Technical Alert

TGO 106: New standard for medicines serialisation and data matrix codes

The TGA has introduced a new standard for **serialisation** of medicines and use of **data matrix codes**, the TGO 106 - *Therapeutic Goods (Medicines - Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021*.

Important notes on if and when the standard applies:

- TGO 106 does not mandate the use of data matrix codes or serialisation of medicines.
- The TGO 106 sets out mandatory requirements if medicine sponsors choose to serialise medicines or use data matrix codes. The Order is designed to put in place minimum technical requirements to ensure the effectiveness and functionality of serialisation and data matrix codes, where sponsors intend to use such technology for medicines supplied in Australia.

  Medicines **released from supply from 1 January 2023** must comply with the requirements of TGO 106 if they:

  - are serialised
  - include a data matrix code that encodes the Global Trade Item Number (GTIN).

Medicine serialisation is the unique identification of each unit of a medicine, allowing a unit to be identified distinctly within its batch. This typically is achieved by applying a serial number to the unit.

A data matrix code is a type of two-dimensional code that can be read by a 2D scanner. It is a small square or rectangle with two solid edges, two dotted edges and pixelated light and dark areas within the matrix. There are no shapes within the matrix. This format captures more and different types of information within a smaller space than traditional linear barcodes.

The *Therapeutic Goods (Medicines - Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021*, commences on **1 January 2023** and provides clarity for adopters of serialisation and data matrix codes on medicines supplied in Australia and is accompanied by TGA guidance: Standard for serialisation and data matrix codes on medicines.

The implementation of this standard follows public consultation in July 2020, after which the proposed standard received support for providing consistent regulatory requirements which align with international standards. Feedback received during consultation on the new standard resulted in a number of changes to TGO 106 and the guidance, including:

- Extending the delayed commencement period to allow sufficient time for medicine manufacturers and sponsors to comply with the standard to 1 January 2023.
- Reducing requirements to allow sponsors to use data matrix codes to identify medicines without a serial number where serialisation is not required. Medicines that are not serialised will not need to include additional data elements in a data matrix. These changes help to maintain benefits for scanning in health care settings where appropriate technology exists and assist those gradually implementing data matrix codes.

- Restructuring the standard to streamline and clarify requirements for medicines that are serialised versus medicines that are not serialised but have a data matrix code that contains a GTIN. Medicines that are serialised are subject to the requirements outlined in Section 8, 9 and 10 of TGO 106. Medicines that are not serialised but have a data matrix code that contains a GTIN must comply with Sections 9 and 10.
- Updating the guidance to clarify requirements for the primary pack and the information that needs to be included in a data matrix code. Primary pack has a different meaning to primary packaging, this is explained further in the guidance.

Questions and concerns with the standard or guidance may be addressed to technical@cmaustralia.org.au

What are the requirements?

The Order requires a medicine that is serialised to carry that serialisation in a data matrix code applied to the medicine packaging as outlined in section 8 of the Order.

In addition, a data matrix code containing a Global Trade Item Number ("GTIN") that is on a unit of a medicine (whether or not the medicine is serialised), must comply with the requirements of the Order as set out in sections 9 and 10. For medicines that must comply with TGO 106, a data matrix code must be formatted as a GS1 Data Matrix as set out in the GS1 General Specifications.

These requirements are designed to align, where possible, with current requirements in international jurisdictions such as the European Union, to provide consistency for sponsors and manufacturers operating in multiple jurisdictions and enable global interoperability.

Benefits of data matrix codes

The beneficial features of data matrix codes include:

- large data carrying capacity
- built-in error correction providing reliability and readability in situations where the label is damaged or if the pack is irregularly shaped
- easily printed at high production speeds, such as those found in medicine manufacturing environments.
- Data matrix codes can be a vehicle for data needed in electronic health systems and 'track and trace' systems.

What is the difference between a data matrix code and other codes?

QR codes are another type of two-dimensional code with some similarities in appearance to data matrix codes. However, unlike data matrix codes, QR codes have large squares in the corners of the code.

Data matrix QR code Linear barcode

Resources

- *Therapeutic Goods (Medicines - Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021*
- TGA guidance: Standard for serialisation and data matrix codes on medicines
- TGA Web page: New standard for serialisation and data matrix codes on medicines
- TGA Web page: Serialisation and data matrix codes on medicines
- TGA Web page: Medicine packaging definitions for sponsors
- TGA Consultation on the new Therapeutic Goods Order 106 - Data matrix codes and serialisation of medicines
- Complementary Medicines Australia submission to the Consultation on the new Therapeutic Goods Order 106 - Data matrix codes and serialisation of medicines