npsa Australia's medicine distribution network

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Dear Vaping Reform Team,

Proposed reforms to the regulation of nicotine vaping products

Thank you for the opportunity to provide comment on the ongoing consultations regarding the regulation of nicotine vaping products (NVPs) in Australia.

The NPSA appreciates the ongoing efforts of the Therapeutic Goods Authority to protect Australian children and the broader community from the risks of nicotine products and notes the specific focus of the current consultation in relation to the proposed reforms concerning good manufacturing process (GMP) and short-fill vapes.

NPSA members are not involved in the manufacture or prescription of NVPs and would not be impacted by the proposal to introduce pre-market notifications of compliance with TGO 110 for the supply of NVPs. As wholesalers, our role is limited to distributing therapeutic NVPs to pharmacies and the proposed changes will not significantly impact our sales or the volume of NVPs we distribute.

We are concerned, as we have previously expressed, about the growing prevalence of vaping and e-cigarettes by Australian adolescents and the potential of these products to act as a gateway to cigarette consumption. As such, we support the proposed bans on disposable single use NVPs and all other NVPs except those for legitimate therapeutic use as determined by the *Therapeutic Goods Act*.

We also support the prohibition of advertisements for NVPs; the regulation of both the e-liquid and device components of NVPs under the same part of the *Therapeutic Goods Act*; the proposed upper limit on the concentration of menthol in NVPs; and the proposed definitions of nicotine and mint flavours. Having the same regulatory controls for zero-nicotine therapeutic vapes as for NVPs is also a proposal we support.

NPSA members are also strongly supportive of limiting therapeutic NVPs purely to those with a closed system of operation where the device and liquid component are combined, not separate. This limits the potential for a therapeutic liquid component to be replaced by a non-therapeutic equivalent and also minimises the safety issues involved with refilling any liquid component.

Finally, we would reiterate our desire to ensure that all NVPs be reclassified as SAS Category C in order to minimise the associated administrative burden and to align NVPs with other high volume SAS lines that can be efficiently and effectively processed.

We would welcome the opportunity to discuss any aspects of the above with you at any point and can confirm that neither the NPSA or any of our members have any conflict of interest in providing the above input. Thank you again for the opportunity to provide comment.

Yours sincerely

[redacted]

[redacted]

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