Australian medicines regulator intends to continue to protect the cigarette trade – we challenge its bizarre reasoning

written by Clive Bates | 16 February 2017



Solid as a rock? The TGA justification for banning e-liquids certainly isn't

This post summarises and gives background to a new harsh-but-fair submission on nicotine classification in Australia – go straight to it > here

In Australia, nicotine is classed as a poison unless in a form exempted from the poison schedules. There are two relevant exemptions: for veterinary or medical use (e.g. NRT) or when nicotine is in the form of:

> *…tobacco prepared and packed for smoking*

This has the effect of making manufacture, import or sale of nicotine e-liquids illegal in most circumstances [see note]. It also bars smokeless tobacco, heated tobacco products, and other low-risk non-combustibles from the market of 2.8 million adult smokers (16 percent of the adult population), while bizarrely granting exclusive market access to cigarettes and other combustible products. So this is obviously insane, so there has been an attempt to change that.

Last year the New Nicotine Alliance with Colin Mendelsohn, a Sydney-based smoking cessation expert, made a proposal for an amendment to the schedule:

> *"to exempt nicotine from Schedule 7 at concentrations of 3.6 per cent or less of nicotine for self-administration with an electronic nicotine delivery system ('personal vaporiser' or 'electronic cigarette') for the purpose of tobacco harm reduction".*

Good idea! And the proposal came with a set of safeguards too.

Initial submission. On 31 August 2016, forty international and Australian experts made a detailed submission in support of the proposed rescheduling.

Response from the regulator. On 2 February 2017, Australia's Therapeutic Goods Administration (TGA) announced an interim decision **not** to allow the rescheduling, and therefore to maintain the *status quo*. The interim decision was open to further comment. So we have worked up a detailed line by line critique of the reasoning given for the TGA interim decisions:

Critique of TGA arguments. On 16 February 2017, a smaller group of us (21) submitted a line-by-line critique of the reasoning that supports the decision (PDF).

Summary of critique from full submission

This is the summary from the 11-page submission.

> *We do not find any elements of the reasoning sufficient, individually or taken together, to justify the interim decision. In our view, the case has not been made and the ACCS-ACMS and delegates should reconsider. In outline, our critique of the reasoning presented is as follows:*
>
> - *There is no credible case for exempting nicotine from schedule 7 only when it is delivered via a tobacco product for smoking – by far the most harmful way of taking nicotine. The reasoning does not confront the absurdity of granting exclusive access to the lawful consumer nicotine market to only the most harmful products. Why grant this protection to the cigarette trade?*
> - *The evidence concerning youth use of e-cigarettes is misrepresented throughout the reasoning. Youth vaping is highly concentrated in*

smokers or adolescents who would otherwise smoke, and is mostly experimental and without nicotine. There is no evidence anywhere of harmful gateway effects. In the U.S., youth smoking is falling at a much greater rate than the long-run trend.

- *The safety risks of nicotine liquids at the strengths envisaged in the rescheduling have been misrepresented and do not amount to a justification for the interim decision. These liquids are widely available in Europe and the United States and are not presenting any serious problems at any significant scale. Any risks are minor, manageable and comparable to other routine hazards.*
- *The reasoning fails to acknowledge the radical reduction in risk arising from switching from smoking to e-cigarettes arising from the completely different chemical and physical processes involved. To actively prevent Australians accessing substitute products with greatly reduced risk would require a strong technical, ethical and legal justification, but none is provided.*
- *The reasoning does not address the harmful unintended consequences of the current scheduling policy: fewer smokers switching and more use of unregulated black or grey markets to access nicotine liquids. No credible attempt has been made, as required under Section 52E of the Act, to objectively assess the benefits of rescheduling or harms arising from retaining the status quo.*

The final decision will be announced on 23 March 2017. We hope the TGA, its advisory committees and the responsible minister reconsider the initial decision, take another look at the evidence and do the right thing: accept the rescheduling. As I think our papers show, it will be hard to defend the decision in parliament or the courts.

Other submissions and articles

- Colin Mendelsohn and 18 Australian experts – *excellent* submission on interim decision – 16 February 2017
- New Nicotine Alliance – submission, 16 February 2017
- Australian Taxpayers' Alliance: ATA responds to TGA's pro-cancer ruling (release) Joint Submission of the Australian Taxpayers' Alliance & MyChoice Australia, 16 February 2017

- Terry Barnes – submission and related blog: The TGA and nanny staters just can't help themselves, 19 February
- Momentum building to legalise nicotine for vaping – Attila Danko, 16 February 2017
- Colin Mendelsohn Australia's looming e-cigarette ban robs smokers of a chance to quit – The Conversation, 13 February 2017
- Application to legalise low strength nicotine for vaping rejected. Now our real battle begins! – Attila Danko, 6 February 2017

[Note]: The current situation as summarised by the TGA

> *Nicotine is in Schedule 7 [Dangerous poison], except in preparations for human therapeutic use or in tobacco prepared and packed for smoking. There are no restrictions on importation, but individuals may commit an offence under state and territory laws when they take possession of, or use, imported nicotine.*
>
> *In the states and territories, it is an offence to manufacture, sell or supply nicotine as Schedule 7 poison without a licence or specific authorisation. This means e-cigarettes containing nicotine cannot be sold in any Australian state or territory. Nicotine can be imported by an individual for use as an unapproved therapeutic good (e.g. a smoking cessation aid), but the importer must hold a prescription from an Australian registered medical practitioner and only import not more than 3 months' supply at any one time. The total quantity imported in a 12-month period cannot exceed 15 months' supply of the product at the maximum dose recommended by the manufacturer. The purchase and possession of nicotine by individuals are not regulated by Commonwealth legislation, except for importation as allowed under Commonwealth law.*
>
> *Non-nicotine e-cigarettes are currently not regulated as a therapeutic good under the Commonwealth Therapeutic Goods Act. To date, none have been approved by the TGA for registration as a medical device.*

You can tell just by reading this that it makes no sense at all.