#### **EXPLANATORY STATEMENT**

# Public Health (Tobacco and Other Products) Act 2023

Public Health (Tobacco and Other Products) Regulations 2024

Public Health (Tobacco and Other Products) Amendment (On-Product Health Messages and Other Measures) Regulations 2024

# **Authority**

Section 185 of the *Public Health (Tobacco and Other Products) Act 2023* (the Act) provides that the Governor-General may make regulations prescribing matters required or permitted by that Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to that Act. The *Public Health (Tobacco and Other Products) Regulations 2024* (the Principal Regulations) prescribe details for the purposes of, among other things, the tobacco product requirements in the Act.

The Public Health (Tobacco and Other Products) Amendment (On-Product Health Messages and Other Measures) Regulations 2024 (the Amendment Regulations) will amend the Principal Regulations to prescribe text as images to appear on cigarettes under subsections 86(3) and 86(4). The text as images are for the purpose of on-product health messages.

# **Conditions**

Subsection 185(2) of the Act provides that before regulations are made under, or for the purposes of, a provision covered by subsection 185(3), the Minister must be satisfied that the regulations will advance the objects of the Act in paragraphs 3(1)(a) and 3(1)(b). Paragraphs 3(1)(a) and 3(1)(b) provide that the objects of the Act are, among other things, to improve public health by discouraging smoking and encouraging people to give up smoking, and to give effect to Australia's obligations under the World Health Organization Framework Convention on Tobacco Control 2003. The Amendment Regulations would advance these objects by requiring that cigarettes display an on-product health message on the tipping paper or filter tip.

Before regulations are made under subsection 86(3) or (4) that prescribe an image or text to appear on, or form part of, a tobacco product, the Commonwealth Chief Medical Officer must have recommended that the image or text be prescribed for the purposes of that subsection.

The Minister has received a recommendation from the Chief Medical Officer recommending that the text of the images as set out in Schedule 1 to the Amendment Regulations to be inserted as new Schedule 10 to the Principal Regulations be prescribed.

#### **Purpose**

The purpose of the Amendment Regulations is to amend the Principal Regulations to prescribe eight on-product health messages that must appear on cigarettes that contain a filter. The text of the images is prescribed, as set out in Schedule 1 to the Amendment Regulations inserted as new Schedule 10 to the Principal Regulations. The messages are required to be printed on the tipping or filter paper of individual cigarettes that contain a filter and duplicated on directly opposite sides of the cigarette.

The on-product health messages and policy approach have been informed by an iterative program of research and market testing, and with input provided by technical experts including in tobacco control, behavioural change and health communication.

The on-product health messages will be provided to manufacturers as a file containing the image of the on-product health message. This will aid accurate printing and ensure consistency of size, font and format. The Department of Health and Aged Care will make available, free of charge, electronic files containing the images to apply on-product health messages for use by tobacco manufacturers.

#### Consultation

The Act and Principal Regulations, which included provision in the Act for the appearance of tobacco products to be prescribed, were subject to extensive consultation. An exposure draft of the proposed Amendment Regulations was consulted on in a public consultation process from 30 October 2024 to 8 November 2024.

Submissions were received from public health stakeholders, including non-government organisations, peak bodies and academia. Overall, the submissions were positive, noting that the measure is supported by evidence and aligns with Article 11 of the WHO FCTC.

Submissions received from industry focused on implementation timeframes and manufacturing practicalities; they did not comment on the content of the on-product health messages. These submissions informed the final drafting of the proposed Regulations which included amendments to address technical matters. Changes to the amendment Regulations did not impact the policy intent of the measure.

The Regulations have been drafted to support the public health objectives of the measure as well as the effective implementation of the product requirements.

#### Commencement

The provisions will commence on the day after the instrument is registered on the Federal Register of Legislation.

#### General

This instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of this instrument are set out in **Attachment A**.

This instrument is 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 B**.

# <u>Details of the Public Health (Tobacco and Other Products) Amendment (On-Product Health Messages and Other Measures) Regulations 2024</u>

# Section 1 - Name of Regulations

This section provides that the title of the Regulations is the *Public Health (Tobacco and Other Products) Amendment (On-Product Health Messages and Other Measures)*Regulations 2024.

# Section 2 – Commencement

This section provides for the instrument to commence on the day after it is registered.

# Section 3 – Authority

This section provides that the instrument is made under the *Public Health (Tobacco and Other Products) Act 2023*.

#### Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the instrument has effect according to its terms.

# Schedule 1 – Amendments

#### Public Health (Tobacco and Other Products) Regulations 2024

# Item 1 - Section 4 (paragraph beginning "Chapter 3")

This item omits the words "and the health promotion inserts in Schedule 8," and substitutes "the health promotion inserts in Schedule 8, and the on-product health messages in Schedule 10,".

This ensures that the simplified outline of the Principal Regulations reflects the addition of this measure.

#### Item 2 - Section 5

This item inserts in section 5 a definition for "on-product health message" which refers to subsection 114A(2).

This updates the definitions section of the Principal Regulations with the new relevant definition.

# Item 3 - Paragraph 20(2)(c)

This item omits "or a health promotion insert" and substitutes ", a health promotion insert or an on-product health message."

Section 20 relates to website inclusions for online tobacco advertisements. There is a range of conduct that is prohibited. Paragraph 20(2)(c) provides that the website must not include 'words that directly or by implication contradict, qualify or modify a health warning or a health promotion insert'. This item amends that paragraph to also refer to "an on-product health message."

# Item 4 - Section 30 (at the end of paragraph (f))

Item 4 adds the words "(including the display of on-product health messages on cigarettes)" to the end of the paragraph 30(f).

This ensures that the simplified outline of the Principal Regulations reflects the addition of this measure.

# Item 5 - Part 3.12 (heading)

Item 5 inserts the words "and tobacco product accessories" in the heading to part 3.12 ("Tobacco products") to encompass the subject matter of the Part.

#### Item 6 - Section 113

Item 6 omits "This Division" in section 113 and substitutes "Unless otherwise stated, this Division." The amendment is to clarify the contents of the Division.

#### Item 7 - After section 114

This item inserts the requirements for on-product health messages on cigarettes that contain a filter. The messages which must appear on the product are intended to discourage the uptake of smoking and encourage the cessation of smoking.

Newly inserted section 114A provides that a cigarette that contains a filter must display a single on-product health message, in full, in accordance with the section.

A note draws attention to the requirement in paragraph 5(b) that the on-product health message must be duplicated on opposite sides of the filter.

Subsection 114(2) defines "on-product health message" as a message set out in the text of an image in a clause of Schedule 10. These are the prescribed messages; one of which must be included on a cigarette with a filter.

Subsections 114(3) and 114(4) provide for the location and dimensions of on-product health messages on cigarettes with a filter.

Subsection 114(3) provides that the full on-product health message must appear, as set out in clause 9 of Schedule 10, within a white rectangular background which meets the criteria in paragraphs (a) to (c). These include that the rectangular background must be located on the imitation cork tip of the paper casing of the cigarette, and be 6mm in height and at least 24mm in length. The right border of the rectangular background must be the same distance from the end of the cigarette that is not designed to be lit as the left border is from the tobacco column end of the paper casing covering the filter.

A note provides that if the paper casing covering the filter is in the same length as the paper casing covering the filter, the distance mentioned in paragraph (c) of this subsection will be 0mm.

Subsection 114(4) provides that the text of the on-product health message must appear such that, as set out clause 9 of Schedule 10 it meets the requirements in paragraphs (a) to (d).

Subsection 114(5) provides for the orientation of the on-product health message. It must, as set out in clause 9 of Schedule 10 be oriented perpendicular to the end of the cigarette and be duplicated on directly opposite sides of the filter.

Subsection 114(6) provides for the application of the on-product health message. It must be printed in black directly onto the paper casing covering the filter using a matt finish and be plainly visible and readable.

Subsection 114(7) provides that the on-product health message must not be distorted in any way, obscured or obliterated in any way, or obscure or obliterate any other mark required or permitted under this Part, be etched, embossed, debossed or applied otherwise than in accordance with paragraph 6(a), be removable or be likely to be erased or damaged when the cigarette is handled.

Subsection 114(8) provides for the meaning of terms used in this section including the meaning of left border, right border, top border and bottom border.

A note directs the reader to see Figure 10.1 in clause 9 of Schedule 10 for an example image of a cigarette oriented in accordance with this subsection.

#### Section 114B - Secretary may approve file containing on-product health messages

Section 114B provides for the Secretary to approve files containing on-product health messages.

Subsection 114B(1) provides that the Secretary may approve one or more electronic files containing images for use in applying on-product messages to cigarettes for the purposes of this Part.

Subsection 114B(2) provides that if such a file has been approved, the on-product health message displayed on a cigarette must be sourced from the file and use the same resolution as the file.

Subsection 114B(3) provides that the Secretary must make a file approved under subsection (1) available to a person on request, free of charge, if the Secretary is reasonably satisfied that the person is involved in manufacturing cigarettes.

# Section 114C - On-product health messages to be displayed equally

Section 114C provides that each on-product health message is to be displayed as nearly as possible in equal numbers for each brand name and variant name of cigarette manufactured in a calendar year.

The section provides that it is the calendar year beginning on 1 January 2025; and each subsequent calendar year.

# Item 8 - Subsection 120(3)

Item 8 amends subsection 120(3) to omit "A filter tip" and substitute "For the purposes of paragraph 124(1)(c) of the Act, a filter tip" to indicate the relevant authority for subsection 120(3).

# Item 9 - Section 121 (table item 5, column headed "Ingredient", after paragraph (b))

For the purposes of subsection 87(3) of the Act, a tobacco product may contain an ingredient set out in the table in the Principal Regulations.

Item 9 inserts in the table "paragraph (ba) for cigarettes – apply the on-product health message required by section 114A."

#### Item 10 - At the end of the instrument

Item 10 inserts the heading 'Schedule 10—On-product health messages'. It includes a note referring to section 114A.

Item 10 also inserts sections 1 to 9.

Sections 1 to 8 provide for the required images of on-product health messages. There are eight such messages.

Section 9 provides for the location and dimensions of the text of the images, of on-product health messages. The on-product health message must be oriented, and the dimensions of the text of the message must be as they are shown in figure 10.1 of the Amendment Regulations.

A note provides that if the white rectangular background is the same length as the paper casing of the filter, there will be no imitation cork on the left or right of the background. A second note provides that the duplicate of the on-product health messages on the opposite side of the filter must be displayed in the same location and dimensions as figure 10.1.

# **Statement of Compatibility with Human Rights**

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

# Public Health (Tobacco and Other Products) Amendment (On-Product Health Messages and Other Measures) Regulations 2024

This Disallowable Legislative Instrument is 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 Disallowable Legislative Instrument

The Public Health (Tobacco and Other Products) Act 2023 (the Act) provides the framework to discourage the use of tobacco and other products, and for related purposes. The Public Health (Tobacco and Other Products) Regulations 2024 (the Principal Regulations) prescribe details for the purposes of, among other things, the tobacco product requirements in the Act. The Public Health (Tobacco and Other Products) Amendment (On-Product Health Messages and Other Measures) Regulations 2024 (the Amendment Regulations) prescribe that cigarettes that contain a filter must display an on-product health message.

These Amendment Regulations provide for on-product health messages to be included on cigarettes. The intention is that they will further discourage the uptake, and encourage the cessation, of smoking.

Subsection 86(3) provides that the appearance of a tobacco product must comply with the requirements (if any) prescribed by regulations made for the purposes of this subsection. Subsection 86(4) provides that the physical features of a tobacco product must comply with the requirements (if any) prescribed by regulations made for the purposes of this subsection.

The tobacco product requirement prescribing on-product health messages complements and extends new and updated health warnings on the tobacco product packaging. Tobacco plain packaging measures have reduced the appeal of smoking by removing imagery that people who smoke use to affiliate themselves with the brand they smoke. Like their packaging, cigarettes themselves can be a powerful communication tool. Compared to a cigarette with no message, cigarettes with on-product health messages better communicate the risks and harms of smoking during the moment of consumption in a manner that cannot easily be avoided. Dissuasive measures on tobacco products, such as on-product health messages, help to increase negative health perceptions about smoking and can contribute to lowering smoking prevalence by discouraging uptake and encouraging cessation.

The purpose of the Amendment Regulations is to prescribe requirements for the appearance of cigarettes, specifically to require on-product health messages, for the purposes of what are tobacco product requirements under the Act. The measure contained in these Amendment Regulations will give effect to certain obligations that Australia has as a party to the World

Health Organization (WHO) Framework Convention on Tobacco Control (2003) (FCTC), an evidence-based treaty. The Guidelines for implementation of Article 11 of the WHO FCTC state that parties should consider requiring health warnings and messages to be printed on individual cigarettes.

The WHO FCTC is Australian Treaty Series 2005 No. 7 ([2005] ATS 7) and could in 2024 be viewed in the Australian Treaties Library on the AustLII website (http://www.austlii.edu.au).

# **Human rights implications**

The Amendment Regulations engage the following rights:

- Right to health—Article 12(2)(c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR);
- Right to life—Article 6 of the International Covenant on Civil and Political Rights (ICCPR);
- Right to freedom of expression—Article 19(2) of the ICCPR;
- Right to a fair trial and fair hearing rights—Article 14(1) of the ICCPR; and
- Right to a presumption of innocence—Article 14(2) of the ICCPR.

# Right to health—Article 12(2)(c)

Article 12(2)(c) of the ICESCR requires States Parties to take steps to achieve the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, including those steps necessary for the prevention, treatment and control of diseases. The Committee on Economic, Social and Cultural Rights considers that this "requires the establishment of prevention and education programmes for behaviour related health-concerns…and the promotion of social determinants of good health".

The Amendment Regulations promote the right to health by aiming, through the achievement of the Act's objectives, to reduce smoking rates and thereby reduce the significant health, social and economic effects of tobacco use. The tobacco product requirement for on-product health messages is intended to promote cessation and discourage uptake of smoking.

# Right to life—Article 6

The right to life is contained in article 6(1) of the ICCPR.

The Amendment Regulations, by requiring on-product health messages, promote the right to life by seeking to reduce the incidence of smoking.

Tobacco use causes more deaths than any other behavioural risk factor. Up to two thirds of deaths in tobacco smokers can be attributed to smoking, and long term smokers die an average of 10 years earlier than non-smokers. Exposure to second-hand smoke is also a cause of preventable death and disability in adults and children. Tobacco use and exposure among pregnant people and their babies is one of the most prevalent preventable causes of infant death and illness and of adverse pregnancy outcomes including preterm birth and still-birth.

Tobacco smoking by youth and young adults has immediate adverse health consequences and accelerates the development of chronic diseases across the full life course. It can lead to nicotine addiction that causes young people to continue smoking for longer, causing increased physical damage. In addition, quitting smoking at any age reduces the risk of premature death and improves quality of life.

The inclusion of on-product health messages is expected to increase consumer knowledge of health harms of smoking and reduce the appeal of tobacco products. In the long term, it is expected to reduce smoking uptake among youth and increase quit attempts among people who smoke, by weakening positive feelings about tobacco products. The messages could act as a deterrent for initiation among youth and young adults, who are especially sensitive to social appearance. Over time, it will contribute to reducing smoking prevalence.

The tobacco product requirement contained in the Amendment Regulations promotes the right to life by seeking, through the achievement of the Act's objectives and the intended effect of the measures, to deter the uptake of smoking, and to encourage people who smoke to quit.

# Right to freedom of expression—Article 19(2)

Under Parts 3.4 and 3.5 of the Act, a person may commit an offence, or be liable to a civil penalty, if the person contravenes a tobacco product requirement in certain circumstances. Chapter 3 of the Principal Regulations prescribes the detail of certain tobacco product requirements for the purposes of the Act. The tobacco product requirement in the Amendment Regulations is to include on-product health messages on cigarettes that contain a filter.

The restriction on the appearance of tobacco products provided for by the Amendment Regulations may engage Article 19 of the ICCPR. Article 19(2) of the ICCPR engages the right to freedom of expression.

Article 19(3)(b) of the ICCPR states that public health is a basis on which the right to freedom of expression can be limited. This right may be limited as provided for by law and when necessary for respect of the rights or reputations of others, for the protection of national security, public order, or of public health or morals. Limitations must be prescribed by legislation necessary to achieve the desired purpose and proportionate to the need on which the limitation is predicated.

These Amendment Regulations engage and may limit the right to freedom of expression, which is protected by Article 19(2) of the ICCPR.

However, these restrictions are directed to the desired purpose of reducing tobacco use and supporting those who already smoke to quit. This is a legitimate public health objective and accordingly the restrictions are necessary to achieve the desired purpose and proportionate to the need on which the limitation is predicated.

The right to freedom of expression is not absolute. It carries with it special responsibilities and may be restricted on several grounds. Article 19(3) of the ICCPR expressly states that the right to freedom of expression may be subject to limitations necessary for the protection of public health. The limitation (if any) of the right to freedom of expression in the Amendment Regulations aims to achieve a legitimate objective – the protection of public health – by

contributing to efforts to reduce smoking rates and to reduce the associated health risks of smoking.

It follows that to the extent that the supporting Amendment Regulations limit freedom of expression it is for the legitimate objective of the protection of public health.

# Right to a fair trial and fair hearing rights—Article 14(1) of the ICCPR; and Right to a presumption of innocence—Article 14(2) of the ICCPR.

The Amendment Regulations engage the right to a fair trial and fair hearing rights along with the right to a presumption of innocence in that it will be an offence to not comply with the tobacco product requirements including this new requirement to display an on-product health message.

The details prescribed by the Amendment Regulations are relevant to determining whether a person has committed an offence, or is liable to a civil penalty, under the Act.

The Act triggers the operation of the *Regulatory Powers (Standard Provisions) Act 2014* (Regulatory Powers Act). The safeguards of Part 4 of the Regulatory Powers Act apply to ensure that fair process is applied, particularly where there is the potential for both criminal and civil proceedings.

#### Strict liability offences

There are a number of strict liability offences contained in the Act and the some of the detail relevant to those offences (i.e., tobacco product requirements for tobacco products to be compliant) is contained in the Amendment Regulations. Strict liability offences engage and limit the presumption of innocence as they allow for the imposition of criminal liability without the need to prove fault. However, the defence of mistake of fact is still available to the defendant. This ensures that a person cannot be held liable if he or she had an honest and reasonable belief that they were complying with relevant obligations. All of the civil penalty and offence provisions throughout the Act are also framed as strict liability offences.

Application of strict liability has been set with consideration given to the guidelines regarding the circumstances in which strict liability is appropriate set out in the Guide to Framing Commonwealth Offences. Accordingly, the penalties for the strict liability offences in the Act do not include imprisonment, and do not exceed 60 penalty units for an individual. The penalty for corporations is 600 penalty units for strict liability offences which is justified based on the need to provide a sufficient level of deterrence for corporations.

To the extent that the Amendment Regulations engage with the right to a fair trial and fair hearing rights and also the right to a presumption of innocence any limitations on these rights are reasonable, necessary and proportionate. They are reasonable because they seek to balance the need for an effective regulatory regime against the right to a presumption of innocence. They are necessary to facilitate the important objects of the Act. They are proportionate particularly given that they are sparingly applied given the large number of offences in the Act. The Amendment Regulations prescribe tobacco product requirements that need to be met for tobacco products to be compliant. The Act only imposes reverse burdens in relation to non-compliance where it is considered strictly necessary and in furtherance of the important objects of the Act.

# Conclusion

The Amendment Regulations are compatible with human rights. To the extent that they limit any human rights, those impacts are reasonable, necessary and proportionate.

The Hon. Mark Butler MP

Minister for Health and Aged Care