Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2020

I, [name], as delegate for the Minister for Health, make the following order.

Dated [day][month][year]

[Name of delegate] **DRAFT ONLY—NOT FOR SIGNATURE**
Department of Health

Contents

Part 1—Preliminary

1 Name

(1) This instrument is the *Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2020*.

(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 July 2021.	1 July 2021

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 10(1) 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) advertise;
(b) container;
(c) export only medicine;
(d) label;
(e) medicine;
(f) primary pack; and
(g) standard.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Barcode Specifications means the *Barcode Specifications for Blood and Blood Products Funded under the National Blood Arrangements* published by the National Blood Authority (5 September 2014).

Note: The Barcode Specifications are available on the internet at 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 'GS1 General Specifications' standard published by GS1 as in force from time to time.

Note: The GS1 General Specifications are available on the internet at www.gs1.org.

GTIN means Global Trade Item Number identifier developed by GS1.

logistic unit, in relation to a medicine, means an item of any composition used for transport or storage of the medicine that needs to be managed through the supply chain, such as cartons and shippers.

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

Regulations means the *Therapeutic Goods Regulations 1990*.

serialisation, in relation to a medicine**,** means the unique identification of a unit of production of the medicine.

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, in relation to a medicine, means the number that uniquely identifies a unit of production of the medicine.

unit of production, in relation to a medicine, means the primary pack, container or unit dose of the medicine.

Note: For the definition of ***container*** and ***primary pack*** see section 3 of the Act.

5 Standard

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

6 Application

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

(a) an export only medicine; or

(b) mentioned in item 1 of Schedule 5 to the Regulations; or

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.

(c) the subject of an approval or authority under section 19 or section 19A of the Act; or

(d) 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.

Part 2—Requirements

7 General requirements

If a medicine:

(a) is serialised; or

(b) has a data matrix code applied to the primary pack which contains a GTIN;

then the medicine must comply with the requirements specified in this Part.

8 Application of data matrix code

(1) A data matrix code must be applied to the label of each serialised unit of production.

(2) A data matrix code must contain a GTIN, batch number and serial number, the combination of which must result in the unit of production being uniquely identifiable at a global level.

(3) A serial number in a data matrix code must consist of at least 4, and not more than 20, alphanumeric characters.

(4) A data matrix code must be formatted in accordance with the requirements applicable to a GS1 DataMatrix as described in the GS1 General Specifications.

(5) A data matrix code must be applied to the label of each unit of production of the medicine so as to minimise the risk of an inadvertent reading of any other machine-readable code on the label.

(6) A data matrix code must be machine-readable for the shelf life of the medicine.

9 Labelling of logistic units

Each logistic unit containing the medicine must be labelled so as to allow the identification of each unit of production of the medicine in the logistic unit.

10 Data matrix code on primary pack

Where a data matrix code containing the GTIN is applied to the primary pack of a medicine:

(a) the data matrix code must contain the following information:

(i) the batch number;

(ii) the expiry date; and

(iii) the serial number;

of the medicine; and

(b) the information contained within the data matrix code must be transcribed in human-readable format that is:

(i) located adjacent to the data matrix code, in accordance with the GS1 General Specifications; and

(ii) in a form that would enable a user to interpret the data without knowledge of the GS1 General Specifications; and

(c) the data matrix code must not take the place of a linear barcode on the primary pack that contains a GTIN.

11 Information in a data matrix code

(1) The information in a data matrix code 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 relating 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 a medicine's product information must identify the current, approved version of the product information in relation to the medicine.

(3) Any information in a data matrix code to enable access to a medicine's consumer medicine information must identify the most current consumer medicine information in relation to the medicine.

12 Prohibition against advertising

A data matrix code containing the GTIN must not be used to advertise or otherwise market a medicine.