NOTIFICATION

Addendum

The following communication, dated 11 September 2023, is being circulated at the request of the delegation of Australia.

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**Title:** Potential reforms to the regulation of nicotine vaping products - consultation paper

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [ ] | Notified measure adopted - date: |
| [ ] | Notified measure published - date: |
| [ ] | Notified measure enters into force - date: |
| [ ] | Text of final measure available from[[1]](#footnote-1): |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [X] | Content or scope of notified measure changed and text available from1:  <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/taking-action-on-smoking-and-vaping?language=en>  New deadline for comments (if applicable): 60 days from notification |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | Other: |

**Description:** In notification G/TBT/N/AUS/151, it was advised that Australia is considering potential reforms primarily to the regulation of Electronic Nicotine Delivery Systems (ENDs). The scope of the proposed reforms has expanded to cover all vapes, including electronic non-nicotine delivery systems (ENNDs).

The proposed reforms to ENDs previously notified are still being pursued. However, subject to further consultation, it is now intended that all vapes (both e-liquids and devices used to produce vapour) will be prohibited unless they are therapeutic products to be used for smoking cessation or to treat nicotine addiction in accordance with Australia's therapeutic goods legislation. It is also intended to prohibit all single use disposable vapes.

It is proposed that this would involve:

* Making changes to Australia's border controls to:
  + Prohibit the importation of all single use disposable vapes;
  + Prohibit the importation of all other vapes without an import permit. Permits would only be granted for therapeutic vapes (mainly ENDs) that comply with Therapeutic Goods Administration (TGA) requirements, including new pre-market requirements and a strengthened product standard regarding minimum quality and safety standards; and
  + Restrict individuals from importing therapeutic vapes for personal use under the Personal Importation Scheme.
* Implementing equivalent restrictions on the manufacture and supply of vapes within Australia. It would only be permissible to manufacture and supply therapeutic vapes that comply with TGA requirements.
* Ensuring therapeutic vapes are only available for the purpose of smoking cessation or to treat nicotine addiction with a doctor's prescription (which is largely the current position).

The objectives of, and rationale for, the proposal outlined in G/TBT/N/AUS/151 also apply to the broader proposal. Due to the health risks of vapes and the escalating use of vapes by young people, it is considered necessary to strictly control access to circumstances where a medical professional has assessed the need for the product (mainly for smoking cessation but also possibly to treat nicotine addiction if clinically appropriate). It is also considered necessary to impose quality standards to mitigate the health risks for lawful users and reduce the attractiveness of vapes to children and adolescents.

The original consultation paper is available at the following link: <https://consultations.tga.gov.au/medicines-regulation-division/proposed-reforms-to-the-regulation-of-nicotine-vap/>. A further consultation paper will be available before 11 September 2023 at: <https://consultations.tga.gov.au/medicines-regulation-division/df36e4a0>.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)