Tobacco Labelling & Packaging Toolkit

A guide to FCTC Article 11

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PREFACE

Tobacco packaging serves as a critical link to consumers, both for the tobacco industry and for governments seeking to convey the health risks of smoking. The brand imagery of the package is the foundation upon which all other marketing is built and plays an even greater role in jurisdictions where traditional forms of advertising, promotion, and sponsorship are restricted.

New international guidelines for tobacco packaging and labelling are being established under Article 11 of the World Health Organization's *Framework Convention on Tobacco Control* (FCTC)—the first international treaty devoted to public health. Article 11 will develop guidelines in three critical areas: 1) government-mandated health warnings, 2) labelling of tobacco constituents and emissions, and 3) the removal of misleading information from the package.

The implementation of these guidelines must be guided by evidence. The growing evidence base from countries that have already implemented comprehensive packaging and labelling regulations can be used to guide the elaboration and implementation of Article 11 guidelines for other FCTC parties.

This Toolkit was created to serve as a resource to support implementation of Article 11. It includes a review of evidence, as well as recommendations for designing health warnings on packages. Overall, the Toolkit is intended to simplify the process of developing effective labelling policies and to provide concrete resources for regulators, researchers, and tobacco control advocates.

EXECUTIVE SUMMARY

The evidence on effective packaging and labelling practices has grown rapidly over the past decade. Although much of this evidence has been collected in Western countries, there is a growing body of knowledge from different regions throughout the world, including low and middle-income countries. Despite regional differences in tobacco markets and labelling practices, a consistent pattern of findings has emerged:

The Package as a Marketing Tool

- Packages are the most direct and critical link to consumers.
- Tobacco packages serve as a "portable" advertisement and a "badge" product.
- Packages play a critical role in point-of-sale marketing.
- Packages are used to promote "below-the-line" marketing activities, sponsorships, and promotional activities.
- The industry continues to expand the boundaries of package design through innovations in printing technology, package shape, and plastic wrapping.
- The importance of the packages increases as other forms of marketing are restricted.

Health Warnings Labels

- Package health warnings are among the most prominent and cost-effective health communications available.
- Health warnings have high awareness and visibility among non-smokers and youth.
- Obscure text warnings have little impact.
- Large, prominent warnings located on the top of packages can increase health knowledge, motivation to quit, and cessation behaviour.
- Pictorial warnings are significantly more effective than text-only messages.
- Pictures are especially important for reaching low-literacy smokers and children.

- Messages that depict health risks in a vivid and emotionally arousing manner are most effective.
- "Graphic" information should be accompanied by supportive cessation information.
- There are no adverse effects in response to pictorial warnings.
- Health warnings must be regularly updated to maintain maximum impact.
- Large pictorial warnings are credible and have high levels of public support.

Emission & Constituent Labelling

- Emission numbers (i.e. tar and nicotine numbers) are not related to the amount of chemicals in a cigarette or the level of risk for a particular product.
- Emission numbers are highly misleading to consumers.
- Scientific bodies have called for the removal of emission numbers from packages.
- Numbers should be replaced with descriptions of emissions, constituents, and their health effects should be printed on packages.

Prohibitions on Misleading Information

- A central objective of tobacco industry marketing is to communicate deceptive differences in the risks of different brands.
- There are three primary packaging strategies that mislead smokers:
    1. Deceptive references to product design, such as the filtration properties.
    2. Misleading use of colour, symbols and brand imagery.
    3. Inherently misleading brand descriptors, such as *light*, *mild*, and *low tar*.
- More than 40 countries have prohibited the terms *light*, *mild*, and *low tar*; however, prohibitions must be broader to eliminate misleading substitutes, such as *smooth*.
- Removing misleading information will require restrictions on colour and brand imagery.
- "Plain" packaging is less appealing to youth, increases the effectiveness of health warnings, and is less likely to mislead smokers regarding the risks of their products.

Chapter 1 Tobacco Labeling Toolkit

EVIDENCE REVIEW

THE PACKAGE

Packaging is an important component in the overall marketing strategy of consumer goods.[1,2,3] Packaging helps to establish brand identity in competitive markets and serves as an effective form of promotion both at the point of purchase and while the product is being used.[4,5,6] Packaging is particularly important for consumer products such as cigarettes, which have a high degree of social visibility.[7,8] Unlike many other consumer products, cigarette packages are displayed each time the product is used and are often left in public view between uses.[9] As John Digianni, a former cigarette package designer noted: "A cigarette package is unique because the consumer carries it around with him all day…It's a part of a smoker's clothing, and when he saunters into a bar and plunks it down, he makes a statement about himself."[10] As a result, the package serves as a "badge" product, and an important form of advertising in its own right.[7]

Brown & Williamson (1985)

"… if you smoke, a cigarette pack is one of the few things you use regularly that makes a statement about you. A cigarette pack is the only thing you take out of your pocket 20 times a day and lay out for everyone to see. That's a lot different than buying your soap powder in generic packaging."[11]

British American Tobacco (1978)

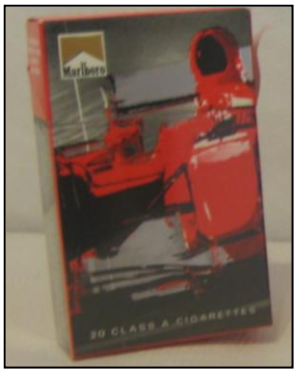
"One of every two smokers is not able to distinguish in blind (masked) tests between similar cigarettes …for most smokers and the decisive group of new, younger smokers, the consumer's choice is dictated more by psychological, image factors than by relatively minor differences in smoking characteristics."[12]

Packaging and other forms of marketing

Cigarette packages also serve as an important link to other forms of tobacco advertising.[13] Package designs help to reinforce brand imagery that is communicated through other media, and play a central role in point of purchase marketing, which

now accounts for a majority of the industry's promotional spending in Canada and the US.[14] Indeed, cigarette "power walls"—rows of cigarette packages prominently displayed behind retail counters—have been shown to be an effective form of marketing, particularly among youth and young adults.[15] Moreover, the marketing value of the cigarette package increases as other forms of marketing are restricted.[16,17] Internal documents from British American Tobacco also indicate that packages have been designed to compensate for restricted forms of advertising: "… given the consequences of a total ban on advertising, a pack should be designed to give the product visual impact as well as brand imagery. . . The pack itself can be designed so that it achieves more visual impact in the point of sale environment than its competitors."[18] Imperial Tobacco Canada, a wholly owned subsidiary of BAT and the largest manufacturer in Canada, recently added a new twist to retail displays by re-packaging its leading du Maurier brand in octagon-shaped packages, with angled edges on the front and back of the package face (see right). Jeff Guiler, vice-president of marketing for Imperial Tobacco Canada, explained that the new shape was a way to attract consumer attention in a market with limited opportunities for advertising and promotion.

Du Maurier (Canada)



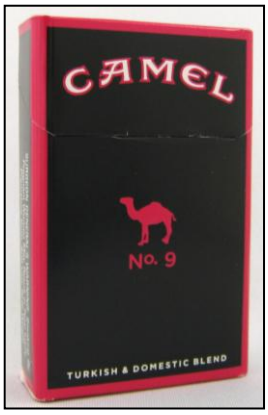
In particular, it was a way to reinforce the ''prestige'' of the du Maurier brand and to distinguish it from the growing number of discount brands in Canada. Guiler explained the implications of the new packages for the point-of-sale environment: ''We decided that in order to leverage the full impact of the Signature Pack and overcome the fact that we are not allowed to do any kind of advertising, we needed to also redesign and refit our in-store displays to mirror the look of the pack.'' [19,20]

Beyond the retail environment, packages also help to increase the reach of "below the line" marketing activities.[21] For example, cigarette packages contain specific references to sponsorship and promotional activities, such as *Formula 1* racing series, concerts, and nightclub promotions. Overall, the cigarette package is the cornerstone of tobacco marketing strategy and poised to become even more important as, the following quote from a Phillip Morris executive indicates: "Our final communication vehicle with our smoker is the pack itself. In the absence of any other marketing messages, our packaging...is the sole communicator of our brand essence. Put another way—when you don't have anything else—our packaging is our marketing."[22]

Cigarette packaging and youth

Research conducted by the tobacco industry consistently demonstrates that the brand imagery portrayed on packages is particularly influential among youth and young adults—the period in which smoking behavior and brand preferences develop.[7,923,24,25] In many cases, initial brand preferences are based less on the sensory properties of product than on perceptions of the package and brand: "One of every two smokers is not able to distinguish in blind (masked) tests between similar cigarettes …for most smokers and the decisive group of new, younger smokers, the consumer's choice is dictated more by psychological, image factors than by relatively minor differences in smoking characteristics."[26] The brand imagery on cigarette packages is effective to the point that large majorities of youth—including non-smoking youth—demonstrate high levels of recall for leading package designs.[27] This is particularly true when packages incorporate brand imagery that has broad appeal to younger audiences, such as the "Old Joe" cartoon image portrayed on *Camel* packages.[28]

Cigarette packaging and young women



Package colours—especially pink and other pastels— are increasingly being used to target young women.[21] Leading brands, such as *Camel*, now offer cigarettes that come in female-oriented pink packages.[29] Other colours commonly used include purples, white, and light yellow.[30] These colours have been shown to suggest positive qualities such as freshness, cleanliness, purity, health, and intelligence.[1] Such colours and the use of other feminine symbols and images are widely acknowledged to portray smoking as feminine and stylish, in an attempt to make cigarettes more appealing to women, as well as to reduce perceived health risks.[33] Brand descriptors such as "*slims*" are used to target young women by exploiting concerns about weight gain and the association between cigarette smoking and thinness.[31,32,33,34] Most recently, Phillip Morris released its newest attempt at targeting young women with "purse packs"—*Virginia Slims "Superslims"* that are contained in slim pink packages that are much narrower in diameter than regular packages, and easier to carry in one's purse.

Packaging and other tobacco control measures

Packaging strategies can also be used to offset the impact of other tobacco control measures, such as increases in price and taxation. For example, internal tobacco industry documents indicate that packaging cigarettes into smaller, more affordable units (such as 10 cigarettes per package rather than 20) are an effective strategy for targeting price-sensitive youth.[23] Although legislation in many countries now prohibits the sale of cigarettes in units less than 20, innovations in the physical shape and construction of packages—such as BAT's "wallet packs" which open like a book and can be separated into two smaller packages—have been criticized as

an attempt to circumvent these prohibitions.[35] BAT's wallet packs were recently banned in Australia after the federal court recently upheld an injunction against their sale. Tobacco companies have also explored packaging strategies to minimize the impact of health warnings, including changes in package design to make warnings less distinctive, as well as the sale of alternate cases and covers that obscure warnings.[36] Further innovation in tobacco packaging is on the horizon[37], as the following quotes indicate:

> *"With the uptake of printed inner frame cards what we will increasingly see is the pack being viewed as a total opportunity for communications – from printed outer film and tear tape through to the inner frame and inner bundle. Each pack component will provide an integrated function as part of a carefully planned brand or information communications campaign."* [38]

> *"Advances in printing technology have enabled printing of on-pack imagery on the inner frame card, outer film and tear tape, and the incorporation of holograms, collectable art, metallic finishes, multi-fold stickers, photographs, and retro images in pack design. In the early 1900s, collectable cigarette cards were a major form of in-pack promotion. A contemporary return to the package as the primary source of advertising is apparent in the following examples."*

In short, the package is a vital marketing channel for the tobacco industry and its value will continue to increase as more traditional forms of marketing are subject to increasing restrictions.

HEALTH WARNING LABELS

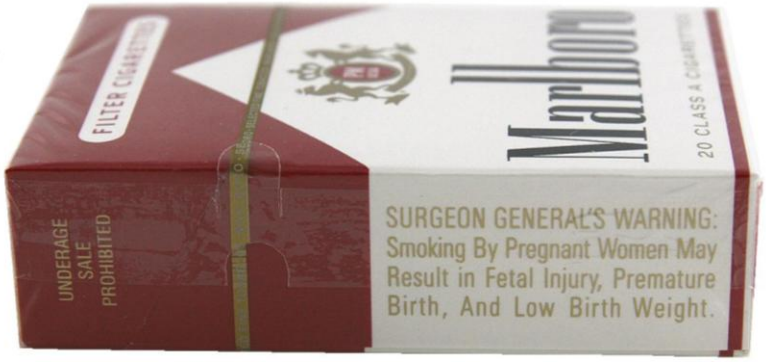
FCTC Article 11

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:

….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 area; (v) may be in the form of or include pictures or pictograms.

In addition to serving as a marketing vehicle for the tobacco industry, cigarette packages also provide governments with a direct means of communicating with smokers. Warning labels are primarily intended to communicate the health risks of smoking and to fulfill the government's responsibility as regulators to warn consumers about hazardous products.

At present, cigarette packages in the vast majority of countries carry a health warning.[39] However, the position, size, and general strength of these warnings vary considerably across jurisdictions. In the US, health warnings were first



U.S. Health Warning

included on cigarette packages in 1966, and in advertisements in 1972. Since 1984, US cigarette packages have carried one of four government-mandated text warnings on the side panels of packages. In contrast, more than a dozen countries currently require large pictorial health warnings that cover at least 50% of the package, consistent with the recommendations in FCTC Article 11.

Cigarette packages are an excellent medium for communicating health information given their reach and frequency of exposure. Package health warnings are also unique among tobacco control initiatives in that they are delivered at the time of smoking and at the point of purchase. As a result, the vast majority of smokers report a general awareness of package health warnings and pack-a-day smokers are potentially exposed to the warnings over 7000 times per year. As a result, health warnings on cigarette packages are among the most prominent sources of health information: more smokers report getting information about the risks of smoking from packages than any other source except television.[40] Findings from Canada, Thailand, and elsewhere, indicate that considerable proportions of non-smokers also report awareness and knowledge of package health warnings.[41,42,43] As a result, health warnings are an extremely cost-effective public health intervention and have tremendous reach. However, the extent to which smokers read and think about, and act upon the warnings is highly dependent on their size, position, and design.

> ◎ ***RESOURCE: Health warning pictures online***
>
> An extensive list of picture-based health warnings that have been implemented throughout the world, as well as additional images used in test-marketing, can be reviewed at: www.tobaccolabels.org

Size and Position of Health Warnings

Smokers are more likely to recall larger warnings, and have been found to equate the size of the warning with the magnitude of the risk.[42,44,45,46,47,48,49,50] One Canadian survey found that smokers judged warnings that covered 80% of the package to be most effective. For example, in studies where youth and adults are asked to rate the

effectiveness of different health warnings, the largest warnings are most likely to be rated as effective.[51,52,53] Smokers also report greater recall for warnings that appear on the front, compared to the side of packages.[44,47,49,50,51] For example, several studies indicate that the US text warnings on the side of packages demonstrate low levels of salience among smokers.[54,55,56,57] In a comparative study of students in Canada and the US carried out in 1995, at a time when Canadian packages carried text warnings on the front of packages, 83% of Canadian students mentioned health warnings in a recall test of cigarette packages, compared to only 7% of US students.[58] A Phillip Morris document also highlights the importance of positioning on the front of packages: "Government required warnings placed on the largest packaging panel, often called the front and/or back, are the biggest marketing threat to all of us in Asia..."[22] Features that distinguish the warning messages from the package design have also been found to increase the salience and recall of warnings.[59] Messages with contrasting colours, such as black lettering on a white background are the easiest to read, whereas the legibility of silver or gold text messages is comparatively poor.[47,60]

Literacy

The message content of text-based warnings must target an appropriate literacy level.[61] The current US warnings, for example, require a college reading level and may be inappropriate for youth and Americans with poor reading abilities.[62] This is particularly important considering that, in most countries, smokers report lower levels of education than the general public. Picture-based warnings may be particularly important in communicating health information to populations with lower literacy rates.[63,64] Preliminary evidence suggests that countries with pictorial warnings demonstrate fewer disparities in health knowledge across educational levels.[65]

Impact on Health Knowledge

Cigarette warnings labels have been demonstrated to have a significant impact on smokers' understanding of the risks of tobacco use. Several studies have shown that large text-based warnings are associated with increased perceptions of risk. Cross-sectional surveys conducted in Canada during the 1990's found

Hungary

that the majority of smokers reported that package warning labels are an important source of health information and have increased their awareness of the risks of smoking.[66,42] In Australia, Borland[67] found that, relative to non-smokers, smokers demonstrated an increase in their knowledge of the main constituents of tobacco smoke and identified significantly more disease groups following the introduction of new Australian warning labels in 1995. Several studies have evaluated enhancement of text warnings in European Union (EU) to a minimum of 30% of the principle display area of the package. First, a study of Spanish university students concluded that text warnings based upon the EU directive significantly increased perceptions of risk.[68] These findings were consistent with results from a series of studies conducted with a representative sample of smokers in the UK, France, Scotland, and Ireland on the effects of similar text warnings that were introduced in 2003 in compliance with the EU directive. [69,70] Collectively these studies indicate that smokers' awareness of the warnings increased following the new warnings and considerable proportions of smokers report thinking about health risks and quitting smoking as a result of the large text warnings.

The use of Pictures and Sybmols in Health Communications

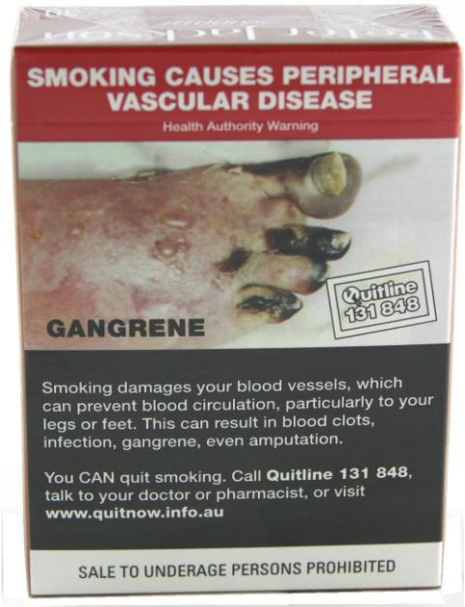
A wide variety of research has clearly demonstrated the effectiveness of using pictures and imagery in health communications.[71,72,73,74,75] This research has demonstrated that warnings with pictures are significantly more likely to draw attention and result in greater information processing, and improve memory for the accompanying text. Picture warnings also encourage individuals to imagine health consequences and are also more likely to be accessed when an individual is making relevant judgments and decisions. As a result, the use of pictorial symbols is a common and effective feature of health warnings for a wide variety of consumer products.[76,77,78,79,80,81,82]

Pictures and Sybmols in Tobacco Warning Labels

Experimental research on cigarette warnings has also found that picture-based warnings are more likely to be rated as effective versus text-only warnings both as a

deterrent for new smokers and a means to increase cessation among current smokers.[83,84,103]

Extensive focus group testing and market-research commissioned by government health agencies also underscores the importance of using pictures in package health warnings. This research consistently demonstrates that health warnings with pictures are rated by smokers and non-smokers as more effective and associated with greater impact and memory for health risks than text-only warnings. The following includes summary statements from several prominent sources.



Summary of Health Canada Research Conducted Prior to 2000

Participants felt that the new larger health warning messages, featuring colour photographs, were a definite improvement over the current warning messages. Teenagers were particularly impressed with the use of pictures and the larger size of the messages that allow for the dissemination of more information.

Overall Responses to New Warning Messages, p.5[85]

Summary of Research Commissioned by the Australian Department of Health

"The graphic packs were more informative about health effects and more effective in general in conveying health information regarding the contents of cigarettes and cigarette smoke than were the "text only" alternatives. They were also more likely to elicit an emotional response from smokers. They will generate controversy and discussion about smoking and its health and social effects. The graphic packs are more likely to: create impact; attract attention; be confronting and difficult to ignore; make it more difficult for smokers to deflect the health message. Overall, the "text only" packs were not considered as impactful or as effective in conveying the potential negative health consequences of smoking as the graphic pack alternatives."

Executive Summary, p.5[86]

Summary of Research Commissioned by Health Canada Since 2000

"It also appears that messages have to be credible and supported by facts and visual depictions wherever possible."

"Other graphic approaches showing dramatic negative health effects, although not necessarily liked, were effective in garnering notice among a number of participants."

Executive Summary, p.3[87]

"The picture was generally the first thing people looked at and related to. It determined the strength of the warning's emotional impact and noticeability. For many participants, the picture played the key role in understanding the message, and tended to override the meaning conveyed by the words in the headline. Therefore, those warnings with a clear, simple and effective headline to support or complement the emotionally strong visual were the ones that consistently generated positive and almost enthusiastic feedback from participants."

Executive Summary, p.4[88]

Summary of Research Commissioned by the New Zealand Ministry of Health

"All experience and evidence suggests that a combination of visual and text provides the best possible communication; the visual element to attract attention and telegraph a strong message, the text to expand and provide information."

Summary, p.14[89]

"Respondents consistently mentioned visuals as being the crucial element-i.e. clear pictorial evidence of the consequences of smoking or the potential gains of quitting."

Summary, p.6[90]

"By way of a high-level summary of findings, the following key consideration emerged from the research:

-Pictorial messages are likely to have significantly more impact than text-only message.

-The larger the pictorial message, the greater its impact."

Summary p.6[91]

Since 2000, when the first pictorial warnings were introduced in Canada, a series of population-based surveys have compared the effectiveness between text and pictorial warnings. These findings are consistent with both the experimental and government commissioned research: graphic warnings are more likely to be noticed and read by smokers, are associated with stronger beliefs about the health risks of smoking as well as increased motivation to quit smoking.[69,84,87,88,90,91,92,93,94,95,96,97,98,99,100,101.102]

Picture warnings appear to be especially effective among youth: more than 90% of Canadian youth agree that picture warnings on Canadian packages have provided them with important information about the health effects of smoking cigarettes, are accurate, and make smoking seem less attractive.[42] Other national surveys of Canadian youth suggest similar levels of support and self-reported impact.[41] A recent longitudinal evaluation of pictorial warnings among Australian school children found that students were more likely to read, attend to, think about, and talk about health warnings after the pictorial warnings were implemented in 2006.[101] In addition, experimental and established smokers were more likely to think about quitting and forge cigarettes, while intention to smoke was lower among those students who had talked about the warning labels and had forgone cigarettes. Recent experimental research conducted among youth in Greece is consistent with these findings.[103] In recognition of this evidence, the Elaborated Guidelines of FCTC Article 11 state that:

FCTC Article 11 Elaborated Guidelines

"Evidence shows that health warnings and messages that contain both pictures and text are far more effective than those that are text-only. They also have the added benefit of potentially reaching people with low levels of literacy and those who cannot read the language(s) in which the text of the health warning or message is written. Parties should mandate culturally appropriate pictures or pictograms, in full colour, in their packaging and labelling requirements."[104]

"Graphic' picture and the use of fear arousing information

Pictorial warnings that contain graphic images of health effects have been criticized on the grounds that threatening information may cause defensive reactions among smokers that lessen the likelihood of quitting.[105] Graphic warning labels showing "shocking" pictures of health effects do indeed cause strong emotional reactions among a considerable proportion of smokers and non-smokers.[98,106] However, strong emotional reactions are associated with increases in the effectiveness of warnings.[98] Indeed, there is no evidence that graphic warnings labels decrease the effectiveness of the warnings in terms of intentions to quit, thinking about health risks, or engaging in cessation behaviour. For example, a recent experimental study compared picture warnings that showed graphic depictions of disease (or "loss-framed" message) versus pictorial warnings that emphasized the positive aspects of abstaining from smoking (or "gain-framed" messages). The results indicated that adolescents had more favorable attitudes toward the loss-framed warnings and perceived them as more effective than the gain-framed warnings. Further, smokers exposed to the loss-framed version featuring decaying teeth had significantly lower intentions to smoke in the future.[107]

Canada

It has also been suggested that smokers will simply avoid warnings that are too strong and will "tune out" the health messages. Although several studies indicate that a considerable portion of smokers make some attempt to avoid graphic pictorial health warnings by covering or hiding the warnings and using another case, these examples of fear control behaviour do not necessarily reflect an adverse outcome or inherent weakness of package warnings. Research has demonstrated that avoidant behaviours and attempts at thought suppression often have the opposite effect of increasing the presence of the unwanted

Singapore

thoughts.[108] One study found that smokers who attempted to avoid the warning were nevertheless no less likely to see the warnings, think about them, or engage in cessation behaviour at 3-month follow-up.[98] Preliminary findings from a longitudinal study of the pictorial warnings in Australia also demonstrate a positive association between "avoidant behaviour" and self-reported measures of effectiveness, such as foregoing a cigarette and increases in motivation to quit smoking as a result of the warnings.[109] In the context of the warning labels, avoidant behaviour might be more reasonably interpreted as a measure of effectiveness. Indeed, if the warnings were ineffective in communicating the threatening consequences of smoking there would be no reason to avoid them.

In fact, research in the field of health communication indicates that messages with emotionally arousing content are more likely to be noticed and processed by smokers.[110] The most consistent finding from this literature is that fear appeals are effective when paired with strong efficacy messages for a specific outcome (i.e. quitting smoking). A recent meta-analysis of the literature on public health communications concluded that 'strong fear appeals and high-efficacy messages produce the greatest behavior change', and found no evidence of any adverse or 'boomerang' effects for strong fear appeals.[110] Graphic warnings in Canada, Australia, Singapore, Brazil, and other countries are entirely consistent with this literature: in addition to information on health risks, they include messages designed to increase self-efficacy for quitting. These messages include both general messages of support, as well as concrete information on ways to quit smoking and specific sources of help, including website addresses and toll-free "quitline" numbers.

Australia

Belgium

The effectiveness of graphic fear-inducing images is supported by surveys and focus groups with smokers. For example, an extensive public consultation was conducted by the UK Department of Health that received more than 20,000 responses. The highest rated warnings were generally those that included the "hardest hitting" messages and images, including graphic pictures of the health effects of smoking (see right).[111] Research conducted on behalf of the Australian, New Zealand, and Canadian governments yielded similar results:

United Kingdom

> *"Participants in all groups consistently expected or wanted to be shocked by HWMs, or emotionally affected in some way. Even if the feelings generated were unpleasant ones to tolerate, such as disgust, fear, sadness or worry, the emotional impact of a warning appeared to predict its ability to inform and/or motivate thoughts of quitting. HWMs which worked on emotions rather than on knowledge or beliefs were often acknowledged as effective and noticeable, and actually motivated thinking. When a strong emotion generated by a HWM was supported by factual information, that was the best combination possible."*
>
> Overview of Findings, p.3[88]

> *"Most participants were moved by the dramatic and scary pictures and messages, such as the woman smoking through a hole in her throat, the sick baby, the cemetery with grieving loved ones, and warnings that depicted the physical and health consequences of smoking, such as the diseased mouth."*
>
> Overall Responses to New Warning Messages, p.5[85]

Health warnings and cessation behaviour

The extent to which health warnings lead to changes in smoking behaviour is difficult to ascertain within the context of population-based data. However, significant proportions of adult and youth smokers report that large comprehensive warnings have reduced their consumption levels, increased their likelihood of quitting, increased their motivation to quit, and increased the likelihood of remaining abstinent following a quit attempt.[42,96,97,98, 112,113,114,115,116,117,118,119,120] In at least three studies, longitudinal studies have demonstrated an association between reading and thinking about health warnings and subsequent cessation behaviour.[97,101,102] Increases in the use of cessation services have also been associated with health warnings. Research conducted in the UK, the Netherlands, Australia, New Zealand, and Brazil has examined changes in the usage of national telephone "helplines" after the contact information was included in package health warnings. Each of these studies reported significant increases in call volumes. [118,121,122,123,124] For example, calls to the tollfree smoking cessation helpline in the Netherlands increased more than 3.5 times after the number was printed on the back of one of 14 package warnings.[122] Therefore, while it is not possible to precisely quantify the impact of health warnings on smoking prevalence or behaviour, all of the evidence conducted to date suggests that health warnings can promote cessation behaviour and that larger pictorial warnings are most effective in doing so.

Brand Appeal

Prominent health warnings that cover a significant proportion of the package also have the potential to undermine a brand's appeal and the impact of package displays at retail outlets.[116,125,126,127,128] One recent study found that including graphic pictures compared to text-only warnings lowered the appeal of non-combustible products, nicotine lozenges, and cigarettes with modified designs.[129] A Quebec Superior Court judge remarked upon this phenomenon in a ruling regarding the industry's challenge to pictorial warnings in Canada: "Warnings are effective and undermine tobacco companies' efforts to use cigarette packages as badges associated with a lifestyle."[130]

Chile

Credibility & Public Support

Research indicates that smokers report graphic warnings to be a credible source of information, particularly when attributed to a well respected Department of Health or a well respected non-governmental authority, such as a cancer society.[90,150,131] The levels of credibility do not appear to be associated with the type or design of warning labels: like text-based warnings, smokers report high levels of believability for graphic picture-based warnings.

Brazil

Uruguay

Several studies also report high levels of public support for graphic pictorial warnings.[98,132,133] For example, in Canada more than 90% of youth agreed that picture warnings on Canadian packages have provided them with important information about the health effects of smoking cigarettes, are accurate, and make smoking seem less attractive.[42] In Brazil, a national survey indicated that 76% of those interviewed approved of the measure, including 73% of smokers.[118] Two years after the introduction of large pictorial warnings in Uruguay, only 8% of adult smokers reported they would prefer less health information to appear on packages, whereas 62% reported they would like more health information on packages.[134] Similar levels of popular support have been observed following the introduction of pictorial warnings in Canada and Thailand.[97,135] Although tobacco companies have suggested that pictorial warnings "harass" smokers, research suggests that, overall, smokers welcome more health information on their packages, including information that presents the health consequences of smoking in a vivid, arousing manner.

"Wear-out" and impact over time

It is widely accepted that the salience of advertising and health communications is typically greatest upon initial exposure.[136,137] For example, a recent study found that new text-based warnings introduced in the United Kingdom in 2003 were considerably more likely to be noticed than Australian text-based warnings which were only slightly smaller, but had been in place for more than eight years at the time of the survey.[96] The frequency with which smokers read and attend to warnings has been shown to lessen over time as smokers become desensitized to the warnings.[138,139,140] As a result, health warnings must be regularly updated to maintain their maximum impact over time.

Government Regulation & Industry opposition

Thailand

The tobacco industry has vigorously opposed comprehensive tobacco labelling policies, especially in the case of pictorial labels.[141] For example, as Alechnowicz and Chapman[142] have noted, in 1995, package warnings were identified by British American Tobacco as one of the key issues facing the company. Protecting the pack design and "neutralizing" the controversy over pack warning labels were among the priorities listed in the document.[143] The same document goes on to state that, "pictorial warnings, and those occupying a major pack face or faces (front and back) or a disproportionately large area of advertising space, should be restricted, as should moves to plain or generic packs. Every effort should be made to protect the integrity of the company's packs and trade marks".[143]

In public, tobacco manufacturers have argued that large comprehensive warnings are not only unnecessary, but are less effective than more obscure text messages.[141] For example, Martin Broughton, the former Chairman of BAT recently stated that: "The growing use of graphic image health warnings …can offend and harass consumers- yet

in fact give them no more information than print warnings."[144] Tobacco manufacturers have also argued that comprehensive warnings constituent an unreasonable and illegal expropriation of cigarette packaging.[7]

To date, courts of law have disagreed. For example, in response to a legal challenge of the Canadian Tobacco Act, the court found that the tobacco companies' right to advertise their products could not be given the same legitimacy as the federal government's duty to protect public health. In short, the courts have ruled that even graphic warnings are warranted considering the societal costs of smoking.

Alternative tobacco products

Labelling requirements for manufactured cigarettes are more advanced than for other tobacco products. In many jurisdictions, tobacco products such as cigars and smokeless products are subject to different regulations and often carry a different set of health warnings or no warning at all. There is a need for research to examine issues such as alternative packaging sizes, as well as the extent to which alternative tobacco products require unique message content to reflect differences in health effects and patterns of use.[145] In addition, in many jurisdictions tobacco products are sold without any manufactured packaging. This practice will inevitably reduce the impact of comprehensive labelling policies. For some products sold without packaging, such as manufactured cigarettes that are sold individually, it may be possible to print health warnings directly on the cigarette itself. For other products sold without packaging, such as "loose" or "fine cut" tobacco, this may be impossible given the nature of the product. Given the lack of information in this area, research on health warnings for "alternative" tobacco products should be regarded as a priority.

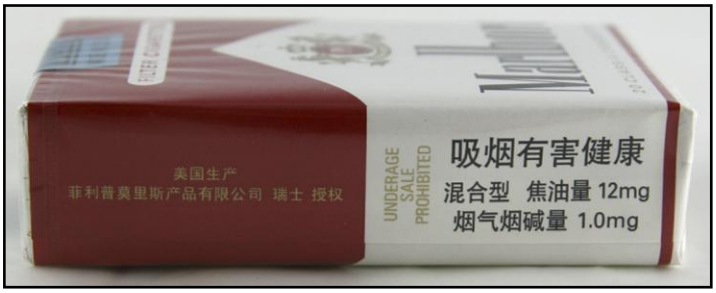
CONSTITUENTS AND EMISSION LABELLING

FCTC Article 11:
Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.

Disclosure of constituents and emissions has presented a unique challenge to regulators. Cigarette smoke contains approximately 4,000 chemicals, including over 60 carcinogens and toxins such as polonium 210, benzene, and arsenic.[146] Although there is general agreement that cigarette packages should include some information on these chemicals, regulators continue to struggle with how best to communicate this information in a feasible and meaningful way to consumers.

Indeed, the primary rationale given for the disclosure of emissions and constituents is to inform consumers about the contents of tobacco products; however, the benefits of communicating this information to consumers are by no means certain.

At present, national authorities have taken much different approaches to labelling constituents and emissions. The traditional regulatory practice in many jurisdictions has been to require manufacturers to print levels for three emissions in the mainstream smoke: tar, nicotine, and carbon monoxide (CO). These numbers are typically printed on the side of packages. In fact, communicating emissions numbers to consumers was originally an industry practice. Tobacco manufacturers have communicated tar and

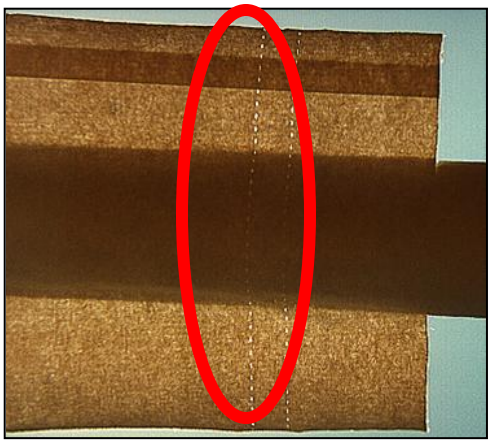


China

nicotine numbers directly to smokers ever since the health risks of smoking became publicly known.[147] These early forms of "product disclosure" were motivated less by consumer protection than by a marketing strategy intended to capitalize upon widespread misperceptions of "lower tar" products. Despite early objections by regulatory authorities such as the U.S. Federal Trade Commission, this industry practice was adopted by regulatory communities throughout the world.[148]

Cigarette emissions

Tar, nicotine, and carbon monoxide emission numbers are misleading. They represent neither the amount of chemicals present in the cigarette (i.e. tobacco "constituents"), nor the amounts actually ingested by human smokers. This is because the emission numbers are determined by a machine that "smokes" cigarettes according to a fixed puffing regime. This machine method does not predict the amount of smoke inhaled by individual consumers or account for design elements such as "filter ventilation"—tiny holes poked in the filter that yield low emission levels under machine smoking, but much higher levels under human smoking.[149] As a result, there is no association between the machine-generated numbers printed on packages and the health risk of different brands. In short, the underlying premise for communicating tar and nicotine numbers directly to consumers—that "low tar" cigarettes are less harmful—has since been rejected.



Filter ventilation

European Union

Although the scientific consensus on tar and nicotine emissions has evolved, the practice of communicating these numbers to consumers remains widespread: not only have manufacturers continued to communicate tar and nicotine levels directly to consumers via advertising, but many regulators continue to do so

through packaging and labelling regulations. Research has repeatedly shown that although many smokers are not able to recall the specific tar level of their brand, a substantial proportion nevertheless equate lower numbers with a reduction in exposure and risk, and many use these numbers to guide their choice of brands.[150,151,152, 153,154,155] Recent findings suggest that smokers even in the most affluent and educated countries continue to hold false beliefs about emission numbers:

- 75% of smokers from Australia, Canada, the U.S., and the UK recently reported that the tar numbers on packs are related to exposure.[156]
- Among smokers in the same study who believe that some brands are less harmful than others, 81% believe that the tar and nicotine levels indicate the brands that are less harmful.[156]
- When shown emission labels on two cigarette brands from the European Union, 92% of smokers recently reported that the 4mg product would deliver less tar than the 10mg product, and 90% reported that they would buy the 4mg product if they were trying to reduce the risks to their health.[100]
- These findings are consistent with the ways in which smokers have been shown to perceive emission numbers when conveyed through advertising.[147]

Overall, printing emission numbers on packages reinforces the tobacco industry's deceptive marketing campaign and the false belief that low tar cigarettes are less hazardous.

In many cases, manufacturers voluntary print emission levels on packages even in the absence of regulation. For example, in the United States there are no requirements to print emission levels on packages. However, a number of manufacturers do so voluntarily, albeit in a highly selective fashion. In 2004 and 2005, tar levels were printed on more than 90% of U.S. brands with less than 3mg of tar, compared to fewer than 2% of brands with 8-11mg of tar.[157] Similar practices have occurred in other jurisdictions, such as Brazil, where regulators have removed the requirement to print numbers, but have not prohibited manufactures from doing so.

In light of these findings, some jurisdictions have supplemented the emission numbers with additional emission information. In 2000, Canada increased the list of emissions that must be reported and added a second set of emission numbers generated under the "Health Canada" method, a more intensive machine smoking method (see right). This emission testing method is no better at predicting exposure or risk than the lower set of numbers.[158]

Canada

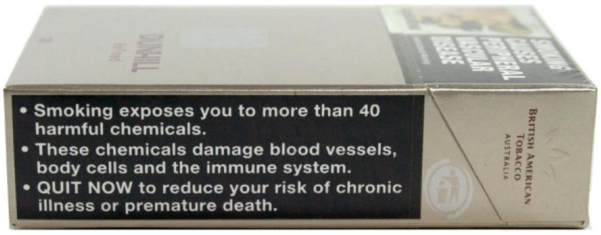
Subsequent research conducted on behalf of Health Canada found that 4 out of 5 smokers did not understand the emission information; nevertheless, more than half reported that they would use these numbers "to find a less harmful brand".[150] More recent research found that Canadian smokers and non-smokers rated the emission information on Canadian packs as significantly more "informative" and "useful" than the emission information on EU and Australian packs; however, the Canadian emission information was also rated as the "most difficult to understand," and the vast majority of smokers reported that the numbers could be used to identify less harmful brands.[100]

Overall, consumer misperceptions are not simply due to flaws in a particular testing method and the actual value of the numbers, but the practice of assigning different brands different numbers. Changing the metric of cigarette emissions by using more intensive testing methods provides little insurance against the likelihood that consumers will interpret brands with lower numbers as lower risk. If the scientific consensus is that there are no measurable differences in risk between conventional cigarette brands, regulators should not communicate numerical toxicant levels that suggest otherwise. Indeed, the "Elaborated Guidelines" for FCTC Article 11 state: "Parties should prohibit the display of figures for emission yields, such as tar, nicotine and carbon monoxide, on packaging and labelling, including when used as part of a brand name or trademark."[104]

Non-numerical emission labelling

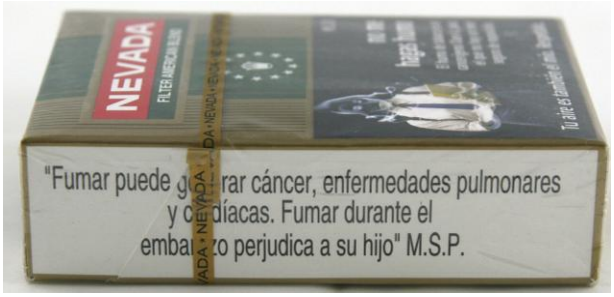
Brazil

Overall, there is no evidence that quantitative emissions constitute effective consumer information and leading scientific bodies have called for the removal of emission numbers from packages.[159] To date, at least five countries have removed emission information from packages and replaced it with descriptive information about toxic constituents and their effects on health. Preliminary research suggests that this information is more meaningful to consumers and less likely to result in misperceptions about the relative risk of different cigarette brands.[100,160] Further work is required to examine what types of descriptive product information are most useful to consumers. For example, it remains unclear whether consumers would be best served by a long list of toxic chemicals, a subset of the most hazardous chemicals, or perhaps the most recognisable toxicants, such as arsenic and benzene. The extent to which additives or design features (such as filter ventilation) might serve as effective consumer messaging is also unclear. See Chapter 3 of this Toolkit for recommendations on designing toxic emission messages, including examples.



Australia


Thailand



Uruguay

PLAIN PACKAGING AND PROHIBITIONS ON MISLEADING INFORMATION

FCTC Article 11:

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:

….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."

Tobacco companies have made extensive use of cigarette packages to convey information regarding the risks of cigarettes.* Prior to the 1950's, tobacco packages rarely included information about tar levels or other information that might cause smokers to reflect upon health risks. However, following the publication of the first Surgeon General's report on the health risks of smoking in 1964, tobacco companies have sought to actively reassure consumers about the potential risks of their products. A central feature of this marketing strategy has been to promote differences in the relative risk of brands and to integrate this marketing strategy into the design of products themselves, largely through the promise of improved filtration and lower emissions. Nicotine-addicted consumers embraced these brands as a welcome alternative to quitting, as well as a means of easing the guilt and cognitive dissonance from smoking.[147]

* Note that several quotes and sources in this section are drawn from a recent review prepare by Freeman, Chapman, & Rimmer[24]

The package has served as an essential medium for executing this marketing campaign. In general, tobacco companies have relied upon implicit means to promote differences in risk, rather than overt health claims on the package.[147] This has been accomplished using a number of packaging elements, including references to product design, the use of misleading descriptors, as well as the use of colours and symbols.

References to product design

Products that are positioned as "low yield" brands often carry images or references to product design on the package.[161] References to filtration are among the oldest and most common examples of this strategy. For more than 50 years, tobacco companies have communicated filter properties to consumers as tangible evidence of emissions reduction and lower risks. Indeed, the rise of filtered cigarettes in the U.S. paralleled the rise in health concerns among consumers.[146] From Kent's *Micronite* filter, to Barclay's *ACTRON* filter, to the charcoal filters currently being test marketed in Marlboro Ultra Smooth—whatever the filtration properties of these designs may be, they reassure smokers when displayed on the package.[162] As Myron Johnston and W.L. Dunn of Philip Morris stated in 1966, "the illusion of filtration is as important as the fact of filtration."[163]

The images on the right provide a contemporary example of this packaging strategy from China, where two leading brands feature images of high-tech filters and references to "laser holes," "active carbon particles," and "colour cellulose particles." Packages with pictures and references to special cigarette filters such as these are rated by a majority of smokers as having less tar and lower health risk.[100] These references to product design and chemical profile on the package are

China

meaningless in terms of actual risk; however, as internal tobacco industry documents indicate, the illusion of improved filtration and technology falsely reassures consumers.[164]

Brand descriptors

Tobacco manufacturers incorporate a variety of common terms into the names of their cigarette brands. Words such as *light* and *mild* are ostensibly used to denote flavour and taste; however, *light* and *mild* brands are often promoted as "healthier" products and have been closely integrated with product design in order to maximize their impact.[9,147,149,161] Brands with descriptors such as *light* and *mild* are typically applied to brands with higher levels of filter ventilation that generate lower machine levels of tar. Not only does filter ventilation dilute cigarette smoke to produce deceptively low emission numbers under machine testing, but it also produces "lighter" tasting smoke and other sensory properties that reinforce the misleading descriptors and images on packages. Indeed, smokers associate the "flavour" and harshness of the smoke with the level of risk.[165] The synergistic but subtle effect of brand descriptors, low emission numbers, and the "lighter" tasting smoke has proven extremely effective in promoting misleading perceptions off risk to smokers.[149,166,167,168,169,170,171] For example these deadly misperceptions have the potential to forestall quitting among many "health concerned" smokers and persist to this day among a considerable proportion of smokers.[149,172] For example, more than 50% of Chinese smokers believe that brands labelled as *light* are less harmful than regular cigarettes.[173]

Words in the name of the brand are persuasive to the point that they can influence sensory properties of smoking a cigarette. One study found that even the name of a cigarette brand is enough to alter people's beliefs about the quality and attractiveness of cigarettes. When Friedman and Dipple had 200 men and women smoke identical cigarettes but told them the brand was called either "April" (a feminine name) or "Frontiersman" (a masculine name), women rated the cigarettes named "April" more favourably, whereas the men rated the cigarettes they believed were named "Frontiersman" more favourably.[174]

Numbers are also used in the name of cigarette brands to distinguish between different varieties. These numbers often correspond to the machine levels of tar emissions.[147] As explained in the previous section, there is extensive research showing that consumers perceive lower tar products as "healthier" than regular or higher tar products. When shown packages with different numbers in the brand name, as many as 80% of smokers report that the brand with the lower number would deliver less tar and may lower risk.[100] The Elaborated Guidelines under Article 11, clearly state that these numbers should be prohibited from packages.[104]

Japan

Canada

Prohibitions on misleading brand descriptors

To date, at least 44 countries have prohibited the use of the words *light*, *mild*, and *low tar* on packaging, including 27 countries from the European Union.[175] Although *light*, *mild,* and *low tar* are the most notable examples of misleading brand descriptors, they are by no means the only ones. Indeed, a wide variety of other descriptors have been designed to reinforce the same false beliefs and perceptions. For example, the term *smooth* has been used as a replacement for *light* and *mild* in a number of jurisdictions with prohibitions.[176] Other common substitutes for *light* and *mild* include the names of colours, such as *silver* and *blue*, which capitalize on the perceptions of these colours as being "lighter". These replacement words have the same misleading effect as *light* and *mild*: a recent study found that more than 70% of smokers reported that packages with words such as *smooth* and *silver* would have lower health risks than *regular* and *full flavour* brands.[100] In addition, recent research conducted in the UK found that 54% of children surveyed identified *Mayfair Smooth* as less harmful than *Mayfair King Size*, similar to the proportion

Canada

that believed that brands described as "light" brand was less harmful (59%).[171]

Therefore, although the removal of *light*, *mild,* and *low tar* terms represent an important first step in removing misleading product information from packages, recent research in Australia and the UK, where these terms have been prohibited, suggests only modest benefits, in terms of reducing false beliefs about the risks of different cigarette brands.[177] The marginal impact of removing the words *light*, *mild,* and *low tar* is likely due to greater colour segmentation, the substitution of other misleading terms such as *smooth,* and the tar and nicotine numbers on UK packages.

"Plain" packaging and the impact of colour and brand imagery

Colour, symbols, and imagery

Colour is routinely used in package design to shape consumer perceptions of risk.[7,9] Research has shown that consumers associate the "lightness" and "strength" of a brand with different colours. For example, blue tones are perceived as "lighter" than red, while products in grey and white packages are perceived to be the "lightest." Recent research in the UK found that cigarettes in a light grey package were rated by four out of ten smokers as less harmful than cigarettes in an otherwise identical red pack. Similar levels of false beliefs were observed among children in the same study. In the same study, different shades of the same colour, as well as the proportion of white space on the package, can also be used to manipulate perceptions of the strength and acceptability of the product itself. The following quote from a Philip Morris researcher describes this phenomenon:[9]

> *"Lower delivery products tend to be featured in blue packs. Indeed, as one moves down the delivery sector, then the closer to white a pack tends to become. This is because white is generally held to convey a clean healthy association."*[178]

Example of colour segmentation with brand varieties (Gauloise—France)

Colour can be used to convey other properties of cigarettes. For example, silver and gold are used to convey status and prestige, particularly for "premium" brands.[7] Red packages and logos convey excitement, strength, wealth, and power.[179,180]

In addition to the use of colour, packaging often includes imagery and symbols with strong associations with health, including images of nature scenes, physical activity, and sport.[7,147]

China

As one indication of the power of colour and imagery, the Canadian subsidiary of Philip Morris recently introduced the U.S. Marlboro cigarette in the Canadian market without the Marlboro name because the trademark is owned by a competitor. This product carries no identifiable name on the package (see below). This speaks not only to the familiarity of the Marlboro chevron logo, but also to how colour alone can be used to distinguish between brand varieties and emission levels.

"Rooftop" Brand Without Identifiable Name on Package (Canada)

Research conducted with adult smokers in the UK, where packs carry the name Marlboro, but use only colour to distinguish between different varieties, found significant levels of false beliefs associated with these brands. Compared to Marlboro packs with a red logo, Marlboro packs with a gold logo were rated as lower health risk by 53% and easier to quit by 31% of adult smokers.[171]

A number of studies have shown that the colour and design of the package are effective to the point where they can affect sensory perceptions of a cigarette, a process known as "sensory transfer." Imperial Tobacco Canada Ltd, a subsidiary of British American Tobacco, summarized extensive research on "brand imagery" that demonstrates how the design of the package alone can affect sensory perceptions of the product.[181] The following provides a description of similar research conducted by Philip Morris:

> *Philip Morris marketing research department compared smokers' responses to cigarette packages in a blue and red pack. Despite the cigarettes being identical in composition, smokers appraised the cigarettes in the blue pack as "too mild" and "not easy drawing". Others felt that the cigarettes in the red pack were "too strong" and "harsher".*[9]

Overall, the colour and brand imagery of a brand has a significant impact upon product perceptions. As Imperial Tobacco Ltd's Vice President of marketing noted: "it's very difficult for people to discriminate blind-tested. Put it in a package and put a name on it, then it has a lot of product characteristics."[182]

Plain packaging

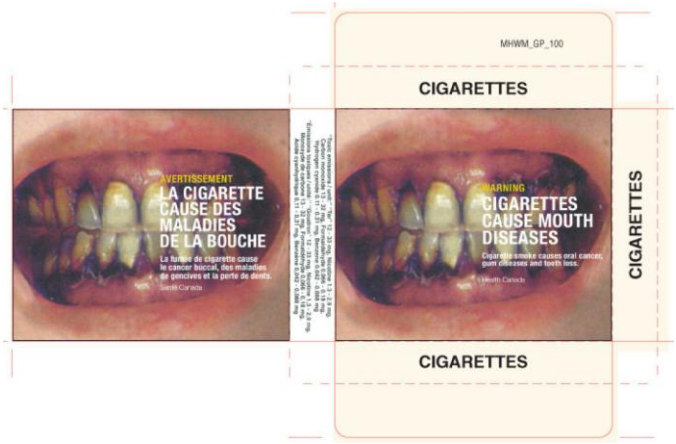
Plain packaging has been proposed as a way to address the impact of colour and other elements of brand imagery on packages. Plain packaging would standardize the appearance of cigarette packages by requiring the removal of all brand imagery, including corporate logos and trademarks. [183] Packages would display a standard background colour and manufacturers would be permitted only to print the brand

name in a mandated size, font, and position. Other mandated information, such as health warnings, would remain, as illustrated below.*

"Regular" Packaging

"Plain" Packaging

One alternative to the example above would be to minimize the proportion of "plain" or "generic" background by enhancing the size of health warnings—see example at right.[52] For example, research conducted in Canada indicates that pictorial health warnings that cover 90 to 100% of the principal display areas may have similar effects to "plain" packaging.[52,53]



Plain packaging and brand appeal

Plain packaging has three potential effects. First, removing the colours and brand imagery from packages has the potential to reduce brand appeal. Research to date suggests that plain packages are less attractive and engaging, particularly to young people.[37] For example, a survey of Canadian youth found that strong majorities "liked" regular packages better than plain packages, and indicated that plain packages are more "boring" and "uglier" than regular packages.[184] Approximately one third of respondents also reported that young

* Note that plain packaging would not address misleading brand descriptors—the term is typically used to refer strictly to the removal of colour and brand imagery. Therefore, prohibitions on misleading words and numbers on packages likely requires a separate regulatory measure.

people their age would be less likely to start smoking if all cigarettes were sold in plain packages. A similar study of Canadian and U.S. youth found that plain packages reduced the positive imagery associated with packages and were associated with greater negative imagery.[185] Recent research conducted with adult smokers in Australia also found that, "cardboard brown packs with the number of enclosed cigarettes displayed on the front of the pack and featuring only the brand name in small standard font at the bottom of the pack face were rated as significantly less attractive and popular than original branded packs. Smokers of these plain packs were rated as significantly less trendy/stylish, less sociable/outgoing and less mature than smokers of the original pack."[186] Similar results have emerged from a recent study conducted in the UK: adult smokers and children rated generic versions of packages as significantly less attractive and youth were less likely to select a general brand if they were to try smoking. [171] Marketing research conducted with adults also suggests that plain packaging reduces some of the appeal of smoking, as the follow quote indicates:

Trachtenberg (Forbes Magazine, 1987)

"…when we offered them Marlboros at half price--in generic brown boxes --only 21% were interested, even though we assured them that each package was fresh, had been sealed at the factory and was identical (except for the different packaging) to what they normally bought at their local, tobacconist or cigarette machine.' How to account for the difference? Simple. Smokers put their cigarettes in and out of their pockets 20 to 25 times a day. The package makes a statement. The consumer is expressing how he wants to be seen by others."[187]

Plain packaging and perceptions of risk

Plain packaging also has the potential to reduce false beliefs about the harmfulness of different cigarette brands. Considerable proportions of smokers in countries such as Canada, Australia, the US, and the UK continue to believe that some types of conventional cigarette brands are less harmful than others.[156] A recent study conducted with adult smokers and youth in the United Kingdom found that, when asked to compare varieties from 8 different cigarette brands, approximately 75% of

adult smokers and children falsely reported that there were differences in risk between at least one of the varieties.[171]

Plain packaging and the salience of health warnings

Plain packaging can also increase the effectiveness of health warnings.[188] In one study, New Zealand youth were significantly more likely to recall health warnings when they were presented on plain packs compared to health warnings presented on "normal" branded packages.[189] A series of surveys and experiments conducted in Canada also demonstrate that health warnings on plain packages are more noticeable, easier to recall, and more believable.[185,27] In 1995, an expert panel from Canada summarized their conclusion on plain packaging based on a comprehensive review:

Expert Panel Report on Plain and Generic Packaging (Canada, 1995)

"Plain and generic packaging of tobacco products (all other things being equal), through its impact on image formation and retention, recall and recognition, knowledge, and consumer attitudes and perceived utilities, would likely depress the incidence of smoking uptake by non-smoking teens, and increase the incidence of smoking cessation by teens and adult smokers."[27]

To date, plain packaging regulations have been considered in several jurisdictions, but have yet to be adopted.[183,190] Industry opposition to plain packaging measures can be expected to be robust. A "plain packs group" was created in 1993 with representative from leading tobacco companies.[191] Documents from this group clearly state that the group did not "want to see plain packaging introduced anywhere regardless of the size and importance of the market."[192]

In recognition of the evidence on "plain packaging" the Elaborated Guidelines of FCTC Article 11 state that:

FCTC Article 11 Elaborated Guidelines

"Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brandimages 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 these and address industry package design techniques that may suggest that some products are less harmful than others..."[104]

Evaluating the removal of information on packages

Unlike other tobacco labelling policies, restrictions on misleading information result in the removal, rather than the provision of information. This presents a challenge when evaluating the impact of these policies, particularly when the information being removed is used as a brand descriptor. In the case of *light* and *mild* bans, the terminology that was previously used to identify a class of products no longer exists. Smokers may retain the same misleading perceptions of these products after the terms have been prohibited, but research measures can no longer refer to "light" or "mild" cigarettes in the same way as in the past. Therefore, survey measures must be designed so that the wording and meaning of questions remains constant before and after the removal of these terms. This creative challenge is only now being confronted by researchers with the recent advent of *light* and *mild* prohibitions.

Another implication of the "removal" of brand information is that the beliefs associated with *light* and *mild* cigarettes are likely to persist for some time after the descriptors disappear from packages. This situation is similar to advertising, promotion, and sponsorship bans: one should not expect beliefs to change immediately upon the implementation of the policy, but more gradually over time. Indeed, anecdotal evidence suggests that many retailers and consumers continue to use the terms *light* and *mild* well after their removal from packages. This issue is distinct from, but complicated by the effect of new descriptors, which are designed to act as substitutes for the banned terms. These considerations are important in terms of how the "effectiveness" of prohibitions on packaging information are evaluated.

Chapter 2 Tobacco Labeling Toolkit

DESIGNING HEALTH WARNINGS

Background

The focus of the current chapter is on planning and designing effective health warning messages. To date, countries have taken much different approaches to the design and selection of health warning messages: some countries, such as Canada and Australia, have invested considerable time and resources in the development of health warnings, whereas other countries with fewer resources at their disposal have adopted a more streamlined process. The goal of this chapter is to simplify this process into a series of steps that can be adapted to local needs and the availability of resources.

Step 1: Layout and Design

The first step in developing health warnings is to determine the general layout and design. Key elements include the size, position, borders, and general appearance of the warnings. The figures below illustrate three different approaches to the design and layout of pictorial warnings.

Canada

Belgium/European Union

Australia

General considerations

Size of warnings

The FCTC requires that warnings must be a minimum of 30% and should cover at least 50% of the principle display areas of the pack. In practice, 50% should be

considered the minimum, while even larger warnings will have even greater effectiveness. In many cases, the size of the warnings is the same on both the "front" and "back" of packages; however, some jurisdictions have used different sizes for each side. In Australia, for example, pictorial warnings cover 30% of the "front" of the package, and 90% of the "back"; in Brazil, warnings cover 100% of either side. Regardless of whether warnings are different sizes, they should cover at least 50% of each principle display surface. This ensures that the warnings are perceptible regardless of which package face is visible. This is especially important at the point-of-sale in retail outlets, where cigarette packages are often seen by children and youth.

Position of warnings

Health warnings should be positioned at the "top" of principle display surfaces in order to maximize their effectiveness at the point-of-sale.

Position of pictures and text

Warnings that occupy a smaller portion of the packages and are rectangular in size, often position the picture and the text horizontally, with the picture to the left and the text to the right (see the example on the "front" of Australian packages, above). Larger warnings that cover half the package or more, typically place the picture above the text description (see the example on the "back" of Australian packages). The amount of space dedicated to the picture versus the text varies across jurisdictions. As discussed, below, some jurisdictions include very little descriptive text. Regardless, the picture should appear on both the front and back of packages and occupy at least half of the space devoted to warnings.

Marker Word

A common feature of warning labels and signs is to use a "marker" word such as "CAUTION", "DANGER", OR "WARNING." Packages in several jurisdictions use "WARNING" as a marker word—see the example from Singapore, at left. In most cases, the font size of the marker word is larger and written in a different colour than other text in the warning.

Tagline

The headline or "tagline" serves as a summary of the main message and is used in conjunction with the picture to attract attention. Jurisdictions will need to choose the position of the tagline. In many cases, the tagline is displayed either at the top of the warning, above the image, or beside the image, immediately preceding the "explanation" text (see example from Canada, above). The tagline should have sufficiently large, bolded font to be clearly legible and to stand out from the warning. Note that the colour of the font and background should contrast in order to maximize legibility. Black lettering on white background and white lettering on black background are examples of effective contrast.

Explanatory text

Many warnings include several sentences of text to help explain the health risk depicted in the picture and the tagline. Although the amount of explanatory text differs considerably across jurisdictions, it should be considered an important element of the warnings. The font size of the explanatory text will typically be smaller than the tagline, but must still be large enough to be easily read.

Attribution of message

Warnings in many countries include text attributing the health warning to the government or some other source. Often, the name of the health ministry is included in small letters at the end of the warning. In other cases, the attribution is included as part of the preamble to the warning, such as: "The Department of Health and Welfare advises…". In countries where the government health ministry is well regarded and has high credibility, attribution to a government source may increase the believability of the information; however, if the government is generally disliked or mistrusted, attribution to government sources may result in rejection of the health warning. Attributions also require valuable space that could be devoted to other information. It should also be noted that the tobacco industry has previously lobbied for government attribution, perhaps to distance itself from the health messages. Overall, however, there is no clear consensus as to whether attributions increase or decrease the credibility of warnings. If attributions are included as part of the warning, the attribution should be made to a health authority rather than the government in general. The attribution should also be relatively small to minimize the space it occupies and should appear at the bottom or end of the text message, rather than at the beginning.

Interior of Package

The external display surfaces of the package represent the most important "real estate" for health warnings or any other information. However, there are also possibilities for using the "inside" of packages. Canada currently requires one of 16 messages to appear on the inside of packages—see right. Although this information is significantly less noticeable than the health warnings on the exterior of the package, interior messages nevertheless represent an added opportunity to communicate with the smoker

which some jurisdictions may wish to pursue. Similar opportunities exist with respect to "onserts", messages attached to the outside of packages.

> ***"Should we conduct research to test the layout of warnings?"***
>
> The general recommendations for size, position, and layout are based upon various research studies conducted across several countries. (See the Evidence Review in Chapter 1 for a comprehensive review.) The basic principles of design and layout appear to be universal: pictorial warnings, for example, appear to be more effective than text-only warnings in every region in which they've been evaluated. Although jurisdictions with considerable resources may wish to test variations on the basic principles of layout and design, there is little need for most jurisdictions to conduct new research to demonstrate these basic principles with respect to size, position, and the use of pictures. The exception may be where politicians or decision-makers require local evidence, in order to be persuaded of the additional benefits of pictorial vs. text-only warnings, or larger warnings, for example. Recommendations for testing design and layout features are included in Chapter 5.

Step 2. Select Number of Warnings and Rotation Period

The FCTC requires that health warnings are "rotated" on packages. Jurisdictions will need to determine the number of warnings per rotation (or "set" of warnings) and the rotation period (or time between sets). For example, Australia recently implemented a set of 7 warnings that will be revised with a second set of 7 warnings after 12 months. Given the time and political resources required to develop and implement new health warnings, developing more than one set of warnings and stipulating a rotation period is an efficient use of resources and ensures regular updates to the warnings.

There is no consensus on either the ideal number of health warnings within each set or the ideal rotation period. In general, each set of warnings should include anywhere from 8 to 12 individual warnings that will appear concurrently. Each set of warnings should be rotated approximately every 1 to 2 years, and no more than every 4 years. Decisions about the number of health warnings in each set and rotation periods must be made early in the process in order to determine how many warnings will need to be developed.

> ◎ **RESOURCE: Layout and Design Worksheet**
>
> A worksheet is included at the end of this chapter to help simplify the steps and decisions that must be taken regarding the layout and design of warnings (see Worksheet #1). Using this worksheet will help to ensure that you have considered all of the major issues before going on to consider the content of the health warning messages.

Step 3: Review Existing Warnings

Before developing new health warnings, existing health warnings in other jurisdictions should be examined to help generate ideas and identify possible themes. To date, well over a dozen countries have recently implemented large pictorial warnings that satisfy the general recommendations for layout and design. Some of these jurisdictions have also developed several sets of health warnings.

> ◎ **RESOURCE: Picture Warnings Online**
>
> An extensive list of picture-based health warnings that have been implemented throughout the world, as well as additional images used in test-marketing, can be reviewed at: www.tobaccolabels.org

Step 4: Content—Identifying Themes & Subjects

Health warnings should be thought of in terms of a communication strategy. Before developing specific warnings, the basic objectives and broad themes of new health warnings should be identified. Broad themes might include addiction, health effects of tobacco, cessation, and various "other" costs of tobacco use, including financial and social costs. While it is possible to target many or even all of these broad themes within a set of health warnings, some jurisdictions have given priority to certain themes in terms of the number of warnings devoted to each.

Possible themes and subjects for health warnings

Theme	Sub-theme	Subject
Addiction	Addictive substances Testimonial Facts & statistics	
Cessation	Benefits of quitting	◦ Health benefits ◦ "Other" benefits
	Supportive "efficacy" messages Quitting tips	
	Cessation services & sources of support	◦ Telephone helpline ◦ Internet sites
Health effects	Effects on self	◦ General morbidity & mortality ◦ Specific types of disease ◦ Quality of life
	Effects on others	◦ Second-hand smoke and types of disease
Toxic Constituents	List of chemicals Effects of chemicals	◦ Specific chemicals
"Other costs"	Financial costs Social costs Aesthetic costs Manipulation	

Each of these broad themes includes several sub-themes and specific subjects. The table above presents common sub-themes and subjects that have been targeted in health warnings to date. For example, the general theme of "health effects" includes sub-themes such as "effects on self" and "effects on others", as well as dozens of specific health effects that serve as the subject of each warning.

Health effects

Depictions of health effects include messages on the general risks of tobacco use (e.g., "Smoking Kills" or pictures of a cadaver or skull), as well as messages on specific health effects or diseases. Specific health effects often include the leading causes of smoking-related death and disability, including cancer, lung disease, heart disease, and stroke. "Novel" diseases that may be responsible for fewer deaths may also be featured in order to communicate the wide range of health effects associated with tobacco use. For example, Australia recently included warnings for blindness and peripheral vascular disease (gangrene) alongside more "conventional" health effects.

In either case, health warnings should not simply promote a basic awareness that smoking causes disease. Messages should target the perceived likelihood and the perceived severity of health effects—two critical components of risk communication. For example, although many smokers know that smoking causes lung cancer, there are many effective and novel ways to communicate the suffering, loss, and personal experience of lung cancer.

Also note that perceived severity is a fairly broad concept. From a public health perspective, severity is most often calculated in terms of the number of lives

attributable to a particular disease. However, from the individual's perspective, perceived severity may be more closely related to the consequences in terms of quality of life or the consequences to ones physical appearance. For example, the health warning for mouth diseases that originally appeared on Canadian packages in 2000 (see below) has been copied in jurisdictions throughout the world and is among the most recognizable and effective package warning developed to date. This warning is not more effective because mouth cancer is any more common or severe than lung cancer or stroke; rather, the mouth cancer warning is effective because it depicts a "gross", aesthetically displeasing health effect. To many smokers, "gross" effects to one's physical appearance may be perceived as more severe than more lethal health effects. Overall, health warnings that increase smokers' perceived likelihood and severity of risks are likely to be most effective. Different techniques and presentation styles for making health effects more vivid and personally relevant are discussed in the next chapter.

Messages targeting health effects should also link common experiences and early symptoms of smoking with serious disease. For example, messages should link serious lung disease with common symptoms such as wheezing, shortness of breath, coughing, and phlegm. (E.g., "Wheezing is the first sign of lung damage that can lead to emphysema and the use of an oxygen tank later in life.") Phlegm may be particularly effective given the negative association of this word.

Cessation

Effective risk communication requires two other critical elements: the *perceived benefit* of changing behaviour or, in this case, quitting smoking, and concrete information on *how* to change. As a result, cessation should be regarded as a critical theme of health warning messages. Cessation information can be broken down into four sub-themes: 1) Information on the benefits of quitting (including both the direct health effects, as well as related benefits, such as improvements in quality of life); 2) General "efficacy" information—supportive messages that are intended to build confidence and motivate a quit attempt; 3) Tips for quitting smoking; and 4) Information on cessation services, such as telephone helpline numbers and internet services. Telephone helpline numbers have proven an especially effective type of information to include, as discussed in Chapter 2.

Toxic constituents & Product-related messages

There is general consensus that health warnings should help to inform smokers about the toxic chemicals in tobacco products. Many jurisdictions require a separate set of health messages on the side of packages to communicate this information—these messages are the subject of Chapter 4. However, some jurisdictions have also chosen to feature constituent information in one of the "main" health warnings on the face of packages—see example at right.

Health warnings could also be used to communicate other important product information. For example, warnings could target widespread misconceptions, such as the belief that "low-tar" products are less hazardous.

Addiction

Several countries have implemented warnings that communicate the addictive properties of cigarettes. Addictive messages should target younger audiences, who may not have personal experience with nicotine dependence. As a result, any smokers portrayed in these warnings should be younger to maximize personal identification with these messages. Focus group testing has occasionally found that messages on addiction are not rated as highly as warnings depicting health effects, largely due to less effective pictures and images. Pictorial warnings on addiction often use "abstract" images that lack the same emotional engagement and vividness of graphic depictions of disease. In addition, simple statements that "smoking is addictive" may not be particularly helpful to the vast majority of smokers who already have personal experience of nicotine dependence. Addiction messages should focus on the consequences of smoking in a way that communicate the essence of addiction, while linking it with a vivid health effect—see example below:

"Other" effects

Some jurisdictions have chosen to target other, non health-related effects in warnings. For example, messages reinforcing the financial costs of smoking help to remind smokers of a very powerful incentive for quitting. Other warnings have highlighted the aesthetic costs of smoking, particularly in terms of physical appearance. These include physical effects that may not be particularly significant in terms of health, but may nevertheless be valued by smokers: stained teeth, wrinkled skin and other aspects of ageing. Some health warnings have also sought to highlight the social consequences of smoking and social norms. For example, the warning developed in the European Union at right, highlights the potential embarrassment associated with impotence from smoking and may help to undermine the social desirability of smoking.

Themes of "counter-marketing" and exploitation could also be targeted through health warnings. Although these themes have been successfully used in mass media campaigns to target younger audiences, they have yet to be featured in health warnings.

Targeting multiple themes

Many health warnings incorporate several message themes within the same warning. In fact, research suggests that health warnings are most effective when "threatening" information on health effects is paired with strong efficacy messages to support behaviour change. In other words, each warning should include themes of cessation information along with messages on health effects. Health warnings from Australia, shown below, provide a good illustration of this principle.

Target groups

Many health warnings are tailored to particular sub-groups of smokers. Some warnings are gender-specific or targeted towards a particular age group, such as warnings on the risks of smoking while pregnant. Many warnings related to second-hand smoke also focus specifically on smokers with children in the household. The decision to target sub-groups should be part of the general discussion regarding priority themes and subjects.

Summary

The final decision regarding which themes and subjects to select will vary for each country. The decision should be guided in part by the following:

- What are the existing levels of health knowledge in the population?
- What messages are included in previous and existing sets of health warnings?
- Are there specific diseases or areas of health knowledge that are considered a priority?

At the end of Step 4, you should have a list of priority themes. It is essential that the process for making these decisions include individuals familiar with the local population and with the domestic tobacco control environment.

"What about health warnings for "other" types of tobacco products?"

The FCTC Article 11 includes all tobacco products; however, health warnings for cigarettes are more advanced than for other tobacco products. In countries, such as Canada, packages for "other" tobacco products, such as cigars and smokeless tobacco, also carry warnings, although these warnings often have a different content than the cigarette warnings. This is important given that some of the specific health effects are different between combustible and non-combustible forms of tobacco, as are some of the toxic constituents.

The size and position of the warnings for non-manufactured cigarette products may also need to be adapted. The images below provide several illustrations of how the layout and design of Canadian health warnings have been adapted to fit different forms of packaging.

Overall, when developing health warnings, be sure to ask:

- Are there any local forms of tobacco use that should be taken into account when selecting themes?
- What are the common packaging forms and sizes?
- To what extent, does the content of the health warnings need to be adapted for alternative products?

In some cases, separate health warnings may be required for different classes of product, such as smokeless forms of tobacco.

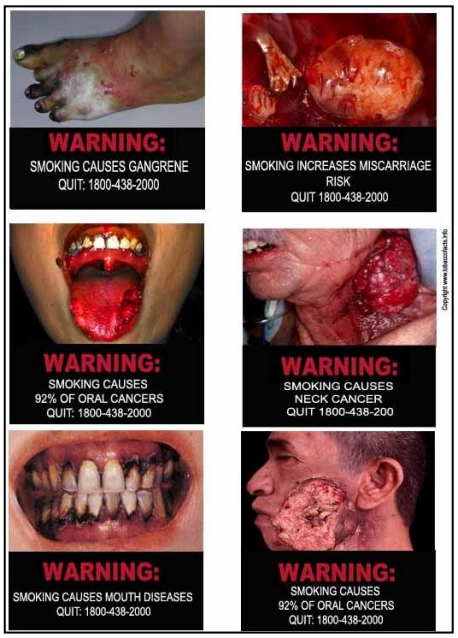
Step 5: Images & Presentation Style

The quality and style of the picture is the most important determinant in the effectiveness of a health warning. Even though a warning may include informative text for an important health effect, the impact of the warning can be limited by the wrong image. Images are particularly important in the long-term effectiveness of warnings.

Once the theme and subject of a warning have been identified, the goal is to develop images to make the information as vivid and personally relevant as possible. "Neutral" images that fail to elicit an emotional reaction should be avoided at all costs. The effectiveness of picture warnings is often highly specific to the particular image—even small differences in the content and configuration of the image can have a large impact on its effectiveness. The first step in constructing an image is to decide on the general "presentation style." The following sections describe several common presentation styles for health warnings.

Graphic depictions of disease

Research in the field of health communication indicates that messages with emotionally arousing content are more likely to be noticed and processed by smokers. Previous research indicates that one of the most effective ways of arousing emotion is to use "graphic" pictures of health effects. Some jurisdictions, such as Singapore, have adopted this approach for the entire set of warnings (see right). Focus group



testing has indicated that graphic pictures that also show the victim's face add personal relevance to the graphic depictions. As noted previously, graphic depictions are also most effective when paired with supportive cessation information.

◎ ***Are there other ways to elicit emotion besides graphic pictures?***

Although graphic depictions of disease may be the most reliable way of eliciting an emotional response, there are other ways of doing so. These often involve pictures depicting the human consequences of disease or messages that connect directly with the smoker. Two examples are provided below. In both cases, the warnings appeal directly to the viewer and add a poignant "human" element to the costs of tobacco use. In the two examples below, the warnings also highlight the consequences for important "others", such as the family and children of tobacco users.

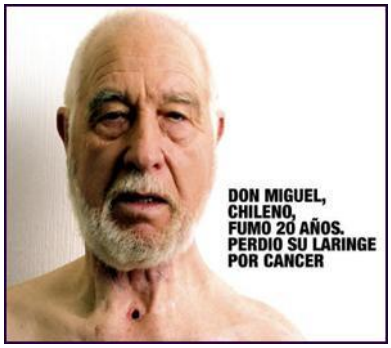
Testimonials

Testimonials are an excellent way to increase the personal relevance of health warnings. Testimonials are often used to communicate a health effect, but they do so within the context of a narrative or story. Providing personal information about "real" victims, such as their name, adds important context and attaches a "human" face to health effects. Testimonials are also highly credible—it is very difficult for

sceptics to reject health risks when they are presented with a real example. Indeed, one of the most common questions asked by smokers during focus group testing is whether the people depicted in the health warnings are real. (For this reason, even warnings that do not adopt a testimonial style should use real people as often as possible). Testimonials may also be a particularly effective way of communicating addiction and cessation themes, although these approaches have yet to be utilized to date.

◎ CASE STUDY: Testimonial warnings

Health warnings in Chile feature Don Miguel, a victim of larynx cancer from smoking. The Chilean warnings were the first to feature a real-life testimonial on package health warnings.



Aesthetics & Personal experience

Some warnings have specifically targeted the effects of smoking on physical appearance, such as yellowed fingers, stained teeth, wrinkled skin, and other effects on ageing. Negative effects on physical appearance may be particularly effective among youth and younger adults, given that the long-term health effects are more remote and may hold less value for younger populations.

Cultural Symbols & Icons

The use of pictorial symbols is a common and effective feature of health warnings for a wide variety of consumer products. For example, the globally harmonized

system (GHS) of classification and labelling of hazardous chemicals (GHS) uses the skull and crossbones as the universal symbol for toxic substances.

Some jurisdictions have used symbols or icons to communicate the risks of smoking. For example, several countries have used a skull to communicate the general risks of smoking (see Venezuelan warning at right). Using widely recognized symbols of death and danger may be an effective approach to risk communication, particularly in regions with low levels of literacy and little existing knowledge of specific diseases or health effects. However, cultural symbols must also be used cautiously, so as not to cause offence or lead to rejection. In Thailand, for example, a warning using a culturally sensitive symbol of a burial proceeding met with some public resistance and was subsequently removed from the warning.

Humour

Humour represents another option for presentation style. Warnings for impotence that use the image of a limp cigarette are the most common example to date (see Brazilian example at left). Although humour may be an effective presentation style in some cases, it should be used with great care so as not to trivialize the importance of health risks.

General principles

In addition to specific presentation styles, there are several general principles for developing the images in health warnings.

- Pictures should be as striking and colourful as possible, and have high resolution.
- Persons depicted in warnings should be somewhat younger, rather than older. Whereas older adults are able to relate to pictures of younger adults, the reverse

is not necessarily true. Using younger adults in pictures also makes the health effects somewhat more immediate for younger smokers.

- Although there is no evidence that health warnings actually increase smoking, it is nevertheless important to avoid pictures that may serve as smoking "cues" for some individuals. For example, some focus groups and one experimental study have found that pictures of cigarettes, smoke from a lit cigarette, and pictures of ashtrays may serve as a cue for some participants and are rated as more pleasant by smokers.[2]

Step 6: General Recommendations for Text

The amount of text included with pictorial warnings varies considerably across jurisdictions. In some countries, only a title or tagline accompanies the picture, while other countries include several sentences or paragraphs of explanatory text. Regardless of the amount of text, several basic principles apply:

- All text should be consistent with the themes and subject depicted in the picture.
- In all cases, text messages should be as clear and direct as possible.
- Text should be at an appropriate literacy level.
- The colour of the font and background should contrast in order to maximize legibility. Black lettering on white background or white lettering on black background are examples of good contrast.

Tagline

The tagline should be relatively concise (e.g., no more than a sentence) and provide a clear summary of the warning presented in direct, unequivocal language.

[2] See: B E M Nascimento, et al., Avoidance of smoking: the impact of warning in Brazil. *Tob. Control* 2008;17;405-409.

Explanatory text

- In all cases, the text should be simple and straightforward: less text that is easier to read will be more effective than long sentences with confusing detail.
- Technical language should be avoided and all text should be understandable by smokers with low literacy levels.
- Text should avoid equivocal language that may create uncertainty or doubt about the risks depicted in messages. Text should not use words such as "can", "may", or "might", when describing health risks. For example, warnings should read "Cigarettes cause lung cancer", rather than "Cigarettes can cause lung cancer."
- Statistics and numbers should be used only in rare cases. Most smokers do not understand even simple statistics and, on their own, numbers may prove misleading. If numbers or statistics are used, they should be presented as simply as possible and should be focus group tested during the development of warnings.

Multiple languages

Health warnings in countries with multiple languages require special consideration. In Canada, which has two official languages, the same warning appears in French on one side of the package and in English on the other side. Other jurisdictions have included more than one language in the same warning. For example, the Belgium warnings, shown at right, display the text in Dutch, French, and German. Because this requires additional space, the size of the Belgian warnings is larger than the minimum European Union standard. Another option is to create separate warnings in each language and then stipulate that the warnings from each language be randomly printed on different packages. In all cases, the use of pictures accompanying the text will be extremely important, given that pictures are universal across languages.

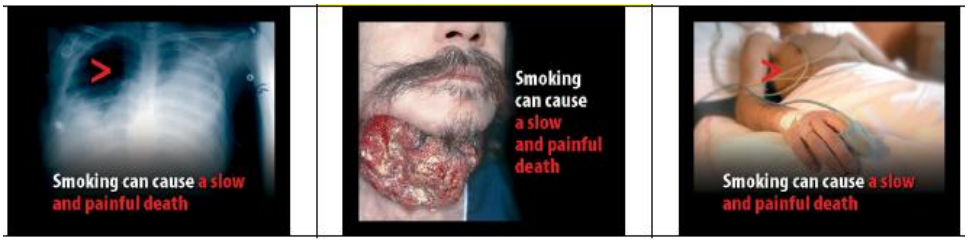
◎ RESOURCE: "Content" Worksheet

As you begin to make decisions about specific themes and the content of information, you may find it helpful to complete a worksheet for each warning. A worksheet is provided at the end of this chapter (Worksheet #2) to help you simplify your overall strategy and your objectives for each of the health warnings you will develop.

Step 7: Develop Warnings

By Step 7, the general layout of the warnings should be established, as well as the specific themes and subject matters to be targeted. At this point, the individual warnings can be developed for testing. Several "concepts" should be developed for each theme and subject in order to determine the best creative execution of each. In other words, several different warnings should be designed that take slightly different approaches to communicating the same message. See the examples on the following page, which were used by the United Kingdom Department of Health to identify which of the three concepts should be selected. Three concepts were tested for each main message or "theme." See Chapter 4 for recommendations on testing concepts.

"*Smoking can cause a slow and painful death.*"



Using existing warnings

The easiest and most cost effective option when developing warnings is to use existing health warnings from other jurisdictions. Seeking permission to use existing warnings is an excellent option for jurisdictions without resources to develop original images and warnings. In some cases, the copyright permission to use pictures from another country may be available; however, even in cases where permission to use an existing warning from another country is not granted, these warnings can nevertheless serve as templates to be modelled.

Developing "new" warnings

Where resources permit, countries should attempt to develop warnings tailored for their own country. This may be important for several reasons. For example, warnings that include pictures of people should broadly represent the ethnic/racial profile of each country. It would be inappropriate to include images of caucasians from Canadian warnings in health warnings for China, for example. Certain images, symbols, or other references may also be culturally specific. In some cases, existing warnings may only require small changes, although many jurisdictions may decide to create completely original warnings to suit their own needs, where resources allow.

A number of countries have hired advertising agencies or communication experts to develop new messages. Countries should always use professional agencies when resources allow; however, some jurisdictions have adopted less costly methods, including taking pictures at local hospitals. Regardless, at the end of Step 7, you should have a set of specific health warnings dedicated to each priority theme.

Designing Health Warnings—Worksheet #1

WORKSHEET FOR LAYOUT & DESIGN OF HEALTH WARNINGS

1. **General**
   Number of "sets" or "waves" of warnings?
   Rotation time period per "set" or "wave"?
   Number of warnings per "set" or "wave"?
   Total number of warnings to be developed?

2. **Layout of warnings**
   General
   - Size of warnings (% of front and back)?
   - Position of warnings?
   - Borders?
   - Picture or text only?
   - Background colour?
   - Position of text and picture?
   - Text colour?
   - Number of languages to be used?

   Marker word (Yes/No)
   - Position
   - Font size
   - Font colour

   Tagline
   - Position
   - Font size
   - Font colour

   Explanatory text
   - Position
   - Font size
   - Font colour

   Attribution (Yes/No)
   - Attribution source
   - Position
   - Font size
   - Font colour

3. **Priority themes & subjects**

- What are the priority themes and subject matters?

4. "Other" tobacco products

- What tobacco products other than manufactured cigarettes are commonly sold in the market?
- How should the content of warnings be adapted?
- How should guidelines on the size and position of warnings be adapted to suit different forms of packaging in which these products are sold?

Designing Health Warnings—Worksheet #2

WORKSHEET TO BE COMPLETED FOR EACH HEALTH WARNING CONCEPT

1. **Theme(s)**
   What are the general themes and sub-themes of this warning?

2. **Subject**
   What is the main subject of this warning?

3. **Target audience**
   Is there a particular target audience for this warning?

4. **Presentation style**
   What is the general presentation style of the warning?

5. **Picture**
   Is the picture clear and easy to understand?
   Does it have immediate impact?
   Does it arouse emotion or interest?
   Does it lead to interest or curiosity in the explanatory text?

6. **Tagline**
   Does the tagline provide a concise summary of the warning?
   Does it stand out from the rest of the text?
   Is it consistent with the picture?
   Is it targeted at the appropriate literacy level?
   Is it simple, direct, and easy to understand?
   Is the literacy level sufficiently low?

7. **"Explanatory" text**
   Is the text easy to understand?
   Is it believable?
   Are there any confusing elements?
   Is the literacy level sufficiently low?

8. **Cessation message**
   Is cessation information included in each warning?

Chapter 3 Tobacco Labeling Toolkit

DESIGNING EMMISSION & CONSTITUENT WARNINGS

BACKGROUND

The goal of this section is to provide recommendations and steps for designing emission and constituent messages on packages. Although this aspect of labelling is more straightforward than designing health warnings, it presents unique challenges. Cigarette smoke contains approximately 4,000 chemicals, including over 60 carcinogens and toxins, such as formaldehyde, benzene, and hydrogen cyanide. Although there is general agreement that cigarette packages should provide some information on these chemicals, regulators continue to struggle with how best to communicate this information in a feasible and meaningful way to consumers.

Article 11 of the FCTC currently requires that packages contain "information on relevant constituents and emissions of tobacco products as defined by national authorities"; however, there remains considerable confusion regarding what constitutes "relevant" information. Some regulators have required manufacturers to print the levels of three emissions (tar, nicotine, and carbon monoxide) on the side of packages. This remains the most common practice throughout the world. However, there is strong evidence that printing emission numbers on packages should be immediately abandoned given that it reinforces the tobacco industry's deceptive marketing campaign and the false belief that low tar cigarettes are less hazardous. For example, the Elaborated Guidelines for FCTC Article 11 state that: "Parties should prohibit the display of figures [i.e. numbers] for emission yields, such as tar, nicotine, and carbon monoxide, on packaging and labelling, including when used as part of a brand name or trademark."[3] A more complete explanation of these issues is provided in Chapter 1.

At present, the most effective practice for meeting the Article 11 guidelines is to provide non-numerical descriptive information on emissions and constituents. The

[3] Conference of the parties to the WHO Framework Convention on Tobacco Control. Final Report Committee A. World Health Organization, 2008. Available at: http://www.tobaccolabels.ca/fctcandh/fctcarticl

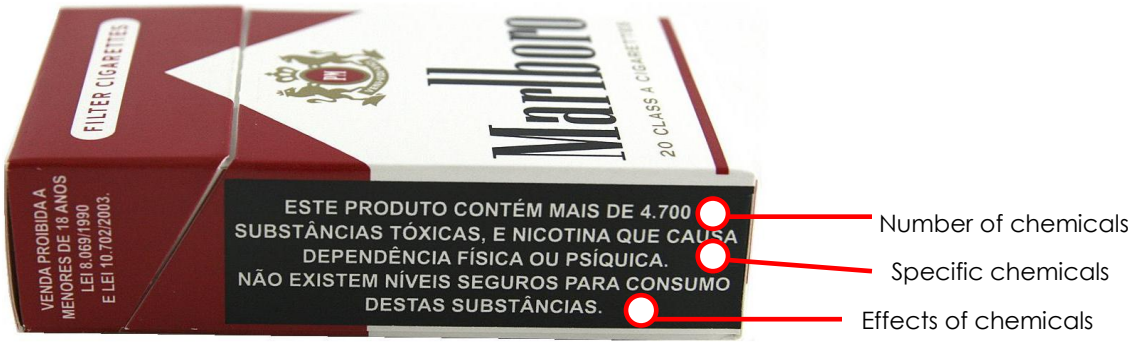
current section provides recommendations on how to follow and improve upon existing practices in descriptive emission and constituent messages.

> ***"What is the difference between a constituent and an emission?"***
>
> *Constituents* generally refer to the chemicals and substances in un-burnt tobacco. This includes "additives", as well as chemicals naturally present in tobacco. *Emissions* refer to the chemicals released by products when they are used by consumers. Although all tobacco products have emissions, the term is usually used to refer to the chemicals found in the smoke of combustible products. Smoke emissions are tested using a machine that "smokes" cigarettes according to a fixed puffing regime then collects and analyzes the smoke. Neither the levels of constituents or emissions in cigarettes are a good predictor of what humans ingest, mainly because each smoker adapts their behaviour to the type of cigarette. A more complete explanation of these issues is provided in Chapter 1.

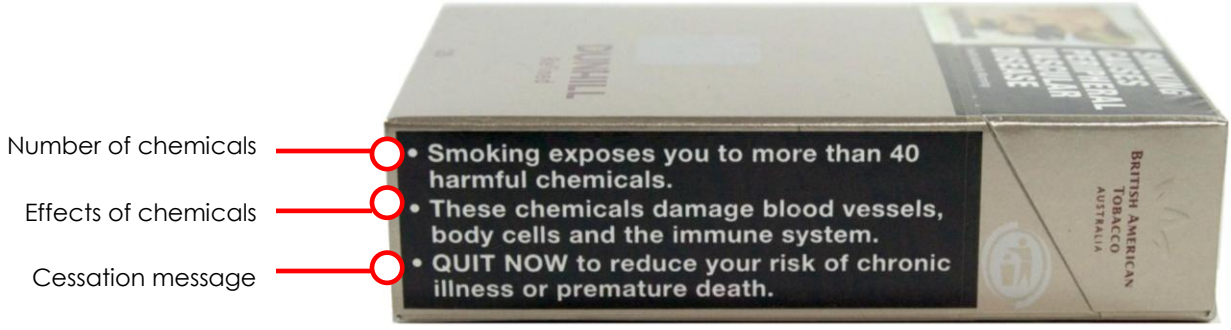
Step1: Layout and Design

The figure below illustrates two recent approaches to the design and layout of the emission and constituent messages.

Brazil

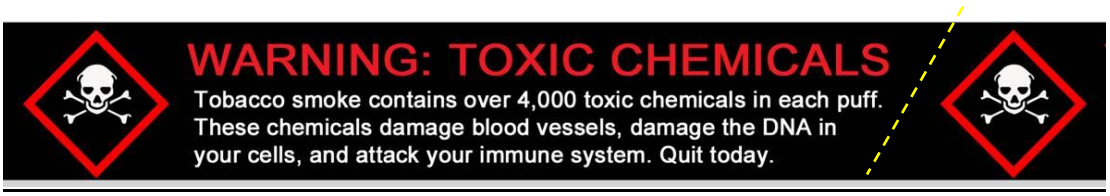


Australia



Size & Position

Emission and constituent messages are typically located on one side of the package. Many jurisdictions have used the entire side, up to the point where the package separates for "flip-top" packages, to avoid cutting off the text information (see example above). However, in some cases, manufacturers use a different background colour and print company information on the "unused" section. In the future, this portion of the pack should be in the same colour as the rest of the TEM (e.g., black) and should either remain blank or should feature the toxic skull symbol, which would appear on either side of the text message. The picture below illustrates this concept using a yellow line to depict the part of the pack that opens.



Contrasting colours

As with health warnings, it is important to ensure high contrast between the wording and the background. White letters on black background or black letters on white background are the most effective combinations. The font size should be sufficiently large to be legible.

Use of symbols and pictures

The most consistent finding from both quantitative and qualitative research conducted among tens of thousands of smokers throughout the world is that pictures enhance the effectiveness of health warnings. The same principles that have been adopted in designing the primary Health Warning Messages should be applied to the toxic and constituent message on the side of packages: use pictures to attract attention and improve risk comprehension.

To date, no jurisdictions have included symbols or pictures in the side messages for emissions and constituents. Previous research with international hazard symbols indicates a picture with signal word, a hazard/marker word, and a precautionary statement is most effective. Pictures can be used in two ways to increase the vividness of these messages. First, a symbol that is widely recognized as a warning for poisonous or dangerous goods could be added to the text. The skull and bones used by the globally harmonized system (GHS) of classification and labelling of hazardous chemicals is one example (see right). There is extensive evidence that using the GHS toxic symbol increases the salience and comprehension of toxic chemical warning messages.[4]

For example:

- Symbols allow consumers to avoid hazards in their environment because they attract attention.[5,6]
- Symbols act as reminders to perform necessary safety behavior by cueing existing knowledge within memory.[7]

[4]Dewar RE. 1999. Design and evaluation of public information symbols. In: Zwaga HJG, Boersma T, Hoonhout HCM, editors. Visual information for everyday use: Design and research perspectives. London: Taylor and Francis. pp. 285–303.

[5]Sojourner RJ, Wogalter MS. 1998. The influence of pictorials on the comprehension of and recall of pharmaceutical safety and warning information. Int J Cog Ergon 2:93–106.

[6]Kalsher MJ, Wogalter MS, Racicot BM. 1996. Pharmaceutical container labels and warnings: Preference and perceived readability of alternative designs and pictorials. Int J Indus Ergon 18:83–90.

[7] Leonard SD, Otani H, Wogalter MS. 1999. Comprehension and memory. In: Wogalter MS, DeJoy DM, Laughery KR, editors. Warnings and Risk Communication. London: Taylor and Francis. pp. 149–187.

- Widely recognized symbols, such as a skull, have been found to be especially effective in diverse populations, including among individuals with low literacy and education.[8]
- In a recent study, more children were able to recognize the skull symbol than any other hazard symbol.[9]

Second, different images could be used for each warning. Finding an image that smokers readily associate with a chemical may be easier in some cases than others. For example, formaldehyde is commonly used as an embalming fluid and lends itself well to an image (see example below). In contrast, chemicals such as benzene may have no recognizable associations or images.

Marker words

Marker words, such as "WARNING" may also be an effective addition to emission and constituent messages. Marker words for each warning should include at least one distinctive word to draw consumers' attention to the message. As with health warnings, marker words should have a larger font size and distinct font colour to attract attention.

[8]Banda SF, Sichilongo K. Analysis of the level of comprehension of chemical hazard labels: A case for Zambia. *Science of the Total Environment* 2006; 363: 22–27.

[9] Hara K, Mori M, Ishitake T, et al. Results of recognition tests on Japanese subjects of the labels presently used in Japan and the UN-GHS labels. *J Occup Health* 2007;49(4):260-7.

Step 2: Select Number of Messages and Rotation Period

To date, most countries require that only than one emission and constituent message appear on packages. In other words, the same descriptive information appears on all packages. This is a significant limitation of existing practices. Jurisdictions should design sets of between 4 and 8 different emission and constituent messages that would appear in rotation on packages. The rotation period for different sets of warnings should be the same rotation period as for the "main" health warnings on the face of packages.

Step 3: Existing Warnings

Before developing new emission and constituent warnings, existing warnings in other jurisdictions should be examined to help generate ideas. To date, the following countries have recently implemented descriptive emission and constituent warnings: Brazil, Uruguay, Venezuela, Chile, Australia, Thailand, and New Zealand.

> ◎ **RESOURCE: Emission and Constituent Messages Online**
>
> An extensive list of emission and constituent warnings that have been implemented throughout the world can be reviewed at: www.tobaccolabels.org

Step 4: Content of the messages

The general theme of emission and constituent messages is relatively fixed. However, there are a number of ways to communicate emission and constituent information, including the amount, type, and effects of chemicals.

Every attempt should be made to "personalize" the text of messages and to link chemical information to specific products and behaviour. As far as possible, the explanatory text should be linked directly with the act of inhaling or puffing to help

smokers visualize the process of ingesting chemicals. Recent focus group testing in Canada found that the following phrase was the most effective: "Every time you inhale, this product releases [chemical name] into your body." A second sentence describing specific health effects or providing specific health effects about the chemicals can follow. For example:

Sentence 1:
Every time you inhale, this product releases arsenic into your body.

Sentence 2:
Arsenic causes cancer of the lung, skin, bladder, liver, and kidney.

As with all health warnings, the text in emission and constituent messages should be as clear and direct as possible. Technical language should be avoided in all cases. For example, rather than saying that a chemical is "carcinogenic", messages should say that a chemical "causes cancer." Text should be at an appropriate literacy level.

Amounts or levels of chemicals

As indicated previously, numbers that refer to the amount of chemicals for each brand (such as tar, nicotine, and carbon monoxide emissions) should not be displayed on packages. These numbers are derived from machine testing and are not related to the amount of chemicals released during human smoking.

Types of chemicals and health effects

There are two approaches to communicating the *types* of constituent and emission chemicals. The first is to include a general statement about the range of toxic or dangerous substances. For example, Australian messages mention "more than 40 harmful chemicals", while the Brazilian messages mention "4,700 toxic substances."

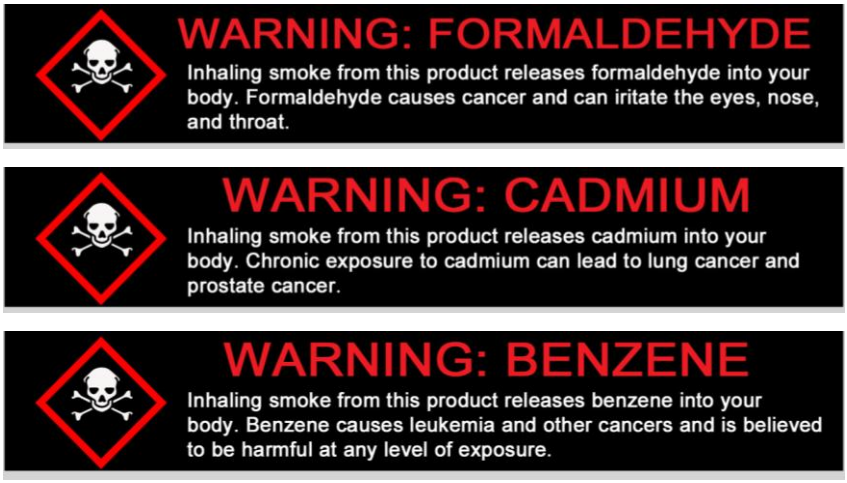
Focus group testing suggests that this may be an effective way to communicate the magnitude of toxic chemicals in tobacco smoke. These messages can be improved by adding a second sentence that refers to specific health effects.

The second approach is to identify specific chemicals in consituents or emissions. Previous research commissioned by Health Canada found that the most common recommendation for improving the side messages was: "explaining the harmful effects of the chemicals found in cigarettes."[10] When shown a series of toxic emission messages, respondents were most likely to select the option that listed a specific chemical followed by an explanation of that chemical: "When shown a series of possible statements, smokers in a qualitative study were most supportive of texts that were short, clear, and simple and that presented only one substance with information on the impact that substance has on health.[11] See examples below.

Effects of chemicals

In addition to naming specific types of chemicals, the most effective emission and constituent messages also explain the effects of those chemicals. Several examples are provided below.

[10] Toxics information on cigarette packaging: Results of a survey of smokers. Environics Research Group; May 2003.
[11] Summary Report of Four Focus Groups in Toronto & Montreal on Awareness and Understanding of Toxic Emissions Information on Tobacco Packaging; Environics Research Group Limited (2003b).



How should I choose what chemicals to display?

As a first step, the most effective approach is to select chemicals that smokers already recognize as poisonous or toxic. In some countries, the general public is aware that chemicals such as arsenic and hydrogen cyanide are very dangerous, although few may be aware that they are present in tobacco smoke. Future versions or "rotations" of emission and constituent messages might also include chemicals that may be very dangerous, but for which there is little awareness. Descriptions of the effects of these chemicals will be particularly important.

Several countries have also developed toxic emission and constituent messages that focus on the nicotine, the primary addictive component of tobacco smoke. Messages on nicotine should go beyond the basic statement that tobacco smoke contains nicotine, a widely known fact in many countries. As far as possible, toxic emission messages should try to communicate new information or to make the addictive properties more vivid for consumers. An example is provided below.

◎ ***Should the messages explain the difference between tobacco constituents and smoke emissions?***

No, the source of the chemical does not need to be explained to smokers. However some of the wording may need to be adapted depending upon whether it is referring to chemicals in the tobacco or the smoke. Messages for chemicals that are only found in constituents (i.e., the tobacco) should read: "This *product* contains…" or "This cigarette contains…" Messages for chemicals that are only present in emissions (i.e., chemicals only found in the smoke) should read: "Cigarette smoke contains…"

Step 5: Develop the Message

By Step 5, the layout and content of the messages should be established. At this point, the individual messages can be developed for testing.

Summary

As with health warnings, there is considerable value in pre-testing emission and constituent messages prior to implementation. This is particularly important given that less research has been conducted on these messages. It is highly recommended that resources be set aside for at least some pre-testing to ensure that the messages are not only noticeable and vivid, but also clear and easily understood. Pre-testing should also focus upon the effectiveness of using images and descriptions of specific health effects.

Chapter 4 Tobacco Labeling Toolkit

EVALUATING HEALTH WARNINGS & MESSAGES

BACKGROUND

The focus of this section is to describe how to pre-test and evaluate the impact of warnings. Although some jurisdictions have conducted extensive evaluation work before implementing health warnings, others have selected and implemented warnings with no pre-implementation evaluation. Although a lack of resources should never act as a barrier to implementation, even modest evaluation work is likely to increase the effectiveness of warnings.

The goal of this section is to describe a range of evaluation activities that can be adapted to local needs and the availability of resources. As with the previous section, special consideration has been made for jurisdictions with minimal resources for evaluation.

A. Pre-implementation: Pre-testing the layout and design of warnings

Primary Objectives

Jurisdictions that wish to explore new design features, or jurisdictions that require evidence of the impact of larger, pictorial warnings may wish to evaluate individual components of layout and design.

Priorities

The following layout and design features may be considered a priority for pre-testing:

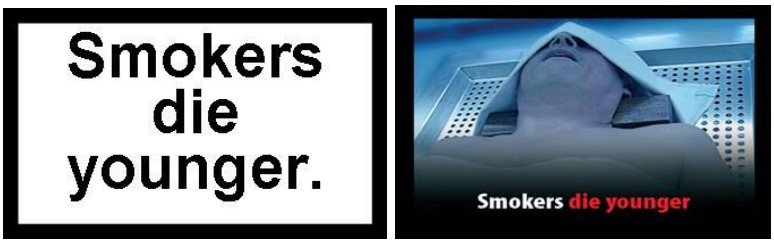
- Text-only vs. picture warning
- Position of text vs. picture
- Inclusion of a government attribution
- Inclusion of a marker word
- Overall size of warning and relative size on the "front" and "back"
- Colour schemes, including contrast between background and text

Methods

The basic principle is to systematically evaluate each design feature so that strong conclusions can be drawn about their effectiveness. This involves creating different versions of the same warning that are identical, except for the feature that is being examined. In marketing research, this type of approach is often called "conjoint analysis." For example, if the value of pictures vs. text-only warnings were being evaluated, two warnings should be created that are identical, except for the addition of the picture. Therefore, the picture vs. text-only should be the same size, have the same text message, same border width, etc. An example is provided below.

Set A: Picture vs. text-only

Set B: Picture vs. text-only



This approach ensures that if the warnings are rated differently by participants, the differences in scores can be attributed to the use of pictures—the only point of difference between the two warnings. Note that the picture that is selected to go along with the text will have some influence on whether the picture warnings are

rated as more effective. Therefore, it is important to repeat the process more than once, to ensure that the success or failure of the picture warnings is not simply due to a particular image. The best option is to use pairs of text-only and picture warnings across different themes. If the same pattern of results is found for both Sets A and B above, for example, the findings will be more robust.

Presentation of warnings and participant ratings

There are two approaches to presenting the warnings to participants. The first approach is to show both warnings in each "set" at the same time, and ask participants to directly compare the warnings. In the example above, participants would be shown both warnings from Set A and B, and asked which of the two warnings had greater immediate impact. The second approach is to show participants each warning one at a time and have participants rate the warnings separately. In other words, each warning would receive a score for immediate impact using a standard rating scale (see below), and these scores could then be compared to examine which warning was rated more highly. The advantage of the second approach—having participants rate each warning individually—is that warnings can then be compared across "sets" or themes fairly easily, without using statistical techniques. In other words, the impact ratings for each of the warnings in Set A could be compared with each of the warnings from Set B.

Developing the questions and rating scales

The design and layout of health warnings can be evaluated on a range of different "outcomes." Potential outcomes include the overall effectiveness of a warning, immediate "impact", noticeability, and the credibility of the information. The choice of outcomes should be guided by what is being evaluated. For example, if you are testing whether a government attribution should be included, you may be most interested in outcomes regarding the credibility of the warning.

Participants are often required to use a rating scale when responding to questions. Participants may be asked to rate each warning by selecting a number or symbol that corresponds to a particular category. The category is often written directly below the number or symbol, and typically ranges from "Very bad" to "Very good", or some version of these words. The use of a number or symbol along with the category helps to ensure that the rating scale is easily understood by low literacy smokers.

Examples of rating scales:

1	2	3	4	5
☆	☆☆	☆☆☆	☆☆☆☆	☆☆☆☆☆
☹☹	☹	😐	☺	☺☺
Very bad	**Bad**	**In the middle**	**Good**	**Very good**

Different questions should use the same rating scale for consistency. In other words, questions about immediate impact, noticeability, and credibility can all use the same 5-point rating scale. At the end of the process, each warning will have a set of ratings that can be compared across questions.

Note that in addition to questions specifically related to the health warnings, basic demographic variables should also be collected from participants, including smoking status, age, gender, and education level. Demographic variables can help to indicate whether different types of participants are providing different patterns of scores or ratings.

◎ *Should I use a focus group or survey when pre-testing warnings?*

Focus groups— A focus group is a form of qualitative research in which a group of people are asked about their attitude towards a product or concept. Questions are asked in an interactive group setting where participants are free to talk with other group members. Focus groups are an effective method for generating new ideas and concepts, particularly during the early stages of development. One limitation of focus groups is that the findings can be somewhat difficult to summarize given the unstructured nature of the group setting. In addition, the responses of each individual can be influenced by the group setting.

Brief Survey— In contrast to focus groups, surveys collect responses from each respondent individually, using more structured word and response options. The main advantage of conducting a survey is that responses can be collected more systematically for each individual, without social influences from other members in a group setting. One of the disadvantages to using surveys is that they are less effective than focus groups at exploring new ideas and concepts, although open-ended questions are capable of this to some extent. Surveys that are used to evaluate warnings will need to be conducted in-person or "face-to-face", rather than by telephone so that respondents can view images. "Self-completed" mail surveys and internet surveys are possible, although are less favourable in most cases.

A combined approach— The most effective and efficient approach may be a combination of surveys and focus groups. For example, participants can be recruited to a group setting, which may begin with a brief background survey on smoking status and demographics. The group can then be presented with the series of warning labels to be evaluated and instructed to complete written survey questions after each presentation. This should be done individually using structured questions, without group discussion or sharing of information. After all the warnings have been presented and the surveys have been completed, the

warnings can then be presented a second time with group discussion following each presentation. It is important to wait until all of the warnings have been presented and all survey questions have been completed before beginning any group discussion; otherwise opinions from different group members may affect how each individual responds to subsequent survey items. This "combined" approach yields structured responses at the individual level, as well as additional context from the group discussions that follow.

There are many other types of studies and techniques available to evaluate the layout and design of health warnings. Methods used to date include eye-tracking, fMRI, and other physiological responses which are all used to examine general levels of attention and the strength of first impressions. Each of these methods can be informative, but they are largely used for basic research purposes and are not necessary as part of a standard approach.

Target audience

A primary goal is to ensure that health warnings are easily understood among all smokers. To this end, it is absolutely critical that evaluation work includes participants with low levels of literacy and diverse socio-economic backgrounds. This is especially important given that, in most countries, smokers have lower levels of education than the general public. In order to ensure a suitable mix of participants, participants should be recruited from public areas with a cross-section of people, such as shopping areas and other public meeting places. In some cases, it may be necessary to specifically target and recruit participants from lower SES areas or occupations. Although many individuals are willing to participate in surveys, providing a small compensation in the form of a small gift or small amount of money can help to increase participation rates.

◎ RESOURCE: How to conduct focus groups

The International Development Research Centre has assembled an overview of how to conduct focus groups, as well as general guides on developing surveys, recruiting participants, and basics of data analysis. The book is available free of charge on the internet: http://www.idrc.ca/en/ev-56615-201-1-DO_TOPIC.html

There are a number of government reports that describe findings from previous focus groups conducted to test health warnings: www.tobaccolabels.org

B. Pre-implementation: Concept and content testing

Primary Objectives

The main objective of concept and content testing are to evaluate the most effective health warning concepts for each theme and subject. Jurisdictions with both the time and resources often conduct this type of evaluation in several stages; initially to generate feedback on early concepts, as well as to test "final" versions before implementation.

Priorities

The main priorities are to ensure that each warning under consideration meets the following criteria:

- Strong initial impact.
- Consistency between text and picture.
- All text is clear and easily understood.
- Engaging and interesting text.
- Personal relevance and emotional impact.
- Credibility of message.
- Overall perceptions of effectiveness.

Methods

The basic principles are the same as evaluating layout and design: the process should be as systematic as possible, while also allowing for the possibility of broad feedback. Early testing of concepts and content is usually somewhat less structured. Often, very different concepts will be presented to participants to collect general feedback on which direction to pursue. However, as the content in the warnings becomes more defined, testing should become more systematic: the best way to test a specific concept is to develop similar versions of the same warning that differ only on one aspect of the content.

Developing the questions and rating scales

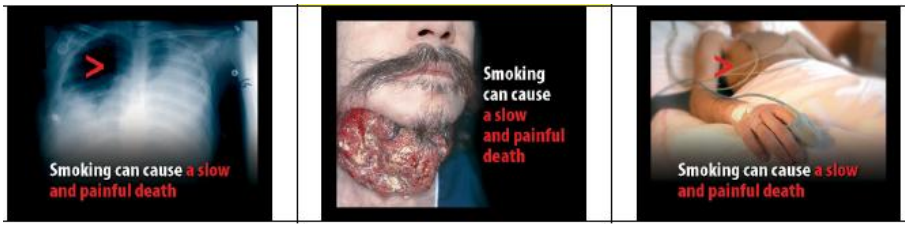
The main difference between layout/design and content/concept testing is the types of questions that will be asked. The questions should focus to a greater extent on how the information and content is received. Questions should be developed to measure immediate noticeability and impact, consistency between text and picture, clarity and meaning of text, interest in text, personal relevance, emotional impact, credibility of the information, and overall perception of effectiveness.

It is often helpful to ask about specific components of the warnings, such as the picture, text message, the cohesiveness of the pictures vs. text, etc. These types of questions provide important feedback about how to improve specific aspects of the warning. A typical approach would be to begin with a general question on the overall effectiveness of a warning before asking separate questions about each main component.

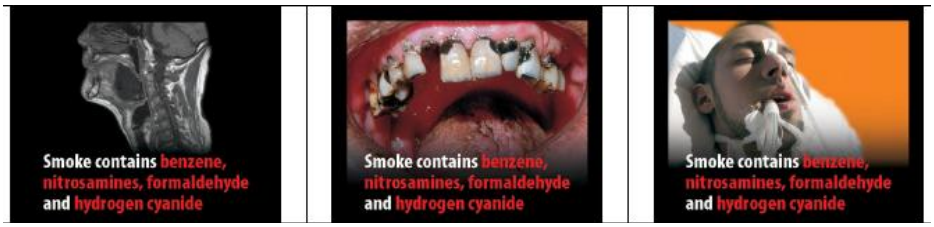
Presentation and Ratings

Several concepts should be developed for each theme or "message". See examples below, where three concepts were tested for each message.

Set A: "*Smoking causes a slow and painful death.*"



Set B: "Smoke contains benzene, nitrosamines, formaldehyde, and hydrogen cyanide."



As with testing the design and layout, there are two approaches to presenting the warnings to participants. The first approach is to show each set of three warnings at the same time, and ask participants to indicate their preference. In the example above, participants would be shown all three warnings from Set A simultaneously and asked which of the three warnings had greater immediate impact, for example. The second approach is to show participants each warning one at a time and have participants rate the warnings separately. The advantage of the second approach is that it allows warnings from different sets to be compared without using statistical analyses. This is especially important to identify whether certain themes or subjects are performing poorly compared to others. In other words, it tells you not only which concept is the best execution of a particular theme, but which themes are having the greatest success.

Note that concept testing and evaluation of layout and design do not necessarily have to be completed in separate surveys or focus groups. In many cases, testing of layout and design is conducted prior to specific concept and content testing

only because basic decisions about text and pictures need to be determined before developing concepts. However, jurisdictions that wish to examine only a few novel layout or design features can incorporate elements of layout/design evaluation and concept/content evaluation in the same survey or focus group. Regardless, the process should be as systematic as possible with respect to the types of information that are varied and the types of questions that are asked.

Summary

Pre-testing of health warnings should be as rigorous as possible given available resources, but should not create any significant delays in implementation. It is possible to complete the entire process of development and pre-testing in several months if necessary, although you should allow at least 6-months for the process if possible. Longer periods will be helpful if time allows.

◎ CASE STUDY: Using the internet to engage and evaluate

In 2006, the Department of Health in the United Kingdom chose to develop a website as a way to engage the public on the issue of pictorial warnings and to solicit their feedback on different alternatives. Visitors to the website were asked to complete a number of demographic questions and to select the warnings they felt would be effective. Over 20,000 people completed the survey during the 3-months the website was in operation. The results were used to inform the final selection of images and received considerable media attention in the process.

C. Implementation evaluation: Monitoring & Compliance

Primary Objectives

The primary objective of monitoring compliance is to examine whether health warnings have been implemented on packages as planned. This type of

evaluation, often called "process" evaluation, is critical to measuring compliance to the regulations.

Priorities

The main priorities of this type of evaluation are to ensure that the warnings are appearing on packages as they were intended, as well as to ensure that the warnings begin appearing by the implementation deadline.

Methods

The most straightforward approach is to visit retail outlets to visually inspect packages. This type of approach is commonly referred to as an "environmental scan." Although there are formal protocols for conducting an environmental scan, even information approaches may be sufficient. The number of retail outlets visited will depend greatly on the availability of resources. While the number of retail outlets need not be exhaustive, a range of retail outlets in different parts of the country should be visited. In many cases, this requires relatively little expertise, with the potential to involve advocates and other public health officials if necessary. In addition, some regulators have visited factories of domestic tobacco manufacturers to ensure that packages are being printed in accordance with the regulations. Another approach is to encourage members of the public to report non-compliance, although this requires resources to publicize the phone number or reporting mechanism.

Overall, implementation evaluation for health warnings is considerably less resource-intensive than for other policies, such as smoke-free legislation. Efforts should focus on the immediate post-implementation period, after which relatively little monitoring is typically required.

D. Post Implementation: Impact Evaluation

Primary Objectives

The primary objective of impact evaluation is to examine the potential effectiveness of health warnings after implementation. In general, impact evaluations are not used to evaluate the effectiveness of individual warnings, but rather the impact of the health warnings as a whole.

Priorities

One of the main priorities is to measure potential "wear-out" of the warnings and the point at which new warnings may be required. This requires measuring whether the health warnings have met and continue to meet their objectives. Although the objectives of health warning systems may differ to some extent across jurisdictions, common objectives include the following:

- Increases in health knowledge and perception of risk.
- Greater awareness of cessation services.
- Increases in motivation to quit and cessation.

Methods

Population-based surveys provide the most comprehensive method for evaluating the impact of health warnings. Ideally, surveys should be conducted before and after the implementation of new warnings. These surveys should also use similar questions and methodology so that changes in key outcomes can be examined. Whereas some jurisdictions have conducted entire surveys devoted to evaluating the impact of health warnings, it is also possible to insert a smaller number of questions into on-going surveys that include other topics. Basic principles for survey design and analysis are provided in the IDRC "Focus Group" resource, presented earlier in this section, as well as the resource described below.

◎ RESOURCE: Designing impact evaluation surveys

A detailed discussion of questions used to evaluate the impact of health warnings is included in a Monograph from the International Agency for Research on Cancer. The Monograph Chapter can be requested from: dhammond@uwaterloo.ca

Questions

The first step in developing questions to evaluate warnings is to identify potential outcomes of interest. Common outcomes include the following:

- Are the health warnings being noticed and how do they compare with other forms of health information?
- To what extent do smokers "process" the warnings in terms of thinking about and discussing warnings?
- Do smokers believe the information in the warnings is credible?
- Have the warnings increased levels of health knowledge and perceived risk?
- Are smokers more likely to quit due to the health warnings?
- Do health warnings reduce the appeal of the package?
- What is the level of public support for health warnings?

The resource listed above includes examples and a discussion of these and other survey questions.

◎ ***"Can I use prevalence figures to evaluate the impact of warnings?"***

Prevalence rates from large national surveys provide the estimate of population-wide changes in smoking behaviour. However, there are several limitations to using prevalence data as a measure of whether health warnings have been effective in promoting cessation. The Canadian experience provides a good illustration of these limitations. In the six years since 2001, when large pictorial warnings were implemented in Canada, the prevalence of smoking has decreased by approximately 4%. This represents a substantial decrease of approximately one million smokers in six years—a considerable public health achievement. However, it would be inaccurate to suggest that the health warnings were responsible for all or even most of the 4% decrease in smoking. Indeed, over this six year period the price of cigarettes have increased, several mass media campaigns have been conducted, and smoke-free legislation has become considerably stronger in Canada. In other words, prevalence data are not specific to health warnings or any other single intervention. Therefore, while health warnings may have played an important role in reducing smoking in Canada, there is no way to precisely estimate the contribution.

Other considerations

Timing of surveys

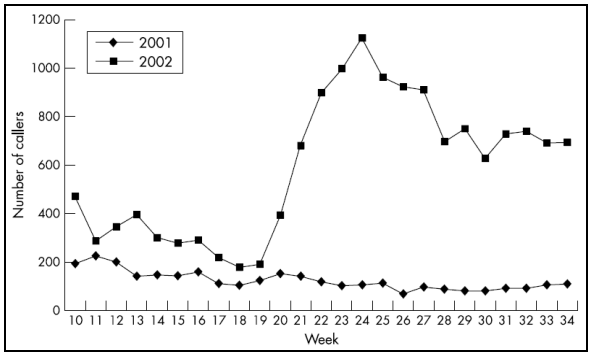
Several months often pass between the implementation date of new health warnings and the time at which they begin appearing on most packages. In addition, the cumulative impact of health warnings may build over time, with repeated exposures to the different messages. As a result, surveys that seek to measure the impact of warnings should wait at least 6 months after the implementation date. Ideally, regular surveys would be conducted to examine potential wear-out of the warnings in the long term, perhaps at 12 or 24-month intervals, if necessary.

Target groups

Unlike some other aspects of evaluation, impact evaluations should include both smokers and non-smokers. The extent to which non-smokers notice and recall health warnings is a very good indication of their overall effectiveness in the general population.

CASE STUDY: Using different sources of data to evaluate health warnings

Concerns about health risks of smoking are among the most common and important reasons for quitting smoking; however, there are a number of other factors that also contribute to the decision to quit and whether or not a quit attempt is successful. Although it may be impossible to measure the precise number of smokers who quit as a direct result of health warnings, some jurisdictions have used alternative data sources to estimate the potential impact, such as tracking the use of cessation services. For example, the UK, the Netherlands, Brazil, and Australia have tracked calls to the free telephone "quitline" number that is displayed on packages in each country. In each case, calls to the national quitline have increased significantly immediately after the telephone number appears on packages. For example, the graph below shows the increase in calls to the Netherlands quitline service after the number was printed on the back of one of 14 package warnings, beginning in Week 19 of 2002. This type of data source indicates that, at the very least, the health warnings are helping to increase the use of effective cessation services.



Source: Willemsen M., Simons C, Zeeman g. Tobacco Control 2002;11: 381-2.

Chapter 5 Tobacco Labeling Toolkit

IMPLEMENTATION

5.0 IMPLEMENTATION

This section review several considerations leading up to the implementation stage of new labelling policies.

Public consultation

Parties should inform the public about proposals to introduce new labelling regulations. One option is to release information through a consultation paper, which can be publicized through the media. Community involvement can also be promoted by holding community workshops. Consultation papers and workshop provide an opportunity to communicate the rationale behind labelling proposals, to share the supporting evidence, as well as to help refined concepts. These activities not only provide helpful feedback on proposals, but also help to generate public support prior to implementation. These activities can be conducted in parallel with the development of new designs and preparation of the regulatory process to prevent unnecessary delays.

Communications and media strategy

The implementation of comprehensive health warnings and other labelling measures tend to be high profile events and Parties should expect considerable media interest. Those responsible for responding to media requests should be prepared to communicate the basic rationale for the regulations, as well as to respond to common complaints and arguments (see below). Timely information should be provided to the media as media coverage can increase the educational impact of new messages. Partners in civil society and non-governmental organizations can also play an important role in publicizing new regulations.

Linking with other tobacco control activities

The introduction of new health warnings and messages represents an excellent opportunity to link and leverage other policy initiatives. Where resources allow, mass media initiatives timed to coincide with the new messages appearing on the market. A coordinated media campaign will reinforce warnings and messages, improve access to target groups, provide additional information on health warnings and messages and also communicate other information that increases tobacco users motivation and confidence in their ability to quit, such as the benefits of quitting, attitudes to quitting, quit advice and contact details of quit organizations.

CASE STUDY: Linking health warnings with other media campaigns

One consideration when developing the warnings is to link them with other mass media or education campaigns in your country. The Australian experience provides a very good illustration of this. One of the pictorial health warnings implemented in 2007 included a theme and subject that was featured in a very successful and well known television campaign that depicted the effects of smoking on arteries. Incorporating the same theme and subject in the package warnings provided an opportunity to capitalize upon this successful campaign and to provide constant reminders to smokers.

New South Wales, one of the five Australian states, also used the health warning messages as a basis for advertisements on the side of busses (see right), as well as several television spots. In both the bus and television spots, the advertisements helped to make the information in health warnings more vivid and provided a compelling narrative to the pictures and text. Smokers who see these advertisements are likely to recall them each time they see the related images on the pack. The print and television ads can be viewed at: http://www.cancerinstitute.org.au/cancer_inst/campaigns/healthwarnings2006.html

Dealing with industry opposition & barriers

The tobacco industry has generally opposed the introduction of large pictorial health warnings on packages. [12] For example, as Alechnowicz and Chapman[13] have noted, in 1995, package warnings were identified by British American Tobacco one of the key issues facing the company. Protecting the pack design and "neutralizing" the controversy over pack warning labels were among the priorities listed in the document.[14] The same document goes on to state that, "pictorial warnings, and those occupying a major pack face or faces (front and back) or a disproportionately large area of

[12] Chapman S, Carter SM. "Avoid health warnings on all tobacco products for just as long as we can": a history of Australian tobacco industry efforts to avoid, delay and dilute health warnings on cigarettes. *Tob Control* 2003; 12 Suppl 3:Iii13-22.
[13] Alechnowicz K, Chapman S. The Philippine tobacco industry: "the strongest tobacco lobby in Asia". *Tob Control* 2004;13 Suppl 2:ii71-8.
[14] BAT (British-American Tobacco Company). 1995. *1995 Key Area Paper: Corporate Affairs*. Web Page. Available at: http://www.library.ucsf.edu/tobacco/batco/html/7200/7265/otherpages/allpages.html

advertising space, should be restricted, as should moves to plain or generic packs. Every effort should be made to protect the integrity of the company's packs and trade marks".[143]

Although tobacco manufacturers have launched legal challenges in countries such as Canada and the European Union, health warning legislation was upheld by the courts in both cases. Although legal challenges are relatively rare, Parties should be prepared to counter common grounds of opposition. The section below summarizes common industry arguments.

Printing capacity & technology

Tobacco manufacturers have previously argued that they lack the technology to print colour pictorial warnings or that the costs of altering their existing printing methods would be prohibitive. Although manufacturers must bear the costs of redesigning their printing practices, such as the costs of re-etching press cylinders or preparing new lithographic printing plates, the technology required to print colour warnings is widespread. In every case to date, the printing changes required by manufacturers can be addressed by providing sufficient notice to manufacturers between the announcement of new regulations and the implementation deadline.

Violation of rights & trademarks

Tobacco manufacturers have argued that large health warnings represent unjustified violations of their rights to freedom of expression and their trademarks. However, courts in Canada have ruled that large warnings were justified given the serious health risks from these consumer products and the consequences for public health.

Infringement of Trade Agreements

Manufacturers in the European Union argued that the labelling directive infringed on Article 20 of the Agreement on the Trade-related Aspects of Intellectual Property

Rights ('the TRIPs Agreement') as set out in Annex 1 C of the WTO Agreement. The European Court of Justice dismissed this argument and upheld the law.

Excessive and Unnecessary

One of the most common arguments against comprehensive warnings is that they are "excessive" and unnecessary, given that most smokers are already aware that smoking is harmful. In fact, virtually all smokers—including those in the most affluent and highly educated societies—fail to understand the full range, likelihood, and severity of health effects from smoking. There is also ample evidence, presented in Chapter 1, that larger, more comprehensive warnings are more effective in communicating this health information—especially among children and others unable to read text warnings. In addition, as the following quote from the Quebec Court of Appeal indicates, the health warnings also help to provide a constant reminder of the health risks.

> *"…even if all smokers and potential smokers were very well aware of the risks associated with tobacco use, Parliament would still be justified in insisting that they be reminded once again of the harmful health consequences of smoking each time they take a cigarette from their packs."*[15]

Harassing smokers

Tobacco manufacturers commonly portray more comprehensive health warnings as an example of the government attacking or harassing smokers. For example, in 2004, former Chairman of BAT, Martin Broughton, argued:

> *"Some health policymakers show signs of having been `captured' by narrowly based, vociferous anti-tobacco activists, who are sometimes even funded by the regulators they are lobbying," said Mr Broughton, who is leaving to chair British Airways later this year. "An example is the growing use of `graphic image' health warnings, which threaten our intellectual property rights and can harass consumers - yet in fact give them no more information than print warnings."*[16]

[15] JTI-Macdonald Corp., Rothmans, Benson & Hedges Inc and Imperial Tobacco Canada Ltd. v. Attorney General of Canada (Quebec Court of Appeal). 2005. [196]

[16] Stevenson R. BAT chief bows out in fit of anger. The Independent; London. 22 April 2004.

In fact, there is evidence from a number of countries that large pictorial warnings are not only supported by a strong majority of non-smokers, but also by most smokers. Indeed, many smokers welcome more health information on their packages, particularly when it includes support for quitting. In addition, support for large pictorial warnings typically increases over time. Therefore, industry claims that comprehensive warnings represent government attacks on smokers are not shared by most smokers themselves.

Chapter 6 Tobacco Labeling Toolkit

LEGISLATION

6.0 LEGISLATION

This chapter provides recommendations for drafting labelling regulations, particularly with respect to health warnings. Packaging and labelling legislation should be as specific as possible to minimize the possibility of loopholes. A lack of specificity may be exploited by tobacco companies and thus reduce the intended benefits of the regulations. Note that this section does not cover all aspects of labelling regulations; rather it is only meant to provide guidance on key issues.[17]

Source document

The most effective approach for health warnings and messages is to include a "source document" in the legislation. A "source document" is a stand alone document referred to in regulations (or included in the regulations, such as in a Schedule or Annex) that visually depicts in full colour the warning messages (including both text and image components) as they are to appear on packages. Using a source document removes the need to specify details such as the font style, given that they are already incorporated in the messages themselves. A number of jurisdictions, including Canada and the European Community have used this approach—examples of these source documents are available for download at: www.tobaccolabels.org. A source document may be in electronic form, such as on a CD.

Specific considerations

Rotation of messages

The rotation period for "sets" of warnings (e.g. every 24-months) should be clearly specified in national legislation. Legislation should also specify that each health warning message appear in equal proportion for each stock keeping unit (each

[17] Several sections in this chapter have been drawn from a Framework Conventional Alliance briefing paper prepared for the Article 11 Working Group: http://www.fctc.org/index.php

format/size of each brand variation). Thus all warnings should appear in equal rotation for Marlboro 100mm 20 pack, for Marlboro 100mm 25 pack, for Marlboro 100mm Menthol 20 pack, etc.

Printing and Quality of Messages

Parties should consider specifying minimum printing requirements. For example in the European Community Directive, picture warnings are to "be printed in four-colour/-CMYK-/ screen 133 lines per inch, as a minimum requirement." The UK and Belgium, for instance, have implemented this required standard.

Legislation should also indicate that health warnings should be parallel to the top edge of the package surface to prevent manufacturers printing warnings at an angle or upside down.

Different shaped packages & cartons

For soft packs, depending on the design of the package and of the warning, the top edge of the warning should be required to be lowered sufficiently on the package surface so that the warning is not severed when the package is opened in the normal way. When some soft packs are opened, the top of the package is permanently removed, and a small portion of the front and back of the package may be removed as well (although for other soft packs, the foil folds open and shut at the top). If a substantive part of the health warning was removed, this would be of concern. If there was a border surrounding the warning (e.g. 3-4mm black border), and only part of the border was removed, this would be of less concern. Other considerations for package sizes include:

- Cylindrical containers (such as for roll-your-own tobacco): Canada has requirements to ensure that the warning appears twice on cylindrical containers, effectively on what could be considered the "front" and "back"; Singapore also has specific requirements; Australia and New Zealand have specific requirements for cylindrical and elliptical containers;

- Bundles of cigars with no packaging: Canadian regulations specify that a label is to be placed on the bundle;
- Individually packaged cigars: warnings should be required to be placed horizontally to ensure better visibility;
- Leaf tobacco sold for consumer use (sometimes sold without packaging, and sometimes referred to as a "hand" of tobacco): a warning on a cardboard or other tag of a specified size could be attached with an elastic, string or other device (somewhat akin to a luggage tag affixed to a suitcase, or a price label for a lamp or some other products).
- Cartons: health warnings should also be located on all sides of cartons. Depending on carton format/dimensions, Parties should consider requiring that a picture-based warning be repeated and appear several times, instead of just appearing once.

Obscuring Messages

Parties should prohibit the industry from obscuring a mandatory package message, such as by printing anything or affixing anything (e.g. a sticker) on the package or on the cellophane in a way that blocks a mandatory message.

Exemptions

No exemptions should be allowed to these requirements. For example, there should not be exemptions for small volume companies or brands. Nor should there be exemptions for products sold in duty-free stores.

Tax markings

When determining packaging and labelling requirements under Article 11, Parties should recall obligations related to packaging under Article 15.2 of the FCTC (illicit trade), including:

- that the origin of the product must be indicated on the package and any outside packaging, e.g. "Made in country X" (Article 15.2);
- "that unit packets and packages of tobacco products for retail and wholesale use that are sold on its domestic market carry the statement: "Sales only allowed in (insert name of the country, subnational, regional or federal unit)" or carry any other effective marking indicating the final destination or which would assist authorities in determining whether the product is legally for sale on the domestic market" (Article 15.2(a)).

Parties should avoid a situation where tax-related markings/stamps cover or replace the area devoted to warnings or other mandatory labelling information.

Implementation period

When implementing new or modified packaging and labelling requirements, one option is for Parties to ensure that there are two implementation dates: one date for manufacturers/importers, and a later date for wholesalers/retailers. Another option would be to have one implementation date that would apply to all levels, including manufacturers/importers, wholesalers, and retailers. At the manufacturer/importer level, the transition period should not be longer than one year from the date the regulation is finalized, although a shorter transition period, such as six months, is preferable. For manufacturers, there should be a ban on not only manufacturing/packaging products with old packages after the implementation date, but also a ban on distributing as well. This would prevent manufacturers from stockpiling product with old packaging.

If a wholesaler/retailer has non-compliant product past the implementation date, that product should be able to be seized by enforcement officials. It is important to have a final implementation date at the wholesaler/retailer level in addition to the manufacturer/importer level. For example, when Australia and Canada

implemented picture-based warnings, there was no implementation date at the retailer level.

Pre-emption

Parties should ensure that packaging and labelling requirements do not relieve tobacco manufacturers and/or others from any obligations to consumers and others, such as to provide further health warnings other than those required by legislation. For example, Parties should avoid including in legislation a pre-emption provision indicating that manufacturers are not liable for an absence of warning messages beyond the messages required by legislation, or that sub-national levels of government may not have additional packaging and labelling requirements.

RESOURCE: Library of existing regulations

Copies of labelling regulations from dozens of countries is available at: www.tobaccolabels.org

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