Plain packaging of tobacco products

EVIDENCE, DESIGN AND IMPLEMENTATION

World Health Organization

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Contents

Executive summary vii
Introduction 1

Part 1. Plain packaging: definition, purposes and evidence 3
1.1 A working definition of plain packaging 4
1.2 Purposes of plain packaging 8
1.3 The evidence base underlying plain packaging 10
1.3.1 The attractiveness of tobacco products and the advertising function of branding 11
1.3.2 Misleading tobacco packaging 12
1.3.3 The effectiveness of health warnings 13
1.3.4 The prevalence of tobacco use 13
1.3.5 Expert reviews of the evidence 15
1.3.6 Conclusions 18
Additional resources 19

Part 2. Policy design and implementation 21
2.1 The policy design process 22
2.2 Implementation of plain packaging 25
2.3 Compliance and enforcement 32
2.3.1 Delayed compliance and penalties for non-compliance 33
2.3.2 Sleeves, stickers, inserts and other devices 34
2.3.3 Sale in the absence of packaging 35
Additional resources 37

Part 3. Legal issues 39
3.1 Domestic law 40
3.2 International law 42
3.2.1 World Trade Organization law 43
3.2.2 International investment law 47
3.3 Strengthening governments' legal positions 49
3.3.1 General 49
3.3.2 The policy process 50
3.3.3 Recommendations on policy design 52
3.4 Conclusion 54
Additional resources 55

Part 4. Other tobacco industry objections to plain packaging 57
4.1 Plain packaging and illicit trade? 58
4.2 Plain packaging and prices? 59
4.3 Plain packaging and retailers? 60
Additional resources 61

Endnotes 62

Navigating the document

PART 1
Plain packaging: definition, purposes and evidence

1.1 A working definition of plain packaging
One of the definitions of plain packaging in the WHO Framework Convention is:

> "*Measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging)*"
> - Article 11 Guidelines

- Section 1.1, page 4

1.2 Purposes of plain packaging
Plain packaging serves several purposes, including:

Reducing the attractiveness of tobacco products

Eliminating the effects of tobacco packaging as a form of advertising and promotion

Addressing package design techniques that may suggest that some products are less harmful than others

Increasing the noticeability and effectiveness of health warnings

- Section 1.2, page 8

1.3 The evidence base underlying plain packaging
A large body of empirical evidence provides strong evidence to justify introduction of plain packaging.

- The attractiveness of tobacco products and the advertising function of branding
  - Section 1.3.1, page 11
- Misleading tobacco packaging
  - Section 1.3.2, page 12
- The effectiveness of health warnings
  - Section 1.3.3, page 13
- The prevalence of tobacco use
  - Section 1.3.4, page 13
- Expert reviews of the evidence
  - Section 1.3.5, page 15

PART 2
Policy design and implementation

2.1 The policy design process
The policy design process will differ from one jurisdiction to another. In each jurisdiction that has passed plain packaging into law, a careful, detailed and prolonged process of policy design was undertaken.

Several guidelines, recommendations, policy questions and other considerations are outlined.

- Section 2.1, page 22

2.2 Implementation of plain packaging
A number of WHO Member States have implemented plain packaging laws. Australia's approach is described in this section, and differences are noted from the approaches to be adopted by Member States of the European Union.

- Section 2.2, page 25

2.3 Compliance and enforcement
Compliance and enforcement are important considerations in designing a plain packaging policy. Several issues should be taken into account:

- Delayed compliance and penalties for non-compliance
  - Section 2.3.1, page 33
- Sleeves, stickers, inserts and other devices
  - Section 2.3.2, page 34
- Sale in the absence of packaging
  - Section 2.3.3, page 35

PART 3
Legal issues

3.1 Domestic law
There are limits on the extent to which it is possible to generalize about the legal issues associated with plain packaging in different jurisdictions. Despite these limitations, it is possible to identify broadly the types of domestic legal claims that tobacco companies threaten or bring against plain packaging. Examples of invoked laws include:

- Laws that protect private property rights, including trademarks
- Laws that protect commercial speech and rights to conduct business

- Section 3.1, page 40

3.2 International law
Tobacco companies often rely on arguments about the purported impacts of international trade and investment agreements in attempts to resist domestic regulation. Disputes relating to several treaties are discussed in more detail:

- World Trade Organization law
  - Section 3.2.1, page 43
- International investment law
  - Section 3.2.2, page 47

3.3 Strengthening governments' legal positions
Governments can take several steps to strengthen their legal positions. In general, these include:

- Defining the regulatory objectives of plain packaging in a way that is linked to the evidence and to the WHO FCTC.
- Ensuring that plain packaging is implemented as part of a comprehensive set of tobacco control measures.
- Ensuring flexibility in the law to permit amendment if necessary.
- Adopting a whole-of-government approach to policy design, implementation, enforcement and evaluation.
  - Section 3.3.1, page 49

Further policy recommendations relating to the policy process and design are made.

- Sections 3.3.2 and 3.3.3, page 50

PART 4
Other tobacco industry objections to plain packaging

4.1 Plain packaging and illicit trade?

There is no rational basis upon which to argue that plain packaging will increase illicit trade.

- Section 4.1, page 58

4.2 Plain packaging and prices?

Governments can address product prices through tax and price measures.

- Section 4.2, page 59

4.3 Plain packaging and retailers?

Retailers can quickly adapt to plain packaging, with product retrieval times returning to normal soon after implementation.

Plain packaging represents an incremental change to be used as part of a comprehensive approach to tobacco control, and not the dramatic policy change suggested by industry. Furthermore, in countries with strong population growth reduced prevalence of tobacco use does not necessarily translate into reduced total sales.

- Section 4.3, page 60

Executive summary

In 2012, Australia became the first WHO Member State to implement laws requiring plain (standardized) packaging of tobacco products. Since then, France, Ireland and the United Kingdom of Great Britain and Northern Ireland (UK) have passed laws to implement plain packaging and several other WHO Member States have initiated legislative processes with the same goal. This legislative activity has generated considerable demand for information from WHO Member States and the public health community more broadly. WHO Member States and civil society groups have published a substantial body of information on implementation of plain packaging at the national level, including with respect to the tobacco industry's objections to the policy. This publication seeks to build upon that important work, to describe developments at the country level and to offer guidance for other WHO Member States that are considering implementing plain packaging.

Plain packaging is distinct from other packaging and labelling measures, such as large graphic health warnings. This publication defines plain packaging in line with guidelines for implementation of Articles 11 and 13 of the WHO Framework Convention on Tobacco Control (WHO FCTC). The Guidelines for Implementation of Article 11 (Packaging and labelling of tobacco products) define plain packaging as "measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging)". The Guidelines for Implementation of Article 13 (Tobacco advertising, promotion and sponsorship) describe plain packaging in the following terms "black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer's name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and standardized shape, size and materials. There should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products."

When viewed in the context of the WHO FCTC, and particularly Articles 11 and 13, plain packaging serves several purposes, including:

1. reducing the attractiveness of tobacco products;
2. eliminating the effects of tobacco packaging as a form of advertising and promotion;
3. addressing package design techniques that may suggest that some products are less harmful than others; and
4. increasing the noticeability and effectiveness of health warnings.

As the WHO FCTC recognizes, tobacco control relies upon implementation of comprehensive multisectoral measures that work together in a complementary way. In this context, plain packaging, itself a demand-reduction measure, complements or builds upon

other measures designed to reduce demand for tobacco products, such as mandatory health warnings and comprehensive restrictions on tobacco advertising, promotion and sponsorship. Plain packaging is not a panacea for the consequences of tobacco consumption, but provides an incremental step that builds upon other policies.

A large body of empirical evidence in the form of experimental studies, surveys and focus group studies provides strong evidence to justify introduction of plain packaging and to support the conclusion that the policy is apt to achieve the objectives identified. Three recent systematic reviews of the evidence support this conclusion, as does early evidence from Australia, which is consistent with the conclusion that plain packaging is an effective public health intervention.

Although plain packaging has certain core elements, implementation may take slightly different forms in different jurisdictions. This variation may be due to different policy choices in the design of the measures, or differences in the context in which the measures are implemented. Where plain packaging is to be implemented, the WHO FCTC and its guidelines:

- imply that plain packaging should apply to all categories of tobacco products;
- recommend that brand names and product names displayed in a standard colour and font style should be the only form of logo, colour, brand image or promotional information on packaging;
- recommend that design features that make tobacco products more attractive to consumers, such as animal or other figures, “fun” phrases, coloured cigarette papers, attractive smells, novelty or seasonal packs, should be addressed in plain packaging laws;
- recommend that the appearance of tobacco products (as opposed to retail packaging) should be standardized;
- recommend that adhesive labels, stickers, cases, covers, sleeves, wrapping and promotional inserts and onserts do not obscure, obliterate or undermine health warnings and messages (and by implication, do not undermine the objectives of plain packaging); and
- recommend that time allocated for implementation of packaging and labelling measures need only be enough to allow manufacturers and importers to organize the printing of new packages.

Beyond these core elements of plain packaging, additional policy questions may include:

- how other plain or standardized aspects of retail packaging must appear, including colours and finish (gloss or matt);
- the extent to which differences across tobacco product categories should affect application;
- the extent to which, and in what form business or company names may appear on packaging;
- how plain packaging will be enforced, including who will be responsible for enforcement and what penalties will be imposed for non-compliance by different actors in the supply chain, such as importers, manufacturers and retailers; and
- whether repackaging of tobacco products after importation should be permitted as a means of meeting the requirements of a plain packaging law.

The design of a plain packaging measure is also closely related to, and affected by, other packaging and labelling measures. Specific issues for consideration include:

- the size of health warnings;
- where health warnings are located on product packaging, such as the top of packaging;
- how misleading elements of packaging, including descriptors, marks and symbols, are addressed;
- how information on constituents and emissions, including misleading information about tar and nicotine yields, is addressed;
- how information on ignition propensity is addressed;
- what information about smoking cessation, if any, is included on product packaging;
- whether tax stamps or markings for purposes of tracking and tracing tobacco products are used on product packaging, including where and how they are placed;
- how barcodes may appear on packaging; and
- how any other government-mandated information may appear on packaging.

Plain packaging laws in Australia, Ireland and the UK have also been the subject of legal challenges by the tobacco industry. Australia successfully defended a domestic constitutional law claim concerning plain packaging, as well as a claim under a bilateral investment treaty. At the time of writing, Australia is still defending claims under the law of the World Trade Organization (WTO) by Cuba, the Dominican Republic, Honduras and Indonesia. Ireland and the UK are each defending claims before their domestic courts that invoke elements of European Union law.

The tobacco industry’s objections to evidence-based tobacco control measures are not new. For many governments, litigation with respect to tobacco control laws is also not new. Nonetheless, governments designing plain packaging measures should be aware of the existing litigation and be aware that there are several approaches that may strengthen or reinforce their legal positions under both domestic and international laws. These include:

General

1. defining the regulatory objectives of plain packaging in a way that is linked to the evidence and to the WHO FCTC;
2. ensuring that plain packaging is implemented as part of a comprehensive set of tobacco control measures;
3. ensuring flexibility in the law to permit amendment if necessary; and
4. adopting a whole-of-government approach to policy design, implementation, enforcement and evaluation.

The policy process

1. gathering the best available evidence;
2. if possible, testing the efficacy of different approaches to plain packaging;
3. respecting due process rights in the policy development process in accordance with national law and Article 5.3 of the WHO FCTC, including its Guidelines;
4. creating a document development and retention policy in accordance with national law from the outset of the policy development process (in order to address frequent freedom-of-information claims lodged by the tobacco industry);
5. giving producers sufficient time to adapt packaging and sell existing stock; and

6. ensuring that commitments are not made to investors in the tobacco sector for purposes of inducing foreign investment.

Policy design

1. applying plain packaging to all categories of retail tobacco packaging and tobacco products;
2. ensuring that brands can be distinguished one from another;
3. permitting registration of trademarks (provided that they are not misleading) and allowing existing trademarks to remain on the register;
4. preventing deregistration of tobacco trademarks on grounds of non-use attributable to plain packaging;
5. permitting the presence of pack features that help to prevent illicit trade, and
6. permitting repackaging of tobacco products at the point of importation.

It is important to stress that the intention is not to suggest that plain packaging measures departing from these recommendations will be inconsistent with domestic or international laws. Moreover, different laws and circumstances in different jurisdictions limit the extent to which it is possible to generalize. Nonetheless, a careful process of policy design, implementation and evaluation can strengthen the measures implemented and the legal positions supporting those measures.

In addition to legal challenges, tobacco companies and their supporters have lobbied against introduction of plain packaging and contested the measure in the political sphere. As far back as 1993 tobacco companies formed what they called a plain packs group to resist development of plain packaging laws. In Australia, the industry's opposition to plain packaging was also far greater than typical industry opposition to introduction of other tobacco control measures. As part of this opposition, tobacco companies and their supporters have made numerous assertions, such as: plain packaging will increase illicit trade in tobacco products, lead to lower prices and have negative effects on retailers. These and other arguments made by tobacco companies align with the industry's self-interest, have not come to fruition in Australia and often lack any rational basis.

Introduction

In December 2012 Australia became the first WHO Member State to implement fully tobacco plain packaging. Since then, interest in plain packaging has grown among WHO Member States so much so that it is now possible to observe a process of policy diffusion or, what some have termed, the globalization of plain packaging. At the time of writing, France, Ireland and the United Kingdom of Great Britain and Northern Ireland (UK) have passed laws that will see implementation of plain packaging in 2016, and Hungary and Norway are in the process of developing laws to implement plain packaging. Singapore is undertaking a public consultation with a view to introducing plain packaging and several other countries, including New Zealand, South Africa and Turkey, have either expressed an intent to implement the measure or are in the policy-development process.

The interest in plain packaging and the tobacco industry's intense opposition to plain packaging have also generated demand for information from WHO Member States. This publication seeks to address that demand by compiling information on plain packaging of relevance to all WHO Member States and by identifying important resources that provide further detail on specific issues relevant to public health. Rather than trying to offer the last word on plain packaging, this publication recognizes that policies on plain packaging are evolving at such a pace that any publication seeking to gather information is quickly out of date. Moreover, some existing resources on plain packaging are updated regularly in ways that a single publication cannot be updated.

Against this backdrop, this publication is divided into four parts. Part 1 first defines the concept of plain packaging and distinguishes it from other packaging and labelling measures. In doing so, it also identifies those provisions of the WHO Framework Convention on Tobacco Control (WHO FCTC) that are of most relevance to plain packaging. Part 1 also sets out the purposes of plain packaging and explains where the policy fits into a comprehensive approach to tobacco control. Finally, it outlines the evidence base supporting plain packaging, which is closely linked to the purposes of, and rationales for, the policy.

Part 2 offers a brief description of the policy design and implementation processes undertaken in Australia, France, Ireland and the UK before identifying policy questions to be considered in designing plain packaging measures. Part 2 makes it clear that plain packaging has several core elements and that much can be learnt and adapted from Australia's

experience of implementing the WHO FCTC guidelines, but that there may be minor variations in implementation in different jurisdictions.

Part 3 briefly describes legal issues surrounding plain packaging under domestic and international law and identifies ways in which governments can reinforce their legal positions. The text is designed to highlight the types of arguments tobacco companies have made in domestic and international claims concerning plain packaging. The purpose is both to provide an update on the status of existing claims and to permit Member States to prepare for the types of legal arguments that can be expected in the tobacco industry's attempts to resist plain packaging. Moreover, Part 3 highlights fundamental contradictions in the tobacco industry's objections to plain packaging. On the one hand, tobacco companies assert that plain packaging will not be effective on grounds that it will not reduce tobacco use, while on the other hand they assert that they are entitled to billions of dollars in compensation for the damage done to their businesses. The inconsistency of these two positions cannot be reconciled.

Finally, Part 4 looks at three other tobacco industry objections with respect to plain packaging. These objections — that plain packaging will increase illicit trade, push prices down and affect retailers — have been made in numerous countries. However, these predictions have not come true in Australia and policies can be developed to address any concerns governments may have in these areas.

This publication is up to date as of 29 February 2016.

PART 1

Plain packaging: definition, purposes and evidence

Tobacco control relies on implementation of comprehensive multisectoral measures that work together in a complementary way. This is recognized in the WHO Framework Convention on Tobacco Control (WHO FCTC), an evidence-based treaty, which with 180 Parties is one of the most rapidly and widely embraced treaties in the United Nations system. Article 4.4 of the WHO FCTC recognizes that "[c]omprehensive multisectoral measures and responses to reduce consumption of all tobacco products at the national, regional and international levels are essential so as to prevent, in accordance with public health principles, the incidence of diseases, premature disability and mortality due to tobacco consumption and exposure to tobacco smoke."[1]

In the context of this comprehensive approach the WHO FCTC obliges Parties to implement various tobacco control measures aimed at reducing demand for tobacco products. Provisions aimed at reducing demand include Article 6 (Price and tax measures to reduce the demand for tobacco), Article 8 (Protection from exposure to tobacco smoke), Article 9 (Regulation of the contents of tobacco products), Article 10 (Regulation of tobacco product disclosures), Article 11 (Packaging and labelling of tobacco products), Article 12 (Education, communication, training and public awareness), Article 13 (Tobacco advertising, promotion and sponsorship) and Article 14 (Demand reduction measures concerning tobacco dependence and cessation). These measures work together by targeting different, or multiple, drivers of tobacco consumption and different population groups.

As the discussion below illustrates, plain packaging (itself a packaging and labelling measure and restriction on tobacco advertising and marketing) complements other demand reduction measures and makes them more effective. Plain packaging is not in itself a panacea for the risks associated with tobacco use, but may be a next step in jurisdictions that are strengthening demand reduction measures or already have strong measures in place. At present, Australia is the only WHO Member State to have taken this next step by implementing plain packaging. France, Ireland and the UK have each passed laws requiring implementation of plain packaging in 2016.

1.1 A working definition of plain packaging

The concept of plain packaging (sometimes referred to as standardized packaging) is defined in guidelines for implementation of Articles 11 (Packaging and labelling of tobacco products) and 13 (Tobacco advertising, promotion and sponsorship) of the WHO FCTC. These guidelines were drafted by working groups comprised of representatives of the Parties to the Convention. The working groups relied on available scientific evidence and the experience of the Parties themselves. Draft versions of the guidelines were open for consultation with all Parties before their submission to the Conference of the Parties to the WHO Framework Convention on Tobacco Control, which subsequently adopted the guidelines by consensus. Accordingly, given the authoritative character of the guidelines, this paper uses the definition of plain packaging in the guidelines, which must be read in the broader context of Articles 11 and 13.

Article 11 obliges Parties to implement "effective measures" to ensure that tobacco packaging and labelling do not promote tobacco products by means that are false, misleading or deceptive (Article 11.1(a)) and to ensure that tobacco packaging carries health warnings describing the harmful effects of tobacco use (Article 11.1(b)). The relevant passages state:

> 1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:
> (a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild"; and
> (b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:
> (i) shall be approved by the competent national authority,
> (ii) shall be rotating,
> (iii) shall be large, clear, visible and legible,
> (iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,
> (v) may be in the form of or include pictures or pictograms.

Guidelines for Implementation of Article 11 "are intended to assist Parties in meeting their obligations under Article 11 of the Convention, and to propose measures that Parties can use to increase the effectiveness of their packaging and labelling measures."[2] The Guidelines were adopted by consensus of the Conference of the Parties to the WHO Framework Convention on Tobacco Control. The process through which this occurred is described in Box 1.

With respect to plain packaging, paragraph 46 of the Guidelines states:

> Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others.

This passage is set out in a broader context of other packaging and labelling measures. For example, the Guidelines stress that the terms and descriptors referred to in Article 11.1(a) are misleading or deceptive, but that the list is not exhaustive.[3]

Similarly, with respect to health warnings, paragraph 3 states:

> Globally, many people are not fully aware of, misunderstand or underestimate the risks for morbidity and premature mortality due to tobacco use and exposure to tobacco smoke. Well-designed health warnings and messages on tobacco product packages have been shown to be a cost-effective means to increase public awareness of the health effects of tobacco use and to be effective in reducing tobacco consumption. Effective health warnings and messages and other tobacco product packaging and labelling measures are key components of a comprehensive, integrated approach to tobacco control.

The Guidelines also provide specific guidance with respect to the size of health warnings. The Parties recognize that the effectiveness of health warnings increases with their size. Paragraph 12 states:

> Article 11.1(b)(iv) of the Convention specifies that health warnings and messages on tobacco product packaging and labelling should be 50% or more, but no less than 30%, of the principal display areas. Given the evidence that the effectiveness of health warnings and messages increases with their size, Parties should consider using health warnings and messages that cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible. The text of health warnings and messages should be in bold print in an easily legible font size and in a specified style and colour(s) that enhance overall visibility and legibility.

In summary, the Guidelines for Implementation of Article 11 recommend that Parties consider adoption of plain packaging in addition to other packaging and labelling measures, including health warnings that cover as much of the principal display areas as possible and other measures prohibiting misleading packaging.

Article 13 obliges Parties to undertake a comprehensive ban (or restrictions)[4] on tobacco advertising, promotion and sponsorship. The phrase "tobacco advertising and promotion" is defined in Article 1(c) as "any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly." As is the case with Article 11, the Guidelines for Implementation of Article 13[5] recommend that Parties consider implementing plain packaging. The relevant passages of Article 13 of the FCTC state:

> 1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.
> 2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and

sponsorship. This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

3. A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, restrictions or a comprehensive ban on advertising, promotion and sponsorship originating from its territory with cross-border effects. In this respect, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.
4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:
   (a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;
   (b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;
   (c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;
   (d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties, pursuant to Article 21;
   (e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and
   (f) prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.
5. Parties are encouraged to implement measures beyond the obligations set out in paragraph 4.

The Guidelines for Implementation of Article 13 address packaging and product features relevant to tobacco advertising, promotion and sponsorship. Paragraphs 15 and 16 state:

15. Packaging is an important element of advertising and promotion. Tobacco pack or product features are used in various ways to attract consumers, to promote products and to cultivate and promote brand identity, for example by using logos, colours, fonts, pictures, shapes and materials on or in packs or on individual cigarettes or other tobacco products.
16. The effect of advertising or promotion on packaging can be eliminated by requiring plain packaging: black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer's name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and

standardized shape, size and materials. There should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products.

The following recommendation is made in paragraph 17:

Packaging and product design are important elements of advertising and promotion. Parties should consider adopting plain packaging requirements to eliminate the effects of advertising or promotion on packaging. Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive.

In summary, the Guidelines for Implementation of Article 13 recognize that tobacco packaging is used as a means of tobacco advertising and promotion and recommend implementation of plain packaging for purposes of restricting use of packaging in that way.

Box 1. Process for adoption of the guidelines for implementation of Articles 11 and 13

Article 7 of the WHO FCTC specifies that the Conference of the Parties to the Convention shall propose appropriate guidelines for implementation of Articles 8–13. At the first session of the Conference of the Parties (Geneva, 6-17 February 2006), the Parties issued a decision on elaboration of guidelines for implementation of the Convention. At its second session (Geneva, 30 June-6 July 2007) the Conference of the Parties established working groups mandated to submit draft guidelines for implementation of Articles 11 and 13 to the Conference of the Parties at its third session (Durban, South Africa, 17-22 November 2008). In each case, participation in the working groups was open to each Party to the Convention, which could nominate itself to serve as either as a Key Facilitator or Partner within the working groups.

In the case of the Guidelines for implementation of Article 11, the first meeting of the working group was held in Manila (7-9 November 2007). The working group formed a drafting group that sent a first draft of the guidelines to members of the working group in February 2008. On 4-5 March 2008 the working group met in Brasília and formulated a second draft of the guidelines, taking account of the comments received from members of the working group on the first draft. In May 2008, the second draft of the guidelines was made accessible to all Parties via a password-protected website. Comments from Parties were distributed to the working group and the Key Facilitators subsequently amended the draft. In August 2008, the Convention Secretariat published the draft guidelines on its public website. In November 2008, the Conference of the Parties at its third session adopted the Guidelines for Implementation of Article 11 in decision FCTC/COP/3(10) by consensus.

In the case of the Guidelines for Implementation of Article 13, a similar process was followed. On 27-29 November 2007, the relevant working group held its first meeting in Helsinki. The Key Facilitators were mandated by the working group to continue drafting in advance of the second meeting of the working group (New Delhi, 31 March-2 April 2008). At that meeting, the working group mandated the Key Facilitators to finalize the draft. In May 2008, the Convention Secretariat made the draft available to all Parties via a password-protected website. Comments from Parties were distributed to the working group and the Key Facilitators subsequently amended the draft. In September 2008, the Convention Secretariat published the draft guidelines on its public website. In November 2008, the Conference of the Parties at its third session adopted the Guidelines for Implementation of Article 13 in decision FCTC/COP/3(12) by consensus.

1.2 Purposes of plain packaging

When viewed in the context of the WHO FCTC, and particularly Articles 11 and 13, plain packaging serves several purposes, including:

1. reducing the attractiveness of tobacco products;
2. eliminating the effects of tobacco packaging as a form of advertising and promotion;
3. addressing package design techniques that may suggest that some products are less harmful than others; and
4. increasing the noticeability and effectiveness of health warnings.

As this suggests, reducing the prevalence of tobacco use is not the sole objective of plain packaging as envisaged in the WHO FCTC. Plain packaging serves a number of intermediate purposes in order to strengthen measures to reduce demand for tobacco products.

Notwithstanding the purposes envisaged in the WHO FCTC, WHO Member States can define their own purposes and objectives for implementing plain packaging. As is discussed in Part 3 (Legal issues), the way in which a Member State defines the purposes and objectives of plain packaging can affect the defensibility of plain packaging measures in the event of a legal challenge. In this respect, it is important to ensure that the objectives of a plain packaging measure are set out in clear terms, that available evidence supports achievement of those objectives and that the impact of the policy can be monitored in light of the objectives.

In Australia, for example, section 3 of the Tobacco Plain Packaging Act 2011 describes the objectives of the legislation in the following terms:

> (1) The objects of this Act are:
>
> (a) to improve public health by:
>
> (i) discouraging people from taking up smoking, or using tobacco products; and
>
> (ii) encouraging people to give up smoking, and to stop using tobacco products; and
>
> (iii) discouraging people who have given up smoking, or who have stopped using tobacco products, from relapsing; and
>
> (iv) reducing people's exposure to smoke from tobacco products; and
>
> (b) to give effect to certain obligations that Australia has as a party to the Convention on Tobacco Control.
>
> (2) It is the intention of the Parliament to contribute to achieving the objectives in subsection (1) by regulating the retail packaging and appearance of tobacco products in order to:
>
> (a) reduce the appeal of tobacco products to consumers; and
>
> (b) increase the effectiveness of health warnings on the retail packaging of tobacco products; and
>
> (c) reduce the ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products.[6]

The purpose of the Irish plain packaging measure is described in the Explanatory and Financial Memorandum accompanying the Public Health (Standardised Packaging of Tobacco) Bill 2014. The Explanatory and Financial Memorandum first recognizes the place of plain packaging within Ireland's broader tobacco control agenda, stating:

> Ireland's public health policy objective in relation to tobacco control is to promote and subsequently move toward a tobacco free society. Tobacco Free Ireland, the policy document approved by Government in July 2013, builds on existing tobacco control policies and legislation already in place in this country, and sets a target for Ireland to be tobacco free (i.e. with a prevalence rate of less than 5%) by 2025.
>
> The Government is implementing a comprehensive suite of reforms to reduce smoking and its harmful effects. As part of these reforms the Government committed to introduce legislation requiring standardised packaging of tobacco products, to remove one of the last remaining frontiers for tobacco advertising. [7]

In this context, the purpose of the Bill was expressed in the following terms:

> The Bill will control the design and appearance of tobacco products and packaging. This means that all forms of branding — trademarks, logos, colours and graphics — would be removed from packaging, except for the brand and variant names, which would be presented in a uniform typeface for all brands on the market. All packs would be in a plain neutral colour, except for the mandatory health warnings and other items provided for by law. It is intended that this Bill will operate alongside other regulatory mechanisms for tobacco products and packaging generally.
>
> The regulation of the appearance of tobacco products and packaging is intended to contribute to improving public health by:
>
> - reducing the appeal of tobacco products to consumers;
> - increasing the effectiveness of health warnings on the retail packaging of tobacco products; and
> - reducing the ability of the packaging of tobacco products to mislead consumers about the harmful effects of smoking.[8]

The Explanatory Memorandum also states that the Bill was intended to give effect to the 2014 European Union Tobacco Products Directive[9] as well as to give effect to Ireland's obligations under the WHO FCTC. In the latter respect, the Explanatory Memorandum explicitly mentions Ireland's obligation to develop and implement comprehensive national tobacco control strategies under Article 5, as well as obligations with respect to packaging and labelling under Article 11 and advertising, promotion and sponsorship under Article 13.

In the UK, the objectives of standardized packaging were described in a public consultation document as follows:

> The objectives of a policy for standardised packaging would be to improve public health by:
>
> - discouraging people from starting to use tobacco products
> - encouraging people to give up using tobacco products
> - helping people who have given up, or are trying to give up, using tobacco products not to start using them again
> - reducing the appeal or attractiveness of tobacco products
> - reducing the potential for elements of the packaging of tobacco products other than

health warnings to detract from the effectiveness of those warnings
- reducing opportunities for the packaging of tobacco products to mislead consumers about the effects of using them
- reducing opportunities for the packaging of tobacco products to create false perceptions about the nature of such products
- having an effect on attitudes, beliefs, intentions and behaviours relating to the reduction in use of tobacco products
- reshaping social norms around tobacco use to promote health and wellbeing.[10]

In France, a press release concerning the national programme for reduction of tobacco use identified a number of reasons for the introduction of plain packaging. These include improving the effectiveness of health warnings, reducing consumer misinformation concerning the dangers associated with tobacco products, neutralizing the attractiveness of packaging and branding, particularly for young people, and improving recall of health warnings by adolescents.[11]

As these passages demonstrate, plain packaging serves multiple objectives within the broader context of efforts to reduce demand for tobacco products. Slight differences in the purposes pursued by different WHO Member States might be attributed to factors such as differences in the tobacco control context in countries, differences in legal and regulatory traditions and different policy priorities. Slight differences in objectives may also affect how Member States implement plain packaging. It is important to stress, however, that the objectives identified above are consistent with one another and with the objectives set out in the guidelines for implementation of Articles 11 and 13 of the WHO FCTC.

1.3 The evidence base underlying plain packaging

The rationales for implementing plain packaging, and the objectives described above, are linked to a growing body of empirical evidence concerning the effects of the measure. In short, a strong evidence base underlies implementation of plain packaging. A body of peer-reviewed evidence in the form of experimental studies, focus groups and surveys has tested different forms of plain packaging in different places. Although individual studies each have their limitations, when viewed together the body of evidence permits generally applicable conclusions to be drawn regarding plain packaging. These conclusions include that plain packaging reduces the attractiveness of tobacco products, restricts use of the pack as a form of advertising and promotion, limits misleading packaging and increases the effectiveness of health warnings.

Although it is too early to measure the full impact of plain packaging as implemented in Australia, the evidence to date is consistent with this broader body of evidence (discussed below) and with the conclusion that plain packaging has contributed to reduction of the prevalence of tobacco use in Australia.

This sub-section gives an overview of the rationale for and evidence base underlying plain packaging.

1.3.1 The attractiveness of tobacco products and the advertising function of branding

Tobacco packaging is a prominent form of tobacco advertising and promotion. As internal tobacco industry documents recognize, packaging plays an increasingly important role in promoting tobacco products as other restrictions on tobacco advertising and promotion are tightened.[12]

Tobacco packs promote tobacco consumption not only at the point of sale, but also after the point of sale. Consumers display tobacco packaging when they use tobacco products, when they offer tobacco products to others and in other ways, such as by placing branded packaging on display in a social setting. In this way, tobacco products are “badge products”, meaning that they have a high degree of social visibility and that consumers identify with the brand image cultivated on product packaging. As counsel for Japan Tobacco International stated in domestic court proceedings concerning plain packaging in Australia, tobacco packaging functions like a billboard.[13] The advertising function served by tobacco packaging has also been targeted specifically at youth[14] in a context where many consumers of tobacco products become addicted before reaching adulthood.[15] It is estimated that approximately 10% of students between the ages of 13 and 15 years smoke cigarettes worldwide. Additionally, among these same students, almost 20% of those who had never smoked cigarettes indicated they were susceptible to initiate smoking during the next year.[16]

A substantial number of peer-reviewed studies that examine plain packaging support the conclusion that the measure reduces the attractiveness and appeal of tobacco products. This body of evidence includes results from recent experimental studies from Australia,[17] Brazil,[18] Canada,[19] New Zealand[20] and the United States of America (USA)[21], survey evidence from Australia,[22] France,[23] the UK,[24] the USA,[25] and focus group studies from New Zealand[26] and the United Kingdom.[27]

Some of these studies also examine smoking attitudes and behaviour, such as the question whether plain packaging influences the intention of smokers to quit, and suggest that this is indeed the case.[28] Although intention does not necessarily indicate future behavior, it is nonetheless a precursor to behavioural change.

Evidence from Australia’s implementation of plain packaging is consistent with the conclusion that plain packaging reduces the attractiveness and appeal of tobacco products. For example, studies have demonstrated a reduction in active smoking, and a sustained reduction in the display of tobacco packs, in outdoor settings.[29] This not only suggests that smokers treat tobacco packaging as less attractive, but also that plain packaging has reduced public exposure to tobacco packaging as a form of marketing.

Evidence from Australia’s implementation of plain packaging also supports the conclusion that plain packaging encourages quitting. This evidence includes studies

showing increased urgency among smokers to quit,[30] a significant and sustained increase in calls to the Quitline (a service that assists consumers in quitting tobacco use),[31] and increased rates of quitting cognitions and quit attempts among adult smokers.[32]

1.3.2 Misleading tobacco packaging

As is evident in Article 11 of the WHO FCTC (discussed above), tobacco branding, including that on packaging, may mislead consumers with respect to the health consequences of consuming different tobacco products. “Light”, “mild” and similar brand variants are misleading to consumers because they suggest that the products with which they are associated are less harmful to health than regular brand variants, when this is not the case.[33] Rather, consumers compensate for the lower tar and nicotine yields in these products, including by smoking more of a cigarette and taking deeper puffs. Machine tests for tar and nicotine yields are also affected by small holes in cigarette filters that are partially blocked by a smoker’s fingers during inhalation.[34]

Notwithstanding bans on misleading descriptors, consumers maintain erroneous views about the risks associated with different tobacco products.[35] This is partly because colours and other elements of package design have been used to preserve misleading brand extensions in the absence of descriptors. Evidence of this comes from numerous sources, including the USA where an Altria brochure, concerning Philip Morris USA products, was distributed to retailers.[36] That brochure showed the new pack identifiers associated with misleading brand variants and enabled retailers to assist consumers in identifying those variants after misleading descriptors were banned from packaging. For example, Marlboro Lights became Marlboro Gold and Marlboro Ultra Lights became Marlboro Silver. The brochure also indicated that “some cigarette and smokeless packaging is changing, but the product stays the same”. In this context, a nationally representative survey of smokers in the USA conducted one year after the ban on misleading descriptors came into effect found that 92% of smokers reported that they could easily identify their usual brands and 68% correctly named the package colour associated with their usual brand by the banned descriptor name.[37]

In this and other ways, there is a strong association between packaging design and how consumers perceive risk.[38] For example, different variants of one tobacco brand can in themselves be misleading to consumers, particularly when presented in the course of trade alongside one another and regular or full flavoured brands. One reason for this is that people try to find attributes among brand variants.[39] Another reason is that packaging, and particularly colour, affects consumers’ perceptions of risk. Early evidence of this can be found in internal tobacco industry documents released to the public through litigation. For example, a 1990 tobacco industry document recognized that so-called “lower delivery products” were featured in lighter packs because they have a clean healthy connotation.[40]

This observation is consistent with other internal tobacco industry documents, including studies that tested consumer reactions to ultra-light products packaged in different colour packs.[41] These reactions included consumers ranking the perceived tar level of products in different colour packs[42] and commenting on factors such as the harshness and strength of the flavour of different colour packs with otherwise identical products inside them.[43]

Against this backdrop, recent peer-reviewed studies suggest that plain packaging will minimize the tendency of tobacco packaging and brand variants to mislead consumers concerning the relative health consequences of different products. This evidence includes the results of experimental studies from Australia,[44] Brazil,[45] and Canada,[46] survey evidence from Australia,[47] France,[48] the UK,[49] and the USA,[50] and a focus group study from the UK.[51]

It is also reasonable to expect that the impact of plain packaging on misperceptions of harm will increase over time as recall of misleading packaging fades. Despite this, the early evidence from Australia suggests that plain packaging has already reduced consumer misperceptions of harm. A national cross-sectional tracking survey found a statistically significant increase in the proportion of adult smokers who believed that brands do not differ in harmfulness (69.8%) during the first year of implementation as compared with the period before implementation (65.7%).[52]

1.3.3 The effectiveness of health warnings

Health warnings inform consumers and non-consumers about the risks associated with use of tobacco products and discourage tobacco consumption. Branding on tobacco packaging distracts from health warnings, reducing the ability of warnings to inform consumers and discourage tobacco consumption.

A number of peer-reviewed studies suggest that plain packaging increases the salience of health warnings on tobacco packaging. This body of evidence includes experimental studies from Australia[53] and Canada,[54] as well as survey evidence from Australia.[55] These studies are consistent with a separate body of evidence, which suggests that the effects of health warnings increase with their size.[56] Importantly, the evidence suggests plain packaging also has effects above and beyond those of large health warnings.[57]

As is described below in Part 2, Australia updated (including introducing new warnings) and increased the size of graphic health warnings on tobacco products at the same time plain packaging was introduced. Although it is difficult to isolate the impact of each action, early evidence is consistent with the conclusion that the policy change is increasing the effectiveness of health warnings in Australia. That body of early evidence focuses on the effects of the change on adult smokers (as opposed to non-smokers) and includes studies that found smokers noticed the warnings more.[58] In addition, more smokers attributed intention to quit to the warnings, avoided specific warnings and covered packs, all of which may indicate effectiveness.[59]

1.3.4 The prevalence of tobacco use

As the discussion in Part 1 indicates, reducing the prevalence of tobacco use is not the sole regulatory objective of plain packaging. The measure serves several intermediate public health objectives associated with complementing other approaches to demand reduction. Nonetheless, it is rational and reasonable to expect that the prevalence of tobacco use will decline as tobacco packaging becomes less attractive, misleading packaging is minimized and health warnings become more effective.

Because plain packaging is intended to be implemented as part of a comprehensive multisectoral approach to tobacco control, and to strengthen existing tobacco control

measures, it will ordinarily be difficult to isolate the impact of plain packaging on the prevalence of tobacco use. For example, in the Australian context, plain packaging was implemented alongside, and interacts with, a number of existing measures, including those identified in Part 2. New measures, such as tax increases, enlarged health warnings and increased cessation support, were also announced at the same time as plain packaging. As plain packaging interacts with existing measures and takes effect with new measures it may be methodologically difficult to attribute declining tobacco use to any one measure.

The impacts of plain packaging can also not be evaluated in a comprehensive manner in the short-term. The policy may have impacts on consumers and non-consumers of tobacco products that are observable in the short-term, such as those described above. These impacts may also have flow-on effects on the prevalence of tobacco use in the short-term. However, plain packaging may also have longer-term impacts as the promotional and misleading impact of tobacco packaging declines over time. In particular, it might be expected that the impact of plain packaging on the prevalence of tobacco use will increase as children reach the age of initiation without ever having observed fully-branded tobacco packaging.

Since the introduction of plain packaging, the Australian government has observed declining total expenditure on tobacco products and declining customs and excise clearances on tobacco products.[60] Statistics also show that a decline in smoking prevalence has continued in Australia. These figures include the following.

- The National Drug Strategy Household Survey for 2013 showed a reduction in the prevalence of daily smokers aged 14 years or over to 12.8% in 2013, compared with 15.1% in 2010.[61]
- The Australian Secondary Students' Alcohol and Drug survey found that in 2014 only 5.1% of 12–17 year olds are current smokers, compared with 6.7% in 2011.[62]
- In the National Health Survey rates of daily smoking among adults (18 years and older) have continued to drop, to 14.5% in 2014-15, compared with 16.1% in 2011-12 and 22.4% in 2001.[63]

Although these studies were not designed specifically to measure the impact of plain packaging, the figures show a correlation between plain packaging, reduced total consumption and reduced prevalence of smoking. Importantly, these official government statistics are consistent with the broader body of evidence set out above.

Moreover, the Australian government released a formal post-implementation review of tobacco plain packaging in February 2016. The review concluded that the measure has begun to achieve its public health objectives.[64] With respect to the impact of the measure on prevalence, the review relies on an expert analysis, which found a statistically significant reduction in the prevalence of consumption attributable to the 2012 changes to tobacco packaging (including the updated and expanded health warnings discussed below). More specifically, the analysis estimated that between December 2012 and September 2015 "the 2012 packaging changes reduced average smoking prevalence among Australians aged 14 years and over by 0.55 percentage points".[65] The report of the analysis also states that the effect is likely understated and expected to grow over time.[66] In short, plain packaging has reduced smoking prevalence in Australia beyond the pre-existing downward trend.

In conclusion, peer-reviewed studies point in one direction and confirm the merits of plain packaging. These studies find further support in the real world experience of Australia.

Nonetheless, tobacco companies have commissioned studies to dispute the impact of the measure; the credibility of these studies is questionable because they have been commissioned by tobacco companies, are not supported by independent studies published in respected peer-reviewed journals and are inconsistent with a far larger body of evidence. The Cancer Council Victoria (Australia) has undertaken more detailed critiques of these industry commissioned studies,[67] which are also addressed in Australia's post-implementation review.

1.3.5 Expert reviews of the evidence

Expert reviews of the evidence base underlying plain packaging include a report prepared by the Australian Preventative Health Taskforce (discussed in Part 2),[68] a review of the evidence prepared by Quit Victoria and Cancer Council Victoria in Australia,[69] and systematic reviews of the evidence commissioned by Ireland and the UK. These reviews examine the empirical evidence and have produced conclusions that are consistent with the evidence summarized above.

1.3.5.1 The UK public health research consortium review and update

In 2011, before implementation of plain packaging in Australia, the UK Department of Health commissioned a review of the evidence concerning the impacts of plain tobacco packaging on public health.[70] The Public Health Research Consortium, including researchers from respected UK academic institutions, conducted the review. The review examined 37 primary research studies with a variety of study designs across a number of disciplines.

The review examined the impact of plain packaging on the appeal of cigarettes, packs and brands and found inter alia consistent conclusions that plain packs were rated as less attractive than branded packaging and that plain packs were rated as containing poorer quality products.[71] Among the studies that examined subgroup differences, non-smokers and younger respondents tended to find plain packs less appealing than smokers and older respondents respectively.[72] The review found that plain packaging may increase the salience of health warnings, although this depends on other conditions such as the size, type and position of the warnings.[73] Perceptions of the harmfulness of tobacco products were found to depend primarily on the colour of packaging, with darker plain packs seen as more harmful.[74] The evidence on smoking-related attitudes, beliefs, intentions and behaviour was mixed, but supportive of the general conclusion that plain packaging would affect behaviour.[75]

Following criticism of the review by the tobacco industry, some of the experts released an update to the research in September 2013, which included 17 published studies that had not been included in the original review. It was concluded in this update that the findings of these studies "suggest that plain packaging would: reduce the appeal of cigarettes and smoking; enhance the salience of health warnings on packs; and address the use of packaging elements that mislead smokers about product harm."[76]

1.3.5.2 The Chantler review in the UK

In November 2013 the UK Parliamentary Under Secretary for Public Health invited Professor Sir Cyril Chantler to advise with respect to the public health impact of standardized packaging.[77] The terms of reference asked Professor Chantler:

> [t]o give advice to the Secretary of State for Health, taking into account existing and any fresh evidence, as to whether or not the introduction of standardised packaging is likely to have an effect on public health (and what any effect might be), in particular in relation to the health of children.[78]

Professor Chantler undertook a review of the evidence, consulted with interested parties, commissioned expert advice to assist in qualitative analysis of the key evidence, including the studies reviewed in the Public Health Research Consortium Review and Update, and undertook field research in Australia. The subsequent report, which was released in April 2014, examined three questions.

First, the report examined whether branded packaging promotes tobacco consumption, especially by encouraging children to take up smoking. On this question, the report concluded:

> In my opinion, the balance of evidence suggests that the appeal of branded packaging acts as one of the factors encouraging children and young adults to experiment with tobacco and to establish and continue a habit of smoking. As British American Tobacco Australia's spokesman acknowledged in our meeting, tobacco companies, like other consumer goods companies, see branded packaging as one of the tools of marketing. This is supported by numerous internal tobacco industry documents. Although the tobacco industry says that the purpose of branded packaging is to encourage brand switching only, they cannot explain how it would only ever attract switchers from one brand to another, and would never encourage initiation from non-smokers or increased overall consumption. Further, they have not been able to explain why, given that advertising and promotion are proven to increase tobacco consumption, the related marketing tool of branded packaging (referred to by Japan Tobacco International's counsel against the Australian Government as their mobile "billboard") should so differ in its effect.[a79]

Secondly, the report examined whether standardized packaging is likely to lead to a reduction in the consumption of tobacco. On this question, the report first considered possible intermediate effects of plain packaging, such as effects on the attractiveness of tobacco products, the salience of health warnings, perceptions of the harmfulness of different products and smoking-related intentions. The report concluded that, although the overall size of the effect cannot be calculated, the evidence base for these intermediate conclusions is methodologically sound and that criticisms made by the tobacco industry are without merit. The report states "[t]aken together the studies and reviews based on them put forward evidence with a high degree of consistency across more than 50 studies of differing designs, undertaken in a range of countries. This conclusion is not seriously undermined by the criticisms made, many of which reflect necessary constraints on study design. This is confirmed by the independent analysis I commissioned."[80]

The report went on to make findings concerning the evidence, stating:

> I am of the opinion that on the basis of the evidence I have seen, it is likely that standardised packaging will result in smokers and potential smokers acquiring more negative feelings about smoking. They will be less deceived into thinking that some brands are healthier than others and that therefore health warnings apply less to them. Susceptible children and young adult smokers will be less likely to associate particular brands with the peers they want to emulate. Health warnings will be more credible, memorable and effective when not confusingly juxtaposed with attractive branded packaging. This is, in turn likely to lead to behavioural changes such as smokers hiding their cigarette packets, thereby diminishing their role in creating an exaggerated view of smoking as a social norm. This may help to make smoking seem less "normal" and therefore less desirable to children to take up smoking to 'fit in' with peers.[81]

Thirdly, the report examined whether it is likely that standardized packaging will lead to an increase in tobacco consumption by lowering the price of tobacco as the market is commoditized or by increasing the consumption of illicit products. The report concluded that the risks of prices falling are small and can be mitigated through taxation and that the solution to illicit trade lies in an effective enforcement regime.[82]

1.3.5.3 The Irish Department of Health Review

In March 2014, the Irish Department of Health released an evidence review on standardized packaging of tobacco products prepared by David Hammond of the University of Waterloo (Ontario, Canada). Reviewing the evidence he examined a total of 75 original empirical articles. The review states:

> The evidence indicates that tobacco packaging is a critically important form of tobacco promotion, particularly in jurisdictions with comprehensive advertising and marketing restrictions, such as Ireland. The evidence indicates that plain packaging reduces false beliefs about the risks of smoking, increases the efficacy of health warnings, reduces consumer appeal among youth and young adults, and may promote smoking cessation among established smokers.[83]

The report also concluded that:

> Overall, there is very strong evidence that plain packaging would be effective in regards to four of Ireland's specific policy objectives:
>
> - Prevent non-smokers including children and young people from starting to smoke
> - Encourage, motivate and support current smokers to quit
> - Reduce recidivism rates among those who have quit
> - Limit the societal impacts of smoking and protect society, especially those under 18 years, from the marketing practices of the tobacco industry.[84]

Although this is an original review of the evidence separate from the UK reviews, it complements the conclusions drawn therein.

1.3.6 Conclusions

In summary, there is a large body of empirical evidence in the form of the results of experimental studies, surveys and focus group studies that provide an evidence base for introduction of plain packaging. This empirical evidence suggests that plain packaging makes health warnings, restrictions on tobacco advertising, promotion and sponsorship and restrictions on misleading tobacco packaging more effective. This evidence base has been relied upon and supported by expert reviews in Australia, Ireland and the UK. Moreover, early evidence from Australia, where plain packaging has been implemented, is consistent with the conclusion that plain packaging is an effective public health intervention.

Additional resources

The WHO Framework Convention on Tobacco Control

- Text of the Convention, available at http://www.who.int/fctc/text_download/en/.
- Guidelines for Implementation of Article 11 of the WHO Framework Convention on Tobacco Control, available at http://www.who.int/fctc/treaty_instruments/adopted/article_11/en/.
- Guidelines for Implementation of Article 13 of the WHO Framework Convention on Tobacco Control, available at http://www.who.int/fctc/treaty_instruments/adopted/article_13/en/.

Evidence reviews

- Moodie C et al, Plain tobacco packaging: a systematic review, Public Health Research Consortium, (2011), available at http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf.
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- Standardised packaging of tobacco, Report of the Independent Review undertaken by Sir Cyril Chantler, (April 2014), available at http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF.
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Websites

- Post-Implementation Review Tobacco Plain Packaging, Australian Government, http://ris.dpmc.gov.au/2016/02/26/tobacco-plain-packaging/.
- Evaluation of tobacco plain packaging in Australia, Australian Government, http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-plain-packaging-evaluation.
- Tobacco key facts and figures, Australian Government, http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-kff.
- Plain Facts, the Cancer Council Victoria https://www.cancervic.org.au/plainfacts/.
- Fact sheet no. 1: What has been the impact of legislation to standardise the packaging of tobacco products in Australia? Cancer Council Victoria, available for download at

https://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=factsheets1.

- Fact sheet no. 2: What has happened to sales of tobacco products since the implementation of plain packaging in Australia? Cancer Council Victoria, available for download at https://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=factsheets1.
- Fact sheet no. 4: What is happening to the prevalence of smoking in Australia? Cancer Council Victoria, available for download at https://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=factsheets1.

PART 2

Policy design and implementation

This chapter describes the policy design processes undertaken in Australia, France, Ireland and the UK, how plain packaging has been approached in those countries and identifies some issues addressed in the context of compliance and enforcement.

2.1 The policy design process

The policy design process will differ from one jurisdiction to another depending on domestic practice and the extent to which legislative as compared to regulatory action is required. In each jurisdiction that has passed plain packaging into law, a careful, detailed and prolonged process of policy design was undertaken.

In Australia, there were many steps over several years. For example, in April 2008, the Australian Government formed the National Preventative Health Taskforce, which was comprised of well-qualified and respected public health experts. The Taskforce was tasked with developing evidence based advice and strategies to address the burden of health challenges caused by alcohol, obesity and tobacco in Australia. In October 2008 the Taskforce released a discussion paper and technical papers that formed the basis for a consultative process that involved 40 consultations with nearly 100 stakeholders. Following the consultation process, on 1 September 2009, the Taskforce launched its National Preventative Health Strategy, entitled "Australia: the healthiest country by 2020."[85]

As part of the Taskforce report a tobacco working group considered the state of tobacco control in Australia and evidence of the likely effect of plain packaging alongside other tobacco control policies before recommending that Australia implement the measure.[86] With respect to the evidence, the working group stated in part:

> Cigarette brand names and package design enable the communication of personal characteristics, social identity and aspirations,[a] and are a crucial aspect of marketing the product[b, c] Consumer research indicates that decreasing the number of design elements on the packet reduces its appeal and perceptions about the likely enjoyment and desirability of smoking.[d] Requiring cigarettes to be sold in plain packaging would reinforce the idea that cigarettes are not an ordinary consumer item. It would also reduce the potential for cigarettes to be used to signify status. Plain packaging would increase the salience of health warnings: research subjects show an improved ability to recall health warnings on plain packs.[e,f,g]

In May 2010, the Australian Government responded to the report and indicated its intention to introduce plain packaging.[87] The Government then initiated targeted consultations with industry and retail organizations and commissioned consumer research. In the latter respect, the Government commissioned a company to conduct consumer and market research between December 2010 and March 2011 to "assess the potential plain packaging design elements to determine which plain packaging options were optimal to achieve the policy objectives [of the plain packaging legislation]". To perform this task, the company sought to assess the optimal combination of colour, font and font size (for brand name), and graphic health warning size and layout.[88]

Almost a year after announcing its intention to implement plain packaging the Australian Government released an exposure draft of the Tobacco Plain Packaging Bill in April 2011 and opened a 60-day public consultation on the draft Bill. A modified Bill that took account of comments received during that consultation period was introduced into the Australian Parliament in July 2011, alongside another Bill to amend Australia's trademark law.

The Australian Government also consulted widely during and after the public consultation on the exposure draft of the legislation in developing more detailed regulations governing cigarettes and cigarette packaging. Additionally, two public consultations were held in the development of regulations applicable to non-cigarette tobacco products and their packaging.

Although this brief summary of the process does not capture all the key events in the policy-design process, it does illustrate the careful and consultative character of the policy design process in Australia. Similarly detailed and careful policy processes have been undertaken in France, Ireland and the UK.

In May 2013, the Irish Department of Health published an outline of a Bill to introduce plain packaging. This was followed by a regulatory impact analysis, public hearings conducted by the Joint Oireachtas Committee on Health and Children, publication of a review of the evidence commissioned by the Department of Health (discussed in Part 1), publication of a report by the Joint Oireachtas Committee on Health and Children, publication of the Bill and publication of a final regulatory impact assessment before the legislation was passed in March 2015.

Similarly, the UK Government published in March 2011 a public health white paper entitled "Healthy lives, healthy people: a tobacco control plan for England", which included a commitment to a public consultation on plain packaging before the end of that year. That consultation was held in August 2012 and accompanied by the release of the UK Public Health Research Consortium Review (discussed in Part 1). The results of the public consultation were published in July 2013. In February 2014 amendments were made to the Children and Families Bill, which would permit Parliament to introduce regulations for plain packaging. In April 2014 the Chantler Report (discussed in Part 1) was released. Subsequently, a consultation was conducted on the introduction of regulations, an impact assessment and equalities analysis was published, and an assessment on the potential impact on the illicit market was published before the Standardized Packaging of Tobacco Products Regulations 2015 were passed in March 2015 by Parliament.

In France, following domestic studies on plain packaging, the introduction of plain packaging was proposed as part of the 2014–2019 National Plan for the Reduction of Smoking. Subsequently, plain packaging was passed into law as part of a revision to the French Public Health Code, which delegated the task of establishing more detailed regulations governing plain packaging to the Council of State. These more detailed regulations were published in May 2015.

Leaving aside domestic policy processes, where plain packaging is to be implemented, the WHO FCTC and its guidelines:

- imply that plain packaging should apply to all categories of tobacco products;
- recommend that brand names and product names displayed in a standard colour and font style should be the only form of logo, colour, brand image or promotional information on packaging;[89]
- recommend that design features that make tobacco products more attractive to consumers such as animal or other figures, "fun" phrases, coloured cigarette papers, attractive smells, novelty or seasonal packs should be addressed in plain packaging laws;[90]
- recommend that the appearance of tobacco products (as opposed to retail

packaging) should be standardized;[91]
- recommend that Parties ensure that adhesive labels, stickers, cases, covers, sleeves, wrapping and promotional inserts and onserts do not obscure, obliterate or undermine health warnings and messages (and by implication, do not undermine the objectives of plain packaging);[92] and
- recommend that time allocated for implementation of packaging and labelling measures need only be enough to allow manufacturers and importers to organize the printing of new packages.[93]

Against this backdrop, related policy questions may include the following:

- how other plain or standardized aspects of retail packaging must appear, including colours and finish (gloss or matt);
- the extent to which differences across tobacco product categories should affect application;
- the extent to which, and in what form business or company names may appear on packaging;
- how plain packaging will be enforced, including who will be responsible for enforcement and what penalties will be imposed for non-compliance by different actors in the supply chain, such as importers, manufacturers and retailers; and
- whether repackaging of tobacco products after importation should be permitted as a means of meeting the requirements of a plain packaging law?

The design of a plain packaging measure is also closely related to other packaging and labelling measures. Specific issues for consideration include:

- the size of health warnings;
- where health warnings are located on product packaging, such as the top of packaging;
- how misleading elements of packaging, including descriptors, marks and symbols, are addressed;
- how information on constituents and emissions, including misleading information concerning tar and nicotine yields, is addressed;
- how information on ignition propensity is addressed;
- what smoking cessation information, if any, is included on product packaging;
- whether tax stamps or markings for purposes of tracking and tracing tobacco products are used on product packaging, including where and how they are placed;
- how barcodes may appear on packaging; and
- how any other government mandated information may appear on packaging.

As this implies, the form that plain packaging takes may differ slightly from one jurisdiction to another for a number of reasons. These include the fact that different jurisdictions may have slightly different objectives, that other packaging and labelling measures may differ, that other related tobacco control measures differ and that other conditions may necessitate differences in the approaches adopted. Nonetheless, plain packaging has certain core elements as defined in the guidelines for implementation of Articles 11 and 13 of the WHO FCTC, and these guidelines address many of the questions identified.

This section briefly describes how these and other policy questions have been addressed in Australia, France, Ireland and the UK. Subsection 2.2 describes Australia's approach before noting some differences from the approaches to be adopted by Member States of the European Union. Subsection 2.3 then addresses concerns relating to compliance and enforcement that have implications for the design of plain packaging.

2.2 Implementation of plain packaging

In Australia, tobacco plain packaging came into law through the Tobacco Plain Packaging Act 2011 and the Tobacco Plain Packaging Regulations 2011 (amended by the Tobacco Plain Packaging Regulations 2012). The legislation and regulations were also complemented by the Trade Marks Amendment (Tobacco Plain Packaging) Act 2011.

The Tobacco Plain Packaging Act 2011 was passed by the Australian Parliament and is the primary law requiring plain packaging in Australia. The Act sets out the objectives of plain packaging in Australia, specifies requirements for the retail packaging and appearance of tobacco products, and establishes offences and civil penalties for violation of the requirements. The Act also specifies that regulations may prescribe additional requirements with respect to the retail packaging and appearance of tobacco products.[94] These regulations may be made by the Governor-General,[95] meaning that they are made pursuant to a delegated authority and that it is not necessary for the Australian Parliament to approve them in order for the regulations to come into force.

The Tobacco Plain Packaging Regulations 2011 set out detailed requirements concerning the appearance of tobacco products and retail packaging. The Regulations define the permitted physical features of retail packaging, colour and finish of retail packaging, trademarks or marks on retail packaging, brand, business and company or variant names, wrappers, inserts or onserts, requirements for the appearance of cigarettes, and the appearance of other tobacco products.

The Tobacco Plain Packaging Act 2011 included provisions that set out the operation of that Act on the Trade Marks Act 1995. In this context, the Trade Marks Amendment (Tobacco Plain Packaging) Act 2011 complemented those provisions and provided, among other things, for regulations specific to the effect of the Tobacco Plain Packaging Act 2011 on the Trade Marks Act 1995. Importantly, nothing in Australia's law prohibited registration of trademarks, and Australia's law permitted trademark owners to protect their trademarks from non-use actions arising from implementation of the plain packaging law. This issue is discussed in further detail in Part 3 (Legal issues).

Before setting out the requirements of the law in further detail, there are some important points to note about the structure of the Australian law. First, in the absence of a preexisting delegated regulatory authority, it was necessary for the Australian Parliament to enact legislation in order for plain packaging to come into effect. Secondly, because plain packaging has implications for Australian trademark law, which is also found in an Act of Parliament, it was necessary for the Tobacco Plain Packaging Act 2011 to address

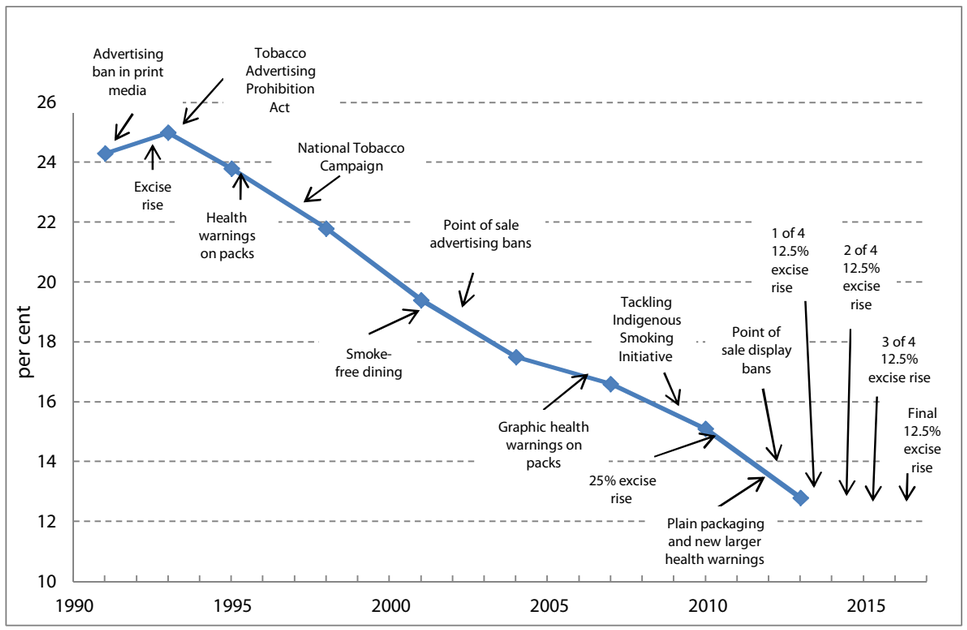
the relationship between these two bodies of law. Thirdly, by delegating power to the Governor-General to make regulations, the Act ensures that Australia can adapt many aspects of its law as circumstances dictate without having to seek parliamentary approval. This flexibility is important given that litigation has been used to challenge not only plain packaging per se, but also how the measure has been implemented.

As the description of the law set out above indicates, the Australian law concerning plain packaging applies both to the appearance of the product itself and to retail packaging. In addition, the law applies to all categories of tobacco products.

In Australia, plain packaging was also implemented alongside existing tobacco control measures, as well as a number of new measures. One related measure was to update and enlarge health warnings to require that they cover 75% of the front of most tobacco packaging, 90% of the back of cigarette packaging and 75% of the back of most other tobacco packaging. Tax increases were also implemented, with a 25% increase in tobacco excise in April 2010 followed by increases in excise and excise-equivalent customs duty of 12.5% on 1 December 2013, 1 September 2014 and 1 September 2015. A further increase is scheduled for 1 September 2016. The Government also increased investments in anti-smoking and social-marketing campaigns and increased penalties for smuggling offences.[96]

The historical context in which plain packaging and these measures were implemented is set out in Figure 1.

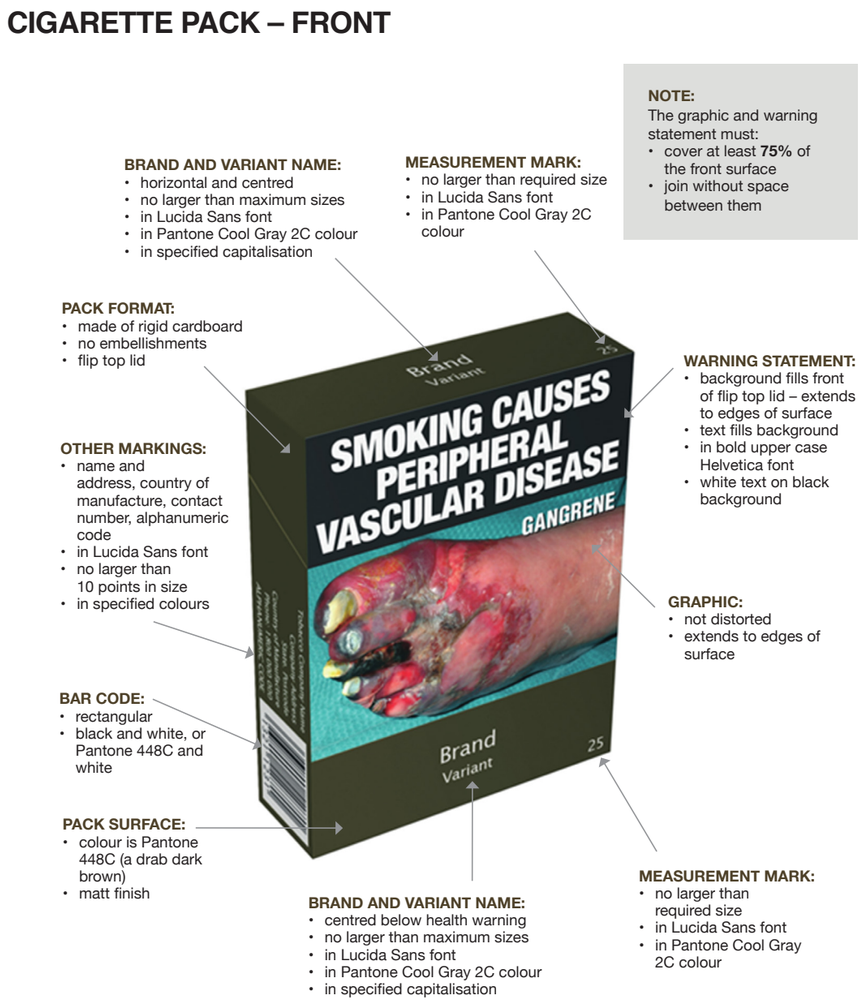
Figure 1. Smoking prevalence rates for persons 14 years or older and major tobacco-control measures implemented from 1990 to 2015



© Commonwealth of Australia
Source: http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-kff adapted from National Drug Strategy Household Survey 1991, 1993, 1995, 1998, 2001, 2004, 2007, 2010 and 2013.

The Australian Government has published guides to implementation of laws governing plain packaging in Australia.[97] These guides illustrate the main features of Australia's approach with respect to a range of tobacco products and provide a readily accessible means by which the law can be understood. Figures 2 and 3 show the requirements for the front and back of cigarette packs as set out in the guide. Figure 4 shows the requirements applicable to the cigarette itself as set out in the guide.

Figure 2. Requirements for the cigarette pack - front



© Commonwealth of Australia
Source: Tobacco Plain Packaging - Your Guide, Australian Government, Department of Health, 09 July 2014, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/tppbook#top

Figure 3. Requirements for the cigarette pack - rear

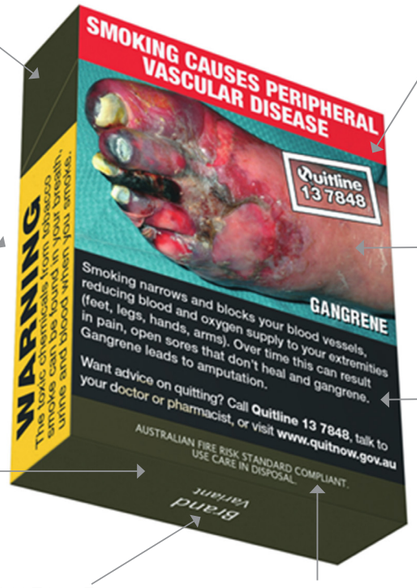
CIGARETTE PACK – BACK

NOTE:
The warning statement, graphic and explanatory message must:
- cover at least **90**% of the back surface
- join without space between them

PACK FORMAT:
- made of rigid cardboard
- no embellishments
- flip top lid

INFORMATION MESSAGE:
- background extends to edges of surface
- text fills background
- in Helvetica font
- in specified size, capitalisation and weighting
- black text on yellow background

PACK SURFACE:
- colour is Pantone 448C (a drab dark brown)
- matt finish



WARNING STATEMENT:
- background fills area above fold line of lid – extends to edges of surface
- text fills background
- in bold upper case Helvetica font
- white text on red background

GRAPHIC:
- not distorted
- extends to edges of surface
- includes Quitline logo

EXPLANATORY MESSAGE:
- background extends to edges of surface
- text fills background
- in Helvetica font
- in specified capitalisation and weighting
- white text on black background

BRAND AND VARIANT NAME:
- horizontal and centred
- no larger than maximum sizes
- in Lucida Sans font
- in Pantone Cool Gray 2C colour
- in specified capitalisation

FIRE RISK STATEMENT:
- below health warning
- no larger than 10 points in size
- in upper case Lucida Sans font
- in Pantone Cool Gray 2C colour

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Source: Tobacco Plain Packaging - Your Guide, Australian Government, Department of Health, 09 July 2014, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/tppbook#top

Figure 4. Requirements for the cigarette

FILTER TIP:
- white

PAPER OVER FILTER TIP:
- imitation cork or white

ALPHANUMERIC CODE:
- in specified position
- no larger than 8 points in size
- in Lucida Sans font
- in black
- not linked to cigarette name or emission yields

PAPER CASING:
- white
- no markings except optional alphanumeric code

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Source: Tobacco Plain Packaging - Your Guide, Australian Government, Department of Health, 09 July 2014, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/tppbook#top

As may be expected, the approaches to plain packaging in other countries are similar, but not identical to the approach in Australia. At the time of writing, Australia is the only jurisdiction in which plain packaging has been implemented. As of 1 January 2016, and as is set out below in Box 2, France, Ireland and the UK have each passed plain packaging laws to be implemented in May 2016.

A number of other WHO Member States are well advanced in the policy process. In December 2015, Hungary notified other European Union Member States that it intends to pass plain packaging into law in March 2016.[98] Also in 2015, Norway conducted a public consultation on plain packaging and it is expected that legislation will be introduced into the Norwegian Parliament in 2016. In 2015, the new Canadian health minister was given a mandate from the Prime Minister to introduce plain packaging.[99] Singapore is conducting

a public consultation on plain packaging until 29 March 2016.[100] Legislators in Chile will soon debate a proposed law to introduce plain packaging and governments in countries such as South Africa and Turkey are at advanced stages in considering implementation of plain packaging.

Box 2. Jurisdictions in which plain packaging laws have been passed as at 1 January 2016

Australia – The Tobacco Plain Packaging Act was adopted in 2011 and fully implemented in December 2012, including through the Tobacco Plain Packaging Regulations 2011.

Ireland – The Public Health (Standardised Packaging of Tobacco) Act 2015 was adopted in March 2015. Draft Public Health (Standardised Packaging of Tobacco) Regulations 2016 were notified to European Union Member States on 20 November 2015 in anticipation of the law coming into force in May 2016. Amendments to the Act are planned to ensure consistency with the Regulations.

France – A law on plain packaging was passed by the French Parliament in November 2015 as part of broader legislation to modernize the French health system. This followed notification to European Union Member States in May 2015 of how France intends to implement plain packaging through the Decree on the conditions of neutrality and standardization for the packaging and paper of cigarettes and rolling tobacco in May 2016. The final version of the law was published in the Official Gazette on 27 January 2016.

United Kingdom - The Standardised Packaging of Tobacco Products Regulations 2015 were passed in March 2016 and will come into force on 20 May 2016. The law applies to England, Wales, Scotland and Northern Ireland.

In the case of France, Ireland and the UK, plain packaging has yet to be implemented and will be implemented alongside the European Union's Tobacco Products Directive (2014/40/EU). This directive establishes a broader set of requirements governing packaging and labelling of tobacco products that European Union Member States are obliged to implement in their domestic laws. These requirements mean that some aspects of packaging and labelling measures in European Union Member States will differ from those in Australia (although the plain packaging laws are based on the same principles and will be implemented in a similar manner).

It is also worth noting that, even though the Tobacco Products Directive (2014/40/EU) does not require European Union Member States to implement plain packaging, it does include language recognizing that European Union Member States may implement plain packaging. Article 24.2 states:

> This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.[101]

As is mentioned in Part 3, this aspect of the Tobacco Products Directive has been challenged under European Union law on grounds that the European Commission does not have competence to address plain packaging in the Directive. It is important to recognize, however, that the question of whether the European Commission had competence to address plain packaging in the Directive is separate from the question of whether European Union Member States may implement plain packaging in their domestic law. Each question involves a separate set of legal issues.

In this context, as part of the UK's consultation on the introduction of standardized packaging of tobacco products, the UK developed an illustration of how standardized packaging is likely to look for cigarettes. The illustration (Figure 5) is subject to the caveat that it "is provided as a general guide as to how a standardised packet of cigarettes may look . . . and is not intended to be a comprehensive or final image of a standardised packet. This illustration does not contain all permissible or required features of standardised packets of cigarettes. For example, the features not shown on the illustration include: duty paid fiscal mark, barcode or text which states the email address and telephone number of the producer. This illustration has been designed using an image of a cigarette packet following the implementation of the [Tobacco Products Directive] which is contained in the [European Commission] guidance available at: http://europa.eu/rapid/press-release_MEMO-14-134_en.htm."

As suggested by comparison of this illustration with images of plain packaging in Australia in Figures 2 and 3, there are commonalities between the Australian and UK approaches, such as the background colour used and the way brand and variant names are presented on packaging. There are also minor differences between the Australian and UK approaches to packaging and labelling, including the following:

- health warnings, such as on cigarette packs, will cover a smaller portion of the total pack in the UK (65%) than in Australia (82.5%);
- plain packaging laws will not apply to cigars in the UK, whereas Australian law applies to all categories of tobacco products; and
- the appearance of the brand or variant name on a cigarette is prohibited in Australia, but permitted in the UK.

It is beyond the scope of this publication to summarize or explain the differences in approaches adopted in different jurisdictions in detail.

Figure 5. Cigarette pack – front and rear

2.3 Compliance and enforcement

In addition to the design features of plain packaging and other packaging and labelling measures, compliance and enforcement are important considerations in designing a plain packaging policy. This is true in the context of many tobacco control policies, including packaging and labelling measures.

In fact, the Guidelines for Implementation of Article 11 of the WHO FCTC include general provisions relating to liability and enforcement. For example, on the question of who is legally responsible for compliance with packaging and labelling measures the Guidelines state: "Parties should specify that tobacco product manufacturers, importers, wholesalers and retail establishments that sell tobacco products bear legal responsibility for compliance with packaging and labelling measures."[102]

With respect to penalties, the Guidelines state: "In order to deter non-compliance with the law, Parties should specify a range of fines or other penalties commensurate with the severity of the violation and whether it is a repeat violation."[103] The Guidelines go on to state: "Parties should consider introducing any other penalty consistent with a Party's legal system and culture that may include the creation and enforcement of offences and the suspension, limitation or cancellation of business and import licences."[104]

With respect to enforcement powers, the Guidelines state:

> Parties should consider granting enforcement authorities the power to order violators to recall non-compliant tobacco products, and to recover all expenses stemming from the recall, as well as the power to impose whatever sanctions are deemed appropriate, including seizure and destruction of non-compliant products. Further, Parties should consider making public the names of violators and the nature of their offence.[105]

More broadly, the Guidelines address enforcement issues such as infrastructure and budget, enforcement strategies to enhance compliance, responses to non-compliance and complaints.[106] These passages underlie the fact that effective enforcement mechanisms are an important component of packaging and labelling measures.

Against this general backdrop, the experience of some jurisdictions with graphic health warnings suggests that a number of methods might be used in attempts to circumvent packaging and labelling laws. Two methods are of particular relevance to plain packaging: delayed compliance and the sale or distribution of sleeves or stickers designed to obscure warnings. Plain packaging laws have sought to address these issues in a number of ways.

The sale of tobacco products in the absence of packaging, such as single stick or loose tobacco sales (including shisha), might also present an issue in some jurisdictions, such that it should be taken into account in design and implementation of plain packaging.

None of these issues, which are specific to enforcing plain packaging, should be confused with the separate question of whether plain packaging will increase illicit trade in tobacco products. Large multinational tobacco companies often argue that tobacco control measures will have such an effect despite the fact that there is no credible reasoning or evidence to support their assertions. This issue is discussed in Part 4.

2.3.1 Delayed compliance and penalties for non-compliance

In some jurisdictions, the introduction of new packaging and labelling requirements, such as graphic health warnings, has been marked by short-term non-compliance. Manufacturers, importers and retailers have sold stock that does not bear the required warnings after the implementation date. Products sometimes also bear warnings that are not in accordance with the requirements of the law, such as warnings that are smaller than the size stipulated in the law, or have warnings obscured, for example by tax stamps.

The extent to which short-term non-compliance occurs differs from one jurisdiction to another and depends on factors such as communication and educational activities

conducted by government agencies, the composition of the market, penalties for non-compliance and the enforcement capacity of authorities.

In Australia, the risk of short-term non-compliance with plain packaging laws was addressed through a so-called "sell-through" period, which gradually depleted stock that was not in plain packaging. From 1 October 2012, all tobacco products manufactured or packaged in Australia for domestic consumption were required to be packed in plain packaging. All retail tobacco products were required to be sold in plain packaging from 1 December 2012. This sell-through period reduced the risk that manufacturers and/or importers would distribute a large quantity of non-compliant products to retailers in advance of 1 December 2012. The risk of non-compliance by tobacco retailers was also addressed through a commitment by the Australian Tax Office to refund taxes paid on non-compliant stock still held after 1 December 2012.

The Australian Government introduced civil and criminal penalty provisions relating to non-compliant tobacco packaging and non-compliant tobacco products. These include fault-based offences and strict liability offences (where there is no need to show fault). Penalties for non-compliance may be imposed on retailers, manufacturers, suppliers or all of them. Each act of non-compliance, may constitute an offence, meaning that the cumulative penalties for large scale non-compliance may be high.

2.3.2 Sleeves, stickers, inserts and other devices

In response to laws requiring health warnings on tobacco packaging, tobacco companies, retailers and other businesses have devised circumvention strategies. These include the development of "sleeves" and stickers designed to obscure warnings, and the inclusion of inserts or other materials inside tobacco packaging. It is reasonable to expect that similar strategies will be developed to address plain packaging unless they are precluded in plain packaging laws.

Circumvention strategies in the context of tobacco packaging and labelling measures are often elaborate and difficult to anticipate. For example, in one country, tobacco companies responded to the introduction of health warnings by developing "open-ended partially transparent sleeve[s] with an innovative design printed at the bottom front and back of the sleeve" that could be placed over cigarette packs.[107] Tobacco manufacturers have also sold tobacco products with stickers inside the pack that are designed to be stuck on product packaging in ways that obscure warnings.[108] Similarly, in Australia, cardboard sleeves have been sold alongside tobacco products at the point of retail for purposes of covering the pack, and product lines such as stickers, sleeves and boxes have been sold separately to tobacco products.[109]

To counter circumvention strategies such as these the Guidelines for Implementation of Article 11 of the WHO FCTC state that "Parties should ensure that adhesive labels, stickers, cases, covers, sleeves, wrapping and tobacco manufacturers' promotional inserts and onserts do not obscure, obliterate or undermine health warnings and messages. For example, adhesive labels might be allowed only if they cannot be removed and are used only on metal or wood containers that hold products other than cigarettes."[110]

Along these lines, plain packaging laws in Australia, Ireland, and the UK prohibit the inclusion of inserts or additional materials or affixations that are not part of tobacco packaging or required to protect the product. For example, the UK plain packaging regulations state that "no insert or additional material may be attached to or included with the packaging of a unit packet or container packet of cigarettes".[111] Similarly, Australia's plain packaging legislation bans the inclusion of inserts or onserts on cigarette packaging,[112] and Ireland's legislation states that a cigarette package shall not contain "any inserted items or affixed items other than as provided for by law".[113] Under these provisions, the inclusion of sticker inserts or sleeves with cigarette packages for retail sale is prohibited. Legislation in Australia, Ireland and the UK does not expressly prohibit the sale of sleeves or stickers if they are sold separately from the cigarette packages and are not applied to the packages at the time of sale.

2.3.3 Sale in the absence of packaging

In some jurisdictions, it is common for tobacco products to be sold in the absence of packaging. For example, in many jurisdictions the sale of single stick cigarettes, bidis or cigars is common. Although Article 16.3 of the WHO FCTC obliges Parties to "endeavour to prohibit the sale of cigarettes individually or in small packets which increase the affordability of such products to minors", in some jurisdictions the practice remains legal or legal for some products such as cigars.

To deal with this issue, Australian law (which already required application of mandated health warnings) requires that single cigars be placed into compliant packaging before sale and that cigar bands themselves are plain packaged. This is illustrated in Figure 6.

The best approach to single stick sales will vary from one jurisdiction to another, depending on factors such as the scale of single stick sales, enforcement capacity and the culture of compliance. With this in mind, two points are of note.

First, in contexts where single stick sales occur, the branding and imagery on the product itself may play a relatively more important role in advertising a product, making the product more attractive or creating misleading perceptions concerning the health consequences of consuming one product as compared to another. Accordingly, applying plain packaging to the product itself and not only to product packaging is likely to take on greater importance in contexts where single stick sales occur.

Secondly, if single stick sales are common the additional question of how products may distinguish themselves from one another in the marketplace arises. In some contexts, single sticks might be sold out of compliant packaging (as in a stick is removed from compliant packaging). In other contexts, such as for cigars, single sticks may have branding in the form of a band. Leaving the specifics of different product categories and practices aside, it is important to give consideration to how different brands will be permitted to distinguish themselves from one another in the marketplace.

Figure 6. Cigar packaging under Australian law

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Source: Tobacco Plain Packaging - Your Guide, Australian Government, Department of Health, 09 July 2014, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/tppbook#top

Additional resources

Legislation

- Australia, Tobacco Plain Packaging Act 2011, available at http://www.comlaw.gov.au/Details/C2013C00190.
- Australia, Tobacco Plain Packaging Regulations 2011, available at http://www.comlaw.gov.au/Details/F2013C00801.
- Australia, Competition and Consumer (Tobacco) Information Standard 2011, available at http://www.comlaw.gov.au/Details/F2013C00598 .
- Tobacco Plain Packaging - Your Guide, Australian Government, Department of Health and Ageing, 9 July 2014, available at http://www.health.gov.au/internet/main/publishing.nsf/Content/tppbook#top.
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- Ireland, Public Health (Standardised Packaging of Tobacco) Act 2015, available at http://www.irishstatutebook.ie/eli/2015/act/4/section/23/enacted/en/print.html.
- Ireland, Draft Public Health (Standardised Packaging of Tobacco) Regulations 2016, available at http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2015&num=650.
- United Kingdom, The Standardised Packaging of Tobacco Products Regulations 2015, available at http://www.legislation.gov.uk/uksi/2015/829/contents/made.
- France, Ministerial Order relating to the conditions of neutrality and standardisation for the packaging and paper of cigarettes and rolling tobacco, https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000032276123.
- France, Decree on the conditions of neutrality and standardisation for the packaging and paper of cigarettes and rolling tobacco, available at https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000032276104.

Websites

- Introduction of Tobacco Plain Packaging in Australia, Australian Government, http://health.gov.au/internet/main/publishing.nsf/Content/tobacco-plain.
- Tobacco Plain Packaging Resources, Australian Government, http://health.gov.au/internet/main/publishing.nsf/Content/tpp-resources.
- Standardised Packaging of Tobacco Products, Department of Health, United Kingdom, available at https://www.gov.uk/government/consultations/standardised-packaging-of-tobacco-products.
- Tobacco, Department of Health, Ireland, http://health.gov.ie/healthy-ireland/tobacco/.

Other

- Consultation on the Proposal for Standardised Tobacco Packaging and the Implementation of Article 5.3 of the Framework Convention on Tobacco Control, Norway Government, available through. http://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2015&num=9009&iLang=EN.
- Draft amendments to the Tobacco Control Act and the Tobacco Labelling Regulations relating to Standardised Tobacco Products, available through http://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2015&num=9009&dLang=EN.

PART 3
Legal issues

It is common for the tobacco industry to claim that tobacco control measures or proposed tobacco control measures are or will be unlawful. The tobacco industry has threatened or brought legal action against a large number of countries in relation to a range of tobacco control measures including packaging and labelling measures (Article 11 of the WHO FCTC), prohibitions on advertising, promotion and sponsorship (Article 13), product regulation and disclosure laws (Articles 9 and 10) and protection from exposure to tobacco smoke (Article 8).[114]

Legal challenges to plain packaging are an example of the tobacco industry's broader strategy of using litigation to contest regulation, rather than a new phenomenon. Australia's plain packaging measures have been the subject of legal claims under domestic law, the law of the World Trade Organization (WTO) and a bilateral investment treaty between Australia and Hong Kong Special Administrative Region, China. At the time of writing, the domestic law claims and the investment treaty claim have each been resolved in Australia's favour, but the WTO claim is ongoing.

In both Ireland and the UK, plain packaging has been challenged before domestic courts, with tobacco companies invoking both domestic laws and the law of the European Union. These challenges are made against the backdrop of existing challenges to the European Union's Tobacco Products Directive of 2014, which have been referred to the European Court of Justice by domestic courts in European Union Member States.

This section describes the legal challenges that have been brought with respect to plain packaging, identifies the types of legal arguments that the tobacco industry tends to make in its opposition to plain packaging, and outlines ways in which WHO Member States might act to reinforce their legal positions in case of challenge. The purposes are to highlight possible legal issues and approaches that governments might consider, and to identify more detailed resources.

3.1 Domestic law

There are limits on the extent to which it is possible to generalize about the legal issues associated with plain packaging in different jurisdictions. Governments may implement plain packaging in slightly different ways in order to account for differences in their domestic contexts. Plain packaging will be brought into effect through different legislative or regulatory processes in different jurisdictions. Different constitutional, administrative and legislative arrangements will also lead to differences in the manner in which plain packaging is passed into law in different jurisdictions. Accordingly, the legal implications of plain packaging, and how it is best implemented, demand a situation specific analysis in each jurisdiction.

Despite these limitations, it is possible to identify broadly the types of domestic legal claims that tobacco companies threaten or bring against plain packaging. For example, in Australia, Ireland and the UK tobacco companies have sought to invoke laws that protect private property rights, including trademarks. In some countries, in challenging other tobacco control measures, tobacco companies have sought to rely on laws that protect commercial speech and rights to conduct business.

Box 3. The tobacco industry's constitutional challenge to Australia's tobacco plain packaging measure

In August 2012, the High Court of Australia (Australia's highest court) dismissed the tobacco industry's constitutional challenge to tobacco plain packaging on the basis that the scheme did not effect an "acquisition" of its property, the relevant test under the Australian Constitution. The Court ruled 6-1 in the Government's favour. The majority was constituted by five separate judgments.

In challenging plain packaging, the tobacco industry made two principal arguments:

- that the restrictions on its property and related rights (including trademarks, copyright, goodwill, design, patents, packaging rights and licensing rights) effected by the Tobacco Plain Packaging Act and Regulations constitute an acquisition of its property (for which just terms had not been provided); and
- that the Act and Regulations give the Commonwealth the use of, or control over, tobacco packaging, in a manner that effects an acquisition of the tobacco industry's property (for which just terms had not been provided).

Crennan J observed that what the tobacco industry (paragraph 287) "most strenuously objected to was the taking or extinguishment of the advertising or promotional functions of their registered trademarks or product get-up".

The essence of the majority's reasons for dismissing the tobacco industry's challenge is set out in the summary provided by the Court:

> On 15 August 2012 the High Court made orders in two matters concerning the Tobacco Plain Packaging Act 2011 (Cth) ("the Act"). Today the High Court delivered its reasons in those matters. A majority of the High Court held that the Act was valid as it did not acquire property. It therefore did not engage s 51(xxxi) of the Constitution, which requires any acquisition of property effected by a Commonwealth law to be on just terms.
>
> The Act imposes restrictions on the colour, shape and finish of retail packaging for tobacco products and restricts the use of trademarks on such packaging. The plaintiffs brought proceedings in the High Court challenging the validity of the Act, arguing that the Commonwealth acquired their intellectual property rights and goodwill otherwise than on just terms.
>
> A majority of the Court held that to engage s 51(xxxi) an acquisition must involve the accrual to some person of a proprietary benefit or interest. Although the Act regulated the plaintiffs' intellectual property rights and imposed controls on the packaging and presentation of tobacco products, it did not confer a proprietary benefit or interest on the Commonwealth or any other person. As a result, neither the Commonwealth nor any other person acquired any property and s 51(xxxi) was not engaged.

All six members of the majority affirmed that, under the Australian Constitution, for there to be an "acquisition of property" requiring just terms compensation, the Government or another must obtain a benefit or interest of a "proprietary nature". As Hayne and Bell JJ put it (paragraph 169), this is a "bedrock principle" which must not be eroded: "there must be an acquisition of property" (emphasis in the original). The tobacco industry's arguments (paragraph 170) "[ran] aground" on this bedrock.

As French CJ expressed it (paragraph 42): "On no view can it be said that the Commonwealth as a polity or by any authority or instrumentality, has acquired any benefit of a proprietary character by reason of the operation of the [Tobacco Plain Packaging] Act on the plaintiffs' property rights". The achievement of the Commonwealth's legislative objects would not be such a benefit. As Kiefel J wrote (paragraph 372), if the Act's central statutory object were to be effective, the tobacco companies' business 'may be harmed, but the Commonwealth does not thereby acquire something in the nature of property itself'. (See also Gummow J paragraphs 143 and 148; and Crennan J paragraphs 296, 300, 306).

In addressing the tobacco industry's argument about use of, or control over, packaging, Hayne and Bell JJ observed (paragraph 181) that the requirements of the Act "are no different in kind from any legislation that requires labels that warn against the use or misuse of a product, or tell the reader who to call or what to do if there has been a dangerous use of a product. Legislation that requires warning labels to be placed on products, even warning labels as extensive as those required by the [Tobacco Plain Packaging] Act, effects no acquisition of property." Crennan J noted (paragraph 301) that "[l]egislative provisions requiring manufacturers or retailers to place on product packaging warnings to consumers of the dangers of incorrectly using or positively misusing a product are commonplace". Similarly, Kiefel J wrote that (paragraph 316) "[m]any kinds of products have been subjected to regulation in order to prevent or reduce the likelihood of harm", including medicines, poisonous substances and foods.

Crennan J underlined (paragraph 294) the significance of the tobacco industry's ability to continue to use brand names on tobacco packaging, "so as to distinguish

their tobacco products, thereby continuing to generate custom and goodwill". She noted (paragraph 290) that the "visual, verbal, aural and allusive distinctiveness, and any inherent or acquired distinctiveness, of a brand name can continue to affect retail consumers despite the physical restrictions on the appearance of brand names imposed" by the Act; "an exclusive right to generate a volume of sales of goods by reference to a distinctive brand name is a valuable right" (paragraph 293).

Although the nature of property rights and laws protecting them differ from one jurisdiction to another a number of themes can be discerned in the reasons of the majority, which would likely be relevant in other legal challenges to tobacco plain packaging that concern intellectual property rights, including:[115]

(a) The relevant rights of the tobacco companies were "negative rights", that is to say rights to exclude others from use, rather than positive rights to use.
(b) The tobacco companies may have lost something of commercial value, but commercial value is not the object of constitutional protection.
(c) The regulatory scheme is no different in kind from other legislation requiring health or safety warnings.
(d) The requirements of the scheme are conditions on the sale of tobacco products—the Australian Government does not use tobacco packaging or products.
(e) The scheme allows the continued use of brand names (including trademarked brand names)—the ability to use such names is valuable.
(f) Intellectual property rights are created to serve public purposes, but they are not sacrosanct and they do not operate above or in isolation from other laws created to serve other public purposes.

Source: McCabe Centre for Law and Cancer, Domestic challenge to plain packaging: High Court of Australia finds plain packaging constitutional (http://www.mccabecentre.org/focus-areas/tobacco/domestic-challenge-to-plain-packaging)

3.2 International law

Tobacco companies often rely on arguments about the purported impacts of international trade and investment agreements in attempts to resist domestic regulation. This is not unique to plain packaging, and can also be observed, for example, in relation to large graphic health warnings and product regulation measures. As a part of their opposition to the introduction of plain packaging tobacco companies have alleged that the measure violates WTO law and commitments governments have made under investment treaties.[116] As has been documented previously, tobacco companies use legal authorities in a selective manner, citing authorities favourable to their position and ignoring unfavourable authorities that tend to confirm the extent of regulatory space under WTO law and investment treaties.[117]

At the time of writing, dispute settlement proceedings in relation to Australia's measures is under way at the WTO.[118] Philip Morris Asia also brought an unsuccessful claim against Australia under an investment treaty. Each of these disputes is described in further detail below.

Claims concerning plain packaging have also been made under European Union law. Among other things, legal challenges to the Tobacco Products Directive of 2014 question whether the European Commission had competence to include a passage indicating that European Union Member States may implement plain packaging.[119] Although the European Court of Justice is yet to rule on these claims, Advocate General Kokott issued an opinion in December 2015 to the effect that the reference to plain packaging is consistent with European Union law.[120]

Tobacco companies have also brought claims before domestic courts in Ireland and the UK, alleging that plain packaging in those jurisdictions will violate European Union law. These claims allege that plain packaging results in a deprivation of property rights under Article 1 (Protection of property) of Protocol 1 of the European Convention on Human Rights, that plain packaging interferes with the free movement of goods contrary to Article 34 of the Treaty on the Functioning of the European Union and that plain packaging violates the Community Trade Mark Regulation. The first two of these arguments turn partly on whether plain packaging is proportionate to a legitimate aim.

Claims under European Union law are not addressed in detail in this section on the basis that European Union law is a specialized body of supranational law that European Union Member States are familiar with.

3.2.1 World Trade Organization law

WTO law limits the ways in which WTO Members may restrict or regulate international trade in goods and services, including through the use of tariffs (customs duties) and non-tariff measures, such as regulatory measures. WTO law also imposes obligations with respect to the protection of intellectual property rights.

WTO law is enforced through a system of dispute settlement between its Members. Only WTO Members (governments) may bring a complaint alleging that another Member has violated a WTO-covered agreement. In the event that a panel finds that a WTO-covered agreement has been violated, the panel will recommend to the Dispute Settlement Body that the Member in question bring the measure into conformity with WTO law.[121] Unless all WTO Members agree otherwise, the Dispute Settlement Body adopts panel and Appellate Body reports.

At the time of writing, a WTO panel is adjudicating complaints by Cuba, the Dominican Republic, Honduras and Indonesia with respect to Australia's plain packaging law. Australia is defending its law against those claims. A complaint by Ukraine has been suspended at Ukraine's request. The panel has advised that it will not issue its final report

to the parties to the dispute before the first half of 2016. That report may be appealed by a party to the dispute. The WTO panel report in *Australia – Tobacco Plain Packaging* will bind only the complainants and Australia. Nonetheless, prior decisions, particularly those of the Appellate Body, play an important role in dispute settlement, meaning that the outcome of the dispute will be relevant to plain packaging measures implemented by other WTO Members.

In *Australia – Tobacco Plain Packaging* the main claims articulated by the complainants before the hearings held by the WTO panel were that plain packaging:

1. breaches the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[122] by failing to provide protection of trademark rights as required under that agreement, including by unjustifiably encumbering the use of trademarks in the course of trade;
2. breaches the WTO's Agreement on Technical Barriers to Trade[123] because it constitutes a "technical regulation" that is "more trade-restrictive than necessary to fulfill a legitimate objective"; and
3. breaches the WTO's General Agreement on Tariffs and Trade (GATT 1994),[124] the Agreement on Technical Barriers to Trade and the TRIPS Agreement because the measure discriminates between like imported and domestic products, as well as discriminating between like imported products.

Whether the measures are achieving Australia's health objectives or are apt to achieve those objectives is relevant to each of these claims.

It is not the purpose of this publication to critique the legal arguments made by the complainants or to interpret WTO law. Nonetheless, it is important to point out well-established principles and rules that demonstrate the flexibility WTO Members have to regulate in the public interest. These principles and rules are routinely ignored or downplayed by tobacco companies and their supporters in their opposition to plain packaging.

1. The TRIPS Agreement provides flexibility for regulation in the interests of public health

The TRIPS Agreement does not provide for a "positive" "right to use" trademarks in the course of trade. Rather, TRIPS provides for "negative rights", that is to say the right to exclude others from using one's trademark.[125] In the ordinary course, plain packaging will not remove a trademark owner's right to prevent others from using its trademarks.

TRIPS places restrictions on how WTO Members may encumber use of trademarks in the course of trade. Article 20 (Other requirements) of TRIPS states (in relevant part):

> The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings…. (emphasis added)

The ordinary wording of Article 20 preserves the flexibility for Members to implement justifiable requirements. The TRIPS Agreement explicitly recognizes in its Principles (Article 8.1) that WTO Members "may … adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement".

The precise relationship between Article 8 and Article 20 has not been determined, but it is widely agreed that requirements necessary to protect public health are justifiable[126] and strongly argued that "justifiable" is a lower threshold to meet than "necessary". The term "unjustifiable" has been interpreted under the General Agreement on Tariffs and Trade 1994 merely to require a rational connection between the measure implemented and the goal pursued.[127] It remains to be seen whether the same interpretation will be given under TRIPS.

In the Doha Declaration on the TRIPS Agreement and public health WTO Members agreed:

> that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.[128]

Another Doha Declaration has been found to constitute a subsequent agreement of the WTO Membership, to be used in interpretation of another WTO-covered agreement.[129] It remains to be seen whether the Doha Declaration on the TRIPS Agreement and public health will be treated in the same way.

In the Punta del Este Declaration on the Implementation of the WHO Framework Convention on Tobacco Control adopted by the Convention's Conference of the Parties at its fourth session in November 2010, the Parties recalled the statement in the Doha Declaration that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health" and declared that, in light of Articles 7 and 8 of the TRIPS agreement and the Doha Declaration, "Parties may adopt measures to protect public health, including regulating the exercise of intellectual property rights in accordance with national public health policies, provided that such measures are consistent with the TRIPS Agreement."

In summary, WTO Members enjoy flexibilities under TRIPS, including when acting to protect public health.

2. The requirement that technical regulations be not more trade-restrictive than necessary to achieve a legitimate objective leaves significant scope for protection of human health

Article 2.2 of the Agreement on Technical Barriers to Trade explicitly recognizes that protection of human health or safety is a legitimate objective. In this context, in determining whether a regulation is more trade restrictive than necessary to protect human life or health a WTO panel will weigh and balance the contribution a regulation makes to protection of human health against its trade restrictiveness, taking account of the risks that non-fulfilment of the legitimate objective would create.[130]

A panel will assess the contribution of a regulation to achievement of a legitimate objective. To establish that a regulation makes a contribution, a Member is only required to demonstrate a genuine relationship of means and ends between the regulation and its

objective. The Member need not bring quantitative evidence, but might rely on qualitative evidence.[131] The degree to which the regulation contributes to a given objective will be discerned from the design, structure and operation of a regulation and from evidence relating to application of the measure.[132] The Appellate Body has also recognized that the full impact of a regulation might not be measurable in the short term, stating that "the results obtained from certain actions—for instance, measures adopted in order to attenuate global warming and climate change, or certain preventive actions to reduce the incidence of diseases that may manifest themselves only after a certain period of time—can only be evaluated with the benefit of time."[133]

A regulation may be considered more trade restrictive than necessary if there is a less trade-restrictive alternative that would make an equivalent or greater contribution to the achievement of the objectives than the plain packaging measure implemented. However, the WTO's Appellate Body has acknowledged the inter-relatedness of different measures that together form part of a package or suite of measures and cannot be examined in isolation from one another. It has held that:

> certain complex public health or environmental problems may be tackled only with a comprehensive policy comprising a multiplicity of interacting measures. Substituting one element of this comprehensive policy for another would weaken the policy by reducing the synergies between its components, as well as its total effect.[134]

Accordingly, complementary or cumulative measures are not considered alternatives under WTO law.[135]

Application of Article 2.2 may also be influenced by Article 2.5 of the Agreement on Technical Barriers to Trade. Under Article 2.5 regulations in accordance with relevant international standards are presumed not to be more trade restrictive than necessary to achieve a legitimate objective. In this respect, the challenge to Australia's implementation of plain packaging may resolve the question whether the guidelines for implementation of Articles 11 and 13 of the WHO FCTC constitute relevant international standards.[136]

Finally, it is relevant to note that in *US – Clove Cigarettes*, what was characterized as a complete ban on clove-flavoured cigarettes (a measure as trade restrictive as possible with respect to clove cigarettes) was found to be consistent with Article 2.2.[137]

3. Rules governing discrimination leave scope for protection of human health

In the context of the General Agreement on Tariffs and Trade 1994, principles of non-discrimination are subject to general exceptions. These exceptions protect measures that are inter alia necessary to protect human life or health. Similarly, under the prohibition on discrimination in Article 2.1 of the Agreement on Technical Barriers to Trade regulations having a discriminatory effect are lawful provided that the effect is based solely on a legitimate regulatory distinction.

In summary, WTO rules governing discrimination leave scope for Members to pursue legitimate objectives, including the protection of human life and health. In fact, protection of human health has been recognized as a policy objective of the highest importance in WTO dispute settlement.[138]

3.2.2 International investment law

International investment agreements, which usually take the form of investment chapters in free-trade agreements and separate bilateral investment treaties, protect the investments of foreign investors, including property rights. Among other things, international investment agreements guarantee foreign investors protection against nationalization or expropriation of investments and so-called "fair and equitable treatment". Typically, foreign investors have standing to bring claims directly against States through international arbitration and compensation is available as a remedy for violation.

Philip Morris Asia brought a claim against Australia under a bilateral investment treaty between Australia and China (Hong Kong Special Administrative Region). Philip Morris Asia sought compensation for losses it claimed were caused by plain packaging.[139] Australia had argued that the claim should be dismissed on jurisdictional grounds, and in December 2015 the Tribunal agreed with Australia that Philip Morris Asia's claim should be dismissed. The Tribunal's award is expected to be published in 2016 once issues regarding redaction of confidential information have been resolved.

In its claim against Australia, the core arguments made by Philip Morris were that plain packaging resulted in indirect expropriation of its property rights (on grounds that the measure has an effect equivalent to expropriating property rights) and unfair and inequitable treatment (on grounds that the measure is arbitrary and unreasonable). Australia contested these claims. As in the context of WTO law, governments retain scope under international investment agreements to regulate in the interests of health. That scope can be summarized in the following terms:

1. Expropriation

Case law applying investment treaties suggests that various factors will be considered in determining whether a measure results in indirect expropriation. Although this case law does not create binding precedent, some of it reflects customary international law, and tribunals do draw upon prior decisions.

One factor for consideration is the extent of interference with an investor's property rights. Although there is no universally accepted standard, case law suggests that there must be "a substantially complete deprivation of the economic use and enjoyment of rights to the property, or of identifiable distinct parts thereof (i.e. it approaches total impairment)" for indirect expropriation to occur.[140] The case law tends to treat this degree of interference as necessary, but not sufficient, for an action to constitute indirect expropriation. Tribunals usually consider other factors in determining whether a measure constitutes non-compensable regulation by the host State or compensable expropriation. It is common for tribunals to consider factors such as whether the measure is within the police powers of the State (or the sovereign power to regulate), the proportionality of the measure to its aims, and the legitimate expectations of the investor.[141]

The concept of police powers recognizes that sovereign States may act to protect public health without being liable for indirect expropriation.[142] When acting in accordance with police powers, the action is not considered to constitute expropriation / require payment of compensation, provided that the State's conduct is not discriminatory and is

not designed to cause a foreign investor to abandon property to the State or sell it at a distress price.[143]

Another relevant factor for consideration is whether in making an investment, an investor has acted in reliance on specific commitments made to it by the state hosting the investment. If so, failure by the State to honour those expectations may form the basis of a claim for indirect expropriation.[144] It should be noted that the fact that a sector is heavily regulated may influence what is considered a reasonable expectation. For example, in one dispute concerning the tobacco sector a tribunal noted that "an investor entering an area traditionally subject to extensive regulation must do so with awareness of the regulatory situation."[145]

2. Fair and equitable treatment

International investment agreements often include clauses requiring that investors be afforded fair and equitable treatment. These clauses can be found in a variety of formulations, making it difficult to generalize.[146] Some clauses establish stand-alone treaty obligations that are of a broad character. Other clauses require the standard of treatment found in the international minimum standard required by customary international law.

Different circumstances exist in which the fair and equitable treatment standard has been violated. These include failure to provide a transparent and stable environment and to observe an investor's legitimate expectations; arbitrary, discriminatory or unreasonable treatment; denial of due process or procedural fairness; bad faith; and government coercion and harassment.

It is generally difficult for an investor to establish a violation of a clause linked to customary international law. For example, the standard was articulated by one tribunal, which stated that "an act must be sufficiently egregious and shocking – a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons – so as to fall below accepted international standards."[147] A higher standard of treatment has been required by some tribunals, which have concluded that customary international law may be violated by acts that are merely unfair, inequitable or unreasonable.[148]

Whatever standard is adopted, it is important to note that arbitral tribunals are reluctant to second-guess good faith regulatory decision-making of host States. For example, in a recent award concerning pharmaceutical regulatory decision-making, one tribunal stressed "the need for international tribunals to exercise caution in cases involving a state regulator's exercise of discretion, particularly in sensitive areas involving protection of public health and the well-being of patients."[149] Another tribunal, when considering a regulation prohibiting the sale and use of an insecticide, stated that the role of a tribunal "is not to second-guess the correctness of a science-based decision-making of highly specialized national regulatory agencies".[150]

In summary, as is the case under WTO law, international investment agreements ordinarily provide States with significant space to regulate in the public interest, including for purposes of protecting health.

3.3 Strengthening governments' legal positions

As the discussion above illustrates, plain packaging is like many other tobacco control measures in the sense that litigation has been used in attempts to prevent and delay implementation. In this context, governments can take several steps to strengthen their legal positions. Examples of these steps are set out below. It is important to stress, however, that legal issues associated with plain packaging will differ from one jurisdiction to another. This is because domestic and international laws applicable to plain packaging differ from one jurisdiction to another. Implementation of the measure and its effects are also likely to differ from one jurisdiction to another. Accordingly, the strategies set out below are intended to assist in the development and design of plain packaging measures, but do not constitute legal advice or a substitute for engaging qualified lawyers with jurisdiction-specific expertise to assist in the process. Nor is anything set out below intended to suggest that taking a different approach from that recommended will violate the law.

Strategies to strengthen governments' legal position can be divided into a number of categories. Some strategies may be relevant in more than one forum.

3.3.1 General

Define the regulatory objectives of plain packaging in a way that is linked to the evidence in support and to the WHO FCTC

Some legal claims will turn on the ability of plain packaging to achieve the objectives underlying the measure. For example, claims brought against plain packaging have alleged that plain packaging is not an effective public health intervention. The effectiveness of a measure, however, must ultimately be judged in light of its objective.

In this context, defining the objective of a plain packaging measure solely in terms of reducing the prevalence of tobacco use may not be sufficiently detailed. A better approach is to frame plain packaging as a measure to reduce demand for tobacco products in combination with other measures, including by:

1. reducing the attractiveness of tobacco products;
2. eliminating the effects of tobacco packaging as a form of tobacco advertising and promotion;
3. addressing package design techniques that may suggest that some products are less harmful than others; and
4. increasing the noticeability and effectiveness of health warnings.

This is not to suggest that these are the only objectives that should be pursued. However, these objectives are evidence-based, closely related to the language of the WHO FCTC and its guidelines, and it is possible to monitor the extent to which a measure has achieved them in the medium-term.

In many instances, it will also be advisable to refer specifically to implementation of the WHO FCTC and its implementation guidelines in framing the objective of a measure. This reflects the fact that courts and tribunals may take account of the WHO FCTC and its guidelines in their decision-making.

Ensure that plain packaging is implemented as part of a comprehensive set of tobacco control measures

If enhancing the effectiveness of tobacco control measures is a central objective of plain packaging, plain packaging should be implemented as part of a comprehensive set of measures and not in isolation. These measures include comprehensive bans on advertising, promotion and sponsorship and other packaging and labelling measures that plain packaging is intended to make more effective.

Adopt a whole-of-government approach to policy design, implementation, enforcement and evaluation

Like many tobacco control measures plain packaging has multisectoral elements that demand input from different parts of a government. A whole-of-government approach to plain packaging is likely to require input from several agencies including those responsible for health, legal affairs, foreign affairs, trade and investment, intellectual property, and customs and tax enforcement. The exact point at which a whole-of-government approach should be adopted will differ from one jurisdiction to another.

Ensure flexibility in the law to permit amendment if necessary

It is prudent to adopt a legislative design that allows for any subsequent necessary amendments to be made. In many jurisdictions this goal can be achieved by delegating power (such as to health authorities) to make and amend a plain packaging regulation. This approach will permit amendment of the regulation if necessary to ensure its effectiveness or in the event that some aspect of implementation raises unexpected issues.

3.3.2 The policy process

Gather the best available evidence

It is implicit in the discussion of regulatory objectives above that plain packaging should be based on evidence, and that governments should use that evidence as the basis for defining their objectives. More broadly, governments can reinforce their legal position by gathering the best available evidence (including that described in Part 2) and considering and articulating its application to their domestic circumstances. Doing so can have at least two benefits.

First, gathering and considering the best available evidence can help to ensure that a plain packaging measure is designed so that it is apt to achieve its objectives. For example, the empirical evidence and experiences of other countries may provide guidance on how to design, implement and enforce plain packaging so as to maximize its effectiveness.

Secondly, gathering and considering the best available evidence, and identifying that evidence as a basis for plain packaging measures, may strengthen the legal position of a government in the event of legal claims relating to due process.

If possible, test the efficacy of different approaches to plain packaging

Although plain packaging has certain core elements, governments can determine how best to implement the measure in their domestic jurisdictions. For example, the background colour used for plain packaging as well as other information required or permitted on packaging may vary between jurisdictions.

In this context, there is merit to pre-market testing different approaches to plain packaging in order to ensure adoption of the most effective approach for the jurisdiction in question.[151]

Respect due process rights in the policy development process in accordance with national law and Article 5.3 of the WHO FCTC, including its guidelines

The provision of due process may be relevant to compliance with domestic law and international investment law. The exact content of due process requirements under domestic law will differ from one jurisdiction to another. Under international investment law the content of the right will depend on factors such as the way in which a law is passed (whether by the legislature or through regulatory action), the domestic rights ordinarily protected in such circumstances and the process through which a foreign investor may be heard.

Public consultations in Australia, Norway, Singapore and the UK provide examples of how different governments have approached this issue. Interested parties have been provided with an opportunity to comment on the merits of plain packaging generally, as well as how it might be implemented.

These processes should, of course, be conducted in accordance with Article 5.3 of the WHO FCTC and its guidelines. Article 5.3 obliges Parties to protect public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry in accordance with national law.

Create a document development and retention policy in accordance with national law from the outset of the policy development process

Tobacco companies have lodged a significant number of freedom-of-information requests in countries implementing plain packaging or considering its implementation. These requests are often designed to tie up government resources. Governments should be aware of this strategy and consider strategies to prepare themselves to respond to such requests, by providing sufficient resources and developing an approach to document management from the outset of the policy development process.

Give producers sufficient time to adapt packaging and sell existing stock

Notice can ensure that producers have sufficient time to sell existing stock and stock produced before adaptation to the new law. Sufficient notice weakens any industry argument that it has suffered loss as a consequence of holding stock that cannot be sold. The question of what is a sufficient period of time may differ from jurisdiction to jurisdiction. As a general rule, guidance can be taken from prior experience in a given jurisdiction, such as in the context of changes to health warnings, as well as from the experience of other jurisdictions implementing plain packaging.

Ensure that commitments are not made to investors in the tobacco sector for purposes of inducing foreign investment

Commitments made to investors, whether they are incentives to invest such as tax holidays or commitments not to regulate, weaken the legal position of tobacco control measures under investment treaties. The offering of incentives to invest is also contrary to the Guidelines for Implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control.[152]

3.3.3 Recommendations on policy design

Apply plain packaging to all categories of retail tobacco packaging and tobacco products

In order to adopt best practice in tobacco control and minimize the risk of violating WTO principles of non-discrimination, WTO Members should ensure that tobacco plain packaging applies equally to imported and domestic products and equally to products from the territory of different trading partners. Although circumstances will differ from one jurisdiction to another, the risk of discrimination is lowest if a plain packaging measure applies equally to all categories of tobacco products (along with health warnings and other measures appropriate to each category).

Ensure that brands can be distinguished from one another

As defined in the guidelines for implementation of Articles 11 and 13 of the WHO FCTC, plain packaging permits the use of brand and product names on packaging (in a standardized form). This enables brands to be distinguished one from another in the course of trade and provides a response to claims that plain packaging makes it impossible for manufacturers to identify their products to consumers.

Permit registration of trademarks (provided they are not misleading) and allow existing trademarks to remain on the register

Article 15.1 of the TRIPS Agreement obliges WTO Members to permit registration of signs and combinations of signs as trademarks so long as they are capable of distinguishing the goods or services of one undertaking from those of another. In the case of misleading trademarks, Article 15.2 clarifies that there is no obligation to permit registration.

Prevent deregistration of tobacco trademarks on grounds of non-use

In many jurisdictions a trademark can be deregistered as a result of non-use. Although it is recommended that plain packaging apply only to retail tobacco packaging, it is prudent to ensure that domestic trademark law protects tobacco trademarks from deregistration that may arise when plain packaging no longer permits use.

Permit the presence of pack features that help prevent illicit trade

As was discussed above in this Part, tobacco companies have claimed that plain packaging and other tobacco control measures will increase illicit trade. In this context, it is prudent to permit markings such as barcodes that are used for purposes of identifying products carrying a counterfeit trademark and tracking and tracing.

Permit repackaging of tobacco products at the point of importation

In some contexts, it will be possible to comply with plain packaging laws by repackaging products at the point of importation. For example, it might be possible to pack loose tobacco into packaging that is compliant with plain packaging laws, or to cover cigar bands with prescribed bands. Permitting repackaging of products lowers the risks associated with a claim that the law is more trade restrictive than necessary to achieve its objectives.

3.4 Conclusion

A careful process of policy design, implementation and evaluation is likely to improve plain packaging measures and strengthen the legal position of governments implementing plain packaging. The legal claims discussed above also illustrate the need for coordination and cooperation across government departments at an appropriate point in the policy-making process, as well as a sustained commitment to defending plain packaging.

Each plain packaging measure will be implemented in unique circumstances, limiting the extent to which it is possible to generalize about legal issues. Nonetheless, by considering the claims against Australia in the broader context of legal challenges against tobacco control measures, it is possible to identify the types of legal claims that might arise in other countries. The legal positions of jurisdictions implementing plain packaging may be strengthened by taking the actions set out above in section 3.3. These strategies should not be confused with detailed legal advice specific to the circumstances, but they do raise legal issues to be considered in more detail. These strategies also highlight the need to evaluate and address legal considerations from the outset of the policy process.

Additional resources

Websites

- Australian Plain Packaging — Dispute in the World Trade Organization, McCabe Centre for Law and Cancer, http://www.mccabecentre.org/knowledge-hub/current/auspp-wto.
- Dispute settlement, World Trade Organization, https://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm.

Document index, Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, http://www.mccabecentre.org/knowledge-hub/current/auspp-wto/docs-auspp.

- Australian Plain Packaging Laws — Investor-State Dispute brought by Philip Morris Asia, McCabe Centre for Law and Cancer, http://www.mccabecentre.org/knowledge-hub/current/auspp-investment.
- Philip Morris Asia Limited v. The Commonwealth of Australia, UNCITRAL, PCA Case No. 2012-12, Italaw, http://www.italaw.com/cases/851.
- Tobacco Control Laws, Campaign for Tobacco-Free Kids, http://www.tobaccocontrollaws.org/.

Books

- McGrady B. Trade and public health: the WTO, tobacco, alcohol and diet. Cambridge, England: Cambridge University Press, 2011.
- Voon T, Mitchell AD, Liberman J, Ares G. eds. Public health and plain packaging of cigarettes: legal issues. Cheltenham, England: Edward Elgar, 2012.
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PART 4

Other tobacco industry objections to plain packaging

Governments intending to implement plain packaging may expect to experience intense, coordinated criticism and lobbying from tobacco companies, both in public and in private. Governments can also expect that tobacco companies will coopt sympathetic groups, such as libertarian-oriented think tanks, intellectual property bodies and retailers. In this respect, tobacco companies have been coordinating their opposition to plain packaging since forming a plain packs group as far back as 1993.[153]

The experience in Australia, France, Ireland, and the UK suggests that tobacco companies will oppose plain packaging in ways that go above and beyond their typical opposition to tobacco control measures. However, in each of those countries there has been very little public support for tobacco companies and little opposition to plain packaging other than that from tobacco companies themselves. Moreover, medical and public health groups in those countries have shown strong support for plain packaging, as have smokers.

Nonetheless, in addition to challenging plain packaging before the courts, tobacco companies and their supporters have made a great number of claims in opposing plain packaging. In some instances, these claims were quite clearly misleading. For example, tobacco companies in Australia argued that the UK had rejected the idea of implementing plain packaging, when in reality the UK was preparing to consider the policy.

In many instances, tobacco companies made predictions about the negative impacts plain packaging might have once implemented. These predictions included suppositions that plain packaging would increase illicit trade, drive prices down, cause consumers to shift to cheaper brands rather than quit smoking, create delays for retailers because they would not be able to identify brands, result in billions of dollars of compensation being due to tobacco companies as a consequence of litigation, and set in place a slippery slope leading to regulation of other products in the same way.

Tobacco companies have made these same predictions and arguments in numerous jurisdictions. However, governments should be hesitant to accept these predictions at face value for a variety of reasons, for instance because they:

- **are made in attempts to prevent plain packaging being passed into law, which aligns with the self-interest of tobacco companies;**
- **have not come to fruition in Australia; and**
- **often lack any rational basis.**

In light of the extent of tobacco industry opposition to plain packaging, it is worth examining some of the more prominent predictions tobacco companies have made in opposing plain packaging.

4.1 Plain packaging and illicit trade?

In opposing the introduction of tobacco control measures it is common for tobacco companies to argue that those measures will increase illicit trade, such as smuggling and trademark counterfeiting. By advancing this argument tobacco companies seek to avoid regulation and to prepare the ground for disputing the impacts of tobacco control measures after implementation. In the latter respect, when official figures suggest that a tobacco control measure has reduced sales, it is common for tobacco companies to argue that declining sales figures are attributable to an increase in illicit trade, which is not captured in official figures. However, in Australia, there is no credible independent evidence to suggest that plain packaging has increased illicit trade.

Australian tobacco companies retained KPMG LLP to provide periodic estimates of the size of the illicit market in Australia. The 2014 full-year report included an important notice indicating that it had been produced in accordance with specific terms of reference agreed by British American Tobacco Australia Limited, Philip Morris Limited and Imperial Tobacco Limited.[154] Because of the specific undisclosed terms of reference, the notice stresses that the "report should not therefore be regarded as suitable to be used or relied on by any other person or for any other purpose."[155] Nonetheless, tobacco companies have used the 2014 full-year report to suggest that illicit trade, particularly in unbranded tobacco products, increased marginally in the full year 2013 to 2014 after implementation of plain packaging. However, the report relies on a voluntary online consumer survey, as well as an empty pack survey, which involved examining empty packs discarded in major cities. Each of these methods is subject to serious constraints.[156]

Other research, using reliable methods, suggests that illicit trade in tobacco products has not increased since implementation of plain packaging. The Australian National Drug Strategy Household Survey found that in 2013 awareness of unbranded tobacco and use of unbranded tobacco had declined since 2010 among smokers aged 14 years or older.[157] Figures from the Department of Immigration and Border Protection show minor variations in seizures of illicit tobacco year-by-year and that the years 2012–2013 and 2013–2014 were similar to figures recorded since 2009–2010.[158] Additionally, other surveys published in peer-reviewed journals have shown that the proportion of smokers reporting current use of unbranded illicit tobacco did not change significantly between 2001 and 2013, which includes periods before and after implementation of plain packaging.[159]

Of course, Australia's experience with illicit trade may differ from the experience in other jurisdictions. Nonetheless, there is no rational basis upon which to argue that plain packaging will increase illicit trade. In this respect, tobacco companies have suggested that it will be easier for counterfeiters to engage in trademark counterfeiting of plain packaged tobacco products. This assertion fails to recognize that counterfeiters are already capable of copying fully branded packs and that governments may choose to permit the presence of anti-counterfeit devices on packaging.

In any case, there are additional enforcement responses that can be used to address illicit trade. These include the measures set out in Article 15 (Illicit trade in tobacco products) of the WHO FCTC, as well as those in the WHO FCTC Protocol to eliminate illicit trade in tobacco products, which is open to ratification by Parties to the WHO FCTC.[160]

4.2 Plain packaging and prices?

Before implementation of plain packaging in Australia, tobacco companies argued that plain packaging would be ineffective because it would ultimately push retail prices down and thereby increase demand for tobacco products. The rationale behind this assertion was that consumers would be unwilling to pay a premium for brands in plain packaging and that this would result in a market for an increasingly homogenized product.

Obviously, governments can address this risk through use of tax and price measures, such as by raising taxes or implementing a price floor. In Australia, for example, when the Government announced its intention to introduce plain packaging, it also introduced an immediate 25% increase in tobacco excise tax. In 2013, the Australian Government announced a further four successive rises, each of 12.5%.

The extent to which tobacco companies compete on price is also a question of choice. In Australia, a handful of cheap tobacco products has entered the market. However, retail prices have increased above and beyond tax increases and homogenization of the market has not been a significant issue.[161]

4.3 Plain packaging and retailers?

In lobbying against plain packaging, it has been argued that the policy will have a negative effect on retailers in two respects.

First, it has been asserted that plain packaging would confuse retailers and create delays. However, even if there may be slight increases in processing time following introduction of a new practice, staff are likely to gain experience and familiarity quickly, bringing processing time back to baseline levels. For example, a study conducted in Australia on cigarette retrieval times before and after the introduction of plain packaging found that "Retailers quickly gained experience with the new plain packaging legislation, evidenced by retrieval time having returned to the baseline range by the second week of implementation and remaining so several months later. The long retrieval times predicted by tobacco industry-funded retailer groups and the consequent costs they predicted would fall upon small retailers from plain packaging are unlikely to eventuate."[162]

Secondly, it has been suggested that declining sales of tobacco products resulting from plain packaging will have a negative effect on retailers. In this respect, it is important to recognize the difference between declining prevalence of tobacco use and declines in total sales. In countries with strong population growth total sales may remain steady or even increase while the prevalence of tobacco use declines. Additionally, it is also important to note that plain packaging is not expected to result in a dramatic and sudden reduction in tobacco sales. As is described above, plain packaging is designed to be implemented as part of a comprehensive approach to tobacco control and to strengthen implementation of existing packaging and labelling measures and restrictions on advertising, promotion and sponsorship. In this sense, plain packaging represents an incremental policy change and not the radical change represented by tobacco companies and their supporters.

Additional resources

Regulatory impact assessments

- Ireland, Regulatory Impact Analysis on the Public Health (Standardised Packaging of Tobacco) Bill 2014, July 2014, available at http://health.gov.ie/wp-content/uploads/2013/12/Standardised-Packaging-RIA-July-2014-FINAL.doc.
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Fact sheets

- Fact sheet no. 3: What has happened to use of illicit tobacco since the introduction of legislation to standardise the packaging of tobacco products in Australia? Cancer Council Victoria, available at https://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=factsheets1.
- Fact sheet no. 5: How much have retailers been affected by plain packaging legislation? Cancer Council Victoria, available at https://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=factsheets1.

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