



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

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

Dated 24 March 2021

Dr Jane Cook  
First Assistant Secretary  
Medicines Regulation Division  
Health Products Regulation Group  
Department of Health

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## Part 1—Preliminary

### 1 Name

- (1) This instrument is the *Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021*.
- (2) This instrument may also be cited as TGO 106.

### 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 January 2023.	1 January 2023

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

### 3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

### 4 Definitions

- Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:
- (a) batch;
  - (b) container;
  - (c) export only medicine;
  - (d) label;
  - (e) medicine;
  - (f) primary pack;
  - (g) product information;
  - (h) standard.

In this instrument:

*Act* means the *Therapeutic Goods Act 1989*.

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**Barcode Specifications** means the document titled *Barcode specifications for blood and blood products funded under the National Blood Arrangements* published by the National Blood Authority (5 September 2014), as in force or existing at the commencement of this instrument.

Note: This document is available on the internet at [www.blood.gov.au](http://www.blood.gov.au).

**data matrix code** means a two-dimensional arrangement of data consisting of blocks or dots in a square or rectangular pattern but does not include a QR code.

**GS1** means the not-for-profit standards organisation known as GS1 that has its headquarters in Belgium.

**GS1 General Specifications** means the standard titled *GS1 General Specifications* published by GS1, as in force from time to time.

Note: This standard is available on the internet at [www.gs1.org](http://www.gs1.org).

**GTIN**, or Global Trade Item Number, means the GS1 identification key used to identify trade items as defined in the GS1 General Specifications.

Note: A GTIN comprises a GS1 company prefix, an item reference and check digit.

**national blood arrangements** has the same meaning as in the *National Blood Authority Act 2003*.

**Regulations** means the *Therapeutic Goods Regulations 1990*.

**relevant level of packaging**, in relation to a medicine, means one of the following:

- (a) the primary pack;
- (b) the container;
- (c) single unit packaging within a container.

Note 1: **Primary pack** is defined in subsection 3(1) of the Act as meaning the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

Note 2: **Container** is defined in subsection 3(1) of the Act as meaning 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.

Note 3: Single unit packaging within a container includes an individual segment of a strip or blister pack, which immediately covers a single dosage unit, and which can be readily detached.

**serialisation**, in relation to a medicine, means the unique identification of each unit of the medicine in a batch, at a relevant level of packaging.

Note: Other grammatical forms of the word **serialisation** (such as **serialised**) have a corresponding meaning (see section 18A of the *Acts Interpretation Act 1901*).

**serial number** means a number that uniquely identifies a unit of a medicine.

## 5 Standard

This instrument constitutes a standard for medicines in relation to serialisation and the use of data matrix codes.

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## 6 Application

This instrument applies to a medicine, other than a medicine that is:

- (a) an export only medicine; or
- (b) blood or a blood product funded under the national blood arrangements and which is required to implement global barcode standards in accordance with the Barcode Specifications; or
- (c) the subject of an approval or authority under section 19 or section 19A of the Act; or
- (d) mentioned in item 1 of Schedule 5 to the Regulations.

Note: Item 1 of Schedule 5 to the Regulations applies to therapeutic goods that are imported for use in the treatment of the importer or the importer's immediate family in certain circumstances.

## Part 2—Requirements

### 7 General requirements

#### *Requirements for medicines that are serialised*

- (1) The requirements in relation to a medicine that is serialised, other than a medicine mentioned in subsection (2), are those requirements specified in:
  - (a) section 8; and
  - (b) section 9; and
  - (c) section 10.
- (2) The requirements in relation to a medicine that is serialised without the application of a data matrix code, but which has a data matrix code containing a GTIN for a purpose other than serialisation, where the medicine satisfies the circumstance specified in subsection (3), are those requirements specified in:
  - (a) section 9; and
  - (b) section 10.
- (3) For subsection (2), the circumstance is that the medicine is dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person by a person mentioned in column 2 of item 1, 2, 3 or 4 in Schedule 8 to the Regulations.

#### *Requirements for medicines that are not serialised*

- (4) The requirements in relation to a medicine that is not serialised, but which has a data matrix code containing a GTIN applied to a unit of the medicine at a relevant level of packaging, are the requirements specified in:
  - (a) section 9; and
  - (b) section 10.

Note: The requirements in sections 9 and 10 only apply in relation to the units of the medicine that have a data matrix code containing a GTIN applied at a relevant level of packaging.

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## 8 Application of a data matrix code

- (1) A data matrix code containing the GTIN of a medicine and a serial number must be applied to the label of each serialised unit of the medicine.
- (2) Subject to subsection (3), the data elements in the data matrix code mentioned in subsection (1) must, when taken together, uniquely identify each unit of the medicine globally.
- (3) If a data matrix code containing a GTIN is applied to the primary pack of the medicine, then the data matrix code must also contain the following information in relation to a unit of the medicine:
  - (a) the batch number; and
  - (b) the expiry date.

## 9 Formatting etc. of a data matrix code

A data matrix code applied to a unit of the medicine must be:

- (a) formatted in accordance with the requirements applicable to a GS1 DataMatrix as described in the GS1 General Specifications; and
- (b) applied to the label of each unit of the medicine so as to minimise the risk of an inadvertent reading of any other machine-readable code on the label; and
- (c) machine-readable for the shelf life of the medicine.

## 10 Information in a data matrix code

- (1) The information in a data matrix code applied to a unit of the medicine must be consistent with:
  - (a) any human-readable information in or on the packaging, including higher and lower levels of packaging and product information and consumer medicine information in relation to the medicine; and
  - (b) the information in any other machine-readable code present on the label of the goods.
- (2) Any information in a data matrix code to enable access to the product information in relation to the medicine must identify the current, approved version of the product information.
- (3) Any information in a data matrix code to enable access to the consumer medicine information in relation to the medicine must identify the most current version of the consumer medicine information.
- (4) If a data matrix code containing a GTIN is applied to the primary pack of a unit of the medicine, then the information contained within the data matrix code must be transcribed in human-readable format that is:
  - (a) located adjacent to the data matrix code, where space permits, in accordance with the GS1 General Specifications; and
  - (b) in a form that would enable a user to interpret the information without knowledge of the GS1 General Specifications.