

## Supplementary Consultation Paper –

### Exposure Draft Public Health (Tobacco and Other Products) Regulations 2023

#### Overview

On 31 May 2023, the Hon. Mark Butler MP Minister for Health and Aged Care released for public comment exposure drafts of the:

- Public Health (Tobacco and Other Products) Bill 2023 and the Public Health (Tobacco and Other Products) (Consequential Amendments and Transitional Provisions) Bill 2023 (together, the **Bills**); and
- Public Health (Tobacco and Other Products) Regulations 2023 (the **Regulations**); and Public Health (Tobacco and Other Products) (Consequential Amendments and Transitional Provisions) Regulations 2023 (the **Consequential Amendments and Transitional Provisions Regulations**).

Public comment was invited between 31 May and 14 July 2023. Following consultation a number of revisions were made to the Bills before consideration by the Parliament – see [Public Health \(Tobacco and Other Products\) Bill 2023 – Parliament of Australia \(aph.gov.au\)](https://aph.gov.au).

Feedback is now sought on a revised exposure draft of the Regulations. Comments are particularly sought on the provisions and images for the purpose of the graphic health warnings (**GHWs**) and health promotion inserts (**HPIs**), as outlined in this consultation paper and the following attachments:

- Schedule 1 – Online tobacco advertisement warnings
- Schedule 2 – Health warning series – cigarettes and tobacco products other than cigars, pipe tobacco, shisha and bidis
- Schedule 3 – Health warning series – cigars packaged in cigar tubes
- Schedule 4 – Health warning series – cigars other than those packaged in cigar tubes
- Schedule 5 – Health warning series – pipe tobacco
- Schedule 6 – Health warning series – shisha tobacco
- Schedule 7 – Health warning series – bidis
- Schedule 8 – Health warning series – health promotion inserts – cigarettes and loose tobacco products
- Schedule 9 – Online e-cigarette advertisement message

The content of the Schedules should be considered in conjunction with the draft Regulations, in which they are intended to be incorporated, and this paper.

Feedback is also sought on changes to other areas of the Regulations following consideration of the first round of consultation. Key changes are outlined below.

The Review of Tobacco Control Legislative Framework Impact Analysis (**Impact Analysis**) provides detailed discussion of the policy objectives and evidence base for the measures. The full version of the Impact Analysis is available on the Office of Impact Analysis website here: [Review of Tobacco Control Legislative Framework \(Thematic Review\) 2023 | The Office of Impact Analysis \(pmc.gov.au\)](https://pmc.gov.au) .

## Consultation process

The exposure draft of the Regulations and this consultation paper are being released for public comment **until Monday 8 January 2024**.

Submissions are invited in response to the specific consultation questions regarding the Exposure Drafts of the Regulations. If you made a submission during the consultation process between May – July 2023, it is not necessary to repeat the content of that submission. To the extent you wish to make further submissions related to the Regulations you are welcome to do so.

The Department of Health and Aged Care (the **Department**) intends to publish submissions received through this consultation process. Direct contact details such as phone numbers and email addresses will be redacted. By providing a submission through this process, you are consenting to having your submission published by the Department in full. The Department retains the right to leave unpublished any submission, or part thereof, including any that contain offensive or defamatory comments, or which are outside the scope of the consultation.

When making your submission, please indicate if you do not want your submission published or if you would prefer to make an anonymous submission. Submissions which are published on the Department's website can be accessed by the general public, including people overseas. Ordinarily, where the Department discloses personal information to an overseas recipient, *Australian Privacy Principle (APP) 8.1* requires the Department to take reasonable steps to ensure that the overseas recipients do not breach the APPs. If you consent to the publication of your submission, APP 8.1 will not apply to this disclosure and the Department will not be accountable under the *Privacy Act 1988 (Cth)* for any subsequent use or disclosure of the submission by an overseas recipient, and you will not be able to seek redress under that Act.

Submissions may be subject to freedom of information requests, or requests from the Parliament, which the Department will consider and respond to in line with procedural and legal requirements.

This consultation process is undertaken in accordance with Australia's obligations under Article 5.3 of the World Health Organization (**WHO**) Framework Convention on Tobacco Control (the **FCTC**). Article 5.3 of the FCTC obliges Australia to take steps to protect its tobacco control policy setting and implementation from interference from the tobacco industry and its interests. This also extends to the e-cigarette industry. Consistent with Australia's obligations under Article 5.3 of the FCTC, consultation with tobacco and e-cigarette industry and individuals and organisations whose interests may be aligned with the tobacco industry will be limited to what is necessary to enact effective tobacco control measures and will be undertaken in a transparent and accountable manner. Written submissions received from individuals or organisations associated with the tobacco or e-cigarette industry will be deemed to have a conflict of interest (whether actual or perceived).

### **Proposed Public Health (Tobacco and Other Products) Regulations 2023**

The objects of the Bill are to: improve public health by discouraging smoking and the use of regulated tobacco items, and encouraging people to give up smoking and to stop using regulated tobacco items; give effect to certain obligations that Australia has as a party to the WHO FCTC; and address public health risks posed by vaping and e-cigarette products.

The proposed Regulations will prescribe requirements for the purposes of the Act, including among other things, product and packaging requirements and advertising and reporting provisions.

### **Proposed Public Health (Tobacco and Other Products) (Consequential Amendments) Regulations 2023**

The proposed Consequential Amendments and Transitional Provisions Regulations will support the Act by repealing the Tobacco Advertising Prohibition Regulation 1993, the Tobacco Plain Packaging Regulations 2011 and the Trade Practices (Consumer Product Safety Standard) (Reduced Risk Cigarettes) Regulations 2008, along with making other consequential amendments.

### **Supplementary exposure draft- areas now subject to consultation**

The requirements for GHWs and HPs were not fully detailed in the first exposure draft and the images for these are now available for review. The proposed GHWs and HPs have been the subject of significant policy development and refinement, with feedback received from technical experts in tobacco control, behavioural change and health communication, and following an iterative program of research and market testing.

To support the rollout of new GHWs and HPs, online information and resources will be developed and updated, including [tobaccofacts.gov.au](http://tobaccofacts.gov.au), which will extend the opportunity to improve health knowledge beyond the content of GHWs; [quitnow.gov.au](http://quitnow.gov.au) which will build on the cessation advice and support in the content of HPs; and the My Quit Buddy mobile application. While these resources are referred to in the new GHWs and HPs, they are not yet available for viewing as part of this consultation process. These resources will be available at the time the proposed Regulations commence.

### **Updated Graphic Health Warnings**

The Bill consolidates the provisions from the *Competition and Consumer (Tobacco) Information Standard 2011* and provides that the retail packaging of tobacco products must display the images or combination of images prescribed by the Regulations.

The proposed requirements for the display of images and combinations of images on the retail packaging of tobacco products are at Part 3.7 of the Regulations. The relevant images are referred to in the provisions as being in schedules of the Regulations.

The proposed images are contained in Schedules 2 to 7 of the Regulations, for:

- cigarettes;
- cigars;
- bidis;
- pipe tobacco; and
- shisha tobacco.

Schedules 2 to 7 of the Regulations prescribe images and combinations of images in vertical, horizontal and square formats to provide requirements for all retail packaging of tobacco products. The proposed content for these Schedules appears in the attachments to this consultation paper.

Schedule 1 of the Regulations contains the images and combination of images specific to online tobacco advertisements.

Schedule 9 of the Regulations contains the messages specific to online e-cigarette advertisements.

The Department will make available, free of charge, electronic files containing images for use in graphic health warnings and online tobacco advertisements, for use by tobacco suppliers, including manufacturers, importers, wholesalers and retailers. Detailed guidance will be available to further assist with implementation and compliance with the Regulations.

The proposed Regulations prescribe the health warnings for the first series circulating from the date the Regulations are made (proposed to be 1 April 2024). This means that the new images may be displayed on packaging from the date the Regulations commence. There will be a 12-month transition period for industry to become compliant with the new packaging requirements, and a further 3 month sell-through period for retailers as set out below. During this transition period, full compliance with either the existing requirements under *Tobacco Plain Packaging Act 2011* and *Tobacco Advertising Prohibition Act 1992* **OR** the requirements under the Bill will be taken to be compliance with the new regime.

<b>Commencement of Regulations (proposed)</b>	<b>Transitional period for industry compliance</b>	<b>Additional 3 month sell-through period for retailers</b>
1 April 2024	1 April 2024 – 31 March 2025	1 April 2025 – 1 July 2025

Future series of GHW and HPs will be introduced following separate consultation and update to the Regulations.

Before the Governor-General makes Regulations prescribing new health warnings, the Commonwealth Chief Medical Officer must have recommended that the images or combination of images be prescribed. As with HPs, where new images are prescribed after the first series, there will be a 6-month period before the new images take effect and then there will be a 6-month sell-through period for retailers. It is intended that each series of warnings and HPs will have effect for a period of 12 months.

### **Health Promotion Inserts**

The Bill requires manufacturers to enclose a HPI into tobacco product packaging (other than packaging for cigars or shisha tobacco products).

The proposed requirements relating to HPs are contained in Part 3.11 of the Regulations. The images (which are a single series) will be defined within Schedule 8 of the Regulations- see the proposed content of Schedule 8 in the attachments.

The Regulations are proposed to prescribe requirements for the HPIs that must be included in the retail packaging of tobacco products. This includes such things as:

- the distribution and placement of HPIs;
- technical requirements (such as provision that they must be printed on recycled paper); and
- the dimensions of the HPI.

The proposed Regulations prescribe the first series of HPIs circulating from the date the Regulations are made (proposed to be 1 April 2024). This means that HPIs may be included in packaging from the date the Regulations commence. There will be a 12-month period for industry to become compliant, and a further 3-month sell-through period for retailers as set out below. During this transition period, full compliance with either regime will be taken to be compliance with the new regime.

<b>Commencement of Regulations (proposed)</b>	<b>Transitional period for industry compliance</b>	<b>Additional 3 month sell-through period for retailers</b>
1 April 2024	1 April 2024 – 31 March 2025	1 April 2025 – 1 July 2025

Future HPI series will be introduced following separate consultation and update to the Regulations.

Before the Governor-General makes regulations prescribing new HPIs after the first series, the Commonwealth Chief Medical Officer must have recommended that the inserts be prescribed. Where there is to be a change in inserts prescribed, there will be a 6-month period before the new images take effect and then there will be a 6-month sell-through period for retailers. The intention is for each series to have effect for 12 months.

**Questions-**

Do you have any comments on the proposed images as set out in Schedules 1-9, or any feedback relating to compliance with, or implementation of, GHWs, HPIs or requirements for warnings to appear online as defined within the regulations?

## Key changes to the Regulations following the exposure draft released on 31 May 2023

Following analysis of the feedback and submissions received during the public consultation, along with further policy development, there have been a number of changes made to the Regulations. Key changes are outlined below:

### *Prescribed amounts of tobacco products*

- Previously:
  - The prescribed amounts for the purposes of paragraphs 17(b) (about when a tobacco product is presumed to be offered for retail sale) and paragraphs 96(3)(b)/110(3)(b) (about the personal use exception for an individual's possession of tobacco products in non-compliant retail packaging) were the same (^11).
  - In addition, this provision included separate prescribed amounts for cigarettes other than those packed in a carton (50 cigarettes) and cigarettes packaged in a carton (200 cigarettes).
- Now:
  - Former regulation ^11 has been separated into two provisions, one dealing with the presumed offer of retail sale (^10) and the other dealing with the exception for an individual who possesses tobacco products for personal use that are in non-compliant retail packaging (^11). These provisions do not distinguish between those cigarettes packed in a carton and those which are not.
  - In addition, the prescribed amount for the purposes of ^11 has been increased to:
    - for cigarettes – 1,000 cigarettes; and
    - for all other tobacco products – 1,000 grams.

### *Distribution of GHWs and HPis*

- Previously:
  - Former regulation ^62 required each unit of primary packaging in secondary packaging (for which there was a health warning series) to display a different health warning in the series (e.g. each cigarette pack in a cigarette carton containing 10 packs must display a different health warning).
  - Former regulation ^106 required each unit of primary packaging in secondary packaging to include a different HPI in the series.
- Now:
  - The retail packaging of cigarettes is taken to comply with the requirement to display GHWs as nearly as possible in equal numbers if, in any random sample of 4 cigarette cartons, the same health warning appears on no more than 2 cigarette packs in any carton (^67).
  - The retail packaging of cigarettes is taken to comply with the requirement to include HPis in the retail packaging as nearly as possible in equal numbers if, in any random sample of 4 cigarette cartons, the same HPI is included in no more than 2 cigarette packs in any carton (^108).

## *Rotation periods*

This change affects both GHWs and HPis.

The rotation periods for GHWs (discussed below) and HPis are intended to support the effectiveness of health warnings and HPis, by supporting even distribution of messages in each rotation and ensuring that people who use tobacco products are exposed to all messages. The rotation periods of GHWs and HPis are aligned to maximise effectiveness and visibility, as well as minimise wear-out effects.

- Previously:
  - The Regulations contained multiple series of GHWs and HPis, each of which applied for a calendar year with an associated 6-month sell-through period.
- Now:
  - The Regulations contain a single series of GHWs and HPis – the provisions giving effect to multiple, rotating series of health warnings and HPis have been amended or (where appropriate) removed. For example, former regulations ^58 to ^60 (relating to the display of health warnings by rotation period) have been removed, as have former regulations ^102 to ^104 (relating to HPis).
  - In addition, the term “rotation period” (as defined in former ^6) has been removed as these Regulations do not prescribe multiple series of GHWs or HPis.

A separate consultation and regulatory update process will be undertaken to prescribe future series of GHWs and HPis, with the second rotation intended to be in circulation from 1 January 2026, and the third from 1 January 2027.

## *New health warning requirements*

- Previously:
  - The same health warnings were prescribed for pipe tobacco, waterpipe/shisha tobacco and loose processed tobacco.
- Now:
  - Separate health warnings will be prescribed for each category of these tobacco products. Consequently, new provisions have been inserted to prescribe the physical features of the primary packaging of loose processed tobacco (^37). The images comprising the health warning series for pipe tobacco and shisha tobacco will be contained in Schedules 5 and 6 to the Regulations.
- Previously:
  - Former regulation ^15 required the display of health warning images for online tobacco advertisements to be either a static display of all images in the series or a dynamic display in which each image is displayed for a period between 5 and 10 seconds.
- Now:
  - The Regulations require the prominent and equal display of the health warnings series (which will have age restriction warnings as part of the health warning) set out in Schedule 1 through manual or automated rotation. Where there is a dynamic display, each image is displayed for a period between 10 and 30 seconds (see ^17).

### *New HPI requirements for loose processed tobacco*

- Previously:
  - The regulations required health promotion inserts to be included inside tobacco pouches, in the section of the pouch that contains tobacco.
- Now:
  - The regulations provide for the placement of health promotion inserts in the retail packaging of loose processed tobacco (^111). In particular, the regulations now allow for the HPIs to be located either:
    - inside the packaging, located in front of, or on top of, the tobacco product (^111(3)); or
    - fixed to the flap of the pouch or lid of the tin and held in place by soft adhesive to allow consumers to easily remove and read both sides (^111(4)).

### *Colour and finish of retail packaging*

- Previously:
  - The regulations required the inner surfaces of cigarette packs and cigarette cartons to be white (^37(3)).
  - The regulations required the inner surfaces of all other primary or secondary packaging to be either white or the colour of the material from which the packaging was made (^37(4)).
  - The regulations required that any means for resealing the primary packaging of a tobacco product (other than a cigarette pack) included in the packaging of that product to be either white or transparent and not coloured (^33(2)). Further, any inserts used in retail packaging (other than a cigarette pack or cigarette carton) to avoid damage to a tobacco product during transportation or storage were required to be either white or the colour of the material from which the insert was made (^98(3)).
- Now:
  - The inner surfaces of cigarette packs and cigarette cartons must be Pantone 448C (^43(3)).
  - The inner surfaces of all other primary or secondary packaging must now either be the natural colour of the metal or wood from which the packaging is made or, in any other case, Pantone 448C (^43(4)).
  - In addition, the means for resealing the primary packaging of a tobacco product other than a cigarette pack must now either be Pantone 448C or transparent and not coloured (^39(2)). Further, any inserts used in retail packaging (other than a cigarette pack or cigarette carton) to avoid damage to a tobacco product during transportation or storage must now either be Pantone 448C or transparent and not coloured (^102(2)).



### *Paper casing for cigarettes*

- Previously:
  - Regulation ^115 required the paper casing of cigarettes to be white with an imitation cork tip.
- Now:
  - The paper casing of cigarettes must also have a matt finish and be free from any mark (other than the marks permitted by Part 3.12) (^117).

### *Prohibited ingredients*

- Previously:
  - All amino acids, sugars and sweeteners (including those which are naturally occurring) were prohibited (^120).
  - Clove oil, clove extract and eugenol, menthol derivatives and synthetic cooling/masking agents were not expressly prohibited (^120).
- Now:
  - Amino acids *that have been added to the product* remain prohibited; naturally occurring amino acids are not prohibited (^121, table item 2).
  - In addition to cloves, clove oil, clove extract and eugenol are prohibited ingredients (^121, table item 4).
  - In addition to menthol, menthol derivatives such as l-menthol and l-menthone are prohibited ingredients (^121, table item 9).
  - Sugars or sweeteners *that have been added to the product* remain prohibited; naturally occurring sugars or sweeteners are not prohibited (^121, table item 13).
  - Synthetic cooling or masking agents such as WS-23 and WS-3 are prohibited (^121, table item 14).

### *Publication of a report*

- Previously:
  - There were no prescribed matters for the Minister to have regard to when deciding whether to publish a report, or part of a report.
- Now:
  - In making a decision about publication of a report, or part of a report, the Minister must have regard to:
    - whether the Minister considers the publication would advance the objects of the Act;
    - whether publication would involve the publication of personal information;
    - whether publication would involve the publication of a document that is an exempt document for the *Freedom of Information Act 1982*; and
    - whether the Minister considers information in the report to be false, misleading or deceptive (^132).

### *Trans-Tasman Mutual Recognition Arrangement*

- Previously:
  - The Public Health (Tobacco and Other Products) legislation did not refer to the Trans-Tasman Mutual Recognition Arrangement.
- Now:
  - New regulation <sup>12</sup> temporarily exempts the Public Health (Tobacco and Other Products) Act from the *Trans-Tasman Mutual Recognition Act 1997* (Cth). A note provides that the exemption operates for a period of up to 12 months.

#### **Questions-**

Do you have any feedback on the key changes to the Regulations following the exposure draft released on 31 May 2023?