Australian Government
Department of Health
Therapeutic Goods Administration

# Guidance for TGO 106

## Medicines—Standard for Serialisation and Data Matrix Codes

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TGA Health Safety Regulation

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# Contents

# Introduction

## How to use this guidance

This guidance provides details and context to *Therapeutic Goods (Medicines – Standard for Serialisation and Data Matrix Codes)(TGO 106) Order 2020*, hereafter known as 'the Order'.

### Terminology

A **machine-readable code** is data encoded into a format that can be read by an electronic device. Examples include linear barcodes, 2D-barcodes (such as QR codes, Aztec and data matrix codes) and radio-frequency identification (RFID) tags.


RFID tag | Linear barcode | QR code | Aztec Code | Data matrix

**Figure 1: Examples of machine-readable codes**

A **data matrix code** is a type of two-dimensional code that can be read by a 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. For the purposes of the Order and this guidance, QR codes are not considered data matrix codes.

A **DataMatrix** is data matrix code formatted in accordance with the **GS1 General Specifications**.[1]

GTIN: 01234567890000
LOT: XC2312
EXP: 31/01/2020
S/N: 555643225C

**Figure 2: DataMatrix encoding four data elements**

**GTIN** is a Global Item Trade Number, a number unique to the product and issued by GS1.

A **serialised medicine** is one where each unit bears a unique identifier, allowing the unit to be identified distinctly within its batch. This typically is achieved through a serial number applied to the unit. The combination of product number (GTIN) and serial number creates a globally unique character chain for the unit.

**Primary Pack** has the same meaning as in the Act. Note that a primary pack is distinct from *primary packaging*. Primary packaging, as used in GS1 and GMP guidance, is the packaging which directly contacts the medicine (injection vial, tablet blister etc). The Act refers to this as the

[1] GS1 General Specifications https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

*container.* The primary pack as defined in the Act is usually *secondary packaging* in GS1 and GMP guidance. Sometimes the primary pack is also primary packaging, such as a bottle of fish oil capsules with no further packaging.

# Using the Order

## Medicines that must comply with the Order

All medicines supplied in Australia that include a data matrix code on their primary pack or are serialised must comply with the requirements of the Order.

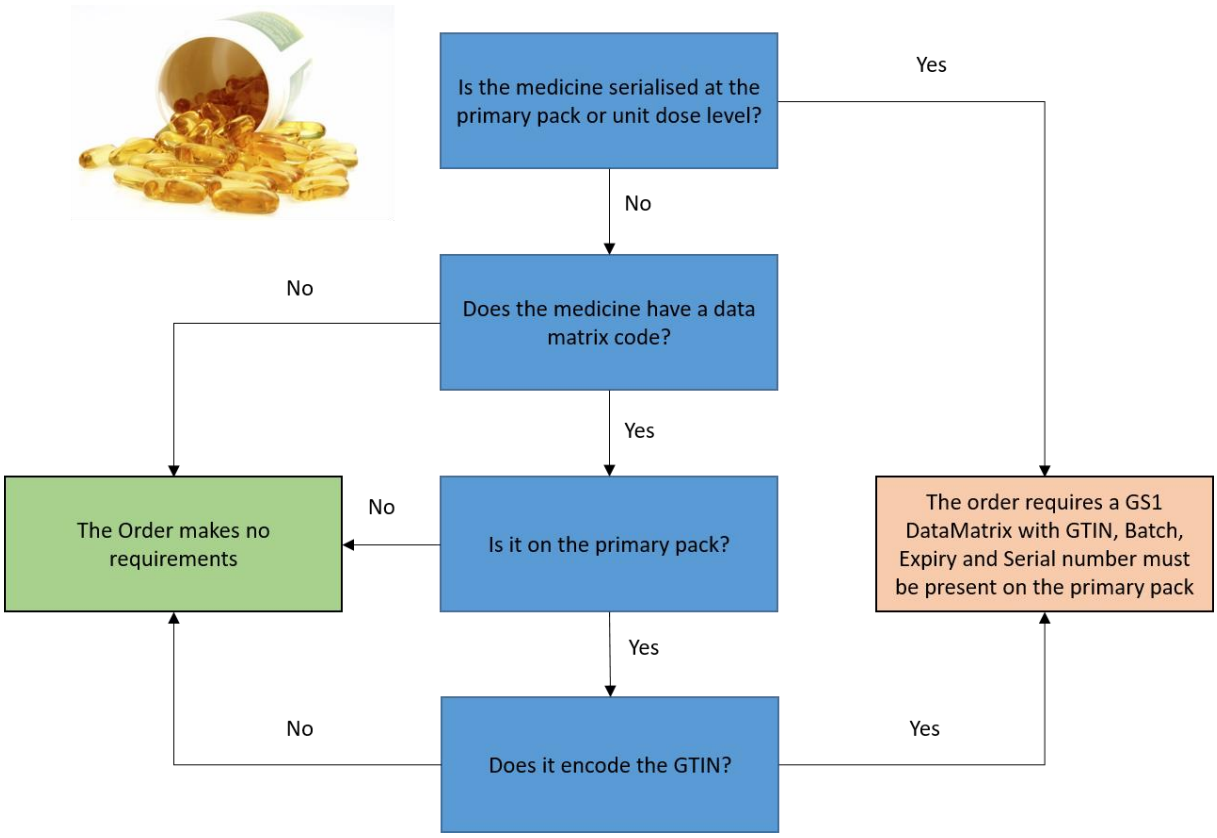
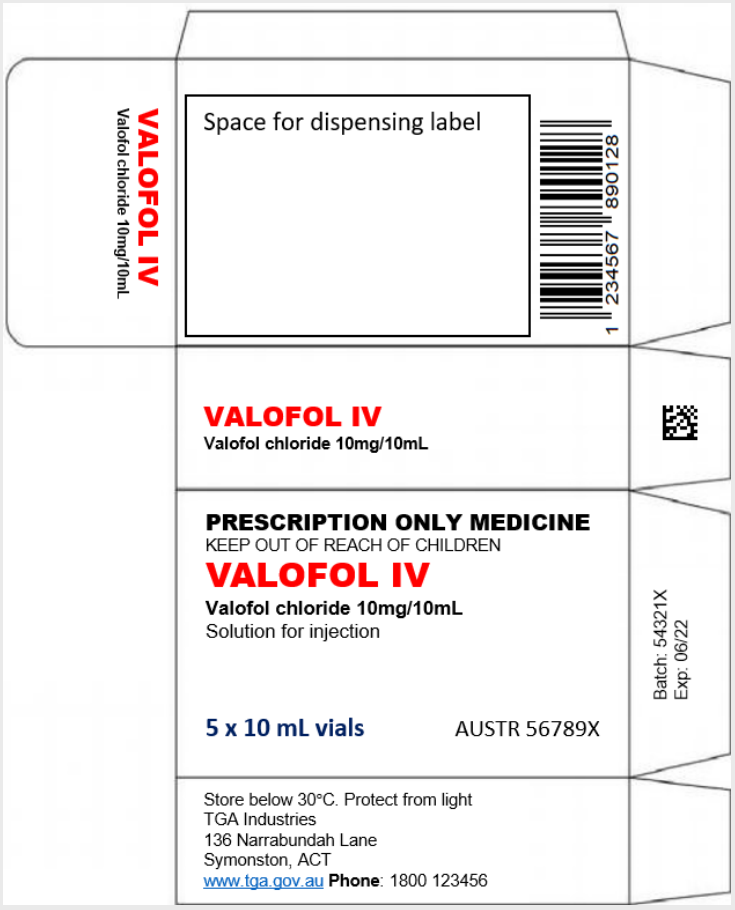



**Figure 3 - When requirements of the Order apply**

Data matrix codes present on a medicine's primary pack that do not encode the medicine's GTIN do not have to comply with the standard. That is, they can be in any format and a human-readable transcription is not required.

**Example – no changes required**




This primary pack label contains a linear bar code encoding the GTIN and a data matrix code on a flap. The data matrix encodes a reference number for the label which is common to all labels for the product and is not unique to the pack. It does not encode the medicine's GTIN.

As the pack is not serialised and the data matrix does not encode the GTIN, no changes to the packaging are required under this order.

# Medicines that are not subject to the Order

## Export only medicines

Export-only medicines are not subject to the order.

## Medicines which are the subject of an approval under section 19/A of the Act

Medicines supplied with an approval under section 19 or 19A of the Act include medicines for clinical trials, those supplied under the special access scheme, or are supplied due to unavailability or shortage of registered medicines. The Order does not apply to these medicines.

## Blood or blood products

Medicines that are subject to the national blood arrangements are required to bear a GS1 DataMatrix and/or ISBT 128 barcode.[2] Where the barcoding requirements of the National Blood Agreement are met, this Order is considered to be complied with.

If the National Blood Agreement ceases to prescribe barcoding requirements, this Order then applies in full to those medicines.

[2] National Blood arrangements https:/www.blood.gov.au/barcoding

# Requirements of the Order

## Application of the data matrix code

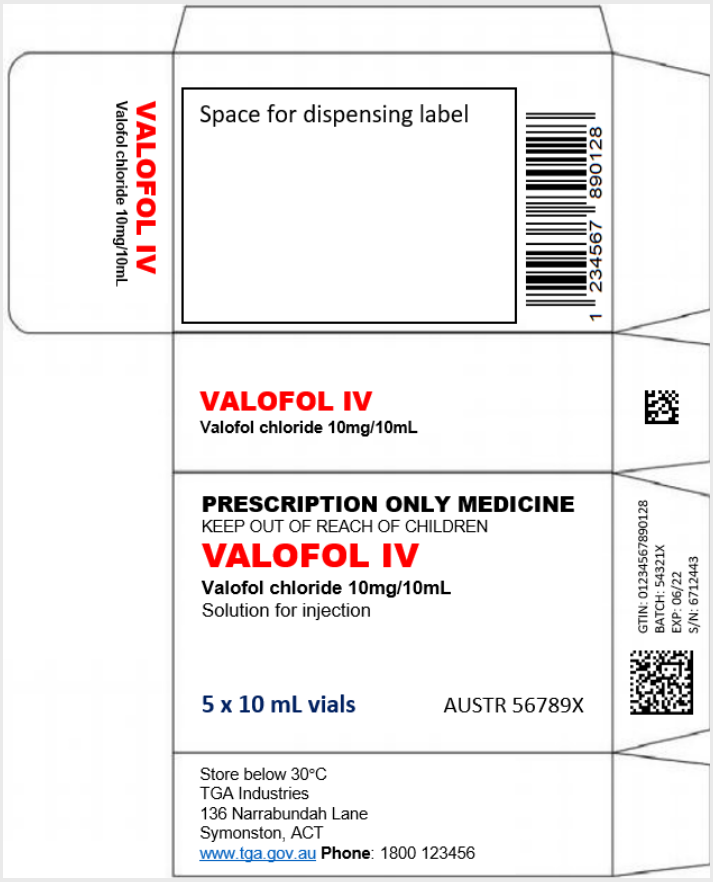
Where a medicine is serialised this must be represented by a serial number encoded into a data matrix that complies with the GS1 General Specifications for a DataMatrix. No other method of serialising complies with the standard.

If any unit within a batch is serialised, the entire batch must be serialised using a DataMatrix. Batches cannot be partially serialised.

The GTIN and serial number should combine to afford a globally unique number for the unit. Consideration should be given to ensure that serial numbers are not re-used for a particular GTIN to ensure no risk of two items with these same numbers.

Multiple machine readable codes may be present on the label. However machine-readable codes should be physically distanced from each other to minimise the risk of inadvertent reading of the wrong code. In the case of primary packs, this may include printing the DataMatrix on a side of the pack devoid of other machine-readable codes.

**Example – Compliant serialised label**




This medicine is serialised so must have a data matrix to carry that information. A second data matrix is now present and formatted to GS1 specifications. It contains the GTIN, batch, expiry and serial number.

The code must be machine-readable for the life of the product. Where a code is smudged, faded or otherwise unreadable, the medicine does not comply with the standard. Consideration should be given to whether machine-readability should be measured in medicine stability studies.

### Serial Numbers

GS1 specifications limit the serial number to 20 alphanumeric characters.

In addition, a minimum of four alphanumeric characters is required in a serial number. This ensures the chance of a serial number being guessed is not more than 1 in 10000 and aligns with EU requirements for serial numbers on medicines.

It is recommended that serial numbers contain only numerical digits.

## Labelling of logistic units

Where serialised units are packed into shippers, pallets etc. the machine-readable codes on these logistic units must allow the serialised contents to be identified. This allows every serialised unit to be accounted for in the time and place that each time the logistic unit is scanned.

## Data matrix code on a primary pack

A data matrix on a primary pack label which encodes a GTIN must be formatted in accordance with the GS1 General Specification for a DataMatrix. This ensures a single, globally recognised format for the data encoded in the matrix.

A data matrix code encoding a GTIN on the primary pack must, as shown in Figure 2, also encode:

a. the batch or lot number;

b. the expiry date of the medicine; and

c. the serial number.

This does not limit the content of the DataMatrix and other information, such as the manufacturing date, may be included at the sponsor's discretion, in accordance with the GS1 General Specifications.

### Linear barcodes

A DataMatrix must not replace a linear barcode encoding a GTIN on the primary pack, although both may be present. If a linear barcode is printed on a container label (e.g. injection vial) this may be replaced by a DataMatrix at the sponsor's discretion.

### Human readability

The information contained in a DataMatrix should be transcribed on the label in human-readable format as prescribed by the GS1 specifications. In addition to the General Specifications, the human-readable information should be presented such that no knowledge of GS1 formatting is required for the information to be understood.

**Example: Human readability**

In this DataMatrix the human-readable data accurately reflects the encoded data, which includes the GTIN, expiry, batch and serial number. However this is essentially meaningless to anyone unfamiliar with GS1 DataMatrix formatting.

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

Below, the same barcode with human-readable information presented to allow the data to be readily understood.

GTIN: 01234567890000
LOT: XC2312
EXP: 31/01/2020
S/N: 555643225C

Parenthesised prefixes have been replaced with abbreviations. Each field is on a separate line and the expiry date has been formatted for easy interpretation.

## Information in a data matrix code

The information in the DataMatrix must agree with all machine-readable and human readable information on the label as well as any relevant content of the Product Information or Consumer Medicine Information. If, for example the expiry date encoded in the DataMatrix does not agree with the human-readable expiry on the label, the medicine is not compliant with the standard.

A DataMatrix may be formatted to retrieve (look up) data from a remote location. This may allow other material such as the medicine's Product Information (PI) or Consumer Medicines Information (CMI) to be accessed via a remote database. Where this capability is applied, the documents accessed must be the current and/or approved versions of those documents.

## Multiple machine-readable codes

Medicines may include more than one machine readable code on their packaging. Some of the reasons that multiple machine readable codes may be present on the same package include:

- transitioning to 2D GS1 DataMatrix codes but still requiring linear EAN barcodes to support existing technology
- regulatory requirement for a code from the country of manufacture
- the label contains a QR code for customer or healthcare practitioner reference.

Where multiple GS1-formatted machine-readable codes are printed on a medicine package, all codes must encode the same Global Trade Item Number (GTIN).

**Example – Label with multiple codes**

The QR code on this label does not contain a unique identifier for the pack so no further action is required.


However if the QR code contains a serial number or other method of uniquely identifying the unit within the batch, a DataMatrix would be required.


The DataMatrix contains the GTIN, batch, expiry and serial number. The data in the data matrix must also concur fully with the other machine-readable codes on the label.

The QR code remains but has been moved to reduce the risk of it being scanned unintentionally when the DataMatrix is read.

## QR Codes

QR codes are permitted to be present on the same labelling as a data matrix code and may contain the same information as the data matrix code, some of same information, or none of it. However if the QR code contains a number or link that is unique to the unit of medicine it is printed on, the unit is considered to be serialised and a DataMatrix must be printed containing the serial number.

**Example: When a machine-readable code necessitates a DataMatrix**

This QR code contains a URL http://www.tga.gov.au/consultations and separately the GTIN. All QR codes on all labels are the same. This does not require the medicine to have a DataMatrix.

This QR code contains the URL www.tga.gov.au/id=1234567890000&sn=5383593 which is unique to the unit. The product is therefore serialised and the serial number must be encoded in a DataMatrix as defined by the order.

# Prohibition against advertising

A data matrix and the information it encodes may not be used to advertise, nor link to advertising or otherwise be used for promotional purposes. This does not apply to other machine-readable codes which may be used for promotional purposes in accordance with the Act and The Therapeutic Goods Advertising Code.

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Scientific Evaluation Branch | draft |

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Reference/Publication #