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](mailto: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):** Nicotine‑containing products intended to be used in vaping devices such as e-cigarettes, e-cigars and other electronic nicotine delivery systems (ENDs).; TOBACCO AND MANUFACTURED TOBACCO SUBSTITUTES (HS 24); PHARMACEUTICAL PRODUCTS (HS 30) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposed new standard for unapproved vaporiser nicotine products - Therapeutic Goods (Standard for Vaporiser Nicotine) (TGO 110) Order 2021. |
| **6.** | **Description of content:** The Therapeutic Goods Administration (TGA) is seeking comments on a proposed standard for vaporiser nicotine products.  Vaporiser nicotine products are nicotine-containing products intended to be used in vaping devices such as e-cigarettes, e-cigars and other electronic nicotine delivery systems (ENDs). This includes vape liquids, e-liquids and e-juices that contain nicotine and/or nicotine salts. This does not include other nicotine replacement therapies (NRTs) containing nicotine, such as patches, gum, lozenges, mouth spray and inhalators nor nicotine-containing products that are not intended for use in ENDs, such as chewing tobacco and snuff.  The proposed standard relates only to unapproved goods – that is, medicines that have not been approved by the TGA and are not registered in the Australian Register of Therapeutic Goods (ARTG). While it is anticipated that a number of vaporiser nicotine products may seek approval by the TGA as medicines in the coming years, it is also anticipated that there will be a significant number of prescriptions written for unapproved goods for smoking cessation.  The proposed standard is in the form of a Therapeutic Goods Order (a TGO) and would be TGO 110. TGOs are legal standards made under section 10 of the *Therapeutic Goods Act 1989* (Act) which specify safety and quality rules for medicines imported into, exported from or supplied in Australia. TGOs can apply to approved or unapproved products, or both, and may be limited to a certain type of medicine. TGOs cannot specify requirements for vaping devices.  The public consultation on the Therapeutic Goods (Standard for Vaporiser Nicotine) (TGO 110) Order 2021 (draft TGO 110) is open until 31 March 2021, available via the link in section 8 below. We will review all feedback received and, if appropriate, revise the requirements in the draft TGO 110 before it is finalised. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the new standard are to:   * Assist in meeting the need for health practitioners and individuals to know what is in the product the person is inhaling for smoking cessation. * Minimise the risk of accidental exposure to and/or ingestion of vaporiser nicotine products, particularly by young children. * Provide clarity for sponsors and manufacturers operating in multiple jurisdictions as to the minimum safety and quality requirements in Australia.   Consumer information, labelling; Protection of human health or safety; Quality requirements; Harmonization |
| **8.** | **Relevant documents:**   * The proposed standard and consultation documents are available at:   <https://consultations.health.gov.au/tga/tgo110-standard-for-vaporiser-nicotine>. |
| **9.** | **Proposed date of adoption:** The standard is proposed to be finalised and published in April or May 2021 to allow enough time for stakeholders to become familiar with the requirements, and to organise procurement of compliant products, before the requirements come into effect on 1 October 2021.  **Proposed date of entry into force:** 1 October 2021 |
| **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 at:  <https://consultations.health.gov.au/tga/tgo110-standard-for-vaporiser-nicotine> |