



Proposed amendments to the Poisons Standard – Nicotine

Submission from Cancer Council Australia, National Heart Foundation of Australia and Australian Council on Smoking and Health, June 2020

Content is authorised by [REDACTED] Chair of the joint Tobacco Issues Committee of Cancer Council and the National Heart Foundation.

Cancer Council Australia, the National Heart Foundation of Australia and the Australian Council on Smoking and Health make this further submission in relation to CAS Number 54-11-5, being an application to amend the current Poisons Standard to exempt nicotine in tobacco prepared and packed for heating from Schedule 7.

We submit that the interim decision of the Delegate of the Secretary to reject the application, published on 10 June 2020, is consistent with the evidence and should be affirmed in the final decision.

It is evident from the Delegate's reasons that the relevant factors in s 52E(1) of the *Therapeutic Goods Act 1989* (Cth) ('Act') have been given careful consideration. Key findings include that:

- there are no benefits to the use of nicotine when in tobacco prepared and packed for heating;
- the available evidence does not support that heated tobacco products (HTPs) are a safer alternative to traditional tobacco products;
- HTPs carry a high risk of nicotine addiction for both new and continuing users;
- HTPs may renormalise smoking among young people who would otherwise be at low risk of initiation;
- there is insufficient evidence regarding the safety of their long term use; and
- nicotine in HTPs has high to extremely high toxicity.

As explained in our joint submission to the initial public consultation, set out over 18 pages with references from the academic and grey literature, the independent evidence indicates HTPs are a tobacco product designed to promote new commercial market opportunities. The Delegate's and the Joint ACCS-ACMS's characterisation of HTPs as a new nicotine delivery-device for non-therapeutic use of tobacco is clearly consistent with that evidence.

The Delegate has also noted that the applicant's focus on using tobacco cigarettes as a relevant comparator is too narrow and does not fully reflect the matters set out in s 52E(1) of the Act. This recognises that the Delegate's task is not to determine whether HTPs are a less harmful alternative to combustible cigarettes, as this would set an unacceptably low threshold for the exercise of power to amend the Schedule.

The evidence supports the Delegate's overall conclusion that there is no net public health benefit from wider availability of nicotine in the form of HTPs. In this respect, we reiterate the strong concerns about public health risks expressed in our original submission in February 2020 and support the interim decision to protect the community from those risks.

These considerations and the evidence which has informed them all lead irresistibly to the conclusion that the current scheduling of nicotine must be maintained. In view of the evidence, no other decision is reasonably open on the materials before the Therapeutic Goods Administration.