Developing Australian requirements for data matrix codes on medicines

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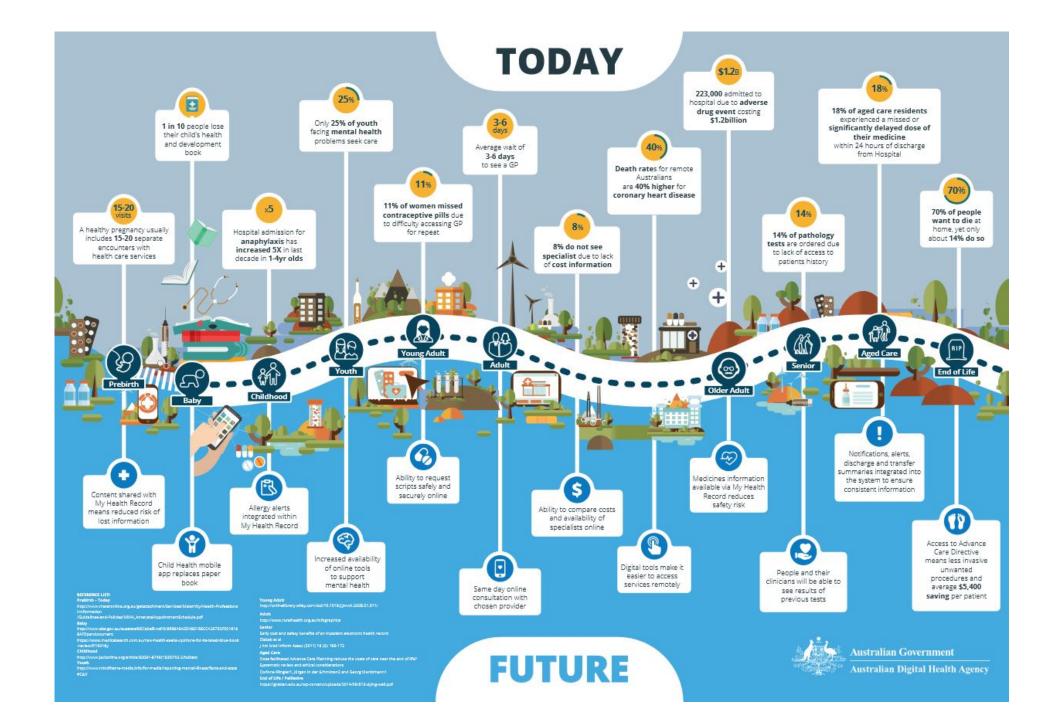
Health Products Regulation Group

Therapeutic Goods Administration (TGA)



Outline

- » Australia's National Digital Health Strategy
- » Role of the Therapeutic Goods Administration
- » Making standards for medicines
- » Traceability & eMedication
- » Data matrix codes
- » Bringing it all together
- » Be part of the conversation



Role of the TGA

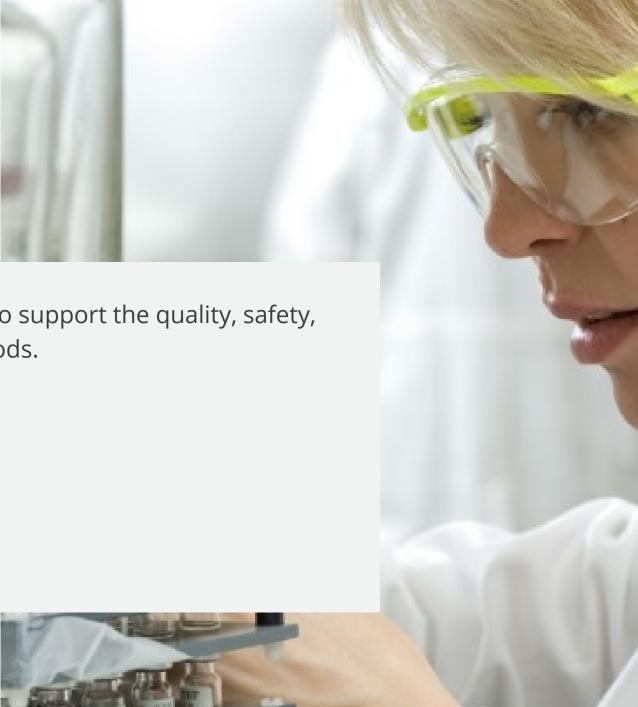
Part of the Department of Health, the TGA regulates therapeutic goods in Australia.

We administer the *Therapeutic Goods Act (1989)* to support the quality, safety, efficacy and timely availability of therapeutic goods.

We:

- approve medicines for supply
- recall and recover products that are not safe
- license manufacturing sites
- set requirements to establish quality.





Making standards for medicines



Medicine identification

Where we started

GTIN uniquely identifies the product

- strengths, pack size, dose forms

GS1 compliant





Australian Government

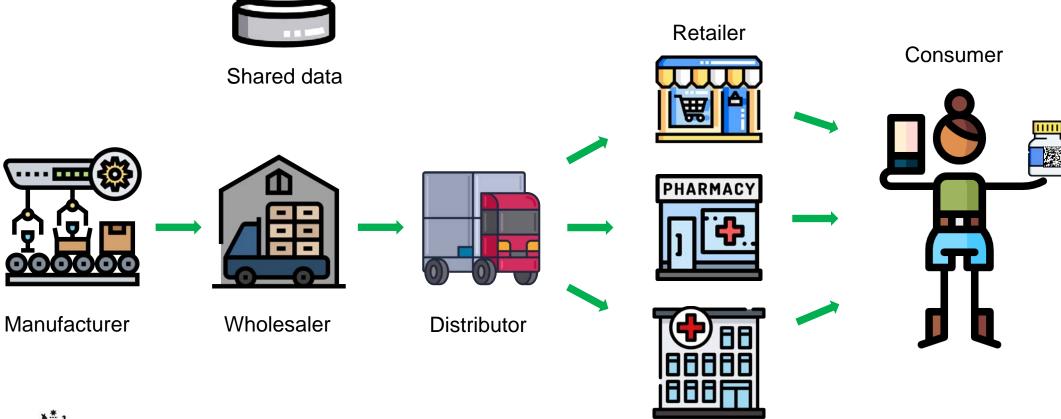
Therapeutic Goods Administration

Department of Health

Medicine supply chain

Hospital

www.tga.gov.au



Traceability

Benefits when data matrix codes are used in a traceability model



Efficient and targeted recalls



Global interoperability



Improved inventory management



Authenticity verification

eHealth

eHealth opportunities enhanced by data matrix codes



Preparing for the future

A standard for data matrix codes is the first step towards medicine traceability in Australia



Why DataMatrix

Linear barcode



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

2D DataMatrix code



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

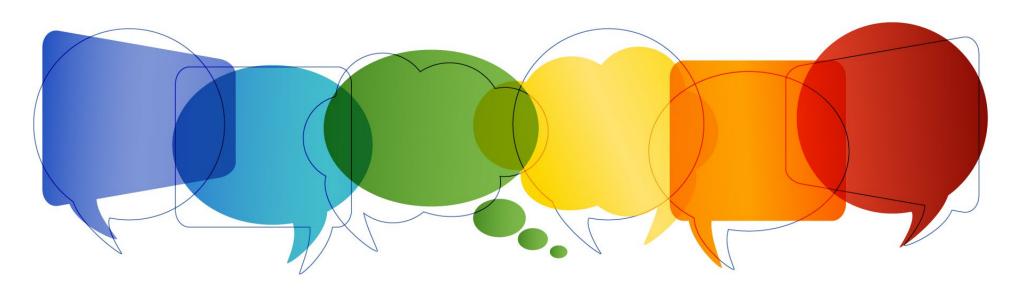
A clear and consistent standard nationally applied and globally interoperable



Our limitations

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





Be part of the conversation

Consultation will be open for comments on the TGA website tga.gov.au/open-consultations-reviews



Questions?

Download a copy of this presentation from the TGA website at tga.gov.au/presentations



Australian Government

Department of Health

Therapeutic Goods Administration