Public Consultation on the Proposed Amendments to the Poisons Standard

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

The delegate of the Secretary to the Department of Health publishes herein all valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard. These submissions were considered by the November 2016 meeting of the Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had their confidential information removed.

to a range of government strategies including smoking restrictions, mass media campaigns, plain packaging, and tobacco excise tax increases. In 2014, 15.7% of South Australians identified as smokers, compared to 19.4% in 2013 and daily smoking prevalence was 12.8%\(^8\). The number of young people aged 15-29 years who smoked daily, weekly or less often also reduced from 19.5% in 2013 to 14.8% in 2014\(^9\).

The World Health Organization advises that countries that have achieved a very low and declining prevalence of tobacco smoking, which would include Australia, should consider that e-cigarette use will not significantly decrease population level disease and mortality associated with tobacco use\(^10\).

In South Australia in 2014, 81.3% of people reported that they had heard of e-cigarettes but only 1.2% were current users of e-cigarettes\(^11\). While daily smokers were most likely to have tried an e-cigarette in the past 12 months (30.1%), only 5.3% were current users\(^12\).

The toxicity of a substance

Nicotine is regulated as a dangerous poison under Schedule 7 of the national Poisons Standard. When ingested, nicotine can cause a range of symptoms including headaches, dizziness, nausea, and abdominal pain. Exposure can also occur through inhalation and absorption through skin and eyes. Exposure to relatively small amounts of nicotine can be fatal.\(^13\)

A study by the US Centers for Disease Control and Prevention found there has been a dramatic increase in e-cigarette related calls to poison centres in America\(^14\). The number of calls to poison centres involving e-cigarette liquids containing nicotine rose from one per month in September 2010 to 215 per month in February 2014. Fifty one per cent of the calls involved young children aged below five years. The study found that the products were a threat to small children because they were not required to be childproof and they could be bought in candy and fruit flavours that made them appealing to children.

It has been reported that e-cigarette related poisonings have also increased significantly in Australia. The number of calls about e-cigarettes to Australia’s four Poison Information Centres increased from two in 2009 to 54 in 2013\(^15\).

Consideration should be given to the safety of nicotine and by extension, the safety of e-cigarettes. In addition, it is important to consider the addictive nature of nicotine and the impact of its use in products where safety and level of risk reduction is yet to be established.

The dosage, formulation, labelling, packaging and presentation of a substance

The amount of nicotine present in liquids used in e-cigarettes can vary widely, but can contain levels up to 34 mg/mL\(^16\). Consequently, the maximum proportion in the current

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\(^9\) Ibid.


\(^11\) Ibid.

\(^12\) Ibid.


\(^14\) Centers for Disease Control and Prevention. Press release. New CDC study finds dramatic increase in e-cigarette-related calls to poison centers newsroom

\(^15\) ABC. Health experts alarmed after rise in accidental poisoning from e-cigarettes. 27 August 2014.

proposal to the Therapeutic Goods Administration of 3.6% or 36mg/mL represents a high nicotine concentration.

Any consideration of the use of a substance should take into account evidence that would demonstrate dosage levels that are safe and effective in achieving the stated aim of any application to the Therapeutic Goods Administration. There is yet to be a body of scientific evidence established that demonstrates a safe level of nicotine associated with use in e-cigarettes. This application seeks a scheduling exemption for a relatively high concentration of a substance that is highly toxic.

Consideration should also be given to the formulation of any liquid that nicotine would be a part of and what evidence exists as to the safety of this formulation and its constituents. Similarly, due to the risks of poisoning to children from exposure to nicotine and uptake by those not already nicotine dependent, consideration should be given to the issue of whether any strategies around dosage levels, child-proof packaging and the use of health warnings for nicotine would be sufficient to mitigate these substantial risk.

The potential for abuse

Research shows that nicotine is a highly addictive substance that activates dopaminergic reward pathways in the brain. If the application to exempt nicotine from scheduling for use in e-cigarettes was approved, it would add a substantially addictive component. Given the possible risks from active and passive exposure to e-cigarette vapour, it is valid to consider the potential risks of enhancing the addictive properties of e-cigarettes. This combined with the use of fruit and confectionery flavourings in nicotine liquids used in e-cigarettes increases the potential for use that impacts health.

Any other matters

The liquid used in e-cigarettes is known by a number of names including 'e-juice'. It often contains propylene glycol and/or glycerol as well as an increasingly large range of flavourings. When heated and vaporised, propylene glycol can form propylene oxide which is classed as a Group 2B carcinogen (possibly carcinogenic to humans) by the International Agency for Research on Cancer. There is still a lack of evidence around the safety of heating food flavourings in e-cigarettes and inhaling the aerosols, but emerging evidence suggests that some food flavourings could pose significantly risks to health.

The World Health Organization report states that while it is very likely that average use of e-cigarettes produces lower exposure to toxicants than tobacco products, there is evidence of health risks from chronic inhalation of toxicants in aerosol produced by e-cigarettes.

There are also risks that e-cigarettes and liquid flavourings will be presented and promoted in a way that could be appealing to young people. There are currently thousands of flavoured liquid designed and promoted for use in e-cigarettes and many of these are sweet or confectionery flavoured. It is already known that flavoured tobacco products are found to
appeal to youth\textsuperscript{22,23}. Consideration should be given to the impact of allowing nicotine to be included as a component of products that commonly have fruit or confectionary flavours and are likely to appeal to young people.


To whom it may concern,

**Re: Proposed amendment to scheduling of nicotine under the Poisons Standard**

I am writing on behalf of [redacted] — and the community we represent — to express my strong support of [redacted] Australia’s recommendation that the Poisons Standard not be amended to exempt nicotine from Schedule 7 (at any concentration) for self-administration with an electronic nicotine delivery system.

This submission outlines four key reasons for not supporting the proposed amendment to the Poisons Standard:

1. Nicotine is a toxic and addictive substance. Research has shown that nicotine poses a number of health hazards.
2. When used in electronic cigarettes, nicotine is combined with other substances which are likely to be harmful when inhaled (whether directly or via second-hand vapour).
3. There is currently insufficient evidence to demonstrate that electronic cigarettes or personal vaporisers are an effective aid to smoking cessation (regardless of whether they contain nicotine).
4. Evidence indicates that cutting down the number of cigarettes smoked does not significantly reduce the harms associated with smoking. In fact, promotion of electronic cigarettes for the purpose of reducing the number of cigarettes smoked (rather than for the purpose of quitting smoking altogether) may actually result in a net increase in harm caused by tobacco use.

To ensure that the Australian community is not subject to the potential harms of widespread electronic cigarette use, we strongly support [redacted]
position that it would be inappropriate to exempt nicotine from the poisons standard when used in an e-cigarette for the purpose of 'tobacco harm reduction'.

If you require any further information in relation to our position on this issue, please contact [redacted].

Yours Sincerely,
4. NICOTINE

Proposed: 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.

Overview

The TGA does not support this scheduling proposal. Unlike existing nicotine products which are registered on the Australian Register of Therapeutic Goods for nicotine replacement therapy, no assessment of electronic cigarettes has been undertaken by the TGA. Therefore the quality and safety of electronic cigarettes in not known.  

The risk and benefits of the use of the substance

The TGA notes that some overseas studies suggest that electronic cigarettes containing nicotine may be dangerous, delivering unreliable doses of nicotine (above or below the stated quantity), or containing toxic chemicals or carcinogens, or leaking nicotine. Leaked nicotine is a poisoning hazard for the user of electronic cigarettes, as well as others around them, particularly children. Dangerous and lethal doses of nicotine can be absorbed through the skin.

There is also limited evidence regarding the effectiveness of e-cigarettes as a smoking cessation device.

The National Health and Medical Research Council (NHMRC) issued a statement on electronic cigarettes in 2015, to inform the Australian community about the current status of the evidence about the potential risks and benefits of electronic cigarettes. The statement concluded:

“There is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting, or about the extent of their potential harms. It is recommended that health authorities act to minimise harm until evidence of safety, quality and efficacy can be produced.”

The NHMRC also stated it is currently funding research into the safety and efficacy of e-cigarettes for smoking cessation.

The 2015 findings of the NHMRC are consistent with a study published in 2014 in the Annals of the American Thoracic Society which stated:

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31 Section 52E(1a) - Therapeutic Goods Act 1989
“Although some data demonstrates that electronic cigarettes may be effective in reducing conventional cigarette consumption, there is no data demonstrating the efficacy of electronic cigarettes as a tool to achieve cessation. Until robust longitudinal evaluations demonstrate the safety of electronic cigarettes and efficacy in treatment of tobacco dependence, their role as a harm reduction tool is unclear”.

believes that until such research is completed and the TGA registers these products as therapeutic products, the current scheduling remains appropriate.

Any other matters necessary to protect public health

Other studies have indicated that e-cigarettes are not emission-free and their pollutants could be of health concern for users and second-hand smokers, in particular, ultrafine particles can be deposited in the lung. One study concluded that “In view of consumer safety, e-cigarettes and nicotine liquids should be officially regulated and labelled with appropriate warnings of potential health effects, particularly of toxicity risk in children”.

There are also concerns e-cigarettes promote continuing use of cigarettes, thus renormalising cigarette smoking behaviours. Personal vaporisers are often promoted as ‘risk free’ and offered in a range of flavours that are likely to appeal to a broad audience, including children and young people.

This has led to some State and Territory Government to regulate e-cigarettes in the same manner as regular tobacco products.

Summary

does not support the proposal and believes the current scheduling remains appropriate.

Concerns regarding the risks to public health, combined with a lack of evidence regarding the safety and efficacy of e-cigarettes warrants a cautious approach.


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35 Section 52E(1a) - Therapeutic Goods Act 1989
38 IBID
40 Options to protect the community from potential harms associated with personal vapourisers (e-cigarettes)’ ACT Government Discussion Paper, November 2014
41 New Restrictions to regulate e-cigarettes in the ACT – Meegan Fitzharris MLA- 5/04/2016
42 Tough new Regulation to protect kids from e-cigarettes – Jill Hennessy 21/05.2016
Therapeutic Goods Administration

Advisory Committee on Medicines Scheduling (ACMS) proposed amendments to the Poisons Standard e-Cigarettes

medicines.scheduling@tga.gov.au

To whom it may concern,

supports moves to change standards for e-Cigarettes to the Poisons Standard, referred by the delegate for scheduling advice to the Advisory Committee on Medicines Scheduling (ACMS).

Specifically, our submission focuses on the proposal 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."

has long supported the ideal of deregulation in order to level the playing field in Australia’s retail sector. We believe deregulation is necessary to enable small businesses to more effectively, and fairly, compete with large businesses, particularly the major grocery chains.

We remain dedicated to assisting in creating healthier outcomes for consumers and support the benefits delivered by diversionary products such as e-cigarettes.

In its consideration of the proposed amendments to the Poisons Standard, the Therapeutic Goods Administration is faced with a similar predicament.

A decision needs be made to either limit the choice available to consumers, including those adult consumers looking for alternatives to help them stop smoking, or to increase the choices available to these consumers.

Retailers also need to wean themselves from the revenue related to tobacco products and see e-cigarette products as an alternative much healthier option to supply consumers who cannot kick their addiction.

Only by increasing the choices available to consumers will we have the capacity to help smokers and retailers.

We are forthcoming in our interests to be able to sell – legally – e-cigarette products to consumers, in accordance with whatever legal framework is deemed appropriate, in order to provide consumers choice.
These products are currently widely available via overseas online alternatives losing Australian based retailers considerable income. The demand clearly currently exists.

We also believe stores should have the right to legally sell other quit-smoking products, such as nicotine gum, lozenges and patches.

International evidence shows that e-cigarettes have the potential to help people reduce smoking and in many case quit altogether. We owe it to the many Australians who smoke to provide them this option.

We welcome the opportunity to work with the Advisory Committee on Medicines Scheduling throughout the consultation and review process.

supports the proposed amendment as it relates to nicotine, this is an opportunity to provide greater choice to consumers and allows retailers to sell a harm reduction product also replacing revenue from the traditional product.

has emphasised the urgent need for Government to develop a framework for the legal sale of e-cigarettes. If Government is serious about reducing smoking among the population, they owe it to people who smoke to conveniently provide a better alternative.

E-cigarettes are a potential solution to reduce the incidence of smoking. We need to give these products a chance to succeed.

We should be making it easier – not harder - for people to access products that might help them quit.

This extends to the legal use of liquid nicotine, in controlled quantities, in these devices. Just as some smokers find nicotine gums, lozenges and patches effective in helping them to quit smoking, providing more alternatives and greater choice for those looking to quit smoking should be a given.

Our members report increasing customer enquiries regarding the availability not only of e-cigarettes, but other stop-smoking products too.

There is clear demand from adult customers for greater access to products with the capacity to help them stop smoking.

If a proper framework is not developed quickly to govern the legal sale of e-cigarettes inevitably, as has proven the case with tobacco, the black market will fill the gap.

Illicit e-cigarettes, like illicit tobacco, are by their very nature non-compliant with any mandatory quality, safety or packaging requirements. Yet they are already available for sale – and not through responsible, trained retailers or a trusted supply chain.

For Australians to capitalise on the potential health benefits of e-cigarettes, it will be essential for Government to avoid subjecting these products to the same tax treatment as other restricted product categories like tobacco and pharmacy products.

If e-cigarettes are too heavily taxed it may discourage or prevent people from investigating this solution.
supports restrictions on the sale of e-cigarettes to minors, ensuring the products are child tamper proof, contain an ingredients list and meet minimum safety and quality standards.

Research by Wells Fargo indicates US retail sales of electronic smoking devices could top the $10 billion mark by 2018 due to ongoing interest by both manufacturers and consumers.

As proven by their responsible sale of restricted products like lottery tickets and tobacco, retail stores are more than capable of responsibly selling these products.

It is worth considering international evidence of the success of e-cigarette devices as a tobacco harm reduction measure and understand the approaches used by other nations around the world.

In the US and UK, among other nations, e-cigarettes have been in circulation and available for sale for much longer than in Australia. These products are relatively new to our market. It therefore makes sense to consider the impacts of these products in other countries.

International studies back up the potential role e-cigarettes can play in tackling smoking, with research showing that e-cigarettes represent a safer alternative to smoking and that they can help some people in their efforts to quit.

An August 2015 study commissioned by Public Health England* stated that e-cigarettes are around 95% safer than smoked tobacco.

In July 2016, Public Health England was joined by numerous other UK public health organisations to release a joint statement** on developing a public health consensus on e-cigarettes, products they state “are the most popular quitting tool in the country with more than 10 times as many people using them than using local stop smoking services”.

The UK approach represents a key step forward in recognising that e-cigarettes are a much safer alternative to smoking and have a real and significant role to play in helping some smokers kick the habit.

There’s growing recognition on an international scale that e-cigarettes are among the most widely used and effective products to help people quit smoking. Australia is at risk of falling behind the rest of the world in making these products available to people who could benefit greatly from their use.

The fact that the UK’s most authoritative and respected public health bodies are calling for a public conversation to improve the general public’s awareness of the use and effects of e-cigarettes demonstrates the enormous opportunity these products provide.

The international evidence has struck a chord with select experts and bodies in Australia, including health professionals.
In Australia, New Nicotine Alliance president Attila Danko has previously labelled draconian laws banning e-cigarettes as "monstrous". Addressing a Senate inquiry in Sydney in early 2016, Dr Danko suggested smoking could become obsolete if laws banning e-cigarettes were overturned.


believes Australia must be part of this growing international movement towards the legal recognition of e-cigarettes as a viable alternative to help people stop smoking.

We need to develop a framework for the responsible sale of e-cigarettes in Australia before the black market – as it inevitably will – fills the gap.

Critical to the effectiveness of these products is the nicotine content, in agreed and controlled quantities, to broaden the choice for consumers from the nicotine gums, lozenges and patches currently on offer.

Please do not hesitate to contact me should you require any further information.

Kind regards,
1 September 2016

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

RE: Proposed Amendments to the Poisons Standard (Medicines)
Joint Submission of the

Executive Summary

1. [Thank the Advisory Committee for Medicines Scheduling (ACMS) for the invitation to make a public submission to the consultation.]

2. [Submit that on the basis of overwhelming medical evidence, and in order to facilitate improvements in public health]
   a. Melatonin be exempt from scheduling in preparations of 1mg or less
   b. Paracetamol compounded with caffeine be exempt from Schedule 2 when supplied in primary packs of not more than, 10 tablets/capsules or, 5 sachets of powders or granules and
   c. Nicotine be exempt 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.

4. [Wish to note that the relatively new development and commercial distribution of e-cigarettes and personal vaporisers represent a repurposing of nicotine for non-medicinal purposes. It is noted that while smoking is harmful, medical literature demonstrates that nicotine itself is not harmful at the concentrations which are absorbed from cigarettes or present in electronic nicotine delivery systems. It is noted that Nicotine at a concentration of 3.6% is low risk to the consumer and very low risk to public safety, and does not meet the standard of a Schedule 7 Dangerous Poison and as such should be removed at the levels proposed.]
Melatonin

5. In 2010 there were an estimated 492,000 Australians with primary insomnia costing the economy $54.6 million\(^1\).

6. Melatonin is a safe and effective hormone used for the treatment of insomnia, as well as to alleviate the symptoms of jetlag and is available over the counter in countries such as the United States in concentrations of up to 10mg.

7. A meta-analysis of the literature into Melatonin conducted in 2013 examined nineteen double blind placebo controlled studies involving 1683 subjects. It concluded that “melatonin decreases sleep onset latency, increases total sleep time and improves overall sleep quality. The effects of melatonin on sleep are modest but do not appear to dissipate with continued melatonin use. Although the absolute benefit of melatonin compared to placebo is smaller than other pharmacological treatments for insomnia, melatonin may have a role in the treatment of insomnia given its relatively benign side-effect profile compared to these agents”\(^2\)

8. It is submitted that given the effectiveness of Melatonin, and given the relatively non existent side effects compared to prescription sleeping aids as well as products currently over the counter such as doxylamine succinate, greater awareness of, and use of, melatonin be considered as an improvement to public health. In addition, there is no medical requirement for it to remain scheduled due to the lack of any risk at the concentrations proposed. It is the position of the ATA and MC that it be removed from the schedule at concentrations of 5mg or less, however, in the alternate, its removal at concentrations of 1mg or less as per the application should be considered the bare minimum for action.

Paracetamol with Codeine

9. It is submitted that, given the increasing popularity of paracetamol and caffeine tablets due to their increased effectiveness, that they be exempt from Schedule two to facilitate greater convenience for consumers and that the potential risks are so negligible that they be discounted.

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\(^1\) Wake Up Australia, Deloitte Access Economics, 2011

Nicotine

10. It is noted that Nictone was scheduled in Australia prior to the commercial development of electronic nicotine delivery systems (ENDS). This new delivery method has since 2004 permitted commercial enterprises to participate in tobacco harm reduction, which represents a repurposing of nicotine for non-medicinal purposes.

11. It is noted that the smoking of tobacco products in Australia costs the Australian Commonwealth and State Budgets over $300 million annually\(^3\), primarily through the provision of health services, in addition to other social costs such as to quality of life and that these harms have justified the pursuit of tobacco harm reduction (THR) strategies by all levels of Australian governments.

12. It is submitted that ENDS have demonstrated themselves to be effective substitutes for smoking, with multiple studies further reporting that they are more effective smoking cessation aids than conventional nicotine replacement therapies (NRT). With nicotine scheduled prior to the commercial development of ENDS.

13. The would also wish to draw the Committees attention to the bioethical framework under which such policy operates, and in particular recent work undertaken by Hall, Gartner and Forlini\(^4\). This work concludes that, under all four of the major pillars accepted as the bioethical foundation of modern medical regulatory policy, it would be *unethical* to prohibit or reduce access to ENDS. Specifically:
   a. Respect for autonomy: Individual adults are currently free to consume nicotine in cigarettes. It would be farcical to continue to block access to individual adults seeking to consume nicotine at safe concentrations in ENDS.
   b. Non-maleficence: The autonomy and interests of current smokers are given very little weight by opponents of THR. Policy decisions that do not respect the autonomy and interests of current smokers will lead to greater than necessary harm to those publics.
   c. Beneficence: Public health regulators should see their goal as “fostering choice and reducing the harm of smoking”, not “eliminating all nicotine use”.
   d. Distributive justice: Smokers should be permitted to access nicotinated e-liquid for ENDS without requiring a prescription and/or the capacity to import it.

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Risks and Benefits of Use

14. A recent study conducted by 15 of the world's leading Tobacco Control experts through Georgetown University's Comprehensive Cancer Centre found that e-cigarettes are likely to provide public health benefits based on "conservative estimates" of the likely uptake of vaping and smoking by adolescents and young adults and that "recent claims by some scientists that e-cigarettes are likely to act as a gateway to the use of tobacco products are overstated".

15. An further study published in August 2016 in Nicotine & Tobacco Research found that after switching from tobacco to e-cigarettes, nicotine exposure remains unchanged, while exposure to selected carcinogens and toxicants is substantially reduced.

16. There is considerable research into the addictive nature and toxicity of nicotine, and the wishes to draw the Committee’s attention to several pertinent facts. Firstly, while the tobacco in the average cigarette contains 10mg of nicotine, only about 1mg of nicotine is absorbed per cigarette, as a result of loss in sidestream smoke. Secondly, the rate of absorption of nicotine is fastest when it is delivered via oral inhalation, compared to the progressively slower rates of absorption observed via skin, mouth, or nose and finally and least efficiently, by oral consumption and digestion. It is further noted that current pharmaceutical NRT options including nicotine gum, nasal spray, and patches. As such it is concluded therefore from these points that ENDS can therefore mimic the effects of smoking most closely, making it the ideal substitute product.

17. It is submitted that a further benefit of granting this exemption would be that it would lower the probability of supporting a black or grey market developing in Australia, by exposing nicotine e-liquid to domestic regulation, ensuring safer and more consistent products.

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7 Tobacco Advisory Group to the Royal College of Physicians (UK) 2016, ‘Nicotine without smoke: Tobacco harm reduction’

8 Ibid, page 53
18. further note that this proposal would specifically permit domestic access to e-liquid for non-medical use (in other words, without a prescription from a registered GP). Consumers are already exposed to the risks of using nicotine outside of a medical context, which already occurs when someone smokes a cigarette. Long term risks of consuming nicotine via ENDS as the specific delivery may be currently unknown, but are expected to be significantly lower than the risk of consuming an equivalent amount of nicotine via smoking cigarettes.  

19. would also like to draw the Committee’s attention to the United Kingdom’s Royal College of Physicians, who note in their comprehensive overview of smoking, nicotine, and e cigarette impact that “At low doses, nicotine is a stimulant, which in the short term increases heart rate and may improve attention, memory and fine motor skills. Although potentially lethal at very high doses, at the blood levels typically achieved by smoking nicotine does not result in clinically significant short- or long-term harms.”  

20. would like to further note that the most severe risk to personal health and safety associated with ENDS use relate to the quality and design of hardware used, not the e-liquid and/or nicotine consumed, and this can be easily addressed through adequate regulation.

Purposes & Extent

21. This exemption would have the effect of permitting domestic purchase/sale of e-liquid for non-medical use in ENDS for the purpose of tobacco harm reduction. These sales could occur within existing regulatory frameworks for wholesale and retail distribution, significantly increasing consumer access to and uptake ENDS, as well as the resulting personal and social health and economic benefits.

22. ENDS are promising as substitutes for cigarettes, and preliminary studies suggest that ENDS are more effective smoking cessation aids than conventional nicotine replacement therapies. Some 10% of English smokers who made quit attempts in the last 12 months without using ENDS, reported starting to use ENDS after quitting tobacco.  

23. With ENDS a substitution good to tobacco products, any increase in ENDS would reduce the market for tobacco due to the similarity of user base. Euromonitor notes that the global ENDS market is a $6 billion industry - bigger in dollar terms than dental floss or liquid soap - and without a single major global brand.

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9 Ibid
10 Ibid, page 184
12 Ibid, p25
13 Euromonitor Research, June 22 2015, ‘Vapour Devices and e-Cigarettes in the Global Tobacco Market’ [online]
24. In England, where e-cigarette use is regulated as a consumer product, it has been determined that
   a. Prevalence of ENDS use in the general population has remained stable since 2013, but prevalence of ENDS use is growing among smokers/former smokers (demonstrating a stabilisation of the market)
   b. Over two thirds of ENDS users are current smokers ('dual users') or former smokers
   c. Using ENDS as primary aids for quitting smoking is still increasing.  

N=11695 adults who smoke and tried to stop or who stopped in the past year; method is coded as any (not exclusive) use

West et al, Op Cit
25. wishes furthermore to draw the committee’s attention to comments we received that it was requested we pass on as lived experience:

Toxicity

26. It is submitted that capping the scheduling exemption of nicotine at solutions of 3.6% would equate to 36mg/mL, an amount which would meet the needs of the vast majority of people who use ENDS for NRT purposes. For reference, a UK study found that only 9% of vapers are using concentrations of 19mg/mL or more.

27. is drawn to the United Kingdoms’ Royal College of Physicians recent comments on the changing consensus regarding the lethal dose of nicotine:

“Although nicotine is a toxic compound, overdosing on nicotine products used as directed is almost impossible, given the individual ability to titrate dose and the short half-life of nicotine ... However, ingestion of high doses (purposeful or accidental) can be fatal. Historically, the lethal dose of nicotine for a human adult has consistently been stated to be about 60 mg, corresponding to an oral median lethal dose (LD50) of approximately 0.8 mg/kg. However, this figure has recently been disputed in the light of reports of non-fatal suicide attempts or accidents involving nicotine ingestion, leading to an estimate that the lower dose limit for fatal outcomes is likely to be 500–1,000 mg ingested nicotine, equivalent to an oral LD50 of 6.5–13 mg/kg.”

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Tobacco Advisory Group to the Royal College of Physicians (UK) 2016, ‘Nicotine without smoke: Tobacco harm reduction’, page 57
28. As such, at a concentration of 3.6%, it would be impossible for a person to receive a lethal dose of nicotine through ENDS ‘liquid’.

29. It is also noted that Royal Society for Public Health (UK) advised in August 2015 that nicotine is “no more harmful to health than caffeine”.16

Potential for abuse

30. Evidence suggests that people who use ENDS for NRT purposes are highly unlikely to become dependent: “The relatively slow delivery of nicotine to the brain achieved by NRT is much less reinforcing, and hence much less likely to generate dependence, than cigarette smoking. However, forms of NRT that deliver nicotine relatively quickly, such as the nasal spray, are thought to be more likely to generate dependence than others. Overall, however, the addictive potential of cigarettes is much higher than that of NRT or other non-inhaled nicotine products. Clinically, very few users of NRT become dependent on it.”17

31. Further submit that the potential for abuse of nicotinated liquid for vapour consumption that is distributed at concentrations of 3.6 percent and lower is inconsequential in relation to both a) The potential harm that is minimized by substituting or incorporating e-cigarette use over continuing current tobacco use, and b) The potential abuse of nicotine using other existing NRT products.

32. It is further submitted that concerns about children using nicotinated e-liquid are without basis in evidence, as almost all minors who have used an e-cigarette with nicotinated e-liquid had also tried at least one cigarette.18 It is also worth noting that a recent study in Tobacco Control Magazine found that “the majority of US youth who use vaporisers and e-cigarettes do not vape nicotine.”19

Additional comments

33. It is noted that, for the purposes of the present application, the committee is considering solely the use of nicotine-containing liquids for use in ENDS. submits that alternative ENDS methods, for instance using “heat not burn” tobacco be included in such an exemption, and that the language remains flexible enough to anticipate further technological developments.

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16 Royal Society for Public Health, 13 August 2015, "Nicotine "no more harmful to health than caffeine” Press release [online]
17 Tobacco Advisory Group to the Royal College of Physicians (UK) 2016 op cit p53
18 Christopher Ingraham (25 August 2016) ‘Teen vaping is not what you think it is, researchers say’ Washington Post [online]
Conclusion

34. It is submitted that the scientific evidence, and the growing consensus in the worldwide public health community, demonstrate that there is no reason to prevent adults from accessing nicotinated e-liquid at a concentration of 3.6 percent or less. It is not potent enough at this concentration to pose a health risk to individual ENDS users or to public health, an would be a great benefit to health system budgets and a benefit to the length and quality of life of many smokers. While recognizing that, if the exemption is granted, individual States may choose not to replicate and implement the decision, recommend to ACMS that nicotine should be exempted from Schedule 7 under the specific circumstances proposed.

Recommendations

35. strongly recommend that the Therapeutic Goods Administration:
   a. Melatonin be exempt from scheduling in preparations of 3mg or less
   b. Paracetamol compounded with caffeine be exempt from Schedule 2 when supplied in primary packs of not more than, 10 tablets/capsules or, 5 sachets of powders or granules.
   c. Nicotine be exempt 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.

36. Neither hold any view on any other application currently before the committee, and a lack of comment is not to be interpreted in any way as opposition.

37. thank the committee once again for the opportunity to present this submission, and note our willingness to present further testimony if required.
PROPOSED AMMENDMENT

CANNABIS

The final decision for cannabis provides for hemp seed oil to be exempt from Schedules 8 and 9 when the levels of total cannabinoids are 50 mg/kg or less.

Due to further information provided after the publication of the final decision, the scheduling delegate is undertaking further consideration.

This proposal seeks to determine whether this cut-off for total cannabinoids is appropriate for hemp seed oil, and the delegate is requesting additional information on the levels of cannabinoids (including tetrahydrocannabinols) in hemp seed oil.

The delegate is also proposing to add to the cannabis entries regarding the hemp seed oil exception the following:

"when labelled with either of the following warning statements:

i  Not for internal use; or
ii  Not to be taken."

COMMENTS FOR CONSIDERATION

In the pursuit of logic, truth and the best interests of humans and animals residing in “Australia”, before being able to comment on the Therapeutic Goods Administration’s proposed cannabinoid cut-off level it is necessary to first step back and address the appropriateness of broadening Tetrahydrocannabinol (THC) prohibition - as was established by the UN Single Convention on Narcotic Drugs in 1961 - to now include “all Cannabinoids” with the obvious, yet not stated objective being that of restricting access to Cannabidiol (CBD).

What reasons do the Australian Government have for wanting to ensure Australians have zero contact with CBD? The Government has undertaken thorough research into CBD - let’s see what they found.

Here are some direct quotes from such Government studies.


“The pharmacological properties of CBD, and its safety profile, have been the subject of extensive research, including studies in humans. In contrast to THC, CBD…does not cause psychoactive effects. Studies in laboratory animals indicate that the oral toxicity of CBD is low.

CBD…has been investigated in clinical trials. CBD has been shown to be well tolerated at doses greater than 1000mg per day. No reports of adverse effects…were located in the published literature"
“No reports of adverse effects in the published literature”

There exists in excess of 1600 published studies on CBD in which the Australian Government could not find one instance where CBD had caused any harm. Here are direct quotes from those studies. This is what the world’s leading scientists have to say about CBD:

In humans, CBD has been tested in rheumatoid arthritis, multiple sclerosis, anxiety and psychosis and shows an extremely safe profile.
Professor Silveira - University of Sao Paulo, Brazil.

“CBD, unlike Rimonabant, has an excellent safety profile and normalises the endocannabinoid system”
Professor Morgan - University College of London, UK

“CBD has an extremely safe profile in humans”
Professor Izzo - University of Naples, Italy.

“The beneficial effects of CBD administration in psychiatric symptoms adds to its safe profile in humans”
Professor Campos - University of Sao Paulo, Brazil

“Multiple experimental and clinical trials portray CBD as a safe agent”
Dr. Kogan - Hebrew University, Israel

“These findings provide compelling evidence for the use of CBD in the treatment of inflammation and neuroprotection both in terms of its efficacy and safety”
Professor Burstein - University of Massachusetts Medical School, USA

“CBD can be safely administered over a wide dose range”
Professor Zuardi - University of Sao Paulo, Brazil

“CBD has proven to be a useful and versatile substance, as we all being safe”
Dr. Schier - Federal University of Rio de Janeiro, Brazil

“CBD is the most investigated non-psychotropic constituent of cannabis and has…a safe profile in humans.”
Dr. Anavi-Goffer - University of Aberdeen, UK

“CBD was safe and well tolerated with encouraging results”
Dr. Yeshurun - Tel Aviv University, Israel

“CBD seems to be devoid of psychoactive activity and other undesirable side effects in humans. CBD neither interferes with several psychomotor and psychological functions in humans nor potentiates alcohol effects on these functions.”
Professor Cunha - The Paulista School of Medicine, Brazil
So, the Australian Government and all the world’s leading Cannabinoid scientists are very clear on the following undisputed undeniable FACT: **CBD IS EXTREMELY SAFE**

Furthermore, in the research undertaken by the Australian Government it quotes research by Leizer and Lachenmeier where it was shown that only THCs and CBD are found in Hemp Seed oil - the other cannabinoids are not detected using even the most sensitive analytical procedures.

**Amendments to the Poisons Schedule are clearly an attempt to prevent access to CBD.**

Knowing that CBD cannot harm people in practically any quantity, something that cannot even be said of clean water, any intelligent, honorable person would surely ask “why prohibit CBD at all?”

If the Government sought to conduct itself honourably and honestly for the best interests of “Australians” - would the opposite course of action actually be the most logical approach to CBD? ie. to promote it instead of prohibit it?

**FACTS FAVOURING CBD CONSUMPTION**

After any competent study of the research into Cannabinoids it quickly becomes abundantly evident that **CBD is conditionally essential to human health.**

The human body manufactures its own Cannabinoids as part of the Endocannabinoid System. In fact, **without Cannabinoids the person reading this sentence would never have come into existence.**

The Cannabinoids in your mother’s body prevented her immune system from destroying you when your developing embryo was identified as foreign material in her womb.

It is well established in the research that unhealthy lifestyle factors - including but not limited to use of pharmaceutical drugs - can damage the Endocannabinoid System preventing it from performing it’s primary role, that of regulating homeostasis (balance) of all body systems.

This dysfunctional state has been termed “Endocannabinoid Deficiency” in the research. The consequences of Endocannabinoid Deficiency are anxiety, depression, heart disease, cancer, respiratory disease and all the other leading metabolic causes of death and disease that plague mankind.

The fact that 8 out of the world’s top 10 selling drugs have “G-Protein Coupled Receptors” (the Endocannabinoid System) as their target is evidence that the pharmaceutical industry has long been aware that Endocannabinoid dysfunction and deficiency is the cause of many if not most diseases.

The evidence reveals that two things are exclusively capable of reversing this dysfunction - phytocannabinoids (cannabinoids from plants) like CBD and providing the raw materials the body requires to make its own cannabinoids and cannabinoid receptors.

And what are those raw materials? Alpha Linolenic Acid (Omega 3) and Linoleic Acid (Omega 6) in a ration of 1:4.
Both CBD plus Omegas 3 and 6 in a 1:4 ratio are only found in one place - the Hemp plant.

Yes - that means Hemp has the potential to safely and naturally reverse most if not all serious diseases. Yes - that is how the body was designed.

When you consider that CBD and Hemp based Omegas are entirely safe and entirely environmentally sustainable, any attempt to prevent humans from having access to these safe, natural, essential nutrients would be less than honourable to say the least.

Here is what US Administrative Law Judge Francis L. Young - the head legal officer for the US Government’s Drug Enforcement Agency (DEA) had to say in his “Findings of fact and conclusions of Law” in “The Matter Of Cannabis Rescheduling Petition, Docket No. 86-22, September 6, 1988:

“It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between people suffering illness and the health benefits offered by Cannabis”

Here is a direct quote of the rationale Judge Young gave for this statement after four years of investigating all relevant information:

“Nearly all medicines have toxic, potentially lethal effects. But Cannabis is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality.

This is a remarkable statement. First, the record on Cannabis encompasses 5,000 years of human experience. Second, Cannabis is now used daily by enormous numbers of people throughout the world. Estimates suggest that from twenty million to fifty million Americans routinely, albeit illegally, smoke Cannabis without the benefit of direct medical supervision.

Yet, despite this long history of use and the extraordinarily high numbers of social smokers, there are simply no credible medical reports to suggest that consuming Cannabis has caused a single death.

By contrast aspirin, a commonly used, over-the-counter medicine, causes hundreds of deaths each year.

Drugs used in medicine are routinely given what is called an LD-50. The LD-50 rating indicates at what dosage fifty percent of test animals receiving a drug will die as a result of drug induced toxicity. A number of researchers have attempted to determine Cannabis’s LD-50 rating in test animals, without success. Simply stated, researchers have been unable to give animals enough Cannabis to induce death.

At present it is estimated that Cannabis’s LD-50 is around 1:40,000. In layman terms this means that in order to induce death a Cannabis smoker would have to consume 40,000 times as much Cannabis as is contained in one Cannabis cigarette.

NIDA-supplied Cannabis cigarettes weigh approximately .9 grams. A smoker would theoretically have to consume nearly 1,500 pounds [680kg] of Cannabis within about fifteen minutes to induce a lethal response.”
In strict medical terms Cannabis is far safer than many foods we commonly consume. For example, eating ten raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough Cannabis to induce death.

Cannabis, in its natural form, is one of the safest therapeutically active substances known to man.”

PROPOSED CHANGES TO THE POISONS STANDARD

Clearly, in light of the information presented here, the question of whether or not it is appropriate to limit all Cannabinoids in Hemp Seed oil to below 50mg/kg (as a veiled means to prevent CBD consumption) is itself an inappropriate question.

Clearly the prohibition of natural CBD, including its limitation in Hemp Seed oil is against the best interests of humans everywhere.

May the honourable members of Government charged with making such decisions use this information to its best effect.

Should any further information or clarification be required please promptly contact the responsible for submitting this information.