NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **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 and Aged Care  **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:**  Australian TBT Enquiry Point  Department of Foreign Affairs and Trade  Canberra ACT 0221  Phone: +61 2 6261 1111  Email: [tbt.enquiry@dfat.gov.au](mailto:tbt.enquiry@dfat.gov.au)  [www.dfat.gov.au](http://www.dfat.gov.au) |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicines |
| **5.** | **Title, number of pages and language(s) of the notified document:** Updates to medicine labelling rules: Public consultation on proposed changes to TGO 91 and TGO 92 to support medicine safety; (54 page(s), in English) |
| **6.** | **Description of content:** The [Therapeutic Goods Administration](https://www.tga.gov.au/) (TGA) is Australia's regulatory authority for therapeutic goods. There are provisions under the [*Therapeutic Goods Act 1989*](https://www.legislation.gov.au/C2004A03952/latest/versions) to establish quality standards for therapeutic goods. These standards, known as Therapeutic Goods Orders (TGOs), can specify particular labelling, packaging or other requirements. Once approved, TGOs are registered as legislative instruments on the Federal Register of Legislation in Australia.  To support the safe use of medicines, the TGA is proposing to update labelling requirements in the following TGOs:   * [Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines](https://www.legislation.gov.au/Series/F2016L01285) (TGO 91) * [Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines](https://www.legislation.gov.au/Series/F2016L01287) (TGO 92).   The TGA is conducting a [public consultation](https://consultations.tga.gov.au/medicines-regulation-division/updates-to-australian-medicines-labelling-rules/) between 30 May and 11 July 2024 to seek feedback on proposed changes to TGO 91 and TGO 92 to address 3 medicines safety related matters. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Medicine labels communicate information to health professionals and consumers that is critical to support the correct and safe use of medicines. If it is difficult to identify medicines, or to locate and understand critical information, then medication errors are more likely to occur.  Certain aspects of the labelling requirements in TGO 91 and TGO 92 need improvements to help make sure medicines are used correctly and safely.  The TGA is seeking feedback to help make sure the proposed updates to TGO 91 and TGO 92 support medicine safety.  The objectives of the proposed updates to TGO 91 and TGO 92 are to:   * Make sure that quantities of active ingredients in injectable medicines intended for electrolyte replacement are clearly expressed in units important to health professionals. * For medicines for injection administered by healthcare professionals that need some preparation before use, make sure that clear instructions on how to prepare and store these products is available to health professionals in the appropriate format. This is to support recent [changes to the Product Information (PI) as a package insert for injectable products](https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg/product-information/changes-product-information-pi-package-insert-injectable-products). We are particularly seeking feedback from health professionals on an option of allowing a QR code to link to electronic information instead of a separate package insert where preparation information cannot fit on the label. * Improve information on [listed medicine](https://www.tga.gov.au/products/medicines/non-prescription-medicines/listed-medicines) labels about large solid oral dosage forms intended to be swallowed whole. This is because the TGA continues to receive reports of serious choking related adverse events.   ; Consumer information, labelling; Protection of human health or safety |
| **8.** | **Relevant documents:**  The consultation paper is available at <https://consultations.tga.gov.au/medicines-regulation-division/updates-to-australian-medicines-labelling-rules>. This document outlines the proposed changes to TGO 91 and TGO 92 in 3 parts. |
| **9.** | **Proposed date of adoption:** The TGA is planning to implement changes to TGO 91 and TGO 92 in 2024 after consideration of feedback received during the public consultation.  **Proposed date of entry into force:** To be determined We are proposing a 2-year transition period to allow medicines sponsors time to update labels to comply with the proposed new rules for:  • expressing quantities of active ingredients in injectable medicines intended for electrolyte replacement (with a volume of 100 mL or less)  • improving information on listed medicine labels about large solid oral dosage forms intended to be swallowed whole.  We welcome feedback in the public consultation about timeframes for the adoption of proposals and proposed transition periods. |
| **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 consultation paper is available at <https://consultations.tga.gov.au/medicines-regulation-division/updates-to-australian-medicines-labelling-rules>.  <https://consultations.tga.gov.au/medicines-regulation-division/updates-to-australian-medicines-labelling-rules/user_uploads/consultation-paper---updates-to-medicine-labelling-rules---public-consultation-on-proposed-changes-to-tgo-91-and-tgo-92-to-support-medicine-safety---may-2024-1.pdf> |