

**2022**

**THE LEGISLATIVE ASSEMBLY FOR THE  
AUSTRALIAN CAPITAL TERRITORY**

**HEALTH LEGISLATION AMENDMENT BILL 2022**

**REVISED EXPLANATORY STATEMENT**

**Presented by  
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November 2022**

# Health Legislation Amendment Bill 2022

## EXPLANATORY STATEMENT

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This explanatory statement relates to the Health Legislation Amendment Bill 2022 (the Bill) as presented to the Legislative Assembly. It has been prepared in order to assist the reader of the Bill and to help inform debate on it. It does not form part of the Bill and has not been endorsed by the Assembly.

The Bill **is not** a Significant Bill. Significant Bills are bills that have been assessed as likely to have significant engagement of human rights and require more detailed reasoning in relation to compatibility with the *Human Rights Act 2004*.

The Statement is to be read in conjunction with the Bill. It is not, and is not meant to be, a comprehensive description of the Bill. What is said about a provision is not to be taken as an authoritative guide to the meaning of a provision, this being a task for the courts.

### OVERVIEW OF THE BILL

#### Legislation to be amended

This Bill amends the following:

- the *Tobacco and Other Smoking Products Act 1927* (TOSP Act);
- the *Medicines Poisons and Therapeutic Goods Act 2008* (MPTG Act); and
- the *Transplantation and Anatomy Act 1978* (TA Act).

#### Proposed changes

The Bill amends the TOSP Act to allow compliance testing to occur for sales of e-cigarettes to minors; to clarify that no smoking products may be sold via vending machine and to exempt community pharmacists from the requirement to source nicotine vaping products from a wholesaler who holds an ACT Tobacco licence.

The Bill amends the MPTG Act to extend the application of Commonwealth therapeutics goods laws in the ACT. The change will enable the Therapeutic Goods Administration (TGA) to take action against sole traders operating wholly within the ACT in relation to nicotine vaping products (aka nicotine containing e-cigarettes) and other matters arising under the *Therapeutic Goods Act 1989* (Cwlth).

The Bill amends the TA Act to resolve technical legal compatibility issues between the TA Act and the *Births, Deaths and Marriages Registration Act 1997* (BDMR Act). The change will enable the issuing of verifying information to confirm a deceased individual's donor status without concern of conflict between the TA Act and the BDMR Act.

## **COSTS AND BENEFITS STATEMENT**

The Bill makes technical amendments. This Bill has no financial implications.

## **CONSISTENCY WITH HUMAN RIGHTS**

This section provides an overview of the human rights which may be engaged by the Bill. The proposed amendments in the Bill have been considered in the context of the objects of the *Human Rights Act 2004* (HRA).

### **Rights Promoted**

The Bill does engage and promote the right to life through facilitating the use of regulatory interventions against smoking products that are associated with harm. The Bill further promotes the right to life by enabling open communications regarding organ and tissue donation.

#### The right to life

The right to life has been interpreted by the United Nations' Human Rights Committee as meaning that States must take appropriate measures to address the general conditions in society that may give rise to threats to the right to life or prevent individuals from enjoying their right to life with dignity and that environmental degradation and climate change are a threat to present and future generations' enjoyment of the right to life. Thus, it has stated that 'implementation of the obligation to respect and ensure the right to life, and in particular life with dignity, depends, inter alia, on measures taken by States parties to preserve the environment and protect it against harm, pollution and climate change caused by public and private actors.'<sup>1</sup>

Similarly, in *Osman v United Kingdom* (1999) 29 EHRR 45 it was determined that Governments owe a duty to take reasonable action to avoid real and immediate risk to life which a government can control and of which it has or ought to have knowledge has been said to be a positive aspect of this right (*Osman* at [116]). Accordingly, it is generally accepted that the right to life - set out in section 9 of the ACT's HRA - not only enjoins a government from the intentional and unlawful taking of a life but also to take appropriate steps to safeguard the lives of those within its jurisdiction.

There is a growing evidence base that demonstrates the public health harms associated with e-cigarette use. As such, regulatory measures to ensure existing restrictions on traditional smoking products (i.e. tobacco products) can be applied to newer or novel smoking products supports the right to life. This is particularly relevant in the context of young people, who may be more vulnerable to the health impacts of smoking products such as e-cigarettes due to physical factors (such as their developing lungs) and unawareness of the potential for addiction.

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<sup>1</sup> UN Human Rights Committee (HRC), [General comment no. 36, Article 6 \(Right to Life\)](#), 3 September 2019, CCPR/C/GC/35.

The Bill promotes the right to life through minor and technical updates to extend the application of Commonwealth therapeutic goods laws in the ACT. The objects of the *Therapeutic Goods Act 1989 (Cwlth)* (the TG Act) include “the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods”. All medicines and therapeutic goods have positive impacts in relation to the enjoyment of life, be it through preventing disease, and/or improving health or the quality of life. Conversely, most medications can impair health or lead to death if manufactured, prescribed or administered unsafely, or generally misused. Therefore, the entirety of the TG Act promotes the right to life in that the systems it establishes in relation to poisons and all therapeutic goods (including medicines) protect the lives of Australians.

The change made by the Bill will enable the TGA to take action against sole traders operating wholly within the ACT, which will be especially advantageous in addressing the emerging and growing risk – particularly to young persons – from nicotine vaping products (also known as nicotine containing e-cigarettes).

This Bill further promotes the right to life through acknowledgment of the significant gift of organ and tissue donation. It enables the clinical organ and tissue donation service (DonateLife ACT) to confirm donor status to the requesting next of kin of a deceased individual in order to facilitate the Tissue Donation Certificate Scheme under s 38A of the BDMR Act.

The Bill will support DonateLife ACT to comply with the relevant disclosure section of the TA Act when doing so.

The Bill engages but does not limit the deceased’s next of kin’s right to privacy. It is, however, the next of kin’s decision to disclose the information, and that consent addresses any potential interference with the right to privacy.

#### The right to equality before the law

Due to constitutional constraints, the TG Act only applies to things done by natural persons in so far as those things are done in the course of trade and commerce either:

- a) between Australia and a place outside Australia,
- b) among the States,
- c) between a State and a Territory; or
- d) between two Territories.

In the absence of the proposed amendment to the MPTG Act, the TG Act does not apply to conduct by natural persons solely within the ACT. This therefore means that a natural person that operates solely within the ACT is not subject to the TG Act unlike a natural person based in the ACT that also engages in trade or commerce between the ACT and another Australian jurisdiction. Accordingly, the status quo treats natural persons trading in medicines and therapeutic goods inequitably, in that a trader that operates solely within the ACT has the benefit of only being subject to the ACT’s MPTG Act, whereas a trader that also operates

outside of the ACT must comply with both the ACT's MPTG Act and the Commonwealth TG Act.

Therefore, the amendment to the MPTG act contained in the Bill promotes equality before the law.

### **Rights Limited**

The measures in the Bill may engage and limit the right to protection of the family and children (section 11 HRA) and the right to presumption of innocence (section 22(1) HRA). The Bill also extends the application of the TG Act to sole traders operating in the ACT and, as a federal law, could be seen to limit associated protections afforded by the HRA.

The preamble to the Human Rights Act 2004 (HR Act) notes that few rights are absolute and that they may be subject only to the reasonable limits in law that can be demonstrably justified in a free and democratic society. Section 28(1) of the HRA provides that in deciding whether a limit on human rights is reasonable, all relevant factors must be considered, including the following:

- a) the nature of the right affected;
- b) the importance of the purpose of the limitation;
- c) the nature and extent of the limitation;
- d) the relationship between the limitation and its purpose; and
- e) any less restrictive means reasonably available to achieve the purpose the limitation seeks to achieve.

### **Protection of family and children (s 11 HRA)**

#### ***Nature of the right and the limitation (ss 28(2)(a) and (c))***

Under section 11 of the HRA, every child has the right to the protection needed by the child because of being a child, without distinction or discrimination of any kind. Children have special rights under human rights law taking into account their particular vulnerabilities. Expanding a regulatory and enforcement scheme that provides for covert and randomised operations involving 'undercover' children to include e-cigarettes, could be a greater limitation on the rights of children involved than that which is currently contemplated by existing provisions of the TOSP Act.

#### ***Legitimate purpose (s 28(2)(b))***

The amendment is directed at the legitimate aim of protecting young people from the harmful effects of e-cigarettes by limiting the availability of these products to be bought and sold to children and young people.

### ***Rational connection between the limitation and the purpose (s 28(2)(d))***

Sale of e-cigarettes to people under the age of 18 is prohibited by the TOSP Act, and covert, ‘undercover’ operations are intended to increase compliance with this prohibition. The amendment is therefore rationally connected to a legitimate aim.

### ***Proportionality (s 28(2)(e))***

It is considered that the limitation on the rights of individual children involved in the compliance testing is proportionate and reasonable having regard to the existing protections for young people who participate in the operations. Safeguards include provision of procedures to ensure the welfare, health and safety and privacy as well as the requirement to obtain informed consent of the young person and/or their guardian. With these safeguards in mind and given the substantial protection to children and young people from tobacco and smoking related harm, any limitation on children’s rights by the amendment to increase compliance with a ban on e-cigarette sales to people under 18, is considered reasonable and proportionate.

### **Right to presumption of innocence (s 22(1) HRA)**

#### ***Nature of the right and the limitation (ss 28(2)(a) and (c))***

##### *Tobacco and Other Smoking Products Act 1989*

Under section 22 of the HRA, everyone charged with a criminal offence has the right to be presumed innocent until proven guilty according to law. The presumption of innocence means that the prosecution has the burden of proving ‘beyond reasonable doubt’ that the accused committed the charged offence.

Under section 67(2) of the TOSP Act, it is a strict liability offence for a retail tobacconist to obtain a smoking product from someone who is not the holder of a wholesale tobacco merchant’s licence. The Bill amends section 67 so that the offence is not made out if the holder of a retail tobacconist’s licence operates a community pharmacy and obtains a personal vaporiser or related product that is a medicine from someone who is not the holder of a wholesale tobacco merchant’s licence. This creates an exception to the general offence provision, but the defendant bears the evidential burden. Per the ‘Guide to Framing Offences’, an evidential burden places the defendant in the position of presenting, or pointing to, evidence that suggests a reasonable possibility that the defence can be established. Requiring the defendant to raise facts in this way amounts to a reversal of the burden of proof and this may engage and limit the right to be presumed innocent.

### ***Legitimate purpose (s 28(2)(b))***

Although the right to be presumed innocent may be limited by this amendment, the reverse burden is for the legitimate purpose of ensuring pharmacies that supply medicines for the public can purchase medicinal personal vaporisers (or related products) from someone who does not hold a wholesale tobacco merchant’s licence.

### ***Rational connection between the limitation and the purpose (s 28(2)(d))***

There is a rational connection between the requirement for a community pharmacy to prove that the product purchased for medicine because the facts of the purchase are likely to be uniquely within the knowledge of the defendant and their evidence would serve to prevent unnecessary prosecution.

### ***Proportionality (s 28(2)(e))***

The amendment is reasonable and proportionate limitation on the right to be presumed innocent. The offence carries a maximum penalty of 50 penalty units which is appropriate to the seriousness of the offence and provides sufficient deterrent to improperly obtaining vaporisers. There is also an existing safeguard within section 67 in that the defence of ‘mistake of fact’ is available to the defendant. This would allow a community pharmacy, for example, to argue that they had a reasonably held belief that the product they were purchasing was a medicine.

### **Obligations of public authorities (Part 5A, HRA); and**

### **Right to presumption of innocence (s 22(1), HRA )**

### ***Nature of the right and the limitation (ss 28(2)(a) and (c))***

### **Medicines, Poisons and Therapeutic Goods Act 2008**

The Bill proposes to permit authorised officers to undertake regulatory action against ACT sole traders for alleged contraventions of the TG Act. Australian Government employees, in exercising functions of a Commonwealth law, are not considered public authorities under section 40 of the HRA and are not obligated to act consistently with human rights by section 40B of the HRA in making regulatory decisions. It is noted that the MPTG Act’s application of the TG Act to sole traders is not restricted to nicotine vaping products and provides for the TGA to broadly undertake compliance activities under the TG Act. This change could therefore be perceived as potentially limiting human rights by extending the application of the TGA Act in the Territory.

Although the TGA and its officers are not bound to comply with the ACT HRA, it would be erroneous to infer or imply that the TGA and its officers can, or are likely to, act unethically, or inconsistently with appropriate standards of public service and regulatory standards of conduct. It is therefore reasonable to expect that although not obligated to act consistently with human rights, the adherence to other principles and requirements in regard to natural justice, procedural fairness, best practice in regulation, and public service ethics will generally result in an indirect or de facto observance of human rights protections.

Section 22 of the HRA is based on article 14 of the ICCPR and provides that everyone charged with a criminal offence has the right to be presumed innocent until proven guilty according to law.

The UNHRC stated in General Comment 32:

‘The presumption of innocence, which is fundamental to the protection of human rights, imposes on the prosecution the burden of proving the charge, guarantees that no guilt can be presumed until the charge has been proven beyond a reasonable doubt, [and] ensures that the accused has the benefit of doubt...’<sup>2</sup>

In order to have a reversal of proof, ‘the substance and effect of any presumption adverse to a defendant must be...reasonable’.<sup>3</sup>

As noted earlier, the amendment to the MPTG Act will apply the Commonwealth TG Act in the ACT to natural persons that trade solely within the ACT, including offences within the TG Act. As strict liability is an element in many of the offences in the TG Act the presumption of innocence under section 22(1) of the HRA is engaged. This is because strict liability removes the fault elements from an offence – or aspects of the offence – the effect of which is it will be sufficient for the prosecution to establish the factual element without needing to prove fault or a mental element in regard to that element of the offence.

### ***Legitimate purpose (s 28(2)(b))***

In facilitating possible TGA compliance activity against sole traders and individuals in the ACT, it is noted that any engagement with human rights would be reasonably limited to activities concerning the TG Act. In particular, any unlawful or arbitrary infringement on a sole trader’s right to privacy and reputation (HRA, s12) is already reasonably protected by the *Privacy Act 1988* (Cwlth) and the TGA is subject to the Australian Government Agencies Privacy Code which commenced on 1 July 2018. Furthermore, privacy complaints against Australian Government agencies or employees may also be investigated by the Office of the Australian Information Commissioner.

In addition to statutory protections afforded by the *Privacy Act 1988* (Cwlth), Australian Government employees are required to observe ethical values and demonstrate respect and integrity under the *Public Service Act 1999* (Cwlth) and the Australian Public Service (APS) Commission’s Code of Conduct. Similarly, as a Commonwealth agency the TGA must follow legal services directions issued by the Commonwealth Attorney-General which, amongst other things, requires the TGA on behalf of the Commonwealth to conduct itself in any legal action as a ‘model litigant’. The TGA is also subject to the Regulatory Performance Framework set down by the Australian Government. In adhering to this Framework, the TGA is obligated to ensure that its actions as a regulator “are proportionate to the regulatory risk being managed” and that they are “open and transparent in their dealings with regulated entities”. To that end the TGA has publicly committed itself to undertake “compliance activities with integrity, professionalism and due regard to procedural fairness”.

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<sup>2</sup> Office of the United Nations High Commissioner for Human Rights, Human Rights Committee, 2007 ‘General Comment 32: Article 14: Right to equality before courts and tribunals and to a fair trial’, para 30

<sup>3</sup> *Attorney General’s Reference No 4 of 2002; Sheldrake v DPP* [2005] 1 AC 264, [21].

Ethical considerations must also be considered by the Commonwealth Department of Public Prosecutions (DPP) in prosecuting alleged breaches of federal laws under the DPP Prosecution Policy. While it is acknowledged these policies do not specifically seek to protect against the infringement of rights listed under the HRA, these policies (in combination with federal laws) are considered to satisfactorily safeguard against unlawful or arbitrary infringement of rights by APS agents or employees.

The primary purpose of applying the Commonwealth TG Act in the ACT to natural persons that trade solely within the ACT is to ensure national consistency, as the same extension is applied in other Australian jurisdictions. Extension of the TGA Act in the ACT also gives effect to the recommendation of a national review of medicines and poisons regulation commissioned by the Council of Australian Governments (COAG), the National Competition Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review). That review focused on key systemic issues, such as licensing, packaging and labelling, and scheduling and advertising, and recommended all states and territories adopt the TG Act as a law of that jurisdiction.

Accordingly, national consistency in the application of laws, particularly to products such as medicines, is a manifestly legitimate purpose not just for ensuring traders across the country are treated equally and equitably, but because it ensures certainty of rights and obligations in respect to therapeutic goods.

***Rational connection between the limitation and the purpose (s 28(2)(d))***

The TGA has a core role in regulating the advertising and sale of medicines and medical devices to ensure Australians have access to quality information and confidence in therapeutic goods. Enabling the TGA to take compliance action against sole traders under the TG Act and its subordinate Therapeutic Goods Advertising Code is critical to ensuring these stakeholders are subject to strict advertising controls that promote the quality and safe use of medicines, as well as public confidence in therapeutic products. In support of these objectives and growing evidence of harm associated with nicotine vaping products, the TGA has listed nicotine vaping products as an advertising compliance priority.

Due to constitutional limitations, the Commonwealth's controls do not extend to persons other than corporations (i.e. 'natural' persons) who operate only within an individual State or Territory. Agreement was therefore reached that all States and Territories would introduce complementary legislation to extend the system of controls put in place by the Commonwealth Act to persons in their respective States and territories who were not otherwise covered by the Commonwealth Act. To give effect to this agreement, the Bill seeks to replicate the approach taken by New South Wales, Queensland, Tasmania and South Australia by directly applying the TG Act to a person who is not a corporation in the ACT and to an act done or omitted to be done in the course of trade or commerce within the limits of the Territory.

The potential limitation on human rights associated with application of the TG Act is aligned with a legitimate purpose of minimising harm arising from therapeutic products, providing uniform medicines and poisons controls under the *Galbally Review*, and minimising the health impacts arising from the misuse or inappropriate advertising of therapeutic goods. Providing that sole traders are subject to therapeutic product advertising controls through application of the TG Act in the ACT seeks to minimise public health harm and promote the HRA's right to life.

***Proportionality (s 28(2)(e))***

The proposed changes to the MPTG Act aim to facilitate the TGA in undertaking priority compliance activities and ensure that suppliers of therapeutic goods are subject to the Commonwealth TG Act. The amendment to the MPTG Act achieves this aim in a manner that is consistent with that in other Australian jurisdictions.

While the HR Act does not apply to agents or employees of the Australian Government, federal statutory and policy controls are considered to appropriately protect Commonwealth authorities from unlawful or arbitrary interference with human rights in undertaking compliance activities under the TG Act. The consistent application of the TG Act across all legal entities is also important to realise recommendations and objectives arising from the *Galbally Review* and provide for the fair application of the public health controls and legal certainty to people supplying therapeutic goods.

Whilst there may have been other means by which comparable obligations and penalties might possibly have been imposed, such as through extensive additions to the MPTG Act, such alternative approaches would have been to the detriment of national consistency. Furthermore, any other alternative means which may have sought to apply the TG Act provisions (or similar) but exercised by an ACT public authority (as defined in section 40 of the HRA) would have significant detriments. Such an approach would have added burden of regulatory oversight to an ACT Government administrative unit, whilst essentially duplicating the role and function performed by an existing Commonwealth regulatory agency, the TGA. Such an approach could therefore hardly be characterised as proportionate.

Therefore, these limitations are considered proportionate in the circumstances as improved regulatory oversight by the TGA would promote the right to life through ensuring all people supplying therapeutic goods are doing so in a safe, ethical and appropriate manner.

*Transplantation and Anatomy Act 1978*

The right to be presumed innocent is similarly engaged by the amendment to section 49 of the TA Act, which creates an exception to the offence of disclosing identifying personal information of people who have donated tissue, in certain circumstances.

In this instance, the exception serves the legitimate purpose of facilitating the policy intent of section 38A of the BDMR Act, by ensuring that people involved in providing Donor Confirmation Letters at the request of next of kin of deceased tissue donors are assured they will not be prosecuted under section 49 of the TA Act where they provide that material in accordance with section 38A of the BDMR Act. Although casting the provision as an exception may engage and limit the right to be presumed innocent, any limitation is reasonable and proportionate as it will provide greater protections from prosecution by excluding people who are complying with the BDMR Act. There is also an existing safeguard in that the prosecution retain the burden of proof in all other elements of the offence.

## CLAUSE NOTES

### **Part 1 Preliminary**

#### **Clause 1 Name of Act**

This is a technical clause that names the short title of the Bill upon its passage in the ACT Legislative Assembly. The name of the Act will be the *Health Legislation Amendment Act 2022*.

#### **Clause 2 Commencement**

This clause provides that the Act will commence on the day after its notification day.

#### **Clause 3 Legislation amended**

This clause lists the legislation amended by the Bill. The Bill will amend the *Medicines, Poisons and Therapeutic Goods Act 2008*, the *Tobacco and Other Smoking Products Act 1927* and the *Transplantation and Anatomy Act 1978*.

### **Part 2 Medicines, Poisons and Therapeutic Goods Act 2008**

#### **Clause 4 Application of Commonwealth therapeutic goods laws to ACT New section 157(3)**

This clause inserts a new section 157 (3) that extends Commonwealth therapeutic goods laws to apply to a person who is not a corporation (e.g. a sole trader) within the ACT. The new section enables officers authorised under the *Therapeutics Goods Act 1989 (Cwlth)* to take action against sole traders operating wholly within the ACT where these traders are breaching the Therapeutics Goods Act.

### **Part 3 Tobacco and Other Smoking Products Act 1927**

#### **Clause 5 What is a *compliance test*? Section 42B (1) (a)**

This clause removes the term ‘tobacco products’ from section 42B (1) (a) and substitutes the term ‘smoking products’ in its place. This substitution allows compliance testing for sales to a minor to be conducted for all products captured within the definition ‘smoking product’ under section 3A of the *Tobacco and Other Smoking Products Act 1927* (e.g. herbal products, personal vaporiser products, etc).

**Clause 6**                      **Section 42B (1) (b)**

This clause removes the term ‘tobacco product’ from Section 42B (1) (b) and substitutes the term ‘smoking product’ in its place. This substitution allows compliance testing for sales to minors to be conducted for all products captured within the definition ‘smoking product’ under section 3A of the *Tobacco and Other Smoking Products Act 1927* (e.g. herbal products, personal vaporiser products, etc).

**Clause 7**                      **Approval of compliance testing programs: Section 42C (2) (a)**

This clause removes the term ‘tobacco products’ from section 42C (2) (a) and substitutes the term ‘smoking products’ in its place. This substitution allows compliance testing for sales to minors to be conducted for all products captured within the definition ‘smoking product’ under section 3A of the *Tobacco and Other Smoking Products Act 1927* (e.g. herbal products, personal vaporiser products, etc).

**Clause 8**                      **No vending machines authorised: Section 49A**

This clause removes the term ‘tobacco products’ from section 49A and substitutes the term ‘smoking products’ in its place. This substitution clarifies that no smoking products may be sold by vending machine.

**Clause 9**                      **Retail tobacconist must obtain smoking products from licensed wholesaler**

**New section 67 (4) and (5)**

This clause inserts two new sections.

Section 67(4) exempts a community pharmacy from the requirement to obtain smoking products, that are also medicines, from a wholesaler who holds an ACT Tobacco licence.

Section 67(5) gives definitions for the terms ‘community pharmacy’ and ‘medicine’ as used in Section 67 (4).

**Part 4**                      **Transplantation and Anatomy Act 1978**

**Clause 10**                      **Disclosure of information**

**New section 49 (4) (aa)**

This clause inserts a new section 49 (4) (aa) to provide that offences under sections 49 (1) and 49 (2) do not apply to a next of kin of a deceased person for the purposes of section 38A (3) of the *Births, Deaths and Marriages Registration Act 1997*. Section 38 A (3) states that requests must be in writing and include information verifying that the deceased person was a tissue donor. The effect of this new section is that information verifying tissue donation by a deceased person can be disclosed to a next of kin without engaging an offence under sections 49 (1) and 49 (2) of the *Transplantation and Anatomy Act 1978*.