NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Australia **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Therapeutic Goods Administration, Department of Health**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Department of Foreign Affairs and Trade Email: tbt.enquiry@dfat.gov.au |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicines; PHARMACEUTICAL PRODUCTS (HS 30) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposed new standard for medicine serialisation and data matrix codes - Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2020 |
| **6.** | **Description of content:** The Therapeutic Goods Administration (TGA) is proposing a new standard to outline requirements for medicine serialisation and the application of data matrix codes to the labels of certain medicines supplied in Australia. The introduction of the standard is not intended to mandate the use of data matrix codes or serialisation. Instead, it sets out the technical requirements where the medicine sponsor chooses to implement either of these. The purpose of the standard is to give clarity and certainty for adopters of data matrix codes and serialisation of medicines supplied in Australia. It is the first step in establishing requirements that support all systems relying on the codes. The requirements align, where possible, with global standards to provide consistency for sponsors and manufacturers operating in multiple jurisdictions and to ensure global interoperability. Australia does not currently have the infrastructure to facilitate medicine tracking. The introduction of the new standard will occur independently from the broader considerations needed before Australia determines which track and trace system is appropriate for our medicine supply chain. A public consultation on the draft standard was open from July to August 2020. Respondents provided a range of suggestions to improve the new standard and associated guidance, with many supporting the implementation of a standard to provide consistent regulatory requirements which align with international standards. The draft standard and consultation documents are available at <https://consultations.health.gov.au/medicines-regulation-division/consultation-tgo106-data-matrix-codes-on-medicines/>.The TGA is reviewing all the submissions received and will make changes to the draft standard and guidance in consideration of this feedback. It is planned that the updated standard will be implemented in January 2021, with a delayed commencement period (up to 2 years) to allow sufficient time for sponsors currently applying data matrix codes and/or serialising to comply with the standard. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the new standard are to: * provide clarity on technical requirements for adopters of data matrix codes and medicine serialisation
* provide a foundation to support all systems relying on the codes
* provide consistency for sponsors and manufacturers operating in multiple jurisdictions and to ensure global interoperability.

; Consumer information, labelling; Harmonization |
| **8.** | **Relevant documents:** The proposed standard and consultation documents are available here: <https://consultations.health.gov.au/medicines-regulation-division/consultation-tgo106-data-matrix-codes-on-medicines/>. The proposed standard will be updated in consideration of the consultation feedback before it is implemented. |
| **9.** | **Proposed date of adoption:** January 2021**Proposed date of entry into force:** An updated version of the standard is likely to be implemented in January 2021 with a delayed commencement period (up to 2 years). |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** The proposed standard and consultation documents are available here: <https://consultations.health.gov.au/medicines-regulation-division/consultation-tgo106-data-matrix-codes-on-medicines/>.<https://consultations.health.gov.au/medicines-regulation-division/consultation-tgo106-data-matrix-codes-on-medicines/> |