

15/2/2017

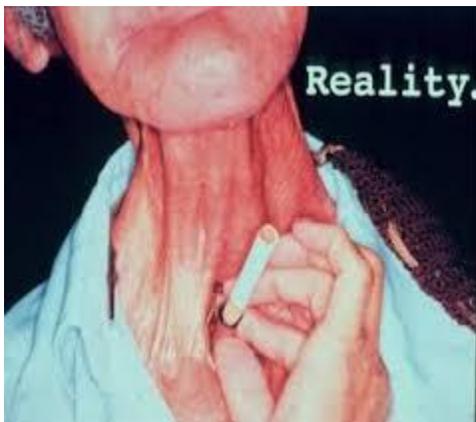
Response to TGA Interim Decision on application to exempt low strength Nicotine from Schedule 7 for self-administration in electronic nicotine delivery devices (e-cigarettes).

The New Nicotine Alliance Australia (NNA AU) welcomes the opportunity to respond to the TGA's Interim Decision to reject our application.

The NNA AU is primarily a consumer advocacy group. Our response is therefore from a consumer's perspective. We are aware of responses from the global scientific and tobacco control community that address the scientific evidence in favour of de-scheduling low strength nicotine for the purpose of tobacco harm reduction. We will therefore be addressing the rejection primarily from the consumer point of view. We implore the TGA to fairly consider the scientific evidence on toxicity and epidemiology that is provided by the global scientific and tobacco control community.

The TGA in it's reasons for rejection almost entirely consider potential risks without considering the benefits in terms of the replacement and displacement of the single most harmful behaviour for health, which is smoking. Tobacco prepared and packed for smoking is currently exempt from Schedule 7 laws, whilst low strength nicotine for use in e-cigarettes is not. Even the most ardent critics of tobacco harm reduction do not deny the clear scientific evidence that the use of nicotine e-cigarettes are less harmful than smoking.

The premise of harm reduction is to replace a harmful activity that people just can't stop with something far safer. The long term success of quit attempts by long term smokers is very low. Illustrative examples include people who have had throat cancer still smoking through the hole in their throat.



There is robust demand for e-cigarettes among consumers with significant uptake in Australia despite the almost total absence of marketing and the fact that the sale, possession and use of nicotine for use in these devices is illegal without prescription under current Schedule 7 laws. Many thousands of Australians have switched to nicotine e-cigarettes because they could not stop smoking any other way. They have failed to quit with all the approved methods of stopping

smoking. When the cost of obedience to a law is death, it is inevitable that such a law is going to be disobeyed.

Whilst the Personal Importation Scheme does allow for legal use of nicotine in e-cigarettes, this requires a prescription from a medical practitioner. As long as many Australian medical institutions and authorities strongly attack the use of these devices under any circumstances, very few Australian medical practitioners will be comfortable providing such a prescription. This is not a viable option for the vast majority of smokers wishing to switch. This also still requires the customer to purchase nicotine online from overseas. Many older smokers do not have the computer skills or access to be able to do this.

The great difficulty in accessing legal nicotine for use in e-cigarettes contrasts with the wide availability and accessibility of cigarettes for retail sale everywhere in Australia. The exemption of tobacco for smoking under Schedule 7 protects the tobacco industry from competition. Why should a safer product be more difficult to access than the far more dangerous alternative? The TGA has not justified why the tobacco industry requires protection from competition. The lack of choice is harmful to consumers.

The TGA claims that the relative protection of cigarettes protects teenagers who might experiment with e-cigarettes. Typically, teenagers interested in trying one behaviour will be interested in trying a similar behaviour. Teenagers wishing to experiment with either behaviour will always find it much easier to steal a cigarette from an adult smoker than to steal an e-cigarette device without being noticed. Typical adult vapers have one or two refillable devices that they use, the loss of one which is readily noticed, while the loss of a cigarette from a packet of 20 or 40 is easily unnoticed.

Never has there been an example of the introduction of a safer, cheaper alternative causing increased use of a more dangerous incumbent product. The extraordinary claim that the introduction of e-cigarettes will increase smoking in a population requires extraordinarily strong evidence. The end of alcohol prohibition in America and the wide availability of safer forms of alcohol did not result in the increased use of contaminated poisonous moonshine, and no-one ever expected that it would. Such a counterintuitive proposition, that vaping increases smoking, has never been robustly proven. The burden of evidence rests on those with extraordinary claims. All the purported evidence for this claim is deeply flawed, and easily explained by shared liability and correlation rather than cause and effect.

There is evidence that some young people who first try e-cigarettes will later try cigarettes. There is no evidence that any significant number of young never smokers become regular e-cigarette users anywhere in the world. There is no evidence that of the miniscule number of young never smoking regular e-cigarettes users in the US (estimated at 0.1%)¹ that any have progressed to regular smoking.

The toxicity of nicotine is exaggerated by the TGA in it's reasons for rejection and is not valid in the terms of the application which is for low strength nicotine of up to 3.6%. The scheduling of many substances depends on the concentration and the method of delivery, such as eucalyptus oil and bleach. Practical scheduling decisions in terms of concentrations and unit volumes

¹ Villanti AC, Pearson JL, Glasser AM, Johnson AL, Collins LK, Niaura RS, et al. Frequency of youth e-cigarette and tobacco use patterns in the U.S.: Measurement precision is critical to inform public health. *Nicotine Tob Res.* 2016 Dec 24;ntw388. [\[link\]](#)

allowed have been made for such substances to reflect real world use despite a toxicity similar to low strength nicotine.

Consumers demand practical workable regulation of low strength nicotine. Our proposal has provided an example of nicotine de-scheduling regulations that would satisfy the needs of most e-cigarette users. There are some e-cigarette products sold elsewhere in the world that are available in concentrations of nicotine of up to 5%. The higher strength products are typically in small low powered and low e-liquid volume devices that more closely resemble cigarettes, made to be disposable and that are more likely to be sold by tobacco companies in convenience stores. Our proposal excludes these from the market, with some consumer harm from less options, however it was deemed prudent to compromise to satisfy risk averse regulators to apply for a lower level of nicotine for de-scheduling.

In matters of poison scheduling and of nicotine and tobacco policy, the decisions of the Secretary can have lethal or life-saving consequences. For that reason, the Secretary is obliged under the law to make a dispassionate assessment of costs, benefits, risks and opportunities and to make decisions that protect the public health and do not cause avoidable harm. Nothing in the advice or the argument supporting the interim decision suggests that this duty has been discharged with appropriate care or objectivity.

Adult consumers will continue to use these products, with nicotine, because the cost of compliance to the current regulations are people's very lives. It is time for regulators to stop protecting tobacco companies and the cigarette market. It is time for regulators to examine the evidence dispassionately and comprehensively as provided by the most prominent scientists and public health experts in the world. It is time for regulators to accept reality and produce workable, practical regulations that satisfy the consumer's need for an alternative to smoking rather than to satisfy a small group of academics with an extremist abstinence only view of nicotine.

Dr Attila Danko
Donna Darvill
Jennifer Stone
New Nicotine Alliance Australia
(A National Not for Profit Organisation)
Ph. 0437 686 594
PO Box 3
Chelsea Vic 3196
Email: donna@nalliance.org.au
www.nalliance.org.au

