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:** Department of Health (Therapeutic Goods Administration)  **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:**  [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 other than specified nicotine replacement therapies and nicotine prepared and packed for smoking. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Notice of an interim decision to amend the current Poisons Standard (20 page(s), in English) |
| **6.** | **Description of content:** The document available at the first link at 8. explains the Delegate's interim decision (nicotine (other than in specified products) for all human use is included in the instrument which regulates poisons in Australia, the Poisons Standard, as a schedule 4 substance so that it may only lawfully be supplied in accordance with a medical practitioner's prescription) and the reasons for it addressing the requirements imposed on the Delegate by the *Therapeutic Goods Act 1989* (Cth). The interim decision is open for public consultation before the Delegate makes a final decision, taking account of all submissions received from the public on or before the closing date, 6 November 2020.  By way of short background, the regulation of nicotine containing e-cigarettes is a shared responsibility between the Commonwealth and state and territory governments:   * The Poisons Standard regulates substances including nicotine; it is a legislative instrument made in accordance with the recommendation of a senior medical officer acting as the delegate of the Secretary of the Department of Health. Each decision is must be made in accordance with the requirements of the *Therapeutic Goods Act 1989* including the [Scheduling Policy Framework for Medicines and Chemicals](https://www.tga.gov.au/sites/default/files/ahmac-scheduling-policy-framework-medicines-and-chemicals.pdf) endorsed by the Australian Health Ministers Advisory Council. * The Poisons Standard consists of decisions regarding the classification of medicines and poisons into Schedules *for inclusion in the relevant legislation of the States and Territories*; the Poisons Standard has no effect under the law of the Commonwealth. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons. The Poisons Standard is the legal title of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).   The documents available at the second link at 8. explain the implications of the Delegate's interim decision if it were to be made final. There is information for consumers, medical practitioners and pharmacists. There are flow diagrams demonstrating the impact on the supply chain if the interim decision is made final.  In sum, the interim decision would have the effect that nicotine containing e-cigarettes along with other nicotine containing products not expressly excluded from the decision (nicotine replacement therapies and in tobacco prepared and packed for smoking) would be a medicine which would only be available on prescription from a medical practitioner. That is, commercially imported e-cigarettes containing nicotine and other affected products could only be supplied following importation if there is a medical practitioner's prescription. Because there is presently no e-cigarette containing nicotine entered on the Australian Register of Therapeutic Goods (established and maintained under the Therapeutic Goods Act) the goods are lawfully imported:   * *commercially* if they are stored in a warehouse 'under lock and key' before being distributed under a state or territory licence and in accordance with an approval or an authority given under the Therapeutic Goods Act and in accordance with a medical practitioner's prescription * *by individuals* for their own or their immediate families use in accordance with a medical practitioner's prescription up to a maximum three months' supply at any one time and 15 months' supply over a 12 month period.   The Delegate is specifically inviting submissions on whether to include a requirement for child resistant closures for liquid nicotine products.  The Delegate's reasons set out how the proposed measure addresses the objectives specified at no. 7. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:**   1. The objectives of the Delegate's interim decision are to:    1. arrest the recent rapid increase in use of nicotine containing e-cigarettes by adolescents and young adults;    2. provide to patients who want to stop smoking efficacious support, not already available (such as the Quit program)- likely in the form of medical practitioner support, including considering whether to prescribe nicotine containing cigarettes    3. reduce the likelihood of child poisoning by accidental consumption of nicotine;   Protection of human health or safety |
| **8.** | **Relevant documents:**  The Delegate's interim decision to clarify that nicotine for all human use (other than in specified nicotine replacement therapies and in tobacco prepared and packed for smoking) is included in Schedule 4 of the Poisons Standard is available here: <https://www.tga.gov.au/scheduling-decision-interim/notice-interim-decision-amend-current-poisons-standard-relation-nicotine>.  More information is available here: <https://www.tga.gov.au/nicotine-scheduling> |
| **9.** | **Proposed date of adoption:** The Delegate's interim decision was published on 23 September 2020 with a final decision expected in December 2020.  **Proposed date of entry into force:** 1 June 2021; The Delegate is likely to consider entry into force on either 1 April 2020 or 1 June 2020. |
| **10.** | **Final date for comments:** 60 days from notification; The Delegate is anticipated to make a decision by December. |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  All information is available here: <https://www.tga.gov.au/nicotine-scheduling>.  <https://www.tga.gov.au/nicotine-scheduling> |