Monitor 12 of 2024 – Ministerial Responses
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Chapter 1: New and ongoing matters:

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The Hon Tony Burke MP
Minister for Home Affairs
Minister for Immigration and Multicultural Affairs
Minister for Cyber Security
Minister for the Arts
Leader of the House

Ref No: MC24-009219

Senator Deborah O'Neill
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation
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by email: sdlc.sen@aph.gov.au

Dear Chair

I write in relation to the matters raised by the Senate Standing Committee for the Scrutiny of Delegated Legislation in its Delegated Legislation Monitor 4 of 2024 on 28 March 2024 in relation to the legislative instrument *Migration (Designated Migration Law—Visa Condition 8208) Determination (LIN 24/009) 2024*, and related correspondence from the Committee Secretary.

I appreciate the time the Committee has taken to consider this instrument. I also acknowledge the delay in responding to the matters raised in relation to the instrument, and thank the Committee secretariat for its continuing engagement with my Department in relation to this matter. My response to the matters raised by the Committee is provided at **Attachment A**.

I trust that this information will assist the Committee in its consideration of this legislative instrument.

Yours sincerely

TONY BURKE

19 / 9 / 2024

Attachment A

Standing Committee for the Scrutiny of Delegated Legislation

Delegated Legislation Monitor
Monitor 4 of 2024

Migration (Designated Migration Law—Visa Condition 8208) Determination (LIN 24/009) 2024 **[F2024L00183]**

Visa condition 8208 – general matters and background

Visa condition 8208 was inserted in the *Migration Regulations 1994* on 1 July 2022, as part of a legislative framework established to enhance the Australian Government's ability to screen for, identify and manage risks associated with the potential unwanted transfer of critical technology. The amendments on 1 July 2022 were made by the following legislative instruments:

- the *Migration Amendment (Protecting Australia's Critical Technology) Regulations 2022* (the PACT Regulations); and
- the *Migration Amendment (Postgraduate Research in Critical Technology—Student Visa Conditions) Regulations 2022*.

While visa condition 8208 is imposed on all Subclass 500 (Student) visas, its effect is limited to student visa holders who either:

- are already studying in the postgraduate research sector (at the masters degree (research) or doctoral degree level), and intend to change their course of study, thesis or research topic to one that relates to critical technology; or
- are not currently studying in the postgraduate research sector, and intend to change their principal course of study to a course at the masters degree (research) or doctoral degree level that relates to critical technology.

In these circumstances, condition 8208 provides that the visa holder must not undertake critical technology related study unless the Minister has approved (in writing) the visa holder undertaking that critical technology related study. To approve a proposed change of course, the Minister must be satisfied that there is not an unreasonable risk of an unwanted transfer of critical technology by the visa holder.

The kinds of technology that are critical technology for the purposes of visa condition 8208 (and the Migration Regulations more broadly) are specified in *Migration (Critical Technology—Kinds of Technology) Specification (LIN 24/010) 2024*. This instrument commenced on 1 April 2024, following a period of extensive consultation with Commonwealth departments of State and other agencies, as well as representatives of the higher education sector, including through the Universities Foreign Interference Taskforce (UFIT), and industry peak bodies through a series of

roundtables and bilateral engagements. Further information in relation to the list of critical technologies and the related consultation is available in the explanatory statement to LIN 24/010.[1] The commencement of LIN 24/010 in effect enlivened the critical technology screening framework, as a result of certain technologies being specified – with effect from 1 April 2024 – as critical technologies.

Migration (Designated Migration Law—Visa Condition 8208) Determination (LIN 24/009) 2024 also commenced on 1 April 2024. The purpose of this instrument is to provide that visa condition 8208 (contained in Schedule 8 to the Migration Regulations) is part of the designated migration law for the purposes of section 495A of the *Migration Act 1958*.

About visa condition 8208 / change of course applications

All Subclass 500 (Student) visas are subject to visa condition 8208, where the visa holder applied for that Student visa on or after 1 July 2022. Under this condition, the visa must obtain written approval before undertaking a critical technology-related course of study in the postgraduate research sector. This includes a:

- postgraduate research course at masters degree (research) or doctoral degree level that relates to critical technology;
- bridging course identified as a prerequisite to a postgraduate research course relating to a critical technology;
- thesis or research topic for a postgraduate research course relating to critical technology.

This approval can only be given after the Minister is satisfied that the visa holder does not pose an unreasonable risk of unwanted transfer of critical technology. This covers the following kinds of technology:

- Advanced manufacturing and materials technologies.
- Artificial intelligence technologies.
- Advanced information and communication technologies.
- Biotechnologies.
- Clean energy generation and storage technologies.
- Quantum technologies.
- Autonomous systems, robotics, positions, timing and sensing technologies.

[1] https://www.legislation.gov.au/F2024L00182/asmade/text/explanatory-statement

The Department maintains an online form on its website[2] for affected Student visa holders to complete if they wish to apply for approval to undertake critical technology related study. This form also includes links to the Department's privacy statement and security statement. Decisions under condition 8208 may be made by the Minister personally or by a delegate of the Minister, consistent with arrangements in relation to other visa processing. Further information about the critical technology visa screening framework is also available to clients and stakeholders on the Department's website at https://www.homeaffairs.gov.au/about-us/our-portfolios/national-security/critical-technology.

Automated decision-making under the Migration Act 1958

Sections 495A and 495B of the Migration Act establish the legislative framework to enable the Minister to arrange for the use of computer programs, under the Minister's control, to make decisions under the Migration Act. These sections were inserted in the Migration Act by the *Migration Legislation Amendment (Electronic Transactions and Methods of Notification) Act 2001*, and commenced on 10 August 2001, establishing a legislative framework to enable the Minister to arrange for the use of computer programs to make certain decisions under migration legislation.

Subsection 495A(1) provides that the Minister may arrange for the use of computer programs to make a decision, exercise a power or obligation, or do anything else relating to a decision, power or obligation, under the "designated migration law". The expression "designated migration law" is defined in subsection 495A(3). Relevantly, nothing in subsection 495A(1) compels the Minister to arrange for such use of computer programs.

Subsection 495A(2) provides, in effect, that the actions taken by the computer program would be taken to be those of the Minister. This ensures the Minister is accountable for the administrative action taken by the computer program, which is important for oversight, accountability and preserving available review mechanisms.

Subsection 495A(3) defines the term "designated migration law" to include Subdivisions A, AA, AB and AC of Division 3 of Part 2 (other than section 48B) of the Migration Act. These provisions essentially relate to the processing of applications for visa grants. In addition, under paragraph 495A(3)(b), the Minister may determine, by legislative instrument, any additional provision of the Migration Act or the Migration Regulations to be part of the "designated migration law".

[2] https://immi.homeaffairs.gov.au/help-support/departmental-forms/online-forms/condition-8208-change-of-course

The power in paragraph 495A(3)(b) is a power to determine that any provision of the Migration Act or the Migration Regulations is part of the designated migration law, alongside the provisions of the Migration Act covered by paragraphs 495A(a) and (aa). Where a legislative instrument is made for the purposes of paragraph 495A(3)(b), this then permits the Minister to make an arrangement under subsection 495A(1) for a computer program to make certain decisions or do things necessary to support making a decision, based on simple and objective rules.

In this context, the purpose of LIN 24/009 is simply to determine that visa condition 8208, in Schedule 8 to the Migration Regulations, is part of the designated migration law. Nothing in section 495A may compel the Minister to arrange for the use of a computer program to make decisions or do anything related to a decision under a provision of the designated migration law. Instead, the effect of LIN 24/009 is simply to expand the scope of the designated migration law to include visa condition 8208.

Where the Department is considering arranging for the automation of certain decisions or processes under s 495A(1) of the Migration Act in relation to the designated migration law, this is done with regard to the Commonwealth Ombudsman's Automated Decision-making Better Practice Guide in relation to providing for automated decision-making. Business rules are developed and considered by technical experts as well as processing and subject matter experts, and legal advice is obtained and considered, including with any updates or changes to business rules ahead of settling and implementing arrangements under s 495A(1). Careful consideration is given to whether business rules are suited to automated decision making, with appropriate objective criteria capable of being automated. This also informs whether only certain decisions may be suitable for automation – for example, any visa refusal decision, involving assessment of subjective matters, is outside the scope of automation and is appropriately a matter for the Minister or delegate.

The Department is also working closely with the Attorney-General's Department and other Commonwealth departments and agencies to develop a consistent legal framework for automated decision-making in government services. This work will support the Government's response to recommendation 17.1 of the Report of the Royal Commission into the Robodebt Scheme, with the framework intended to support a consistent approach to automation of government services, without bias and with appropriate safeguards.

Response to matters raised by the Committee

… whether further detail can be provided about the scope and nature of decision making under the instrument, including which aspects of decisions relating to visa condition 8208 will be made by a computer program and the extent to which these involve discretion…

The purpose of LIN 24/009 is to determine that visa condition 8208, in Schedule 8 to the Migration Regulations, is part of the designated migration law for the purposes of subsection 495A(1) of the Migration Act. No decisions are made under LIN 24/009.

The effect of LIN 24/009 is to enable the Minister to make arrangements under subsection 495A(1) of the Migration Act in relation to decisions that may be made under condition 8208 (including in relation to matters relating to making that decision). Decisions under condition 8208 are not presently automated – and are instead made by delegates of the Minister, supported by appropriate policy and procedural instructions and training.

Where a Student visa holder is seeking to change course to undertake critical technology related study covered by condition 8208, the Minister's decision whether to approve the holder undertaking that critical technology related study is made under subclause 8208(1). The Minister may not approve a course change unless the Minister is satisfied that there is not an unreasonable risk of an unwanted transfer of critical technology by the holder (paragraph 8208(1)(a)). "Unwanted transfer of critical technology" is defined in regulation 1.15Q of the Migration Regulations.

Consideration of applications for a course change under condition 8208 is supported by policy and procedural guidance under the Department's Policy and Procedure Control Framework. Where a visa holder who is subject to condition 8208 submits an application to undertake critical technology related studies, consideration of this application is undertaken by a delegate of the Minister. The delegate is required to:

- consider individual requests and determine if there is an unreasonable risk of unwanted critical technology transfer by the visa holder and
- approve or refuse the student visa holder's request to undertake critical technology-related studies.

The Minister or delegate's decision is informed by consideration of any information provided by the visa holder to support their application, as well an information held by the Department, available through open-source or engagement with other relevant agencies. In the event the decision-maker is considering refusing the application, they also provide procedural fairness to the visa holder. As noted in the explanatory statement to the *Migration Amendment (Postgraduate Research in Critical Technology—Student Visa Conditions) Regulations 2022* (F2022L00866),

common law procedural fairness, including the fair hearing rule, would apply in relation to a decision made under paragraph 8208(1)(b).

If the Minister decides not to approve the visa holder undertaking the proposed critical technology related study, merits review of that decision is available under Part 5 of the Migration Act (see paragraph 4.02(4)(u) of the Migration Regulations). Information concerning the decision, reasons for the decision and the availability of merits review would be provided to the applicant, consistent with processes for other visa decisions.

… whether detail can be provided regarding the information which informs the decision made by the computer program, including whether advice is provided by other government departments and agencies …

… whether consideration has been given to the Commonwealth Ombudsman's Automated Decision-making Better Practice Guide in relation to providing for automated decision-making …

The effect of LIN 24/009 is to enable the Minister to make arrangements under subsection 495A(1) of the Migration Act in relation to decisions that may be made under condition 8208 (including in relation to matters relating to making that decision). While the Department maintains an online form for Student visa holders to apply for a change of course in order to undertake a critical technology related course of study in the postgraduate research sector, decisions under condition 8208 are not presently automated – and are instead made by delegates of the Minister, supported by appropriate policy and procedural instructions and training.

In the event that automated decision-making were to be enabled for decisions made under condition 8208, the effect of subsection 495A(2) is that actions taken by the computer program would be taken to be those of the Minister. This ensures the Minister is accountable for the administrative action taken by the computer program, which is important for oversight, accountability and preserving available review mechanisms.

The effect of subsection 495A(2) also means that a computer program covered by subsection 495A(1) arrangements is bound or subject to the same laws the Minister is subject to when making decisions. In practical terms, this means that consideration must be given in relation to the suitability of a particular kind of decision to automation – having regard to departmental guidelines on automation of administrative decisions, functional and technical specifications and business rules, any related legal advice, as well as broader guidance for Commonwealth agencies, including the Commonwealth Ombudsman's *Automated Decision-making Better Practice Guide*.

… why it is considered necessary and appropriate for the instrument to provide for automated decision-making, noting that it appears automated decision-making may be used for any purpose in relation to making a decision, exercising a power or complying with any obligation relating to visa condition 8208 …

Paragraph 495A(3)(a) of the Migration Act provides that Subdivisions A, AA, AB and AC of Division 3 of Part 2 of the Migration Act (other than section 48B) are designated migration law for the purposes of section 495A. This allows for the Minister, acting under subsection 495A(1), to arrange for the use, under the Minister's control, of computer programs for any purposes for which the Minister may, or must, under those Subdivisions of the Migration Act:

- make a decision; or
- exercise any power, or comply with any obligation; or
- do anything else related to making a decision, exercising a power, or complying with an obligation.

Of note, Subdivisions A, AA, AB and AC contain the provisions of the Act that provide for the making of visa applications, as well as decisions on those visa applications. The Department has long-standing arrangements under section 495A in relation to automation of certain processes and decisions in relation to visa applications – and particularly Student visa applications, where online lodgement and auto-grant arrangements for certain Student visa applications have been in place since 2001. Auto-grant is an automated process by which an electronic visa application is checked against departmental alert lists, security and immigration risk systems and business rules (developed in alignment with visa criteria) and, if the automated processes and checks are satisfied, the visa may be granted automatically in certain circumstances. Applications that do not satisfy automated checks are referred for manual assessment by a visa processing officer (a delegate of the Minister for visa processing and decision-making purposes).

As the decision-making power in Student visa condition 8208 is not covered by paragraphs 495A(3)(a) or (aa) of the Migration Act, a legislative instrument made under paragraph 495A(3)(b) is required in order to extend the 'designated migration law' to cover this provision, as part of the Student visa framework. As noted previously, while LIN 24/009 allows for automation arrangements in relation to condition 8208 under subsection 495A(1), decisions under this condition are currently made by a delegate of the Minister.

… what safeguards are in place to ensure that the minister (or their delegate) exercises their discretionary powers under subclause 8208(1) of Schedule 8 to the Migrations Regulations personally and without fetter …

In the event that decisions under subclause 8208(1) were automated, subsection 495A(2) makes clear that a decision made by a computer program covered by a subsection 495A(1) arrangement is taken to be a decision made by the Minister. This means that the computer program is bound or subject to the same laws the Minister is subject to when making decisions. Where automation is enabled in visa processes, appropriate care is taken to consider business rules and the approach to the exercise of discretion or judgment by the decision-maker. It is a standard administrative law principle that a decision-maker is not fettered in exercising their discretion, and any policy must be consistent with the underlining statutory discretion that it seeks to inform.

… the mechanisms used to identify errors in automated decision-making and, where errors arise, the mechanisms to correct those errors …

Subsection 495B(1) provides that the Minister may substitute a more favourable decision for that of the computer program. This power is intended to operate as a safeguard to enable the Minister to address any injustices caused to applicants, as a result of potential computer-related errors. This power will be used, for example, where a computer program has incorrectly refused to grant a visa or has granted the wrong visa subclass. The Minister may only substitute a more favourable decision if it could have been made under the “designated migration law” as defined in new subsection 495A(3). For example, a visa applicant must continue to meet all of the criteria for the grant of a visa before the Minister exercises this power.

In the event that, for example, decisions to approve course changes under condition 8208 are automated, such decisions would be subject to ongoing monitoring and quality assurance – consistent with the principle established in subsection 495A(1) that a relevant computer system is to be under the Minister’s control. Business requirements, business rules and functional and technical specifications are carefully considered, and where necessary also supported by legal consideration and advice. The Department also implements and maintains a randomised quality assurance process for any automated decision-making to ensure the decision is made consistent with the legislative framework and associated business rules (with similar quality assurance mechanisms and methodologies also used in broader caseload management). If errors are identified, the Department also reviews and where necessary updates underlying system rules to ensure errors are addressed effectively and not replicated in future automated decisions.

… noting that it is unclear which aspects of the decisions will be made by a computer program, how merits review is intended to operate as a safeguard and whether applicants will be provided with a written statement of reasons for relevant decisions …

As noted previously, the instrument-making power in paragraph 495A(3)(b) is solely a power for the Minister to determine that a provision of the Migration Act or Regulations is part of the designated migration law (alongside the provisions covered expressly by paragraphs 495A(a) and (aa) of the Act). The power in 495A(3)(b) does not extend to the detail of what aspects of a decision made under the designated migration law will be made by a computer program; instead, this would be covered by arrangements (if any) made under subsection 495A(1).

The effect of subsection 495A(2) is such that a decision made by a computer program under the Minister's control per subsection 495A(1) is taken to be a decision of the Minister. Whether a decision is made by the Minister, the Minister's delegate or a computer program under subsection 495A(1) does not alter or affect the availability of merits review, if another provision of the Act or regulations provides that merits review is available.

In the case of visa condition 8208, merits review is appropriately made available under Part 5 of the Migration Act, by paragraph 4.02(4)(u) of the Regulations, where the Minister makes a decision under subclause 8208(1) not to approve a visa holder changing course. In the event that a decision is made not to approve a course change, the visa holder will be provided with a record of that decision, including reasons for the decision and details of available merits review – consistent with the approach in all decisions in relation to visa matters, including decisions to refuse visa grant. In addition to the availability of merits review, where a decision is made by a computer system per arrangements under subsection 495A(1), section 495B of the Act also provides that the Minister may substitute a more favourable decision for certain computer-based decisions.

The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC24-014237

Senator Deborah O'Neill
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Dear ~~Chair~~ Deb

Thank you for your correspondence of 12 September 2024 on behalf of the Senate Standing Committee for the Scrutiny of Delegated Legislation seeking my advice in relation to the Committee's concerns about the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (**Amendment Regulations**). I provide the following advice.

- **whether further detail can be provided about the nature and scope of the powers inserted by items 4 and 28 in Part 1 of Schedule 1 to the instrument, including how these powers have been, or are intended to be, exercised, any constraints on the grant and exercise of these powers, and what factors are likely to be taken into account in exercising the discretion under these provisions;**

1. The Amendment Regulations amend the *Therapeutic Goods Regulations 1990* (**TG Regulations**) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (**MD Regulations**). These regulations are made under the *Therapeutic Goods Act 1989* (**TG Act**). The purpose of the amendments is to uphold the integrity of the therapeutic goods scheme established by the TG Act by creating powers to support the efficient regulation of therapeutic vaping goods.

2. The powers inserted by items 4 and 28 in Part 1 of Schedule 1 of the Amendment Regulations allow the Secretary to effectively monitor the quality, safety and performance of therapeutic vaping goods that are permitted to be supplied in Australia in accordance with the relevant exemptions. The powers are therefore intended to be used to ensure compliance with regulatory requirements under the TG Act, TG Regulations and MD Regulations.

3. There are currently no therapeutic vapes that have been evaluated by the Therapeutic Goods Administration (**TGA**) for inclusion on the Australian Register of Therapeutic Goods for smoking cessation or the management of nicotine dependence. Accordingly, the TGA relies on sponsors to provide a notice under the relevant exemptions, stating that relevant therapeutic vaping goods comply with applicable standards and that the only indications of those goods are for smoking cessation or the management of nicotine dependence.

4. Following notification, the Secretary may determine that the supply of therapeutic vaping goods notified to the TGA be stopped or should cease because:

- the supply of the vaping goods compromises public health and safety; and/or

- the vaping goods do not conform with a standard applicable to the Goods, namely the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO), the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* (MDSO), or the essential principles.

5. Without the regulatory powers in items 4 and 28 in Part 1 of Schedule, there is a risk that the Secretary will have insufficient information to monitor the quality, safety and performance of therapeutic vapes and make the determinations where necessary. The ability to make determinations to protect public health and safety is compromised without powers to require the production of documents and samples from sponsors of notified therapeutic vapes, and to allow entry and access to relevant premises.

6. Patients, pharmacists, and prescribers rely on monitoring activities conducted by the TGA to provide confidence in the quality, safety and performance of therapeutic goods supplied in Australia, including those on the notified vape list. Therapeutic vapes are subject to the therapeutic goods framework. Without powers to support the TGA to test the accuracy of statements made by sponsors in notifications for therapeutic vapes, those vapes may continue to be supplied in the pharmaceutical supply chain without appropriate checks or balances.

7. The nature and volume of information, and the level of access to premises, that may be required by an authorised officer, or authorised person, is intended to be directly related to the risk associated with relevant therapeutic vapes. The provisions are necessary therefore to support efficient regulatory action and to provide confidence and assurance to the Australian public in the role of TGA as a regulator of quality, safety and performance.

- **whether further detail can be provided as to why the provisions are necessary and appropriate, including how the public interest is served by their inclusion in the instrument;**

8. I note that the powers inserted by items 4 and 28 in Part 1 of Schedule 1 to the Amendment Regulations are based on the statutory conditions under sections 28(5) and 41FN of the TG Act with respect to sponsors importing or supplying other medicines and medical devices in Australia.

9. I consider the notification system established under the regulations for unapproved vaping goods to be analogous to registration and inclusion frameworks under the TG Act. The public interest and confidence in the regulatory scheme is served by ensuring sponsors of therapeutic vaping goods are subject to many of the same conditions that the TG Act automatically applies to sponsors of other medicines and medical devices with general marketing approval in Australia.

- **who is an 'authorised officer' that exercises powers under these provisions – including authorised officers that may enter premises outside Australia – and whether they are required to possess specific skills or qualifications to exercise these powers;**

10. The terms 'authorised officer' (and 'authorised person') are relevantly defined in the TG Act, TG Regulations and MD Regulations as persons authorised by the Secretary to exercise powers under certain provisions.

11. This includes persons employed by a Commonwealth department, and more recently in the context of therapeutic vaping goods, persons employed by state and territory departments with responsibility for health and law enforcement. In practice, the classes of authorised officers and authorised persons exercising powers under these provisions, have the relevant training, skills and experience to carry out regulatory compliance action.

12. In accordance with the TG Act, TG Regulations and MD Regulations, authorised officers and authorised persons must carry and present identity cards to persons prior to entry into any premises. Further, authorised officers and authorised persons must comply with applicable Commonwealth, state and territory codes of conduct.

- **the legislative authority under which 'authorised officers' may enter premises outside of Australia and how these provisions operate in practice to enable officers to do so in different jurisdictions;**

13. I understand that most therapeutic vaping goods are manufactured overseas and imported into Australia. In practice, it is anticipated that the production of information and samples will obviate the need for authorised officers or authorised persons to enter and inspect premises outside Australia. However, the power would remain available to authorised officers or authorised persons if needed.

- **whether independent merits review is available of decisions made and actions taken in connection with exercise of the broad discretionary powers; and**

14. Independent merits review is not available with respect to decisions made by the Secretary under items 4 and 28 in Part 1 of Schedule 1. Judicial review will still be available to a person affected by these decisions.

15. This reflects a balanced compromise between the needs to effectively monitor the quality, safety and performance of unregistered therapeutic vaping goods and a persons' right of review, noting that analogous powers ordinarily apply to other medicines and medical devices regulated under the TG Act, not just vaping goods.

16. The Administrative Review Council has recognised that preliminary or procedural decisions, which facilitate or lead to the making of a substantive decision, are unsuitable for review. This is because preliminary decisions generally do not have substantive consequences.[1]

17. I consider that decisions under items 4 and 28 in Part 1 of Schedule 1 to the Amendment Regulations are unsuitable for merits review because the exercise of those powers:

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[1] Administrative Review Council, *What Decisions Should Be Subject To Merits Review?*, Canberra 1999, paragraphs 4.2 to 4.7 <What decisions should be subject to merit review? 1999 | Attorney-General's Department (ag.gov.au)>.

- **are preliminary in nature** – decisions, such as those requiring the sponsor to provide the Secretary a reasonable number of samples of a therapeutic vaping device, have no substantive effect but could assist the Department of Health and Aged Care in making determinations or taking further compliance and enforcement action.

- **protect public health and safety** – the Department of Health and Aged Care is responsible for protecting consumers from the supply of therapeutic goods that are non-compliant with relevant applicable standards. In circumstances where the department holds significant concerns about the quality, safety or performance of therapeutic vaping goods, the exercise of merits review rights could delay timely regulatory, compliance or enforcement action, particularly where the goods pose a grave or imminent risk to public health and safety.

18. I draw the committee's attention to pages 27 to 28 of the Explanatory Memorandum to the Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2022. This Bill amended the TG Act to exclude the availability of merits review for the use of information gathering powers for a range of investigative, compliance and post-market surveillance purposes. I consider these observations to be equally applicable in the context of items 4 and 28 in Part 1 of Schedule 1.

- **whether the Attorney General's Department's Guide to Framing Commonwealth Offences was considered in drafting these provisions.**

19. I confirm that the Attorney General's Department's Guide to Framing Commonwealth Offences was considered when drafting these provisions, in particular, paragraph 8.6 which covers the limited circumstances in which consent or a warrant to enter and search a premises may not be necessary.

20. For the reasons discussed above, I consider that exceptional circumstances exist to authorise entry without consent or warrant. I note that the present situation is analogous to circumstances relating to licensed premises discussed in paragraph 8.6 of the Guide. Entry to premises in which therapeutic goods are dealt with or manufactured is a condition of participating in the regulatory scheme for therapeutic goods. I further note that the relevant powers are limited in nature and do not confer broad powers to seize documents and other evidential material, in contrast to ordinary search and seizure powers.

- **the nature and scope of any documents or information that may be required to be produced to and collected, used or disclosed by, authorised officers under the instrument, with particular reference to items 4 and 28 in Part 1 of Schedule 1, and whether these are likely to include personal information; and, if so,**

21. The documents or information that are likely to be required to be produced or collected are those relevant to the sponsor's compliance with the relevant exemption. These documents will ordinarily relate to the activities of commercial entities and may include some personal information of individuals associated with those entities. Personal information is not expected to be collected as a matter of course.

22. By way of an example, documents or information required to be produced or collected by the TGA may include certificates of analysis and product specifications, including formulation details and performance data.

- **whether any safeguards apply to protect any personal information collected, used or disclosed under the instrument, and whether these are set out in law or policy, including whether the Privacy Act 1988 applies.**

23. I note that, if personal information is provided to the Department of Health and Aged Care in response to the exercise of these powers, the collection, storage, use and disclosure of such information is subject to the safeguards and limitations in the *Privacy Act 1988* (**Privacy Act**).

24. The Department of Health and Aged Care takes seriously its obligations and compliance with requirements applying to personal information under the Privacy Act. This includes adherence to the Australian Privacy Principles, the Australian Government Agencies Privacy Code and the department's Privacy Policy.

25. The Privacy Policy includes procedures for:
    - collecting personal information only where it is reasonably necessary for, or directly related to, a function or activity that the department performs;
    - using or disclosing information only for the purpose for which it was collected by the department unless the Privacy Act permits otherwise; and
    - storing and disposing personal information in accordance with the *Archives Act 1983* and relevant authorities, which includes destroying or deidentifying information the department no longer needs for the purpose it was collected, unless the law requires the information to be retained.

- **the nature and scope of items 3 and 33 of Schedule 1 to the instrument and whether they are intended to apply retrospectively as understood by the committee and reflected in principle (h) of its guidelines; and, if so,**
- **why the retrospective effect is considered necessary and appropriate; and**
- **whether any person has been or may be disadvantaged and, if so, what steps will be taken to avoid such disadvantage.**

26. These provisions are not intended to apply retrospectively. Items 3 and 33 of Schedule 1 only apply on and from 1 July 2024, not before that date. Further, the instrument does not contain any specific application, saving or transitional provisions that would change the law as at a past date.

27. Items 3 and 33 of Schedule 1 to the instrument have the effect of bringing certain therapeutic vaping devices imported or manufactured before 1 March 2024, that were previously exempt from regulation under the TG Act, within the regulatory scheme.

28. In any case, I note that arrangements under the *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024* (**Determination**) are intended to mitigate the effects of these provisions. If previously excluded devices are possessed by individuals, retailers and other entities, the Determination permits possession by those persons for certain periods of time to facilitate (a) the use, disposal or exportation of the goods by the persons (b) return to wholesalers and sponsors through the pharmaceutical supply chain, or (c) surrender of those goods to the Department of Health and Aged Care. The relevant items are items 1 of Schedule 1 and items 1, 4, 5, 6 of Schedule 2 to the *Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024*.

- **the scope of the immunity from liability under new regulation 46B inserted by item 22 in Part 1 of Schedule 1 to the instrument, and those individuals who are likely to be included as 'protected persons' under subsection 57(1A) and paragraph 62(3)(b) of the Therapeutic Goods Act 1989; and**
- **whether further justification can be provided as to why this immunity from liability is considered to be necessary and appropriate, noting the potentially broad scope of individuals it may apply to.**

29. 'Protected persons' includes persons employed by a Commonwealth department and persons employed by state and territory departments with responsibility for health and law enforcement who have been delegated powers and functions under Chapter 5A, section 52AAA and/or section 52AAB of the TG Act. This includes persons at both junior and senior levels.

30. The *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* amended the TG Act to implement a federal cooperative scheme between the Commonwealth, states and territories with respect to the regulation of vaping goods. The new framework authorises state and territory officials to undertake regulatory, compliance and enforcement action with respect to vaping goods. In practice, compliance may be undertaken by a range of state and territory agencies and by officers at a range of levels. In these circumstances, it is considered necessary that the immunity extend to all classes of persons specific in subsection 57(1A) of the TG Act.

31. For completeness, I note that the states and territories have enacted corresponding laws that apply the Commonwealth TG Act, and associated instruments of a legislative or administrative character made under it, as laws of the relevant state or territory. As a result, effective regulation, compliance and enforcement is shared between the Commonwealth, states and territories to ensure comprehensive coverage.

- **whether the explanatory statement can be amended to correct the possible drafting errors identified above.**

32. I confirm that the Department of Health and Aged Care is currently taking steps to correct the drafting errors identified by the Committee.

I appreciate the Committee's consideration of this instrument and trust that the above information provides sufficient explanation of the matters raised.

Thank you for writing on this matter.

Yours sincerely

Mark Butler

26 / 09 / 2024

The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC24-014238

Senator Deborah O'Neill
Chair, Senate Standing Committee for the Scrutiny of Delegated Legislation
Senator for New South Wales
Sdlc.Sen@aph.gov.au

Dear Chair, Deb.

Thank you for your correspondence of 12 September 2024 on behalf of Senate Standing Committee for the Scrutiny of Delegated Legislation seeking my advice in relation to the Committee's concerns about the Therapeutic Goods (Vaping Goods—Possession and Supply) Determination 2024 and the Therapeutic Goods (Vaping Goods—Possession and Supply Amendment Determination 2024.

- ***why it is considered necessary and appropriate to include the exceptions to the offences in Division 1 of Part 4A-2 of the Therapeutic Goods Act 1989 in delegated legislation, rather than primary legislation:***

1. The content of the exceptions to the offences and civil penalty provisions (**exceptions**) in Division 1 of Part 4A-2 is principally specified in the *Therapeutic Goods Act 1989* (TGA Act). However, some content is specified in delegated legislation, namely, vaping goods that may be determined by the Minister (or his delegate) in a legislative instrument made under section 41R of the TG Act as being lawfully supplied or possessed in Australia in particular circumstances (**Determination**).

2. The Determination made under section 41R of the TG Act is driven by public health objectives to ensure that:

    - unused stock of unlawful vaping goods in the community as at 1 July 2024 may be surrendered, exported, disposed and/or destroyed in controlled circumstances that minimise the risk of diversion

    - the department has oversight of the supply and possession of lawful vaping goods by certain persons in the pharmaceutical wholesale or retail supply chains who do not otherwise hold a licence or authority to do so

    - adequate protection is afforded to certain specified persons where the supply or possession of vaping goods without a licence or other authority for a bespoke reason outweighs the public health and safety concerns, such as supply or possession for scientific research or testing.

3. Paragraph 2.3.4 of the Attorney General's Department's Guide to Framing Commonwealth Offences (Guide) recognises that it may be appropriate to specify content in delegated legislation where the relevant content involves a level of detail that is not appropriate for an Act or involves material of such a technical nature that is not appropriate to deal with it in the Act.

4. The expression 'relevant content' is understood to include any exceptions to the offences. Further, the circumstances outlined in paragraph 3 above are apposite in the context of the Determination. Specifically, it necessary and appropriate to include exceptions in delegated legislation because:

   (a) **the exceptions depend on complex interactions between laws that are subject to change:** the regulation of vaping goods is complex, being subject to overlapping Commonwealth and state and territory laws. Commonwealth delegated legislation (such as controls in the *Customs (*Prohibited Imports*)* Regulations 1956*)* and state and territory laws may change from time to time. It is necessary and appropriate to have a power to include exceptions to the offences in delegated legislation to deal with unintended situations that arise because of the complex interaction between, or changes to, these laws

   (b) **the exceptions are highly detailed**: a significant number of persons, including those who play a role in the wholesale or retail supply chain, may be permitted to avail themselves of an exception under the Determination and thereby may lawfully possess or supply vaping goods. Further, the circumstances and conditions where the possession and supply of vaping goods may be lawful are detailed to mitigate against the risk of diversion. This detail is more appropriately dealt with in the Determination for brevity and clarity

   (c) **the exceptions are technical in nature:** in contrast to other exceptions to offences and civil penalty provisions in the Act, the exceptions reflected in the Determination are technical and peculiar to vaping goods; and

   (d) **the exceptions are transitional:** the majority of the exceptions are time limited for two main reasons. First, to ensure appropriate enforcement action is available for the possession and supply of unlawful vapes following the sunsetting of the instrument. Secondly, to ensure the lawful supply and possession of certain vaping goods by certain persons in the supply chain who otherwise do not have a licence or authority to do so, until a consent scheme is implemented and adopted by industry.

5. The Determination therefore provides an appropriate mechanism to enable the Minister to provide exceptions for legitimate dealings with vaping goods.

- ***whether further detail can be provided about the nature and scope of the conditions in table items 3-6 of Schedule 1 and table items 4-11 and 13 of Schedule 2 of the instrument (as amended by items 18 and 21 of the amendment instrument), including how the powers to request information or the production of lists or records for inspection have been or are intended to be exercised, the scope of 'any information' and 'any other person', and any constraints on the grant and exercise of these powers:***

6. I appreciate the Committee's consideration of these matters. Conditions enabling the provision of information to the Department were designed to mitigate the risks associated with diversion of vaping goods to the black market. However, in response to the Committee's concerns, I am prepared to arrange for the Determination to be amended to repeal the conditions requiring the production, seizure and inspection of documents and information. Namely, the conditions specified in:

    (a) paragraph (h) in column 5 to item 3 of Schedule 1
    (b) paragraph (f) in column 5 to item 4 of Schedule 1
    (c) paragraph (i) in column 5 to item 5 of Schedule 1
    (d) paragraph (g) in column 5 to item 6 of Schedule 1
    (e) paragraph (a) in column 5 to item 4 of Schedule 2
    (f) paragraph (g) in column 5 to item 5 of Schedule 2
    (g) paragraph (a) in column 5 to item 6 of Schedule 2
    (h) paragraph (i) in column 5 to item 7 of Schedule 2
    (i) paragraph (c) in column 5 to item 8 of Schedule 2
    (j) paragraph (b) in column 5 to item 9 of Schedule 2
    (k) paragraph (j) in column 5 to item 10 of Schedule 2
    (l) paragraph (i) in column 5 to item 11 of Schedule 2
    (m) paragraph (d) in column 5 to item 12 of Schedule 2

7. Similarly, I am minded to arrange for the Determination to be amended to repeal the condition in item 3 of Schedule 2 relating to the production of information at the request of a customs officer, authorised officer or authorised person (subparagraph (c)(iii) only).

8. In response to the Committee's concerns, I am also inclined to amend the Determination to remove the conditions requiring the person to whom the exception applies to notify state or territory police, as soon as practicable and no later than the end of the next business day, if that person reasonably suspects that the goods have been lost or stolen. Namely, the conditions specified in:

    (a) paragraph (g) in column 5 to item 3 of Schedule 1
    (b) paragraph (d) in column 5 to item 4 of Schedule 1
    (c) paragraph (h) in column 5 to item 5 of Schedule 1
    (d) paragraph (f) in column 5 to item 6 of Schedule 1
    (e) paragraph (f) in column 5 to item 4 of Schedule 2
    (f) paragraph (f) in column 5 to item 5 of Schedule 2
    (g) paragraph (i) in column 5 to item 6 of Schedule 2
    (h) paragraph (h) in column 5 to item 7 of Schedule 2
    (i) paragraph (i) in column 5 to item 10 of Schedule 2
    (j) paragraph (h) in column 5 to item 11 of Schedule 2

9. These conditions were included to mitigate the risk of diversion of vaping goods to the black market. However, it is considered that the risk may be adequately managed in guidance.

- **factors that are likely to be taken into account by officers of the department in determining what is 'any other matter' considered relevant and whether examples can be provided of such matters:**

10. I understand that my advice on this question is no longer required as the conditions outlined in paragraph 6 above are now intended to be repealed.

11. For completeness, it should be noted that, in considering 'any other matter' that may be relevant, departmental officers would be required to be satisfied that such matters were relevant to an investigation into potential unlawful possession or supply of vaping goods and would be expected to act in accordance with standard operating procedures.

- **whether further detail can be provided as to why the above provisions are necessary and appropriate, including how the public interest is served by their inclusion in the instrument, rather than in primary legislation:**

12. I refer the Committee to my response at paragraphs 3 to 5 above. In addition, I note that the inclusion time of limited exceptions in a standalone Determination, rather than in the TG Act, results in a simplified framework that is easier for the public to locate and apply.

- **which officers of the department are authorised to request the production of 'any information' under table items 3-6 of Schedule 1 and table items 4-11 and 13 of Schedule 2 of the instrument and whether they are required to possess specific skills or qualifications to exercise these powers:**

13. I understand my advice on this question is no longer required as the conditions outlined in paragraph 6 above are now intended to be repealed.

- **whether independent merits review is available of decisions made and actions taken in connection with exercise of the broad discretionary and coercive powers under the above provisions:**

14. I understand my advice on this question is no longer required as the conditions outlined in paragraph 6 above are now intended to be repealed.

- **whether the Attorney General's Department's Guide to Framing Commonwealth Offences was considered in drafting these provisions:**

15. The Guide was considered in drafting these provisions. With respect to the delegation of offence content, the Department specifically considered paragraphs 2.3.4 to 2.3.5 of the Guide.

- **the nature and scope of any documents or information that may be required to be produced and collected, used or disclosed under the instrument and whether these are likely to include personal information; and, if so,**

- **whether any safeguards apply to protect any personal information collected, used or disclosed under the instrument, and whether these are set out in law or policy, including whether the Privacy Act 1988 applies:**

16. I understand my advice on this question is no longer required as the conditions outlined in paragraph 6 above are now intended to be repealed.

17. For completeness, I note that if personal information is provided to the Department the collection, storage, use and disclosure of such personal information would be subject to the requirements and limitations in the *Privacy Act 1988* (Privacy Act).

18. The Department of Health takes seriously its obligations and compliance with requirements applying to personal information that it holds and collects under the Privacy Act. This includes adherence to the Australian Privacy Principles, the Australian Government Agencies Privacy Code and the Department's Privacy Policy.

19. Specifically, the Department's Privacy Policy includes procedures for:

    - collecting personal information only where it is reasonably necessary for, or directly related to, a function or activity that the Department performs
    - using or disclosing information only for the purpose for which it was collected by the Department unless the Privacy Act permits otherwise
    - storing and disposing personal information in accordance with the *Archives Act 1983* and relevant authorities, which includes destroying or deidentifying information the Department no longer needs for the purpose it was collected, unless the law requires the information to be retained.

- **whether the instrument can be amended to correct the possible drafting error identified above:**

20. I confirm that the Department is currently taking steps to amend the drafting error identified by the Committee.

I appreciate the Committee's consideration of the Determination and trust the above information provides sufficient response to the matters raised.

Thank you for writing on this matter.

Yours sincerely

Mark Butler

16 / 09 / 2024