EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Department of Health.

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test, or require that the goods be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, consent in writing to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021* ("the Order") is made under section 10 of the Act. The purpose of the Order is to establish a ministerial standard for medicines in relation to serialisation and the use of data matrix codes. The Order specifies the minimum requirements for the formatting of data matrix codes and the information that must be encoded if medicines, other than those that are identified as not being subject to the Order, include a data matrix code on their labels or are serialised.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part (for therapeutic goods other than medical devices) by specifying ministerial standards under section 10 of the Act by reference to a range of matters, including the manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in three international pharmacopoeias defined in the Act.

Most medicines supplied in Australia include a machine-readable code on their label. Machine-readable codes include linear barcodes and two-dimensional ("2D") codes such as data matrix and Quick Response ("QR") codes. Most commonly, medicine labels include a linear barcode with the familiar sets of parallel lines of different widths and spacings. Widespread use of linear barcodes and barcode scanning practices has provided many benefits

including the improvement of efficiencies at the point of sale, and the reduction of medication errors in clinical settings.

A data matrix code is a type of 2D 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. This format captures more information, and different types of information, within a smaller space than traditional linear barcodes. For instance, a serial number can be included to uniquely identify an individual pack of medicine within a batch. In conjunction with a 'track and trace' system, medicine serialisation (this term refers to the unique identification of each unit of a medicine in a batch, at a relevant level of its packaging) allows a medicine to be tracked as it moves through the supply chain. This provides a number of benefits from a safety perspective in relation to medicines, including allowing for better targeted recall processes in the event of a medicine safety problem, and greater visibility of stock quantities and locations, allowing for improved management of potential medicine shortages.

The Order is the first step to assist Australia to align with many international jurisdictions that are implementing traceability systems to more effectively track medicines from their manufacture to administration to better manage risks presented by counterfeit medicines and medicine shortages.

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, without mandating the use of such technology in Australia at this stage. In so doing, the Order will support the safe use and timely availability of medicines in Australia for which such technology is utilised.

The Order applies in relation to medicines that are supplied in Australia, other than the following medicines that are identified as not being subject to the Order:

- export only medicines (that is, those not for supply in Australia);
- blood or blood products funded under the national blood arrangements and which are required to implement global barcode standards in accordance with the *Barcode specifications for blood and blood products funded under the National Blood Arrangements* published by the National Blood Authority (5 September 2014); and
- certain goods that are exempt, or otherwise approved or authorised in relation to the requirement to be registered or listed in the Australian Register of Therapeutic Goods.

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. 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.

Consultation

A draft of the Order and associated guidance and background documents were released for public consultation from 2 July 2020 to 20 August 2020. All peak industry bodies representing prescription medicines, over-the-counter medicines and complementary medicines were notified of the impending consultation, along with relevant professional

associations, representatives of State health authorities and consumer advocacy groups. The draft Order was published on the Department of Health website along with instructions on how to submit comments.

The TGA received 43 submissions in response to the consultation. The proposed standard received support for providing consistent regulatory requirements which align with international standards. Feedback provided by respondents has been taken into consideration in the final drafting of the Order.

A number of pre-consultation activities were also conducted, including a workshop in October 2019 with a broad range of stakeholders including representatives of State health authorities and professional representative bodies, to discuss potential uses and benefits of electronic health systems. These activities informed the development of the draft standard prior to consultation.

Incorporation by reference

The Order adopts the *GS1 General Specifications* for the formatting of data matrix codes as defined in section 4 of the Order. This publication is the foundational standards document of the GS1 system and specifies how identification numbers and barcodes should be used. The Order incorporates this document as in force from time to time, an approach authorised by subsection 10(4) of the Act. This document is published by GS1 and is available for free on the internet at www.gs1.org. It is also expected that most persons affected by the adoption of these specifications (in this case, sponsors and manufacturers of medicines) would be familiar with these specifications.

The Order also refers to the *Barcode specifications for blood and blood products funded under the National Blood Arrangements* ("Barcode Specifications") dated 5 September 2014. This document is published by the National Blood Authority, and sets out requirements for barcode standards in relation to procurements for blood and blood products funded under the national blood arrangements (as defined in the *National Blood Authority Act 2003*). The Order incorporates this document as it is in force or existing at the commencement of the Order. This document is available for free on the internet at https://www.blood.gov.au/barcoding.

Details of the Order are set out in **Attachment A**.

The Order is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Order is a disallowable legislative instrument and commences on 1 January 2023.

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

Part 1—Preliminary

This Part provides for the name of the Order, its commencement, authority and application, and a small number of other matters including, for example, setting out definitions for key terms used in the Order.

Section 1 Name

This section provides that the name of the Order is the *Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021*, and that it may also be cited as TGO 106.

Section 2 Commencement

This section provides that the Order commences on 1 January 2023.

Section 3 Authority

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 Definitions

This section sets out definitions for a number of terms used in the Order. In particular, these include 'data matrix code', 'relevant level of packaging', 'serialisation' and 'serial number'.

This section also makes it clear that a number of terms have the same meaning as given in subsection 3(1) of the Act, for example 'medicine' and 'primary pack'.

Section 5 Standard

This section provides that the Order constitutes a standard for medicines in relation to serialisation and the use of data matrix codes.

Section 6 Application

This section provides that the Order applies to therapeutic goods that are medicines. This section also makes it clear that the Order does not apply to the medicines identified in paragraphs 6(a) to (d) including, for example, export only medicines, and blood and blood products funded under the national blood arrangements and which are required to implement global barcode standards in accordance with the Barcode Specifications.

Part 2—Requirements

This Part sets out requirements for medicines in relation to serialisation and data matrix codes.

Section 7 General requirements

Subsection (1) of this section provides that if a medicine is serialised, other than a medicine mentioned in subsection (2), it must comply with the requirements specified in sections 8, 9 and 10. Under subsection (2), a medicine that is serialised without the application of a data matrix code, but which has a data matrix code containing a Global Trade Item Number ("GTIN") applied for another purpose, and which satisfies the circumstance set out in subsection (3), must only comply with the requirements in sections 9 and 10.

Subsection (4) of this section provides that a medicine that is not serialised, but which has a data matrix code that contains a GTIN applied to a unit of the medicine at a relevant level of packaging, must comply with the requirements specified in sections 9 and 10.

Section 8 Application of a data matrix code

This section sets out specific requirements for applying a data matrix code when a medicine is serialised.

Section 9 Formatting etc. of a data matrix code

This section sets out requirements for formatting, placement and durability of a data matrix code applied to a unit of medicine.

Section 10 Information in a data matrix code

This section sets out the specific requirements for information in a data matrix code that is applied to a unit of medicine.

Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021* ("the instrument") is made by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989*.

The purpose of the instrument is to establish a ministerial standard for medicines that specifies minimum requirements for serialisation and data matrix codes, other than those medicines that are identified as not being subject to the instrument.

The instrument principally requires medicines that are serialised (other than those mentioned in subsection 7(2)), to carry that serialisation in a data matrix code applied to the medicine packaging in accordance with requirements specified in section 8 of the instrument. 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 sections 9 and 10 of the instrument in relation to formatting and information requirements.

A small number of therapeutic goods that are medicines are identified as not being subject to the instrument. These are:

- export only medicines (that is, those not for supply in Australia);
- blood or blood products funded under the national blood arrangements and that are required to implement global barcode standards in accordance with the *Barcode specifications for blood and blood products funded under the National Blood Arrangements* published by the National Blood Authority (5 September 2014); and
- certain goods that are exempt, or otherwise approved or authorised in relation to the requirement to be registered or listed in the Australian Register of Therapeutic Goods.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR"). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000),* the United Nations Committee on Economic, Social and Cultural Rights states that health is a '*fundamental human right indispensable for the exercise of other human rights*', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by helping to ensure the quality and safety of therapeutic goods that are medicines through accurate and consistent electronic identification within electronic health systems.

The instrument is designed to put in place minimum 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, but without mandating the use of such technology in Australia at this stage. In so doing, the instrument will support the safe use and timely availability of medicines in Australia for which such technology is utilised.

The format of data matrix codes specified under the instrument captures more information, and different types of information, within a smaller space than traditional linear barcodes. In conjunction with a 'track and trace' system, medicine serialisation allows a medicine to be tracked as it moves through the supply chain, which provides a number of benefits from a safety perspective, including allowing for better targeted recall processes in the event of a medicine safety problem, and greater visibility of stock quantities and locations, allowing for improved management of potential medicine shortages, and also risks presented by counterfeit medicines.

The requirements of the instrument are further bolstered in this regard by the criminal, civil and regulatory sanctions that may apply under the Act for persons who import, supply or export therapeutic goods that do not comply with applicable standards.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.