About the Thoracic Society of Australia and New Zealand (TSANZ)

The Thoracic Society of Australia and New Zealand (TSANZ) is the only Peak Body in Australia that represents all health professionals working in all fields of respiratory health. The Society's mission is to lead, support and enable all health workers and researchers who aim to prevent, cure and relieve disability caused by lung disease.

TSANZ has a membership base of approximately 1800 individual members from a wide range of health and research disciplines. TSANZ is a leading provider of evidence-based guidelines for the treatment of respiratory disease in Australia and New Zealand, undertakes a large amount of professional education and training, is responsible for significant research administration, and coordinates an accredited respiratory laboratory program

TSANZ Submission on the Interim Decision to amend the Nicotine Entry in the Poisons Standard.

TSANZ welcomes the opportunity to submit a response to the Therapeutic Goods Administration's (TGA) consultation on the interim decision in relation to the scheduling of nicotine. In responding to this consultation TSANZ has considered the published evidence base and actively sought feedback from our medical members on the interim decision.

We have appended a copy of the TSANZ position paper on e-cigarettes.

We view this draft decision as one element of a whole of Government approach to problems associated with the emergence of e-cigarettes (ECs). The positions taken and policies developed must be consistent and actions complementary. TSANZ commends the Delegate for the broad focus on the public health implications of various modes of Nicotine Scheduling.

What are the problems that need to be addressed?

TSANZ believes that the current personal importation scheme has significant flaws.

1. There is essentially no limit on nicotine concentration or volume and hence no guarantee that it is for personal use

2. There is no form of quality control. All e-liquids are harmful but there is no warranty that the product imported is consistent , free from contaminants and not containing substances of particular added toxicity

3. In reality there is no age validation and no form of assurance that the personal importer is eligible for and holds a genuine prescription

4. The nicotine prescriber may not be the ordinary GP for a patient and we note that contraindications may not be elicited and personal behavioural support may not have been implemented to augment any benefit of nicotine in achievement of smoking cessation

5. Given that less than 10% of smokers are currently using e-cigarettes and amongst those smokers who use e-cigarettes only one-third say they are using them to help with cessation, this importation provision is not commonly being used for the achievement of smoking cessation.(1) Among daily e-cigarette users in 2016, around a third reported being daily smokers of combustible cigarettes. (2)Dual use confers no harm reduction.

Therefore, change is necessary but the changes must be incremental and able to be effectively reversed in a timely manner should the desired outcomes not be achieved.

Where do e-cigarettes fit in?

In common with the position of RACGP, we agree the short-term use of ENDS is not a first line treatment option for smoking cessation in smokers who express to their own doctor a desire to cease smoking using e-cigarettes. Evidence-based effective therapies should always be recommended first. Concurrent smoking and EC use does not reduce harm. Use of e-cigarettes after smoking cessation increases the risk of relapse to smoking and therefore we believe that ex-smokers should use these products for the least period possible.(2, 3) E-cigarettes should never be used by current non-smokers. (4)

We wish to comment on some statements in the interim decision.

"In my assessment of the evidence, I find that the use of nicotine containing e-cigarettes for non-therapeutic use has contributed to, and is likely to contribute to, communal harm."

We support this conclusion and add that therapeutic use must be defined narrowly for the specific purpose of cessation of smoking. The ANU report clearly demonstrates the population harm associated with e-cigarettes with regard to uptake by young people and the gateway effect amongst non-smokers. (2)The report notes that current "patterns of use [of ECs] in Australia are largely inconsistent with short term use of e-cigarettes for smoking cessation. Patterns are more consistent with people using e-cigarettes in addition to combustible cigarettes, substitution of combustible tobacco smoking with e-cigarettes and uptake of e-cigarettes by people who have never smoked."(2)

"In my view, restrictions on the availability of e-cigarettes are necessary to mitigate the potential uptake of smoking in young adults who would otherwise be at low risk of initiating nicotine addiction."

We support this conclusion, although we contend that "potential" may be an inapt descriptor. Uptake of combustible tobacco use in youth exposed to EC is now unequivocally proven. New Zealand, the United Kingdom, Canada and the United States are commonly referred to by promoters of e-cigarettes as countries that Australia should follow as having liberal and successful regulatory environments and retail availability. These countries have, in common, dramatic increases in youth vaping, and easy access which has expanded the number of young people addicted to nicotine. Canada, NZ and the UK have recently seen at best a flat-lining of long-term declines in youth smoking rates. (5-7)In these countries, easy corner-store and vape shop access has not been of assistance in public health, and is an approach we must not replicate.

"I note the available evidence does not support that e-cigarettes are a safer alternative to smoking cessation aids currently available and that there is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting."

We agree with these conclusions, which require that there be considerable circumspection in changes. Changes must be an effective response to identified issues and must not create additional issues to be addressed at a future time.

For example, as there is no evidence to support the contention that flavoured nicotine solutions are advantageous compared with simple solutions of nicotine/propylene glycol, there should be no need for importation and prescription of flavoured solutions(see further comments below on the role of prescribers). No data address the question of whether pod-based flavoured nicotine salt solutions achieve smoking cessation. The same applies to novel heat-not-burn tobacco products. Therefore, TSANZ **does not** support and will vigorously oppose importing mechanisms for Heat not Burn and JUUL or similar products.

The evidence demonstrates that 1) e-cigarettes have not yet been demonstrated to be effective and safe as a cessation aid 2) e-cigarette use is associated with progression to smoking combustible cigarettes, 3) that there is no harm reduction achieved through dual use of ANDS and combustible cigarettes, 4) e-cigarette use may result in higher relapse rates and increased nicotine addiction resulting in increased difficulty in quitting. (2, 3) We note the recent Cochrane report which suggests the potential for e-cigarettes as a smoking cessation aid however caution is warranted as the Cochrane study is correctly identified as being "limited by imprecision".(8)

"The Schedule 4 entry will capture nicotine when prepared for use in e-cigarettes, e-juice, heat-not-burn tobacco products, chewing tobacco, snuff and other novel nicotine products, even if no therapeutic claims are made."

TSANZ finds this statement perplexing – perhaps it is the use of the term "capture". Given that other elements of the interim decision describe a prescription route to nicotine access, we are puzzled that any sort of system needs to be available for products other than nicotine solutions. We do not support the use of snuff, chewing tobacco or heat-not-burn tobacco by any mechanism.

Child Resistant Closures for Liquid Nicotine Products

The e-cigarette market is characterised by a lack of quality control and production standards.(9) TSANZ is concerned that there remains nicotine in non-nicotine e-liquids, along with a host of other ingredients which are not proven safe for inhalation. (9)

The requirement for child-resistant closures for **all** liquid nicotine products is strongly supported.

If ANDS and nicotine e-liquids are prescription products, then they must conform to all advertising, safety and product information requirements of prescription products.

TSANZ would also suggest that a warning to use devices as intended and not beyond recommended heat settings or to include any additional products is advised. For example; the use of ECs to inhale

illicit substances and the use of ECs to develop hot-shots or “wasping” to increase a high have been associated with ARDS and death. (10)

TSANZ Response to the Interim Decision

TSANZ notes that the Delegate’s decision to classify nicotine as a prescription only medicine essentially clarifies the existing ability of medical professionals to prescribe nicotine containing e-liquids. TSANZ acknowledges the Delegate’s Interim Decision is a practical response and we support the intent of making nicotine containing products available by prescription only, but we have serious reservations about the short circuiting of the TGA regulatory process.

Should the decision be implemented, on-going evaluation and monitoring for impact on public health must occur and the ability to reverse decisions in a timely manner must be possible. The prescription only model is preferable to a retail consumer goods model and it is the position of TSANZ that ANDS are not suitable as a consumer product.

We would bring to the Delegate’s attention the following concerns of the TSANZ:

1. ANDS including e-cigarettes, heat not burn and oral tobacco products have not been through the regulatory process and are not listed on the ARTG. The evidence of their effectiveness as cessation products is not yet established and the plethora of products on the market makes it virtually impossible to translate trial outcomes to all ANDS products.

2. We note the need for the development of a prescription guidance document should the interim decision become final, but would much prefer to see products submitted to the TGA for inclusion on the ARTG such that prescribers could access reliable evidence about products they are being asked to prescribe.

3. Prescription products require a Product Information (PI) document to assist prescribers to correctly prescribe. The PI must be approved by the TGA and include objective information about the quality, safety and effectiveness of the product. All nicotine products should have an accompanying PI document.

4. Whilst the use of the word therapeutic has been deleted in the amendment to the schedule, it is still the case that the public expect therapeutic actions from prescribers. The TGA is therefore asking Drs to prescribe a poison, with an untested efficacy and safety profile to patients. We are very concerned that advice on dosage and use is being promulgated in the absence of evidence.

5. If this decision proceeds, suppliers should be required to submit their product for independent Quality control testing. Only those products which have successfully been through an independent QC process should be prescribed. Prescribed products should not contain flavourings.

6. To date, no ANDS product has been approved for cessation purposes. Given that all the major tobacco companies now have ANDS products, it is not plausible to argue that the cost of an application is the prohibiting factor. Likewise, we do not permit small backyard operators to produce and market therapeutic goods without going through a robust

regulatory framework. ANDS products should be subject to the regulatory processes of the TGA if they are to be prescribed as a cessation product.

7. We understand that these changes will also apply to all ANDS products including heat not burn products such as IQOS or Juul. TSANZ **does not** support this amendment. These products should remain prohibited products in Australia.

8. The marketing of prescription products is regulated in Australia and prevents direct to consumer advertising. If ANDS products are only available via prescription then they should be managed under the same marketing regulations as other prescription products. Mechanisms must be in place to prevent vested commercial interests from making therapeutic claims about ANDS.

9. Smokers seeking to use ANDS should not be prescribed these as a first line cessation product. Prescribers must ensure combination therapy with behavioural support is completed prior to considering prescribing ECs. The TGA must ensure that robust mechanisms are in place to prevent prescribing of ANDS without first utilising evidence based tobacco dependence treatment.

10. When prescribing ANDS for cessation the same requirements for accessing currently available tobacco dependence medicines should apply ie. to attend behavioural support and time limited use. We also advise that there should be no repeat prescriptions without medical review.

11. The authorised prescriber model greatly simplifies the prescribing process. However, there must be mechanisms in place to ensure that the process, if implemented, operates as planned. This includes managing the potential for over-prescribing and ensuring that these products are not prescribed as first line treatment or to non-smokers or smokers not willing to quit or completely substitute away from combustible cigarettes.

12. ANDS devices which dispense prescription nicotine should be considered a medical device to ensure they meet safety standards and should be regulated as a therapeutic device.For example, a recent study demonstrated that use of a nichochrome heating element in e-cigarettes at high power induced the potentially lethal lung condition EVALI in the absence of tetrahydrocannabinol, vitamin E, or nicotine.(11)

13. TSANZ believes a prescription only approach may assist in reducing uptake amongst young people provided that access to these products through other channels eg online, vape shops is restricted.

Barriers to Prescribing

Doctors already have the ability to prescribe nicotine for e-liquids. Whilst this decision clarifies the process, it does little to address the lack of evidence for the use of these products as a cessation product. Feedback from members identified the following barriers to prescribing non-therapeutic nicotine:

- ANDS are not a homogenous product class; there are literally thousands of devices and e-liquids available to consumers. As none of them are listed on the ARTG, prescribers are unable to make informed evidence based decisions about safety and efficacy for patients. If products are being used for cessation they should be listed on the ARTG.

- Tobacco Dependence Treatment (TDT) is more than writing a prescription. At the present time, prescribers' understanding of existing cessation treatments and compliance with PBS prescribing requirements are sub optimal. Prescribers require additional TDT training and more time to support smokers seeking to quit..

- The ability to easily customise e-liquid products in electronic cigarettes, including by adding illicit substances and even household items in order to achieve a "high" is not an acceptable format for a prescription product.

- It is prescribers who will be responsible for prescribing unproven nicotine products to patients leaving them exposed to potential legal challenge.

- There is concern that prescribing the product will imply that its use has therapeutic benefit or that it is safe despite the lack of evidence for therapeutic benefit and evidence to support long term harm.

- TSANZ members expressed concerns about the purity and quality control of ANDS products as a barrier to prescribing

- Lack of credible information about what is in the product when prescribed, what can be added to the product by the user and/or what the product becomes when heated. For example, flavourings which are safe for ingestion but unknown safety profile for inhalation.

- Flavourings are not demonstrated to be safe .Therefore, prescriptions must be limited to the nicotine containing solution only. As part of responsible prescribing, the prescriber, should advise the smoker that no flavour solution will be recommended. The consequences of later adding flavours then becomes an assumed risk on the part of the smoker/quitter.

Other Matters

Australia has well established cessation medicines and access to these should be enhanced. The current post market review of cessation medicines should ensure restrictions that prevent combination therapy are removed, that engagement with behavioural support is enhanced and that prescribers are fully trained in effective, evidence based tobacco dependence treatment.

Most Australian smokers quit unaided. Those smokers who do require assistance deserve access to treatment that is effective and safe. At the present time ANDS have not been demonstrated to be either effective in cessation not is their safety profile established. The 95% safer claim is a persistent "factoid" lacking data to support it.(12)

TSANZ notes that Australia is a signatory to the WHO Framework Convention on Tobacco Control and we strongly urge the TGA to ensure that the robust regulatory framework is not influenced by the lobbying of the tobacco and related industries.

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