1 September 2016

Medicines Scheduling Secretariat
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Secretary,

SUBMISSION ON AN APPLICATION TO AMEND SCHEDULE 7 OF THE POISONS STANDARD IN RELATION TO NICOTINE

I write in support of the application made by New Nicotine Alliance Australia (NNA) proposing an amendment to the terms of listing of nicotine in Schedule 7 (the Schedule) of the Poisons Standard as of July 2016, and its consideration by the Advisory Committee on Medicines and Chemicals Scheduling (the Committee) in November 2016.

As outlined in the Appendix to this letter, I have a background in health policy, administration and regulation. I am not medically or scientifically qualified in relation to medicine, pharmacology and addiction.

On the other hand, my experience in policy-making is relevant to assessing the public interest benefits of the NNA application, and to its underlying intentions of promoting safer and lawful access to harm-reducing new technologies, and further reducing the prevalence of tobacco smoking in Australia.

Support for the application

I have seen the comprehensive submission to the Committee of Dr Colin Mendlessohn and a remarkable coalition of Australian and international expert clinicians and researchers, making a documented clinical and scientific case in support of the NNA application, backed by their high professional reputations.

That submission has been co-signed by some of the biggest names in this field, including the principal authors of the landmark 2015 Public Health England report on e-cigarettes, Professors Ann McNeill and Peter Hajek, who concluded that Electronic Nicotine Delivery Systems (ENDS) are at least 95 per cent safer for active and passive users than combustible tobacco.

Being a public policy expert, rather than a clinician or researcher, it was not appropriate for me to join that group as a co-signatory. They are qualified to express considered scientific opinions and I am not.
On the basis of my own involvement in the harm reduction policy debate, however, I endorse and support the Mendlessohn et al submission as a comprehensive position statement, and urge the Committee not only to give it careful and comprehensive consideration as measured and documented scientific advice, but also to test against it arguments opposing the proposed Schedule amendment.

The Mendlessohn et al submission, complementing the findings of PHE and the Royal College of Physicians this year – both of which in turn analysed and synthesised the body of emerging evidence on the efficacy and use of ENDS – affirms what the weight of that evidence so far indicates: that nicotine, isolated from the chemical and gaseous by-products of tobacco combustion, is not in itself a great harm to consumers if used in low-level quantities.

When it comes to smoking, it follows the addictiveness of nicotine is not the biggest problem to be combated: it is exposure to the full chemical mix of tobacco smoke.

Therefore, if there is a nicotine delivery platform that mostly eliminates the risks of that deadly chemical mix, if should be considered in the public interest. Novel technologies, like ENDS, should not be dismissed on safety grounds simply because they are new or disrupt settled approaches to tobacco control.

For that reason alone, the NNA application should be considered favourably on its merits.

**Consideration of the application by the Committee**

Effectively, there are only two regulatory questions for the Committee to decide. The first is whether the use of ENDS solutions containing nicotine, not exceeding a prescribed “safe” level of nicotine content, can legally be permitted in Australia as it is in the United Kingdom, in the European Union, and shortly in New Zealand.

The second is whether the proposed nicotine content and product safety conditions are appropriate, or whether these should be modified if the Schedule is amended.

Any other policy and regulatory consequences beyond these are matters for Commonwealth, state and territory policy-makers and regulators. That includes regulating the sale, marketing and protocols of lawful public use of nicotine-containing ENDS devices, and any resulting implications for tobacco control and smoke-free policies, regulations and programmes.

While the Committee should be aware of these potential flow-ons, it does not need to concern itself with addressing these in addressing the scientific and clinical claims of the proposed Schedule amendments.

What matters here simply is the appropriate treatment of nicotine in the Schedule, and that the Committee determines, on the full range of available evidence, and with reference as appropriate to practice in overseas jurisdictions, whether nicotine-containing ENDS solutions are, on balance, safer than Schedule’s current provision exempting “tobacco prepared and packed for smoking” from the general prohibition on nicotine.

That includes evaluating relative risks for active smokers and vapers from their chosen nicotine-ingesting paths, and for people exposed to their passive smoke or vapour as a result.
If the Committee’s conclusion is the use of ENDS is relatively safer for nicotine delivery than combustible tobacco, the NNA application should be approved in the public interest. This is on the presumption that a basic principle of good public health policy and regulation is promoting the elimination and mitigation of harm wherever possible.

**Harm reduction is the key public interest criterion**

The decision-making criteria for the Minister or delegate’s justifying scheduling decisions, as set out in section 52E of the *Therapeutic Goods Act 1985*, boil down to one thing: whether or not the terms of listing a scheduled substance confer a net benefit in the public interest without compromising individual and public safety.

In relation to the NNA application, if the Committee is satisfied there is a net benefit to individuals and the community supported by the weight of available evidence and best practice, it should approve the application on one rationale and one only: given we know the deadly damage caused to the health of active and passive users by combustible tobacco, permitting safer legal alternatives to be contestable with cigarettes and other combustible tobacco products on the open market, and not simply as restricted-access smoking cessation aids, is clinically, scientifically, and ethically appropriate and defensible.

If the purpose of regulating poisons like nicotine is eliminating or mitigating known serious harms for individuals and the community – and tobacco smoking is one of the most well-known deadly harm – then not to agree to the application if satisfied that ENDS are at least significantly less dangerous than combustible tobacco would not only be contrary to the public interest, but would contradict the harm reduction principle at the heart of sound public health science, policy and regulation.

It therefore is important that the Committee determines the application on its scientific and clinical merits, nothing more. The flow-on policy and regulatory implications of the Committee’s decision should be left to policy-makers and regulators, and not be direct factors in this decision-making process.

**Public interest implications of the application**

Allowing the NNA application would open the way to legalising the open sale in Australia of nicotine-containing ENDS, provide a basis for product quality and safety standards, and recognise the technological and moral contradiction in the Poisons Standard that prohibits nicotine-containing ENDS while allowing the mass sale of the very nicotine delivery system – combustible cigarettes – whose by-products bring death and illness to millions.

The application’s proposed addition of a new paragraph (d) to existing three conditions of nicotine’s listing on the Schedule is prudent, practical and sensible from a public interest perspective.

It would:

- Give vapers, and smokers seeking to reduce or eliminate their cigarette habit, legalised access to ENDS products and nicotine-containing vaporising solutions without invoking personal importation rules or resorting to black or grey markets (including Internet mail order) to obtain supplies.
- Subject to jurisdictions’ policy and regulatory regimes, facilitate a carefully-regulated Australian retail market for ENDS products and nicotine-containing solutions that can operate in direct competition to deadlier combustible tobacco products, especially cigarettes.
• Allow jurisdictions to regulate ENDS products for safety and quality, including childproofing, which cannot be assured by the back-door market.
• Make the illicit market for nicotine-containing ENDS far less viable.
• Allow the Commonwealth to determine the appropriate fiscal treatment of nicotine-containing ENDS solutions.
• Accept that nicotine-containing ENDS pose much lower, and arguably minimal, health risks compared to combustible tobacco, offering a lawful and safer alternative to ingesting safe and modest quantities of nicotine than smoking; and, above all
• Potentially make big further inroads on the prevalence of tobacco smoking in the Australian population, on smoking-related mortality and morbidity, and on related economic and social costs to the Australian community and taxpayers.

These factors reflect the rationale the New Zealand government is adopting in its August 2016 decision to legalise nicotine-containing ENDS, although it must be noted a similar public consultation process is under way in New Zealand before enabling legislation is finalised later this year.

If the NNA application is upheld, policy-makers and regulators could then turn their minds to best addressing these factors, which fall into their jurisdictions and areas of responsibility rather than those of the Committee or the TGA.

**Could the application’s recommended scope be broader?**

The proposed paragraph (d) in the NNA application relates entirely to nicotine-containing liquids for use in ENDS. It reflects the state of play in the legal Australian market for ENDS, which is almost entirely in ENDS using non-nicotine vaporised solutions.

If the application is accepted, the Committee could also ask whether it also is appropriate to clarify the status of ENDS not using “e-liquids”, including those using tobacco on a heat-not-burn basis. It may be that such products are already legitimate under the “tobacco prepared and packed for smoking” condition (c) in the Schedule, but it may be useful to clarify any ambiguity while there is an opportunity.

It may also be desirable to ensure that any adopted ENDS conditions in the Schedule are sufficiently flexible to embrace the likelihood of further technological advances in ENDS, especially given these products have evolved rapidly since the first commercially-successful e-cigarette appeared in 2003.

**Conclusion**

While, as stated earlier, they are mostly outside of the Committee’s direct decision-making ambit, the outcome of the Committee’s decision has major implications for tobacco and harm reduction policy and regulation, and the public interest generally.

The value of ENDS as a legitimate smoking-cessation option for smokers, and as a far lower-risk alternative to “tobacco prepared and packed for smoking”, and its by-products, for those wanting access to modest quantities of nicotine to satisfy their low-level addiction, is a highly-contested clinical and scientific debate. In Australia it has been characterised by emotive and unfortunately *ad hominem* arguments, with selective use and disregarding of scientific evidence and expert opinion, to make a case against ENDS with or without nicotine.

Indeed, evidence that does not fit their preferred picture, such as the detailed meta-analyses of Public Health England (2015) and the Royal College of Physicians (2016), has largely been ignored by Australian anti-ENDS advocates.
The NNA application, being scrutinised by this public consultation process before deliberative expert consideration by the Committee, therefore should be considered on its merits, free of the controversy and emotiveness that has affected the tobacco control public debate since ENDS came into common use in Australia and overseas.

The Committee is qualified and highly-placed to consider the substance of, and issues around, this important application objectively and dispassionately, and that in itself will provide something that has been lacking in the public debate.

I would be very happy to discuss this submission if requested.

Yours faithfully,

Terry Barnes
Principal
Cormorant Policy Advice
APPENDIX

About the author

I have a background in politics and policy-making as a federal and state government official, and as a senior ministerial adviser to two Commonwealth heath ministers, Michael Wooldridge and Tony Abbott. My chief expertise is in social policy, particularly health and aged care.

Policy based on the principle of reducing harm has interested me over a long time, and I have worked in developing and implementing policy with a harm reduction emphasis, including drug and HIV policy. I have also advocated Private Health Insurance incentives promoting people to take greater personal responsibility for their behavioural choices, especially in relation to smoking, alcohol consumption and improving diet and exercise.

Since 2007 I have run my own practice as a policy and regulatory analyst and consultant. In this capacity, in 2013-15 I was centrally involved in the policy debate over mandatory co-payments for GP services, after I was commissioned to write a discussion paper for a private health think tank, the Australian Centre for Health Research.

In 2015 was appointed as a part-time fellow in lifestyle economics of the UK Institute for Economic Affairs1. As an IEA fellow I have complete freedom to write and advocate, and this submission represents my views, not those of the IEA’s or any third party.

I write and comment on harm reduction and ENDS in the media, but I have a long-standing interest in the collision between harm reduction, encouraging personal responsibility and related public policy in other lifestyle activities including food and alcohol regulation, and gambling.

I personally have never smoked. My concern is ensuring those who do and want to quit have the widest possible range of alternatives to smoking.

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1 www.iea.org.uk – Like Australian think tanks, the IEA is an independent organisation that receives donations from a wide range of private sector sources and philanthropy.