Cracking the code: Developing requirements for data matrix codes on medicines

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Outline

- Terminology
- Reasons for the new standard
- New standard – TGO 106
  - Requirements

Medicine identification

Linear barcode

- GTIN uniquely identifies the product
  - strengths, pack size, dose forms

- GS1 compliant

DataMatrix

Linear barcode

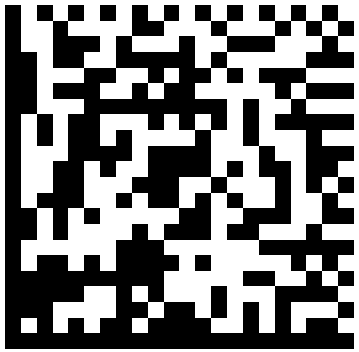
- ✗ The more data encoded, the bigger the barcode
- ✗ Not practical for small packs
- ✗ Sensitive to scan

2D DataMatrix code

- ✓ Holds more data in a smaller area
- ✓ High level error correction mechanism
- ✓ Better scanning reliability
- ✓ Industry standard

DataMatrix vs QR codes

DataMatrix code

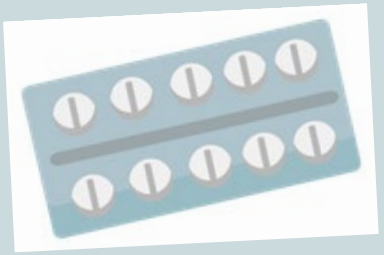


- Two solid edges, no shapes in the matrix
- Preferred 2D code for medicines
- DataMatrix is a data matrix code formatted in accordance with GS1 General Specifications

QR code

- Three squares in the corners and a small square in the lower right
- Widespread reader technology

Primary pack is different to primary packag*ing*

Therapeutic Goods Act 1989, SUSMP	GS1, GMP, ISO
'Container' the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion 	**Primary packaging** First level of packaging 
'Primary pack' (that is a container) 	
'Primary pack' (that is secondary packaging) the complete pack in which the goods, or the goods and their container, are to be supplied to consumers 	**Secondary packaging**

https://www.gs1.org/docs/healthcare/position-papers/Discussion-paper-on-medicines-identification-requirements-on-primary-level-packaging-using-GS1-standards-final.pdf

TGA's role

Industry is already adopting this technology.

Absence of regulation risks multiple formats and methods of serialisation

An order ensures uniformity of uptake and clarity for stakeholders.

Traceability

Benefits when data matrix codes are used in a traceability model

Efficient and targeted recalls

Global interoperability

Improved inventory management

Authenticity verification

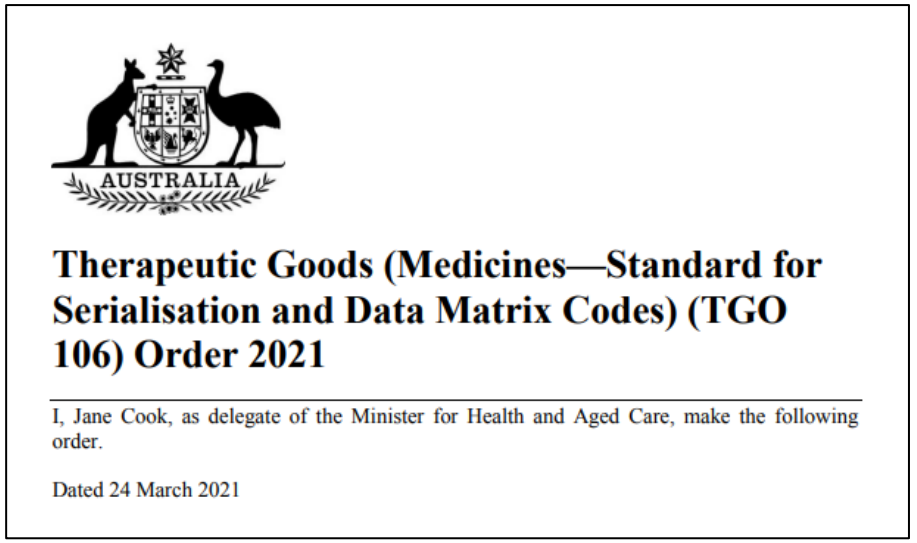
A clear and consistent standard nationally applied and globally interoperable

Existing requirements

- Barcode specifications for blood and blood products funded under the National Blood Arrangements
- Any manufacturer that supplies to the EU must have capability to serialise.
- TGO 91 (prescription medicines labelling order) already requires a machine-readable code that complies with GS1 requirements.

TGO 106

- ✓ Specify essential information
- ✓ Relies on global standards - GS1
- ✓ Specifies rules about encoding additional non-mandatory information
- ✓ Medicines released for supply from 1 January 2023 must comply if they (1) are serialised or (2) include a data matrix code that encodes the GTIN



AUSTRALIA

Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021

I, Jane Cook, as delegate of the Minister for Health and Aged Care, make the following order.

Dated 24 March 2021

TGO 106 does not

- ✗ Mandate the use of DataMatrix codes on medicines
- ✗ Preclude or regulate on codes, such as QR codes*

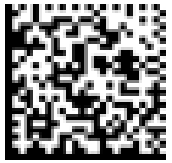
Australian Government
Department of Health

Requirements

- Presentation
  - GS1 DataMatrix
- Content – GTIN, Batch, expiry and serial number on the primary pack.
- Relationship with other machine readable codes
- Human readability

GTIN: 01234567890000
LOT: XC2312
EXP: 31/01/2020

S/N: 555643225C



(01)01234567890000
(17)200131(10)XC2312
(21)555643225C

- Must form a number chain that is globally unique to the unit it is placed on.
- TGO 106 does **not** set out any requirements regarding reporting, storage and verification of serialisation data.

Building foundations

The standard is a starting point

Complex systems - many sectors and large datasets

Extended implementation timelines

Preparing for the future

Limitations

- ✗ Track and trace policy for medicines
- ✗ Policies and practices for health professionals, software vendors or other parts of government
- ✗ Regulation of medicine distribution
- ✗ Visibility of supply information
- ✗ Consolidated data

Questions?

Australian Government

Department of Health

Therapeutic Goods Administration