EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021

Therapeutic Goods (Exempt Monographs) Determination 2021

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Department of Health.

Section 3 of the Act defines a 'standard' in relation to therapeutic goods as a standard that is constituted by the matters specified in an order under section 10 of the Act that is applicable to the goods, any monographs to which the goods are subject in the British Pharmacopoeia ("BP"), European Pharmacopoeia ("Ph. Eur."), United States Pharmacopeia-National Formulary ("USP") (each defined as a 'default standard') and homeopathic and anthroposophic standards.

Section 3C of the Act provides that the Minister may, by legislative instrument, determine that specified default standards, or specified statements in specified default standards, are exempt for the purposes of the definition of 'standard' in section 3 of the Act (i.e. do not constitute a 'standard' for particular therapeutic goods specified in the order or therapeutic goods generally).

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Exempt Monographs) Determination 2021* ("the Determination") is made under section 3C of the Act. The purpose of the Determination is to exempt nicotine vaping products that are not registered in the Australian Register of Therapeutic Goods ("the ARTG") ("unregistered nicotine vaping products") from default standards that would otherwise apply to those products.

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* ("the Order") is made under section 10 of the Act. The purpose of the Order is to establish a ministerial standard for unregistered nicotine vaping products. The Order specifies the minimum requirements for the quality and safety of unregistered nicotine vaping products, principally by reference to the labelling, packaging, ingredients and nicotine content of those products.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part by requiring compliance with the default standards under the Act and specifying ministerial standards under section 10 of the Act by reference to a range of matters including the manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in three international pharmacopoeias defined in the Act.

Nicotine vaping products are finished products that contain nicotine in solution, whether in salt or base form, and are intended to be vaporised and administered by inhalation using a vaping device. Vaping devices include e-cigarettes, e-cigars, e-hookahs pens, e-pens, e-pipes and vape pens. Nicotine vaping products are often also described as nicotine vape liquids and nicotine e-liquids.

On 17 December 2020, a delegate of the Secretary made a decision to amend the NICOTINE entries in Schedules 4 and 7 of the *Standard for the Uniform Scheduling of Medicines and Poisons* ("the Poisons Standard") ("the Scheduling decision"). As a result of the Scheduling decision, from 1 October 2021, all nicotine vaping products will be captured by the Schedule 4 entry for NICOTINE in the Poisons Standard.

In practice, this means that, from 1 October 2021, consumers will need a prescription from a medical practitioner to import nicotine vaping products into Australia (including when purchasing those products online from an overseas supplier). Currently, consumers are able to import these products without a prescription from a medical practitioner (although possession and use of nicotine vaping products without a prescription is an offence in each State and Territory, except South Australia).

The Scheduling decision aligns with current State and Territory laws, which generally allow nicotine vaping products to only be supplied to consumers by duly authorised health care practitioners ("HCPs"), such as medical practitioners, and pharmacists dispensing on prescription from duly authorised HCPs.

There are currently no nicotine vaping products registered on the ARTG and none are expected to be registered prior to the Scheduling decision coming into effect. Unregistered nicotine vaping products are, and will continue to be, accessible with a prescription through the access pathways for unapproved goods established under the Act. The TGA does not evaluate the safety, quality and efficacy of goods accessed via these pathways.

At least in the short term, it is expected that most unregistered nicotine vaping products accessed via these pathways will be imported from countries that regulate such products as consumer (rather than therapeutic) goods.

Products regulated as consumer goods in other countries are unlikely to have been manufactured to meet the default standards. Requiring compliance with the default standards would therefore likely hinder people's ability to access unregistered nicotine vaping products via the access pathways for unapproved products even with a prescription from a duly authorised HCP.

However, the lack of information and controls regarding unregistered nicotine vaping products is of concern to medical practitioners, who are expecting to see an increase in demand for prescriptions when the Scheduling decision comes into effect, and also to pharmacists, who may be asked to dispense these products on prescription. Users, too, have expressed support for a product standard for nicotine vaping products, to be informed about the content, quality and safety of products being inhaled.

Purpose

The Order is intended to address concerns held by medical practitioners and pharmacists about the lack of information and controls regarding unregistered nicotine vaping products by establishing minimum safety and quality requirements for unregistered nicotine vaping products with a view to:

- ensuring that HCPs and consumers have access to accurate information about the content of these products;
- ensuring that substances with known, demonstrable inhalation risks are not used as ingredients in these products; and

- minimising the risk of, and risks associated with, accidental exposure to or ingestion of these products, particularly by children, given the toxicity of nicotine.

The Order achieves these objectives by specifying a range of labelling, packaging, ingredient, nicotine content (or concentration) and record-keeping requirements. Most notably, these include:

- requiring disclosure of an ingredients list, the nicotine concentration and specific safety warnings on or attached to the container or primary package (including by way of over-stickering) or supplied with the product (including in an information sheet);
- prohibiting the use of active ingredients other than nicotine and eight specific ingredients with known, demonstrable inhalation risks;
- specifying that the nicotine concentration of these products must not exceed 100 mg/mL (base form concentration or equivalent base form concentration);
- requiring nicotine concentration or content to be within +/- 10% of that stated on or attached to the product, or its container or primary package, or in information provided with the product;
- requiring products to have child-resistant packaging ("CRP"); and
- requiring those responsible for import, export or manufacture for the purpose of supply, of these products to maintain records demonstrating conformance with the Order.

The Determination complements the Order by providing that those products covered by the Order need not also conform to the default standards that might otherwise apply to them. This is because the Order represents an acceptable standard for the safety and quality of unregistered nicotine vaping products in Australia. The default standards, however, will continue to apply to any nicotine vaping product that may be registered in the ARTG.

Incorporation by reference

Incorporation of exempt monographs by reference in the Determination

The Determination exempts unregistered nicotine vaping products from complying with all default standards that might otherwise apply to them, being all monographs in the BP, Ph. Eur., and the USP to which the products would otherwise be subject.

The reference to all applicable monographs in the BP, Ph. Eur. and the USP relating to nicotine vaping products to which the Order applies is incorporated in the Determination, notwithstanding any additions or amendments to those monographs or creation of new monographs. This is consistent with the definitions of the relevant pharmacopoeia in section 3 of the Act, noting that expressions used in instruments made under an Act have the same meaning as in the Act (section 46 of the *Acts Interpretation Act 1901* refers). Consequently, the exempt monographs are identified with reference to the pharmacopoeia in which the monographs are contained, irrespective of any new editions of the relevant pharmacopoeia.

The exempt monographs in the pharmacopoeia may be obtained from www.pharmacopoeia.com, www.edqm.eu/en and www.uspnf.com. Unfortunately, these publications are not available without charge, and varying prices apply depending on whether a person wishes to subscribe to the pharmacopoeia or purchase a particular edition.

It is not anticipated that the persons to whom the Order applies would need to obtain copies of the exempt monographs specified in the Determination to the extent that the exemption made under section 3C of the Act expressly excuses those persons from conforming to the monographs.

In any case, the TGA may facilitate access to view the relevant pharmacopoeia without charge by prior written arrangement with the TGA at the TGA office in Symonston, ACT. It should also be

noted that the National Library's Trove online system (wwww.trove.nla.gov.au) allows users to identify libraries in Australia that are open to the public where (in most cases, earlier) editions of these pharmacopoeia may be viewed.

Members of the public may also approach libraries that participate in inter-library loans to request an inter-library loan with libraries holding the pharmacopoeia to obtain a photocopy of a particular monograph for personal study or research. At the time of making this Order, the ordinary cost of making such request is $16.50. Enquiries should be made directly with local libraries, state libraries and the National Library.

Incorporation of child-resistant packaging requirements by reference in the Order

The Order incorporates by reference section 8, section 9 (other than subsection 9(6)) and section 10 of the *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017* (TGO 95) ("TGO 95"). TGO 95 is a legislative instrument, which similarly constitutes a standard for the purposes of section 10 of the Act, and sets out the requirements for child-resistant packaging.

The Order also incorporates by reference the child-resistant packaging requirements specified in:

- sections 50 to 54 of the Vaping Products Labelling and Packaging Regulations of Canada;
- Article 20(3)(g) of the *Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014*;
- any regulations that may made under the *Smokefree Environments and Regulated Products Act 1990* (NZ);
- paragraph 36(7) of the *Tobacco and Related Products Regulations 2016* of the United Kingdom; and
- 6 CFR § 1700.15 of the Poison prevention packaging standards of the United States.

The sections of TGO 95 and the international regulations identified above are incorporated as in force from time to time, in accordance with subsection 10(4) of the Act. TGO 95 is available for free from the Federal Register of Legislation and may be accessed on the internet at www.legislation.gov.au. Similarly, the international regulations are also available without charge from the following websites:

- Canada – https://laws-lois.justice.gc.ca/eng/;
- Europe – https://eur-lex.europa.eu/homepage.html;
- New Zealand – https://www.legislation.govt.nz/;
- the United Kingdom – https://www.legislation.gov.uk/; and
- the United States – https://ecfr.federalregister.gov/.

Consultation

The Office of Best Practice Regulation ("OBPR") advised that a regulation impact statement was not required in relation to the making of the Order (OBRP ID 44038). Additionally, the Determination was considered to be machinery in nature as a result of the Scheduling decision (OBPR ID 26377), in that the Scheduling decision will bring all unregistered nicotine vaping products within the scope of the Act and will, therefore, result in those products being subject to the default standards unless the Determination is issued. OBPR was not specifically consulted on the development of the Determination.

Extensive consultation was conducted in relation to the development of the Order and the Determination. Between 17 February and 31 March 2021, the TGA publicly released early draft versions of the Order and the Determination, and an associated consultation paper, and sought submissions from interested parties. People who made a submission in relation to the Scheduling decision were specifically invited to make a submission in relation to the draft Order and draft

Determination. A request for comment on this consultation and the draft Order was also provided to member countries through a World Trade Organization Technical Barriers to Trade ("WTO TBT") notification in March, closing 30 April 2021. A public webinar was conducted by TGA in March 2021 to explain the proposed requirements in the draft Order and draft Determination.

The TGA received 103 responses to the public consultation, including from HCP representative bodies, health and consumer advocacy groups, researchers, Australian and State Government entities, Poisons Information Centres, pharmaceutical, tobacco and vaping industry participants and consumers. No comments were received in response to the WTO TBT notification.

Most submissions received through the public consultation were supportive of the development of the Order, although opinions differed on a number of the proposed and potential requirements, even between members of the same stakeholder group (e.g. between different HCP representative bodies). Submissions on the Determination were divided, but most comments focussed on general concerns about the quality of these products, rather than the content of the Determination itself.

The TGA also considered the feedback received in the course of the 2020 inquiry by the Senate Select Committee on Tobacco Harm Reduction and the submissions made as part of the public consultation which informed the Scheduling decision. The TGA engaged in the following targeted stakeholder consultation between December 2020 and April 2021:

- discussions with regulators in the United Kingdom and Canada, and correspondence with regulators in the United States and New Zealand, regarding their respective approaches for nicotine vaping products and proposed future changes (December 2020-January 2021);
- monthly roundtable discussions with relevant health practitioner representative bodies and health advocacy groups regarding the Order and the development of complementary clinical and pharmacy guidelines (January – April 2021);
- discussions with researchers and non-Government organisations conducting research on nicotine vaping products (January – February 2021);
- targeted discussions with other Australian and State and Territory Government agencies (January – April 2021); and
- discussions with other interested parties, including medical indemnity insurers and companies that may consider applying to register nicotine vaping products on the ARTG (March – April 2021).

Detailed feedback on many of the requirements was incorporated into the drafting of the Order and Determination where appropriate.

Details of the Order and the Determination are set out in **Attachment A** and **Attachment B**, respectively.

The Order and the Determination are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment C**.

The Order and the Determination are disallowable legislative instruments. The Order commences on 1 October 2021 and the Determination commences at the same time as the Order. The Determination only commences if the Order commences.

Attachment A

Details of the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*

Part 1 – Preliminary

This Part provides for the name of the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* ("the Order"), its commencement, authority and application, and sets out definitions for key terms used in the Order.

Section 1 – Name

This section provides that the name of the Order is the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*, and that the Order may also be cited as TGO 110.

Section 2 – Commencement

This section provides that the Order commences on 1 October 2021. The commencement date provides sufficient time for manufacturers, sponsors, health practitioners and consumers to conform to the requirements.

Section 3 – Authority

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 – Definitions

This section provides the definitions of key terms used in the Order, including 'active ingredient', 'finished product', 'flavour', 'nicotine', 'nicotine vaping product', 'other ingredient', 'stated content', and 'TGO 95'. This section also notes that some expressions used in the Order, namely 'container', 'export only medicine', 'label', 'manufacture', 'medicine', 'primary pack', 'Register', 'registered goods', and 'sponsor', are defined in the Act, and therefore have the same meaning as in the Act.

In particular, this section provides that 'nicotine vaping product' means a medicine containing nicotine in solution, whether in salt or base form, that is a finished products and intended to be vaporised and administered by inhalation using a vaping device.

Section 5 – Standard

This section provides that the matters specified in the Order constitute a standard for nicotine vaping products.

Section 6 – Application

This section provides that the Order applies to nicotine vaping products, except those that are registered in the Australian Register of Therapeutic Goods ("the Register"), carried by a passenger on a ship or aeroplane in accordance with item 1 of Schedule 5 to the *Therapeutic Goods Regulations 1990* ("the Regulations"), medicines that are starting materials used in the manufacture of therapeutic goods as mentioned in item 9 of Schedule 5 to the Regulations, or are imported by particular persons or are part of the medical supplies of a visiting ship or aircraft as mentioned in items 4, 8, 10, 11 and 12 of Schedule 5A to the Regulations.

Part 2 – Requirements

This Part provides for general requirements for nicotine vaping products.

Section 7 – Ingredients

This section provides the requirements for ingredients used in nicotine vaping products. The only active ingredient that may be used in a nicotine vaping products is nicotine (whether in base or salt form). An active ingredient is a therapeutically active component of the medicine's final formulation that is responsible for its physiological or pharmacological action.

The base form, or equivalent base form, nicotine concentration of nicotine vaping products must not exceed 100 mg/mL and the nicotine concentration or content of the product must be within +/- 10% of any stated nicotine concentration or content, including any stated equivalent base form nicotine concentration, set out on, or attached to, the container or primary pack of the product or supplied with the product. This is to ensure that the information provided to health practitioners and consumers is accurate.

The substances listed in Schedule 1 to the Order, which carry known, demonstrable inhalation risks, are prohibited from being used as ingredients in nicotine vaping products.

Section 8 – Labels

This section provides that nicotine vaping products must be labelled with the information set out in Schedule 2 to the Order.

It notes that the information must be either be on or attached to the container or primary pack of the product, including by way of over-stickering, or supplied with the container or primary pack of the product, such as in an information sheet. It is not necessary for each piece of information to be provided in the same manner; a product may include some of the information on the container or primary pack of the product and provide other aspects of the information in an information sheet.

All information must be in English, legible, visible and not obscured, and durable.

Section 9 – Child-resistant packaging

This section requires nicotine vaping products to have child-resistant packaging complying with the requirements in section 8, section 9 (except subsection 9(6)) and section 10 of the *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017 (TGO 95)* ("TGO 95"), unless the product is packaged for supply in Canada, the European Union, New Zealand, the United Kingdom or the United States, and has child-resistant packaging compliant with the requirements in that jurisdiction.

Section 10 – Record keeping

This section provides that the sponsor of a nicotine vaping product must maintain records containing sufficient information to demonstrate that the product conforms to the requirements of the Order.

The sponsor of the product is a person who exports, imports, or manufactures in Australia (for the purpose of supply), the product or arranges for the exportation, importation or manufacture in Australia (for the purpose of supply), of the product. It does not include a person who undertakes these activities on behalf of another person who, at the time of the importation, exportation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

This section does not apply to products that are imported into Australia under the personal importation scheme in accordance with item 1 of Schedule 5 to the Regulations.

Section 11 – Alternative conformity

This section provides that nicotine vaping products that are the subject of a Premarket Tobacco Product Application marketing order from the United States Food and Drug Administration are taken to comply with the ingredient, child-resistant packaging and record-keeping requirements set out in sections 7, 9 and 10 of the Order.

Schedule 1 – Prohibited Ingredients

This schedule sets out the substances that must not be used as ingredients in nicotine vaping products pursuant to subsection 7(3) of the Order.

Schedule 2 – Labelling Information

This schedule sets out the information with which nicotine vaping products must be labelled pursuant to section 8 of the Order, being:

- an ingredients list setting out the name of each active ingredient, either a description of the flavour with the word 'flavour' (e.g. "cherry flavour") or the name of each component ingredient of the flavour (if any) and the name of each other excipient ingredient;
- the base form, or equivalent base form, nicotine concentration of the product in mg/mL;
- the following warning statements: 'KEEP OUT OF REACH OF CHILDREN', 'Avoid contact with eyes' and 'Avoid contact with skin'.

Attachment B

Details of the *Therapeutic Goods (Exempt Monographs) Determination 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Exempt Monographs) Determination 2021* ("the Determination").

Section 2 – Commencement

This section provides that the Determination commences at the same time as the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* ("the Order"). The Determination does not commence at all if the Order does not commence.

Section 3 – Authority

This section provides that the legislative authority for making the Determination is section 3C of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 – Definitions

This section provides the definitions of key terms used in the Determination, including 'TGO 110' and 'nicotine vaping products'. This section also notes that some expressions used in the Order, namely 'British Pharmacopoeia', 'European Pharmacopoeia', 'standard', 'therapeutic goods' and 'United States Pharmacopeia-National Formulary', are defined in the Act, and therefore have the same meaning as in the Act.

In particular, this section provides that the term 'nicotine vaping products' has the same meaning as in the Order.

Section 5 – Exemption

This section provides that, for the purpose of subsection 3C(1) of the Act, the monographs of the pharmacopoeia specified in Schedule 1 to the Determination are exempt from the definition of 'standard' in section 3 of the Act in relation to the therapeutic goods also specified in Schedule 1 to the Determination. This means that the specified monographs will not apply to the specified therapeutic goods as default standards.

Schedule 1 – Exempt Monographs

This Schedule specifies all monographs applicable to the relevant therapeutic goods in the British Pharmacopoeia, European Pharmacopoeia, and the United States Pharmacopeia-National Formulary for the purpose of the exemption from the definition of 'standard' in section 5 of the Determination. It also specifies that the relevant therapeutic goods, in relation to which the exemption in section 5 of the Determination applies, are nicotine vaping products to which the Order applies.

This means that, pursuant to section 5 of the Determination, all of the monographs in the British Pharmacopoeia, European Pharmacopoeia, and the United States Pharmacopeia-National Formulary that would otherwise be applicable to nicotine vaping products to which the Order applies will not apply to those products.

Attachment C

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods (Exempt Monographs) Determination 2021

Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021

These disallowable legislative instruments are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instruments

The *Therapeutic Goods (Exempt Monographs) Determination 2021* ("the determination") is made under section 3C of the *Therapeutic Goods Act 1989* ("the Act"). The purpose of the determination is to exempt therapeutic goods that are nicotine vaping products that are not registered in the Australian Register of Therapeutic Goods ("the Register") from being required to comply with monographs in the British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopeia-National Formulary ("the default standards").

This is intended to ensure that people with a prescription from a duly authorised health practitioner are able to access unregistered nicotine vaping products through the established access pathways under the Act. In the short term, it is expected that most products available will be imported from countries that regulate such products as consumer goods. Such products are unlikely to meet the default standards.

The *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021* ("the order") is made under section 10 of the Act. The purpose of the order is to establish a ministerial standard for therapeutic goods that are unregistered nicotine vaping products. The order specifies the minimum requirements for the quality and safety of unregistered nicotine vaping products, principally by reference to the labelling, packaging and ingredients of those products.

The order will support the regulation of unregistered nicotine vaping products and is intended to ensure that health practitioners and consumers have access to accurate information about these products, to ensure that substances with known inhalation risks are not used as ingredients in these products, and to minimise the risks of, and associated with, accidental exposure to, or ingestion of, these products. Most notably, the order:

- requires disclosure of an ingredients list, the nicotine concentration and specific safety warnings on or attached to the product, its container or primary package (including by way of over-stickering) or supplied with the product (including in an information sheet);
- prohibits the use of active ingredients other than nicotine and eight specified ingredients with known, demonstrable inhalation risks;
- specifies that the nicotine concentration of these products must not exceed 100 mg/mL (base form concentration or equivalent base form concentration);
- requires nicotine concentration or content to be within +/- 10% of that stated on or attached to the product, or its container or primary package, or in information provided with the product;
- requires products to have child-resistant packaging; and
- requires records to be held demonstrating conformance with the order.

The order and determination are disallowable legislative instruments. The order commences on 1 October 2021. The determination commences at the same time as the order but only commences if the order commences.

Human rights implications

The order and determination engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR"). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The determination takes positive steps to promote the right to health by ensuring that a person with a prescription from a duly authorised health practitioner is able to access a suitable unregistered nicotine vaping product.

The order takes positive steps to promote the right to health by helping to ensure the safety and quality of therapeutic goods that are unregistered nicotine vaping products which have not been evaluated by the TGA for safety, quality and efficacy. The order establishes a ministerial standard for nicotine vaping products and specifies the minimum requirements that must be met in relation to these products.

As such, the order and determination together address aspects of the right to health that relate to recognising the right of everyone to the enjoyment of the highest attainable standard or physical and mental health.

The requirements of the order are further bolstered in this regard by the criminal, civil and regulatory sanctions that may apply under the Act for persons who import, supply or export therapeutic goods that do not comply with applicable standards.

Conclusion

The order and determination are compatible with human rights because they promote the right to health in Article 12 of the ICESCR and otherwise do not raise any other human rights issues.