



Australian Government
Department of Health
Therapeutic Goods Administration

Proposed changes to the way nicotine is supplied

Consumers and Health Professionals



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Health Products Regulation
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TGA Health Safety
Regulation



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Introduction

These webinar information sessions are intended to explain the proposed changes to the way nicotine is supplied

- What is the problem?
- Current status
- What are the proposed changes?
- What would the proposed changes mean for consumers, doctors and pharmacists?
- The scheduling process and what the decision maker must take into account
- Q&A
- Next steps

Scheduling is a separate from the Government's proposed prohibition on the importation of e-cigarettes containing vaporiser nicotine – decisions on this are made by Government

What is the current legal situation re nicotine e-cigs?

- Nicotine in e-cigarettes is **already a Prescription Medicine** when used for smoking cessation
- Nicotine in e-cigarettes/ e-juice for **non-medical use**:
 - **Sale is currently illegal** in all Australian States and Territories
 - **Possession (even if bought online) is currently illegal** everywhere but South Australia
 - Because it is defined as a Schedule 7 “dangerous poison in law”
 - Despite this, confusion exists regarding the legal status of nicotine e-cigarettes when not for therapeutic use

What is the problem?

Two policy goals for e-cigarette usage in Australia

- Simple and legal access to nicotine containing e-cigarettes for smoking cessation – provide an OFF RAMP for smokers
- Prevent the rapid growth of youth uptake – avoid an ON RAMP for youth non-smokers

Significantly increasing use of nicotine e-cigarettes by youth

- Australians aged 15-24 - 4.5 % are current e-cig users in 2019 up from 2.3 % in 2016
- US High Schools - 27.5 % are current e-cigarette user in 2019 up from 11.7% in 2017
- Canadians aged 15-19 - 15 % are current e-cigarette users in 2019 up from 6% in 2017
- Strong evidence of nicotine e-cigarettes as a '**gateway**' to smoking in youth
- Exposure to nicotine in **adolescents** may have long-term consequences for brain development



Nicotine and the adolescent brain

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Abstract Adolescence encompasses a sensitive developmental period of enhanced clinical vulnerability to nicotine, tobacco, and e-cigarettes. While there are sociocultural influences, data at preclinical and clinical levels indicate that this adolescent sensitivity has strong neurobiological underpinnings. Although definitions of adolescence vary, the hallmark of this period is a profound reorganization of brain regions necessary for mature cognitive and executive function, a working memory, reward processing, emotional regulation, and motivated behavior. Regulating nicotine saturation during this time with nicotine, via tobacco or e-cigarettes, has a profound impact on the developing brain's distinct neurobiology and unique sensitivity to nicotine. This review, we highlight recent clinical and preclinical data on the neurochemical systems. We argue that a low-dose nicotine exposure during adolescence can have unique perturbations of critical facets of neurochemistry. We argue that a low-dose nicotine exposure during adolescence can have unique perturbations of critical facets of neurochemistry. We argue that a low-dose nicotine exposure during adolescence can have unique perturbations of critical facets of neurochemistry.

ADDICTION

RESEARCH REPORT

SSA SOCIETY FOR THE STUDY OF ADDICTION
doi:10.1111/add.14558

Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project

Shannon Gravely¹, Pete Driezen¹, Janine Ouimet¹, Anne C. K. Quah¹, K. Michael Cummings², Mary E. Thompson¹, Christian Boudreau¹, David Hammond¹, Ann McNeill^{3,4}, Ron Borland⁵, James F. Thrasher^{6,7}, Richard Edwards⁸, Maizurah Omar⁹, Sara C. Hitchman¹⁰, Hua-Hie Yong^{5,10}, Tonatiuh Barrientos-Gutierrez⁶, Marc C. Willemsen¹¹, Eduardo Bianco¹², Marcelo Boado¹³, Fastone Mathew Goma¹⁴, Hong Gwan Seo¹⁵, Nigar Nargis¹⁶, Yuan Jiang¹⁷, Cristina De Abreu Perez¹⁸ & Geoffrey T. Fong^{1,19}

ABSTRACT

Aims This paper presents updated prevalence estimates of awareness, ever-use, and current use of nicotine vaping products (NVPs) from 14 International Tobacco Control Policy Evaluation Project (ITC Project) countries that have varying regulations governing NVP sales and marketing. **Design, Setting, Participants and Measurements** A cross-sectional analysis of adult (≥ 18 years) current smokers and ex-smokers from 14 countries participating in the ITC Project. Data from the most recent survey questionnaire for each country were included, which spanned the period 2013–17. Countries were categorized into four groups based on regulations governing NVP sales and marketing (allowable or not), and level of enforcement (strict or weak where NVPs are not permitted to be sold); (1) most restrictive policies (MRPs), not legal to be sold or marketed with strict enforcement: Australia, Brazil, Uruguay; (2) restrictive policies (RPs), not approved for sale or marketing with weak enforcement: Canada, Malaysia, Mexico, New Zealand; (3) less restrictive policies (LRPs), legal to be sold and marketed with regulations: England, the Netherlands, Republic of Korea, United States; and (4) no regulatory policies (NRP), Bangladesh, China, Zambia. Countries were also grouped by World Bank Income

Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context

24 September 2020

Prepared by: Emily Banks, Katie Beckwith

Present from reports by: Emily Banks, Miranda Ha Baenziger, Amelia Yazidjoglou, Sinan Brown, Iqbal, Grace Joshy, Katie Beckwith, Katherine van Maddox, Alexandra Marmor, Christina

FOCUS | CLINICAL

Smoking cessation



CPD

Nicholas A Zavar

Background

Although Australia is a world leader in tobacco control, smoking remains the largest behavioural risk factor making the largest contribution to death and disease. Smoking rates remain high in Aboriginal and Torres Strait Islander people and in people with mental health problems. Priority groups for cessation include women who are pregnant and people with cardiovascular disease.

Objective

This article, based on the recently published second edition of *Supporting smoking cessation: A guide for health professionals*, provides an update on current evidence-based practice to support quitting. A brief, time-efficient intervention approach (Ask, Advise, Help) is proposed. New approaches to the use of pharmacotherapy are covered, as is the controversial role of nicotine-containing e-cigarettes and advice for groups with special needs.

Discussion

A combination of behavioural support along with pharmacotherapy to treat nicotine dependence maximises the chances of successful long-term cessation. Combination nicotine replacement therapy (patch and short-acting oral form) or varenicline are the most effective forms of pharmacotherapy.

Australia has been a global leader in tobacco control and has one of the lowest rates of daily smoking in the world (currently 12.2%). However, national targets to reduce daily smoking to <10% and to halve the Aboriginal and Torres Strait Islander adult daily smoking rate by 2018 were not achieved. Smoking rates remain high in key population groups including people with mental illness. Smoking still causes a higher burden of disease than any other behavioural risk factor; in 2015, nearly 21,000 deaths in Australia were attributable to tobacco smoking. Smoking is directly responsible for serious adverse effects both for the mother and the developing fetus. As shown in Figure 1, quitting smoking has remarkable and rapid health benefits.

Primary care practitioners including general practitioners (GPs) and practice nurses are familiar with the challenges in promoting and supporting smoking cessation. This article addresses the challenges from a patient and provider perspective, and provides the most up-to-date evidence-based solutions to support busy practitioners. Brief advice and is highly cost effective. The most effective approach is a combination of both behavioural support and smoking cessation pharmacotherapy.

For the publication *Supporting smoking cessation: A guide for health professionals*, on which this article

is based, the Expert Advisory Group (EAG) reviewed the recommendations from the first edition and also posed new questions in the PICO (patient, intervention, comparator, outcome) format. The Royal Australian College of General Practitioners commissioned the Joanna Briggs Institute (JBI) and the JBI Adelaide GRADE Centre to conduct evidence reviews on these questions, which resulted in Grading of Recommendations, Assessment, Summary of findings (GRADE) tables were incorporated into an 'evidence to decision' framework, which is making practice recommendations. All recommendations received a GRADE rating on the quality of the evidence (certainty) and the strength of recommendation. Recommendations arising from the new PICO questions are shown in Table 1.

Brief intervention: Ask, Advise, Help

One of the barriers mostly frequently cited by health professionals to offering smoking cessation advice is the time required. When time is short, an option is the three-step Ask, Advise, Help structure developed by Quit Victoria. This brief intervention model (Figure 2) can be summarised as:

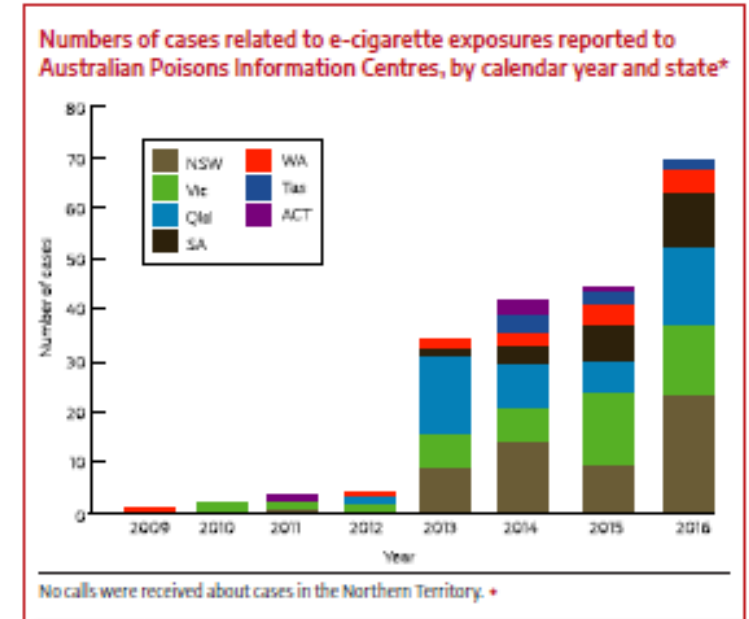
- Ask and record smoking status

What would change if the interim decision is made final?

- From early-mid 2021, if made final, **nicotine e-cigarettes/liquids would only be supplied in accordance with a doctor's prescription**
- The proposed changes **clarify the scheduling for these products, which are**
 - currently prescription-only medicines (Schedule 4) when for human therapeutic use
 - Sale/possession of non-prescription nicotine e-cigs are already largely illegal
- This is to ensure that consumers receive the appropriate **advice from their doctor** on their use for smoking cessation
- The proposed change is intended **to strike a balance between**
 - protecting young people from the risks with using nicotine containing e-cigarettes and
 - access to e-cigarettes to assist smokers to quit on the advice of their doctor

Accidental poisoning

- Risk of **accidental ingestion** of liquid nicotine
 - just 1-2 mL can kill a toddler
 - fruit/candy flavours can be attractive
- Significant increase in **poison centre calls** from 2009 to 2016
- 33 cases of liquid nicotine ingestion in Victoria alone in 2019
 - up from 22 in 2018
- Proposal considers use of **child-resistant packaging for e-liquids**



Toddler killed by mum's liquid nicotine used for vaping

AAP
Mon, 8 July 2019 1:29PM



If the interim decision is made final – importation

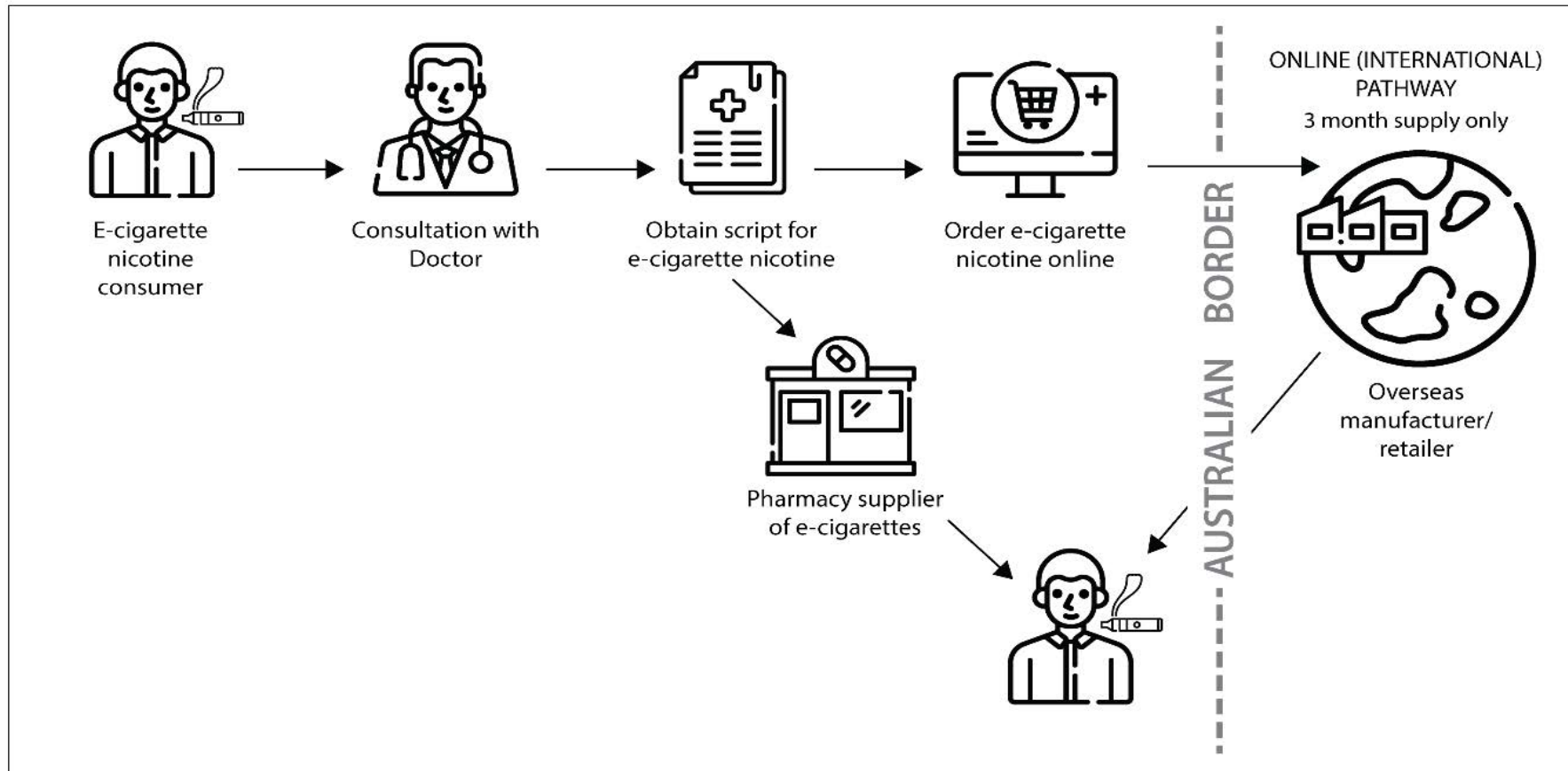
Importation under the TGA Personal Importation Scheme is legal, if the following rules are followed:

- The product must only be used to help you quit smoking
- You must have a current valid prescription from an Australian-registered medical practitioner.
- You can only import nicotine-containing e-cigarettes for personal use or for immediate family
- You can't import more than 3 months' supply at one time
- You should check whether there are other restrictions under state and territory law

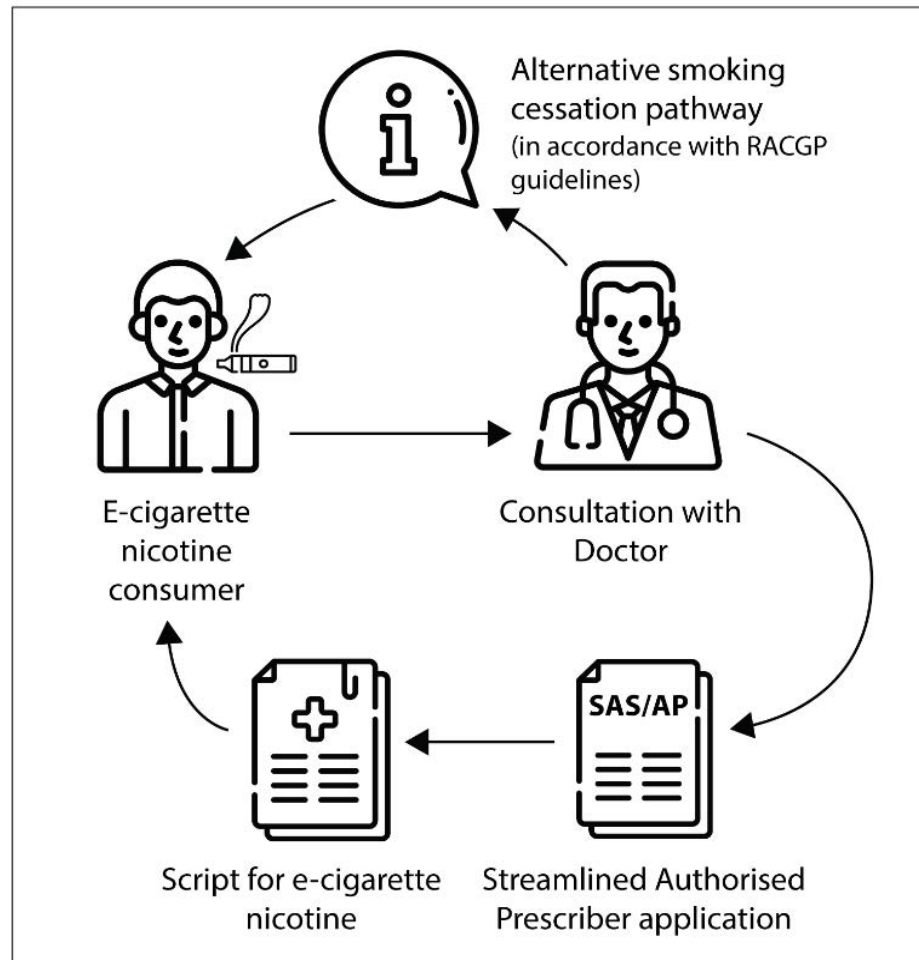
If you attempt to import personally (**without a prescription**) or commercially (**without prescription medicines wholesale approvals**)

- Products may be impounded and destroyed as they are illegal prescription medicine imports
- Australian Border Force (Customs) works closely with the TGA on seized products

CONSUMERS: What the proposed changes would mean



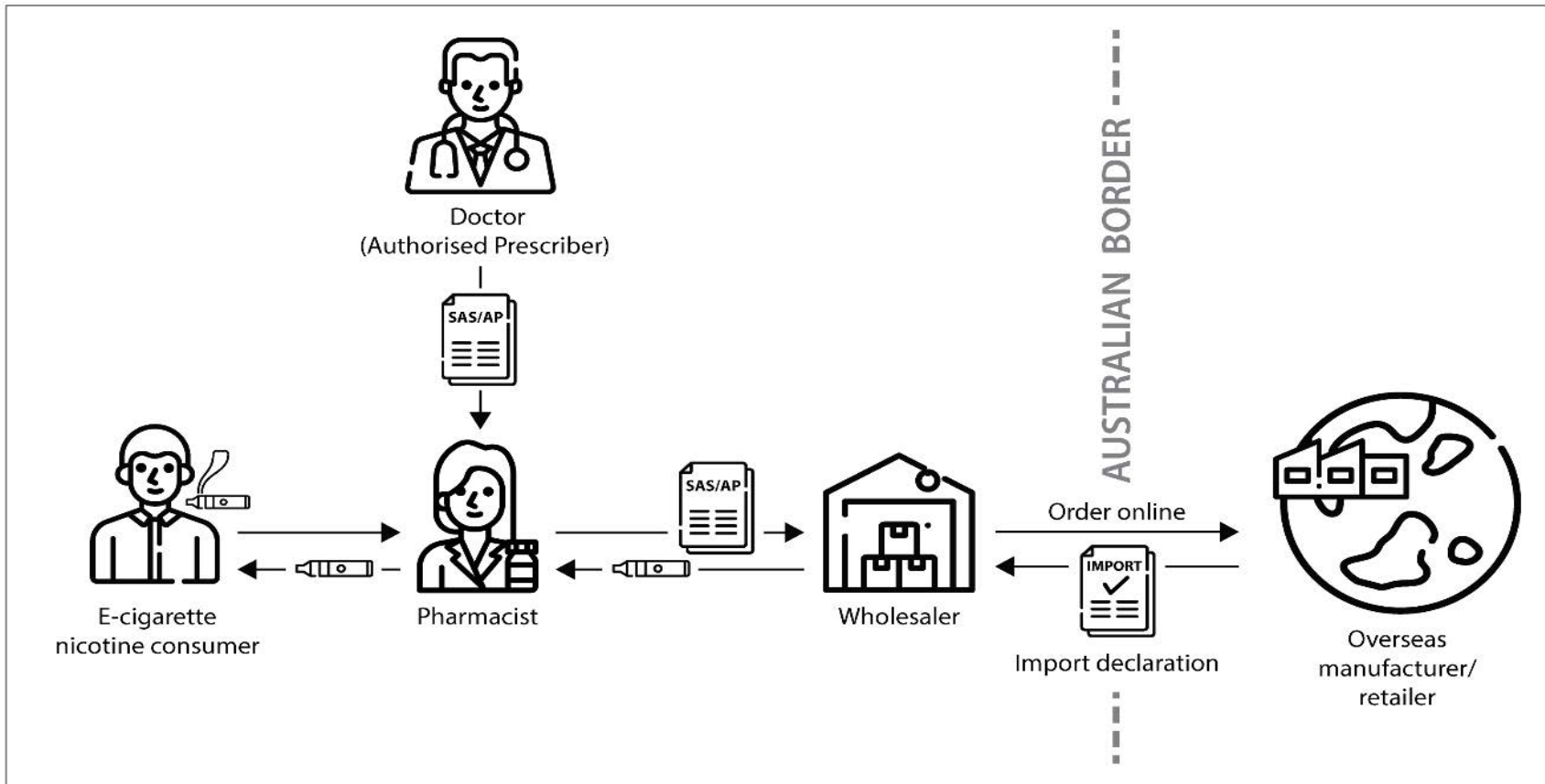
DOCTORS: What the proposed changes would mean



Streamlined Authorised Prescriber

- GP can prescribe for unlimited number of patients
- Online application only requires name, address and AHPRA number to be filled in
- Free of charge
- Valid for five years
- Prescribing info on TGA website

PHARMACISTS: What the proposed changes would mean



Pharmacist dispensing through either/both:

- Local community pharmacies
- Online Australian pharmacies

Vape shops and the black market

- **Vape shops – will be able to continue business exactly as before**
 - Nicotine sale are already illegal across Australia
 - No change to regulations on sale of vaping devices – free to sell except in WA
 - No change to regulation on non-nicotine e-liquids – free to sell
- No controls on product choices and flavours (possible requirement for child-resistant caps)
- Costs should not increase with local pharmacy availability
 - vapers currently pay significant international courier charges
- **Black market controls**
 - Domestic sales already illegal – police can act
 - Border Force (Customs) have unequivocal powers to stop black market imports



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Scheduling process

Consumers and Health Professionals



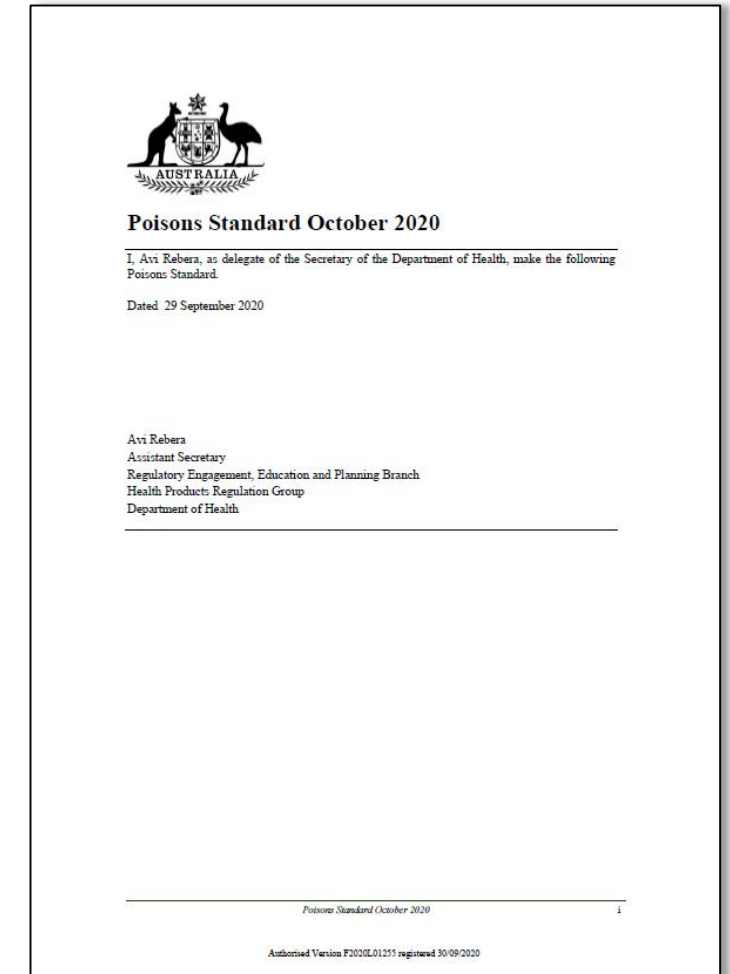
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What is scheduling?

- A national system that controls how medicines and chemicals (“poisons”) are **made available to the public**
- Medicines and poisons are classified into Schedules according to the level of regulatory control over the **availability required to protect public health and safety**
- The Schedules are published in the Poisons Standard and are given **legal effect through state and territory legislation**
- The higher the schedule the greater the controls
 - Medicines are Schedules 4 and 8 (prescription) or 2 and 3 (OTC)
 - Complementary medicines are often unscheduled




What is scheduling?

Schedule 1	Not currently in use
Schedule 2	Pharmacy Medicine
Schedule 3	Pharmacist Only Medicine
Schedule 4	Prescription Only Medicine OR Prescription Animal Remedy
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	Controlled Drug
Schedule 9	Prohibited Substance
Schedule 10	Substances of such danger to health as to warrant prohibition of sale, supply and use

How are scheduling decisions made?

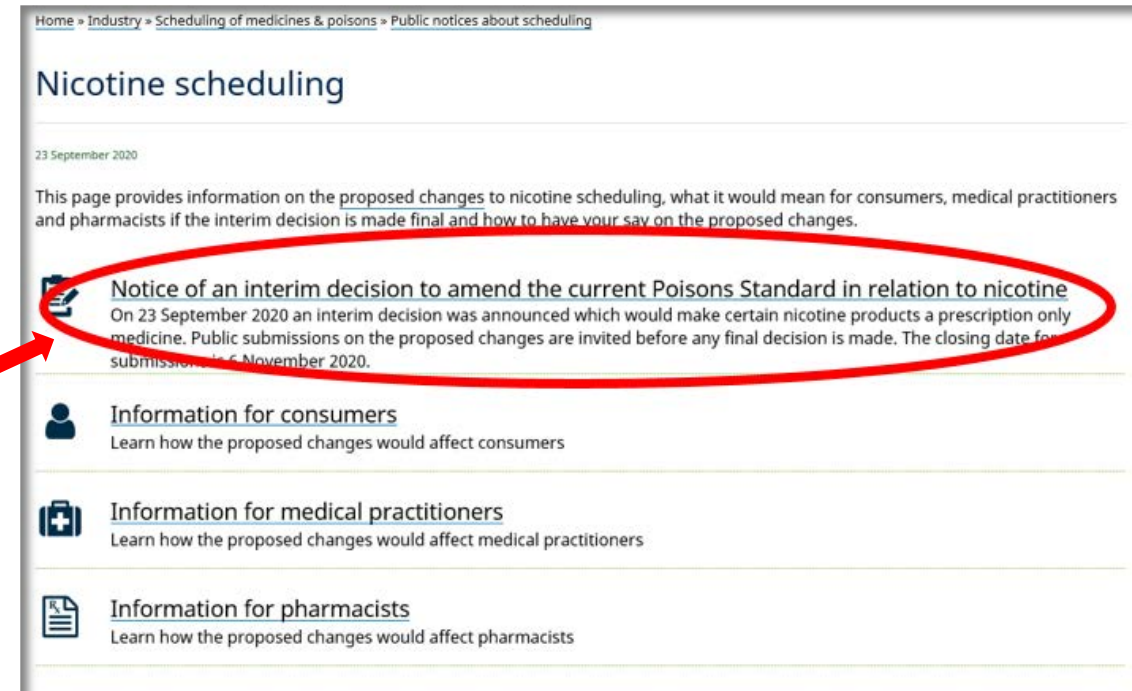
- **Process prescribed in legislation**, underpinned by the Scheduling Policy Framework
 - Therapeutic Goods Act 1989
 - Therapeutic Goods Regulations 1990
- Decisions are made by a **senior medical officer**, independent of Ministers or elected politicians
- Section 52E of the Therapeutic Goods Act defines the criteria by which decisions are made:
 - the **risks and benefits** of the use of a substance;
 - the **purposes** for which a substance is to be used and the **extent of use** of a substance;
 - the **toxicity** of a substance;
 - the **dosage, formulation, labelling, packaging** and **presentation** of a substance
 - any other matters that is considered necessary to **protect public health**
- Prior to making a decision the delegate may seek submissions from the public and advice from an independent advisory committees

The scheduling process for nicotine

- 
- Delegate's nicotine scheduling proposal announced (17 April 2020)
 - Public consultation on scheduling proposal (closed 18 May 2020)
 - Advice received from the Joint ACMS-ACCS #25 (23 June 2020)
 - Delegate's interim decision (published 23 September 2020)
 - **Public consultation on interim decision (closing 6 November 2020)**
 - Delegate's final decision (mid December 2020)

Next steps

- These are **public webinar information sessions only**
- **Slides and outcomes of webinar** published on TGA website
- Make your submission on the interim decision through the **TGA website**
<https://www.tga.gov.au/nicotine-scheduling>
- **Review of public submissions**
- **Delegate's final decision** expected mid December 2020
- **Implementation** 1 April or 1 June 2021



More information



Nicotine

<https://www.tga.gov.au/nicotine-scheduling>



TGA website

www.tga.gov.au



TGA Facebook

<https://www.facebook.com/TGAgovau/>



TGA Twitter

<https://twitter.com/TGAgovau>



TGA YouTube

<https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



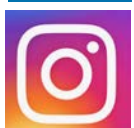
TGA topics blog

<https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn

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TGA Instagram

<https://tga.gov.au/blogs/tga-topics>



Contact us

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Questions?



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