

# Plain Packaging of Tobacco Products

# TOOLKIT

Smoking causes  
strokes and  
disability



Fumer nuit à vos  
dents et à vos  
gencives



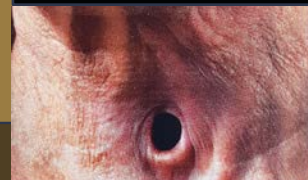
Smoking causes  
peripheral vascular  
disease



Smoking causes  
heart attacks



Smoking causes  
mouth and throat  
cancer



## A Practical Guide to Policy Development and Drafting Legislation for Tobacco Plain Packaging

Get help to stop tobacco branding at  
[www.tobaccofreekids.org](http://www.tobaccofreekids.org)

Campaign for Tobacco-Free Kids  
November 2017

# CONTENTS

## BRIEF POLICY GUIDES

<b>GETTING PREPARED</b>	<b>GUIDE 1.1</b> Set policy objectives	<b>GUIDE 1.2</b> Establish document development and retention policy	<b>GUIDE 1.3</b> Prepare for tobacco industry interference
<b>COLLECTING THE EVIDENCE</b>	<b>GUIDE 2.1</b> Evidence review	<b>GUIDE 2.2</b> Regulatory impact analysis	<b>GUIDE 2.3</b> Stakeholder input / public consultation
<b>CRAFTING THE LEGISLATION</b>	<b>GUIDE 3.1</b> Make key policy decisions	<b>GUIDE 3.2</b> Draft the law	
<b>PROCEDURAL STEPS FOR A SECURE POLICY</b>	<b>GUIDE 4.1</b> Coordinate across government	<b>GUIDE 4.2</b> Obtain legal advice	<b>GUIDE 4.3</b> WTO notification

Further **TOOLS AND RESOURCES** can be found at [www.tobaccofreekids.org/plainpackagingtoolkit](http://www.tobaccofreekids.org/plainpackagingtoolkit)  
These include the following:

### Policy tools

- A. Policy briefings
  - What is Plain Packaging and why is it needed?
  - Countering industry arguments
  - Is plain packaging legal?
- B. Regulatory impact analysis template
- C. Consultation document template

### Legislation drafting tools

- D. Drafting the legislation in detail
- E. Comparison table of existing plain packaging laws
- F. Template draft model law

### Evidence

- G. Research evidence
- H. Australia's post-implementation evidence
- I. Tobacco product branding
- J. Opposing Arguments and how to counter them

### Legal issues and international developments

- K. Legal issues and case summaries
- L. International developments

# Set policy objectives

## 1. Establish the aims and objectives

It is critical to establish clear aims and objectives for an effective policy development process of a tobacco control policy. Many domestic and international courts and tribunals apply legal tests to establish whether or not a measure is proportionate or justified in relation to its intended objectives. Where a government fails to formally establish those objectives, a legal challenge may be more difficult to defend.

Plain packaging serves multiple objectives within the broader context of tobacco demand reduction strategies. The broad objectives for plain packaging are to improve public health by:

- discouraging people from taking up smoking, or using tobacco products; and
- encouraging people to give up smoking, and to stop using tobacco products; and
- discouraging people who have given up smoking, or who have stopped using tobacco products, from relapsing.

### The objectives of plain packaging are achieved by

- **reducing** the appeal and attractiveness of tobacco products to consumers,
- **increasing** the noticeability and effectiveness of health warnings on the packaging of tobacco products,
- **reducing** the ability of the packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products,

#### **AND**

- **eliminating** the ability of tobacco packaging to advertise and promote tobacco consumption,
- **having a positive** effect on smoking-related attitudes, beliefs, intentions and behaviors or assisting with the denormalization of tobacco products.

This list is drawn from the objectives set out in the WHO FCTC guidelines for Articles 11 and 13; Australia's Tobacco Plain Packaging Act 2011; Ireland's Public Health (Standardised Packaging of Tobacco) Act 2014; and the public consultation documents from the UK.

Governments proposing plain packaging should consider which objectives are relevant for them, but it is recommended that governments take a broad inclusive approach to the aims they wish to achieve and the means by which they should be achieved through the implementation of plain packaging.

These objectives are evidence-based and capable of being monitored and evaluated.

## 2. Set out the objectives in official documents

It is important that a government sets out the aims for the policy clearly in official, publicly available documents or publications. For example, this can be in the preamble or explanatory notes of the legislation itself (as Australia and Ireland did); in public consultation documents (as the UK and Canada have done); or in a Regulatory Impact Assessment (such as the one published by New Zealand). Links to these documents are given below.

## 3. Establish that plain packaging is in furtherance of the WHO FCTC

It is also important that a government formally recognizes that plain packaging is a policy recommended in the implementing guidelines for Articles 11 and 13 of the WHO FCTC. The fact that a country is adopting a policy in furtherance of its international legal obligations can be a significant factor for courts or tribunals asked to consider that policy. Giving effect to obligations in the WHO FCTC is stated as an objective of both Australia and New Zealand's legislation, and is detailed in the UK consultation document.

## 4. Plain packaging objectives work as part of a wider tobacco control policy

It is critical for policy and legal reasons that plain packaging is part of a wider tobacco control strategy that includes:

- A comprehensive tobacco advertising, promotion and sponsorship (TAPS) ban, including a ban on point of sale advertising; and
- Effective (large) graphic health warnings in line with WHO FCTC recommendations.

The reasons for this are:

### Policy issues

- It makes little sense to remove the advertising and promotional elements on tobacco packets but still allow advertising or promotion of tobacco products in other ways.
- One of the key aims of plain packaging is that it increases the noticeability and effectiveness of the graphic health warnings. Therefore, a country should either have in place, or be introducing concurrently with plain packaging, health warnings that are in line with the recommendations of WHO FCTC Article 11 guidelines – at least 50% front and back with graphic pictures.
- In Australia and in the EU countries that have introduced plain packaging, health warnings increased in size at the same time plain packaging was introduced.

## Legal issues

- International legal challenges, as well as many national legal jurisdictions, often include a test of whether it is necessary or justified to introduce a measure that has the potential to restrict trade in goods or commercial activity. This type of legal argument includes consideration of whether there are less restrictive alternative measures that could also meet the policy objectives. If a comprehensive TAPS ban is not in place or being introduced, a court could consider that a TAPS ban may be a less restrictive option for achieving the policy objectives than introducing plain packaging.
- Tobacco companies could argue that the efficacy of the policy would be undermined by other forms of advertising.
- There is significant research evidence that shows plain packaging is effective at increasing the noticeability of health warnings. But without regulations requiring effective health warnings that are in accordance with WHO FCTC recommendations, it would be difficult to use that to support the defense of plain packaging in a legal challenge.

### Key resources

- WHO publication Plain Packaging of Tobacco Products – Evidence, Design and Implementation:  
[www.who.int/tobacco/publications/industry/plain-packaging-tobacco-products/en/](http://www.who.int/tobacco/publications/industry/plain-packaging-tobacco-products/en/)
- Australian legislation that sets out the objectives of the law:  
[www.comlaw.gov.au/Details/C2013C00190](http://www.comlaw.gov.au/Details/C2013C00190)
- The UK's 2012 consultation that describes the aims and objectives of the proposed policy:  
[www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/170568/dh\\_133575.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170568/dh_133575.pdf)
- New Zealand's Regulatory Impact Assessment from 2012 that sets out the objectives for the proposal:  
<http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/plain-packaging-tobacco-products-regulatory-impact-statement-consultation-phase>

# Establish document record

It is important that a comprehensive document development and retention policy, in line with government practice, is in place so that the policy-development processes can be fully demonstrated if the measure is legally challenged.

**Each step of the policy development and drafting process should be recorded and documented. This means keeping a careful record of:**

1. Key Ministry of Health meetings, where the policy is discussed or decisions are taken on aspects of the policy;
2. The reasons for policy decisions taken about any aspect of the policy (see for instance the key initial policy development decisions outlined in **Guide 3.1**);
3. Communications or meetings with other government departments (see **Guide 4.1**);
4. Communications or meetings with external public health bodies, experts, or civil society organizations with documentation of attendees;
5. Interactions with industry or industry representatives outside of public consultations with documentation of attendees\*;
6. All the evidence that has been considered as part of the evidence review, when it was considered, and by whom;
7. Any external written submissions received from organizations or industry, whether as part of the a consultation or otherwise; and
8. Both internal and external correspondence including emails relating to the policy.

*\*Meetings with the tobacco industry or industry representatives should only take place and be conducted in line with the WHO FCTC Article 5.3 and the FCTC Article 5.3 guidelines so as to protect tobacco-control policies from commercial and other vested interests.<sup>1</sup>*

Internal government discussions between different departments are an important part of the policy-development process, so demonstrating that they took place can show proper due process. Records of meetings should include agendas and minutes. A regulatory impact analysis (see **Guide 2.2**) can act as a useful part of the record of policy development.

**LEGAL CHALLENGES** to a tobacco-control policy, in both national courts and international tribunals, can often include a claim that due process has not been adhered to or that effective consideration of all the relevant evidence and issues was not had before a final decision was made. It is important that a government can demonstrate the steps it has taken.

**IN THE INTERNATIONAL INVESTMENT ARBITRATION** claim brought by Philip Morris International against two of Uruguay's tobacco-control laws,<sup>2</sup> the arbitrator appointed by Philip Morris, Gary Born, gave a dissenting opinion on certain issues, where he disagreed with the outcome of the tribunal award (see **Guide 4.2**). Gary Born's dissenting opinion was that Uruguay's Single Presentation Requirement (which only permits each brand to have a single variant) was adopted without due process or proper consideration of the evidence and was therefore arbitrary and in breach of Uruguay's Bilateral Investment Treaty with Switzerland:

“In my view, **the record does not support** a conclusion that the single presentation requirement . . . was preceded by any meaningful internal study, discussions or deliberations at the Ministry of Public Health, or by other Uruguayan authorities . . .

It is significant that the evidentiary record contains no minutes, agendas, protocols, preparatory materials, memoranda, letters, emails or other documentary evidence suggesting that any meetings, conference calls or other interactions concerning the single presentation requirement ever occurred.” [¶108 –109] (emphasis added)

The position of the Uruguayan Government was that the policy was properly considered before being adopted, and the majority of the tribunal agreed, but the fact that one of the three arbitrators was prepared to find a breach of the Bilateral Investment Treaty that could have led to huge damages being awarded is a reminder to governments of the need to follow due process and **keep a record of that process**.

## Freedom of information requests

In addition, governments need to be aware that tobacco companies have lodged a significant number of freedom-of-information requests in countries considering plain packaging. These requests can be designed to tie up government resources and to be “fishing” exercises in preparation for legal challenges. Governments should consider strategies to prepare themselves to respond to such requests by developing an approach to document management from the outset.

1. The International Union Against Tuberculosis and Lung Disease has produced a Toolkit with guides on how to implement the FCTC Article 5.3 and prevent tobacco industry interference: [www.theunion.org/what-we-do/publications/english/pubtc\\_Guides-set.pdf](http://www.theunion.org/what-we-do/publications/english/pubtc_Guides-set.pdf).
2. Philip Morris Brand Sàrl (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v. Oriental Republic of Uruguay (ICSID Case No. ARB/10/7). The award and dissenting opinion are available from: [www.italaw.com/cases/460](http://www.italaw.com/cases/460).

# Prepare for tobacco industry interference

Details and examples of the media campaigns and interference tactics used by the tobacco industry are given on the **OPPOSING ARGUMENTS (and how to counter them)** webpage of the online toolkit. These demonstrate how the industry arguments are flawed, often lacking any rational basis, and sets out the counter arguments that can be used to combat the industry campaigns. That section highlights the industry's use of experts that lack independence and whose evidence does not meet basic standards, as well as the fact that the industry has never disclosed any of its own consumer research into the likely impacts of plain packaging.

In addition, the **POLICY BRIEFS** include a short paper that sets out the main counter arguments to each of the key arguments used by the industry, which can be given to politicians or the media.

## 1. The tobacco industry coordinates aggressive and well-funded campaigns

These campaigns oppose plain packaging in every country that has proposed or considered the policy. These campaigns go much further than the typical opposition to tobacco-control measures. With plain packaging, the industry campaigns have used:

- full-page advertisements in national newspapers
- billboard campaigns
- dedicated websites set up to promulgate the tobacco industry's views
- social media
- short films
- strong political lobbying at all levels
- street-level campaigning and surveys
- heavy use of proxy organizations or front groups , and
- in Sweden, JTI even set up a whole fake supermarket at a political convention, where all the goods (coffee, bread, milk, etc.) were in plain packaging

These campaigns have the potential to be effective in swaying public opinion and some parts of government. **The reason the tobacco industry is so vehemently opposed to plain packaging is because the policy works.**



## 2. The tobacco industry's flawed arguments

The tobacco industry's arguments opposing plain packaging are now well established and vary little from one country to another, although the focus can be different. For instance, in France, the tobacco retailers (backed by the industry) generated much of the opposition with the argument that it would lead to job losses. Whereas in Slovenia, the argument that it would increase illicit trade and fund criminal gangs was used more. But the industry has no hesitation in recycling arguments in multiple jurisdictions, even after they have been wholly discredited elsewhere.

### Commonly used tobacco industry arguments:

- **There is no evidence** that plain packaging will work
- **It will increase the illicit trade** in tobacco – because plain packs are easier to counterfeit
- **It is the start of a slippery slope** or domino effect – leading to plain packaging of other products
- **It will breach intellectual property laws** – leading to huge compensation claims
- **It will lead to price reductions** – thereby increasing consumption
- **It will increase costs for small retail businesses** – by increasing consumer transaction times
- **It will cause job losses** in domestic tobacco manufacturing industries

These arguments are largely made by mere assertion, with no evidence to back them up, and can be easily refuted by using available evidence and judgments from decided legal cases. See [the POLICY BRIEFS: Industry Arguments](#) for a series of short counter arguments to the industry's claims.

To date, no empirical studies conducted by, or on behalf of, tobacco companies have been published. The tobacco companies have refused to disclose any of their own consumer research or behavioral studies into the impacts of plain packaging.

Where the tobacco companies have sought to use experts to support their arguments, for instance, in the High Court legal challenge to the UK plain packaging regulations, the Court strongly criticized the experts describing their evidence as *“not peer reviewed,” “frequently unverifiable,”* and failing to *“accord with internationally recognized best practice.”*

## 3. What can be done to prepare?

An important aspect of progressing any tobacco-control policy and in particular plain packaging, is for governments and civil society to prepare a strategy to both pre-empt and respond to tobacco-industry interference:

- **Anticipate the likely arguments** by the tobacco industry and prepare the counter arguments at an early stage.
- **Directly refute the industry arguments** before the industry has a chance to promulgate them.
- **Use pre-prepared briefing papers** covering key issues for the media, other government departments, and interested members of parliament (*See the POLICY BRIEFS in the Tools and Resources*).
- **Generate positive media campaigns** that include information about the global movement towards adopting the policy and the positive results from Australia.

- **Engage early with other government departments** (see **GUIDE 4.1: Coordinate across government**).
- **Seek endorsements** — the use of local and international experts, including prominent doctors, to speak to the media and other government departments about tobacco’s harms and the real facts about plain packaging is highly advisable.
- **Launch a civil society media campaign** supporting the policy, setting out the facts and shining a light on the industry’s tactics.

## 4. Civil society organizations, medical associations, and public health bodies

These bodies can play an important role in countering the arguments put forward by the tobacco industry by organizing positive publicity campaigns to promote plain packaging in a way that it may not be possible for government to do while it is going through the policy development and decision-making process. Medical and public health bodies can make their views known about the evidence and provide **credible** experts to speak with the media. Organizations can pre-empt the tobacco industry opposition by engaging with the media ahead of any government announcement to provide the real facts in anticipation of the false opposing arguments the industry and its front groups will put forward.

Cancer Research UK led the campaign to promote plain packaging in the UK. A useful insight into civil society action can be found on their blog post, which provides thirteen steps that shaped the successful campaign including sending flashy cigarette packs to MPs and attending political party conferences.<sup>2</sup>

## 5. Use the evidence to refute industry arguments

The post-implementation evidence from Australia as to what actually happened after implementation is extremely useful in combatting many of the false tobacco industry claims about the negative impacts of the plain packaging.

Industry claims before implementation	Australia’s post implementation evidence
<b>Retailer confusion and loss of trade</b>	Quick adaptation by retailers – consumer transaction times actually reduced after implementation, and there was no decline in use of small retailers.
<b>Explosion in use of illicit tobacco</b>	No detectable change in major indicators pre- versus post-implementation. No counterfeit plain packs discovered. Reduced use of unpackaged tobacco.
<b>Reduction in tobacco prices</b>	Tobacco price increase across all sectors.
<b>Increase in consumption</b>	Continuing decline in overall consumption and significant reductions in smoking prevalence rates.

Key facts about the research evidence and studies that demonstrate these post-implementation results can be found on the Cancer Council Victoria website:

<http://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=industryopposition>

## 6. Highlight contradictory statements

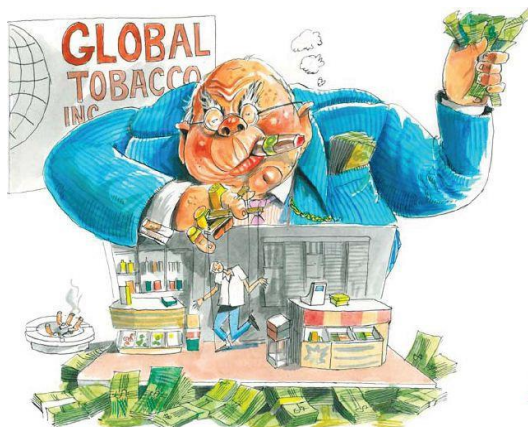
The tobacco companies regularly say different things in different contexts. Highlighting this can be an effective means of countering their arguments. For instance, in the industry challenge to the UK regulations, the tobacco companies sought to argue that branding on packaging is not the same as advertising and has a different function. However, in the challenge before the High Court of Australia, the tobacco companies made a direct comparison between the space on the packets for branding and advertising billboards (*see the **CASE SUMMARIES** webpage of the online toolkit*).

Another example of this relates to illicit trade. Philip Morris International claimed that branded packaging is difficult or impossible to counterfeit when arguing against plain packaging, but, at the same time, confirmed that branded packaging is easy to counterfeit in a 2012 brochure on Codentify (a track-and-trace-system developed by PMI). A report by into illicit tobacco in Australia commissioned by Philip Morris Limited confirms that no counterfeit plain packs have been identified since implementation. The KPMG report is the only statistical evidence the industry uses to support its contention that plain packaging increases illicit trade, but the methodology was so flawed that the industry did not use it (or any other evidence) to support that argument in its legal challenge to UK plain packaging regulations.

The two faces of PM I on illicit trade and plain packaging	
“Tobacco manufacturers go to great lengths to design overt authentication features that are difficult, if not impossible, for counterfeiters to imitate.” <sup>3</sup> [2012]	“[Cigarette packs] are easily counterfeited, despite the inclusion of innovative holograms, special inks and elaborate design details. Evidence shows that counterfeiters can make copies of even the most sophisticated paper stamps in three weeks.” <sup>4</sup> [2012]
“Plain packs will be easier to counterfeit.” <sup>5</sup> [2012]	“. . . none of the counterfeit packs collected as part of the Empty Pack Survey [in Australia] were in plain packaging.” <sup>6</sup> [2015]
“KPMG has concluded that illicit tobacco in Australia has reached record levels. . . KPMG’s methodology is widely accepted.” <sup>7</sup> [2014]	“The Tobacco Claimants submit that standardised packaging would increase illicit trades. But they have conducted no material analysis or evidence (that they are prepared to place before the Court) of the impact on illicit trades. . .” <sup>8</sup> [2016]

## 7. Know the industry tactics

**FRONT GROUPS.** The tobacco industry regularly establishes and finances front groups or co-opts third-party organizations, such as think tanks or libertarian groups, often via public relations agencies, which are then used to give the impression of broad support for the opposing arguments.<sup>9</sup> For instance, when plain packaging was proposed in Australia, a front group was established, which claimed only to represent the retail industry. However, internal documentation about this group and other industry counter measures were leaked to the media, revealing that the group was receiving support from several tobacco companies.<sup>10</sup>



## The campaign against plain cigarette packs. Guess who's pulling the strings.

The so-called Alliance of Australian Retailers was created last month so global tobacco companies can pump a reported \$5m into an ad campaign opposing Australia's introduction of plain cigarette packaging. Both Coles and Woolworths hurriedly distanced themselves from it. Even the spokesperson for the campaign changed in the last week.

The ads say plain packaging won't work. But if it won't work, why spend millions hoodwinking the Australian public with a sham organisation opposing it? Plain packaging will stop children taking up the habit. It will reduce smoking and save Australian lives. And Big Tobacco knows it. Next time you see ads with long-faced retailers saying we shouldn't introduce it, remember who's pulling the strings.

A public health message supported by



Authorised by Professor Mike Double Public Health Association of Australia 20 Major Closes, Deakin ACT 2600

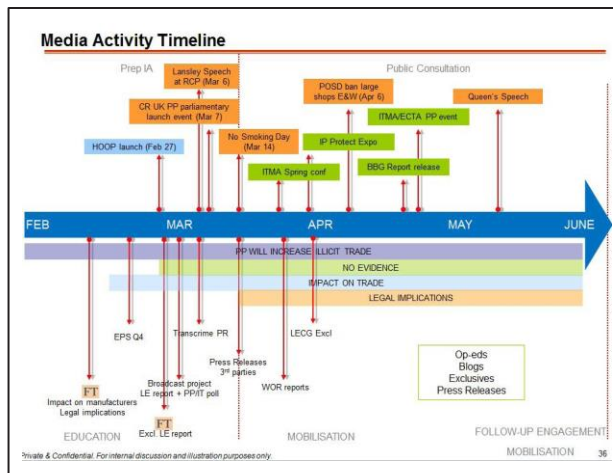
In the UK, a university study showed three-quarters of the organizations outside the industry had direct financial links to one or more of the big four tobacco companies, and these were responsible for 60% of the anti-plain packaging campaigning identified. The study, found that organizations that actively opposed plain packaging (including campaigners and business groups) rarely reported any relationship with tobacco companies transparently.<sup>11</sup>

**SOPHISTICATED AND WELL PLANNED CAMPAIGNS.** In 2013, leaked internal tobacco industry documents, including power points, revealed the inner-workings of Philip Morris International's anti-plain packaging campaign in the UK during the previous year. The two examples of slides shown below demonstrate PMI's key media messages and the sophisticated and detailed timeline planning of which arguments to use and when. Other parts of the documents demonstrate the use of third parties to promulgate the messages.<sup>12</sup>

### Leaked: PMI's detailed strategy to oppose plain packaging in the UK

**Media**

- **Overall objective:**
  - Ensure that PP is not adopted in the UK
- **Communications objective:**
  - Raise awareness with decision-makers and general public about key concerns related to plain packaging – *no evidence; impact on trade; legal issues and illicit trade*
  - Highlight long-term and on-going legal case in Australia (2-3yrs)
- **Strategy:**
  - Illicit trade → PP will make problem worse → PP consequences
  - Broad 3<sup>rd</sup> party media engagement
  - High profile opinion pieces



1. The tobacco tactics website detailing the use of the media by the tobacco industry opposing plain packaging in the UK is available from: [www.tobaccotactics.org/index.php/Plain\\_Packaging\\_Opposition\\_in\\_the\\_UK](http://www.tobaccotactics.org/index.php/Plain_Packaging_Opposition_in_the_UK); see also Simon Chapman, "Removing the Emperor's clothes," which includes a section that describes the campaigns in Australia: [http://ses.library.usyd.edu.au/bitstream/2123/12257/7/9781743324295\\_Chapman\\_RemovingtheEmperorsClothes\\_FT.pdf](http://ses.library.usyd.edu.au/bitstream/2123/12257/7/9781743324295_Chapman_RemovingtheEmperorsClothes_FT.pdf).
2. See <http://scienceblog.cancerresearchuk.org/2015/03/17/13-things-that-shaped-our-campaign-for-standardised-cigarette-packaging/>.
3. Philip Morris International response to the 2012 UK consultation on standardised packaging of tobacco products: Available from: <https://www.tobaccofreekids.org/assets/microsites/plainpackaging/PMI-UK-Submission-and-All-Annexes-combined-2012-reduced.pdf> , p.21.
4. Philip Morris International, Codentify, Brochure, 2012. Available from: [https://www.tobaccofreekids.org/assets/microsites/plainpackaging/Codentify\\_E\\_Brochure\\_English.pdf](https://www.tobaccofreekids.org/assets/microsites/plainpackaging/Codentify_E_Brochure_English.pdf)
5. See note 2.
6. KPMG Illicit Tobacco in Australia Full Year Report 2015, commissioned by Philip Morris, British American Tobacco, and Imperial Tobacco, et al., p.44.
7. Philip Morris Limited Response to the consultation on "standardised packaging", August 7, 2014.
8. Judgment in tobacco industry challenge to UK regulations R (British American Tobacco & Ors) v. Secretary of State for Health [2016] EWHC 1169 (Admin) at paragraph 669.
9. WHO (2008), Tobacco industry interference with tobacco control is available from: [http://apps.who.int/iris/bitstream/10665/83128/1/9789241597340\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/83128/1/9789241597340_eng.pdf) , p. 5.
10. See [www.tobaccotactics.org/index.php/Main\\_Page](http://www.tobaccotactics.org/index.php/Main_Page).
11. See <http://medicalxpress.com/news/2016-10-lid-big-tobacco-campaigning-methods.html>.
12. See [http://tobaccotactics.org/index.php/PMI%E2%80%99s\\_Anti-PP\\_Media\\_Campaign](http://tobaccotactics.org/index.php/PMI%E2%80%99s_Anti-PP_Media_Campaign).

# Evidence review

There are considerable volumes of evidence, including research studies from a number of countries and statistical evidence from Australia, which demonstrate plain packaging is a policy that will contribute to reducing tobacco use. Standard texts on marketing and branding also show how effective packaging can be at attracting consumers, and this is no different for tobacco products.

In order to ensure robust policy development, governments should consider the full evidence base relating to plain packaging, including all the arguments against the policy put forward by the industry. Good evidence leads to good policy, but, in case of legal challenge, a *careful record* of what evidence has been considered, when and by whom, can also be crucial in demonstrating proper due process.

**The review of the evidence should include:**

## 1. Supporting research evidence

*(full details on the [RESEARCH EVIDENCE](#) webpage of the online Toolkit)*

Over the course of 20–30 years, there have been many peer-reviewed scientific research studies looking at the likely impact plain packaging of tobacco would have on smoking behaviors and attitudes and how that would impact on smoking rates. Research has been conducted in ten different countries using a range of methodologies, and each study taken in isolation only provides part of the picture.

Countries that have already adopted plain packaging have commissioned independent reviews of the research to ensure that there is a clear, complete, and balanced picture of what the overall evidence is on the impact plain packaging will have. By the time of the Hammond Review in 2014, a total of 69 original empirical research studies were reviewed (as of October 2016 that number had increased to over 75 relevant studies). The five reviews show that the evidence on plain packaging is notable for its breadth and diversity of methods but also for its consistency in the results. The evidence reviews are:

- i. Cancer Council Victoria (Australia 2011)<sup>1</sup>
- ii. The Stirling Review (United Kingdom 2012 and updated 2013)<sup>2</sup>
- iii. The Chantler Review (United Kingdom 2014)<sup>3</sup>
- iv. The Hammond Review (Ireland 2014)<sup>4</sup>
- v. The Cochrane Review (2017)<sup>5</sup>

All these reviews reach the same conclusion: that there is strong and highly consistent evidence to support the argument that plain packaging would contribute to its objectives (as set out in [Guide 1.1](#)).

The Chantler Review notably concluded that “[all the evidence] points in a single direction, and I am not aware of any convincing evidence pointing the other way.”

## 2. Post-implementation evidence from Australia and elsewhere

(full details on the [AUSTRALIAN POST-IMPLEMENTATION EVIDENCE](#) webpage of the online Toolkit)

The official Post-Implementation Review (PIR) was published by the Australian government in February 2016<sup>6</sup>. The review concludes that:

“While the full effect of the tobacco plain packaging measure is expected to be realised over time, the *evidence examined in this PIR suggests that the measure is achieving its aims*. This evidence shows that tobacco plain packaging is having a positive impact on its specific mechanisms as envisaged in the TPP Act. *All of the major datasets examined also showed on-going drops in national smoking prevalence in Australia.*”

Plain packaging contributed a statistically significant decline in smoking prevalence of 0.55 percentage points over a 34-month post-implementation period, one quarter of the total decline in average prevalence rates observed.<sup>7</sup>

**Official statistics on smoking rates** and tobacco consumption in Australia are published on the Department of Health’s website.<sup>8</sup> There are a range of independent surveys conducted by different research organizations and using different methods and cohorts. Each new survey has shown a continued fall in rates since implementation of plain packaging in 2012.

The *British Medical Journal* edition of **Tobacco Control** in April 2015 on the implementation and evaluation of the Australian plain packaging policy included eighteen research papers<sup>12</sup> dealing with various aspects of policy impact and implementation. These demonstrated that plain packs were impacting positively on the aims and objectives of the policy.

The studies also showed that, contrary to the tobacco-industry predictions, there was no evidence that plain packaging led to lower prices for tobacco products or to an increase in the use of illicit tobacco products.

One quarter of the 2.2 percentage point drop in prevalence is attributed to plain packaging. That’s equivalent to **118,000 fewer people smoking in Australia in just three years** as a direct result of plain packaging.

### Australia’s declining smoking rates

- From 2014 to 2015, 14.7% of adults aged 18 years and over smoked daily (approximately 2.6 million smokers), decreasing from 16.1% in 2011–2012<sup>9</sup>
- From 2012 to 2015, there was an overall 20% decline in the proportion of secondary students and young adults (aged 18–24) smoking at least 100 cigarettes in their lifetime<sup>10</sup>
- In 2014, 5% of 12–17 year olds were current smokers, down from 7% in both 2011 and 2008<sup>11</sup>



### 3. Evidence about branding on packaging and its influence on smoking

(full details on this topic are set out on the [TOBACCO BRANDING](#) webpage of the online Toolkit)

It is useful to consider tobacco packaging within the broader context of branding, marketing, and packaging of products more generally.

**Marketing theory** demonstrates that packaging has a number of functions, including assisting consumers to identify and distinguish brands, but that it is also used to promote the product as an important component of overall marketing strategy. Packaging can heighten a product's appeal and create positive impressions and emotional connections to help "drive the sale."

**Packaging of tobacco products** has been shown to be more important as a promotional tool than for other products. Firstly, in many countries where there are TAPS bans, it is the last remaining means of advertising a brand. Secondly, tobacco product packs are a "badge product," because users regularly openly display their packs in public<sup>12</sup>.

**Internal tobacco industry documents show the importance of packaging in promoting tobacco products.** There have been a number of studies looking into internal industry documents that have been leaked or released in US litigation settlements. **The Hammond Review** in particular includes the results of this research, which demonstrates how the industry places significant importance on the role of packaging in promoting and advertising its product.

"...the pack provides a direct link between consumers and manufacturers, and is particularly important for consumer products such as cigarettes, which have a high degree of social visibility. Unlike many other consumer products, cigarette packages are displayed each time the product is used and are often left in public view between uses. As a result, both smokers and non-smokers report high levels of exposure to tobacco packaging..."

Tobacco Labelling & Packaging Toolkit: A guide to FCTC Article 11.

David Hammond, 2009

### 4. Conducting a market survey of the tobacco products and packaging

**A survey of tobacco products** (and their packaging) available on the market in a country can assist in the design of the plain packaging policy. It also acts as a demonstration of what branding exists on the market, which can assist in showing why the policy is necessary. The issues that the survey should address include: What is the most common form of packet for each type of product? Are there any particularly novel forms of packaging? Is certain packaging clearly aimed at a certain sections of the community? Are there brand families that continue to mislead consumers as to the relative harms of each brand variant (for instance, are there 'gold' and 'silver' variants of a particular brand)?



**A comprehensive sample of the tobacco product packaging** available in a country should be kept as it can be very useful for demonstrations and as evidence in case of a legal challenge. One of the most powerful ways of demonstrating the need for plain packaging to people unfamiliar with smoking or tobacco control is to show examples of attractive or health-reassurance packs that are available on the domestic market.



## 5. Country specific statistics on smoking prevalence and tobacco consumption

In order to establish that it is necessary and justified to introduce plain packaging, the aims and objectives should be set within the context of a country's public health agenda, which will include consideration of the smoking prevalence and tobacco-consumption rates, and whether these have been falling, rising, or stagnating.

## 6. Arguments opposing plain packaging

(full details are available on the **OPPOSING ARGUMENTS** webpage of the online Toolkit)

It is important for a full and complete policy-development process to properly consider the views and arguments of the tobacco industry, proxy organizations or other interested stakeholders. This should include the tobacco companies' analysis of the evidence and their claims about the possible wider impacts in particular the potential or alleged links to down trading and illicit trade. This consideration can lead to better a policy development, and, importantly, it protects a government from accusations of an unfair process.

This process should take into account the vested interests of the tobacco companies' views and also where legitimate criticisms of their arguments have been made. For instance, none of the expert analyses or studies relied upon by the tobacco industry to support their claims have been subjected to peer-review process, but have been the subject of both academic<sup>13</sup> and judicial criticism. The judge in the High Court legal challenge to the UK's plain packaging laws was highly critical of the evidence put forward by the tobacco companies and said that:

*"On the basis of my own review of the methodologies adopted by the [tobacco companies'] experts ... I conclude that that body of expert evidence does not accord with internationally recognized best practice."*<sup>14</sup>

As the **OPPOSING ARGUMENTS** pages of the online Toolkit show, the tobacco-industry arguments opposing plain packaging are almost wholly unfounded, and there are a number of research studies that have demonstrated this<sup>15</sup>; but a fair process requires proper consideration of all views.



## 7. Local evidence and research

In addition to the solid global evidence base supporting the adoption of plain packaging, it is a policy recommended by the implementation guidelines to the evidence based WHO FCTC. This provides effective grounding for a government decision to proceed with the policy without the need to commission new local research or studies into its likely impact in a particular country. From a legal perspective, this position has been confirmed in the ruling by the international investment tribunal in *PMI v. Uruguay*.<sup>16</sup>

However, governments should not be dissuaded from commissioning or conducting studies or research into the policy in their country. Additional evidence will be useful for any government seeking to defend the policy against tobacco-industry attacks. In addition, there may be circumstances particular to a country that would warrant new research. For instance, in Uruguay, there is a brand of cigarettes that has packaging using a color very similar to the green/brown color used for tobacco-product plain packaging in Australia, the UK, France, Ireland, and Hungary. Positive associations may have already developed in relation to that color on the part of some consumers. Some country-specific research into the most appropriate color could be useful in such circumstances.



Add pictures of packaging from your country to the Policy Briefs available to download from the online Toolkit.

1. See <http://www.cancervic.org.au/plainfacts/plainfacts-evidence>.
2. See <http://www.stir.ac.uk/media/schools/management/documents/Plain%20Packaging%20Studies%20Update.pdf>.
3. See <http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF>.
4. See <http://health.gov.ie/blog/publications/standardised-packaging-d-hammond/>.
5. See <http://www.cochrane.org/news/new-evidence-finds-standardized-cigarette-packaging-may-reduce-number-people-who-smoke>
6. See <https://ris.govspace.gov.au/2016/02/26/tobacco-plain-packaging/>.
7. 2014 population of Australia was 23,490,700; 81.2% (or 19,074,448) were over 14; 0.55% drop in prevalence of a 19,074,448 cohort of over 14s is 104,909, rounded up to 105,000. Population figures from Australian Bureau of Statistics. Adjusting for population increase gives a figure of 118,000. See also: <http://www.ft.com/cms/s/0/6248cfee-11e3-11e6-91da-096d89bd2173.html#axzz48RqRYOE>.
8. See <http://www.health.gov.au/internet/main/publishing.nsf/content/tobacco-kff>.
9. Australian Bureau of Statistics, National Health Survey: First Results 2014–15.
10. Australian Institute of Health and Welfare. Tobacco indicators: measuring midpoint progress—reporting under the National Tobacco Strategy 2012–2018. Available from: <http://www.aihw.gov.au/publication-detail/?id=60129557116>.
11. Cancer Council Victoria, Australian secondary school students' use of tobacco in 2014.
12. See [http://tobaccocontrol.bmj.com/content/24/Suppl\\_2?utm\\_source=World%20Congress%20on%20Tobacco%20and%20Health&utm\\_medium=E-mail&utm\\_campaign=plain%20packaging](http://tobaccocontrol.bmj.com/content/24/Suppl_2?utm_source=World%20Congress%20on%20Tobacco%20and%20Health&utm_medium=E-mail&utm_campaign=plain%20packaging).
13. A. A. Lavery, et al. "Use and abuse of statistics in tobacco industry-funded research on standardised packaging." *Tobacco Control* 2015;24:422–424.
14. R (British American Tobacco & Ors) v. Secretary of State for Health [2016] EWHC 1169 (Admin), paragraph 374.
15. For instance, this peer-reviewed study that looks at the tobacco industry arguments used in New Zealand: <http://tobaccocontrol.bmj.com/content/early/2016/09/29/tobaccocontrol-2016-053146.abstract?paperoc>.
16. A fact sheet summary of the case is available from: [http://www.tobaccofreekids.org/content/press\\_office/2016/2016\\_07\\_12\\_uruguay\\_factsheet.pdf](http://www.tobaccofreekids.org/content/press_office/2016/2016_07_12_uruguay_factsheet.pdf).

# Regulatory impact analysis

## 1. What is it and is it needed?

The purpose of a regulatory impact analysis is to provide a detailed and systematic appraisal of the potential positive and negative impacts of a new law or regulation in order to assess whether or not it is likely to achieve the desired objectives and what the potential unintended consequences may be.

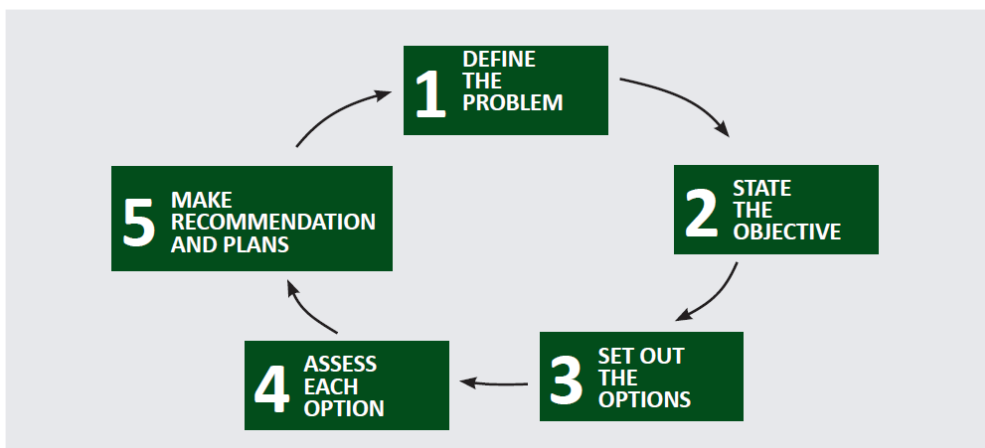
This analysis may not always be a necessary requirement for every country and may be unusual for some governments for a public health measure. However, an assessment of the predicted economic, social, and public health impacts can assist with the arguments for proceeding with plain packaging that need to be made with politicians and the public.

In both domestic and international courts, the tobacco industry regularly alleges that tobacco-control laws, especially plain packaging, are arbitrary, not supported by evidence, and not adopted with proper due process. A regulatory impact analysis can act as an internal record of the government's effective policy development and can help to protect the policy against legal challenges.

In some countries, for instance the UK, an impact assessment is a government requirement for any policy that has an impact on business with specified procedures for how one must be produced. In other countries, such as Kenya, there is specific legislation that stipulates when a regulatory impact assessment must be carried out and what it must contain.

There is a draft template for a regulatory impact assessment that can be downloaded from the online Toolkit and which can be adapted for a particular country.

## 2. How to approach a regulatory impact analysis



The graphic above shows the process for undertaking and recording a regulatory impact assessment. It will incorporate the evidence review of the policy (see **Guide 2.1**) when the options are assessed at stage 4. An assessment of the options could also include undertaking stakeholder input or a public consultation (see **Guide 2.3**). Ultimately it will lead to a recommendation of a preferred option for the government decision makers.

### 3. Examples of regulatory impact assessments for plain packaging of tobacco policies

**Ireland produced a regulatory impact assessment** that looked at the costs and benefits of the policy. It concluded that:

“The implementation of this measure together with the other measures outlined in Tobacco Free Ireland would have the benefit of reducing smoking prevalence in Ireland and thereby reducing deaths associated with smoking related diseases. This in turn would reduce the costs to the state related to smoking related diseases. A very conservative estimate of the costs of illness attributable to smoking was in the region of €664 million in 2009. The cost of premature mortality in Ireland due to smoking in the same year was estimated at €3.5 billion.”

<http://health.gov.ie/wp-content/uploads/2013/12/Standardised-Packaging-RIA-July-2014-FINAL.doc>

**France did not produce an impact assessment**, and this omission was used as an argument to challenge its legality under the French constitution, although the argument was dismissed.

**New Zealand produced a similar impact assessment** to Ireland’s. It concluded that:

“The status quo does not address the continuing ability of the tobacco industry to use packaging in a way that allows advertising and promotion of tobacco products, despite the ban on tobacco advertising (and other controls). Similarly, though to increase health warning coverage on tobacco packets would reduce the amount of space left on the packet for industry promotions, it does not fully address this gap... Accordingly, this regulatory impact statement recommends that option 3, Regulatory change to require plain packaging of tobacco products, be agreed in principle...”

<http://www.health.govt.nz/system/files/documents/pages/regulatory-impact-statement-plain-packaging-tobacco-products.pdf>

**The UK produced an economic impact assessment**, which fully monetized the impact of the policy on the UK economy as a whole and concluded that it would lead to a potential **£30 billion benefit over ten years compared to a £5 billion cost** (most of the costs were loss of tax revenues from the reduction in tobacco consumption). The sort of detailed calculations undertaken by the UK were required by internal government rules and can be attacked by the tobacco industry as they rely on assumptions to make future predictions about economic impacts. Even where one is produced, an impact assessment should not be relied on as the principle reason for proceeding, but rather one element of the decision-making process. In legal challenges in the UK, the tobacco industry focused on what it said were flaws in the economic impact assessment (although ultimately the court did not agree with the tobacco companies).

[http://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/403493/Impact\\_assessment.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403493/Impact_assessment.pdf)

# Stakeholder input / public consultation

A Template Consultation Document that can be adapted for a particular country is included in the online Toolkit.

## 1. What is it and is it needed?

For novel or complimentary tobacco-control policies, allowing all potential stakeholders, including the tobacco industry, the opportunity to make submissions or comments means the policy is developed having taken all issues and views into account. The advantages of a consultation are that:

- government may receive useful comments from public health organizations and experts;
- tobacco companies may submit comments in a transparent fashion rather than behind closed doors;
- from a legal perspective, consultation gives governments another rebuttal to the typical tobacco-industry arguments about poorly crafted policies or unfair processes; and
- media coverage of the consultation can help promote the measures in advance of implementation.

Most countries (but not all) that have adopted plain packaging laws did so after a process that allowed stakeholder input.

The process for stakeholder input should be guided by the normal administrative procedures in each country. One option is to have full public consultation; alternatively the process may form part of parliamentary committee procedures that allow key stakeholders to make written submissions or by way of public hearings, which can be a shorter procedure. In Ireland, the Public Health (Standardised Packaging of Tobacco) Bill was referred to the parliamentary Joint Committee on Health, which ran public hearings for key stakeholders.

It may be unusual for the Health Ministry in some countries to run public a consultation for a public health measures. Governments do not need to undertake a process for plain packaging that is outside of its normal constitutional requirements. It is also important to bear in mind that a poorly run public consultation, which does not allow effective responses or is a mere sham because the government has already made up its mind, can lead to greater legal problems than not running one at all.

## 2. Article 5.3 of the WHO FCTC

When seeking comments or submissions from tobacco companies, governments need to be careful to comply with Article 5.3 of the WHO FCTC, which stipulates that Parties shall act to protect tobacco-control policies from commercial and other vested interests of the tobacco industry. They key to interaction with the industry is to be clear about exactly what issues comments are sought on and to ensure there is complete transparency in respect of any meeting or discussion.

Tobacco companies can provide written submissions, which should then be made publicly available. Meetings can take place but should be limited to where specific information is needed in relation to potential costs to industry or to technical drafting of the legislation which may impact on the manufacturing process in an unnecessary way. Where meetings do take place, full records should be made publicly available about the arrangements, who was present at the meeting and minutes of what was discussed. It is important that government officials give no commitments to tobacco industry representatives in any meeting but just seek information from them.

### 3. How should it be run?

If a public consultation is run by the Health Ministry, sufficient time needs to be factored into the process to allow stakeholders to respond and also to allow the Health Ministry officials time to properly consider the submissions and any amendments to the legislation that flow from those submissions.

Consultations on tobacco-product plain packaging have generated huge volumes of responses because of campaigns funded by the tobacco industry on one side, and tobacco control advocacy groups on the other. This led to 650,000 responses to the first UK consultation — more than any previous public consultation. If resources are not available to consider huge numbers of responses, an alternative method of allowing key stakeholders to provide their submissions should be used that invites the key interested bodies or organizations to make submissions. A consultation is not a vote but a means of ensuring all relevant issues and views are considered.

A decision must be taken as to the best stage to have stakeholder input, and this will depend on local circumstances. One option is to consult or take submissions on the principle of whether or not to proceed with the plain packaging, but it may be preferable to consult not on whether or not to proceed but on the detail of proposal.

### 4. Key principles

- Set clear time frames — these need to be tailored to the specific country's circumstances. For the purposes of planning a legislative timetable, it is suggested that a consultation run for a minimum of six weeks and that the time to review and consider the responses be at least four weeks, although this is very dependent on how many responses are received.
- Set clear parameters of the policy intentions and the questions that are being asked.
- Ensure that all relevant stakeholders have convenient access to the consultation document and an efficient means of responding.
- Mobilize an alliance of health-orientated stakeholders to respond and communicate with the media.
- Do not commit to responding to individual submissions.

A consultation document also needs to be meaningful and provide stakeholders with sufficient information to respond. It is recommended that it includes the following:

- a. the existing tobacco-control measures already in place in the country;
- b. the current smoking prevalence and consumption rates and the costs and harms to society they cause;
- c. the intention of the government to reduce the smoking rates;

- d. a proposal that plain packaging of tobacco products be introduced (alongside any other tobacco-control measures that are being introduced at the same time);
- e. the aims and objectives of the policy (as described in **Guide 1.1**);
- f. a summary of the evidence base that supports the introduction of plain packaging (**Guide 2.1**);
- g. what the features the proposed legislation would include in sufficient detail to allow comment (or a draft of the proposed legislation if that is available);
- h. the time frame that the government proposes; and
- i. how to make submissions and the deadline for them.

## Country examples

- 1. NORWAY.** Public consultation paper [June 2015]

<http://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2015&num=9009&iLang=EN>

- 2. UNITED KINGDOM.** Public consultation paper [April 2012]

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/170568/dh\\_133575.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170568/dh_133575.pdf)

- 3. SINGAPORE.** Public consultation paper [March 2016]

[http://www.healthhub.sg/sites/assets/Assets/PDFs/HPB/News/HPB%20News%2029Dec2015%20-%20Public%20Consultation\\_Tobacco%20Control.pdf](http://www.healthhub.sg/sites/assets/Assets/PDFs/HPB/News/HPB%20News%2029Dec2015%20-%20Public%20Consultation_Tobacco%20Control.pdf)

- 4. CANADA.** Public consultation paper [May 2016]

<http://healthycanadians.gc.ca/health-system-systeme-sante/consultations/tobacco-packages-emballages-produits-tabac/document-eng.php>

- 5. NEW ZEALAND.** Public consultation paper [May 2016]

<http://www.health.govt.nz/publication/standardised-tobacco-products-and-packaging-draft-regulations>

- 6. IRELAND.** Report of the Joint Committee on Health following public stakeholder hearings [April 2014]

<https://www.oireachtas.ie/parliament/media/committees/healthandchildren/Public-Health-SPT-Bill--Vol-1.pdf>

# Make key policy decisions

Plain packaging of tobacco products involves many different elements and, as with all tobacco-control policies, the tobacco industry will look for loopholes or ways to get around or undermine the policy. It is important to get the detail right to ensure the policy is robust and “future proofed.”

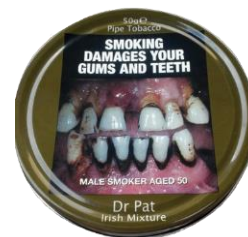
This means the legislation will likely be quite detailed — aiming for simplicity risks the tobacco industry developing novel ways to differentiate their products that don’t currently exist on the market (see **GUIDE 3.2: DRAFT THE LAW**). The key initial policy development decisions are listed below.

## 1. Apply plain packaging to all tobacco-product categories

The WHO FCTC guidelines to Article 13 imply that plain packaging should be applied to all tobacco products. Failure to include all tobacco products could result in those products not subject to the requirements gaining market share (in Canada, for instance, flavored cigarillos became popular after flavored cigarettes were banned).

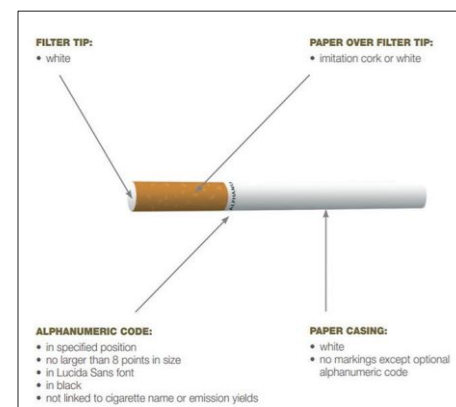
There must be good policy reasons for any decision to apply the policy to only some products, because otherwise there is a risk that a claim could be made that the policy is discriminatory and in violation of World Trade Organization (WTO) rules (see **GUIDE 4.3 WTO NOTIFICATIONS**). Australia and Ireland’s legislation apply to all tobacco products. However, the UK, Norway, France, and Hungary apply the legislation to just cigarettes and hand-rolled tobacco. Decisions in those countries were made because of the limited prevalence of less-common tobacco products, such as cigars or pipe tobacco, especially among younger people.

Government’s should also consider applying plain packaging to new tobacco products including heat-not-burn (HNB) products (for instance Philip Morris’ IQOS) and the devices used to heat the tobacco sticks. There is no reliable independent evidence on the potential harms of these new products and the industry’s aggressive new marketing campaigns may attract new young consumers. HNB products and the heating devices do not fall under the definition of tobacco products in the existing tobacco control laws for many countries. Amending the existing definition may need to be considered in the drafting process.



## 2. Regulate individual sticks

All existing plain packaging legislation applies plain cigarette stick requirements - white sticks with a white tip or imitation cork tip. In Australia, an alphanumeric code is permitted that cannot amount to branding. Australia also prohibits “slim sticks”. In the UK and Ireland, the brand name and variant are permitted in a specified typeface and location on the stick. It is recommended that sticks be regulated because failure to do so could lead to more branding and the use of attractive colors on the cigarette sticks themselves. If sticks are being regulated, then consideration should be given whether to allow the brand name on them or not.





### 3. Minimum quantity per pack

**Most countries are adopting 20 cigarettes as the minimum individual pack size** as part of their plain packaging requirement. Australia and the EU also put minimum quantities on hand rolled (or roll your own) tobacco per pack (30g). The legislation should also prohibit the sale of tobacco in the absence of packaging as this prevents the sale of individual cigarettes or bidi's, a common practice in some countries.

The principle reason for prohibiting smaller packs and individual sticks is that these are cheaper and therefore more accessible to young people and children, thereby encouraging smoking initiation and addiction. This element of the measures is in accordance with WHO FCTC Article 16.4.

### 4. Information permitted on the pack

**Other than the brand and variant name, and the mandatory prescribed health warnings, there is information that a government may want to allow or require on tobacco packs.** These other pieces of information (sometimes given as symbols) may already appear on packs. Depending on how the legislation is drafted, it may need to specifically provide for or allow any additional information that is required by other laws (i.e., consumer protection) or is otherwise desirable. Examples could include:

- barcodes
- age of sale
- place of origin
- duty tax paid stamps or stickers
- manufacturer's name and address for consumer protection
- amount of product per pack
- information about assistance with quitting
- track and trace code or other fraud prevention markings
- tar, nicotine and CO<sub>2</sub> (TNC) emissions\*
- recycling symbol\*
- no littering symbol\*

*\* Symbols for recycling and no littering are not permitted in Australian, Irish or UK legislation because they imply a positive social connection for the tobacco industry. WHO FCTC Article 11 implementation guidelines (paragraph 44) recommends that TNC emissions information should not be permitted on packs because emission yields are misleading to consumers.)*

A review of existing requirements and legislation (including general consumer laws that apply to all product packaging) is recommended to identify which information should continue, which should be not be allowed, and whether there is legislation that already permits or requires any information on tobacco packaging. This will inform the how the law is drafted.

### 5. Apply only to retail packaging

**In order to ensure that the policy is least restrictive, it needs to be aimed at consumers and no wider.** Therefore, it should be applied to 'retail packaging' or only packaging that will or could be seen by consumers; (rather than 'in trade' packaging that is only used in warehouses or wholesalers).

There are good legal reasons for this limitation. Plain packaging is a measure designed to merely control the use of tobacco trademarks rather than to completely prohibit the trademarks in all circumstances. Applying the measure only to packing that consumers may see will assist in defending some of the legal claims the tobacco industry may make against the policy.

In some countries, small shopkeepers use the large boxes that are normally only used in warehouses and would not be classed as 'retail packaging'. In such situations, where consumers may be exposed to branding on what is normally 'trade packaging', a government may consider extending the application of the law and if so, different ways of drafting the legislation can be developed and CTFK can assist or advise on possible options.

## 6. Transition arrangements and sell through periods

**Manufacturers and retailers will have existing stock that does not comply with new packaging laws.** Sufficient notice of when the law will come into force ensures that producers and retailers have sufficient time to sell existing stock before changing packaging to comply with the new law. This weakens any industry argument that it has suffered loss as a consequence of holding unsold stock. Australia allowed a three-month sell-through period for plain packaging, after which old packs could no longer be sold; the UK allowed a full year.

The question of what constitutes a sufficient period of time may differ from country to country. Officials should consider what periods have been allowed for previous packaging requirements, such as changes to health warnings.

## 7. Technical details in parliamentary act or subsequent regulations / decree

**The recommendation is that new and specific legal authority is obtained from the legislature or parliament to implement the plain packaging, rather than relying on existing ministerial or executive powers.**

A parliamentary Act could provide simple powers, so that the Minister of Health can later adopt regulations or a decree that set out the detailed requirement; or the Act could set out most of the detailed requirements.

This will depend on the style of legal drafting and law-making practices for each country as well as the political situation. A short Act, or a short provision that is part of a wider tobacco control Act, which just provides simple powers may be easier to get through parliament and less subject to political interference. On the other hand, if there is a strong movement in Parliament to proceed, then it may be better to include the detail in the Act and set a legislative timetable for implementation.

It is important that a legal power to make regulations or a decree to regulate for plain packaging is drafted to give authority to regulate all aspects of the packaging *as well as* the appearance of individual tobacco products, such as cigarette sticks.

Where plain packaging is adopted at the same time as other tobacco control measures, it is sensible to have a separate decree or regulation that deals only with the plain packaging measures. Plain packaging is more likely to be subject to tobacco industry interference and legal challenges which can lead to delays. The other tobacco control measures are less likely to be delayed if they are in a separate regulation or decree.

# Draft the law

Drafting the detailed legislation can take time, and it is sensible to start the process early, making adjustments as policy decisions are made. The International Legal Consortium at the Campaign for Tobacco-Free Kids can provide technical legal assistance with drafting the law.

Full details are on the [EACH CLAUSE EXPLAINED](#) webpage of the online Toolkit, together with a [TEMPLATE MODEL LAW](#) which can be downloaded. These provide recommended solutions to all the issues listed below and the reasons for them, together with straightforward options on how the legislation could be drafted. They draw on existing legislative examples and the policy development undertaken in Australia, the UK, Ireland, and France.

## 1. Regulate every part of the pack

**Every aspect of the packaging presents the tobacco industry with a potential opportunity to introduce novel or different elements that could differentiate and promote the product and undermine the intention to create truly standard packs.** Experience shows that tobacco companies will seek to exploit whatever avenue is left to them to differentiate their product in a way that is attractive or that allows positive associations with the brand. The guiding principle behind plain packaging is that the only means of differentiation is through the brand and variant name, which are presented in a standard typeface. Achieving this requires regulating each aspect of the packaging and the appearance of individual products, such as cigarette sticks, including:

- the exact color of each element of the packaging (exterior and interior)
- permitted text (such as name and address of manufacturer)
- typeface and text-point size of text
- type of opening
- material used
- pack shape
- pack size
- surface texture and embossing
- multipacks and multiple layers of packaging
- beveled or rounded pack edges
- plastic wrappers and tear strips
- cigarette pack foil linings
- inserts, stickers, and additional materials
- sounds and smells
- quantity per pack
- flavoring
- bar codes and calibration marks
- track-and-trace or origin marks
- the length and nature of brand and variant names
- changeable packaging

This means the legislation can end up being quite detailed — aiming for simplicity risks the tobacco industry developing novel ways to differentiate their products and undermining the legislation.



## 2. Emulate existing laws

The legislation in force in Australia, the UK, Ireland, France, Norway and Hungary (and, at the time of writing, the proposed laws in New Zealand and Slovenia) are, in their effect, all very similar (although there are some differences, which are highlighted in this Toolkit).

There have been a number of positive legal rulings on challenges to plain packaging laws in Australia, the EU, and the UK (and a ruling is expected in late 2017 on a WTO dispute - see **Guide 4.3**). Some of the evidence supporting plain packaging and used by governments in those legal challenges, is based around the specific policy decisions that were first developed in Australia. Deviating from those key evidence based policy decisions could risk providing tobacco companies with sufficient grounds to mount legal challenges.

Countries considering plain packaging should therefore be cautious of introducing legislation that differs significantly from the plain packaging laws already in force. Emulating existing laws will allow the government to rely on both the evidence base and the positive legal rulings from around the world.

## 3. Keep it flexible

It is prudent to adopt legislation that allows for subsequent changes through delegated regulatory powers to the appropriate ministry so that changes can be made without having to go back to parliament. Unanticipated issues may arise and the tobacco industry will inevitably try to find ways to undermine the policy.

## 4. Color

The color of packs provides a good example of the need for detail and for emulating existing legislation. Unless the exact color required for the packaging is prescribed very precisely, variations of color will appear, defeating the intention of standardizing packaging. Simply requiring ‘brown’, or a ‘green/brown’ in legislation is insufficient. Australia commissioned research into which color was perceived to be the least appealing for tobacco packaging:

The color of this box is Pantone 448C, and this text is Pantone Cool Grey 2C

**Pantone 448C** (opaque couche) with a matt finish is the dull brown/green color specified in the Australian, the UK, Ireland, France, and Hungary legislation for the packaging.<sup>1</sup>

**Pantone Cool Grey 2 C** with a matt finish is the color specified in those countries for any text permitted on the packaging, such as brand name or contact details.

Unless there is specific evidence or research that demonstrates different colors would be more effective in a particular country at achieving the aims of the policy, it is recommended that these colors are used in all plain packaging legislation because of the research already conducted that demonstrates the color’s effectiveness. A matt finish to the surface should also be specified to avoid some packs appearing with a glossy finish.

## 5. Shape, size and opening of pack

This is another area where it is recommended that particular care be taken to provide detail and to follow existing legislation. Many of the policy decisions in Australia, the UK, and Ireland require cigarette packs to be in the form that is generally the standard or most common type of packet - a cuboid box made of cardboard with 20 cigarettes in it, which uses a flip top lid. Because this is the most common form of packaging for cigarettes, tobacco companies will not have to make any major adjustments to their machinery to produce this packaging and therefore it is a least restrictive approach that should be followed unless a different type or style of packet is more common in the particular country considering plain packaging.



## 6. Plain packaging ‘light’ policy should be avoided

For instance, legislation should not allow for a small amount of space for branding on a pack or permit certain figurative logos (such as a small logo in the same color as the text as in the picture shown). With no specific evidence available as to if or how effective such a policy would be, a policy choice of that nature could introduce unnecessary legal risks.



1. Market research to determine effective plain packaging of tobacco products: report. GfK Bluemoon, August 2011, available at <http://www.health.gov.au/internet/publications/publishing.nsf/Content/mr-plainpack-mr-tob-products>.

## 7. Include a trademark registration saving provision

There are important legal reasons to ensure that tobacco companies can maintain their trademark registrations, even if the use of those trademarks is severely restricted by plain packaging. There are international, regional, and national laws that oblige states to maintain trademark registrations.

For instance Article 15 of the World Trade Organization Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) obliges member states to permit registration of signs as trademarks so long as they are capable of distinguishing the goods of one undertaking from those of another.

In most jurisdictions non-use of a trademark in practice can lead to applications for de-registration of that trademark, typically after five years, where there is no good reason for the non-use.

If a country's plain packaging laws mean that tobacco trademarks are fully prohibited in all circumstances or if the trademark registration will be liable to cancellation, this may breach international obligations.

Therefore, most plain packaging legislation has a trademark registration saving provision that states that the legislation does not amount to a prohibition of the use of the trademarks in all circumstances, and that non-use of a trademark as a result of the legislation amounts to a good reason for non-use.

Trademark registration saving provisions examples:

- **Australia** – Section 28 of the Tobacco Plain Packaging Act 2011
- **UK** – Regulation 13, of the Standardised Packaging of Tobacco Products Regulations 2015
- **Ireland** – Section 5, Public Health (Standardised Packaging of Tobacco) Act 2015

The way in which plain packaging might otherwise intersect with a country's domestic trademark laws needs to be considered carefully.

An example of a trademark registration saving provision is Article 13 of the **TEMPLATE MODEL LAW** that can be downloaded from the online Toolkit – but this needs to be adapted and amended so that it aligns with the trademark laws in a particular country.

# Coordinate across government

Because of issues such as business regulation, excise tax, and cooperation in combating the illicit trade in tobacco, the tobacco industry will often have closer links with Ministries other than Health Ministries — such as trade, business, treasury, customs and revenue, intellectual property, and the foreign affairs office. These other ministries will have their own concerns and agendas and may seek to delay or prevent adoption and implementation of plain packaging because of those concerns.

To assist with the initial coordination with other government ministries, the online Toolkit includes a series of **POLICY BRIEFS**, which provide basic information about the policy and address the key opposing arguments, explaining the evidence and why those arguments are flawed.

Plain packaging does have implications for these other ministries which they will need to provide input on. For instance, plain packaging will impact on treasury receipts and there are *alleged* impacts on pricing and illicit trade (see **GUIDE 1.3**). Notwithstanding these concerns, the critical public health agenda should remain the priority.

## 1. Whole of government approach

It is important that coordination occurs across departments to ensure that there is an agreed approach; that the other ministries understand the need for the policy and are not influenced by the tobacco industry's contrived arguments opposing it. It is useful to have agreed lines on each of the key issues that will be alleged by the industry so that mixed messages are not put out by different parts of government.

One possible approach is to form a cross-government working group (as happened in Australia). Another is to ensure all correspondence to any government department about plain packaging are directed to the Ministry of Health for a response. Establishing a whole of government approach to the policy, where possible, can be important for its success and *early engagement* with the other ministries can be key. For instance, in the UK, Her Majesty's Revenue and Customs produced a full analysis of the likely impact of plain packaging on the illicit market. This analysis identified no evidence or reasons that plain packaging would increase the overall burden of illicit tobacco,<sup>1</sup> which was useful in combatting industry arguments.

## 2. The issues on which cross-government agreement should be developed

- The impact of plain packaging on illicit trade – Ministry of Customs and Revenue.
- The impact of alleged down trade or price reductions – Treasury / Ministry of Business/Finance.
- The impact on tax receipts – Treasury.
- The impact on tobacco industry jobs – Ministry of Business/Finance.
- The impact on trademark registration and compatibility with intellectual property law – Ministry for Intellectual Property.
- The 'slippery slope' argument (*i.e. if tobacco now, what next – plain alcohol packaging?*) – Ministry responsible for Intellectual Property and food/alcohol regulation.
- Compatibility with international legal obligations – Ministry of Foreign Affairs.

### 3. External experts and officials from other governments

It can sometimes help to have external experts on these issues address officials from the other ministries. For instance, one of the arguments that is put forward most strongly by the tobacco industry is that plain packaging will increase illicit trade. This argument can be very effective in causing concern within other government departments or with members of parliament. However, it is a contrived argument used by the industry to oppose many tobacco-control measures, and the evidence to support the argument in relation to plain packaging is extremely weak. There are a number of academic researchers who are able to demonstrate effectively and convincingly how the industry is wrong in its allegations about illicit trade. If a Ministry of Health considers that an external expert could assist in the policy development or governmental/parliamentary processes, CTFK may be able to help with identifying appropriate persons and organizing their visit.

In addition, government officials from countries that have already implemented plain packaging are often willing to provide information about their policy development, and there are many instances of official government visits taking place in relation to the proposed policy. It is highly recommended that Ministry of Health officials make contact with counterparts in those countries that have already adopted plain packaging laws.

1. See [www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/403495/HMRC\\_impact\\_report.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403495/HMRC_impact_report.pdf).



# Obtain legal advice

The tobacco industry has a long track record of using legal challenges to prevent or delay governments' tobacco-control measures. Countries that were early adopters of plain packaging laws have faced legal challenges in domestic and regional courts, in international investment arbitration tribunals, and under the World Trade Organization dispute settlement procedures. **All the legal challenges decided, as of the end of November 2017, have upheld the legality of plain packaging of tobacco products.**

The key message is that if plain packaging of tobacco products is adopted using appropriate domestic constitutional, administrative, and legislative arrangements, then there is no inherent reason why plain packaging should be found unlawful. However, this Toolkit can only provide generalized legal information, taking into account the academic literature and the results of legal challenges that have already been decided across different jurisdictions. The procedural steps and drafting advice set out in these Guides and the online Toolkit should provide the good grounding needed to secure a robust plain packaging law.

## OBTAIN LEGAL ADVICE

It is important that a country specific legal analysis (by internal government lawyers and/or through an opinion from external lawyers) is undertaken on the legal issues raised by plain packaging. Constitutional requirements and the priority given to different rights and obligations in national legal jurisprudence vary from country to country. Given the possibility of legal challenge and the likely threats and allegations that will be made by the industry if the measure is proposed, it is a sensible precaution to have ready answers to the legal issues that will be raised.

## 1. Key legal issues

The tobacco industry continues to aggressively assert that plain packaging is unlawful in countries considering the policy, even though industry legal challenges have all so far been defeated in Australia, France, the UK, and the European Union. There are similar broad themes to the legal arguments used by the industry across jurisdictions. They are that plain packaging:

- Is an expropriation/deprivation of property;
- Is an unreasonable, dis-proportionate or unnecessary measure, because it is not justified by the evidence;
- Is adopted without due process or in an arbitrary manner;
- Breaches rights to freedom of expression and to run a business;
- Is incompatible with intellectual property laws and the 'right to use' a trademark; and
- Breaches international obligations under World Trade Organization rules and investment treaties.

These issues may arise out of domestic laws or constitutions, regional obligations or international law. More explanation of these issues is set in the [LEGAL ISSUES](#) pages of the online Toolkit.

## 2. Legal challenges

There have been a number of legal challenges to plain packaging laws already decided and some that are ongoing. As of November 2017, the time of writing, all the challenges that have been determined have resulting in the claims being dismissed. More details about these cases are given in the [CASE SUMMARIES](#) page of the online Toolkit.

### → AUSTRALIA

- Constitutional challenge in the High Court of Australia – *dismissed August 2012*
- International investment arbitration claim – *dismissed December 2015*
- Complaint before the WTO dispute panel – *proceedings concluded but ruling due in 2017*

### → UNITED KINGDOM

- Claim in the High Court of England and Wales – *dismissed in May 2016 [ruling upheld by Court of Appeal in December 2016]*

### → FRANCE

- 1 referral to the Conseil Constitutionale and 6 challenges in the Conseil d’Etat (the highest administrative court) – *dismissed January 2016 and December 2016*

### → IRELAND

- Challenge in the High Court – *struck out November 2016*

### → EUROPEAN UNION

- Challenge to the EU Tobacco Products Directive in the EU Court of Justice – *dismissed in May 2016*

### → NORWAY

- Injunction application to delay introduction for snus tobacco – *dismissed in November 2017*

## 3. Highlights from key judgments

These rulings express legal principles and decisions that will be of value to lawyers in other jurisdictions that may have to defend plain packaging in their own countries. The judgments also contain clear and concise passages that will help policymakers and civil society organizations to provide information about the policy or promote its implementation. These are explored in more detail in the [LEGAL ISSUES](#) pages of the online Toolkit, but here are some highlights:

- Plain packaging requirements “are no different in kind from any legislation that requires labels that warn against the use or misuse of a product.”<sup>1</sup>
- “[The tobacco companies’] body of expert evidence does not accord with internationally recognized best practice.”<sup>2</sup>
- “In my judgment the qualitative evidence relied upon by the [Government] is cogent, substantial and overwhelmingly one-directional in its conclusion.”<sup>3</sup>
- “[WTO] TRIPS and the FCTC can be read together without any risk of them colliding or being mutually inconsistent.”<sup>4</sup>
- Trademarks provide “a right of use that exists vis-à-vis other persons, an exclusive right, but a relative one. It is not an absolute right to use that can be asserted against the State.”<sup>6</sup>
- “Manufacturers and distributors of harmful products such as cigarettes can have no expectation that new and more onerous regulations will not be imposed.”<sup>5</sup>

1. JTI SA v Commonwealth of Australia; BAT Australasia Ltd & ORS v Commonwealth of Australia [2012] HCA 43 at paragraph 81.

2. R (British American Tobacco & Ors) v Secretary of State for Health [2016] EWHC 1169 (Admin) at paragraph 374

3. See note 2 at paragraph 592

4. See note 2 at paragraph 186

5. Philip Morris Products S.A. and Abal Hermanos S.A. v. Uruguay (ICSID Case No. ARB/10/7) at paragraph 429

6. See note 5 at paragraph 267

# WTO notification

## 1. World Trade Organization Article 2.9 of the Technical Barriers to Trade agreement

To avoid accusations that a government has failed to notify a relevant standard, it is recommended that plain packaging legislation is notified to the World Trade Organization (WTO) under Technical Barriers to Trade (TBT) Article 2.9. This is a procedural process that allows other governments to comment on a technical requirement and does not mean that plain packaging of tobacco products breaches any of the WTO agreements.

The purpose of the TBT Agreement is to avoid unnecessary regulatory obstacles to international trade while **allowing for the regulatory autonomy of states to protect legitimate public interests such as public health**. Article 2.9 obliges WTO member to notify drafts of technical regulations that could impact on international trade and which are not international standards, so that other WTO members can consider the regulations and make comments.

A technical regulation is defined as being a regulation that: *“lays down product characteristics or their related processes and production methods. Compliance is mandatory. They may also deal with terminology, symbols, packaging, marking and labelling requirements.”*

**Plain packaging falls within the definition of a technical regulation** that relates to the trade in goods and is one that has not as yet been established as an international standard.

## 2. The notification should be of draft legislation

This means that it should be at a stage that sets out the detail of what the government intends to adopt but is still capable of amendment. The WTO TBT procedure then requires **a sixty-day standstill period** during which amendments could still be made to the law, so that written comments from other WTO members can be sent on the draft measure.

There is also a further requirement under Article 2.12 that the final adopted measure be published and it is recommended that there is a six-month period between publication and the date the new regulations come into force. This is to allow exporters from other WTO member countries sufficient time to change their manufacturing processes to comply with the new regulations.

**The sixty-day standstill period for the draft regulations and the six-month period between publication and coming into force should be factored into the legislative timetable if possible.**

The WTO webpage that provides details and materials on the WTO notification procedure can be found at [www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_notifications\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_notifications_e.htm) and the guidelines and forms are available in English, Spanish, and French.

**Most governments have a single agency or department that administers all the country’s notifications.** But the Ministry of Health responsible for plain packaging will need to coordinate with that other department or agency to enable the notification to be made effectively.

## 3. Examples of plain packaging of tobacco products WTO notifications

To date, each country to have adopted plain packaging has notified their legislation under TBT 2.9. Examples of existing notifications can assist any government seeking to comply with the notification procedures.

- Ireland's WTO TBT notification of June 17, 2014, is available from:  
[https://docs.wto.org/dol2fe/Pages/FE\\_Search/DDFDocuments/125256/q/G/TBTN14/IRL1.pdf](https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/125256/q/G/TBTN14/IRL1.pdf)
- The UK's WTO TBT notification of September 2014 is available from:  
[https://docs.wto.org/dol2fe/Pages/FE\\_Search/DDFDocuments/126836/q/G/TBTN14/GBR24.pdf](https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/126836/q/G/TBTN14/GBR24.pdf)
- Norway's WTO TBT notification of May 18, 2015, is available from:  
[https://docs.wto.org/dol2fe/Pages/FE\\_Search/DDFDocuments/132085/q/G/TBTN15/NOR23.pdf](https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/132085/q/G/TBTN15/NOR23.pdf)
- Hungary's WTO TBT notification of December 12, 2015, is available from:  
<https://docs.wto.org/imrd/directdoc.asp?DDF-Documents/t/G/TBTN15/HUN31.DOC>

Many of these notifications received comments from other member countries in TBT committee meetings. Some countries, including those that brought a WTO dispute procedure against Australia (such as Indonesia, Dominican Republic, Cuba, and Honduras) and some tobacco-producing countries (such as Malawi, Zimbabwe, and Nicaragua), have given negative comments to the committees. However, many countries, including New Zealand, Norway, Canada, Uruguay, and the EU, also provided positive comments supporting the position that plain packaging does not breach the WTO agreements and is a legitimate public health measure. In a number of committee meetings where Member State's proposals for plain packaging were discussed, a representative of the World Health Organization provided support for the measure and stressed that there is a strong body of evidence to support the position that plain packaging will achieve its objectives.<sup>1</sup>

None of these comments in committee have led to further dispute procedures being commenced against any country that has adopted plain packaging laws, other than Australia.

## 4. WTO Dispute Procedures against Australia

At the time of writing, a WTO dispute settlement panel is adjudicating complaints by Cuba, the Dominican Republic, Honduras and Indonesia with respect to Australia's plain packaging laws. It has been widely reported that British American Tobacco and Philip Morris are providing funding and legal support for Honduras and the Dominican Republic in the proceedings.

The panel's decision is expected to be made public in 2017. The media has reported that a leaked interim report showed that Australia had won the case.

Most commentators expected a positive result for Australia. There are well-established principles and rules that demonstrate the flexibility for WTO Members to regulate for public health. These are described in the WHO publication on plain packaging of tobacco products<sup>2</sup> and are set out briefly in the **LEGAL ISSUES** pages of the online Toolkit. The main issues of dispute fall under Article 2.2 of the TBT Agreement and Article 20 of the Trade Related Aspects of Intellectual Property Agreement (TRIPS).

The WTO panel decision may be the subject of an appeal by the Parties but in the meantime it appears unlikely that any further dispute will arise concerning plain packaging laws of other WTO Members until that dispute is fully resolved.

**The issues in this dispute are separate from the procedural requirement to notify regulations under TBT Article 2.9.**

1. See, for instance, the TBT committee meeting on November 27–28, 2012, where New Zealand's notification of its plain packaging laws was discussed: G/TBT/M/58 Document 13-0617.
2. See <http://www.who.int/tobacco/publications/industry/plain-packaging-tobacco-products/en/>, pp 43–46.