Australian Government
Department of Health
Therapeutic Goods Administration

Notice of final decision to amend the current Poisons Standard - nicotine

21 December 2020

TGA Health Safety Regulation

Contents

1 Notice of a final decision to amend the current Poisons Standard - nicotine

This web publication constitutes a notice for the purposes of regulation 42ZCZS of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulation 42ZCZS, this notice publishes:

- the decision made by a delegate of the Secretary pursuant to regulation 42ZCZR;
- the reasons for the final decision; and
- the date of effect of the decision.

2 Final decision on a proposed amendment in relation to nicotine referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #25, June 2020)

2.1 Final decision in relation to nicotine

Final Decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to make a variation to the interim decision by creating a new listing for nicotine in Part 2, section 2.4 of the Poisons Standard to make it mandatory for child resistant closures (CRC) to be fitted in liquid nicotine preparations when in Schedule 4.

The final decision is to amend the current Poisons Standard in relation to nicotine as follows:

Part 2, Section 2.4 of the Poisons Standard – New entry

Column 1 Name of the poison	Column 2 Nominal capacity
NICOTINE in liquid preparations when in Schedule 4.	All sizes.

Schedule 7 – Amend Entry

NICOTINE except:

~~a) when included in Schedule 6;~~

a) when included in Schedule 4; or

b) in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking; or

c) in tobacco prepared and packed for smoking.

Schedule 6 – Amend Entry

~~NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.~~

Schedule 4 – Amend Entry

NICOTINE in preparations for human ~~therapeutic~~ use **except**:

a) in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking ~~in preparations for oromucosal or transdermal use.~~; or

b) in tobacco prepared and packed for smoking.

(Secretariat note: substances marked # in Schedule 4 of the Poison Standard are listed in Appendix D)

Appendix D, Item 5 – New Entry

5.	Poisons for which possession without authority is illegal (e.g. possession other than in accordance with a legal prescription):
	NICOTINE.

(Secretariat note: the Appendix D listing applies only in relation to preparations included in the Schedule 4 nicotine entry)

Appendix F, Part 3 – No change

POISON	WARNING STATEMENTS	SAFETY DIRECTION
NICOTINE **except** when in tobacco.		1, 4
1: Avoid contact with eyes. **4**: Avoid contact with skin.		

Appendix J, Part 2 – No change

POISONS	AUTHORISATION CONSIDERATIONS
NICOTINE **except** when in tobacco.	

Index – Amend entry

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Materials considered

In making this final decision, the Delegate considered the following material:

- the proposal to amend the current Poisons Standard with respect to nicotine;
- the 13 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations.
- the advice received from the Advisory Committee on Medicines and Chemicals Scheduling in joint session June 2020 (Joint ACMS-ACCS #25);
- the 2385 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- provisions of the *Therapeutic Goods Act 1989* (the Act) relating to the scheduling of substances (Part 6-3) in particular those matters identified in subsection 52E(1) of the Act;
- provisions in the Regulations relating to the procedure for amending the current Poisons Standard (Division 3D of Part 6);

- the Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- the Scheduling Handbook: Guidance for amending the Poisons Standard (version 1.1 July 2019);
- the Royal Australian College of General Practitioners publication, Supporting smoking cessation - A guide for health professionals (second edition, December 2019);
- The Irish Health Research Board publications:
  - Electronic cigarette use and tobacco cigarette smoking initiation in adolescents. An evidence review (12 October 2020);
  - Electronic cigarette and smoking cessation. An evidence review (12 October 2020);
  - Harms and benefits of e-cigarettes and heat-not-burn tobacco products. A literature map (12 October 2020);
- The European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) publication, Preliminary opinion on electronic cigarettes (23 September 2020);
- The Australian National University publication by Banks, E. *et. al.*, (pre-print version), E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis (September 2020);
- The Cochrane Review publication by Hajek, P. *et. al.*, Can electronic cigarettes help people stop smoking, and do they have any unwanted effects when used for this purpose? (14 October 2020);
- WHO European Region, Summary results of the global youth tobacco survey (2 December 2020).
- The publication by Soule, EK. *et al.*, Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes (published February 2020).
- The Regulatory Impact Statement prepared by the Australian Department of Health but only to the extent that it includes considerations which are consistent with the criteria specified in ss 52D and 52E of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*. Those *relevant* considerations are duplicative of the materials set out above. [I note the decision of Jagot J in the matter of *Eve Hemp Pty Limited v Secretary to the Department of Health* [2017] FCA 1051, [Paragraph 31]. Her Honour held that 'in making a decision under s 52D(2) [of the Act] [the Delegate] must have regard to the matters in s 52E(1) and *may* have regard to matters within the subject matter, scope and purpose of Part 6-3 of the Act construed in context.]
- The Report of the Senate Select Committee on Tobacco Harm Reduction released on 18 December 2020, as well the submissions to the Senate Inquiry and testimony at the public hearings held on 13 November and 19 November 2020, to the extent that these are relevant under s 52E of the Act.

Reasons for the final decision (including findings on material questions of fact)

I have made, a final decision, to confirm my interim decision in the following manner:

- Re-schedule nicotine for non-therapeutic human use (other than nicotine when in tobacco prepared and packed for smoking, or for therapeutic oromucosal or transdermal administration as a smoking cessation aid) from Schedule 7 to Schedule 4 of the current Poisons Standard;
- delete the Schedule 6 nicotine entry as there are no longer any registered agricultural and veterinary products containing nicotine.

I have made, a final decision, to vary my interim decision in the following manner:

- create a new listing for nicotine in Part 2, section 2.4 of the Poisons Standard to make it mandatory for child resistant closures (CRC) to be fitted in liquid nicotine preparations when in Schedule 4.

In making my final decision, I have taken into account the material detailed in the interim decision and the 2384 public submissions received in response to the call for further submissions, published on 23 September 2020, under regulation 42ZCZP of the Regulations.

The reasons for my final decision are set out below.

My final decision is to make certain nicotine containing products, including e-cigarettes, only available with a prescription from an Australian medical practitioner. The basis on which I have made my final decision balances consumer demand for nicotine e-cigarettes to support smoking cessation and the public health need to reduce and prevent the initiation of nicotine addiction among non-smokers, in particular, in adolescents.

The reasons that follow focus on e-cigarettes containing nicotine (which will be referred to as 'nicotine e-cigarettes') due to the current evidence on the direct health harms associated with nicotine e-cigarette use, concurrent use of nicotine e-cigarettes with tobacco products, and the potential for nicotine e-cigarette use to lead to nicotine addiction and tobacco use, particularly among adolescents. In my view, the arguments on the harms of nicotine addiction are relevant to other novel nicotine delivery systems captured in my final decision, these include e-juice, heat-not-burn tobacco products, and nicotine in other electronic nicotine delivery systems (ENDS).

My reasons for making this final decision are those set out in the interim decision. I have had particular regard for the new body of evidence, published since the time of making my interim decision, and the public submissions on my interim decision, including a number of significant systematic reviews:

- The Irish Health Research Board systematic reviews (which will be collectively referred to as the 'Irish HRB reports'):
  - Electronic cigarette use and tobacco cigarette smoking initiation in adolescents. An evidence review (12 October 2020);
  - Electronic cigarette and smoking cessation. An evidence review (12 October 2020);
  - Harms and benefits of e-cigarettes and heat-not-burn tobacco products. A literature map (12 October 2020);
- The European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) report, Preliminary opinion on electronic cigarettes (23 September 2020);

- The Australian National University (ANU) report by Banks, E. *et. al.*, (pre-print version), E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis (September 2020);
- The Cochrane Review by Hajek, P. *et. al.*, Can electronic cigarettes help people stop smoking, and do they have any unwanted effects when used for this purpose? (14 October 2020);

Nicotine e-cigarettes have a high addiction potential.[1] Of particular concern, is the attractiveness of these products to adolescents,[2,3,4] and the recent rapid increase in their use by adolescents.[5,6,7] Adolescents and youth are vulnerable and particularly susceptible to nicotine addiction. I reiterate the concerns highlighted in my interim decision regarding the harms associated with use of nicotine by adolescents and note the 2016 report of the US Surgeon General, which concluded that youth use of nicotine in any form, including e-cigarettes, is unsafe.[8] I have considered the Irish HRB reports, which conclude that adolescents using e-cigarettes are between three to five times more at risk of future initiation of cigarette smoking when compared to those who have never smoked e-cigarettes.

The findings of the Irish HRB reports were consistent with the SCHEER report, which concluded that there is strong evidence that e-cigarettes are a gateway to smoking for young people. Similar conclusions were reached in the ANU report, which found that, across multiple settings, non-smokers who use e-cigarettes are consistently more likely than non-e-cigarettes users to initiate cigarette smoking.

I regard the reports of the Irish HRB, SCHEER and ANU to be independent, credible and relevant to my deliberations on nicotine addiction associated with e-cigarette use in adolescents. It follows that I have attached significant weight to these reports on the basis that these are current and comprehensive scientific reviews undertaken by leading international organisations. I note that the findings of the three reports are broadly consistent.

Tobacco use remains one of the leading causes of preventable death and disability among Australians.[9] I am satisfied that there is a powerful argument that reducing the ease with which nicotine e-cigarettes can be accessed by adolescents will act to safeguard current and future generations from nicotine addiction. I find that the prevention of nicotine addiction is a matter relevant to my considerations under part (f) of section 52E of the *Therapeutic Goods Act 1989*, that is, any other matters that the Secretary considers necessary to protect public health, and which I must consider in making my final decision.

I will now set out my deliberations leading to the component of my final decision, which would enable access to nicotine e-cigarettes to support smoking cessation, when such products are supplied in accordance with a doctor's prescription. I have considered the current use patterns of nicotine e-cigarettes in Australia, which according to the AU report, are largely inconsistent with short-term use of e-cigarettes for smoking cessation.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6655516/

[2] https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_10_en

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6651627/

[4] https://onlinelibrary.wiley.com/doi/full/10.1111/1753-6405.13056

[5] https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/contents/table-of-contents

[6] https://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2020/summary-results-of-the-global-youth-tobacco-survey-in-selected-countries-of-the-who-european-region-2020

[7] https://www.tobaccoinaustralia.org.au/chapter-18-harm-reduction/indepth-18b-e-cigarettes/18b-3-extent

[8] https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf

[9] https://www.aihw.gov.au/reports/burden-of-disease/burden-disease-study-illness-death-2015/contents/table-of-contents

Additionally, the ANU report finds that the '*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*', which I have noted with great concern.

I have had regard for the substantial number of submissions from individuals who wish to continue to use nicotine e-cigarettes in the absence of medical supervision. I have considered arguments on the perceived inconvenience and additional effort of having to make, and attend, an appointment for a consultation with a doctor for those who presently use nicotine e-cigarettes. In this regard, I have reflected on the role of the doctor in safeguarding the patient's health against the harms of continued nicotine addiction. A patient's doctor is uniquely placed to give the support required for long-lasting smoking cessation.[10,11] The long-term health risks of nicotine e-cigarettes use are still unclear and, at the time of making my final decision, the Therapeutic Goods Administration (TGA) has not approved any e-cigarette product as a smoking cessation aid. The TGA has approved many other products such as patches, gum, lozenges, mouth spray and inhalators as quitting aids that are safe to use and are demonstrated to increase likelihood of quitting smoking. It follows that nicotine e-cigarettes are not first-line treatments for smoking cessation.[12] Taking into account the current body of evidence and consistent with the Royal Australian College of General Practitioners Supporting smoking cessation - A guide for health professionals (second edition, December 2019) (RACGP guidelines) it is my view that a consultation with a doctor will ensure:

- patients have the opportunity to discuss with their doctor whether approved pharmacotherapy interventions and nicotine replacement therapy (NRT) products would be suitable. If approved pharmacotherapy interventions or NRT are not appropriate then the option to use nicotine e-cigarettes may be considered by the doctor;
- greater likelihood of using a quality nicotine e-cigarette product with reduced risk of injury from the provision of advice on appropriate use;
- close monitoring and management of long-term side effects and health complications from the use of nicotine e-cigarettes;
- greater chance of stopping smoking and relapse prevention through behavioural and advice-based support.

The circumstances under which there may be clinical justification to supply nicotine e-cigarettes to a patient, the doctor's clinical decision-making process, should be guided by the RACGP guidelines. These guidelines provide that nicotine containing e-cigarettes may be a reasonable intervention for individuals who have failed to achieve smoking cessation with approved pharmacotherapies, but remain motivated to quit smoking and have raised e-cigarette usage with their healthcare practitioner.

The question of whether nicotine e-cigarettes are an effective aid to smoking cessation is still contested. I have reflected on the personal experiences shared by many individuals in their submissions on my interim decision and I acknowledge the successful use of nicotine e-cigarettes as an aid to quit smoking for these individuals.

[10] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000165.pub3/full#CD000165-abs-0004

[11] https://pubmed.ncbi.nlm.nih.gov/26928569/

[12] https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation

However, while some individual smokers have successfully used nicotine e-cigarettes to quit smoking, evidence at a population level is lacking. The most reliable evidence on the efficacy of nicotine e-cigarettes for smoking cessation is obtained through systematic reviews of evidence from independent, large scale randomised controlled clinical trials (RCT) undertaken by multiple groups. I have considered the recent ANU, SCHEER reports and the findings of the Cochrane Review. All three groups found evidence for the potential use of nicotine e-cigarettes as an aid for smoking cessation. Importantly, all reports concluded that more reliable, large-scale studies are required to verify these findings. It should be noted that the Cochrane Review suggested that nicotine e-cigarettes may be more effective than nicotine replacement therapy. The differences in the conclusions of the ANU and SCHEER reports, in comparison to the Cochrane Review, on the efficacy of nicotine e- cigarettes, are likely to be a function of the available evidence analysed and the different statistical methods chosen. My detailed views on nicotine replacement therapy will be explored in the reasons that follow.

I have taken into account the public submissions in which individuals expressed a desire to use nicotine e-cigarettes as a long-term substitute for smoking. It is my firm view that the use of nicotine e-cigarettes should be considered in the context of a smoking cessation tool for short-term use and under medical supervision. While the long-term effects of e-cigarette use are still unclear, there is emerging evidence for long-term adverse health effects on the respiratory and cardiovascular system.[13]

I find that the appropriate duration for the reliance on nicotine e-cigarettes to cease smoking is an individual consideration and it should be a clinical decision, made by a doctor, in consultation with a patient. A doctor would take into consideration current medications, physical and mental health and other interventions available, to inform their clinical decision. Indeed, the need to control the access and duration of a therapy by a doctor is consistent with the Schedule 4 Scheduling Factors, according to the Scheduling Policy Framework (SPF). Having considered the current use patterns in Australia, and the requirements of the SPF, I am satisfied that it is in the interest of promoting public health outcomes to change the current access controls on nicotine e-cigarettes to ensure they are only accessible under the supervision of a doctor.

On balance, it is my view that while there are currently promising signs that nicotine e-cigarettes may be of value in smoking cessation, at the time of making my final decision, the evidence is not sufficiently strong to make a firm conclusion. In any event, the inclusion of a substance in a Schedule does not indicate that the substance is available; nor that is has been approved or is efficacious for any use that may be specified in a Schedule.

I have considered the 2385 public submissions received on my interim decision, of which 2243 were from individuals, the majority of these having personal experience with the use of nicotine e-cigarettes. A substantial number of submissions called for nicotine e-cigarettes to be controlled in the same manner as tobacco cigarettes citing the claim that e-cigarettes are 95% less harmful than combustible cigarettes.[14] I am not persuaded that there is merit to this claim having considered a publication, Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes (published February 2020). The authors determined that the claim that e-cigarettes are "95% less harmful" is not credible noting that, among other things, a limitation of the original study is the lack of hard evidence for the harms of most products on most of the criteria. The editorial of the Lancet at the time of the publication of the original claim was also sceptical of the validity of the claim.[15]

[13] https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_10_en

[14] https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction

[15] Lancet Editorial Vol 386 August 29, 2015

A number of public submissions drew comparisons between nicotine e-cigarettes and nicotine replacement therapies (NRT) such as patches and gums available for retail sale. Some of the submissions queried why it was not possible for nicotine e-cigarettes to be made available at the retail sales level in the same manner as NRTs. There are a number of differences between nicotine e-cigarettes and NRTs, including the way nicotine is delivered into the body and subsequently, how it affects the body. It is important to note that NRT products approved in Australia deliver nicotine to the body through the lining of the mouth and cheeks (sprays, inhalator, gums and lozenges) or the skin (patches) whereas nicotine e-cigarettes deliver rapid boluses of nicotine to the lungs. NRTs are designed to reduce nicotine withdrawal and cravings while minimising the potential for abuse. Importantly, NRT products have been approved in Australia, which means the safety, quality, and efficacy of these NRT products have been assessed by the TGA and determined that they can be sold in retail outlets with reasonable safety. I also note submissions advocating that nicotine e-cigarettes be available as Pharmacist Only Medicines (Schedule 3). As previously detailed, I consider that nicotine e-cigarettes currently meet the Scheduling Factors for Schedule 4. However, this does not preclude a down scheduling application in the future if there is sufficient supporting evidence, for example, based on safety data from an Australian approved product should one be included on the Australian Register of Therapeutic Goods (ARTG). I note that NRT, such as patches, were initially approved as prescription medicines and were down-scheduled when supporting safety data became available.

I note the submissions from health peak bodies, professional organisations and researchers, including the Cancer Council, Royal Australian College of General Practitioners, the Public Health Association of Australia, The Pharmacy Guild of Australia and the Australian Medical Association who expressed support for the interim decision. Many organisations, while supportive of the interim decision, also highlighted challenges for implementation in the absence of an approved product included on the ARTG. These submissions called for sufficient time to develop robust prescribing guidelines and the development of quality and safety standards for unapproved products, which would address excipients, labelling, limits on nicotine concentrations and volumes as well as requirements for child resistant closures.

I have reflected on the submissions from vaping businesses and retailers including the Australia Lottery and Newsagents Association and the National Retail Association, many of whom opposed the interim decision and are advocating for nicotine e-cigarettes to be regulated as consumer products. In this regard and as detailed in my interim decision, I consider that nicotine in e-cigarettes satisfies the Schedule 4 factors in the Scheduling Policy Framework. Furthermore, I am of the firm view that nicotine in e-cigarettes or other novel delivery systems does not meet the principles of 'reasonable safety' described in the Scheduling Handbook, which guides the assessment of whether a substance is suitable for exemption from scheduling. While the majority of vaping business expressed opposition, there was some support from within the sector, recognising the benefits for Australian consumers of prescription access to nicotine e-cigarettes.

My interim decision also called for views on the need for child resistant closures for liquid nicotine, noting that NRT products approved by the TGA must be supplied in containers with child resistant closures. I note the overwhelming support in the public submissions for measures that would require child resistant closures for liquid nicotine products. Many individual users of nicotine e-cigarettes noted in their submissions that the products they are importing are already supplied with child resistant closures.

I have considered the legislative instrument, *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95), which applies to medicines registered on the ARTG. In accordance with TGO 95, nicotine is a substance for which a child resistant closure is required regardless of whether the nicotine-containing medicine is available only on prescription or available for retail sale. However, TGO 95 does not capture unapproved products. In my view, there is a need for consistency in the requirements for child resistant closures for any liquid nicotine product, whether or not it is approved or unapproved. Accordingly, my final decision is to include liquid nicotine in Part 2, Section 2.4 of the Poisons Standard, which lists substances for which the containers are required to have child resistant closures. Noting that the Poisons Standard, including Part 2, Section 2.4, is implemented and enforced by the States and Territories, I consider that consistent Commonwealth legislation would also be of benefit. On this basis, consideration should be given to including child resistant closure requirements for nicotine in approved or unapproved products in a therapeutic goods order made under s 10 of the Act. If this is agreed, an option would be to amend TGO 95 to ensure that it applies to both approved and unapproved nicotine products.

In addition to the overwhelming support for child resistant closures, I note that many submissions both opposing and supporting the interim decision have called for quality and safety standards for nicotine e-cigarettes. Stakeholders have highlighted the importance of standards in the current circumstances, where there are no nicotine e-cigarettes included on the ARTG and consumers will be accessing unapproved products. While the development of such a standard is beyond the scope of scheduling and the powers delegated to me, I consider there would be benefit from further work with stakeholders to develop appropriate standards that would apply to unapproved products. These may include labelling requirements, warnings, limits on concentration and volumes and excipients.

A number of stakeholders, including the Royal Australian and New Zealand College of Psychiatrists (RANZCP), have highlighted the importance of considering the impacts of the scheduling decision on vulnerable populations, such people with mental illness who use or may benefit from using nicotine e-cigarettes but do not regularly engage with the health system. I recognise that my decision will not benefit these groups but concur with Professor Allan, President of the RANZCP, in his testimony at the public hearings of the Senate Inquiry[16]; that potentially negative impacts for marginalised populations would not justify treating nicotine as a consumer good.

I note in some public submissions there was confusion as to the relationship between my interim decision and the prohibition on importing e-cigarettes containing vaporiser nicotine (the 'customs restriction), which I note, has been deferred as of October 2020. It should be clarified that my final decision is not concerned with the customs restriction, which is a separate decision of the Australian Government. I would further clarify that my final decision does not impact the availability of personal importation scheme to import nicotine e-cigarettes in accordance with a doctor's prescription.

I have considered the Report of the Senate Select Committee on Tobacco Harm Reduction[17], and note that the nature of the submissions and testimony to the Senate Inquiry are similar to those received on the interim scheduling decision. I note Recommendation 4 of the Senate Committee's Report, which supports the implementation of any prescription pathway recommended by the TGA and measures to ensure a smooth process by which medical professionals can prescribe nicotine e-cigarettes. I also note Recommendation 5, which calls for

[16] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Tobacco_Harm_Reduction/TobaccoHarmReduction/Public_Hearings

[17] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Tobacco_Harm_Reduction/TobaccoHarmReduction/Report

the implementation of minimum product quality and safety standards. As outlined above, I support the development of standards in consultation with stakeholders.

I signify my support for views expressed in the public submissions and the Senate Committee's Report for a post-implementation review of the impact of this scheduling decision on healthcare practitioners and the extent to which it has met its objectives.

Date of effect of the decision

I have decided to delay the implementation date until **1 October 2021**.

I find that an implementation date of 1 October 2021 balances the need to remove the current accessibility of nicotine e-cigarettes to adolescents while allowing businesses time to carry out the necessary steps to prepare for the changes and comply with the requirement for child resistant closures.

I have had regard for requests made in the public submissions on the interim decision, as well as the submissions to the Senate Inquiry, to delay the implementation date. A number of stakeholders, including the Royal Australasian College of Physicians (RACP) in their submission to the Senate Inquiry and the Pharmaceutical Society of Australia (PSA) in their submission on the interim decision, requested further time to allow for clinician and consumer education and development of evidence based prescribing guidelines and quality and safety standards for unapproved products. In particular, I have taken into account the considerable responsibility placed on general practitioners to ensure there is an evidence-informed, shared decision-making process whereby the patient is aware of the risks of nicotine e-cigarettes.

On balance, I find that an implementation date of 1 October 2021 sufficiently addresses the need to arrest the rapid increase use of nicotine e-cigarettes in adolescents while allowing time for business to respond to the changes and the provision of resources for healthcare practitioners and patients to support evidence-based decision making on prescribing nicotine e-cigarette.