NOTIFICATION

Addendum

The following communication, dated 1 April 2021, is being circulated at the request of the delegation of Australia.

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**Title:** Proposed new standard for medicine serialisation and data matrix codes - Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021

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| **Reason for Addendum:** | |
| [  ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 24 March 2021; The title has been amended to: "Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021" to reflect the date of adoption. |
| [X] | Notified measure published - date: 25 March 2021 |
| [X] | Notified measure enters into force - date: 1 January 2023 |
| [X] | Text of final measure available from[[1]](#footnote-1):  <https://www.legislation.gov.au/Series/F2021L00333> |
| [  ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [  ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [X] | Interpretive guidance issued and text available from1:  <https://www.tga.gov.au/resource/standard-serialisation-and-data-matrix-codes-medicines> |
| [  ] | Other: |

**Description:** In March 2021, a new standard, Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021 was registered on the Federal Register of Legislation. The standard commences on 1 January 2023.

TGO 106 does not mandate medicine serialisation or the application of data matrix codes to medicines, but sets out the technical requirements if the medicine sponsor implements either of these.

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

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

TGO 106 defines the requirements for the presentation and content of data matrix codes including human readability requirements and relationship with other machine readable codes. The requirements include:

* Where a medicine is serialised this must be represented by a serial number encoded into a data matrix code that complies with the GS1 General Specifications for a DataMatrix.
* If a data matrix code containing a GTIN is applied to a unit of a medicine, this must be formatted as a GS1 DataMatrix that complies with the GS1 General Specifications.

TGO 106 does not set out any requirements regarding reporting, storage and verification of serialisation data.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)