a mechanism to support greater access to information for consumers. Smartphone apps that use the unique identifier information as a key to unlock databases would provide:

- Verification of authenticity of medicines
- Database links to:
  - medicine information e.g. consumer medicines information leaflets
  - administration information including videos on how to correctly use the medicine
  - consumer information such as allergen information or locations of manufacture.

TGA standard for data matrix codes

The TGA's standard for data matrix codes for medicines will be implemented in mid-2020. Introduction will ensure the codes will be applied consistently, allowing technology solutions and policies to be developed and implemented.

By September 2020, all prescription medicines must include a machine-readable code on their label. This code can be a GS1 linear EAN-13 code or a GS1 DataMatrix code.

Medicines have been utilising GS1 linear EAN-13 codes for many years. Much of the medicine supply chain has invested in technology to read the linear codes; however, there has only been limited uptake of newer technology necessary for data matrix codes. For this reason, full transition to sole use of data matrix codes is not yet possible. From implementation of systems overseas, it is evident that transitions to the new technology take at least five years.

By setting out the key data elements that must be encoded, the new standard will assist those choosing to move to a data matrix code. Its introduction will not mandate serialisation of medicines; market forces and international requirements will drive adoption of these codes.

Domestically, hospitals are moving to closed-loop medication management systems. Optimally, product, expiry and batch information is used to identify medicine in these systems. We anticipate an increase in requests from procurement teams for medicines to include a data matrix code on packaging to assist in patient safety, inventory management and accurate record keeping.

Creating new health data sets

Comprehensive data linkages

Data matrix codes used on medicines typically encode four key data elements: GTIN, batch details, expiry date and a serial number. Beyond this, the power of the codes is their ability to link to comprehensive information in databases. While this capability exists to a degree with linear barcodes, it is significantly enhanced in data matrices.

Links can be made to a multitude of information, including but certainly not limited to:

- medicine identifiers other than those encoded in the data matrix
- active ingredient information

- product information and consumer medicines information documents
- pharmaceutical benefit status
- recall status
- the price of the goods

Current digital health systems are often localised databases, within a particular hospital or pharmacy group for example. Each system has its own database and internal data linkages. It is difficult to consolidate medicine information collected in one location with data gathered in other digital health systems. The absence of common terminology confounds the lack of interoperability, impeding holistic and comprehensive data sharing.

Widespread use of data matrix codes on medicine labels offers opportunities to improve clinical practice, changing the way we collect and analyse data affecting patient safety. A fully interoperable track and trace system would further expand on these opportunities.

A track and trace system allows information in currently siloed health systems to be aligned so that the valuable health data from each can be viewed as one dataset. The detection of trends and anomalies, not recognisable within a single system, becomes possible. These new insights can support better health policies, earlier detection of medicine problems and ultimately better health outcomes for Australians.

Data stewardship

Medicine data can be used to improve public health outcomes but also has huge commercial value. While there may be some benefits to realising this value, it is critical that we protect patient privacy and safety. If adoption of medicine traceability using data matrix codes is market-driven, there is a risk that systems and databases will be established for marketing purposes, not health benefits.

Internationally, other jurisdictions address this problem by requiring such databases to be established and maintained by a government entity. Similar considerations must be made if databases are established in Australia, particularly in the context of our existing privacy laws affecting health data.

Future possibilities

Widespread use of data matrix codes brings with it more possibility for medicine data capture and sharing. Our vision for data matrix codes is limited to the data elements that we know about now. There is rapid development in technology and systems to enable medicine traceability and electronic health systems. The Australian Government's Public Data Policy Statement[1] recognises the importance of publishing, linking and sharing of data to create opportunities that neither government nor business can currently envisage.

The TGA's introduction of a standard for data matrix codes is the first regulation to underpin the important translation of medicine information within a data matrix code into electronic data. The full potential of this action will only be realised if stakeholders in the Australian medicine supply chain use the standard to leverage their own visions and objectives for a contemporary digitally-enabled Australian health system.

[1] Australian Government Public Data Policy Statement:
https://www.pmc.gov.au/sites/default/files/publications/aust_govt_public_data_policy_statement_1.pdf

Further reading

International developments in medicine traceability

- World Health Organization: WHO Member State Mechanism
  https://www.who.int/medicines/regulation/ssffc/mechanism/en/
- European Commission: Falsified Medicines: https://ec.europa.eu/health/human-use/falsified_medicines_en
- United States Food and Drug Administration: Drug Supply Chain Security Act (DSCSA):
  https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
- National Blood Authority Australia: Barcode Specifications:
  https://www.blood.gov.au/barcoding
- GS1 Presentation: Traceability: How to choose a traceability model? Learnings from the APEC toolkit:
  https://www.gs1.org/sites/default/files/docs/addisababa/20180508.%20Addis_Day1_Panel2b_Traceability%20how%20to%20choose%20a%20model_Ulrike.pdf

Electronic health systems

- Australian Digital Health Agency: Australia's National Digital Health Strategy:
  http://sharepoint.central.health/divisions/mrd/teams/som/_layouts/15/WopiFrame.aspx?sourcedoc=/divisions/mrd/teams/som/2D%20Code%20references/Australia%27s%20National%20Digital%20Health%20Strategy.pdf&action=default
- CSIRO: Future of Health – Shifting Australia's focus from illness treatment to health and wellbeing management: https://www.csiro.au/en/Showcase/futureofhealth
- Society of Hospital Pharmacists of Australia: Closing the loop of medication management in hospitals to improve patient safety with barcoding technology on unit dose packaging – Position Statement: https://www.shpa.org.au/sites/default/files/uploaded-content/website-content/Fact-sheets-position-statements/position_statement_-_unit_dose_packaging.pdf

Version history

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V1.0	Original publication	Scientific Operations Management Section Scientific Evaluation Branch	July 2020

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