Australian Government
Department of Health
Therapeutic Goods Administration

TGO 106 - Data matrix codes and serialisation of medicines

Consultation paper

Version 1.0, June 2020

TGA Health Safety Regulation

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Introduction

Purpose

The Therapeutic Goods Administration (TGA) is seeking feedback on proposed requirements for the use of data matrix codes on the labels of certain medicines in the Australian supply chain. The proposed requirements are outlined in:

- a draft Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2020, hereafter described as 'the standard'*;* and
- draft Guidance for TGO 106 (Medicines – Standard for Serialisation and Data matrix Codes).

It is proposed that the requirements in the standard must be followed when a data matrix containing a Global Trade Item Number (GTIN) is used on the primary pack[1] of a medicine, or when a medicine is serialised, either at the primary pack or unit dose level. The implementation of TGO 106 is not intended to mandate serialisation, nor the use of data matrix codes on medicines. Instead, it sets out the requirements that are proposed to apply where the medicine sponsor chooses to do either of these.

Where the above conditions are met, the standard stipulates:

- the information that must be encoded
- additional information that can be included
- how this information must be formatted.

Background

Machine readable codes

Most medicines already have a machine readable code on their label and from September 2020 this is compulsory for prescription medicines. Most retailers scan the code at the point of sale when goods are purchased. These codes are used for supply chain management and security.

Types of codes

Machine readable codes include linear barcodes and two-dimensional (2D) codes such data matrix and Quick Response (QR) codes. Linear codes are the familiar sets of parallel lines of different widths and spacings and are currently the most widely used codes on medicines. The GTIN is typically encoded within this barcode and differentiates medicines by their name, active ingredients, strength, dosage, pack size and packaging details. Widespread use of linear barcodes and barcode scanning practices to read GTINs has provided many benefits including efficiencies at point of sale, while their scanning in clinical settings may reduce medication errors.[2]

[1] 'Primary pack' is defined in the *Therapeutic Goods Act (1989)*. It is the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

[2] Barcoding and other scanning technologies to improve medication safety in hospitals: https://www.safetyandquality.gov.au/sites/default/files/migrated/Barcoding-and-other-scanning-technologies-to-improve-medication-safety-in-hospitals.pdf

2D codes are squares or rectangles consisting of many small black and white squares or dots. This format captures more and different types of information within a smaller space than traditional linear barcodes.

Overview of differences between some common codes

	Linear	Data matrix	QR
Example			
Type	One–dimensional (1D) Data is included along the length of the code in one direction	2D Data is included in width and height	2D Data is included in width and height
Benefits	Widespread use and easily read by current scanning equipment	Large data capacity Built-in error correction Easily printed and read at high speed Widespread use in logistic supply chains	Large data capacity Widespread reader technology (e.g. mobile devices)

Benefits of data matrix codes

In addition to the increased data carrying capacity of 2D codes, data matrix codes have built-in error correction providing reliability and readability in situations where the label is damaged or if the pack is irregularly shaped. These codes are easily printed at high production speeds, such as those found in medicine manufacturing environments. For these reasons data matrix codes are internationally recognised as the preferred machine readable code for medicines.

Data matrix codes can be a vehicle for data needed in track and trace systems and electronic health systems. These data can include information about a medicine, beyond the GTIN or product identification. Batch and expiry details provide an additional level of production identification. This information could be scanned and recorded electronically to, for example, assist with managing stock or providing warnings to prevent expired medicines being given to patients.

Further, a serial number can be included to uniquely identify an individual pack of a medicine within a batch, allowing tracking as it moves through the supply chain. Having this level of additional information provides many benefits, including targeted recall processes in the event of a medicine safety problem, improved inventory management and supply chain security.

We need to understand the multiple potential uses of these codes to ensure we develop a standard that is meaningful and fit for purpose. We have explored some of these future possibilities in the context of a mature traceability and electronic health system, in *Better Healthcare – A vision for use of data matrix codes and medicines traceability*.

Why we have developed a standard for serialisation and data matrix codes

Increasingly, the control and exchange of information is a critical part of ensuring the quality, safety and efficacy of medicines. Implementation of requisite data systems is occurring within individual supply chains, as national programs within countries or as part of wider global networks. As of late 2017, Argentina, Brazil, China, Colombia, the European Union (EU), Japan, Mexico, Nigeria, Russia, South Africa, Turkey and the United States of America (USA) either had, or were implementing, systems to track and trace medicines throughout the supply chain.[3] The EU, for example, has implemented safety feature requirements and centralised data repositories to track and trace medicines to ensure medicine authenticity.[4]

Different markets have implemented individualised track and trace systems, responding to local problems and requirements. However, there must be commonality in the fundamental principles underpinning these systems. Without this, there is a risk of introducing a lack of interoperability, meaning the full benefits of medicine traceability cannot be realised across the global medicine supply chain.

While a comprehensive medicines traceability system has not yet been implemented in Australia, it is critical that TGA assists in the development and implementation of robust and consistent systems to allow international trade and facilitate global interoperability. This is particularly important given Australia's reliance on international supply of medicines. The type of information used for identification, and how it is presented, must be agreed on and applied consistently within markets.

To provide a foundation for early adopters in Australia and ensure alignment with medicine regulators overseas, the TGA has drafted a standard for serialisation of medicines using data matrix codes and supporting guidance. Where possible the standard aligns with those already in place overseas. This will provide consistency for sponsors and manufacturers operating in multiple jurisdictions.

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 approves medicines for supply and recall or recover products that are not safe, but does not regulate the flow of information in health systems or the broader diversity of stakeholders in the medicine supply chain. However, we recognise our responsibility to set requirements that ensure consistent use of data matrix codes and support systems relying on the codes.

Draft standard

When the standard will apply

The standard applies to medicines supplied in Australia and makes requirement for them when:

- a medicine has a data matrix code containing a GTIN on the primary pack, or
- a medicine is serialised.

[3] Existing technologies and 'track and trace' models in use and to be developed by [WHO] member states: https://www.who.int/medicines/regulation/ssffc/mechanism/country-experience-table_updated-nov2017.pdf?ua=1

[4] Falsified medicines: overview: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/falsified-medicines-overview

Some medicines will be exempt from the standard. This includes medicines exported from Australia, medicines supplied under the Special Access Scheme and some blood product medicines that are already required to have a data matrix code under the National Blood Agreement.[5]

Data that must be encoded

To keep the standard in line with local and international requirements, including those set by the National Blood Authority in Australia for blood and blood products[6], we have identified the four mandatory elements that must be encoded in a data matrix code on the primary pack if the standard applies:

1. GTIN
2. Batch or lot number
3. Expiry date of the medicine
4. Serial number.

Data matrix presentation

The data matrix code must be formatted in accordance with the GS1 General Specifications requirements (as a DataMatrix). It should also be located in a position to minimise inadvertent reading of other codes and be machine-readable for the shelf life of the product.

The code, when printed on a primary pack, must be transcribed in a human-readable format so a user is able to interpret the data without knowledge of the relevant code standard. Where practical, this information should be located adjacent to the code.

Using codes on multiple levels of packaging

To allow accurate identification of medicines, consistent information is required across multiple levels of packaging – from the container (unit dose) to primary pack, and through to aggregated primary packs in transport. [7]

Implementation

Introduction of the standard will ensure that data matrix codes will be applied consistently, allowing technology solutions and policies to be developed and implemented.

To allow sufficient time for sponsors and manufacturers to make any necessary changes, a delayed commencement of 12 months will apply.

There will be no requirement to replace linear barcodes on labels.

[5] National Blood Authority Barcode Specifications: https://www.blood.gov.au/barcoding
[6] Barcode specifications for blood and blood products funded under the National Blood Arrangements: https://www.blood.gov.au/system/files/documents/Barcode%20specification%20for%20blood%20and%20blood%20products%20funded%20under%20the%20national%20blood%20arrangements.pdf
[7] Discussion paper on aggregation in the pharmaceutical supply chain: https://www.gs1.org/docs/healthcare/Publications_position-papers/201905.Discussion-paper-on-aggregation-in-pharmaceutical-supply-chain.pdf

Consultation questions and next steps

Our aim is to provide a standard that is meaningful and fit for purpose, which accommodates early adopters in Australia, and provides consistency and clarity to stakeholders.

We are seeking feedback on the suitability and potential impact of the proposed standard and its supporting guidance. Submissions must be relevant to the draft standard for data matrix codes on medicines and must be received by the closing date.

Questions

1. Do you think the requirements set out in the draft standard are clear and easy to understand?
2. Do you think the draft standard applies to the right medicines? Should there be other exemptions?
3. Do you think the requirements in the draft standard are suitable?
4. For medicines that are already serialised, or utilise data matrix codes, do you think the delayed commencement period is adequate?
5. Do you think anything is missing from the draft standard?
6. Do you think the guidance is clear and easy to understand?
7. Is there anything you would like to be included in the guidance?
8. Data matrix codes that contain a GTIN must follow the standard. Implementation of the standard will mean that if you use data matrix codes with a GTIN on the primary pack of a medicine, you must follow the standard and include serialisation. Will this affect your business? Tell us how
9. Implementation of the standard will mean that if you serialise your medicines you must use a data matrix that conforms to the standard. Will this affect your business? Tell us how

To provide your feedback follow the link on the consultation page to complete the online survey.

All feedback will be considered after the consultation period ends and will be published on the TGA website with your consent.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Scientific Evaluation Branch	June 2020

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