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 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:**  Department of Foreign Affairs and Trade  [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 [****X],** **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):** Nicotine-containing products intended to be used in vaping devices such as e-cigarettes, e-cigars and other electronic nicotine delivery systems (ENDs).  One of the possible reform options would also affect the importation of vaping devices that do not contain nicotine (ENNDs).  TOBACCO AND MANUFACTURED TOBACCO SUBSTITUTES (HS 24); PHARMACEUTICAL PRODUCTS (HS 30) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Potential reforms to the regulation of nicotine vaping products - consultation paper; (25 page(s), in English) |
| **6.** | **Description of content:** The Therapeutic Goods Administration (TGA) is seeking comments on possible reforms to the regulation of 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.  One of the possible reform options would also affect the importation of vaping devices that do not contain nicotine.  Since 1 October 2021, ENDs have been regulated as prescription medicines in Australia. The aim of the 2021 reforms was to prevent children and adolescents from accessing ENDs, whilst allowing smokers to access these products for smoking cessation with a doctor's prescription. However, evidence is emerging that the reforms are not meeting these aims. The TGA is considering whether refinements to the existing regulatory requirements for ENDs could be introduced to better support the intent of the 2021 reforms, namely preventing children and adolescents from accessing ENDs while supporting access to products of known composition and quality for smoking cessation with a doctor's prescription.  The TGA is seeking comment on potential reforms in 4 main areas:   1. Changes to border controls for ENDs – to curb the unlawful supply of ENDs in Australia (one option includes to change the border controls for ENNDs to assist with the enforcement of the controls on ENDs (rather than with the aim of limiting access to ENNDs)) 2. Pre-market TGA assessment of ENDs against a product standard – to create a regulated source of quality ENDs to encourage doctors to prescribe, pharmacies to supply and vaping consumers to purchase 'safer' products lawfully 3. Strengthening the product standard regarding minimum quality and safety standards for ENDs – to make them less attractive to children and adolescents, for example by not permitting certain flavours or labelling 4. Clarifying the status of ENDs as 'therapeutic goods' – to ensure that any vaping product containing nicotine is captured by the regulatory framework. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The broad objectives of the potential reforms are to prevent children and adolescents from accessing ENDs, while supporting access to ENDs of known composition and quality for smoking cessation with a doctor's prescription.  Australia takes a precautionary approach to the regulation of ENDs because of the potential adverse health effects associated with their use. There is evidence that END use by young people can be a gateway to smoking and nicotine addiction. Further, given that ENDs are relatively new products, the effect on most clinical outcomes is unknown.  However, there is some evidence that ENDs can be useful for smoking cessation, and they are available for this purpose in Australia with a doctor's prescription. Some of the possible reforms are directed at ensuring that ENDs that are accessed for smoking cessation meet minimum quality and safety requirements, including relating to consumer information and labelling.; Consumer information, labelling; Prevention of deceptive practices and consumer protection; Protection of human health or safety; Quality requirements |
| **8.** | **Relevant documents:** The consultation paper is at: Proposed reforms to the regulation of nicotine vaping products - Therapeutic Goods Administration - Citizen Space (tga.gov.au) |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **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:**  Proposed reforms to the regulation of nicotine vaping products - Therapeutic Goods Administration - Citizen Space (tga.gov.au) (see also link to relevant document in section 8 of this notification). |