Sambrook Research International

A review of the science base to support the development of health warnings for tobacco packages

This report has been prepared for European Commission, Directorate General for Health and Consumers.

The views expressed in this document are the sole responsibility of its authors and do not necessarily reflect the views of the European Commission.

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EXECUTIVE SUMMARY

Main findings and overall conclusions

• The purpose of this report is to provide the European Commission with a review of the scientific knowledge on health and tobacco labelling, an evaluation of the impact of the existing textual and pictorial warnings and a proposal for warning messages based on a state-of-the-art knowledge on tobacco-related harm.

Scientific knowledge on health labelling generally

• Consumers usually examine packaging in a systematic way, looking at the elements in order of visual dominance. Warning labels are more effective if they systematically address key behaviour processes – attention, reading, comprehension, recall, judgement, behaviour compliance.

Scientific knowledge on the effect / impact of tobacco warning labels on consumers

- There is clear evidence that tobacco package health warnings increase consumers' knowledge about the health consequences of tobacco use and contribute to changing consumer's attitudes towards tobacco use as well as changing consumers' behaviour. They are also a critical element of an effective tobacco control policy.
 - Warnings have a high impact in educating consumers of the health risks of tobacco use
 - Warnings have a medium impact in changing smokers attitudes (in particular thinking about quitting and smoking in the presence of non-smokers)
 - Warnings have a medium impact in changing smokers' behaviour (including smoking less, smoking less around others, using quit lines, attempting to quit and quitting)

Principles of effective tobacco warning labels

- Combined pictorial + text warnings are significantly more effective than text only warnings, especially educating the public of the health risks and changing consumer behaviour. They are also more effective than text only in minimising 'wear out' over time
- Fear inducing warnings (using strong 'shocking' images related to health risks) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings' effectiveness is enhanced if they are used in conjunction with advice on where to obtain help, e.g. a quit line.
- Many warning messages have universal appeal. However, developing messages that target specific consumer groups is also of value. Certain messages clearly have higher resonance with one target group and less resonance with others.
- The report provides detailed recommendations regarding the key design parameters and their optimum specification. The key parameters of importance are as follows:
 - > Size optimally 100% and at least 50% (excluding borders) of the total facial area.
 - Colour pictures used in all warnings together with short easily understood text messages that are clearly linked to the graphical image.
 - ➤ Location pictorial + text warnings should preferably be used on both sides, and as a minimum requirement on the front of packs.
 - The warning should be hung from the top of the pack to maximise visibility. For packs that have a front opening mechanism, front warning should be hung from the 'cut line' (to avoid the warning being severed when the package is opened).
 - ➤ Toll free quit line number on every pack ideally this should be separate from the warning to avoid reducing the size (and impact) of the pictorial within the warning.

➤ Plain packaging — using an unattractive standardised colour with the removal of logos / brand images and associated colours, with brand names in a standardised colour (black) and font size.

Inserts that contain information on the immediate health benefits of quitting as well as advice on how to quit and details of the quit line number could also be considered.

- Warnings should be optimally split into two sets, each set rotated ideally every 12 months (maximum every 18 months) to minimise wear out effects.
- The optimum renewal period for the warning messages is broadly seen as every 2-5 years. If a rotation period of 12 months is adopted, then the warnings / images should be reviewed after 4 years (allowing each message to be used at least twice).

Scientific evidence of the health effects of tobacco use

• The key diseases associated with smoking for which the research shows there is strong evidence of a causal link are given below.

DISEASES CAUSED BY ACTIVE SMOKING

Cancer diseases

Lung cancer (bronchus, trachea)

Head / neck cancer (mouth, larynx, pharynx, oesophagus, nasal/sinus)

Kidney / ureter cancer

Pancreatic cancer

Stomach cancer

Bladder cancer

Cervical cancer

Leukaemia (especially acute myeloid leukaemia)

Non- cancerous respiratory diseases

Chronic obstructive pulmonary disease COPD (emphysema / chronic bronchitis)

Other respiratory effects (asthma, coughing, phlegm, wheezing and dyspnoea)

Pneumonia

Cardiovascular diseases

Heart attack / coronary heart disease / aortic aneurysm

Angina

Stroke

Atherosclerotic / peripheral vascular disease

Reproductive and pregnancy related diseases

Male / female fertility

Reduced foetal growth / low birth weight baby

Miscarriage / spontaneous abortion

Perinatal death

Increased risk for sudden infant death syndrome

Premature birth

Premature rupture of the membrane

Increased risk of placenta previa

Increased risk of placental abruption

Impotence / erectile dysfunction

Other diseases

Blindness / age related macular degeneration / cataracts; Ageing of the skin; Osteoporosis / hip fracture; Gastric ulcer; Dental disease;

Other diseases that are associated with smoking where evidence is suggestive but not sufficient to infer a causal relationship include; anal cancer, vagina/ vulva cancer, ovarian cancer, penis cancer, prostate cancer, colorectal (bowel) cancer, liver cancer, breast cancer, chronic rhinitis, multiple sclerosis, goitre, diabetes and crohn's disease asthma, breast cancer, rheumatoid arthritis.

DISEASES CAUSED BY SECOND-HAND SMOKE

Diseases caused in adults

Coronary heart disease; Lung cancer; Reproductive effects in women / low birth weight; Respiratory symptoms (nasal irritation)

Diseases caused in children

Middle ear disease; Sudden infant death syndrome (SIDS); Respiratory diseases;

Other diseases that are associated with passive smoking where evidence is suggestive but not sufficient to infer a causal relationship include: *Adults* - nasal sinus cancer, stroke, COPD / asthma, AMD, atherosclerosis/ peripheral vascular disease and pre-term delivery. *Children* - brain tumours, lymphoma, asthma, leukaemia, meningitis, cognitive development and behaviour problems.

Proposed new warning messages

• 24 new warning messages have been developed, based on analysis of the scientific evidence, discussions during in-depth interviews and stakeholder feedback. Some have universal appeal others have additional resonance with specific age groups / gender.

Type of	Proposed warning message	Primary target groups						
message		A	В	\mathbf{C}	D	\mathbf{E}		
	Messages related to cancer diseases							
Health	1. Smoking causes 9 out of 10 lung cancers				$\sqrt{}$	$\sqrt{}$		
appeal	2. Smoking causes mouth and throat cancer			$\sqrt{}$	$\sqrt{}$	\checkmark		
messages	3. Smoking doubles the risk of cervical cancer		$\sqrt{}$		$\sqrt{}$			
	4. Smoking causes leukaemia	$\sqrt{}$	$\sqrt{}$		$\sqrt{}$	$\sqrt{}$		
	Messages related to non cancerous respiratory diseases							
	5. Smoking destroys your lungs	$\sqrt{}$	$\sqrt{}$		$\sqrt{}$	$\sqrt{}$		
	6. Smoking causes suffocating breathlessness for life	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$		
	Messages related to cardiovascular diseases							
	7. Smoking causes heart attacks					$\sqrt{}$		
	8. Smoking causes strokes and severe disability							
	9. Smoking causes leg amputations					$\sqrt{}$		
	Messages on other illnesses caused by smoking							
	10. Smoking causes blindness	$\sqrt{}$	$\sqrt{}$		$\sqrt{}$	$\sqrt{}$		
	11. Smoking causes rotten teeth and gums							
Social	12. Smoking can kill your unborn child							
appeal	13. Your smoke harms your children, family and friends		$\sqrt{}$	$\sqrt{}$	$\sqrt{}$			
messages	14. If you smoke your children will smoke			$\sqrt{}$	$\sqrt{}$	$\sqrt{}$		
Cessation	15. Quit now – stay alive for your children			√		$\sqrt{}$		
appeal	16. Stop smoking now - your health benefits immediately	$\sqrt{}$	$\sqrt{}$	V	V	V		
messages	17. Get professional help – it makes it easier to quit	V	V	V	V	V		
	18. Smoking makes it harder to have children			V				
Other	19. Smoking reduces your sexual performance	$\sqrt{}$		V	•			
messages	20. Smoking is severely addictive - don't start	V	$\sqrt{}$	•				
messages	21. Smoking reduces your sports performance	V	V	$\sqrt{}$	$\sqrt{}$			
	22. Smokers die younger	,	•	•	•	$\sqrt{}$		
	23. Smoking causes wrinkles				$\sqrt{}$,		
	24. Tobacco smoke contains highly toxic chemicals		į	$\sqrt{}$	Ž	$\sqrt{}$		
	21. 1000000 Smoke contains many toxic enemicals	•	•	•	•	•		

Note. The target groups are indicated marked with A to E. A = teenage male, B = teenage female, C = young adult men (aged 20-40), D = young adult females (aged 20-40), E = other older adults

Summary - overall conclusions

The research has identified over 30 health risks for which there is a proven causal link and supported by evidence at two major International organisations – the US Surgeon General and IARC. Some of these risks are already well known, others will be new to consumers. There is strong, conclusive evidence that pictorial warnings are significantly more effective than text only warnings. There is clear evidence that they have a strong impact in educating consumers about the health risks of tobacco use and stimulating discussion with family members and friends. They also have a positive impact in changing smokers' attitudes and behaviour (in particular not smoking around others, smoking less and trying to quit). Fear inducing images (related to health risks) and strong emotion inducing images (especially children and unborn babies) is the most effective way to stimulate consumers to notice and read the associated text warning messages, which is enhanced if they are used in conjunction with advice on where to obtain help, e.g. a quit line, and plain packaging.

24 new health warnings are suggested, which include health risk appeal warnings, social appeal, cessation appeal and other messages. Many have universal resonance, some have particularly high resonance with specific age groups or gender.

Recommendations

The following set of recommendations for the future development of tobacco package health warnings are suggested, in order to <u>maximise</u> the effectiveness of the warnings' ability to educate consumers and influence attitudes and behaviour related to tobacco use. They are based on the research findings, and assume that the 24 proposed warnings (or variants of them following market testing) are adopted. The recommendations also take into account the guidelines issued in the context of the World Health Organisation Framework Convention on Tobacco Control, to avoid conflicting requirements.

The recommendations, in approximate order of priority, are as follows:

- 1. Test the 24 proposed warnings, together with appropriate images, fine tune the wording (if required) and adopt them in place of the existing 14 messages.
 - ➤ Two general warnings should also be retained and used, but worded as follows a) Smoking kills; b) Smoking seriously harms other people.
- 2. Split the 24 warnings into 2 groups of 12 (with similar numbers of health risk / social appeal / cessation appeal / other messages) and rotate every 12-18 months.
- 3. Introduce mandatory quitline information on all warnings, preferably as a separate message independent of the main warning message.
- 4. Introduce mandatory pictorial warnings for all EU Member States, based on the optimum design criteria highlighted in the report. In particular:
 - > The pictorials should be on both sides of the tobacco packaging. The pictorial on the front should cover 75% of the surface area and hang from the cut line for packs with hinged openings. The pictorial on the rear side should cover 100% of the surface area.
- 5. Introduce mandatory 6-sided packaging, the dimensions of which to be determined after further consultation to ensure warnings are of adequate size to be effective.
- 6. Develop a plain packaging strategy and mandate plain packaging on all tobacco products.

BACKGROUND, OBJECTIVES, METHOD AND SAMPLE

Background, objectives and overall research requirements

The European Commission Directorate-General for Health and Consumers commissioned research to review health warnings used on tobacco packages, and recommend a set of future warnings, based on state of the art scientific knowledge.

Background

There is a great wealth of scientific evidence demonstrating the detrimental health effects on smokers, including increased risks of heart disease, lung cancer and other respiratory diseases. Research has also highlighted the health risks to non-smokers from second hand smoke, in particular in the work environment, but also to non-smoking partners / children in the home environment as well as health damage to foeti in pregnant women.

Health warnings on the packages of tobacco products are a cost-effective tool (the cost is borne by the industry) for communicating the dangers of tobacco usage as well as encouraging consumers to quit. The first EU wide requirements for tobacco labelling were introduced in 1989 through the labelling Directive (89/622/EEC) and amended in 1992 through Directive 92/41EC. This stated that all tobacco products should carry specific warnings but only required the warnings to cover 4-8% of the front and back of the pack. Initially, the health warnings were in text form.

The Tobacco Product Directive (2001/37/EC) introduced bolder health messages and radically increased the size of the warnings and improved their legibility. According to the Directive each unit packet of tobacco products intended to be smoked must carry a general warning ("Smoking Kills / Smoking can kill" or "Smoking seriously harms you and others around you") covering at least 30-35% of the front and one of the fourteen additional warning sets covering at least 40-50% of the back. Non-combustible tobacco products shall carry the general warning "This tobacco product can damage your health and is addictive".

The Directive allows Member States to require additional warnings in the form of colour photographs and other illustrations. For that purpose the Commission adopted rules for the use of pictorial warnings (Decision 2003/642EC) and established a library of 42 selected sourced documents. There are three images for each health warning. Member States can choose illustrations most suitable for consumers in their country. Belgium was the first EU Member State to introduce pictorial warnings on cigarette packs in November 2006, followed by Romania in July 2008 and the UK in October 2008. Latvia has also adopted legislation to require the use of pictorials from March 2010, and six further EU Member States plan to introduce pictorial warnings in the near future.

Outside the EU the following 15 countries have introduced pictorial warnings: Canada (2000), Brazil (2001), Singapore (2004), Venezuela (2005), Thailand (2005), Australia (2006), Uruguay (2006), Chile (2006), Jordan (2007), Hong Kong (2007), New Zealand (2008), Brunei (2008), Egypt (2008), Panama (2008) and Cook Island (2008).

Other countries that have adopted legislation to introduce pictorial warnings in 2009 / 2010 include China, Djibouti, India, Iran, Kyrgyzstan, Malaysia, Mauritius, Peru, Switzerland and Vietnam.

The Commission was therefore keen to obtain a rigorous review of the <u>current</u> scientific knowledge on health and tobacco labelling, an evaluation of the impact of existing textual and pictorial warnings, and proposals for future warning messages, based on state of the art knowledge on direct / indirect tobacco related risks / harm. The results will be used by the Commission to develop proposals for a new set of warning texts and graphical images (based on reliable scientific evidence) that will be more effective in warning consumers of the potential risks and harm associated with both direct and passive smoking.

Main objectives of the research

- 1. Review of the scientific knowledge on health labelling.
- 2. An evaluation of existing warnings on tobacco packages.
- 3. Review of the scientific evidence on the health effects of tobacco.
- 4. Development of possible future warning messages.

Research method

Phase 1

A systematic literature search was carried out using a range of databases / search engines (the main ones being Google, Google Scholar, Scirus, Medline, Pubmed, Science Direct) using variations of the terms (effective health labelling / effective food labelling, effective drug warning labels, effective alcohol warning labelling, effective tobacco warning labelling / effective tobacco pictorial warnings / health effects of tobacco, tobacco smoking plus name of identified diseases associated with smoking) with a focus to identify relevant scientific evidence published between 2000 and 2008. Further material was identified by searching related company / industry and national government websites and cross-referencing cited reports. Bibliographies and conference extracts were also examined to identify additional evidence.

Titles and abstracts were reviewed for relevance. Potentially relevant studies / evidence were assessed to identify which ones included relevant scientific evidence appertaining to the projects goals. Key data was extracted from these studies, evaluated and summarised in the report, where appropriate. The table shows the overall results of the literature search.

Total number of titles / abstracts screened	8,250
Number of potentially eligible studies / reviewed	7650
Number of studies / evidence evaluated and assessed	229

Phase 2

During phase 2, key organisations and individuals that have relevant knowledge of the effectiveness of textual and pictorial warnings used on tobacco packages and / or the health effects of tobacco were identified and interviewed at a mutually convenient time. A total of 111 people were interviewed (87 in Europe and 24 in the rest of the World) involving 103 organisations, details of which are provided in the appendices.

A note of thanks

Sambrook would like to thank all the organisations and respondents that provided feedback as well as evidence / reports on the various issues addressed in this report.

SCIENTIFIC KNOWLEDGE ON HEALTH LABELLING

How consumers look at packaging / labels

Research has shown that consumers use a certain pattern when looking at packaging / labels. Viewing patterns are driven by packaging layout. Consumers tend to look at the dominant visual element first and are then drawn to the next strongest element.

Typical consumer viewing patterns of packaging / labels (References A1, A2)

Research on how consumers examine packaging / labels has been carried out using eye tracking technology. The results of these studies are used by marketers to help develop, assess and improve packaging systems.

Certain consistent, general patterns have emerged regarding how shoppers typically view packaging – and these patterns apply across different product categories, packaging structures and international borders.

- 1: Most packages are not systematically "read" like books, magazines, or newspapers. Consumers don't usually start in the top-left corner and work their way across and down the packaging in typical Western reading patterns. Instead, shoppers typically start at the dominant visual element (often the brand name), and are then drawn to the next strongest element (usually the next most dominant visual element).
- 2: A related and important point is that viewing patterns are driven by packaging layout rather than a function of "what people want to look at" or what they think is important. In other words, the fact that a message is frequently missed or overlooked does not mean that shoppers think it is unimportant. It simply means that the message was not adequately highlighted on the package. There is clear evidence that designers have the power to impact shoppers' viewing patterns by changing the layout of a package or label.
- **3:** In the few seconds that shoppers typically spend looking at a package, they can actively consider only three or four primary design elements (often the branding, a main visual, and a primary claim). Research repeatedly found that adding extra messages does not usually increase packaging viewing time, but instead results in more elements fighting for attention in a 'zero-sum' game. Package viewing patterns suggest that the "less is more" axiom is nearly always true. It is more effective to clearly highlight one key point than to give equal weight to four different claims and run the risk that none is consistently seen.
- **4:** Package viewing patterns are largely consistent across cultures and product categories because they are driven mainly by human physiology rather than by cultural patterns of preferences.
- 5: Is it important for a packaging design to establish a dominant viewing flow that leads consumers from their "start point" to the other critical packaging elements (key claim, messages, icons etc). What doesn't work well is a balanced lay out in which the main visual starts consumers in the middle and the other design elements surrounding it are all secondary. The ineffective balanced layout forces consumers to 'randomly' choose among directions, and this often causes them to miss important / key elements of the labelling.

Effectiveness of warning labels generally

Warning labels are more effective if they systematically address key behaviour processes – attention, reading, comprehension, recall, judgment and finally behaviour compliance.

Effectiveness of warning labels in general (*References B1, B2, B3, B4*)

Over the past decade a growing number of companies have included warning labels on their products or packaging due in part to changing government regulations and concerns of public safety etc. Given the potential consequences for consumer harm, research has been carried out to find out how effective warning labels are.

Research on the effectiveness of warning labels has used a variety of different measures to try to understand the effectiveness of warning labels in conveying hazardous information to consumers. There are several different aspects of the warning process, namely: attention, reading / comprehension, recall, judgement and behaviour compliance. Attention is the first dimension of effectiveness. It determines whether or not consumers notice a warning label that appears on a product. Once the warning label has attracted consumers' attention, the next issue is whether or not they proceed to read/understand its information. Then consumers must be able to remember the information presented in the warning label. Next warning labels need to influence consumers' judgment concerning their perception of how hazardous and dangerous a product really is. Finally, the consumer has to engage in behaviour that complies with the safety precaution conveyed in the label.

Some researchers see behaviour compliance as the ultimate test of warning label effectiveness while others argue that the other dimensions such as attention, recall or judgment are equally important depending on the purpose of the label. For example, if consumers are able to understand and accurately recall the dangers associated with the consumption of a particular product, but choose not to follow them, the warning label has still effectively served a purpose.

Effectiveness of warning labels

Based on the literature review on the effectiveness of the different dimensions of warning labels (in general) the following findings emerge.

Attention: Well designed warning labels can be very effective in catching the attention of consumers. Critical design elements are: font, size, colour, spacing, degree of details, symbols/pictures and location of warning message.

Reading / comprehension / recall: Unless the message is clear and easily understood the warning is likely to be ineffective. Pictorial images / symbols are seen as critical in order to address users with lower language skills.

Judgement / behaviour compliance: Many warning labels are not effective in influencing behaviour change. One common reason for non compliance is the cost of compliance. Other factors depend on different consumer attitudes. Some people are risk takers and more willing to risk the consequences. Other people less likely to comply are young people that lack experience, people that have used a product many times with no negative consequences and people that have an addiction to a product. However, based on the experience gained from the tobacco sector with introduction of large, well designed tobacco warning labels, such labels can be effective even among end-user groups that are not easily influenced (reference F7, F21, F27, F34)

SCIENTIFIC KNOWLEDGE ON TOBACCO WARNING LABELS

Background information on tobacco warning labelling

Three EU Member States and fifteen countries outside the EU have already introduced pictorial warnings and several others are planning to introduce them in 2009 / 2010.

Back ground information on tobacco warning labelling

Communicating the health effects of tobacco use is a primary goal for tobacco control policy and health warnings on tobacco packages are among the most widespread policy initiatives implemented to raise awareness of the health risks of tobacco. Package warnings are seen as unique given their reach and the high frequency of exposure at the point of purchase and time of smoking.

The first EU wide requirements for tobacco labelling were introduced in 1989, which required the warnings to cover 4-8% of the front and back of the pack. The new Tobacco Product Directive (2001/37/EC) introduced bolder health messages and radically increased the size of the warnings. The directive also allows Member States to require additional warnings in the form of colour photographs and other illustrations. Belgium was the first EU Member State to introduce pictorial warnings on cigarette packs in November 2006, followed by Romania (July 2008) and the UK (October 2008). Latvia has also adopted legislation to require the use of pictorials from March 2010, and six further EU Member States plan to introduce pictorial warnings in the near future. Outside the EU 15 countries have already introduced pictorial warnings and at least 10 other countries have adopted legislation to introduce pictorial warnings in 2009 / 2010.

Many jurisdictions are currently preparing similar legislation in response to the international packaging and labelling regulations under Article 11 of the World Health Organisation's Framework Convention on Tobacco Control (FCTC). The FCTC is a global public health treaty and requires Parties to adopt a comprehensive range of measures designed to reduce the devastating health impacts of tobacco. So far it has been signed by 168 of the 192 WHO Member States and 164 WHO Member States have become Parties to the Convention.

Article 11 of the Convention stipulates that each Party shall adopt and implement, in accordance with its national law, effective packaging and labelling measures within a period of three years after entry into force of the Convention for that Party. The third Conference of the Parties to the Convention adopted comprehensive guidelines intended to assist Parties in meeting their obligations under Article 11 and increase the effectiveness of their packaging and labelling measures. The guidelines cover the following areas:

- Design elements for an effective warning message (location of message, size of message, use of pictures, colour, rotation, message content, language, plain packaging).
- Information on constituents and emissions.
- Process for developing effective packaging and labelling requirements (product category considerations, different types of packaging, targeting population subgroups, pre-marketing testing).
- Preventing misleading or deceptive claims on tobacco packaging (different type of packaging, ban of misleading terms such as light or mild, plain packaging).

Review of scientific knowledge on general tobacco warning labelling

There is clear evidence that tobacco health warnings are effective in informing consumers about the health consequences of tobacco use and in increasing their motivation and intention to quit. They also contribute towards changes in consumer behaviour.

Effectiveness of tobacco health warning labels (Major References F5 – F80)

The desk research has identified a number of studies carried out during the last 8 years looking at the effectiveness of tobacco health warnings in general (i.e. pictures + text or text only). There is clear evidence that most consumers have an imperfect understanding of the nature and magnitude of the risks of tobacco.

However, there is also clear evidence that warning labels can be effective in changing consumer behaviour, although there are no reliable estimates available from any country on how many smokers have changed their behaviour because of tobacco health warning labels. The decision to stop smoking is often multi-factorial, influenced by other tobacco control policies such as price, clean air laws, smoking restrictions at home, family considerations and social pressure, as well as risks to health.

Most countries that have introduced tobacco warning labels on cigarette packs have also introduced a number of other tobacco control measures either simultaneously or in close proximity which makes it difficult to measure the impact of one initiative. There is clear evidence that the most successful campaigns have implemented a combination of control policies.

The evidence identified by the literature search highlighting the effectiveness of health warning labels on tobacco packaging falls into five broad groups, as shown below. *Note:* research evidence for each of the subsequent bullet points can be found in appendix 2.

- i. Warning labels are effective at educating consumers of the health risks of tobacco use
- ii. Tobacco package warnings are a critical element of a health risk publicity campaign
- iii. Warnings increase motivation to quit / undermine brand value and sales
- iv. Targeting specific consumer groups enhances effectiveness of warning messages
- v. Other factors can enhance the impact of tobacco health warnings

i. Warning labels are effective at educating consumers of the health risks of tobacco use

- Consumers see health warnings as a credible source of information especially when the information is attributed to a well respected authority / organisation.
- Most consumers have an imperfect understanding of the nature and magnitude of the risks of tobacco.
- Tobacco health warnings can be effective in informing consumers about the health consequences of smoking. Large, prominent warnings are significantly more effective than more obscure warnings.

• There is considerable support from consumers for putting large health warnings on tobacco packages.

ii. Tobacco package warnings are a critical element of a health risk publicity campaign

- Health warnings on tobacco packages are among the most prominent source of health information.
- Health warnings are a very cost effective public health intervention and have a high reach. A person that smokes a pack of cigarettes each day is potentially exposed to the warning over 7,000 times per year. Non smokers, including children and young adults are also exposed to the warnings.
- An effective tobacco package warning system is seen as a critical component of any comprehensive tobacco control strategy.

iii. Tobacco package warnings increase motivation to quit/undermine brand value/sales

- Tobacco health warnings increase motivation to quit and cessation behaviour. It can also act as a deterrent for new smokers.
- Health warnings help to make tobacco packages and the package displays at retail outlets look less attractive. This clearly undermines its ability to communicate brand value and helps to reduce sales of tobacco products.

iv. Targeting specific consumer groups enhances the effectiveness of warning messages

- The main groups that are likely to benefit most from tobacco warning labels on tobacco packets are smokers who are contemplating quitting and young people experimenting with smoking.
- In order to be effective health warnings need to be tailored to particular user groups and they should take into account cultural sensitivities.

v. Other factors that can enhance the impact of the warnings

- Health warnings must be regularly rotated and updated to maintain maximum impact and reduce "wear out".
- Health warnings that include information on cessation services, such as a toll-free "quit line" number, have a significant impact on the use of these services and represent a low cost method of promoting cessation / supporting efforts to change.
- The introduction of plain packaging would reduce positive brand imagery and strengthen the health warning.

Table cross referencing the findings with evidence sources in the appendices

The following table shows the evidence sources for the different ways that tobacco health warnings are effective highlighted in the previous section, together with the countries where the evidence was sourced (if relevant). More detailed extracts for each evidence point can be found in the appendix 2.

Although there is a significant amount of research evidence emanating from Canada (mainly from David Hammond), there is also extensive evidence from a wide range of countries including the USA, Australia / New Zealand and several EU Member States.

Evidence reference number and country where evidence sourced	i. Warning labels effective at educating consumers	ii. Warning are critical element of health risk campaign	iii. Warnings increase motivation to quit / undermine brand values	iv. Target specific consumer groups to enhance effectiveness	v. Other factors
F6 – Canada	$\sqrt{}$		1		
F7 – Thailand			V		
F9 – France			V		-1
F10 – Netherlands	.1.1				V
F11 – Canada / USA	$\sqrt{}$	ا			
F12 – USA	-1	V			
F15 – Canada	N al	V			-1
F16 – Canada/USA/UK/Aus (07)	V	ا			V
F17 – Canada / Mexico		V	2/	-1	
F19 – Belgium F21 – Canada/USA/UK/Aus (06)	$\sqrt{}$	$\sqrt{}$	2/	V	
F23 – USA	VV	V	V	2/	
F27 – Netherlands			$\sqrt{}$	2/	
F28 – Canada			VV	V	
F29 – UK				2/2/	N
F31 – New Zealand	$\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{$	V		V V	٧
F34 – Canada	V V V	V			
F35 – Canada	$\sqrt{}$	•	•		
F37 – General review	•	$\sqrt{}$			$\sqrt{}$
F38 – Canada		,			į
F40 – General review			$\sqrt{}$,
F41 – USA		$\sqrt{}$,		
F43 – General review	$\sqrt{}$,			$\sqrt{}$
F47 – Canada					V
F48 – New Zealand					$\sqrt{}$
F49 – General review					$\sqrt{}$
F50 – Netherlands			$\sqrt{}$		
F55 - Belgium	$\sqrt{}$		$\sqrt{}$		
F56 – Poland	$\sqrt{}$				
F57 – Brazil		$\sqrt{}$	$\sqrt{}$		
F 58 – Brazil		$\sqrt{}$	\checkmark		$\sqrt{}$
F60 – 27 EU Member States	$\sqrt{}$			$\sqrt{}$	
F61 - Norway	$\sqrt{}$,	,	$\sqrt{}$
F62 – France	$\sqrt{}$		$\sqrt{}$	$\sqrt{}$	
F64 – Switzerland	$\sqrt{}$	1	$\sqrt{}$	1	
F65 – Australia	V	V	V	V	
F79 – New Zealand F81 / 82 – Canada	3/		V		
F84 / 85 – Canada	V		$\sqrt{}$		V
F87 – Romania	٧		V		٧
			٧		

A NOTE ON THE DATA COLLECTED

When analysing and comparing the findings in surveys that address text only warning messages or combined pictorial + text warnings, the following points should be noted.

- Survey methods varied greatly, comprising focus groups, mini focus groups, face-to-face interviews, telephone interviews, web-based surveys and discussion groups involving students (at school / university).
- Most of the outcomes are self reported behaviour, rather than observed behaviour. It
 cannot be automatically assumed that the intention to quit and self-reported behaviour
 correspond to actual behaviour. Clearly there are limitations on the accuracy of selfreported outcomes (although the use of face-to-face / telephone techniques and focus
 groups moderated by professional interviewers will maximise the veracity of the
 feedback), and these findings should therefore be treated with a degree of caution.
- Some surveys include self-reporting of people that say that the health warnings influenced them to actually quit, smoke less or avoid smoking in the presence of non-smokers. However, it is very difficult to isolate the effects of a separate measure (such as a health warning on smoking behaviour) from the effects of other tobacco control measures and general social trends, and this should be borne in mind when evaluating any reported outcomes.
- Some studies were representative of whole populations, some focused on specific age groups. Some studies involved smokers (hardened smokers / potential quitters) and non-smokers (never smokers / past smokers), others only obtained feedback from smokers.
- Most surveys were unclear about what is meant by 'effective', and definitions were not given in reports. However, in most cases, when used in relation to the 'effectiveness of health warnings', the use of the word 'effective' is generally related to consumers' perception of how warnings firstly attract their attention and secondly convey a meaningful message. Findings that address the impact on changing consumer behaviour (such as intentions to quit) are nearly always addressed separately as specific questions.
- Finally, images and warnings used outside the EU are different to those used within the 27 EU Member States. Within the EU itself, when combined pictorial and text warnings have been researched, some of the surveys provide feedback on all 42 images, some provide feedback on 14 images selected / used by specific EU Member States and some surveys only obtain feedback on a small selection of images. Furthermore, some of the studies are pre-testing warnings / images others are researching attitudes to warnings / pictorials that have been used in the market place for several months.

<u>Summary</u>: It is clear that there are limitations regarding how these surveys can be compared and analysed in a meaningful way. However, despite these limitations, consistent outcomes have been identified both for text only and for combined pictorial and text warnings, from which reliable conclusions and policy recommendations can be developed.

Evaluation of the effectiveness of TEXT ONLY tobacco health warnings

Text only warnings are not very effective because most smokers don't read them. However, some people that do read them feel text only messages can be effective provided they are personalised as much as possible, easy to understand and relevant to the target group.

Effectiveness of text only warning messages - summary

The desk research has identified several countries that have undertaken market research (surveys / focus groups) to assess the impact of the various text warnings on consumers. Summaries of the key studies with relevant findings are given below. The findings vary slightly from country to country, however there are some general themes that are true for all countries.

- Text warning messages are noticed by consumers provided they are large enough.
- ➤ Many consumers don't read the warning messages in detail which reduces their effectiveness significantly.
- ➤ Different target groups respond to different messages.
 - Young people generally don't respond well to factual health related warnings however they respond to descriptive and emotional warnings.
 - Women generally respond well to emotional messages and to messages that are related to their looks, pregnancy and protection of children.
 - Middle aged people (40+ years) generally respond well to factual health messages partly because they start to see some of the symptoms of health effects on themselves.
 - Messages that provoke fear and anxiety tend to be quite effective across all age groups.

Effectiveness of text only warning messages – Pan European study (reference 62)

In 2004, Cancer Research UK Centre for Tobacco Control was leading a Pan European research project exploring European consumers' response to the new larger text warnings. The response to three message contents was tested (fear, social and support appeal) Fifty six focus groups were conducted across seven European countries (Finland, France, Germany, Greece, Spain, Sweden and the UK) with 17-64 year old smokers, half of whom were thinking of quitting in the next six months and half of whom were not thinking of quitting. The key findings of the research were:

- The majority of respondents were supportive of the new warning format.
- The new warning format clearly undermined brand value (it was the first aspect of the pack mentioned),
- The new warning format provoked an emotional response.
- Fear appeal messages were seen as relevant and effective to all. They were easily understood and provoked anxiety and guilt.
- Social appeal messages were seen as relevant to all but seemed especially effective with female participants who showed a more emotional reaction.
- Support appeal messages showed no or little effect with committed smokers but they were seen as effective with smokers contemplating to quit. They found them supportive and encouraging.

Effectiveness of text only tobacco warning messages in Belgium (reference 55)

In January 2004 a representative sample of 2,002 people aged 15 plus were interviewed to obtain feedback on awareness, attitudes and behaviour changes attributed to the 'new' health warning messages (large text only warnings that had been increased in size since September 2003 to cover 35% to 50% of the tobacco packet). 32% of the sample was smokers and 68% non-smokers.

<u>Smokers</u> were asked which warning messages they were aware. The ten most frequently recalled messages are shown in the table below.

Main text warnings recalled	All smokers	15-24 year old smokers
Smoking kills	78%	82%
Smoking seriously damages your health and those around you	47%	52%
Smoking causes fatal lung cancer	36%	38%
Smokers die younger	29%	44%
Smoking when pregnant harms your baby	28%	50%
Smoking can damage the sperm and decrease fertility	27%	38%
Smoking causes ageing of the skin	24%	25%
Smoking clogs the arteries and causes heart attacks and strokes	24%	34%
Smoking can cause a slow and painful death	22%	28%
Stopping smoking reduces the risk of fatal heart and lung diseases	20%	32%
Your doctor or your pharmacist can help you stop smoking	20%	32%

Other findings

- 47% of respondents that recalled warnings agreed with the statement that they had already discussed the new warnings with friends or members of their family.
- 42% agreed with the statement that photos or images on the packets would be more convincing than just the text.
- 29% agreed with the statement that the new warnings provide additional motivation to quit smoking (the percentage amongst smokers that would like to quit smoking within a year was 46% compared to only 16% amongst smokers that don't contemplate quitting).
- 27% agreed with the statement that after reading the warning I am better informed of the health risks.
- 8% of smokers said they now smoke less since the introduction of the new large text warnings, 2% smoke more and 88% smoke the same amount.

Effectiveness of text only warning messages in France (reference 63)

In 2002, the effectiveness of the new larger textual warning messages (EU Directive 2001/37) were pre-tested in 8 focus groups with a total of 48 smokers and compared to the small text warnings used on tobacco packs in 2002. The following were the key findings:

- The new (larger) warning messages were better received and accepted compared to the small messages that were still in use.
- Health appeal messages were generally well received and were considered to be effective. Especially effective was the message "smoking can cause a slow and painful death".
- Social appeal messages were generally considered to be effective. Especially effective were the second hand smoking messages aimed at protecting children.
- Support appeal messages were quite well received by the majority of participants.
- Aesthetic appeal message (smoking causes aging of skin) was not considered to be very credible by the majority of participants.
- Economic appeal messages (do you know how much you spend on cigarettes) were not seen as very effective. Participants agreed that smoking was expensive but they did not see it as a reason to quit.
- Sex related appeal messages were seen as not as very effective. The majority found the messages less credible because they struggled to see the link with smoking.

Effectiveness of text only warning messages in Norway (reference 61)

On behalf of the Directorate for Health and Social Affairs, SIRUS evaluated in 2006 the effectiveness of the new health warning format based on data gathered from the annual tobacco survey. The survey took place in 2004 amongst 903 smokers aged 16 to 74. The evaluation found high levels of awareness about the new warnings but only 10% said that they have read the warnings in detail, 38% said they did not read them at all. An overview of the key findings can be seen in the table below:

Question asked	Result
Have you noticed new, larger warnings?	91% of respondents confirmed that they
	have noticed new larger warnings.
Have your read the new warnings messages?	10% said that they have read warning
	messages in detail.
	38% said that they have not read the
	warning message at all.

How much do you agree with the Results following statement

ionowing statement	
The source of the warning messages is	44% completely agreed
trustworthy?	11% completely disagreed
The new warning messages make me	12% completely agreed
worried about my own health?	36% completely disagreed
The new warning messages encourage me to	15% completely agreed
smoke less?	43% completely disagreed
The new warning messages make me think	18% completely agreed
about quitting?	33% completely disagreed
I knew about all the health effects covered	18% completely agreed
by the warning messages?	25% completely disagreed

Effectiveness of text only tobacco warning messages in Poland (reference F90)

A national face-to-face survey was carried out in Poland in November 1998 and November 1999 by the Cancer Centre in Warsaw to examine the influence of the 30% health warnings on cigarette packs that were introduced in July 1998 (*NOTE* - these warnings were different to the 14 contained in Directive 2001/37/EC). 1,116 adults and 3,294 school children (aged 13 to 15) were interviewed. Key findings from the survey were as follows.

- In 1999, 4% of females and 2% of males said they had given up smoking as a result of seeing the larger health warnings, compared to 2% for both gender in 1998.
- In 1999, 24% of females and 22% of males said they had made attempts to stop smoking or smoke less as a result of the enlarged warnings, compared to 16% for both gender in 1998.
- In 1999 22% of females and 24% of males said they became better aware of the harmfulness of smoking as a result of the enlarged warnings, compared to 19% and 14% respectively in 1998.

Effectiveness of text only tobacco warning messages in Romania (reference F86)

The Ministry of Health commissioned a survey in June 2008 to obtain views on the awareness and impact of text only warnings used on tobacco packages prior to the introduction of pictorial warnings in July. 444 smokers were interviewed by face to face personal interviews, of which 48% were male and 52% female. 18% were aged 15-24, 25% were aged 25-34, 20% were aged 35-44 and 37% were 45+. 57% of the interviews were in urban locations and 43% in rural locations. The main results are given below.

Smokers were asked to give examples of 3 (warning) texts that appear on tobacco packages.

Main text warnings recalled	Total	1 st example	2 nd example	3 rd example
Smoking damages your health	59.4%	35.3%	15.8%	8.3%
Smoking can kill	55.8%	31.0%	15.8%	9.0%
Smoking can cause cancer	36.8%	11.6%	12.9%	12.3%
Smoking damages your health and those around you	13.6%	5.2%	4.1%	4.3%
Smoking causes lung cancer	9.2%	2.1%	3.6%	3.5%
Smoking during pregnancy harms your foetus	9.2%	-	6.2%	3.0%
Smoking causes impotence	8.9%	1.8%	3.1%	4.0%
Smokers die younger	8.1%	2.5%	3.1%	2.5%
Smoking is addictive	5.2%	-	1.9%	3.3%

Other findings

- 63% of smokers had spoken about the text warnings with at least one other person.
- 21.4% of smokers said that having seen the information on the tobacco package they had tried to quit, and 27.9% said they had reduced the number of cigarettes they smoke each day.

Conclusion: There is a significant level of recall of the text only warnings in Romania and the different health messages they contain. The text warnings are having a significant effect in educating smokers of the health risks of smoking as well as having a positive impact in changing consumer behaviour (trying to quit / smoking less).

PAN EU STUDY - Flash Eurobarometer – March 2009 (ref F60)

In December 2008, 26,500 randomly selected citizens aged 15 years and over were interviewed (by telephone / face-to-face) in the 27 EU Member States and Norway. The following findings summarise the feedback from the 24 EU Member States that currently use text only warnings, involving a total of 21,569 citizens.

- 30.1% of never / former smokers and 28.4% of current smokers thought that the current (text) health warnings were either somewhat or very effective in informing them of the health effects of tobacco.
- 27.9% of never / former smokers thought that the (text) warnings were somewhat or very effective in persuading them not to start smoking (again).
- 20.7% of current smokers thought that the (text) health warnings had been somewhat or very effective in getting them to smoke less, and 18.0% getting them to try to quit smoking.
- 55% of all respondents in the 24 EU Member States that have text only warnings thought it would be somewhat or very effective to add a colour picture to illustrate the health effects of smoking in order to strengthen the text-only health warning.

Effectiveness of text only tobacco warning messages in Switzerland (reference 64)

A sample of 5680 smokers aged 14 to 65 was surveyed in 2006/ 2007 regarding the effectiveness of text only warnings as part of the "Tabakmonitoring" survey. The main research findings were:

- 38% of respondents said that they look at the warning message frequently (14%) or every time they smoke (24%). There was no significant difference between the different age groups and sexes. However, occasional smokers looked at the warnings more often than heavy smokers.
- 37% of respondents said that the warning messages made them think about the health effects of tobacco and that they frequently discussed the warning messages with other people.
- 12% of smokers indicated that they smoked less because of the warning messages.
- 18% of respondents indicated that the quitline number would be their first call if they wanted to stop smoking.

Effectiveness of text only tobacco warning messages in Australia (reference 65)

In 2002, Elliot & Shanahan assessed the reaction to proposed new tobacco health warning messages amongst defined target groups. The research consisted of 44 mini discussion groups (4-5 people in each group) conducted with current smokers, recent and long-term ex smokers and non-smokers. Participants were aged between 15 and 70 years. The key findings were:

Target group	Key findings
15-17	• Typically young smokers did not personalise many of the messages because the health problems detailed were not associated with smokers of their age.
	• Descriptive or emotive messages such as "living, breathing hell" and "slow and painful death" had considerable impact across this age segment.
18-24	 Many smokers in this age group were sensitive to the warnings but showed little concern about the long term health effects of smoking – perceived them as too far in the future.
	• Messages that had considerable impact on this age group were on issues such as ageing of the skin, pregnancy (females), and emotive messages ("living, breathing hell").
25-49	• This group includes many life segments (young singles, married with and without children) and their reaction to the messages varied significantly.
	• Messages that had a considerable impact on this age group included messages about children. Health related messages had an impact on people approaching middle age (40+ years), in particular messages about heart disease and stroke.
50-70	• This age group had the most entrenched behaviour and attitudes towards smoking of all. Most of them accepted many of the health warnings, however many of them felt it was too late to quit to obtain any real benefit from giving up.

Evaluation of the effectiveness of specific pictorial tobacco health warnings

Warnings with strong 'fear / 'emotion' inducing warnings / images related to health risks (such as rotten teeth or throat cancer) and the harm of smoking on children or unborn babies are the most effective across 11 EU Member State surveys.

Table comparing pictorial + text warnings rated as most effective in 11 EU surveys

Message	Image	‡EU	BE	BG	†IE	†FR	*EL	*IT	RO	ES	UK
W1. Smokers die	#1										
younger	#2		3							7	9
younger	#3			7							
W2. Smoking clogs the	#4										
arteries and causes heart	#5	5=	5		Y		5			6	
attacks and strokes	#6	3=		4		4 / Y				5	4
W3. Smoking causes	#7									10	
fatal lung cancer	#8	2		2	Y	8=/Y	1		4	3	3
Tatai rung cancer	#9		2					2		4	7
WA Smoking is highly	#10										
W4. Smoking is highly addictive, don't start	#11					Y					
addictive, don't start	#12		8			Y			3		
W5. Stopping smoking	#13										
reduces the risk of fatal	#14										
heart and lung diseases	#15				Y	10					
W.C. Carrelline and access	#16									8	
W6. Smoking can cause	#17	1		3	Y	1 / Y			8	1	1
a slow and painful death	#18		6				2				
W7 Constitution	#19		7		Y						
W7. Smoking causes	#20	10					6				
aging of the skin	#21					5			10		
W8. Smoking can	#22										
damage the sperm and	#23										
decrease fertility	#24			7		2			6		
W9. Smoking may	#25										
reduce the blood flow	#26						7				
and causes impotence	#27			8	Y				2		
W10. Smoke contains	#28										
benzene, formaldehyde	#29	3=		1	Y	7 / Y		1	1	2	2
and hydrogen cyanide	#30										8
W11. Smoking when	#31	8=									
pregnant harms your	#32	_							9		
baby	#33		1	10	Y	Y	3				10
W12. Protect children:	#34	5=	4								6
don't let them breathe	#35	5=	•	8	Y	3 / Y	4	3	5	9	5
your smoke	#36										
W13. Your doctor or	#37										
your pharmacist can help	#38										
you stop smoking	#39					6					
	#40										
W14, Get help to stop	#41	8=		9		8=			7		
smoking	#42	J							,		
* note surveys in Greece of		1 , ,	1 11	L			1.0	·	1 \	L	

^{*} note surveys in Greece and Italy only tested small numbers of messages (7 and 8 respectively)

^{† (}Y) highlights the most effective messages / graphics from qualitative focus groups in Eire and France

[‡] The EU survey was the 42 warning / image pre-test survey in 2004 involving 25 EU Member States

The 12 pictorial themes rated as most effective (across all the studies) are as follows.

- ➤ Image #35 picture of child with breathing mask (9 EU Member State surveys)
- > Image #8 picture of healthy and damaged lungs (8 EU Member State surveys).
- ➤ Image #29 picture of rotten teeth (8 EU Member State surveys).
- ➤ Image #17 picture of man with throat cancer (7 EU Member State surveys)
- ➤ Image #33 picture of baby in an incubator (6 EU Member State surveys)
- ➤ Image #5 picture of man being resuscitated (5 EU Member State surveys)
- ➤ Image #6 picture of patient undergoing open heart surgery (5 EU Member State surveys)
- ➤ Image #9 picture of man with oxygen mask (4 EU Member State surveys)
- ➤ Image #41 picture of two hands reaching out to each other (4 EU Member State surveys)
- ➤ Image #2 Picture of a corpse (3 EU Member State surveys)
- ➤ Image #27 picture of a cigarette with bent ash (3 EU Member State surveys)
- > Image #24 picture of woman pushing empty pushchair (3 EU Member State surveys)

The methodology used in the 11 surveys identified varied widely from web-based data to focus groups. Furthermore, some studies only reviewed a small selection of the images / warnings, other included all 42. Where all 42 images were rated, our report has highlighted the ten images / warnings that received most votes, in order to illustrate which ones are more effective. It is also important to note that all 42 images received some votes, although some images received very low votes, reflecting the importance to a small proportion of the sample, although the surveys do not identify the nature of these niche cells.

Despite the above points and the limitations they set on comparing the surveys, the following broad findings emerge.

- ➤ Warnings with strong, shocking images are clearly very effective in gaining attention, and are affecting people's attitudes and behaviour, despite concerns raised in some of the research reports that people can become immune to shocking images.
- Messages with appropriate images that highlight serious health risks (including premature death, heart attacks, strokes, cancer, a slow painful death and blindness) are also clearly effective with significant proportions of the population.
- ➤ Images relating to harm to children and the unborn child (through direct or passive smoking) are also strong social messages that have high resonance with a significant proportion of the population.
- ➤ Warnings that address intimate and vanity related issues (e.g. impotence, fertility, ageing of the skin) are considered more effective by younger people, females in particular, highlighting their importance within a broad warning message strategy.
- The warning get help to stop with the picture showing two hands is also considered effective by some. The message is right, and there is clearly a need for powerful evocative images to gain the consumer's attention in the first place.
- Warnings that were <u>text only</u> received very low votes in all the surveys, confirming the limited effectiveness of text only warnings compared to those with pictures.
- ➤ In order to get the maximum benefits from warning messages on tobacco packages other tobacco control policy tools are required. In particular an effective cessation support infrastructure is needed to support people ready to quit.

Additional analysis of the effects and impact of combined pictorial + text warnings, as well as text only warnings (where relevant), can be found on pages 42-45. Summaries of the key studies with relevant findings are given below.

Effectiveness of different picture warnings in Belgium (reference F19)

As part of a survey carried out by IPSOS in October 2007 (face to face interviews at home amongst representative sample of population) on behalf of the Belgium Cancer Foundation 1,194 smokers were shown the 14 pictorial warnings which had been selected for the first wave of 3 rotating sets of images (which would thus use all 42 images in the EU library) used on cigarette packets since 31st May 2007. They were asked which of these warnings they considered to be the most meaningful / effective.

The eight warnings that received most votes are summarised in the table below.

Ranking	Combined pictorial and warning message	Proportion of votes
1	Picture with child in incubator (smoking when pregnant harms your baby) - #33	29%
2	Picture showing man with oxygen mask (Smoking causes fatal lung cancer) - #09	28%
3	Picture showing a dead man with face covered (smokers die younger) - #02	25%
4	Picture showing child breathing in smoke (protect children: don't make them breath your smoke) - #34	24%
5	Picture showing man being resuscitated (smoking clogs the arteries and causes heart attacks and strokes) - #05	23%
6	Picture of a man in hospital (Smoking can cause a slow and painful death) - #18	16%
7	Picture of an apple with wrinkled skin (Smoking causes ageing of the skin) - #19	15%
8	Picture showing man behind prison bars made of cigarettes (Smoking is highly addictive – don't start) - #12	15%

Note - # suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

Key subtrends by age / gender were as follows

- The warning 'Smoking when pregnant harms your baby' (image #33) had a particularly high resonance amongst girls aged 15-17 (44% in this group rated it effective) and young women aged 25-44 (42%)
- The warning 'Smokers die younger' (image #02) had a very high resonance with aged 15-17 (61% rated it effective) and young men aged 18-24 (41%)
- The warning 'Smoking can damage the sperm and decrease fertility' (image #24) had a high resonance with boys aged 15-17 (27% rated it effective) and young men aged 18-24 (23%)

In addition, the research including the following findings

- 37% of all smokers said that they had discussed the new images with friends or family members
- 29% of smokers feel that the images act as an additional incentive to guit smoking
- 38% of smokers said that the new images make the tobacco packages less attractive

Effectiveness of different picture warnings in Bulgaria (reference F80)

In Bulgaria 2,185 citizens (1,156 never smokers, 653 non-smokers, 376 ex-smokers) participated in a web based survey in 2008 organised by the Ministry of Health. Participants had to choose the 14 most effective pictures out of the EU library of 42 images. Based on the research findings respondents tended to find shocking images that were disturbing and unpleasant to look at the most effective. The ten warning images judged to have the most impact were:

Ranking	Combined pictorial and warning message	Number of votes received
1	Picture with rotten teeth (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide) – #29	1,662 (76%)
2	Picture showing lungs (smoking causes fatal lung cancer) – #08	1,561 (71%)
3	Picture showing man with throat cancer (smoking can cause a slow and painful death) $- #17$	1,398 (64%)
4	Picture showing open heart surgery (smoking clogs the arteries and causes heart attacks and stroke) – #06	1,357 (62%)
5	Picture showing woman pushing empty pushchair (smoking can damage the sperm and decrease fertility – #24	1,262 (58%)
6	Picture showing bent / burned down cigarette (smoking reduces blood circulation and leads to impotence) - #27	1,154 (52%)
7	Picture showing foot of dead body with label (smokers die younger) – #3	1,120 (51%)
8	Picture showing child with oxygen mask (protect children: don't make them breath your smoke) – #35	1,111 (51%)
9	Picture showing two hands reaching out to each other (get help to stop smoking) - #41	1,097 (50%)
10	Picture showing baby in incubator (smoking when pregnant harms your baby) – #33	1,031 (47%)

Note - #suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

Effectiveness of different warnings in Ireland (reference F67)

A study in Ireland carried out in 2008 aimed to identify the most appropriate images from the 42 provided by the European Commission. 8 quality discussion groups were conducted amongst people aged 16 to 70. All were regular smokers – a mix of social smokers through "lifelong veterans" of smokers. The participants were grouped into different target groups, namely; teenage men, teenage women, young adult men, young adult women, older adults contemplating to quit and older adults non-contemplating to quit. An overview of the 4 pictures considered most effective by different target groups can be seen below.

Target group	Pictures most effective
Teenage men	 Picture showing man with throat cancer (smoking can cause a slow and painful death). #17
	 Picture showing healthy and damaged lung. (smoking causes lung cancer). #08
	 Picture showing man on exercise machine (stopping smoking reduces the risk of fatal heart and lung disease). #15
	 Picture showing bent / burned down cigarette (smoking may reduce the blood flow and cause impotence). #27

Teenage women

- Picture showing man with throat cancer (smoking can cause a slow and painful death). #17
- Picture showing healthy and damaged lung. (smoking causes lung

cancer). #08

- Picture showing mouth with rotten teeth (smoke contains benzene, formaldehyde and hydrogen cyanide). #29
- Picture showing wrinkled apple (smoking causes aging of the skin). #19

Young adult men

- Picture showing man with throat cancer (smoking can cause a slow and painful death). #17
- Picture showing healthy and damaged lung. (smoking causes lung cancer). #08
- Picture showing bent / burned down cigarette (smoking may reduce the blood flow and cause impotence). #27
- Picture showing mouth with rotten teeth (smoke contains benzene, formaldehyde and hydrogen cyanide). #29

Young adult women

- Picture showing man with throat cancer (smoking can cause a slow and painful death). #17
- Picture showing wrinkled apple (smoking causes aging of the skin). #19
- Picture showing baby in incubator (smoking when pregnant harms you baby). #33
- Picture showing child with oxygen mask (protect children: don't make them breathe your smoke). #35
- Picture showing man with throat cancer (smoking can cause a slow and painful death). #17
- Picture showing man being resuscitated (smoking clogs the arteries and causes heart attacks and strokes). #05
- Picture showing healthy and damaged lung. (smoking causes lung cancer). #08
- Picture showing mouth with rotten teeth (smoke contains benzene, formaldehyde and hydrogen cyanide). #29

- Picture showing man with throat cancer (smoking can cause a slow and painful death). #17
- Picture showing man being resuscitated (smoking clogs the arteries and causes heart attacks and strokes). #05
- Picture showing healthy and damaged lung. (smoking causes lung cancer). #08
- Picture showing child with oxygen mask (protect children: don't make then breathe your smoke). #35

Note - # suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

Effectiveness of different picture warnings in France (references F91, F9, F92 and F93)

Quantitative survey (2006) – ref F91

In France, a representative sample of 2,062 citizens (990 men, 1072 women, aged 15 and more), among whom 37.3% were smokers, participated in a survey organised in 2006 by the French National Institute for Health Prevention and Education (INPES). Respondents were interviewed face to face at their homes. Each participant provided views on 7 of the 14 warnings (computer randomly selected). For each of the 7 warnings, the participant was shown a photo with the 3 "brand" packs proposed by the UE and then asked to choose the most effective warning via several questions, including the best to prevent smoking / to stop smoking / to smoke less at home / to call the quit line, etc.

The 10 warning images judged to have the most impact on "intention to quit" and "prevent from starting smoking" were:

Older adults

completing

Ranking	The most effective out of the 3 messages	% of votes on this message out of the 3
1	Picture showing man with throat cancer (smoking can cause a slow and painful death) - #17	69%
2	Picture showing woman pushing pushchair (smoking can damage the sperm and decreases fertility) - #24	61%
3	Picture showing child with breathing mask (protect children: don't make them breath your smoke) - #35	57%
4	Picture showing open heart surgery (smoking clogs the arteries and causes heart attacks and stroke) - #06	55%
5	Picture showing a women's face and a skull (smoking causes aging of the skin) - #21	51%
6	Picture of a doctor (your doctor or your pharmacist can help you stop smoking) - #39	50%
7	Picture with rotten teeth (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide - #29	48%
8=	Picture showing healthy and damaged lung. (Smoking causes fatal lung cancer) - #08	47%
8=	Picture showing two hands reaching out to each other (get help to stop smoking) - #41	47%
10	Picture showing man on exercise machine (stopping smoking reduces the risk of fatal heart and lung disease). #15	42%

Note – Topics numbers and # suffixes in the table refer to the 42 pictorials which can be found in appendix 6

Other findings / comments:

- emotional and fear appeals messages appear to be the most effective messages;
- text only messages are perceived as not effective compared to visual warnings;
- 'abstract messages' are not perceived as effective and are not well understood (images #22, #23, #25, #28, #31).

Focus group study (2007) – ref F9

Six focus groups were conducted in Rennes, Paris and Brest in 2007 with a total of 50 people. Each group was composed of seven to nine individuals, aged 15 to 46, smokers and non-smokers, men and women. The aim of the survey was to determine the impact of the new European graphic warnings on French people. Participants were asked to give their opinion on 12 visuals from the EU library that may appear in France.

Result: Fear appeal warnings seemed to be the most effective, especially the teeth and the mouth picture, the lung picture and the external disease of he neck. However these images have also shown that some smokers react with rejection. Based on the research findings the three pictures most effective to motivate smokers to quit were:

- Picture of the lungs #08
- Picture with external disease of the neck #17
- Picture with the teeth and mouth #29

The most effective to prevent non smokers from smoking were:

- Picture with external disease of the neck #17
- Picture of lungs #08
- Picture of teeth and mouth #29

The most effective to prevent young people from smoking were:

- Picture of teeth and mouth #29
- Picture with external disease of the neck #17
- Picture with man and woman in the bed (impotence) #26

Individual interviews in Brittany (2007) – ref F92

Individual in-depth interviews were conducted in Brittany (North West of France) in March 2007 with 25 people aged from 15 to 45 (14 smokers, 11 non-smokers, 11 female, 14 male). The material tested included the full set of the 42 visual warnings proposed by the EU. Participants were also asked questions on current textual warnings. The most effective (to pay attention, easy to understand, to influence behaviors of smokers and non smokers, etc.) amongst the 42 visual warnings are:

- Picture of man with throat cancer (very striking, effective on young people) #17
- Picture with rotten teeth (very striking, effective on young people) #29
- Picture showing lungs (easiest to understand and the most credible)- #08
- Picture showing open heart surgery #06
- Picture showing child with oxygen mask (the one that solicited the most concern)- #35
- Picture showing baby in incubator (relevant, credible and important) #33
- Picture showing a man in jail #11
- Picture of syringe with cigarette inside #12

Other findings

- Some current warnings are well remembered ("Smoking kills") but respondents do not pay attention to them anymore (they are overexposed)
- Visual warnings are judged more effective than text only, especially on young people
- Warnings that are perceived as the least effective amongst the 42 messages are the abstract messages, the text-only warnings (do not pay attention and difficult to understand), the messages in which the link between text and visual is not clear, the self-efficacy-messages (#39, #41, etc.) and the messages related to skin
- Other information people would like to find on tobacco packs was as follows:
 - > The financial cost of smoking
 - > The effect of smoking on sport performance
 - ➤ More precise figures (number of death people, etc.)
 - > Opinion leaders' testimonies (singers, actors, etc.)

Focus group study (2007) – ref F93

Six focus groups were conducted in Paris in 2008 with 34 people aged from 15 to 45 years of age (17 smokers, 17 non-smokers, 14 females, 20 males). Four packs of Marlboro were tested with new and visual warnings on different topics (and each packs contained an insert with more details on the problem evoked on the outside warning). The 4 new warnings were i) "Smoking is harmful for the environment" (effect of tobacco on environment); ii) "If you smoke one pack a day, you spend 1,800 euros a year" (financial cost); iii) "Smoking stinks" and iv) "I decided to stop smoking" (an opinion leader's testimony - Renault, a French singer. The key findings were as follows

- Information inserts in the tobacco packs were liked a lot because they provide further information on the short warnings used on the outside of the packs
- financial cost was the most effective warning (very relevant, especially for young people)
- people considered the opinion leader warning "commercial" and effective
- The "smoking stinks" message was also considered interesting but was judged negatively by smokers and not so relevant because it is not a severe problem
- people found it hard to believe the warning on environment (mainly because they are not familiar with this topic, but found it relevant when the issue was explained)

Effectiveness of different picture warnings in Greece (reference F78)

A sample of 574 teenage adolescents (aged 12 to 18) was recruited at schools in Crete in 2007. 19.4% were current smokers and 80.6% were non-smokers. Seven specific warnings from the European Commission library of 42 warnings were tested, using a mock-up cigarette packet (with the word 'Brand' where the company logo would normally be) firstly with text only and then with the picture and relevant text. They were asked to choose between the text only and the graphic warning label - first which they considered more effective in preventing them smoking (smokers only) and then which warnings make them think more of the effect that smoking has on health.

Pictorial warning category	Which warning is more effective in preventing you from smoking (non-smokers)		Which warning make you think more of the effect smoking has on health (all)	
	Graphic + text	Text only	Graphic + text	Text only
'Smoking causes fatal lung cancer' + picture of two lungs - #08	96.1%	3.9%	90.1%	9.9%
'Smoking can cause a slow and painful death' + picture man in hospital - #18	95.5%	4.5%	85.5%	14.5%
'Smoking when pregnant harms your baby' + picture of baby in hospital - #33	93.3%	6.7%	89.0%	11.0%
'Protect children: do not make them breathe your smoke' + picture child with mask - #35	91.1%	8.9%	88.5%	11.5%
'Smoking clogs the arteries and causes heart attack and stroke' + picture of man in hospital being resuscitated - #05	88.7%	11.5%	84.5%	15.5%
'Smoking causes aging of the skin' + picture of aging hands - #20	79.2%	20.8%	80.5%	19.5%
'Smoking may reduce blood flow and cause impotence' + picture of couple in bed - #26	72.1%	27.9%	71.6%	28.4%

They were also asked the strongest anti-tobacco message of the 7 proposed

Warning message	% rated as strongest message
'Smoking causes fatal lung cancer'	38.0%
All are equally strong	31.1%
'Smoking when pregnant harms your baby'	11.7%
'Protect children: do not make them breathe your smoke'	6.6%
Others combined (< 5% each)	12.6%

Significant differences by gender were also noted for two warnings

Smoking causes fatal lung cancer girls 32.3% boys 44.7% Smoking when pregnant harms your baby girls 16.8% boys 5.7%

Effectiveness of different warnings in Italy (reference F52, and F73)

The research report Doxa-Iss 2006 (3,039 interviewees from 15 years to over 65 years of age) aims to know the public's opinion on the merit of seeing various images on packets of cigarettes and how useful they would be in convincing the young to not take up smoking and for smokers to give up. For the research 8 photos were chosen from the 42 proposed by the European Commission, of which 4 had a strongly emotive content and 4 had a lighter message. In general results show that the first 4 have a stronger impact (in particular the piciture with the rotten teeth and the picture showing a man with an oxygen mask) and are likely to be more effective in the struggle against the smoking habit.

Ranking	Combined pictorial and warning message	Proportion of votes received
1 st	Picture with rotten teeth (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide - #29	25.5%
2^{nd}	Picture showing man with oxygen mask (Smoking causes fatal lung cancer) - #09	24.4%
3 rd	Picture showing child with breathing mask (protect the children: don't make them breath your smoke) - #35	14.6%
	Picture of man in hospital being resuscitated (smoking clogs the arteries and causes heart attacks and stroke) - #05	Unknown
	Picture showing a dead man with face covered (smokers die younger) - #02	Unknown
	Picture showing a women's face and a skull (Smoking causes aging of the skin) - #21	Unknown
	Picture showing two hands reaching out to each other (get help to stop smoking) - #41	Unknown
8 th	Picture showing bent / burned down cigarette (smoking reduces blood circulation and leads to impotence) - #27	2.4%

Note - # suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

Effectiveness of different picture warnings in Romania (reference F20)

This section summarises feedback from Romanian citizens that participated in a public consultation in October 2006. A questionnaire was posted on the Ministry of Public Health website and sent to internet discussion groups and various public bodies. 92 members of the public and 2 NGOs answered the questionnaire. Respondents were asked to select which <u>one</u> of three images for each of the 14 warning messages they thought was most appropriate. The ten warning pictures that received the highest proportion of votes are shown in the table below, in descending.

Ranking	Combined pictorial and warning message	% of votes received
1	Picture with rotten teeth (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide - #29	72%
2	Picture showing bent / burned down cigarette (smoking reduces blood circulation and leads to impotence) - #27	63%
3	Picture showing man behind prison bars made of cigarettes (Smoking is highly addictive, don't start) - #12	63%
4	Picture showing lungs (smoking causes fatal lung cancer) -#08	62%
5	Picture showing child with breathing mask (protect children: don't make them breath your smoke) - #35	55%
6	Picture showing woman pushing pushchair (smoking can damage the sperm and decreases fertility) - #24	55%
7	Picture showing two hands reaching out to each other (get help to stop smoking) - #41	51%
8	Picture showing man with throat cancer (smoking can cause a slow and painful death) - #17	49%
9	Picture showing scan of a foetus (smoking during pregnancy harms your baby) - #32	47%
10	Picture of a white face and a skull (Smoking caused ageing of the skin) - #21	43%
Note - # suf	fixes in the table refer to the 42 nictorials used in the ELL which can be	found in appendix 6

Note - # suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

Research following the introduction of pictorial warnings (reference F86 / F87)

In addition, the Ministry of Health commissioned a survey in November 2008 to obtain feedback on the awareness of combined (picture and text) warnings on tobacco packages, 4 months after the introduction of pictorial warnings in July 2008. 440 smokers (that had been interviewed in June 2008) were re-interviewed again using face-to-face personal interviews. When asked to give 3 examples of text warnings that appear on tobacco packages, three specific warnings not mentioned when the text only warnings were researched in June 2008) were recalled (in addition to those that were mentioned) – "Smoking causes infarction" (4.8%), "Don't let children inhale cigarette smoke" (3.1%) and "You can succeed - we can help you" (1.8%).

Smokers were also asked to give 3 examples of images they recall seeing on tobacco packages.

Main images recalled	Total	1 st example	2 nd example	3 rd example
Lungs affected by cancer (image #08)	36.0%	19.6%	11.1%	5.3%
Throat cancer (image #17)	26.7%	10.7%	10.2%	5.8%
Damaged teeth (image #29)	19.6%	6.2%	6.7%	6.7%
Child with mask (image #35)	16.4%	8.0%	4.0%	4.4%
A corpse (image #02)	16.0%	5.8%	4.9%	5.3%
A dead baby in the uterus (image #32)	13.7%	4.0%	5.3%	4.4%
Curved cigarette (image #27)	5.3%	-	3.1%	2.2%
Skull (image #21)	4.4%	2.2%	2.2%	-
Ageing of the (facial) skin (image #21)	2.7%	2.7%	-	-
Female pushing an empty pram (image #24)	2.7%	-	-	2.7%

Five of the six most frequently recalled images were those with strong (shocking) images, and five of the images were also highly rated in the pre-pictorial public consultation (as shown in the previous table) – the exception being the picture of the corpse.

Other findings

- Following the introduction of the combined text + pictorial warnings, smokers remember more of the specific health messages and had lower recall of the general health warnings compared to recall levels for text only warnings.
- 21.8% of smokers agreed (15.6% agree / 6.2% strongly agree) with the statement that they had thought about quitting having seen the pictograms, which is significantly higher than the attitudes to text only warnings (14.2%).
- 31% of smokers said that they had tried to quit having seen the combined text and pictorial warnings, which is significantly higher that the quit attempts resulting reported from having seen the text only warnings (21.4%)
- 28.4% of smokers said they had reduced the number of cigarettes smoked daily having seen the combined text and pictorial warnings (up slightly from 27.9% for the text only warnings)

Conclusion: Smokers awareness of health risks of smoking changed following the introduction of pictorial warnings, with increased level or recall of specific health warnings. The stronger, more shocking, pictorials have a higher recall level, and to a lesser extent images involving children / unborn baby. The pictorials warnings have also influenced smokers' attitudes and behaviour by increasing the number of smokers that have thought about quitting as well as those that tried to quit.

Effectiveness of different picture warnings in Spain (reference F53)

The Spanish National Distance Learning University based in Madrid carried out research in 2007 regarding the effectiveness of tobacco warnings. 106 university students (40 males and 66 females) aged 18-24 were shown 36 (of the 42) warnings the European Commission library that combined pictures and text warnings (the 6 text only warnings were not tested). They rated each warning for the activation it produced in them using a 1-4 scale – (0) none, (1) low, (2) moderate, (3) high and (4) very high and also its potential utility for a hypothetical anti-smoking campaign, also using a 0-4 scale. Participants were split into 2 groups - group 1 saw photographs in isolation and group 2 saw the photographs complete with the warning message. The 12 pictures that were seen as the most effective were:

Rank	Combined pictorial and text warning message	Activation level	Utility Level
1	Picture showing men with throat cancer. (Smoking can cause a slow painful death) #17	3.62	3.60
2	Picture showing mouth with rotten teeth. (Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide) #29	3.43	3.46
3	Picture showing healthy and damaged lung. (Smoking causes fatal lung cancer) - #08	3.15	3.55
4	Picture of hospital patient with oxygen mask (Smoking causes fatal lung cancer #9	2.78	2.92
5	Picture showing open heart surgery (smoking clogs the arteries and causes heart attacks and stroke) - #06	2.61	2.74
6	Picture showing man being resuscitated (smoking clogs the arteries and causes heart attacks and strokes)#05	2.58	2.74
7	Picture of a corpse. (Smokers die younger) #02	2.51	2.75
8	Picture of x-ray showing serious pulmonary damage (Smoking can cause a slow and painful death) #16	2.40	2.30
9	Picture of child wearing an oxygen mask (Protect children: don't make them breathe your smoke) #35	2.23	2.84
10	Computerised picture showing lung tumour (Smoking causes fatal lung cancer) #7	2.03	2.07
11	Picture of hospital patient smoking (Smoking is highly addictive: don't start) #10	2.20	2.19
12	Picture of syringe with cigarette inside (Smoking is highly addictive: don't start) #11	2.01	2.50

Note - # suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

In most cases, warnings that provoked most activation were also those rated most useful for inclusion in anti-smoking campaigns. Several images evoked higher activation levels amongst females, including images 17, 8 and 29 in the above table plus images associated with protection of the child during pregnancy (ultrasound of foetus - #31 / baby in hospital - #33). Females also rated utility higher for images related to fertility (artificially fertilised ovum - #22) and to protection of children (girl looking a heart shape smoke ring - #36) and to ageing (old wrinkled hands - #20 and woman with face pack next to skull - #21).

The study also showed that the presence of relevant descriptive text corresponding to the photograph was strongly decisive for some photographs. The conclusion was that images should always be accompanied by relevant descriptive text where possible.

Effectiveness of different picture warnings in the UK (reference F14, F81)

In the UK 20,944 participated (all respondents were smokers aged between 16 and 60) in a web based survey run from 27 May to 25 August 2006 by the NHS. Respondents were asked to identify the most effective warning out of the EU library of 42 images. Based on the research findings respondents tended to find shocking images that were disturbing and unpleasant to look at the most effective. The ten warning images judged to have the most impact were: (reference F14).

Ranking	Combined pictorial and warning message	Number of votes received
1	Picture showing man with throat cancer (smoking can cause a slow and painful death) – #17	15,975 (76%)
2	Picture with rotten teeth (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide) – #29	15,356 (73%)
3	Picture showing lungs (smoking causes fatal lung cancer) -#08	14,288 (68%)
4	Picture showing open heart surgery (smoking clogs the arteries and causes heart attacks and stroke) – #06	9,596 (46%)
5	Picture showing child with oxygen mask (protect children: don't make them breath your smoke) – #35	9,528 (45%)
6	Picture showing child face surrounded by smoke (protect children: don't make them breath your smoke) – #34	9,463 (45%)
7	Picture showing man in intensive care with oxygen mask (smoking causes fatal lung cancer) – #09	9,045 (43%)
8	Picture showing man in intensive care (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide) – #30	8,806 (42%)
9	Picture showing dead man, face covered with blanket (smokers die younger) – #02	8,679 (41%)
10	Picture showing baby in incubator (smoking when pregnant harms your baby) – #33	8,627 (41%)
ST		1 0 11 11 6

Note - #suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

In 2005, the UK Department of Health commissioned 12 focus groups with 8 participants in each group to obtain views on combined pictorial and text warnings. All participants were smokers, aged between 16 and 60 years old and from the social economic groups C1, C2, D and E. The study highlighted certain drivers and warning preferences by age and gender, which are summarised below.

Young male smokers

Key drivers 'Risk of impotence', 'breathlessness'

Effective warnings 'Smoking may reduce the blood flow and cause impotence'

Young female smokers

Key drivers

'Aging of the skin', 'harm to own / peer babies / children'

'Protect children: don't make them breathe your smoke'

'Smoking causes aging of the skin'

Family aged smokers

Key drivers 'Fears of own longer term health as parent', 'risks of passive smoking' 'vanity related issues'

Older male and female smokers

Key drivers 'Cancer / stroke / heart / lung health related messages'

'Exposure of family to second hand smoke related illnesses'

Effective warnings 'Smoking causes fatal lung cancer'

'Smoking clogs the arteries and causes heart attacks and strokes'

PAN EU STUDY - Flash Eurobarometer – March 2009 (ref F60)

In December 2008, 26,500 randomly selected citizens aged 15 years and over were interviewed (by telephone / face-to-face) in the 27 EU Member States and Norway. The findings below highlight the findings in the 3 EU Member States (Belgium, Romania and UK) that had introduced combined pictorial + text warnings prior to the survey, which involved a total of 3,009 citizens.

The impact of pictorial warnings on attitudes in Belgium, Romania and the UK

Romania and UK. Attitudes in Romania and UK were well above the EU27 average for the responses to three key issues researched - a) the extent to which tobacco health warnings are thought to inform non smokers about the health effects of tobacco, b) how effective they are in persuading never / former smokers not to start smoking (again) and c) the proportion of current smokers that thought the warnings had been effective in getting them to smoke less or to try to quit.

For example 62% (Ro) / 47% (UK) compared to 31% (EU27) of never / former smokers thought the warnings were somewhat or very effective in informing them of the health risks of tobacco. Similarly, 39% (Ro) / 30% (UK) compared to 21% (EU27) of smokers thought that the health warnings had been somewhat or very effective in getting them to smoke less and 35% (Ro) / 24% (UK) compared to 18% (EU27) of smokers found the warnings effective in getting them to try to quit smoking.

One reason for this may be that both countries had pre-tested the 42 warnings, selected the 14 that consumers found most effective, and had introduced them only 6 months prior to the Eurobarometer survey. The UK also has a strong supportive media campaign highlighting the health risks of smoking.

Belgium. The results in Belgium were quite different. Attitudes to the issues surveyed were either average or well below the EU27 average, despite the use of combined pictorial and text warnings on cigarette packets. For example, 29% of never / former smokers in Belgium (compared to 31% EU27) and 19% of current smokers (compared to 29% EU 27 say that the warnings are either somewhat or very effective in informing them of the health effects of tobacco. Similarly, 15% of current smokers in Belgium (compared to 18% for the EU27) said that they felt the warnings were somewhat or very effective in getting them to try to quit.

Discussions with stakeholders in Belgium highlighted several issues that may explain the above attitudes in Belgium (and shed light on issues related to the use / application of combined pictorial warnings).

• The images associated with the text warning messages had been used in Belgium for over 18 months, possibly indicating 'wear out' effects (Belgium experienced difficulties in achieving the annual rotation initially planned, and is currently developing new policies to address this)

- The 14 images initially selected for the first wave (in the planned 3-year rotation) excluded several of the strong shocking / emotional images that were rated as highly effective and used in both Romania and UK
- Belgium requires text warnings to be written in three languages, resulting in smaller text and smaller images being used compared to Romania and the UK, where only one language is used.

CURRENT PROJECTS IN THE EU AVAILABLE IN THE FUTURE

During the discussions with stakeholders, a couple of current studies into the impact of tobacco health warnings and associated pictorials were identified, the results of which should be available later in 2009, which would provide additional evidence to the findings already identified. A brief note about the scope of these studies is given below.

Hungary – The National Institute for Health Development is planning to conduct interviews with 4 key target groups (including teenagers at elementary schools and adults) in April 2009. Questions will address which health warning messages are most effective and which pictures are considered most appropriate, as well as feedback on attitudes towards passive smoking in public places. Results should be available in June / July 2009.

Romania – The Ministry of Health is currently running a survey amongst teenagers (aged 12 to 19), involving smokers and non-smokers, to obtain feedback on the impact of the new pictorial health warnings on attitudes and behaviour. The results should be available by December 2009.

In addition, the Ministry of Health has planned a third wave of 440 interviews in July 2009 amongst smokers (who were interviewed in June and November 2008) to obtain additional feedback on the impact of the pictorial warnings 12 months after their introduction in Romania. Results are expected by November 2009.

UK – The Department of Health is evaluating the impact of the introduction of pictorial warnings in the UK. The baseline study (wave 1) was conducted in September 2008 prior to the introduction of the new pictorial warnings and provides a benchmark of awareness and attitudes towards the text only messages that were required on tobacco packets and any impact they had on behaviour. Wave 2 will be conducted in the summer of 2009, and will compare the impact of the pictorial warnings with the text only, in particular levels of awareness, any changes in attitudes and the impact on behaviour. The findings of both waves should be available towards the end of 2009.

EUROPEAN COMMISSION – PRE TESTING RESEARCH (PAN-EUROPE)

Most effective combined picture warnings based on an EU wide pre-test

In 2004, Synovate conducted a survey on behalf of the European Commission to develop a central library of 42 combined warnings to be carried on packages of tobacco products. For each of the 14 health warnings, 6 combined warnings were developed (84 in total) which were then pre-tested across 25 Member States. A representative sample of 5000 participants (200 in each country) evaluated the warnings through an online interview process. The participants were asked to rate each warnings on a scale from 1 (not effective) to 6 (very effective) with regards to their effectiveness in informing and alerting Europeans about the health risks related to smoking.

An overview of the 10 combined warnings that were rated as the most effective across the 25 Member States can be seen in the table below.

Ranking	Combined pictorial and warning message	Average rating across all EU Member States
1	Picture showing man with throat cancer (smoking can cause a slow and painful death) $-#17$	5.0
2	Picture showing lungs (smoking causes fatal lung cancer) – #08	4.9
3=	Picture with rotten teeth (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide) – #29	4.8
3=	Picture showing open heart surgery (smoking clogs the arteries and causes heart attacks and stroke) – #06	4.8
5=	Picture showing child with oxygen mask (protect children: don't make them breath your smoke) – #35	4.6
5=	Picture showing child breathing in smoke (protect children: don't make them breath your smoke) – #34	4.6
5=	Picture of man in hospital being resuscitated (smoking clogs the arteries and causes heart attacks and stroke) - #05	4.6
8=	Picture showing woman scan of unborn baby (smoking when pregnant harms your baby) – #31	4.4
8=	Picture showing two hands reaching out to each other (get help to stop smoking) - #41	4.4
10	Picture showing aging hands (smoking causes aging of the skin) - #20	4.3

Note - #suffixes in the table refer to the 42 pictorials used in the EU which can be found in appendix 6

Other findings

- Overall findings across the 25 Member States match quite well on the selection of the most effective visuals.
- Furthermore, almost all countries were unanimous in their selection of the three images / warnings ranked as most effective.

FEEDBACK FROM COUNTRIES OUTSIDE THE EU

Effectiveness of different picture warnings in Australia (references F65 and F94)

<u>Survey in 2003</u> (ref F65)

In 2003, Elliot & Shanahan assessed the reaction to proposed new tobacco health warning designs (text with pictures) on mock up packs. The research consisted of 20 mini discussion groups (4-5 people in each group) conducted with current smokers, recent and long-term ex smokers and non-smokers. Participants were aged between 15 and 70 years. The main behaviour responses to the combined text and picture warnings were as follows:

- Respondents from all age groups said that the new warnings cause them to think about their habit.
- Respondents from all age groups said that the new warnings are encouraging to smoke less / seek ways of quitting.
- Smokers that were already contemplating quitting felt further encouraged to quit.
- Young people were more likely to admit that the graphics are likely to affect them.
- Young people were especially affected by images of external disfigurement.
- Some "hardened" smokers responded with anger, denial, avoidance behaviour and challenging the validity of the warnings.

<u>Survey in 2008</u> (ref F94)

In 2008, Elliot & Shanahan evaluated the effectiveness of the graphic health warning messages that were introduced in 2006 through a representative telephone survey with the following results:

- 60% considered the pictures on the packs to be effective in communicating health effects. Young people generally were more likely than older people to consider the pictures to be effective.
- 63% of non smokers and 45% of smokers claimed that the graphic health warnings would help prevent people from taking up smoking. The graphic health warnings nominated to be most effective at discouraging people from smoking were:
 - 1. Smoking causes throat and mouth cancer (15% smokers, 21% recent quitters)
 - 2. Smoking causes lung cancer (11% smokers / 14% recent quitters)
 - 3. Smoking causes peripheral vascular disease (10% smokers/10% recent quitters)
 - 4. Smoking harms unborn babies (10% smokers / 9% recent quitters)
- The graphic health warning messages also had a significant effect on quitting intentions and behaviour. When prompted respondents agreed that the graphic health warnings had:
 - 1. Raised your concerns about smoking (57% smokers, 72% recent quitters)
 - 2. Helped you smoke less (36% smokers / 62% recent quitters)
 - 3. Helped you give up smoking (62% recent quitters)
 - 4. Helped you try to quit (34% smokers / 64% recent quitters)
 - 5. Have made you think about quitting (57% smokers / 75% recent quitters)
 - 6. Have helped you stay quit (55% recent quitters)

Effectiveness of different picture warnings in Canada (references F6, F84, F85)

<u>Wave 1-12 surveys 2001 – 2006</u> (ref F6)

The Tobacco Control Program has been monitoring and evaluating the impact of health warnings since the introduction of picture based health warnings in 2000 through regular representative surveys that were carried between 2001 and 2006 (wave 1 survey to wave 12 survey). The main objective of these surveys was to provide information to evaluate the impact of health warnings found on tobacco packaging. Respondents were asked in these surveys, what specific health warning images they can recall without looking at a tobacco package and whether or not the warnings are effective. The following results were taken from findings in the latest survey carried out in November 2006 (wave 12).

Ranking	Recollection of specific images	% range of all respondents recalling message between 2001 and 2006
1	Diseased lungs	23% - 33%
2	Bad rotten teeth	14% - 20%
3	Pregnant women with cigarette	6% - 17%
4	Mouth disease	8% - 14%
5	Heart disease	6% - 10%
6	Gum disease	4% - 11%
7	Children / kids / babies	4% - 11%
8	Limp / broken / burning cigarette	3% - 9%
* 1		

*smokers, non-smokers, potential quitters

Note: While the recall rate for some of the images varied quite significantly from survey to survey (mainly a result of relative small sample and of additional anti smoking campaigns run at the time of the surveys) the ranking order has largely stayed the same across all 12 wave surveys.

Additional feedback on the effectiveness of warning messages included the following:

- 73% of smokers and 80% of potential quitters said that the warning messages were either very effective or somewhat effective in informing them about the health effects of smoking.
- 55% of smokers and 66% of potential quitters said that the warning messages were either very effective or somewhat effective in getting them to smoke less around other people.
- 49% of smokers and 60% of potential quitters said that the warning messages were either very effective or somewhat effective in increasing their desire to quit.
- 45% of smokers and 54% of potential quitters said that the warning messages were either very effective or somewhat effective in getting them to try to quit smoking.
- 39% of smokers and 44% of potential quitters said that the warning messages were either very effective or somewhat effective in getting them to smoke less.

Analysis of the results from all 12 wave surveys that were carried out between March 2001 and November 2006 shows that overall the results have been very consistent across all the 5 measured effectiveness areas

Recall of graphic images and health warning messages in 2008

In a survey carried out by Environics (references F84 / F85) in 2008 on behalf of Health Canada, 2,000 respondents (1,000 adults aged 18+ and 1,000 youths aged 12-18) were asked what graphic images on health warnings they were able to recall without looking at a cigarette package. The 10 most frequently recalled graphical images used on the warnings are summarised in the table below.

Decell of graphics on health warning massage	Recall in %		
Recall of graphics on health warning message	Youth	Adults	
Lung / cancer disease	66%	58%	
Mouth/teeth/gums/tongue	53%	65%	
Pregnancy warning / pregnant women	30%	38%	
Children / babies / kids	23%	33%	
Heart / heart disease	15%	20%	
Limp / bent cigarette	7%	22%	
Children with mother / father	11%	8%	
Brain / brain damage	9%	10%	
Person with breathing machine	4%	12%	
Impotence	2%	12%	

In addition, respondents were asked what specific health warning messages they were able to recall without looking at a cigarette package. An overview of the top 10 recalls is shown in the table below.

Pagell of toyt of health warning maggages	Recall in %		
Recall of text of health warning messages	Youth	Adults	
Cancer in general	20%	18%	
Causes lung cancer	14%	14%	
Warnings / health warnings / stop smoking	13%	9%	
Dangerous / bad for health	11%	16%	
Second hand smoke is harmful / dangerous	10%	14%	
Death / premature death	10%	14%	
Harmful to children / babies / kids general	8%	14%	
Harmful during pregnancy	8%	13%	
Lung damage / disease	6%	7%	
Impotence	4%	18%	

Other key findings

- It should be noted that the level of recall for specific graphics and specific texts used on the health warning messages is fairly similar for youths as well as adults, although recalls associated with messages addressing impotence and children / babies was higher amongst adults.
- 78% of adult smokers and 87% of youth smokers say the current messages have been effective in informing them about the health effects of smoking.
- 52% of adult smokers and 41% of youth smokers say the current messages have been effective getting them to smoke less around others
- 52% of adult smokers and 55% of youth smokers say the current messages have been effective in increasing their desire to quit and 44% / 52% respectively in getting them to try to quit.

Effectiveness of different picture warnings in New Zealand (reference F30)

In New Zealand BRC Marketing and Social Research carried out 100 face to face interviews between 1 and 21 November 2004. Representatives from the following four key audience were interviewed; current Maori smokers, current young female smokers aged 15 – 24 years of age, currently smoking parents of children aged zero to 16 who live with their children, young ex smokers aged 15 – 24 years of age. The overall research objective was to test the combined pictorial and text health warnings developed by the Ministry of Health in conjunction with Clemenger BBDO, in terms of whether or not they prompt people to consider their smoking related behaviour. Eight messages were tested and ranked in terms of highest and lowest impact. For details see table below.

Ranking	Combined pictorial and warning message	% of respondents ranking message 1 ST or 2 ND
1	Smoking can give you mouth cancer	93%
2	9 out of 10 lung cancers are caused by smoking	46%
3	Smoking causes blindness	32%
4	A stroke from smoking can disable or kill you	15%
5	Emphysema is a living hell	12%
3	Quitting smoking improves your health	12%
7	Poisonous chemicals and an addictive drug	8%
8	Smoking slows you down	6%

Effectiveness of different warnings in Brazil (references F54, F74, F75, F76)

<u>Federal University Rio de Janeiro / Fluminense Federal study</u> (2008). 212 undergraduate students with an average age of 21 evaluated two sets of warning pictures, 9 of which were displayed in 2002-2004 and 10 were displayed in 2006-2008. 18% of the sample were smokers which is similar to the prevalence of young smokers in Brazil. The pictures evaluated for their emotional characteristics, using a psychometric tool, combining ratings using a -4 to +4 scale (extremely unpleasant to extremely pleasant) and a 1-10 arousal scale (low arousal to high arousal). The ten most aversive pictures (combination of valence and arousal scores) are shown in the table below, the most aversive picture being ranking 1.

Ranking	Pictorial theme	Average scores (valence, arousal)
1	Picture of a premature baby	-3.1, 5.8
2	Picture of woman with lung cancer and endotrachael tube	-2.8, 5.6
3	Picture of a pregnant woman smoking a cigarette	-2.6, 5.8
4	Picture of a premature baby	-2.6, 5.4
5	Picture of a foetus in a jar	-2.5, 5.5
6	Picture of a leg with an open wound	-2.3, 5.3
7	Picture of a man with a breathing tube in his throat	-2.4, 5.1
8	Picture of a man in wheelchair with one leg amputated	-2.4, 4.9
9	Picture of damaged teeth	-1.8, 5.0
10	Picture of damaged lungs	-1.7, 5.2

Note – valence range -4 (extremely unpleasant) to +4 (extremely pleasant). Arousal range 1 (low) to 9 (high)

RESULTS: The judgements of hedonic content of the warning pictures ranged from neutral to very unpleasant. None was classified as highly arousing. Smokers judged warning pictures representing people smoking significantly more pleasant than pictures without smoking scenes, and significantly more so than non-smokers. No significant differences between smokers and non-smokers were found for warning pictures without these smoking scenes. The three least aversive pictures were a picture of a cigarette with a long stem of ash bent into a curve, a picture of a couple in bed and a picture of a man short of breath loosening his tie.

CONCLUSION: Previous studies have shown that the most threatening and arousing pictures prompt the greatest evidence of defensive activation. Emotional ratings of Brazilian warning pictures described them as unpleasant but moderately arousing. To intensify avoidance of the packages, future graphic warnings should therefore generate more arousal.

<u>Household Survey</u> (2003): Risk Behaviour & morbidity related to non-communicable diseases - Ministry of Health / Secretary for Health Surveillance / National Cancer Institute. This survey tested warnings from the first set of warnings used on cigarette packs 2002 to 2004. The two warnings chosen as the ones that most motivate smokers to quit show the most dramatic situations (a premature baby and a women with lung cancer).

Ranking	Pictorial theme	Proportion of votes
1	Picture of a premature baby (In pregnant women smoking causes premature delivery, baby weight below normal and increases the chances of asthma)	79%
2	Picture of woman with lung cancer and endotracheal tube (smoking causes lung cancer)	78%

The images that provided least motivation were those with pictures showing social or humorous situations including a man short of breath and loosening his tie (message those who smoke are short of breath for any activity), a man and a boy (children start smoking when they see adults smoke), an man using one cigarette to light another (nicotine is a drug and causes addiction) and a man smoking plus a women with a facial expression of disgust (smoking causes bad breath, tooth loss and mouth cancer).

PRINCIPLES OF EFFECTIVE TOBACCO WARNING LABELS

Effectiveness of graphic warnings versus text only messages

The desk research shows that pictorial (visual and text) warnings are more effective than text only warnings, in particular in educating the public of the health risks of tobacco usage, but also in changing consumer behaviour and minimising wear out of messages.

Effectiveness of text-only warnings versus pictorial warnings (References F1 – 80)

There have been a large number of surveys that looked at the effectiveness of text-only warnings versus pictorial (visual and text). The findings from these reports are very consistent - pictorial warnings are more effective than text only warnings in three broad areas i) educating the public about the health risks, ii) changing consumer behaviour and iii) minimising wear out of the warning messages. The key findings are summarised below (and the research evidence for each of the bullet points can be found in appendix 3).

Pictorial warnings are more effective at educating the public about the health risks

- Pictorial warnings are more likely to be noticed and read than text-only warnings including by non-smokers. Picture warning are more effective in increasing awareness and recall of the health effect from tobacco. It encourages individuals to imagine health consequences.
- Pictorial warnings are important for reaching low-literacy smokers and children and they are also essential in countries with multiple languages. Pictorial messages are a key tool to help to reduce disparities in health knowledge amongst the population.
- Consumers based in countries that have introduced graphic tobacco health warnings have a greater knowledge on the health effects of tobacco use.
- Picture warnings are more likely to encourage discussion about the health effects of smoking.
- Fear inducing pictures of disease and emotionally arousing pictures are more effective and more likely to be recalled.

Pictorial warnings are more effective in changing consumer behaviour

- Picture warnings are more effective than text only warnings in changing consumer behaviour (reduce consumption levels, motivation to quit, likelihood of remaining abstinent following a quit attempt).
- Picture warnings appear to be especially effective among youth (deterring young people from starting, motivate young smokers that are not yet addicted to stop) provided they are targeting issues that are relevant to them.

Pictorial warnings are more effective than text only to minimise 'wear out' over time

• Pictures warnings are more effective in helping to minimise the "wear out" of health warnings that is happening over time.

<u>Table cross referencing the findings with evidence sources in the appendices</u>

The following table shows the evidence sources for the findings above that compare the effectiveness of pictorial tobacco health warnings with text only warnings together with the countries where the evidence was sourced (if relevant). More detailed extracts for each evidence point can be found in the appendix 3.

As seen in the table below, there is strong evidence that pictorial warnings are more effective in educating the public about the health risks of tobacco, but less evidence (at the present time) to support the findings that pictorial warnings are more effective than text only warnings in changing consumer behaviour and minimising 'wear out' over time. In addition, most of the research evidence for these findings is based on research in Canada, the USA, UK and Australia.

Evidence reference number and country where evidence sourced	i. Pictorial warnings more effective at educating the public about health risks	ii. Pictorial warnings more effective in changing consumer behaviour	iii. Pictorial warnings more effective than text only to minimise 'wear out' over time
F12 – USA	$\sqrt{}$		
F17 – Canada / Mexico	$\sqrt{}$		$\sqrt{}$
F21 – Canada/USA/UK/Aus (06)	$\sqrt{}$		
F24 – Canada/USA/UK/Aus (02)	$\sqrt{}$		
F25 – USA	$\sqrt{}$	$\sqrt{}$	
F35 – Canada	$\sqrt{}$	$\sqrt{}$	
F42 – Canada		$\sqrt{}$	
F60 – 27 EU Member States	$\sqrt{}$		
F67 - Ireland	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
F79 – New Zealand	$\sqrt{}$	$\sqrt{}$	
F84 / 85 – Canada	$\sqrt{}$		
F86 / 87 - Romania	$\sqrt{}$	$\sqrt{}$	

Analysis of warning effectiveness

The effectiveness of a group of warning messages can be improved where certain messages are developed that are targeted at specific groups. Messages are also enhanced when they contain simple, direct, personalised language and strong, evocative images.

Effectiveness of warning messages amongst different target groups

The research shows that many warning messages have a strong resonance with all consumer groups. However, analysis of reports that looked at the effectiveness of warning messages amongst different target groups also shows that targeting is of value. Certain messages are clearly more effective with one target group and less effective with others. The key differences that emerge between different target groups are as follows.

- Young men and women respond more to intimate and vanity related messages such as impotence, fertility, premature aging of the skin and disfigurement.
- Young men and women generally respond less to factual health related warnings.
- Females generally respond well to emotional messages and to social appeal messages especially regarding protection of children, family and friends.
- Middle aged and older smokers (40+ years) generally respond well to factual health messages in particular to terminal illnesses such as stroke, heart attack and lung cancer.
- Messages that provoke fear tend to be quite effective across all target groups.

Effectiveness of message style and message content

An analysis of the relevant research studies shows that the effectiveness of warning messages is increased by using personalised and direct language. Examples of what is seen as effective or not so effective can be seen in the table below.

Effective

- Smoking causes lung cancer
- Smoking doubles the risk of stroke
- Smoking causes mouth cancer
- Smoking damages your skin

Not so effective

- Smoking leads to lung cancer
- Smoking causes stroke
- Smoking causes mouth disease
- Smoking may damage your skin

Some messages are not seen as very effective because they includes words that are not easily understood such as oral, gangrene or age related macular degeneration. Messages are also less effective when people don't see an obvious link with tobacco use or if an illness is predominantly caused by other factors that are well known. For example in Australia the research found that the message "smoking damages your skin" was not seen as very effective because sun exposure was known to have a far greater impact. Messages that are too general are also not seen as effective (e.g. "smoking is related to many cancers").

The importance of pictures

The evidence clearly shows that text only warning messages are not very effective because many consumers don't bother to read them. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message.

The importance of warning size

The evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada (reference F81, F82) in 2007 showed that young and adult smokers / non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The effectiveness indicators measured included:

- Perceived communication impact
- Personal persuasiveness
- Persuasiveness associated with different social style of smokers
- Smoker image
- Product image
- Emotional impact
- Packaging attractiveness

Research carried out in Canada by Environics on behalf of Health Canada (ref F84 / F85) in 2008 also tested warning size options. Respondents were presented with several different size options (50%, 75%, 90% and 100%) of the health warning message on mock up packs and asked to select the best options for warnings in Canada with the following result:

Size of warning message on	Seen as best option		
cigarette pack	Youth	Adult	
50%	13%	34%	
75%	11%	12%	
90%	17%	13%	
100%	54%	35%	

Avoidance of Messages

Research carried out in Canada and Romania (see below) shows that pictorial warnings have a significant effect on smokers' behaviour in terms of actions they have taken to avoid looking at the stronger pictorial warnings and associated messages.

Canada. Research carried out by Environics (ref F6) has looked in detail at specific behaviour pattern of smokers with regards to avoidance of pictorial warning messages on cigarette packs. Smokers were asked in a series of wave surveys that looked at the effectiveness of health warnings in Canada between 2003 and 2006 about their specific behaviour intended to avoid looking at or thinking about the health warning labels. The following were the results in the last survey in 2006.

Avoidance behaviour	Percentage of smokers		
Avoidance benaviour	Adults	Youth	
Keeping the pack out of sight	14%	26%	
Buying packs with particular warning messages	12%	16%	
Transferring cigarettes to another container	11%	29%	
Placing cover or case over the package	9%	17%	

The results in 2006 amongst adult smokers were very similar to those found in 2003 when the question was first asked. The result amongst youth smokers suggests that there is an increase amongst youth smokers who have avoided the health warnings.

Romania. Research carried out by the Ministry of Health in Romania in November 2008 (ref F86/87) explored affects on smokers' emotions and behaviour after the introduction of pictorial warnings in 2008. Many of the new pictorial warnings included 'strong' images, which clearly had a significant impact on smokers emotions and behaviour, in particular that they seek to avoid the warnings, as summarised in the key findings below.

- 23.1% of smokers surveyed said they don't look at the packets (compared to 12.6% that didn't look when there were text only warnings)
- 13.8% of smokers said they ask the vendor for another packet with other text / picture (compared to 2.0% when packets only had text warnings)
- 7.1% put the cigarettes into a cigarette case in order to avoid looking at the pictures (compared to 2.5% when packets only had text warnings)

The impact of 'fear warnings'

The nine studies within the EU and studies in 4 countries outside the EU consistently show that explicit warnings with strong, fear inducing images (e.g. showing damage to the mouth, throat or internal organs) have the greatest impact (in terms of recall as well as behaviour changes) compared to 'neutral' images (relating to social or other issues) or text only warnings. Warnings with strong emotional images that contain pictures of children, babies or an unborn foetus are also rated as more effective in some countries and by specific consumer groups.

However some reports raise possible adverse affects of fear inducing images – smokers avoid the warnings; pictures undermine the credibility of the messages; warnings lead to unnecessary or excessive anxiety and warnings summon up resistance, possibly even leading to an increase in tobacco consumption. However, these reports also conclude that self reported desired effects of the warnings were greater than the self reported adverse effects, which are generally small. A recent study by Fathelrahmen et al (ref F88) also found 'no evidence of any adverse effects of avoidance, and any indirect effects were slightly positive'. Furthermore, the Research voor Belied report (ref F10) states that 'warnings in Canada are in keeping with literature on fear appeals - the chance of fear-arousing warnings being effective is higher if the warnings are combined with messages which emphasise that quitting is possible and good for the health and the warnings advise how to quit or where to obtain help.' A research paper by Strahan et al (ref F39) also concludes that messages are more likely to be persuasive if they not only promote negative outcomes towards an undesired behaviour (e.g. smoking) but also promote positive attitudes towards a mutually exclusive desired behaviour (e.g. quitting smoking).

Overall conclusion. Fear inducing images are a powerful and effective way to educate consumers on the health risks of tobacco use and to achieve changes in behaviour. However, their effectiveness is enhanced if they are used in conjunction with advice on how to quit and where to obtain help or advice, e.g. a free quit line number.

How tobacco health warning messages affect consumers' attitudes and behaviour

It is important to understand the nature of the impact that well designed health warning messages can have in changing peoples' knowledge, attitudes and behaviour. It is not possible to quantify the specific effects / impacts attributable to the tobacco package health warnings alone, because knowledge, attitudes and behaviour changes are also influenced by other tobacco policies in force as well as social trends and other factors. However, the following table provides a qualitative analysis of the effects and level of impact, based on findings in the previous chapters.

The analysis below is mainly based on research findings identified in countries where recent research has been carried on the effects of large, combined pictorial + text warnings, although findings in other countries (on text only warnings) are also taken into account.

Effect	Impact	Commentary
		• This report has identified evidence that most smokers and non-smokers have an imperfect understanding of the nature and magnitude of the risks of using tobacco.
Educating smokers and non-smokers about the	HIGH	• The evidence identified reports as well as surveys across the EU and outside that consistently show that significant proportions (19% - 78%) of smokers and non-smokers report that combined pictorial + text warnings are effective or very effective in informing them about the health effects of tobacco.
health effects / risks of tobacco usage		• The evidence shows that some smokers / non-smokers were encouraged by seeing the warnings to think about their health (up to 37%) or have discussed the health effects of smoking highlighted in the warnings with friends and family members (up to 63%), which is often a pre-cursor to an attempt to quit.
		• Warnings that highlight a range of different specific health risk associated with tobacco use have increased the ability of the warnings to educate consumers.
Changing smokers' attitudes towards		• The evidence contains self reported findings that warnings have influenced significant proportions of smokers (21% - 55%) to think more about quitting and have also increased their motivation to quit.
tobacco use		• The evidence also shows that some smokers think more about smoking in the presence of non-smokers, especially children and pregnant women, as a result of seeing the warnings.
Changing smokers'	MEDIUM	• A few surveys identified self reported evidence that warnings have motivated some smokers to change their behaviour (although in some areas, notably quitting, the proportions are relatively low). Self reported behavioural changes identified in the evidence include:
behaviour	MEDIUM	 Smoke less (8% - 28%) Smoking less around others (up to 52%) Attempts to try to quit (18% - 55%) Increased usage of quitlines (up to 300%) Quit smoking (2% - 8%)

Key design parameters to create effective warning labels

This section recommends design parameters that the research has identified as being most appropriate for creating effective tobacco package health warnings. It also addresses the guidelines adopted by the Parties to the WHO framework Convention on Tobacco Control.

The following recommendations regarding the key design parameters that are considered most appropriate to create effective tobacco health warnings are summarised below, based mainly on analysis of findings identified in the desk research.

Position of warning: To be most effective warning messages should be positioned at

the top / middle of the pack, both front and back face. The

warning should not be severed when the package is opened.

Size of warning message: The warnings have to be large enough to make it difficult for

them to be ignored by consumers. Generally speaking the larger the warning the more effective it is likely to be. The evidence shows that a warning message should be optimally 100% and at least 50% of the facial area (excluding borders) to maximise the

effectiveness of the warning.

Strong contrast: Create strong contrast to highlight message (for example white

text on black background). Don't allow warning text to be placed

over images or logos, which impairs its effectiveness.

Use borders: Features such as borders surrounding the warnings can help to

distinguish the warning message from the package design and

increase notice-ability of the warnings.

Font: Use sans serif typefaces such as Arial, Helvetia and Univers.

Avoid simulated handwriting and ornate typefaces.

Font size and style: Make body text as large as possible (don't go below 12 point),

use bold or semi bold style and upper and lower case (sentences

in capital letters or italic type are harder to read).

Warning content: Use a range of warning messages that cover different health

warnings as well as social appeal messages, cessation support messages and other innovative messages that might be suitable for specific target groups. Clearly associate tobacco products with the warning message and personalise the warning texts as

much as possible.

Warning message style: The message should be clear and easy to understand. The

language used should be consistent and hard hitting. Words such

as "may" should be avoided.

Information on quitting: Add information on how to get help to quit on every pack.

Providing a telephone number on the pack is more effective than

telling smokers to seek advice from a doctor or pharmacist.

Pictures:

There needs to be a connection between the graphic and the text associated with the graphic. Pictures need to be emotive, hard hitting and/or provocative. Full colour pictures have the highest level of impact. Pictures on both sides of the packaging would have a greater impact than on one side only.

Rotation:

Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. There is widespread support for regular rotation of the warning messages amongst all people consulted for this project but the views vary on the optimum rotation time.

Health Canada has carried out repeated cross sectional surveys over a 6 year period which have shown only a gradual decline in the recall rate of warning messages, although feedback on the effectiveness of the messages recalled was not researched.

A review of the effectiveness of tobacco warnings in Australia in 2008 (ref F94) looked at the wear out issue in more detail. Some smokers who took part in the 24 group discussions felt that "some of the graphic health warnings, and specifically the graphic images, had become so familiar that their potency in conveying a health message had decreased" - the images referred to had been used for 18 months prior to the survey. The Australian study also consulted various stakeholders on the rotation issue. Some of these stakeholders advocated shortening the rotation time frame to six months and introducing a "sale by" date, to prevent tobacco companies and retailers from stockpiling old warnings. However, other stakeholders asserted that it was important that the warnings were circulated for at least 12 months, so that they could be effectively reinforced through promotions via other media.

Anecdotal evidence from Belgium also suggests that after 12 months wear out effects become significant.

Taking all available evidence and feedback from respondents into consideration the optimal rotation time is around 12 to 18 months. The FCTC guidelines suggest 12-36 months.

Renewal:

Warning messages should be renewed every few years, 2-5 years considered optimum.

Targeting specific groups: Warning texts and pictures should be tailored to specific target groups (e.g. smokers that have just started / smokers that want to quit, committed hard core smokers, younger and older smokers, male and female smokers). Cosmetic effects and effects on sexual activity are likely to be more salient to younger smokers. Older smokers are likely to be more concerned with illness.

Plain packaging

Plain packaging on cigarette packets would significantly increase the ability of the warnings to convey the health risks consumers. Tobacco packaging provides a direct link between consumers and manufacturers and serves as a vital marketing tool for the tobacco industry. Removing the colour, brand imagery and logos from packages reduces the attractiveness and appeal of the packaging and enhances the ability to communicate the health warning to the consumer. (Note: more information about plain packaging can be found in appendix 7)

Inserts:

These could include additional information on the immediate health benefits of quitting plus advice on how to quit and the toll free quit line number, to help people thinking about quitting.

Standardised packaging: It is also worth noting a recent trend in Canada where manufacturers introduced hexagonal shaped cigarette packs (i.e. top, bottom plus a hexagonal section to give 6 side faces, which reduces the area of the effective 'front' and 'back' surfaces, which reduced the space available for the health warnings). Packaging should be standardised (i.e. a 6-sided 'box') the dimensions of which need to be determined after further consultation to ensure warnings are of adequate size to be effective and to prevent other attempts by the tobacco industry to circumvent labelling requirements with very small / narrow (lipstick-like) packs.

Other pack issues that may help to increase warning effectiveness

- Attach specific type of messages to certain brands (for example youth brands)
- Use an appropriately positioning marker word such as "warning" together with the specific warning message (e.g. "WARNING - Smoking causes fatal lung cancer" rather than just "smoking causes fatal lung cancer".
- All health warnings on tobacco packages should be pre-tested in order to explore consumers' comprehension and acceptability.

SCIENTIFIC EVIDENCE OF HEALTH EFFECTS OF TOBACCO

Overview of the main illnesses related to smoking and second-hand smoke

There is a large list of diseases and conditions that are associated with smoking. For many of them the link between the disease and smoking is well researched and well documented.

Background information on smoking tobacco (ref.G1)

Smoking continues to be the largest single cause of death and disease in the European Union (EU). Over 650,000 Europeans die prematurely every year because they smoke and over 13 million more are suffering from a serious, chronic disease as a result of smoking.

Tobacco smoke contains many chemical agents, including substances that are known carcinogens, co-carcinogens (substances that may cause cancer) or tumour promoters. Smoking tobacco has negative health impacts on people of all ages: unborn babies, infants, children, adolescents and adults of all ages.

In addition, the World Health Organisation (WHO) has classified smoking as an addiction (tobacco dependence syndrome). Tobacco use shows regular and compulsive patterns, with a withdrawal syndrome usually accompanying tobacco cessation. The pharmacological and behavioural processes that determine tobacco addiction (caused primarily by nicotine) and which involve dopamine release in the nucleus accumbens, are similar to those that determine addiction to other drugs such as amphetamines and cocaine.

List of diseases and conditions caused in part by smoking

There is a large list of diseases and conditions that are associated with smoking. For many of them the link between the disease and smoking is well researched and well documented, for others there is only vague or inconclusive evidence. This section presents the recent evidence available where the linkage to smoking is proven (i.e. evidence is strong). The diseases caused by smoking are grouped into the following main groups: cancer diseases, non cancerous respiratory diseases, cardiovascular diseases, reproductive disease and pregnancy related diseases and other miscellaneous diseases. In addition, they are grouped into diseases caused by active smoking and diseases caused by second-hand smoke.

DISEASES CAUSED BY ACTIVE SMOKING

Cancer diseases

Lung cancer (bronchus, trachea)
Head / neck cancer (mouth, larynx, pharynx, oesophagus, nasal/sinus)
Kidney / ureter cancer
Pancreatic cancer
Stomach cancer
Bladder cancer
Cervical cancer
Leukaemia (especially acute myeloid leukaemia)
Other cancers

Non- cancerous respiratory diseases

Chronic obstructive pulmonary disease COPD (emphysema / chronic bronchitis) Other respiratory effects (asthma, coughing, phlegm, wheezing and dyspnoea) Pneumonia

Cardiovascular diseases

Heart attack / coronary heart disease / aortic aneurysm Angina Stroke

Atherosclerotic / peripheral vascular disease

Reproductive diseases and pregnancy

Male / female fertility
Reduced foetal growth / low birth weight baby
Miscarriage / spontaneous abortion
Perinatal death
Increased risk for sudden infant death syndrome
Premature birth
Premature rupture of the membrane
Increased risk of placenta previa
Increased risk of placental abruption
Impotence / erectile dysfunction

Other diseases

Blindness / age related macular degeneration / cataracts Aging of the skin Osteoporosis / hip fracture Gastric ulcer Dental disease

Other diseases that are associated with smoking where evidence is suggestive but not sufficient to infer a causal relationship include; anal cancer, vagina/ vulva cancer, ovarian cancer, penis cancer, prostate cancer, colorectal (bowel) cancer, liver cancer, breast cancer, chronic rhinitis, multiple sclerosis, goitre, diabetes and crohn's disease asthma, breast cancer, rheumatoid arthritis. There is also some evidence that smoking negatively affects the recovery from a wide range of illnesses and diseases and it negatively effects wound healing after surgery.

DISEASES CAUSED BY SECOND-HAND SMOKE

Diseases caused in adults

Coronary heart disease Lung cancer Reproductive effects in women / low birth weight Respiratory symptoms (nasal irritation)

Other diseases that are associated with passive smoking where evidence is suggestive but not sufficient to infer a causal relationship include nasal sinus cancer, stroke, COPD / asthma, AMD, atherosclerosis/ peripheral vascular disease and pre-term delivery.

Diseases caused in children

Middle ear disease Sudden infant death syndrome (SIDS) Respiratory diseases

Other diseases that are associated with passive smoking where evidence is suggestive but not sufficient to infer a causal relationship include brain tumours, lymphoma, asthma, leukaemia, meningitis, cognitive development and behaviour problems.

Review of the scientific evidence of the health effects of tobacco

This chapter reviews the scientific evidence of the health effects of tobacco, focusing where there is a proven link, and highlighting recent scientific evidence identified during the research programme.

Cancer diseases

This section provides an overview of the different cancers that are linked to smoking. The main sources used to collect information for the description of the diseases, symptoms and key risk factors (in addition to the references listed) were various websites from cancer organisations (British Lung Foundation, European Lung Foundation, Mouth Cancer Foundation UK, National Cancer Institute USA and Cancer Research UK).

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Lung cancer	Up to 20 times higher	Increased risk of death	- Smokers - Passive smokers	Strong
Head / neck cancer	Up to 6 times higher	Increased risk of death / disability	SmokersHeavy drinkers	Strong
Kidney cancer	Up to 2 times higher	Increased risk of death / disability	- Smokers over 50 - Obese people	Strong
Pancreatic cancer	Up to 4 times higher	Increased risk of death	- Smokers over 40 - Obese people	Strong
Nasal / sinus cancer	Up to 2 times higher	Increased risk of impaired health	smokersworkers with exposureto some chemicals	Strong
Stomach cancer	Up to 2 times higher	Increased risk of death	Smokers / drinkersPeople over 55People with salty diet	Strong
Bladder cancer	Up to 3 times higher	Increased risk of death	Smokers over 50Workers with exposure to some chemicals	Strong
Cervical cancer	Up to 2 times	Increased risk of death	- Smokers - Women under 35	Strong
Leukaemia	Up to 2 times Higher	Increased risk of death	Smokersexposure to high levels of radiation and benzene	Strong

Lung cancer (ref. G3, G5, G6, G86, G87)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Lung cancer	Up to 20 times	Increased risk of	- Active smokers	Strong
-	higher	death	- Passive smokers	_

What is lung cancer? — Lung cancer develops when cells become abnormal and grow out of control. Over time they form a clump also known as a tumour. Lung cancer usually develops in the tubes that carry air in and out of the lungs (the airways). It can grow within the lung and spread outside the lung. Lung cancer often develops slowly and the lungs do not feel pain. The result of this is that by the time lung cancer is diagnosed, it has often spread outside the lung. If this happens the cancer is not curable. Common symptoms are: a cough that won't go away, breathlessness, wheezing, coughing up blood, and weight loss.

Who is at risk? Lung cancer is the most common cause of death from cancer in the world (reference G3). Anyone can develop lung cancer, but people who smoke are most at risk. Over 80% of lung cancers are caused by smoking. Smokers are up to 20 times more likely to develop lung cancer than non-smokers. The risk increases with the total number of cigarettes smoked. Stopping smoking prevents further increase in the relative risk of lung cancer. Passive smoking can also cause lung cancer.

What is the evidence? The association between lung cancer and smoking was demonstrated in the 1950s and has been recognized by public health and regulatory authorities since the mid 1960s. There have been a large number of studies looking at the effect of smoking on the lungs but most of these studies have been carried out before 2000.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"Cigarette smoking is causally associated with lung cancer. Additional epidemiological, pathological and experimental data not only confirm the link but strengthens the causal relationship."

Reference G84 – US Department of Health and Human Service. The health consequences of involuntary exposures of tobacco smoke: a report of the Surgeon General (2006).

"The evidence is sufficient to infer a causal relationship between second-hand smoke exposure and lung cancer among lifetime non-smokers. This conclusion extends to all second-hand smoke exposure, regardless of location. The pooled evidence indicates a 20 to 30% increase in the risk of lung cancer from second-hand smoke exposure associated with living with a smoker."

Reference G6 – IARC monograph* on the evaluation of carcinogenic risks to humans volume 83 2004

"According to the latest monograph study from the International Agency for Research on Cancer (IARC) carried out in 2004 the major cause of lung cancer is tobacco smoking, primarily of cigarettes. In populations with prolonged cigarette use, the proportion of lung cancer cases attributable to cigarette smoking has reached 90%. The duration of smoking is the strongest determinant of lung cancer in smokers. Hence, the earlier the age of starting and the longer the continuation of smoking in adult-hood, the greater the risk. Risk of lung cancer also increases in proportion to the numbers of cigarette smoked. The carcinogenic effects of cigarette smoking appear similar in both woman and man."

Note: Monograph is a program by the IARC to evaluate the carcinogenic risk of chemicals to humans. It reviews relevant reports that are published or accepted for publications.

<u>Head / neck cancer</u> - cancer of the mouth, larynx, pharynx, oesophagus, nasal cavity / sinus cancer (ref G3, G5, G6, G7, G88)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Head / neck	Up to 6 times	Increased risk of	- Active smokers	Strong
cancer	higher	death / disability	- Heavy drinkers	

What is cancer of the mouth? Mouth cancer can appear in different forms in the mouth. Sometimes it appears as a white or red patch, but most often it appears as a painless ulcer that doesn't heal. After treatment, which may require surgery, patients may have problems with breathing, swallowing, drinking and eating. Speech may also be affected, and occasionally lost for ever. Facial disfigurement can also occur.

What is cancer of the pharynx/larynx / oesophagus? This is a disease in which malignant cells form in the tissue of the larynx / pharynx. The symptoms for cancer of the larynx can be similar to the symptoms for other illnesses and include: hoarseness or change of voice, difficulty of swallowing, coughing and shortness of breath, weight loss, a feeling that there is a lump in the throat and bad smelling breath. The treatment options include radiotherapy, surgery and chemotherapy. If the larynx has to be removed the person is no longer able to speak and breathe normally.

What is nasal / sinus cancer? Possible symptoms of nasal cancer may include: nose problems (blockages that don't go away, nose bleeding, mucus coming from the nose), eye problems (bulging of one eye, complete or partial loss of sight, double vision, watery eyes).

Who is at risk? Cancer of the oesophagus is the 6th most common cancer in the world while cancer of the mouth is the 11th most common cancer. Cancer of the larynx and pharynx are less common (reference G3). There is conclusive evidence that smoking plays a causative role in all head and neck cancers. Smokers have up to 6 times more risk to develop head and neck cancer than non-smokers. The risk increases with the total number of cigarettes smoked. Another common cause is drinking excessive amounts of alcohol. Nasal cancer can also be caused by exposure to certain chemicals (such as glue fumes, formaldehyde fumes, isopropyl alcohol fumes, chromium dust and nickel dust).

What is the evidence? A monograph study on smoking carried out by the International Agency for Research and Cancer (IARC) carried out in 1986 and again in 2004 (reference G6) showed conclusively that smoking plays a causative role in the respiratory and upper digestive tract cancers, particularly cancer of the mouth, larynx, pharynx and oesophagus. Since then evidence from many more studies has accumulated that further confirms this association. The most recent study from the National Cancer Institute (2007) (reference G7) again concerns these findings. The new study also finds that smoking plays a greater role in the development of head and neck cancer in woman than in men.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"There is sufficient evidence to infer a causal relationship between smoking and laryngeal cancer, oral cavity and pharyngeal cancer and oesophagus cancer."

Reference G6-IARC monograph* on the evaluation of carcinogenic risks to humans volume $83\ 2004$

"Tobacco smoking, including cigarette smoking, is causally associated with cancer of the oral cavity (including lip and tongue). Tobacco is also causally associated with cancer of the oesophagus, particularly squamous-cell carcinoma and cancer of the larynx and pharynx. For all these conditions the risk increases substantially with duration of smoking and number of cigarette smoked."

Reference G6 – IARC monograph* on the evaluation of carcinogenic risks to humans volume 83 2004

"An increased risk of sinonasal cancer among cigarette smokers has been reported in all casecontrol studies for which results were available. Of seven studies that have analysed dose response relationship, a positive trend was found in five and was suggested in the other two. In all five studies that have analysed squamous-cell carcinoma and adenocarcinoma separately, the relative risk was clearly increased for squamous-cell carcinoma.

Reference G7 – National Cancer Institute (USA), smoking increases risk for head and neck cancers for men and women (2007).

"Incidence rates of head and neck cancer were higher in men and women in all categories examined but smoking was associated with a larger relative increase in head and neck cancer risk in woman than in men"

<u>Kidney / renal cancer</u> (ref. G3, G5, G6, G8, G9)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Kidney cancer	Up to 2 times	Increased risk of	- Active smokers over 50	Strong
	higher	death / disability	- Obese people	

What is kidney cancer? When kidney cancer first starts to develop, there are often no obvious symptoms. Once the cancer begins to grow, the following are the main symptoms: blood in the urine, a lump or a mass in the area of the kidneys. Other more vague symptoms may include tiredness, loss of appetite, weight loss, a pain in the side that won't go away, high temperature and heavy sweating.

Who is at risk? Cancer of the kidney is the 15th most common cancer in the world (reference G3). The disease is rare in people under 50. The main known risk factors are smoking and obesity. Smokers have up to 2 times more risk of developing kidney cancer than non-smokers. The risk increases with the total number of cigarettes smoked.

What is the evidence? There is sufficient evidence to infer a causal relationship between smoking and kidney cancer (renal cell and renal pelvis) cancer. The evidence was demonstrated by various IARC monograph studies (reference G6) and by reports published by the Surgeon General (reference G5). New studies (reference G9) carried out in the USA in 2005 and 2007 have again confirmed that smoking is a risk factor.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and kidney cancer (renal cell and renal pelvis)."

Reference G8 – Wendy Setiawan – Risk factors for renal cell cancer: the multiethnic cohort (2007).

"Smoking was confirmed to be a risk factor for renal cancer for both sexes. Results also show that body mass index and hypertension are risk factors for renal cancer."

Reference G9 – Hunt JD at al, renal cell carcinoma in relation to cigarette smoking: meta-analysis of 24 studies.

Based on the analysis of 19 case-control and 5 cohort studies the relative risk for renal cell carcinoma (RCC) for ever smokers as compared to lifetime never smokers was 1.38 (male 1.54, female 1.22). Inhaled tobacco smoke is clearly implicated in the epidemiology of RCC, with a strong dose dependent increase in risk associated with numbers smoked per day and a substantial reduction in risk for long-term former smokers."

Pancreatic cancer (ref. G3, G5, G6, G10, G11, G12)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Pancreatic	Up to 4 times	Increased risk of	- Active smokers over 40	Strong
cancer	higher	death	- Obese people	
			- Heavy drinking	

What is pancreatic cancer? The cancer typically starts in the cells lining the ducts of the pancreas. The symptoms can be quite vague and they vary depending on where the cancer is in the pancreas – in the head, body or tail. Early symptoms can include: loss of appetite, weight loss, pain in the stomach area and jaundice.

Who is at risk? Pancreatic cancer is the 14th most common cancer worldwide and about 30% of cases are attributable to smoking (reference G3). The disease is uncommon in people under 40. The main known risk factors are smoking, diets with very high levels of fat and sugar and excess alcohol consumption. Smokers have up to 4 times more risk of developing pancreatic cancer than non-smokers. The risk increases with the total number of cigarettes smoked.

What is the evidence? There are more than 80 studies that contain information about smoking and pancreatic cancer and there is sufficient evidence to infer a causal relationship. Recent studies carried out by European Institute of Oncology (reference 12) and the University of Washington/Seattle (reference G11) confirm smoking is a strong risk factor

Evidence - Research report extracts:

Reference G6 – IARC monograph* on the evaluation of carcinogenic risks to humans volume 83 2004.

"Cancer of the pancreas is causally associated with cigarette smoking. The risk increases with duration of smoking and number of cigarettes smoked daily."

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and pancreatic cancer. Smoking cessation reduces the risk of pancreatic cancer, compared with continued smoking, although this reduction in risk may only be measurable after 10 years of abstinence."

Reference G10 – Couglinn SS – Predictors of pancreatic cancer mortality among a large cohort of US adults (2003).

"Our findings confirm that cigarette smoking is an important predictor of pancreatic cancer mortality. Cigarette smoking at baseline was associated with fatal pancreatic cancer among men, relative risk 2.1 and women relative risk 2.0. A trend risk was observed with increasing number of cigarettes smoked per day among smokers at baseline."

Reference G12 – Iodice et al, Tobacco and the risk of pancreatic cancer. A review and meta analysis (2008).

"The overall risk of pancreatic cancer estimated from the combined results for current and former smokers was respectively 1.74 and 1.2. This means that smoking cigarettes causes a 75% increase in the risk of pancreatic cancer compared to non-smokers and the risk persists for at least 10 years after smoking cessation.

Stomach / gastric cancer (ref. G£, G5, G6, G51, G52

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Stomach	Up to 2 times	Increased risk of	- People over 55	Strong
cancer	higher	death	- People with salty diet	
			- Active smokers	
			- Heavy drinkers	

What is stomach cancer? There are different types of stomach cancer but most of them arise from the glandular tissue lining of the stomach. The symptoms of stomach cancer can be quite vague and may include: indigestions / acidity / burping, feeling full, bleeding and feeling tired and breathless, blood clots, pain in the upper abdomen.

Who is at risk? Stomach cancer is the fourth most common cancer in the world (reference G3). Anyone can develop stomach cancer. Age is a significant risk. 9 out of 10 cases are diagnosed in people over 55 years old. Other risks include a diet high in salt and smoking and drinking. Smokers have up to 2 times more risk of developing stomach cancer. The risk increases with the total number of cigarettes smoked.

What is the evidence? The research has identified more than 40 studies providing a quantitative estimate of the association between stomach cancer risk and tobacco smoking. Most of these studies were carried out prior to the year 2000. Recent studies reconfirm the causal relationship between smoking and stomach cancer

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and stomach cancer. The evidence is suggestive but not sufficient to infer a causal relationship between smoking and noncardia gastric cancer."

Reference G6 – IARC monograph* on the evaluation of carcinogenic risks to humans volume 83 2004.

"Since 1986 various cohort and case control studies conducted in various parts of the world have shown a consistent association of cancer of the stomach with cigarette smoking in both men and women."

Reference G51 – Carlos A. Gonzales at al. Smoking and the risk of gastric cancer in the European Prospective Investigation into cancer and nutrition (2003)

"After adjustment for educational level, consumption of fresh fruit, vegetables and preserved meat, alcohol intake and body mass index (BMI), there was a significant association between cigarette smoking and gastric cancer risk: the hazard ration for current smokers was 1.73 in males and 1.87 in females. The risk increases with intensity and duration of cigarettes smoked".

Reference G52 – Stevens J, Maastrich University, Belgium. Large cohort study links stomach cancer to smoking (2008).

"The results of this study again confirms the link of stomach cancer and smoking. But it also suggests that there are other risks factors (alcohol, obesity, diet, occupational exposure)."

Bladder cancer (ref. G3, G5, G6, G14, G53, G54)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Bladder	Up to 3 times	Increased risk of	- Active smokers	Strong
cancer	higher	death	- Workers with exposure	
			to some chemicals	

What is bladder cancer? The most common bladder cancer is a cancer of the cells of the bladder lining. Typical symptoms include, blood in the urine, needing to pass urine very often, needing to pass urine very suddenly and pain when passing urine.

Who is at risk? Bladder cancer is the ninth most common cancer worldwide. Anyone can develop bladder cancer. Known factors that increase the risk include smoking and regular exposure to certain chemicals. The risk if one smokes is up to 3 times higher than that of a non smoker. The risk increases with the total number of cigarettes smoked. People exposed to certain chemicals used in rubber, paint, dyes and printing also have an increased risk.

What is the evidence? The research has identified 10 studies that looked at the link between bladder cancer and smoking and there is sufficient evidence to infer a causal relationship between smoking and bladder cancer. Most of these studies were carried out prior to 2000. Recent studies from a university in Barcelona, Spain (reference G14), the American Urological Association (reference G53) and the National Cancer Institute (reference G54 concluded that smoking increases the overall risk of bladder cancer.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"Smoking is a cause of bladder cancer: cessation reduces risk by about 50% after only a few years, in comparison with continued smoking"

Reference G6 – IARC monograph on the evaluation of carcinogenic risks to humans volume 83 2004.

Evidence from several cohort and case control studies have shown that tobacco smoking is a major cause of transitional-cell carcinomas of the bladder."

Reference G14 – University of Popeu Fabra, Barcelona. Risk of bladder cancer: results from the Spanish bladder cancer study and meta analysis (2005)

"Compared with NAT2 rapid or intermediate acetylators, NAT2 slow acetylators had an increased overall risk of bladder cancer that was stronger for cigarette smokers than for never smokers (relative increased risk ranged from 1.2 to 1.7)."

Reference G54 – National Cancer Institute. Smoking and bladder cancer effects of tobacco type, timing environmental tobacco smoke and gender (2006)

"Current smokers and former smokers had significantly increased risk of bladder cancer compared to non-smokers. We observed a significant positive trend in risk with increasing duration and amount smoked."

Cervical Cancer (ref. G3, G5, G6, G15, G55)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Cervical	Up to 2 times	Increased risk of	-Women under 35	Strong
cancer	higher	death	- Poor diet	
	-		- Active smokers	
			- Taking the pill	

What is cervical cancer? Cervical cancer is caused by changes in the cells covering the cervix. The most common symptom is bleeding from the vagina at other times than when having a period. Some women also have vaginal discharge that smells unpleasant and discomfort or pain during sex.

Who is at risk? Cancer of the cervix is the second most common cancer among women worldwide, second only to breast cancer (reference G3). Any woman can get cervical cancer but it is the second most common cancer in women under 35 years old. Known factors that increase the risk include sexually transmitted infections, smoking, poor diet, taking the pill. The risk for smokers is about 2 times that of a non smoker. The risk increases with the total number of cigarettes smoked.

What is the evidence? The research has identified 10 studies that looked at the link between cervical cancer and smoking and there is sufficient evidence to infer a causal relationship. Most of these studies were carried out prior to 2000. A pooled analysis of the IARC multi centric case control study carried in 2003 by Plummer M et al and a meta-analysis by UK Cancer Research concluded that smoking increases the risk of cervical cancer among human papilloma virus (HPV) positive women.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"Smoking has been consistently associated with an increased risk for cervical cancer and the evidence is sufficient to infer a causal relationship between smoking and cervical cancer."

Reference G6 – IARC monograph on the evaluation of carcinogenic risks to humans volume 83 2004.

"There is now sufficient evidence to establish a causal association of squamous-cell cervical carcinoma with smoking."

Reference G15 – Plummer M et al (2003) Smoking and cervical cancer: pooled analysis of the IARC multi-centric case control study.

"There was an excess risk for ever smoking among HPV positive women. When results were analysed by histological type, an excess risk was observed among cases of squamous cell carcinoma for current smoker (OR 2.3) and ex-smokers (OR 1.8)."

Reference G55 – Cancer Research UK (2004). Comparison of risk factors for squamous cell and adenocarcinomas of the cervix: a meta-analysis.

"Current smoking was associated with a significantly increased risk of squamous cell carcinoma, with a summery odds ratio of 1.95 (95% confidence interval) but not of adenocarcinoma."

<u>Leukaemia</u> (ref. G3, G5, G6, G16, G17, G56, G57)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Leukaemia	Up to 2 times	Increased risk of	- Exposure to high levels of	Strong
	higher	death	radiation and benzene	
			- Heavy smokers	

What is leukaemia? Leukaemia is a cancer of the white blood cells and bone marrow. The symptoms can be quite vague. Symptoms may include: general weakness, feeling tired, high temperature, weight loss, frequent infections, bruising or bleeding easily and pain in the joints. One may also feel flu symptoms.

Who is at risk? Leukaemia is the eleventh most common cancer worldwide. Known factors that increase the risk include smoking and exposure to very high levels of radiation, exposure to the chemical benzene at work over a long time.

What is the evidence? The research has identified 15 studies that looked at the link between leukaemia and smoking and there is sufficient evidence to infer a causal relationship (the link is mainly with acute myeloid leukaemia). Most of these studies were carried out prior to 2000. There have been a few more recent studies both confirming a causal relationship between smoking and the disease though the link was mainly to heavy smokers (reference G17) and for FAB subtype M2 (reference G56).

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and acute myeloid leukaemia. The risk increases with the number of cigarette smoked and with duration of smoking."

Reference G6 – IARC monograph on the evaluation of carcinogenic risks to humans volume 83 2004.

"Myeloid leukaemia in adults was observed to be causally related to smoking. Support for a causal relationship of smoking with myeloid leukaemia is provided by the finding of known leukaemogens in tobacco smoke, (one of which benzene) present in sufficient amounts to account for up to half of the estimated excess of acute myeloid leukaemia."

Reference G17 – Smoking and acute myeloid leukaemia (AML): association with morphology and karyotypic patterns and evaluation of dose-response relations (2003)

"Smoking status (ever smokers versus life-long non-smokers) showed no evident effect on AML risk. However, an effect of smoking was indicated at high cumulative smoking doses. For example 40 pack years was associated with an odds ratio of 1.5."

Reference G56 – Smoking and risk of acute myeloid leukaemia: Result from a Los Angeles county case-control study.

"Consistent with previous studies, smoking was not a substantial risk factor for AML overall (odds ratio 1.2). However increased risk was observed for FAB subtype M2 where odds ratio was 2.3."

Non- cancerous respiratory diseases

This section provides an overview of the different non-cancerous respiratory diseases that are linked to smoking. The main sources used to collect information for the description of the disease, symptoms and key risk factors (in addition to the references listed) were the websites of the following organisations: British Lung Foundation, European Respiratory Society, European Lung Foundation.

<u>Chronic obstructive pulmonary diseases COPD and other respiratory effects</u> (ref. G4, G5, G19, G20, G58, G89)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
COPD	Up to 14 times	Increased risk of	- Active smokers	Strong
	higher	death	- Passive smokers	

What is COPD (emphysema / chronic bronchitis)? This is a progressively disabling disease. It can cause prolonged suffering due to difficulty in breathing because of the obstruction or narrowing of the small airways in the lung and the destruction of the air sacs in the lung. The symptoms of COPD are coughing, breathlessness, phlegm, wheezing, dyspnoea and chest infections. The disease is not reversible.

Who is at risk? COPD is a common disease. Smoking is the main cause of chronic obstructive pulmonary diseases. At least 80% of deaths from this disease can be attributed to smoking. Other known risk factors are air pollution and polluted work conditions. Symptoms typically begin in people aged over 40 who have smoked for 20 years or more. Stopping smoking at an early stage of the disease will make a big difference. There is evidence that the risk of developing COPD falls by about 50% with smoking cessation (reference G58). However any damage already done to the airways cannot be reversed.

What is the evidence? The research identified more than 100 studies that looked at the relationship between COPD and smoking. Most of these studies were carried out before the year 2000. The more recent studies focus on smoking cessation and the impact of smoke abstinence in COPD patients. The evidence is sufficient to infer a causal relationship between smoking and chronic obstructive pulmonary diseases.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between active smoking and chronic obstructive pulmonary disease morbidity and mortality. Cigarette smoking is the most important of the causes of chronic bronchitis in the United States. There is also sufficient evidence to infer a causal relationship between active smoking and respiratory symptoms including coughing, phlegm, wheezing and dyspnoea."

Reference G4 – Ghadirian P, Faculty of Medicine, Canada (2004). Sleeping with a killer: the effects of smoking on human health.

The evidence suggests that the risk of death from COPD for smokers is estimated to be up to 14 times higher than in non-smokers. In terms of respiratory symptoms (wheezing, chronic cough, chronic phlegm and dyspnoea) the risk associated with smoking is up to 8 times higher. The causal role of smoking in COPD and respiratory symptoms is beyond doubt."

Reference G20 – European Respiratory Society (2003). The European Lung White Book, the first comprehensive survey on respiratory health in Europe.

"The evidence suggests that smoking is the most important cause of COPD. Smoking causes nearly 90% of all cases of emphysema. There is also some evidence that suggests that females may have more symptoms of COPD than males even if they have smoked the same amount over the same number of years."

Pneumonia (ref. G5, G20, G21, G22, G59, G60)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Pneumonia	Up to 3 times	Increased risk of	- Smokers	Strong
	higher	death	- Long term sick	

What is Pneumonia? This is an infection which causes the air sacs in the lungs, and the smaller bronchial tubes to become inflamed and fill with fluid. Special white blood cells then travel to the lungs to fight the infection. This makes it hard for the lungs to do their job: which is to get oxygen from the air into the bloodstream and then around the whole body.

Who is at risk? Anyone can get pneumonia – even the young and fit. However, it is more common and usually more serious in the very young, the very old, people who smoke and anyone weakened by long term sickness and damaged immune systems. The risk for smokers is up to 3 times higher compared to non-smokers.

What is the evidence? There have been numerous studies (most of which were carried out prior to 2000) looking at the link between smoking and pneumonia. The evidence is sufficient to infer a causal relationship between smoking and chronic obstructive pulmonary diseases. A review carried out by the University of Milan 2006 (reference G21) concluded that smoking is a major risk factor.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and acute respiratory diseases including pneumonia. Evidence suggests that smoking cessation reduces the risk of respiratory symptoms and respiratory infections such as bronchitis and pneumonia, compared with continued smoking."

Reference G59 – Gonzales C, Hospital of the Consorci Sanitari de Mataro, Barcelona (1999). Smokers pneumonia risk three times greater.

"Our study provided evidence that men and women who smoke more than 20 cigarettes per day were almost three times more likely to acquire pneumonia than a person who never smoked"

Reference G60 – Bagby J, Louisiana State University Health Science Centre (2005). Smoking, drinking raises pneumonia risk.

"The research has shown that smoking and drinking allow streptococcus pneumonia bacteria to spread faster towards the lung, raising the risk of pneumonia and other lung infections."

Reference G21 - Blasi F, Alberti S, Institute of Respiratory Disease, University of Milan (2006) Pneumonia: how important are local epidemiology and smoking habits

"The effects of tobacco smoke on the airway mucosa are well known. The proportion of smokers in hospitalised pneumonia is generally increased, which would indicate a role of smoking in the acquisition of infection.

Cardiovascular diseases

This section provides an overview of the different cardiovascular diseases that are linked to smoking. The main sources used to collect information for the description of the disease, symptoms and key risk factors (in addition to the references listed) were the websites of the following organisations: British Heart Foundation, The Stroke Association, American Heart Association and the World Health Organisation.

Heart attack, abdominal aortic aneurism, angina, stroke and peripheral vascular disease (ref. G5, G23 to G30, G84, G90)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Cardiovascular	Up to 10 times	Increased risk of	 Active smokers 	Strong
disease	higher	death	- Passive smokers	
			- Obese people	
			- Physically inactive	
			- Diabetes	
			- High blood pressure	
			- High cholesterol	

What is a heart attack? A heart attack (also known as coronary heart disease) occurs when the arteries that supply blood and oxygen to the heart muscle becomes narrowed by a gradual build up of fatty materials within their walls. If the fatty material becomes unstable it may break off and form a blood clot which could block the artery and starve the heart muscle of blood and oxygen. Common symptoms of a heart attack include: central chest pain, the pain can spread to the arms, neck and jaw, feeling sick or sweaty and feeling short of breath.

What is abdominal aortic aneurism? An aneurysm is an abnormal bulge in the wall of an artery. Normally, the walls of arteries are thick and muscular, allowing them to withstand a large amount of pressure. Occasionally, however, a weak area develops in the wall of an artery. This allows the pressure within the artery to push outwards, creating a bulge or ballooned area called an "aneurysm." It can press on other organs and cause pain or a blood clot may form at the site and dislodge, increasing the risk of stroke. Rupture of an aneurysm can cause loss of consciousness, stroke, shock or a heart attack. Common symptoms include: tearing pain in the chest, abdomen and/or middle of the back between the shoulder blades.

What is angina? Angina is an uncomfortable feeling or pain in the chest. In the majority of cases angina occurs as a result of coronary hearth disease. The artery may become so narrow that it cannot deliver enough oxygen-containing blood to the heart muscle when it needs it – such as when exerting oneself. The main symptoms of angina are: uncomfortable feeling or pain in the chest which may spread to the arms, neck, jaw, back or stomach.

What is stroke? A stroke is what happens when the blood supply to part of the brain is cut off. Blood carries essential nutrients and oxygen to the brain. Without a blood supply, brain cells can be damaged or destroyed and won't be able to do their job and it may affect body function or mental processes. Common stroke symptoms are: numbness / weakness / paralysis on one side of the body, slurred speech, sudden blurred vision or loss of sight, confusion and a severe headache.

What is atherosclerotic / peripheral vascular disease? Peripheral artery disease is a condition where fatty deposits build up in the inner linings of the artery walls. These blockages restrict blood circulation, mainly in arteries leading to the kidneys, stomach, arms, legs and feet. In its early stages common symptoms are cramping or fatigue in the legs and buttocks during activity.

Who is at risk? Anyone can get a cardiovascular disease. There are six major independent risk factors for cardiovascular disease, namely: cigarette smoking, high blood cholesterol, high blood pressure, physical inactivity, obesity and diabetes. Cigarette smoking increases the risk of cardiovascular disease by itself, however when it acts with other factors, it greatly increases the risk. Quitting smoking can substantially reduce the risk of mortality by up to 1/3 compared to those who continue smoking (reference G29).

What is the evidence? The research identified more than 100 studies that looked at the relationship of cardiovascular disease and smoking. The majority of these studies were conducted before the year 2000. The evidence is sufficient to infer a causal relationship between smoking and cardiovascular disease.

Evidence - Research report extracts:

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and heart attack." "Cigarette smoking is a major cause of cerebrovascular disease (stroke), evidence is sufficient to infer a casual relationship between smoking and stroke." "The evidence is sufficient to infer a causal relationship between smoking and peripheral vascular disease. Smoking is the most powerful risk factor predisposing to atherosclerotic peripheral vascular disease."

Reference G84 - US Department of Health and Human Service. The health consequences of involuntary exposure to environmental tobacco smoke: a report of the Surgeon General (2006).

"The evidence is sufficient to infer a causal relationship between exposure to second-hand smoke and increased risk of coronary heart disease morbidity and mortality among both men and women. Pooled relative risk from meta-analyses indicates a 25 to 30% increase in the risk of coronary heart disease from exposure to second-hand smoke.

Reference G23 - Willigendal, et al, Journal of Vascular Surgery, Volume 40 (2008). Influence of smoking and incidence and prevalence of peripheral arterial disease.

"The prevalence of symptomatic peripheral arterial disease (PAD) was increased 2.6 fold in current smokers. In former smokers prevalence was substantially increased by a factor of 2.3. A clear dose relationship with a strong increase in risk for PAD in heavy smokers was observed."

Reference G25 - Hirotsugu et al, Shiga University of Medical Science (2006). Cigarette smoking as a risk factor for stroke death in Japan.

"Smoking in cohort with moderate serum total cholesterol level was a potent risk for stroke especially cerebral infarction for men and women (relative risk 2.17 for men and 3.91 for women). Smoking was also a potent risk for developing ischemic heart disease for men but not for women."

Reference G29 – Julia A et al, University of Liverpool (2003). Mortality risk reduction associated with smoking cessation in patients with coronary heart disease.

"The results showed a 36% reduction in crude relative risk of mortality for patients who quit compared with those who continued smoking. The risk reduction appears to be consistent regardless of age, sex, cardiac event and ethnicity."

Reproductive diseases and pregnancy

This section provides an overview of how smoking negatively affects reproductive health, sexual health and pregnancy. The main sources used to collect information for the description of the disease, symptoms and key risk factors (in addition to the references listed) were the websites of the following organisations: British Medical Association, Sexual Dysfunction Association, BUPA and American Society for Reproductive Medicine.

Male / female infertility (G5, G31-G44, G61, G62)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Infertility	Up 2 times	- Delayed conception.	- Smoking	Strong
	higher	- Reduced fertility	- STD (sexually	
		- Reduced response to	transmitted diseases)	
		fertility treatments	- being underweight	

What is infertility /delayed conception? Infertility is usually defined as not having conceived after 12 months of regular unprotected sex. Eight out of ten couples having regular unprotected sex will conceive within 12 months, and nine out of 10 within 18 months.

Who is at risk? Any couple can suffer from infertility. There are a number of risk factors that affect fertility, namely age, sexual transmitted diseases, smoking, unbalanced hormones and being underweight (this list excludes physical (medicinal) and psychological factors).

Women who smoke have increased risks for conception delay for both primary and secondary infertility. Women who smoke produce less eggs and smoking appears to accelerate the loss of eggs and reproductive function and may advance the time of menopause by several years. Components in cigarette smoke have been shown to interfere with the ability of cells in the ovary to make estrogens and to cause a woman's eggs to be more prone to genetic abnormalities (reference (G37). Men who smoke have a lower sperm count and a higher proportion of malformed sperm (G37). Men and women who smoke have a poorer response to fertility treatment (G37).

What is the evidence? The research has identified more than 30 studies that looked at the relationship of smoking and reproductive health. Most of these studies were conducted before the year 2000. However, detailed reviews of all the studies by the US Surgeon General in 2004 (reference G5) and by the British Medical Association (reference G62) concluded that the evidence is sufficient to infer a causal relationship between smoking and reduced fertility in women and men.

Evidence - Research report extracts:

Reference G61- US Department of Health and Human Services (2001). Smoking and women's health, a report of the Surgeon General.

"The evidence is sufficient to infer a causal relationship between smoking and reduced fertility in women. Women who smoke have increased risk for conception delay and for both primary and secondary infertility."

Reference G62 –British Medical Association (2004). Smoking and reproductive life. The impact of smoking on sexual, reproductive and child health.

"Based on a review of studies that looked at the relationship of smoking and reproductive health the report concludes that men who smoke have a lower sperm count than non-smokers and their semen contains a higher proportion of malformed sperms. Women who smoke take longer to conceive. Among smokers, the chances of conceiving are decreased by 10-40% per cycle. The greater the number of cigarettes smoked the longer a woman is likely to take to achieve pregnancy."

Reference G32 - Soares SR et al., University of Valencia, Spain. Cigarette smoking affects uterine receptiveness (2007).

"The results of our study showed that the pregnancy rate in light smokers (1-10 cigarettes /day) was significantly higher than in heavy smokers (>10 cigarettes per day. (52.2% versus 34.1%)."

Reference G40 - Zhang JP et al, Jining Medical College, China (2000). Effect of smoking on semen quality of infertile men in Shangdong.

"The result of our study supports the view that smoking affects the semen quality of smokers, particularly in heavy smokers Smoking significantly reduced the semen volume and the semen Zn levels. Low Zn levels in turn contribute to reproductive failure.

Impotence / erectile dysfunction (G5, G45 – G50, G62 – G64)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Impotence	Up 2 times	- Unsatisfactory sex life	- Heavy smoking	Medium
	higher	- Depression	 Heavy drinking 	

What is impotence? Erectile dysfunction, or impotence, is the persistent or recurrent inability to attain or maintain an erection sufficient to complete sexual intercourse or another chosen sexual activity.

Who is at risk? Most men have an occasional failure to get or keep an erection. Impotence is quite common and affects about one in every ten men. It can be caused by psychological factors (stress, anxiety, depression), physical factors (diabetes, high blood pressure, high cholesterol) and life style factors (heavy drinking / heavy smoking). Smoking damages blood vessels and so increases the risk of erection problems.

What is the evidence? The research has identified more than 25 studies that looked at the relationship of smoking and impotence. Most of these studies were conducted before the year 2000, however the research identified 9 studies that were carried out since 2000 (ref G45 – G50, G62, G63, G64). The scientific evidence available so far is mixed. While many of the studies conclude that there is a link between smoking and impotence a detailed reviews by the US Surgeon General in 2004 (reference G5) concluded that the evidence is suggestive but not sufficient to infer a causal relationship.

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is suggestive but not sufficient to infer a causal relationship between smoking and erectile dysfunction."

G45. Jane Y et al, Queen's University Kingston, Canada (2005). Smoking and other lifestyle factors in relation to erectile dysfunction.

"A clinic based case control study carried out in Kingston, Canada amongst 1,288 men aged between 50 and 80 years old between 1997 and 1999 found that men with erectile dysfunction were twice as likely to be smokers / former smokers. Cumulative smoking in pack-years suggests a dose response pattern.

G63 – C. Millet et al, Health Promotion Unit, Sydney, Australia (2005). Smoking and erectile dysfunction: findings from a representative sample of Australian Men.

"An analysis of cross-sectional survey data from 8367 Australian men aged 16-59 found that almost 1 in 10 of the respondents reported erectile dysfunction that lasted for at least one month over the previous year. Men who smoked a pack or more of cigarettes per day were 40% more likely to be impotent than non smokers.

G64 – University of California (2001). The link between smoking and impotence: two decades of evidence.

"A meta analysis of 19 studies that reported the smoking habits of 3,819 impotent men between 1980 and 2000 found that 40% of impotent men were current smokers compares with 28% of men in the general public. The study concluded that tobacco use is an important risk factor for impotence."

Smoking in pregnancy (G5, G61, G62, G65, G84, G85)

Disease Complications during pregnancy	Level of risk Up to 3 times higher	Impact - Etopic pregnancy - Miscarriage* - Perinatal death** - Foetal malformation - Premature birth - Low birth weight - Placental complications - Slow lung growth	Who is mainly at risk - Active smoking - Passive smoking - Heavy drinking - Obese people	Evidence Strong
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^{*}Miscarriage is defined as loss of pregnancy before 24 weeks' gestation.

**Perinatal death encompasses both stillbirth – loss of the foetus after the 24th week of pregnancy – and neonatal death – death of the newborn during the first 4 weeks of life.

How is pregnancy affected by smoking? Smoking is associated with an increased risk of etopic pregnancy (up to 3 times higher). Smoking increases the risk of miscarriages (up to 25%) and perinatal death (up to 40%). One of the main causes of perinatal death is placental complications such as placental abruption and placenta praevia. Smoking increases the risk of placental complications by up to 3 times compared to non smokers. Smoking is also associated with an increased risk of foetal malformation (birth defects). For example the risk for oral clefts and limb reduction (absent or shortened limbs) increases by up to 30%. Smoking is also associated with low birth weight, women who smoke during pregnancy are 3 times more likely to have a low birth weight baby. The greater the number of cigarettes smoked during pregnancy, the greater the risk of all the diseases listed above.

Who is at risk? Any women can suffer from complications during pregnancy. There are five major risk factors that can negatively affect the pregnancy, namely: active smoking, passive smoking, heavy drinking, obesity and age (this list excludes physical (medicinal) and psychological factors).

What is the evidence? The research has identified more than 50 studies that looked at the relationship of smoking and pregnancy. Most of these studies were conducted before the year 2000. However, detailed reviews of all the studies by the US Surgeon General in 2004 (reference G5) and by the British Medical Association also in 2004 (reference G62) concluded that the evidence is sufficient to infer a causal relationship between maternal active smoking and etopic pregnancy, miscarriage, perinatal death, sudden infant death syndrome (SIDS), foetal malformation, premature birth, low birth weight and placental complications. There is also sufficient evidence to infer a causal relationship between passive smoking and low birth weight (reference G84, G85).

Evidence - Research report extracts:

Reference G62 – British Medical Association (2004). Smoking and reproductive life. The impact of smoking on sexual, reproductive and child health. A review of the latest scientific knowledge.

"Studies that looked at the relationship between maternal active smoking and ectopic pregnancy found that in women who smoke the risk is increased by up to 2.5 times."

"Based on a study carried out by the Royal College of Physicians in the UK, smoking increase the risk of miscarriage by 25%. A study of almost 60,000 women in Canada found a clear dose response, with the risk of miscarriage increasing with the number of cigarettes smoked."

"Based on research carried out by the Royal College of Physicians women who smoke during pregnancy are three times more likely to have a low birth weight baby. On average, smokers have babies that are 200 to 250g lighter than those of non smokers. The greater the number of cigarettes during pregnancy, the less well the foetus grows and develops."

"A study of more than 600,000 pregnancies in Sweden found that the risk of perinatal death increased 40% in smokers compared to non-smokers."

"Based on a studies carried out in the 1980s smoking increases the risk of placental disruption by up to 2.5 times while the risk of placenta previa increases by up to 3 times. The risk increases with number of cigarettes consumed."

"In certain studies, smoking during pregnancy has been associated with an increased risk of foetal malformation (birth defects). A recent expert review concluded that while smoking during pregnancy does not increase the overall risk of foetal malformation, it may nonetheless be related to a moderate increase in risk for certain malformation (especially limb reduction).

Reference G84 - US Department of Health and Human Service. The health consequences of involuntary exposure to environmental tobacco smoke: a report of the Surgeon General (2006).

"The evidence is sufficient to infer a causal relationship between maternal exposure to secondhand smoke during pregnancy and a small reduction in birth weight."

"The evidence is sufficient to infer a causal relationship between maternal smoking during pregnancy and persistent adverse effects on lung function across childhood."

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004)

"The evidence is sufficient to infer a causal relationship between maternal active smoking and miscarriage (spontaneous abortion), placental complications (premature rupture of the membrane, placenta previa and placental abruption), preterm delivery and shortened gestation, foetal growth restriction, low birth weight and SIDS."

"The evidence is sufficient to infer a causal relationship between maternal active smoking and reduced risk for preclampsia."

"The evidence is suggestive but not sufficient to infer causal relationship between maternal active smoking and ectopic pregnancy, oral clefts.

Reference G61- US Department of Health and Human Services (2001). Smoking and women's health. A report of the Surgeon General.

"Women who smoke may have a modest increase in risk for ectopic pregnancy. Smoking during pregnancy is associated with increased risk for preterm premature rupture of membranes, placental disruption and placenta previa and with a modest increase in risk for preterm delivery.

"The risk for perinatal mortality and the risk for sudden infant death syndrome (SIDS) are increased among the offspring of women who smoke during pregnancy."

"Infants born to women who smoke during pregnancy have a lower average birth weight and are more likely to be small for gestational age than are infants born to women who do not smoke."

Other diseases

This section provides an overview of how smoking negatively affects a range of other diseases that can not be grouped into one of the above mentioned categories. The main sources used to collect information for the description of the disease, symptoms and key risk factors (in addition to the references listed were: various websites from organisations such as BUPA, European Blind Union, the RNIB, the Royal College of Ophthalmologists and the American Academy of Periodontology.

Blindness (G5, G66 - G72, G93, G94, G96, G99, G100)

Disease Age related macular degeneration and nuclear	Level of risk Up 3 times higher	Impact - Possible blindness	Who is mainly at risk - People over 50 - Smokers	Evidence Strong
cataract				

What is age related macular degeneration (AMD)? The macula is a small but crucial area of the retina at the back of the eye. Cells in the macula are important for clear central vision as well as distinguishing colours. In AMD, the cells gradually deteriorate so that they are no longer able to do their job properly. The main symptoms are blurred and distorted vision.

What is a nuclear cataract? A cataract is a clouding of the natural lens, the part of the eye responsible for focusing light and producing clear, sharp images. As the lens becomes more opaque, seeing out of the eye becomes more difficult.

Who is at risk? Older people are most at risk of AMD. It generally affects people over 50 years old. Other known risk factors are smoking, high blood pressure, obesity and eating a diet high in fat (especially saturated and mono-unsaturated fats).

What is the evidence? The research has identified more than 30 studies that looked at the relationship between smoking and age related macular degeneration (AMD) / cataract. Most of these studies were conducted before the year 2000. The US Surgeon General in 2004 concluded that the evidence is sufficient to infer a causal relationship between smoking and nuclear cataract and that the evidence is suggestive but not sufficient to infer a causal relationship between smoking and age related macular degeneration. New studies carried out in England (reference G66, G70) in 2005/06 strongly confirm the link between smoking and AMD.

Reference G66 - Evans JR et al, British Journal of Ophthalmology 2005. 28,000 cases of age related macular degeneration causing visual loss in people aged 75 years and above in the UK may be attributable to smoking.

"A UK study (2005) involving more than 4,000 Britons aged 75 and older on smoking and AMD showed that those who smoked were twice as likely to have age related macular degeneration as those who did not."

Reference G67 – Thornton et al (2005). Smoking and age related macular degeneration: a review of association.

"A review of the association between smoking and age related macular degeneration in Eye in Sept 2005 that examined the results of 17 relevant studies found robust and consistent evidence that smoking causes visual impairment through age related macular degeneration."

Reference G71 - Sannapaneni K et al, Prasad Eye Institute, India (2205). Smoking and its association with cataract: Results of the Andhra Padesh eye disease study.

"A population based cross sectional epidemiologic study was conducted in the South Indian state of Andhra Pradesh. A total of 10,293 subjects of all ages were interviewed and each underwent a detailed dilated ocular evaluation by trained professionals. The results showed that cigar and cigarette smokers had a significant higher prevalence (up to 2 times) of any cataract compared with those who had never smoked. A dose response relationship was seen with respect to smoking."

Reference G72 - Tan J at al, Centre for Vision Research, Sydney (2008). Smoking and the long-term incidence of cataract: the Blue Mountain Eye Study.

"In a population based cohort of Australians aged 49 years and over, 3654 participants were seen at baseline (1992-1994) and 2406 were seen after 5 years and/or 10 years and had photographs taken to assess incident cataract. Smoking status was recorded at interview. After controlling for age, sex and other factors, ever smokers had an increased risk of developing cataract compared to never smokers (relative risk 1.41:95% confidence interval."

Reference G99 – Silke Schmidt, et al (2006), Cigarette smoking strongly modifies the association of LOC387715 and age-related macular degeneration.

"The study, based on a population of 810 unrelated patients with early (grade 3) or advanced (grades 4 & 5) AMD, concludes a genetic susceptibility coupled with a modifiable lifestyle factor such as smoking confers a significantly higher risk of AMD than either factor alone."

Reference G100 – Wilson, G and Field, A (2006), Smoke gets in your eyes: Smoking and visual impairment in New Zealand.

"The study, based on a review of 6 large population studies and use of NZ morbidity and smoking prevalence data concludes that smoking is a major cause of untreatable visual impairment and a significant reason for cataract surgery in New Zealand"

Skin problems (G73-G76)

DiseaseLevel of riskImpactWho is mainly at riskEvidenceSkin problemsUp 3 times
higher- Deep wrinkles and
leathery skin
- Akne- Exposure to sun
- SmokingMedium

What is premature aging of the skin? Each person has its own natural aging process (intrinsic aging). How quickly the normal aging process unfolds is controlled by genes someone inherits. However, there are also external factors (extrinsic aging) such as environmental and life-style factors that influence the aging process. The main symptoms are an unnatural acceleration of aging process causing deep wrinkles and leathery skin.

Who is at risk? 90% of premature aging is caused by sun exposure. Other external factors are smoking, lack of sleep, stress, poor diet, lack of exercise, sleeping position, repetitive facial expression and gravity. There are also some rare diseases such as Werner's syndrome linked to premature aging.

What is the evidence? The research has identified more than 20 studies that looked at the relationship between smoking and premature aging. However most of these studies were either conducted before the year 2000 or by companies associated with skin care products. None of the major medical research review bodies such as US Surgeon General have reviewed the relationship of smoking and premature aging. However, the research identified four key studies (ref G73 – G76) published since 2000 that suggest a causal link.

Reference G73 - Akimichi Morita et al. Nagoya city University Medical School, Japan (2000). Smoking has a damaging effect on the skin.

"Research carried out in a laboratory found that cells exposed to smoke produced far more enzyme responsible for breaking down skin. The research also found that smoke caused a drop in the production of fresh collagen by up to 40%. The combined affect is what is causing premature skin aging in smoking.

Reference G74 - Koe Jae Sook at al, the Catholic University of Korea (2002). Cigarette smoking associated with premature facial wrinkling: image analysis of facial skin replicas.

"123 non smokers, 160 smokers and 67 past smokers aged 20-69 years were studied. The result of the study showed that current smokers have a higher degree of facial wrinkling than non smokers. The relative risk of moderate to severe wrinkling for current smokers compared with non smokers was 2.72 when adjusted for age group.

Reference G75 - Helfrich Y et al, University of Michigan (2007). Smoking ages skin across the body.

"Researchers photographed 82 people's upper inner right arms. Participants were aged 22 to 91 .Half of those studied had a history of smoking and had smoked on average for 24 years. The number of packs they smoked ranged from a quarter of a packet to four packs per day. After controlling for age and other variables the study concluded that smoking in itself causes significant degree of damage to the skin.

Reference G76 - Schaefer T et al, University of Munich (2001). Epidemiology of acne in the general population: the risk of smoking.

896 citizens aged 1 to 87 were dermatologically examined. The prevalence and severity of acne were recorded and further information on demographic variables, medical history and alcohol and cigarette consumption were obtained. According to multiple logistic regression analysis acne prevalence was significantly higher in active smokers compared to non smokers (40.8% versus 25.2%).

Osteoporosis (G5, G77, G78, G79)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Osteoporosis	Up 2 times	- Risk of fractures	- Elderly women	Strong
	higher	especially wrist, spine	- Smokers	
		and hip.	- Low body weight	

What is osteoporosis? Osteoporosis is a condition in which bones weaken and are more likely to fracture. In particular it is a risk factor for fractures which occur most commonly at the wrist, spine and hip. Osteoporosis is a silent disease: it can progress for many years without symptoms until a fracture occurs.

Who is at risk? Osteoporosis is more common in women than in men. It is a particularly common condition among elderly women in affluent countries. Other important risk factors related to an excessive decrease in bone mass include such causes as physical inactivity, smoking, low body weight, a history of fractures and the use of corticosteroids.

What is the evidence? The link of smoking and osteoporosis has been established more than 20 years ago. The research identified more than 80 studies that looked at this relationship, however, most studies were conducted before the year 2000. Four studies published after the year 2000 (including the review of the US Surgeon General in 2004) conclude that there is a causal relationship between smoking and osteoporosis.

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and low bone density in postmenopausal women." "The evidence is sufficient to infer a causal relationship between smoking and hip fracture."

Reference G77 - Molly T et al, University of Pittsburgh, USA (2000). The effect of cigarette smoking on the development of osteoporosis and related fractures.

"The study concluded that by the age of 80 years, axial and appendicular bone mineral density was on average 6% to 10% lower in smokers compared to non smokers. This decreased density translates into a doubling of risk for spine and hip fractures."

Reference G78 - K Ward et al, University of Memphis, USA (2000). A meta analysis of the effects of cigarette smoking on bone mineral density.

"This meta analysis that looked at data from 86 studies enrolling 43,753 subjects concluded that smokers had significantly reduced bone mass compared with non-smokers at all bone sites, averaging a one tenth standard deviation deficit for combined sites. Deficits were especially pronounced at the hip, where bone mass of current smokers was one third of the standard deviation less than that of never smokers.

Reference G79 - J.A Kanis et al, WHO collaboration centre for Metabolic Bone Diseases, University of Sheffield Medical School, UK (2004).

"A large international cohort study involving 59,232 man and women concluded that smoking is associated with a significantly increased risk of any fracture compared to non smokers. The highest risk was observed for hip fracture (RR 1.84; 95% confidence interval.)

Dental disease (G5, G80-G83)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Periodontal	Up 6 times	- Inflamed gums	- Poor dental hygiene	Strong
disease	higher	- Tooth loss	- Smokers	
			- Poor diet	

What is periodontal disease? The word periodontal means "around the tooth". Periodontal disease is a family of related chronic inflammatory diseases that are caused by bacterial infection. The disease results in red swollen gums and can lead to the destruction of the connective tissue and bone that hold teeth in place.

Who is at risk? Specific species of bacteria must be present for periodontal disease to develop but usually other risk factors must be present as well. Apart from bacteria, age and poor dental hygiene the mayor risk factors are stress, poor diet, smoking, viral infections and medical conditions, examples being, diabetes, AIDS and inflammatory bowel disease.

What is the evidence? The link of smoking and dental disease has been established more than 20 years ago and the evidence is sufficient to infer a causal relationship between smoking and dental disease. Since 2000 there have been a number of new studies (references G80 to G83) which all confirmed that smokers have a higher prevalence of moderate and severe periodentitis.

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

"The evidence is sufficient to infer a causal relationship between smoking and periodentitis."

"The evidence is suggestive but not sufficient to infer a causal relationship between smoking and root surface caries."

Reference G80. - S Tomar et al (2000), Centre for Disease Control and Prevention, Chicago. Smoking may be responsible for more than half of the cases of periodontal disease among adults.

"Researchers analysed government dental health data of 13,650 people aged 18 and older. The study found that smokers are significantly more likely (up to 6 times depending on number of cigarettes smoked per day) compared to non-smokers to have periodentitis.

Reference G81. - School of Clinical Dentistry, University of Belfast (2004). The influence of tobacco smoking on the onset of periodentitis in young people.

"A review of the latest evidence from across the world confirmed that cigarette smoking is a major risk factor for the development of severe destructive periodontal disease in young adults. The study also found that the effects are dose related and that stopping smoking gradually erases the harmful effects of tobacco use on periodontal health. The study concludes that the occurrence of severe periodentitis in young adults can have devastating effects on their dentition because treatment can be unsuccessful.

Peptic (gastric) ulcer (G5)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Gastric ulcer	Up 2 times	- Indigestion	- H-pylori positive	Strong
	higher	- Heartburn	- nonsteroidal anti-	
			inflammatory drugs	
			- Tobacco and alcohol	

What is a gastric / peptic ulcer? A peptic ulcer is a sore in the lining of the stomach or duodenum. The duodenum is the first part of the small intestine. If peptic ulcers are found in the stomach, they're called gastric ulcers. The symptoms include indigestion and heartburn in the middle of the upper abdomen, nausea and loss of appetite, weight loss and repeated episodes of gastrointestinal bleeding.

Who is at risk? Gastric ulcers are most commonly caused by the use of nonsteroidal antiinflammatory drugs such as aspirin and ibuprofen. Gastric ulcer may also develop from the presence of Helicobacter pylori (H-pylori), which decreases resistance of the lining of the stomach to gastric acids, and increases production of gastric acids and infection. Ulcers can also be caused by the use of tobacco, alcohol and caffeine. The disease is most common amongst men aged over 45.

What is the evidence? The link of smoking and peptic (gastric) ulcers has been established more than 20 years ago and the evidence is sufficient to infer a causal relationship between smoking and peptic ulcers. No new studies were identified since 2000.

Reference G5 – US Department of Health and Human Service. The health consequences of smoking: a report of the Surgeon General (2004).

The evidence is sufficient to infer a causal relationship between smoking and peptic ulcers disease in people who are H-pylori positive.

Children and their exposure to second-hand smoke (G62, G84, G85, G98)

The scientific evidence indicates that there is no risk free level of exposure to second-hand smoke. Children are particularly vulnerable to second hand smoke and the following illnesses are linked to exposure to second hand smoke.

- Sudden infant death syndrome (SIDS)
- Middle ear disease
- Respiratory diseases

Sudden infant death syndrome SIDS (ref. G62, G84, G85, G98))

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
SIDS	Up to 3 times	Increased risk of	- Children exposed to	Strong
	higher	death	parental smoking during	
			and after pregnancy.	

What is SIDS? SIDS (sudden infant death syndrome) is also known as cot death. It is the sudden unexpected death of an apparently well baby aged from birth to two years.

Who is at risk? All babies aged from birth to two years can be affected by SIDS. However, 90% of deaths from SIDS occur during the first six months. There are a number of known risk factors which include babies sleeping on their stomachs, babies born to mothers who smoke during their pregnancy, premature or low weight babies and exposure to environmental smoke, especially parental smoke.

What is the evidence? There have been numerous studies looking at the link between smoking and SIDS. According to a study carried out by the Institute of Child Life and Health, University of Bristol, UK maternal smoking is now the most important avoidable risk factor for Sudden Infant Death Syndrome (SIDS). The US Surgeon General in its detailed review carried out in 2007 stated that the evidence is sufficient to infer a causal relationship between parental smoking and SIDS.

Evidence – Research report extracts

Reference G98 – British Medical Association (2007). Breaking the cycle of children's exposure to tobacco smoke – a review.

"Studies have shown that in homes where both parents smoke, the risk of SIDS is nearly four times as high as in homes where neither parent smokes. The greater the number of cigarettes smoked in a household the greater the risk."

Reference G85 - US Surgeon General (2007). Children and second-hand smoke exposure

"The evidence is sufficient to infer a causal relationship between exposure to second-hand smoke and sudden infant death syndrome."

Middle ear disease (ref. G62, G84, G85, G98)

Disease	Level of risk	Impact	Who is mainly at risk	Evidence
Middle ear	Up to 2 times	- Pain	- Children exposed to	Strong
disease	higher	- Hearing	parental smoking during	
		impairment	and after pregnancy.	

What is middle ear disease? This is an infection of the middle ear which is characterized by an accumulation of fluids in place of the air which normally occupies the middle ear (behind the ear drum). Symptoms of middle ear infection include earache, fever and temporary hearing loss.

Who is at risk? The majority of children experience an ear infection before they reach the age of three and many of them will have experienced three or more infections. Known risk factors include age (children between 6 months and 6 years are most prone to ear infections), attending day nurseries (which is a major source for spreading upper respiratory infections which often cause middle ear disease) and exposure to environmental smoke especially parental smoking.

What is the evidence? There have been several studies looking at the link between smoking and middle ear disease. According to a detailed review by the US Surgeon General carried out in 2007 the evidence is sufficient to infer a causal relationship between environmental smoke and middle ear disease.

Evidence – Research report extracts

Reference G98 – British Medical Association (2007). Breaking the cycle of children's exposure to tobacco smoke – a review.

"The review concludes that exposure to tobacco smoke in childhood causes acute and chronic middle ear disease, which are major sources of childhood morbidity. Ear infections can cause temporary hearing impairment. In chronic cases of "glue ear" hearing may be permanently compromised."

Reference G85 - US Surgeon General (2007). Children and second-hand smoke exposure

"The evidence is sufficient to infer a causal relationship between parental smoking and middle ear disease in children, lower respiratory illnesses in infants and children, cough, phlegm, wheeze and breathlessness among children in school age and persistent adverse effects on lung function across childhood."

Respiratory diseases (ref. G62, G84, G85, G98)

Disease Respiratory diseases	Level of risk Up to 2 times higher	Impact - Lower respiratory tract infections - Respiratory symptoms - Lower level of lung function	Who is mainly at risk - children exposed to parental smoking during and after pregnancy	Evidence Strong
		lung function		

What are respiratory diseases? Second hand smoke puts children at risk of a number of respiratory diseases including lower respiratory tract infections such as bronchitis and pneumonia as well as respiratory symptoms such as cough, phlegm, wheeze and breathlessness. In addition second hand smoke causes more frequent and more severe asthma attacks and it reduces lung growth and lung functionality.

Who is at risk? Any child can suffer from respiratory diseases. Some children have genetic disposition to develop respiratory diseases. Other known risk factors are environmental factors such as air pollution and tobacco smoke, especially for infants under two.

What is the evidence? There have been a number of studies looking at the link between second hand smoke and respiratory diseases in children. According to a detailed review by the US Surgeon General carried out in 2007 the evidence is sufficient to infer a causal relationship between second hand smoke and respiratory diseases in children.

Evidence – Research report extracts

Reference G98 – British Medical Association (2007). Breaking the cycle of children's exposure to tobacco smoke-a review.

"The review concludes that exposure to second hand smoke, in particular parental smoking, is an important cause of lower respiratory tract illnesses including bronchitis and pneumonia. Young children whose parents smoke are nearly twice as likely to be admitted to hospital with serious lower respiratory tract infections than children that are not exposed. The risks are highest in infants aged under two. In addition exposure to second hand smoke reduces lung functionality by reducing the growth rate of the lung and it exacerbates symptoms of asthma."

Reference G85 - US Surgeon General (2007). Children and second-hand smoke exposure

"The evidence is sufficient to infer a causal relationship between parental smoking and lower respiratory illnesses in infants."

"The evidence is sufficient to infer a causal relationship between parental smoking and cough, phlegm, wheeze and breathlessness among children of school age. There is also a causal link between parental smoking and persistent adverse effects on lung function across childhood."

Health and other benefits from smoking cessation

Quitting smoking has a quick, positive impact on the health. In particular the lung's functional abilities start to improve within days. The excess risk of coronary heart disease falls to about half of that of a smoker within a year.

Health benefits from smoking cessation

Stopping smoking can make a big difference to somebody's health and lifestyle. Evidence conclusively shows that it is never too late to stop smoking to gain health benefits. Even for smokers that are already suffering from smoke related diseases such as COPD or heart disease, the outlook is much improved for people that stop smoking. An overview of proven health benefits that occur after stopping smoking can be seen in the recovery benefit timetable below.

Within	Health benefits
12 hours	• Carbon monoxide levels will have dropped to normal and blood oxygen levels will have increased to normal.
3 days	• Breathing becomes easier and the lungs functional abilities are starting to increase.
3 months	• Heart attack risk starts to drop, lung function has further improved, cough, wheezing and breathing problems start to improve.
1 year	• Excess risk of coronary heart disease falls to about half that of a smoker.
10 years	• Risk of death from lung cancer has declined by almost half that of a smoker. Risk of stroke has declined to that of a non smoker. Risk of mouth, throat and oesophagus cancer also decreases.
15 years	• Risk of heart attack falls to the same level as someone who has never smoked.

References:

- U.S. Department of Health and Human Services, The Health Consequences of Smoking: A Report of the Surgeon General, 2004;
- Hughes, JR, Effects of abstinence from tobacco: valid symptoms and time course, Nicotine and Tobacco Research, March 2007, Volume 9(3), Pages 315-327;
- Mamede M, et al, Temporal change in human nicotinic acetylcholine receptor after smoking cessation: 5IA SPECT study, Journal of Nuclear Medicine, November 2007, Volume 48(11), Pages 1829-1835.

PROPOSALS FOR NEW TOBACCO HEALTH WARNINGS

Proposed new warning messages

24 new warning messages are proposed, based on analysis of the scientific evidence gathered by the literature / evidence review and in-depth interviews.

An overview of the proposed warning messages, how they group by type of message and the primary target group (where applicable) where specific messages are expected to have a particular resonance (marked $\sqrt{\ }$) are given in the table below.

Type of	Proposed warning message	Primary target groups				
message	•	A	В	\mathbf{C}	D	\mathbf{E}
9	Messages related to cancer diseases					
Health	1. Smoking causes 9 out of 10 lung cancers			$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
appeal	2. Smoking causes mouth and throat cancer			$\sqrt{}$	$\sqrt{}$	
messages	3. Smoking doubles the risk of cervical cancer		$\sqrt{}$		$\sqrt{}$	
	4. Smoking causes leukaemia	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
	Messages related to non cancerous respiratory diseases					
	5. Smoking destroys your lungs	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
	6. Smoking causes suffocating breathlessness for life		$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
	Messages related to cardiovascular diseases					
	7. Smoking causes heart attacks					$\sqrt{}$
	8. Smoking causes strokes and severe disability					$\sqrt{}$
	9. Smoking causes leg amputations					$\sqrt{}$
	Messages on other illnesses caused by smoking					
	10. Smoking causes blindness	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
	11. Smoking causes rotten teeth and gums	√	√	$\sqrt{}$	√	$\sqrt{}$
Social	12. Smoking can kill your unborn child		$\sqrt{}$			
appeal	13. Your smoke harms your children, family and friends	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
messages	14. If you smoke your children will smoke			$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
Cessation	15. Quit now – stay alive for your children					$\sqrt{}$
appeal	16. Stop smoking now - your health benefits immediately		$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
messages	17. Get professional help – it makes it easier to quit		$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
	18. Smoking makes it harder to have children					
Other	19. Smoking reduces your sexual performance			V		
messages	20. Smoking is severely addictive - don't start	V	$\sqrt{}$			
	21. Smoking reduces your sports performance	V	V			
	22. Smokers die younger	•	•			$\sqrt{}$
	23. Smoking causes wrinkles		$\sqrt{}$		$\sqrt{}$	•
	24. Tobacco smoke contains highly toxic chemicals		V	$\sqrt{}$	V	$\sqrt{}$
	= = = = = = = = = = = = = = = = = =	•	,	,	•	•

Note. The target groups are indicated marked with A to E. A = teenage male, B = teenage female, C = young adult men (aged 20-40), D = young adult females (aged 20-40), E = other older adults

How the new warning messages were developed

A brainstorming meeting by the research team produced an initial list of 50+ messages, using information gathered in the scientific review and feedback from interviews. Key issues that were taken into account were as follows:

- ➤ Health risks proven to be caused by direct and second hand smoking
- ➤ Health risks that have high risk factors
- ➤ Health risks where consumers are more likely to accept the linkage to smoking

- ➤ Health risks that will be new to consumers and will raise awareness of the health risk as well as initiate debate with other people
- ➤ The consumer groups most affected by these illnesses
- The need for a balanced mix of messages to cover key health risks, social appeal, cessation appeal and other issues such as addiction and reproductive health
- ➤ Identification of specific messages for specific target groups
- The need of messages to be direct, and using short easy to understand text
- Messages need to avoid complex phrases that are not easily translatable, bearing in mind that over 20 different languages are used throughout the European Union
- Messages and images that the research shows are considered to be effective
- ➤ Identification of gaps in the EU current list of warnings / warnings used elsewhere
- ➤ Best practice guidelines adopted by the Parties to the WHO framework convention on tobacco control

Initial analysis of the 50 ideas for relevance / suitability reduced the list to 31 potential messages. Further analysis identified some messages were duplicated and others were considered unlikely to have a significant impact with consumers, eliminating a further 6 potential warning messages.

The final list of new messages

A provisional final list of 25 proposed warning messages were selected.

The basic themes of all 14 existing warnings currently mandatory in the EU are included in the recommended new list, although several have been changed / updated to reflect the findings from the research and increase the likely impact of the new messages. The scientific evidence and reasons for selecting each of the proposed warning messages, together with the key target audiences at which each message is aimed and views on the likely effectiveness of each message is provided in the following pages.

Following the dissemination of the second interim report, additional suggestions for new messages were received from key stakeholders, as well as suggested amendments to the initial list of 25 proposed warnings developed by the team. Several warnings were amended to take on board these comments, and one warning was dropped (because it duplicated another similar message). In addition, the four messages suggested by public health stakeholders were analysed and added to the list, making a total of 28 warnings.

Finally, the draft interim report findings were presented to the Tobacco Products Regulatory Committee, during which discussions the text of four warnings was amended, and four warnings (listed below) were dropped to make an agreed final list of 24 warnings.

WARNINGS DROPPED

- Smoking causes chronic disabling cough
- Smoking blocks your arteries
- Smoking causes severe asthma in children
- Smoking causes a slow and painful death

It is <u>strongly recommended that the recommended new warnings are tested</u> with consumers across the EU, in order to fine tune the wording so that the messages have maximum resonance across the EU (and also bear in mind the different languages into which they must be translated).

The 2 general warnings

Respondents interviewed during the fieldwork phase were also asked their views on the relevance of the 2 general warnings – "Smoking kills / smoking can kill" and "Smoking seriously harms you and others around you". There was a consensus view that both general warnings are still relevant, and the following general observations were made.

- ➤ 'Smoking kills' is perceived as the stronger message, and some respondents also felt that EU should adopt this rather than allowing individual states a choice.
- The research findings suggest that an alternative message 'Smoking kills you' would also be acceptable, although this message was not tested with respondents.
- Smoking seriously harms you and others around you' is considered to be too long and a weaker warning than the simpler 'Smoking kills'. However, the basic concept is still relevant. A shorter message such as 'Smoking seriously harms other people' would be more effective.

Smoking causes 9 out of 10 lung cancers

Scientific justification

- There is conclusive evidence that smoking plays a causal role in lung cancer.
- ➤ Lung cancer is the most common cause of death from cancer in the world. Smoking is the primary cause for lung cancer. 80-90% of lung cancers are caused by smoking.
- Most lung cancer is diagnosed too late for curative treatment to be possible. Only about 10% of lung cancer sufferers are still alive 5 years after diagnosis.

Target audience

Primary target audience is adults over 40 years old, and to a lesser extent young adults aged 20-40.

- This warning message is a replacement of the existing warning message "smoking causes fatal lung cancer". This will help to reduce wear out.
- ➤ The effectiveness of the warning message is likely to be high because it clearly spells out that smoking is the primary cause of lung cancer. Based on research carried out in several EU countries the current picture (#8) showing a healthy and diseased lung is effective.
- ➤ The warning is likely to have greatest impact amongst older adults of both gender, especially those aged 40 and above. This is the primary age group affected by lung cancer and research has shown that this age group is quite receptive to health related messages. However, it is likely to be less effective with young (teenage) people who are less affected by this type of health risk partly because the risk to them is perceived to be to far away in the future.

Smoking causes mouth and throat cancer

Scientific justification

- ➤ There is conclusive evidence that smoking plays a causal role in mouth and throat cancer.
- Mouth cancer is the 11th most frequent cancer affecting many thousands of people every year. Smoking is a major risk factor. Smokers are up to six times more likely to develop mouth and throat cancer compared to never smokers.
- The impact of mouth and throat cancer can cause a slow and painful death. It can also cause facial disfigurement and loss of voice.

Target audience

➤ Primary target audience is adults over 40 years old, and to a lesser extent young adults aged 20-40.

- This is a new message that is not yet used in Europe. Similar messages are used in Australia, New Zealand and Brazil and are found to be effective.
- ➤ The effectiveness of the warning message is likely to be high because of the potential consequences that can be supported in graphical images. Image #29 (showing a mouth and rotten teeth) is consistently rated as affective across 7 EU Member State surveys
- The warning is likely to have greatest impact amongst older adults of both gender, especially those aged 40 and above, because research has shown that this age group is receptive to health warning messages. However, it is also likely to be quite effective with younger adults because of the potential impact on their looks (facial disfigurement). The message also has some potential resonance with teenagers again due the potential impact on their looks.

Smoking doubles the risk of cervical cancer

Scientific justification

- There is conclusive evidence that smoking plays a causal role in cervical cancer.
- ➤ Cervical cancer is the second most common cancer among women world wide. The main risk group is women under 35.
- The final stages of cervical cancer can involve pain, extreme loss of weight, humiliation and social isolation.

Target audience

Primary target audience is females under 35 years old.

- ➤ This is a new warning message that is not yet used in the EU and it is likely to attract attention because it is unlikely that many people are aware of the link between smoking and cervical cancer.
- This is a highly targeted warning message that is likely to be effective with women in general but in particular with women under 35, since they are the age group at greatest risk from this disease and in some countries young females is a consumer group where smoking prevalence is growing.
- The effectiveness of this message could be diminished in young women in EU Member States where information campaigns on vaccination against human papillomavirus (HPV) have been introduced.
- ➤ However, cervical cancer is still highly prevalent and this message is therefore considered very relevant for the lifespan of the new warnings (i.e. the next 4-5 years)

Proposed warning message 4

Smoking causes leukaemia

Scientific justification

- ➤ Leukaemia is the 11th most common cancer worldwide, and there is conclusive evidence that smoking plays a causal role in leukaemia.
- The risk of death for smokers is up to two times higher compared to non-smokers.

Target audience

> Primary target audience is all consumers.

- This is a new warning message that is not yet used in the EU and it is likely to attract attention because many smokers might not be aware of the link between smoking and leukaemia.
- ➤ The addition of leukaemia to the list of health risks will reinforce the other health risk warnings, by educating consumers (over time) that smoking causes a wide range of serious diseases, many of them fatal.

Smoking destroys your lungs

Scientific justification

- There is conclusive evidence that smoking plays a causal role in non-cancerous respiratory diseases.
- > Smoking is the main cause of chronic obstructive pulmonary disease (COPD). More than 80% of deaths from this disease can be linked to smoking.
- The effects of smoking on the respiratory system (damage to the airways) can not be reversed once established.

Target audience

> Primary target audience is all consumers.

- This is a new warning message that is not yet used in the EU. It is likely to attract attention because it points out the negative effects of smoking on the lungs in clear and easy to understand terms.
- ➤ This message is likely to be most effective with middle aged and older adult smokers that start to feel lung related symptoms themselves and with young people that enjoy sport and competing with others.

Smoking causes suffocating breathlessness for life

Scientific justification

- There is conclusive evidence that smoking plays a causal role in non-cancerous respiratory diseases.
- > Smoking is the main cause of chronic obstructive pulmonary disease (COPD). More than 80% of deaths from this disease can be linked to smoking.
- ➤ The effects of smoking on the respiratory system (damage to the airways) can not be reversed once established, and one of the symptoms is 'suffocating breathlessness', caused by the destruction of air sacs and narrowing of the airways in the lungs,

Target audience

> Primary target audience is all consumers.

- ➤ This is a new warning message that is not yet used in the EU and it is likely to attract attention because many smokers might not be aware of the link between smoking and severe breathlessness from respiratory diseases.
- A similar message highlighting breathlessness is used in Canada. Messages highlighting emphysema are used in Australia and Brazil. However, breathlessness is considered a more effective message as many consumers, especially people with lower levels of education, may not be aware of what emphysema is. The addition of the word 'suffocating' will strengthen the fear element of this message.
- This message is likely to be most effective with middle aged and older adult smokers that start to feel breathless symptoms themselves and with young people that enjoy sport and competing with others.

Smoking causes heart attacks

Scientific justification

- ➤ There is conclusive evidence that smoking plays a causal role in cardiovascular diseases including heart attack.
- > Smokers are up to 10 times more likely to get a heart attack compared to non-smokers.
- ➤ Heart attacks often lead to sudden death.

Target audience

> Primary target audience is middle aged and older adults.

- This is an adaptation of an existing EU warning message 'Smoking clogs the arteries and causes heart attack and strokes'. It has been reworded to simplify the message to highlight one specific health risk.
- ➤ Health warnings highlighting the risk of heart attacks / coronary heart disease are also used in Brazil, Australia, Canada and New Zealand.
- > The effectiveness of the warning message is likely to be high. Heart attack is an illness that is feared because it often leads to sudden death.
- ➤ This is a targeted message aimed particularly at middle aged and older adult smokers for whom the risk of a heart attack is significantly increased.

Smoking causes strokes and severe disability

Scientific justification

- ➤ There is conclusive evidence that smoking plays a causal role in cardiovascular diseases including stroke.
- > Smokers are up to 10 times more likely to get a stroke compared to non-smokers.
- The damage caused by stroke can lead to severe disability (paralysis, speech difficulties, cognitive difficulties, etc).

Target audience

> Primary target audience is adults over 40.

- This is an adaptation of an existing EU warning message 'Smoking clogs the arteries and causes heart attack and strokes'. It has been reworded to simplify the message to highlight one specific health risk, namely the prospect of becoming severely disabled from stroke. Similar warnings highlighting the risk of strokes are also used in Australia, Canada and New Zealand.
- ➤ The effectiveness of the warning message is likely to be high. Warning about the possibility of becoming severely disabled because of smoking is a strong and direct 'fear message' and research has shown that fear messages are effective.
- This warning message is likely to be most effective with middle aged and older adult which are more responsive to illness related messages.

Smoking causes leg amputations

Scientific justification

- There is conclusive evidence that smoking plays a causal role in cardiovascular diseases including peripheral vascular disease
- Smokers are up to 10 times more likely to get peripheral vascular disease compared to non-smokers.
- Peripheral vascular disease (narrowing of arteries) mainly affects arteries that take blood to the legs. In severe cases it leads to the amputation of a foot or lower leg.

Target audience

> Primary target audience is adults over 40.

- This is a new warning message that points out the potential consequences of blocked arteries that can result in foot or leg amputation. Health warnings highlighting the risk of amputation exist in Brazil. Health warnings that smoking causes gangrene (which can lead to amputation) is used in New Zealand.
- ➤ The effectiveness of the warning message is likely to be high. Warning about the risk of losing a foot or lower leg because of smoking is a strong and direct 'fear message' and research has shown that fear messages are effective.
- ➤ This warning message is likely to be most effective with middle aged and older adults who are more responsive to illness related messages.

Smoking causes blindness

Scientific justification

- There is conclusive evidence that smoking plays a causal role in getting cataracts and there is strong evidence that smoking doubles the risk of age related macular degeneration. Both illnesses can cause blindness.
- ➤ Smokers are up to 2 times more likely to suffer from cataract and age related macular degeneration compared to non smokers.
- > Suffering blindness is severely disabling.

Target audience

> Primary target audience is all consumers.

- ➤ This is a new warning message for the EU. A similar message is already used in Australia and New Zealand.
- ➤ The effectiveness of the warning message is likely to be high. The link between smoking and blindness is not well known. The prospect of going blind because of smoking is a strong and direct 'fear message' and research has shown that fear messages are effective.
- This message is likely to be effective with all age groups because blindness is a disease that is of high concern to all people.

Smoking causes rotten teeth and gums

Scientific justification

- ➤ There is conclusive evidence that smoking plays a causal role in dental disease which can lead to infected gums and tooth loss.
- > Smokers are up to six times more likely to suffer from dental disease (in particular periodontal disease) compared to non smokers.
- ➤ Dental disease can negatively affect the overall health and it can cause serious cosmetic problems.

Target audience

> Primary target audience is all consumers.

- This is a new message that is not yet used within the EU. However the EU picture library contains a picture showing a mouth with inflamed gums and rotten teeth combined with the message "smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide" which is rated as highly effective in seven EU surveys.
- A warning message that includes the phrase "loss of teeth" is used in Brazil. A related warning that 'smoking causes foul and offensive breath' is used in New Zealand.
- ➤ The effectiveness of the warning message is likely to be high. Most people easily understand the problems related to inflamed gums and rotten teeth and how it would affect them personally.

Smoking can kill your unborn child

Scientific justification

- There is conclusive evidence that smoking kills unborn children through miscarriages and stillbirth.
- ➤ Women who smoke during pregnancy have up to 3 times higher risk of miscarriage and still birth, premature birth and low birth weight.

Target audience

➤ Primary target audience is pregnant women and women that are trying to get pregnant.

- ➤ This warning replaces the existing EU message "smoking when pregnant harms your baby". Health warnings in Brazil include the wording "causes premature birth and death".
- > The effectiveness of the warning message is likely to be high because spelling out in clear words that smoking kills unborn children is a strong and direct 'fear message' and research has shown that fear messages are effective.
- ➤ This message is likely to be most effective with pregnant women of women that are planning to get pregnant. However, the message will also have resonance with all smokers that potentially subject pregnant women to passive smoking.

Your smoke harms your children, family and friends

Scientific justification

- There is conclusive evidence that second hand smoke is responsible for a number of diseases in particular for lung cancer and respiratory diseases.
- Living with a smoker increases the risk for lung cancer and respiratory diseases by up to 40%. It also worsens asthma.

Target audience

> Primary target audience is all consumers.

- This message is an adaptation of the existing EU warning message "protect children: don't make them breathe your smoke". Renewing the message is likely to help reduce wear out. In addition, the message appeal is widened by including the words "family and friends".
- The effectiveness of the warning message is likely to be high. Studies that looked at the effectiveness of different warning messages found that people respond well to social appeal messages, especially where children are involved. The research also indicates that the impact is likely to be greater amongst females.

If you smoke your children will smoke

Scientific justification

- Most children perceive their parents (as well as older siblings and other adults) as life role models, and many often try to copy their parents' actions, which would include smoking.
- ➤ There is evidence gathered in this report that messages highlighting risks to children have a strong resonance with adults, especially parents.

Target audience

> Primary target audience is all adults.

- This is a new warning message that is not yet used in the EU and it is likely to attract attention because warnings highlighting risks to children have a high resonance with many adults, especially parents and grandparents.
- ➤ A similar message is already used in Canada "Children see children do".

Quit now – stay alive for your children

Scientific justification

- ➤ There is conclusive evidence that smoking can reduce life expectancy by up to 14 years.
- > Stopping smoking makes a big difference to someone's health and lifestyle. There is conclusive evidence that much of the damage done by smoking can be reversed when people quit, in particular a reduced risk of heart attacks and strokes and reduced effects of COPD.

Target audience

> Primary target audience is parent smokers contemplating to quit.

- ➤ This is a new warning message. It combines encouragement to quit with an implied warning of premature death when continuing smoking.
- ➤ The warning message is likely to be more effective when a quitline number is provided with the message. Research has shown that quit messages combined with a quitline number significantly increase call volume.
- The message is likely to be most effective with the key target group (smoking parents).

Stop smoking now – your health benefits immediately

Scientific justification

- ➤ Stopping smoking makes a big difference to a smoker's health and lifestyle. There is conclusive evidence that much of the damage done by smoking can be reversed when people quit, in particular a reduced risk of heart attacks and strokes and reduced effects of COPD.
- The research evidence shows that improvements to lung functionality are achieved within days, and risks from heart attacks fall within 3 months.

Target audience

> Primary target audience is all smokers.

- This message is an adaptation of the existing EU message "Stopping smoking reduces the risk of fatal heart and lung disease". The renewal of this message is likely to reduce wear out. In addition, the new message is considered to be more encouraging because benefits materialise immediately.
- A similar message that "Quitting will improve your health" is used in Australia.
- ➤ The warning message is likely to be more effective when a quitline number is provided with the message. Research has shown that quit messages combined with a quitline number significantly increase call volume.
- ➤ The message is likely to be most effective with smokers already contemplating to quit. However, it should also encourage some committed smokers to contemplate quitting.

Get professional help – it makes it easier to quit

Scientific justification

Many people find it very difficult to stop smoking. However, the success rate can be increased significantly through professional cessation support.

Target audience

> Primary target audience is all smokers.

- ➤ This warning is an adaptation of the EU existing message "Get help to stop smoking". The renewal of this message is likely to reduce wear out. In addition, the new message is considered to be more encouraging because of the use of "easier".
- ➤ The warning message is likely to be more effective when a quitline number is provided with the message. Research has shown that quit messages combined with a quitline number significantly increase call volume.
- ➤ The message is likely to be most effective with smokers contemplating to quit. However, it should also encourage some committed smokers to contemplate quitting.

Smoking makes it harder to have children

Scientific justification

- There is strong evidence that smoking plays a causal role in reducing the fertility in both women and men.
- The scientific evidences shows that an estimated 10% of couples do not conceive within 18 months of unprotected sex, and a further 10% do not conceive within 12 months, which is one of the definitions for infertility.

Target audience

> Primary target audience is younger couples generally under the age of 40 that are trying to have a family.

- ➤ This warning message is an adaptation of the existing EU message 'Smoking can damage the sperm and decrease fertility'. The new message takes on board the scientific findings that smoking affects fertility in both males and females.
- The warning message is likely to be quite effective because a significant proportion of the population experiences either short term or longer term fertility problems.
- ➤ The warning is likely to have greatest impact amongst young couples, mainly under the age of forty, as this is the group that are directly affected by the message in the health warning.

Smoking reduces your sexual performance

Scientific justification

- There is a reasonable amount of evidence that heavy smoking can cause erectile dysfunction or impotence through damage to blood vessels.
- > Smokers are up to 2 times more likely to suffer from impotence compared to non-smokers.

Target audience

> Primary target audience is young males, especially teenagers and young adults.

- ➤ This warning is an adaptation of the existing EU message "Smoking may reduce the blood flow and causes impotence". A shorter message and the removal of the world "may" is likely to increase the effectiveness of the message.
- ➤ The warning message is likely to be quite effective and provides an opportunity for including less shocking images, that provide a balance to the more arousing images likely to be selected for some of the 'health appeal' warnings.
- The warning is likely to have greatest impact amongst males that are involved in sexual relationships, which is reflected in the research evidence available.

Smoking is severely addictive – don't start

Scientific justification

- There is clear evidence that smoking is highly addictive in nature, although many people express a desire to quit, they find it very difficult to achieve.
- Research carried out in Ireland showed that 80% of smokers started smoking before the age of 18 and feedback from interviewees also confirmed that most smokers start before the age of 18. Many of them believe that they will be able to quit when they are adults and before the negative health affects occur.

Target audience

Primary target audience is young teenage people, in particular non smokers.

- ➤ The new warning is an adaptation of the existing EU message "smoking is highly addictive, don't start. Changing the wording from 'highly' to 'severely' addictive, should help reduce wear out.
- The warning message is likely to be quite effective because of the potential to influence non-smoking teenagers from starting smoking in the first place.

Smoking reduces your sports performance

Scientific justification

- There is clear evidence that smoking negatively affects sports performance. Smoking destroys airs sacs on the lungs and causes narrowing of the airways in the lungs, which results in breathlessness. This in turn reduces the amount of oxygen that is distributed through the body (including muscles). Smoking also increases the heart beat because nicotine is a stimulant.
- ➤ People who smoke usually can't compete in sports (as well as any other activities that involve strenuous physical exercise) as effectively against non-smoking peers because they tire more quickly and take longer to recover.

Target audience

➤ Primary target audience is teenagers and young adults (aged 18-35).

- This is a new warning message to warn a specific age group (teenagers and young adults of both genders) about the negative impact of smoking on athletic performance (sports and also other physical activities). It is not yet used by any other country, although some countries (for example Australia) make available fact sheets about the negative impact of smoking on athletic performance.
- The effectiveness of the warning message is likely to be high amongst teenagers and young adults (male and female) that are keen on sporting activities.

Smokers die younger

Scientific justification

- ➤ There is conclusive evidence that smoking plays a causal role in a range of cancers, as well as several cardiovascular diseases (including heart attacks and stroke) and non-cancerous respiratory diseases.
- ➤ The scientific evidence also shows that life expectancy amongst male smokers is reduced by up to fourteen years.

Target audience

> Primary target audience is adults aged 40-60.

- This is an existing message, and the research indicates that the message is still relevant.
- The warning is likely to have greatest impact amongst smokers over forty, as they are in the age range where the health effects are starting to become more prominent.
- ➤ It is generally thought that this message will have least effect amongst young people (under 18), because to them death is a distant concept.

Smoking causes wrinkles

Scientific justification

- > There is scientific evidence that smoking contributes to premature aging of the skin, in particular leathery skin, deep wrinkles.
- ➤ Physical appearance is a highly sensitive issue for many people, particularly females and younger people.

Target audience

> Primary target audience is teenage and young adult females

- > This warning is an adaptation of the existing EU message "Smoking causes ageing of the skin".
- The warning is likely to have greatest impact amongst young adult females and teenage girls, confirmed by research findings on pictorial messages in the UK, Greece and Australia.
- ➤ However, the message is also likely to have resonance with older female smokers (over 40 years of age) where the ageing affects are more imminently linkable to their age group.

Tobacco smoke contains highly toxic chemicals

Scientific justification

- Research evidence shows that previous message (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide) was amongst the most highly ranked messages when used in conjunction with the image of rotten teeth, although the key driver was the graphical image.
- Research in Australia shows that messages of the toxicity of the chemicals contained in tobacco smoke have an impact on consumers.

Target audience

> Primary target audience is all consumers.

Likely effectiveness of the warning

- ➤ The warning message is a replacement for the current message (smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide). The statement of "Tobacco smoke contains highly toxic chemical" will be much simpler for consumers to understand, especially people with lower education levels, compared to a list of four chemicals.
- ➤ In addition, inclusion of the words 'highly toxic' will further increase the effectiveness of the message.

OVERALL CONCLUSIONS AND RECOMMENDATIONS

Main findings and overall conclusions

Scientific knowledge on health labelling generally

• Consumers usually examine packaging in a systematic way, looking at the elements in order of visual dominance. Warning labels are more effective if they systematically address key behaviour processes – attention, reading, comprehension, recall, judgement, behaviour compliance.

Scientific knowledge on the effect / impact of tobacco warning labels on consumers

- There is clear evidence that tobacco package health warnings increase consumers' knowledge about the health consequences of tobacco use and contribute to changing consumer's attitudes towards tobacco use as well as changing consumers' behaviour. They are also a critical element of an effective tobacco control policy.
 - Warnings have a high impact in educating consumers of the health risks of tobacco use
 - Warnings have a medium impact in changing smokers attitudes (in particular thinking about quitting and smoking in the presence of non-smokers)
 - Warnings have a medium impact in changing smokers' behaviour (including smoking less, smoking less around others, using quit lines, attempting to quit and quitting)

Principles of effective tobacco warning labels

- Combined pictorial + text warnings are significantly more effective than text only warnings, especially educating the public of the health risks and changing consumer behaviour. They are also more effective than text only in minimising 'wear out' over time.
- Fear inducing warnings (using strong 'shocking' images related to health risks) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings' effectiveness is enhanced if they are used in conjunction with advice on where to obtain help, e.g. a quit line.
- Many warning messages have universal appeal. However, developing messages that target specific consumer groups is also of value. Certain messages clearly have higher resonance with one target group and less resonance with others.
- The report provides detailed recommendations regarding the key design parameters and their optimum specification. The key parameters of importance are as follows:
 - > Size optimally 100% and at least 50% (excluding borders) of the total facial area.
 - Colour pictures used in all warnings together with short easily understood text messages that are clearly linked to the graphical image.
 - ➤ Location pictorial + text warnings should preferably be used on both sides, and as a minimum requirement on the front of packs.
 - The warning should be hung from the top of the pack to maximise visibility. For packs that have a front opening mechanism, front warning should be hung from the 'cut line' (to avoid the warning being severed when the package is opened).
 - ➤ Toll free quit line number on every pack ideally this should be separate from the warning to avoid reducing the size (and impact) of the pictorial within the warning.
 - ➤ Plain packaging using an unattractive standardised colour with the removal of logos / brand images and associated colours, with brand names in a standardised colour (black) and font size.

Inserts that contain information on the immediate health benefits of quitting as well as advice on how to quit and details of the quit line number could also be considered.

• The warnings should be optimally split into two sets and each set of warnings rotated ideally every 12 months (and maximum every 18 months) to minimise wear out effects.

SUGGESTED MIX OF WARNINGS			
SET 1 (years 1 and 3)	SET 2 (years 2 and 4)		
Smoking causes mouth and throat cancer	Smoking causes 9 out of 10 lung cancers		
Smoking causes leukaemia	Smoking doubles the risk of cervical cancer		
Smoking destroys your lungs	Smoking causes suffocating breathlessness for life		
Smoking causes strokes and severe disability	Smoking causes heart attacks		
Smoking causes blindness	Smoking causes leg amputations		
Smoking can kill your unborn child	Smoking causes rotten teeth and gums		
Your smoke harms your children, family and friends	If you smoke your children will smoke		
Smokers die younger	Quit now – stay alive for your children		
Stop smoking now your health benefits immediately	Get professional help – it makes it easier to quit		
Smoking reduces your sexual performance	Smoking makes it harder to have children		
Smoking reduces your sports performance	Smoking is severely addictive - don't start		
Tobacco smoke contains highly toxic chemicals	Smoking causes wrinkles		

• The optimum renewal period for the warning messages is broadly seen as every 2-5 years. If a rotation period of 12 months is adopted, then the warnings / images should be reviewed after 4 years (allowing each message to be used at least twice).

Scientific evidence of the health effects of tobacco use

• The research has identified over 30 different health risks where there is a proven causal link to direct tobacco use, including cancer diseases, non-cancerous respiratory diseases, cardiovascular diseases, reproductive diseases / pregnancy and other diseases. The research has also identified 7 health risks to adults and children where there is a proven causal link to passive smoking.

Proposed new warning messages

• 24 new warning messages have been developed, based on analysis of the scientific evidence, in-depth interviews and stakeholder feedback, which include health risk appeals, social appeals, cessation appeals and other miscellaneous messages. Some have universal resonance others have additional resonance with specific age groups / gender.

Summary - overall conclusions

The research has identified over 30 health risks for which there is a proven causal link and supported by evidence at two major International organisations – the US Surgeon General and IARC. Some of these risks are already well known, others will be new to consumers.

There is strong, conclusive evidence that pictorial warnings are significantly more effective than text only warnings. There is clear evidence that they have a strong impact in educating consumers about the health risks of tobacco use and stimulating discussion with family members and friends. They also have a positive impact in changing smokers' attitudes and behaviour (in particular not smoking around others, smoking less and trying to quit).

Fear inducing images (related to health risks) and strong emotion inducing images (especially children and unborn babies) is the most effective way to stimulate consumers to notice and read the associated text warning messages, which is enhanced if they are used in conjunction with advice on where to obtain help, e.g. a quit line, and plain packaging.

24 new health warnings are suggested, which include health risk appeal warnings, social appeal, cessation appeal and other messages. Many have universal resonance, some have particularly high resonance with specific age groups or gender.

Recommendations

The following set of recommendations for the future development of tobacco package health warnings are suggested, in order to <u>maximise</u> the effectiveness of the warnings' ability to educate consumers and influence attitudes and behaviour related to tobacco use. They are based on the research findings, and assume that the 24 proposed warnings (or variants of them following market testing) are adopted. The recommendations also take into account the guidelines issued in the context of the World Health Organisation Framework Convention on Tobacco Control, to avoid conflicting requirements. However, a step-by-step approach to developing the warnings is recommended (rather than implementing all the recommendations at once) to enable EC procedures to obtain commitments and agreements by EU Member States to adopt and implement the recommendations.

The recommendations, in approximate order of priority, are as follows:

- 1. Test the 24 proposed warnings, together with appropriate images, fine tune the wording (if required) and adopt them in place of the existing 14 messages.
 - ➤ Two general warnings should also be retained and used, but worded as follows a) Smoking kills; b) Smoking seriously harms other people.
- 2. Split the 24 warnings into 2 groups of 12 (with similar numbers of health risk / social appeal / cessation appeal / other messages) and rotate every 12-18 months.
- 3. Introduce mandatory quitline information on all warnings, preferably as a separate message independent of the main warning message.
- 4. Introduce mandatory pictorial warnings for all EU Member States, based on the optimum design criteria highlighted in the report. In particular:
 - The pictorials should be on both sides of the tobacco packaging. The pictorial on the front should cover 75% of the surface area and hang from the cut line for packs with hinged openings. The pictorial on the rear side should cover 100% of the surface area.
- 5. Introduce mandatory 6-sided packaging, the dimensions of which to be determined after further consultation to ensure warnings are of adequate size to be effective.
- 6. Develop a plain packaging strategy and mandate plain packaging on all tobacco products.

APPENDICES

Appendix 1 – References regarding effectiveness of health warnings

The research has identified 126 reports / publications / articles that were used as the basis of this section of the report. Details regarding title, source / name of author and date of publishing for each report can be found on the following pages.

References regarding how consumers look at packaging / labels

- A1. Package Design Magazine, article by Scott Young, June issue 2007.
- A2. Perception Research (<u>www.prsresearch.com</u>)

References regarding effectiveness of warning labels

- B1. Argo J, Main K. Meta-analyses of the effectiveness of warning labels, University of Alberta, USA, 2004
- B2. Mayer A, Boron J et al. Making sense of the warning literature, Georgia Institute of Technology, USA, 2007.
- B3. Wogalter M et al. Research based guidelines for warning design and evaluation, Department of Psychology, North Carolina State University.
- B4. Green M. Warning and warning labels, Visual Expert Human Factors.

References regarding labelling of foodstuff

- C1. European Public Health Alliance Food labelling in the EU purposes, principles and challenges, 2006.
- C2. EuroFIR Food labelling schools' resource (www.eurofir.net)
- C3. D. Mackison, A. Anderson and W. Wrieden, Dundee University A Review of consumer use and understanding of nutrition information on food labels 2008.
- C4. European Commission Survey in 28 countries on consumer attitudes and expectations about labelling 2005
- C5. Various research projects carried out or commissioned by the UK Food Standards Agency. (Signpost Labelling Research 2005, Nutritional Labelling Research 2001, Qualitative Research into Food Labelling 2007
- C6. Grunet (2006). A review of research on consumer response to nutrition information on food labels, European Food Information Council, Brussels (EUFIR).
- C7. Drichoutis et al (2006). Consumers' use nutritional labels: a review of research studies and issues, Academy of Marketing Science Review, volume 2006, no6.
- C8. Cowburn G & Stockley L, 2005. Consumer understanding and use of nutrition labelling: a Systematic review. Public Health Nutrition 8 (1), 21-28
- C9. European Heart Network (2003). A systematic review of the research on consumer understanding of nutrition labelling, EHN, Brussels
- C10. Food Standard Agency, New Zealand, 2007. Final assessment report on food labelling
- C11. UK Faculty of Public Health A position statement on food labelling 2008

References about drug warning labels

- D1. European Commission, 2005. Guidelines on the packaging of medicinal products for human use.
- D2. Consumer Health Information Corporation, USA, 2007 A Warning about prescription drug warning labels.
- D3. Franklin, Deborah. "The Consumer: And Now, a Warning About Labels." The New York Times online: October 2005.
- D4. National Patient Safety Agency, UK, 2007 "A guide to the graphic design of medication packaging / labelling.

References regarding alcohol warning labels

E1. European Alcohol Policy Alliance (EUROCARE), Belgium – Overview of labelling and key documents (2008).

- E2. International Center for Alcohol Policies (ICAP). ICAP Reports 3 (1997): Health Warning Labels. Washington, DC: ICAP. Update 2007.
- E3. World Health Organisation, Geneva 2004 Global Status Report Alcohol Policy
- E4. Dr. Douglas Carrie, University of Auckland Advances in the development and Testing of Alcohol labels, 2008.
- E5. Centre for Addiction Issues (DHS), Germany. Consumer labelling and alcoholic drinks (2008) (study commissioned by European Commission).
- E6. Centre for Addiction Issues, Germany. Pathway for Health Project (PHP) Ongoing project to improve and foster the exchange of programmes and good practice in binge drinking, drink driving and consumer information and labelling of alcohol beverages.
- E7. International Centre for Alcohol Policies, Washington, DC, USA Health warning requirements in labelling and advertising (2007).
- E8. Stockwell T, Centre for Addiction Research, University of Victoria, Canada 2006. A review of research into the impacts of alcohol warning labels on attitudes and behaviour.
- E9. Institute of Alcohol Studies, London, 2006. Alcohol in Europe (study commissioned by European Commission).
- E10. Ingrid Vanhaevre, Research and Information Centre for Consumer Organisations (CRIOC), Belgium Health Warnings and Labelling, 2006.
- E11. Alcohol Healthwatch, New Zealand, 2003 Alcohol Health and Safety Advisory Statements (Warning Labels) in New Zealand.
- E12. Centre for Addiction and Mental Health, Canada, 2001 Guidelines for effective alcohol warning labels.
- E13. McKinnon D, Nohre L et al (2000), Department of Psychology, Arizona State University. The alcohol warning on adolescents: 5 year effect.
- E14. Greenfield, T., Graves, K. and Kaskutas, L. (1999). Long-term effects of alcohol warning labels: Findings from a comparison of the United States and Ontario, Canada. Psychology & Marketing, Vol 16(3), 261-282.
- E15. Greenfield, T.K. (1997). Warning labels: Evidence on harm reduction from long-term American surveys. In M. Plant, E. Single & T. Stockwell (Eds.), *Alcohol: Minimising the Harm. What Works?* (pp. 105-125). New York, NY: Free Association Books, Ltd.

References regarding tobacco warning labels

- F1. Framework Convention Alliance (2008) Switzerland. Framework Convention on Tobacco Control (FCTC), Article 11 Fact sheet.
- F2. World Health Organisation (2008) Switzerland. Mpower A policy package to reverse the tobacco epidemic.
- F3. Canadian Cancer Research Society. Cigarette package health warnings an international status report (2008).
- F4. European Network for Smoking Prevention (ENSP). Overview of the textual and combined warnings on tobacco products (2008).
- F5. Hammond D (2008), University of Waterloo, Canada. Health warnings on tobacco packages. Summery of evidence and legal challenges.
- F6. Environics Research Group, Canada (2001 to 2006. The health effects of tobacco and health warning messages on cigarette packages surveys on adults and adult smokers. Wave 1 to Wave 12 surveys prepared for Health Canada.
- F7. Silpasuwan P, Faculty of Public Health, Thailand (2008). Potential effectiveness of tobacco health warning labels among employees in Thailand.
- F8. Office of Tobacco Control, Ireland (2008). Graphic Warning Research.
- F9. IAE, France (2008). New European Tobacco graphic warnings: effect on French people.
- F10. Research voor Beleid, Netherlands (2007). Colour photos on tobacco packages, experience in other countries. Investigation on behalf of the Ministry of Health, Welfare & Sport.
- F11. O'Hegarty M et al, Centre for Disease Control and Prevention, Atlanta (2007). Young adults' Perceptions of Cigarette Warning Labels in the United States and Canada.
- F12. Brown J et al, University of California (2007). Tobacco Control Worth more than a thousand words.
- F13. Health Improvement Directorate, London, UK (2007). The introduction of picture warnings on tobacco packs Final Regulatory Impact Assessment.
- F14. Department of Health, London, UK (2007). Consultation on the introduction of picture warnings on tobacco packs.

- F15. Hammond D, University of Waterloo, Canada (2007). FCTC Article 11 Tobacco Packaging and Labelling: A review of evidence.
- F16. Hammond D et al (2007). Text and graphics warnings on cigarette packages. Findings from the International Tobacco Control Four Country Study.
- F17. Thrasher F et al (2007). Smokers' reaction to cigarette warnings with graphic imagery and with only text: a comparison between Mexico and Canada.
- F18. Institute for Therapy Research, Munich (2007). Literature review regarding effectiveness of health warnings on cigarette packets.
- F19. IPSOS survey, Belgium 2007. Effectiveness of picture warnings on behalf of the Belgium Cancer Foundation.
- F20. Ministry of Health, Romania (2007). Conclusions of the public consultation carried out via internet on the images to be used in combined warnings on tobacco packages
- F21. Hammond D et al. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Control (ITC) Four Country Survey. Tobacco Control 2006:15.19-25
- F22. Etter JF, Institute of Social and Preventative Medicine, Switzerland (2206). Informing smokers on additives in cigarettes: A randomised trial.
- F23. Heather C et al, School of Medicine Indiana University (2006). Perceived believability among adolescents of health warning labels on cigarette packs.
- F24. Siapush M et al, Centre for Behavioural Research in Cancer, Australia (2006). Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke.
- F25. O'Hegarty M et al. Reactions of young adult smokers to warning labels on cigarette packages. AM J Prev med 2006 Ju:30(6):467-73.
- F26. Poetschke-Langer M, & Schulze A, (2005). Warnhinweise auf Zigarettenschachteln. Bundesgesundheitsblatt, 48,464-468.
- F27. Willemsen et al, (2005). The new EU cigarette health warnings benefit smokers who want to quit the habit: results from the Dutch continuous survey of smoking habits.
- F28. Koval J et al, University of Western Ontario (2005). The potential effectiveness of warning labels on cigarette packages, the perception of young adult Canadians.
- F29. Cancer Research UK, Centre for Tobacco Control Research, University of Sterling, UK (2005). Targeting smokers via tobacco product labelling: A pan European survey looking at opportunities and challenges for health promotion.
- F30. Clemenger BBDO, New Zealand 2005. Marketing input to assist the development of the health warnings for tobacco packages. Report for the Ministry of Health.
- F31. BRC Marketing & Social Research. Smoking health warning study: the effectiveness of different pictorial health warnings in helping people consider their smoking related behaviour. Prepared for the New Zealand Ministry of Health (2004).
- F32. BRC Marketing & Social Research. Smoking health warnings Stage 2. Optimising smoking health warning text graphics, size and colour testing. Prepared for the New Zealand Ministry of Health; August 2004.
- F33. Synovate Research (2004). Technical and scientific report regarding the follow up of the decision on colour pictures used as additional health warnings on packages of tobacco products. Prepared for the European Commission.
- F34. Gospodinov N et al, Concordia University, Montreal (2004). Global health warnings on tobacco packaging: Evidence from the Canadian experiment.
- F35. Hammond D at al (2004). Graphic Canadian cigarette warning labels and adverse outcomes: Evidence from Canadian Smokers.
- F36. Hammond D et al (2004). The impact of cigarette warning labels and smoke free bylaws on smoking cessation: evidence from former smokers.
- F37. Levy D et al, Journal of public health Management & Practice. 10(4):338-353, July/August 2004. The effects of tobacco control policies on smoking rates: A tobacco control scorecard.
- F38. Mahood G, Tobacco Free Initiative, World Health Organisation (2003). Canada's tobacco package label warning system: "Telling the truth" about tobacco product risk.
- F39. Strahan EJ et al (2002), Enhancing the effectiveness of tobacco warning labels: a social psychological perspective.
- F40. Wakefield M et al (2002). The cigarette pack as image: new evidence from tobacco industry documents.
- F41. Crawford M A et al (2002), University of Alabama. Responses to tobacco control policies among young.

- F42. Willemsen MC et al. Impact of the new EU health warnings on the Dutch quite line. Tobacco Control 2002. 11:382.
- F43. Jha P, Paccaud F, Nguyen S (2000), University of Illinois of Chicago. Tobacco control in developing countries,
- F44. Environics Research Group. Testing new health warnings messages for cigarette packages: A summary of three phases of focus group research: Prepared for Health Canada 2000.
- F45. Cummings et al, Are smokers adequately informed about the health risk of smoking and medicinal nicotine. Society for Research on Nicotine and Tobacco 2004.
- F46. Impact of graphic art—smoking photos burning out. Canwest News Service July 2008 (extract from new poll carried out by Environics.)
- F47. Goldberg M et al. Ministry of Health Canada (1995). When packaging can't speak: possible impact of plain packaging of tobacco products.
- F48. Beede et al, University of Otago, New Zealand (1992). The promotional impact of cigarette packaging, a study of adolescent response to cigarette plain packaging.
- F49. Rootman I et al, Addiction Research Foundation: A study on youth smoking plain packaging, health warnings, event marketing and price reductions (1995).
- F50. Willemsen MC. The altered view of tobacco products. The effects of the new health warnings on smokers. DEFACTO, the Hague, Netherlands 2002.
- F51. Willemsen MC. The new EU cigarette health warnings benefit smokers who want to quit the habit: results from the Dutch Continuous Survey of Smoking Habits. Eur J Public Health. 2005 Aug; 15(4):389-92.
- F52. Istituto Superiore di Sanità, Roma, Italy (2006) Dr. Mirella Taranto "Smoking: even more Italians are abbaonding the habit, especially aongst women. However, the cigarette still fascincates young poeple".
- F53. Universidad Nacional Education a Distancia, Madrid, Sapin. El periodico Mediterraneo Conscience raising in the war against the cigarete. "Only 37% of smokers read the antitobacco texts on the packets" 28/05/2007 ANTONIO M. YAGÜE.
- F54. Avoidance of smoking: the impact of warning labels in Brazil. Nascimento BE, Oliveira L, Vieira AS, Joffily M, Gleiser S, Pereira MG, Cavalcante T, Volchan E. Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brazil (2005).
- F55. Joossens L, Report on the effects of health warnings on cigarette packets in Belgium, Vlaams Instituut voor Gezondheidspromotie, Brussel, 2004.
- F56. Witold Zatonski, Democracy and Health: Tobacco Control in Poland. (Zatonski, Przewosniak and Prebski 2000).
- F57. Instituto Datafolha, Brazil, Report April 2002. Source Rev.Psiq. Clin. 32 5; 2005 Tobacco Control in Brazil: Advances and Challenges, Tania Maria Cavalcante.
- F58. Tobacco Control in Brazil: Advances and Challenges, Tania Maria Cavalcante. Source Rev.Psiq. Clin. 32 5; 2005
- F59. Avoidance of smoking: the impact of warning labels in Brazil. Nascimento BE, Oliveira L, Vieira AS, Joffily M, Gleiser S, Pereira MG, Cavalcante T, Volchan E. Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brazil.
- F60. Flash Eurobarometer, European Commission (2008)
- F61. SIRUS, Norway (2004). Evaluation of the effectiveness of the new health warning format approved in the autumn 2003.
- F62. Cancer Research UK (2005). Targeting smokers with tobacco warning labels opportunities and challenges for Pan European health promotion.
- F63. K Gallopel et al (2002) Impact of health warning messages in the fight against tobacco usage.
- F64. H. Krebs at al, University Zurich, Tabakmonitoring Swiss survey on tobacco consumption.
- F65. Elliot & Shanahan Research, Australia (2002 / 2003). Development research for new Australian health warnings on tobacco products. Stages 1 and 2.
- F66. G Beroggi et al (2005). Effectiveness of warning messages amongst you people.
- F67. TNS mrbi / 175967 / Graphic Warning Research (2008), Ireland
- F68. IFT, Munich (2007). Literature review on the effectiveness of warning messages on cigarette packages.
- F69. C Jansen et al. Radboud University, Holland (2005). The scarier, the better? Effects of adding images to verbal warnings on cigarette packages.
- F70. Hammond D (2007). Plain packaging and misleading information a review of evidence.
- F71. Freeman B et al, University of Sidney (2008). The case for the plain packaging of tobacco products a review of evidence.

- F72. Moradi P et al (2007). Teenagers' perceptions of blindness related to smoking: a novel message to a vulnerable group.
- F73. Pacifici R, OSSFAD, Istituto Superiore di Sanita (2006). Rapporto nazionale sul fumo.
- F74 Instituto Nacional de Cancer (2008). Brazil Health warnings on tobacco products 2009.
- F75. Nascimento B, et al (2008). Avoidance of smoking: the impact of warning labels in Brazil.
- F76 Ministério da Saúde. Secretaria de Vigilância em Saúde. Instituto Nacional de Câncer. Inquérito domiciliar sobre comportamentos de risco e morbidade referida de doenças e agravos não transmissíveis. Brasil, INCA; 2004
- F77 Crespo et al, Cognitive processing and assessment of anti smoking combined warning labels proposed by the European Commission.: An empirical study with a Spanish sample, 2007.
- F78 Vardavas et al, (2009). Adolescents perceived effectiveness of the proposed European graphic warning labels.
- F79 Hoek J et al, Massey University (2006). Effects of cigarette on-pack warning labels on smokers' reception and behaviour.
- F80. Ministry of Health, Bulgaria (2008). Most effective pictures out of 42 images web based survey.
- F81. Createc report prepared for Health Canada (2008). Effects of modified packaging through increasing the size of warnings on cigarette packs. Quantitative study of Canadian youth smokers and vulnerable non-smokers.
- F82. Createc report prepared for Health Canada (2008). Effects of modified packaging through increasing the size of warnings on cigarette packs. Quantitative study of Canadian adult smokers.
- F83. Peters E et al, University of Oregon, USA (2007). The impact and acceptability of Canadian style cigarette warning labels among U.S. smokers and non-smokers.
- F84. Environics report prepared for Health Canada (2008). Consumer research on the size of health warning messages, quantitative study of Canadian youth.
- F85. Environics report prepared for Health Canada (2008). Consumer research on the size of health warning messages, quantitative study of Canadian adult smokers.
- F86 Ministry of Health, Romania (2008). Evaluation of the impact of (text only) health warnings.
- F87 Ministry of Health, Romania (2008). Evaluation of the impact of diverse control measures.
- F88 Fathelrahman A, et al (2009). Smokers' responses towards cigarette pack warning labels in predicting quit intention, stage of intent and self efficacy.
- F89 Hoog N, Stroebe W, de Wit J, (2007). The Impact of vulnerability to and severity of a health risk on processing and acceptance of fear arousing communications; a meta analysis.
- F90 Witold Zatonski (2002). Stigmatizing the cigarette pack by enlarged health warnings: Polish experience and results.
- F91 Wilquin J-L, French National Institute for Health Prevention (2006). Quantitative survey, the choice of one out of three images for each of the 14 tobacco health warnings.
- F92 Gallopel-Morvan K, et al (2008) The impact of visual health warnings and plain cigarette packaging on French people.
- French National Committee against tobacco (2009). An evaluation of the opportunity to use 'non-health' messages and tobacco pack inserts.
- F94 Shanahan and Elliott (2008). Evaluation of the effectiveness of the graphic health warnings on tobacco product packaging.

Appendix 2 – Evidence on effectiveness of tobacco health warning labels in general

Appendix 2 provides research evidence in the form of extracts from research relevant reports that have been identified and assessed.

i. Warning labels are effective at educating consumers of the health risks of tobacco use

• Consumers see health warnings as a credible source of information especially when the information is attributed to a well respected authority / organisation.

Evidence - Research report extracts:

Reference F31 – The effectiveness of different pictorial health warnings in helping people consider their smoking related behaviour.

"A survey carried out in the UK in 2004 (100 in-depth face to face interviews) found that the majority (63%) of respondents agreed or strongly agreed that the images and messages on cigarette packets would be more effective if associated with the Ministry of Health. Comments from those who agreed with the association said that it gave the message more credibility.

Reference F35 – Graphic Canadian cigarette warning labels and adverse outcomes: evidence from Canadian smokers.

"Based on a telephone survey amongst 616 adult smokers carried out in Canada in 2004 87% of respondents regarded the new graphic warnings as credible. This provides further evidence that government mandated cigarette warnings are seen as a credible source of health information."

 Most consumers have an imperfect understanding of the nature and magnitude of the risks of tobacco.

Evidence - Research report extracts:

Reference F11 – Young adults' perception of cigarette warning labels in the United States and Canada based on focus groups carried out in 2007.

"A survey based on 11 focus groups consisting of a total of 95 young US adults (54 smokers and 41 non smokers) aged 18 to 24 found that more than 50% of participants did not know about the smoking-stroke relationship. The majority of participants were unaware that smoking could cause impotence"

Reference F45 - Are smokers adequately informed about the health risk of smoking and medicinal nicotine.

"A survey of 1,046 smokers found that "the suggestion that the health risks of smoking are universally known and appreciated is clearly wrong". For example, 65% of smokers surveyed were misinformed about the harmful effects of low tar-cigarettes."

Reference F21 – Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the ITC four country survey.

"A telephone survey conducted in 2006 with 9058 adults smokers from the USA (n=2138), UK (n=2401), Canada (n=2214) and Australia (n=2305) found that 94.3% of smokers associated smoking with lung cancer, 88% associated smoking with heart disease but only 73% believed that smoking causes stroke and 70% believed that causes lung cancer amongst non-smokers. Only 41% of respondents agreed that smoking causes impotence."

Reference F72 –Moradi P et al (2007). Teenagers' perceptions of blindness related to smoking: a novel message to a vulnerable group.

"Based on survey of 260 teenagers, awareness of the risk of blindness from smoking is low amongst teenagers, but fear of blindness may be more likely to motivate teenagers to stop smoking than their fear of lung or heart disease."

• Tobacco health warnings can be effective in informing consumers about the health consequences of smoking. Large, prominent warnings are significantly more effective than more obscure warnings.

Research Report Extracts:

Reference F11 – Young adults' perception of cigarette warning labels in the United States and Canada based on focus groups carried out in 2007.

"A survey based on 11 focus groups consisting of a total of 95 young US adults (54 smokers and 41 non smokers) aged 18 to 24 found that participants considered Canadian cigarette warning labels (large pictorial warnings) as more visible, more credible and more informative than US cigarette warning labels (small warning located at the bottom of the package)."

Reference F16 – Text and graphic warnings on cigarette packages, findings from the international tobacco control four country study.

"Based on telephone surveys conducted with representative cohorts of adult smokers (n=14,975) in Canada (n=3687), United States (n=4273), UK (n=3634) and Australia (n=3381) between 2002 and 2005, findings strongly suggest that more prominent health warnings are associated with greater levels of awareness and perceived effectiveness among smokers"

Reference F31 – The effectiveness of different pictorial health warnings in helping people consider their smoking related behaviour.

"A survey carried out in the UK in 2004 (100 in-depth face to face interviews) revealed that respondents highlighted colour and bold text as hugely important design elements for effective tobacco health warnings."

Reference F55 – Bigger / clearer warnings motivate smokers to stop smoking in Belgium

"A survey in Belgium carried out in 2004 found that bigger and clearer warnings motivate smokers to stop smoking. It also found that it makes cigarette packs less attractive."

Reference F56 – the introduction of large clear warning proves to be effective in Poland

"A survey found that as a result of the introduction large clear warnings on cigarette packs in Poland 3% of smokers stopped smoking, 16% attempted to quit and another 16% are now more aware of the harm done by smoking."

Reference 60 – Flash Eurobarometer on tobacco

"A telephone survey carried out for the European Commission in 2008 amongst more than 26,500 randomly selected citizens aged 15 years and over in the 27 EU Member States and in Norway found that 1/3 of EU citizens thought that health warnings on cigarette packs were effective in informing them about the health effects of tobacco."

Reference F81 / F82 - Createc reports prepared for Health Canada (2007).

"A survey in 2007 showed that young and adult smokers are sensitive to the size of health warning messages and warning messages that cover 100% of the pack are significantly more effective across a range of effectiveness indicators that warning messages that cover only 50% of the pack."

Reference F84 / F85 - Environics reports prepared for Health Canada (2008).

"A survey of 2,000 adults and youths showed that warning messages that cover 100% of the pack are rated as the best option compared to messages that cover 50% or 75% of the pack. In addition, 78% of adult smokers and 87% of youth smokers say the current messages have been effective in informing them about the health effects of smoking"

Reference F87 - Evaluation of the impact of diverse control measures in Romania (2008)

"A survey in Romania involving 444 smokers found that following the introduction of combined text and picture warnings, smokers had higher recalls of a larger number of the specific health warnings."

 Health warnings on tobacco packages are among the most prominent source of health information.

Evidence - Research Report Extracts:

Reference F6 – The health effects of tobacco and health warning messages on cigarette packages, survey of adults, adult smokers and youth.

"Based on a telephone survey in 2006 amongst a nationally representative sample of Canadian adults and youths, nine in ten Canadians (90% adult smokers: 93% youth) say they have seen health warning messages on cigarette packages"

Reference F15 – Tobacco packaging and labelling: a review of evidence.

"Based on a review of evidence carried out by Hammond D in 2007 the vast majority of smokers report a general awareness of package health warnings (warning is delivered at each time of smoking and point of purchase). A considerable proportion of non-smokers also report awareness and knowledge of package health warnings."

Reference F21 – Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the ITC four country survey.

"A telephone survey conducted in 2006 with 9058 adults smokers from the USA (n=2138), UK (n=2401), Canada (n=2214) and Australia (n=2305) found that cigarette packages were a prominent source of health information in all four countries. In Canada and Australia it was the second most prominent source (behind TV). In the UK it was the third most prominent source (behind TV and magazine / newspapers and in the US it was the fourth most prominent behind TV, magazine / newspapers, posters)."

Reference F31 – The effectiveness of different pictorial health warnings in helping people consider their smoking related behaviour.

"A survey carried out in the UK in 2004 (100 in-depth face to face interviews) revealed that 60% of respondents regarded TV as an appropriate communication channel for tobacco health warnings and quit advice. Cigarette packages were seen as an appropriate channel by 50% of respondents."

ii. Tobacco package warnings are a critical element of a health risk publicity campaign

• There is considerable support from consumers for putting health warnings on tobacco packages.

Evidence - Research report extracts:

Reference F12 – Worth more than a thousand words: picture based tobacco warning labels and language rights in the US.

"A survey carried out in 2005 among 150 smokers in the area of San Francisco found that 89 percent of respondents supported health warnings on tobacco packaging including images and pictures.

Reference F17 – Smokers reaction to cigarette package warnings with graphic imagery and with only text: a comparison between Mexico and Canada.

"Based on a survey amongst 1,081 Mexican smokers in 2007 more than 80% want their cigarette packs to contain more information regarding the health effects of smoking than they currently contain."

Reference F31 – The effectiveness of different pictorial health warnings in helping people consider their smoking related behaviour.

"A survey carried out in the UK in 2004 (100 in-depth face to face interviews) revealed that 50% of respondents mentioned cigarette packs as an appropriate communication channel for health warnings".

Reference F57, F58 – There is considerable support for graphic warning images in Brazil.

"The Instituto Datafolha in Brazil commissioned research amongst 2,216 people over 18 years old in 126 municipalities. 77% of the non-smokers and 73% of smokers were in favour of the graphical images."

"The investigation (carried out by the "Disque Pare Fumar" service itself) involved 89,305 respondents, of which 80% were smokers. 92% of all the respondents support the introduction of graphic images, 79% said that the photographic warnings should be more shocking."

• Health warnings are a very cost effective public health intervention and have a high reach. A person that smokes a pack of cigarettes each day is potentially exposed to the warning over 7,000 times per year. Non smokers, including children and young adults are also exposed to the warnings.

Evidence - Research Report Extracts:

Reference F15 – Tobacco packaging and labelling: a review of evidence.

"Based on a review of evidence carried out by Hammond in 2007 the vast majority of smokers report a general awareness of package health warnings because the warnings are delivered at each time of smoking and at the point of purchase. A considerable proportion of non-smokers also report awareness and knowledge of package health warnings."

Reference F21 – Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the ITC four country survey.

"A telephone survey conducted in 2006 with 9058 adults smokers from the USA (n=2138), UK (n=2401), Canada (n=2214) and Australia (n=2305) found that health knowledge was significantly greater in countries with health warnings on tobacco packages, even after allowing for the number of other information sources cited by respondents."

• An effective tobacco package warning system is seen as a critical component of any comprehensive tobacco control strategy.

Evidence - Research report extracts:

Reference F34 – Global health warnings on tobacco packaging: evidence from the Canadian experiment.

"A review of evidence by Nikolay Gospodinov clearly shows that tobacco health warning messages on cigarette packages alone are not effective. Other policy measures that are seen as part of a comprehensive control strategy are education (more education and higher income

define individuals who are less likely to smoke) and price (high prices for tobacco products are associated with decline in smoking).

Reference F37 – The effects of tobacco control policies on smoking rates. A tobacco control scorecard.

"A review of studies carried out by David Levy in 2004 shows that the most successful campaigns have implemented a combination of tobacco control policies. Of those policies substantial evidence indicates that higher taxes and clean air laws can have a large impact on smoking rates. Evidence also indicates that media campaigns and tobacco warning labels on cigarette packets when implemented with other policies can be effective".

Reference F41 – Responses to tobacco control policies among youth in the USA.

"A survey amongst 785 respondents from across the USA carried out in 2002 revealed that teenagers were generally familiar with laws and rules about access and possession for minors, but believed them ineffective. They were knowledgeable about prices and reported that a sharp and sudden increase could lead them to adjust their smoking patterns but could also have negative consequences. They found a list of chemical names of cigarette ingredients largely meaningless, but believed that disclosing and publicising their common uses could be an effective deterrent, especially for those who were not yet smoking. They were aware of current warning labels, but considered them uninformative and irrelevant."

iii. Tobacco package warnings increase motivation to quit/undermine brand value/sales

• Tobacco health warnings increases motivation to quit and cessation behaviour. It can also act as a deterrent for new smokers.

Evidence - Research Report Extracts:

Reference F7 – Potential effectiveness of health warning labels among employees in Thailand.

"Based on a survey among 1,637 employees in workplaces from four regions the new health warning labels encourage smoking cessation. 3.8% reported to have stopped smoking after seeing the new pictorial health warning labels."

Reference F21 – Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the ITC four country survey.

"The research indicates that planning to quit smoking was positively associated with health knowledge. The odds of planning to quit were greater among smokers who endorsed each of the five diseases, and increased in linear fashion with the total number of health effects reported."

Reference F27 – The new cigarette health warnings benefit smokers who want to quit the habit; results from the Dutch continuous survey of smoking habits."

"Based on an omnibus internet survey among 3,937 Dutch adult smokers 14% of smokers became less inclined to purchase cigarettes because of the new warnings, 31.8% said they prefer to purchase a pack without the warnings, 17.9% reported that warnings increased their motivation to quit and 10.3% said they smoked less".

Reference F34 – Global health warnings on tobacco packaging: evidence from the Canadian experiment.

"Out of 2,031 respondents 62% noticed a change in packaging. 33% felt that they consequently knew either a lot or a little more about the health consequences of smoking. A similar percentage of respondents indicated that they were more concerned about the consequences of smoking. 18% of respondents said that they smoked less because of the new health warnings. 14% of respondents said that the new warning messages were a major factor in their most recent attempt to quit."

Reference F50 - Williemsen MC. The altered view of tobacco products. The effects of the new health warnings on smokers. DEFACTO, The Hague, Netherlands 2002.

"A survey of 8.836 people aged 15 and older in the Netherlands in 2002 found that 16% of smokers surveyed said that the new, larger health warnings made them more motivated to quit. Among smokers who intended to quit at some point the percentage was 28%. 9% of smokers reported that they were already smoking less because of the health warnings."

Reference F57, F58 – There is considerable support for graphic warning images in Brazil.

"The Instituto Datafolha in Brazil commissioned research amongst 2,216 people over 18 years old in 126 municipalities. 67% of the smokers claimed they felt the desire to give up smoking, and 73% of people with low income said they felt the desire to give up smoking, having seen the photographs on the cigarette packages."

Reference F79 Hoek J et al, Massey University (2006). Effects of cigarette on-pack warning labels on smokers' reception and behaviour

"Based on a sample of 310 smokers in New Zealand who rated 2 warnings with text only compared to text with a strong graphical image, the pictorial warnings were more effective than the text only in influencing future behaviour, including discouraging non smokers, reducing consumption and quitting altogether."

Reference F84 / F85 - Environics reports prepared for Health Canada (2008).

"A survey of 2,000 adults and youths in 2008 showed 52% of adults smokers and 41% of youth smokers say the current warnings have been effective in getting them to smoke less around others, 52% adults / 55% youths say they have been effective in increasing their desire to quit and 44% adults / 52% youths say they have been effective in getting them to try to quit."

Reference F55 – Bigger / clearer warnings motivate smokers to stop smoking in Belgium

"A survey in Belgium carried out in 2004 found 29% of respondents agreed that the new health warnings provide additional motivation to quit smoking and 8% of smokers said they now smoke less."

Reference F87 - Evaluation of the impact of diverse control measures in Romania (2008).

"A survey in Romania involving 444 smokers found that 21.4% said that having seen the information on tobacco packages they had tried to quit and 27.9% said they had reduced the number of cigarettes they smoke each day."

 Health warnings help to make tobacco packages and the package displays at retail outlets to look less attractive. This clearly undermines its ability to communicate brand value and helps to reduce sales of cigarettes.

Evidence - Research report extracts:

Reference F19 - Effectiveness of different picture warnings in Belgium

"As part of a survey carried out by IPSOS in 2007 (face to face interviews at home amongst representative sample of population) on behalf of the Belgium Cancer Foundation 1,194 people were asked to comment about the new picture warnings. 38% of all respondents said that the new pictorial health warnings make the cigarette packs look less attractive."

Reference F27 – The new cigarette health warnings benefit smokers who want to quit the habit; results from the Dutch continuous survey of smoking habits."

"This representative study amongst 3937 Dutch adults showed that the new health warnings made cigarette packs less attractive, especially to smokers who already intended to stop smoking."

Reference F40 – the cigarette pack as image: new evidence from tobacco industry documents.

"A review of tobacco company documents reveals that, especially in the context of tighter restrictions on conventional avenues for tobacco marketing, tobacco companies view cigarette packaging as an integral and important component of marketing strategy. In particular they see it as a vehicle for creating a significant in-store presence at the point of purchase and use it for communicating brand image. Health warnings on tobacco packages are an effective tool to reduce the attractiveness of the package."

Reference F9 – New European tobacco graphic warnings: effects on French people.

"Respondents participating in six focus groups conducted in France (Rennes, Paris and Brest) in 2007 found that when comparing different packs of cigarettes with different warning formats, the pack of Marlboro with visual warnings was judged less attractive than the current Marlboro pack with two textual warnings only."

iv. Targeting specific consumer groups enhances the effectiveness of warning messages

The main groups that are likely to benefit most from tobacco warning labels on cigarette
packets are smokers who are contemplating quitting and young people experimenting with
smoking.

Evidence - Research report extracts:

Reference F19 - Effectiveness of different picture warnings in Belgium

"As part of a survey carried out by IPSOS in 2007 (face to face interviews at home amongst representative sample of population) on behalf of the Belgium Cancer Foundation 1,194 people were asked to comment about the new picture warnings. The result showed that 38% of young adults (15 to 24 years old) saw the picture warnings as an additional motivation factor to try to stop smoking only 17% of people aged between 45 and 64 saw it as an additional motivation. In addition, 43% of people with plans to quit the habit considered the new picture as an additional motivation factor but only 17% of dedicated smokers considered them to be a motivation to stop."

Reference F27 – The new cigarette health warnings benefit smokers who want to quit the habit; results from the Dutch continuous survey of smoking habits."

"This representative study amongst 3,937 Dutch adults showed that the new health warnings made cigarette packs less attractive, especially to smokers who already intended to stop smoking."

Reference F29 – Targeting smokers via tobacco product labelling: opportunities and challenges for pan European health promotion.

"According to the results of 56 focus groups carried out across seven countries (Finland, France, Germany, Greece, Spain, Sweden and the UK) with 27-64 year old smokers participants felt that the new health warnings would be most effective with young people by deterring them from starting".

Reference F23 – Perceived believability among adolescents of health warning labels on cigarette packs.

"A survey amongst 691 students in grades 5 to 12 carried out in the US in 2006 revealed that young smokers are less likely to accept specific health risk associated with smoking than young non-smokers."

Reference 60 – Flash Eurobarometer on tobacco

"A telephone survey carried out for the European Commission in 2008 amongst more than 26,500 randomly selected citizens aged 15 years and over in the 27 EU Member States and in

Norway found that younger respondents, the less educated respondents and manual workers across all groups (those who had never smoked, former smokers and current smokers) appeared slightly more likely to perceive health warnings on tobacco packs as being effective."

• In order to be effective health warnings need to be tailored to particular user groups and they should take into account cultural sensitivities.

Evidence - Research report extracts:

Reference F28 – The potential effectiveness of warning labels of cigarette packages: the perceptions of young adult Canadians.

"A survey amongst 1,267 young Canadian adults between 20 and 24 concluded that current warning labels need to be modified to target issues that are relevant to young adults; gender differences are also important in this modification."

Reference F29 – Targeting smokers via tobacco product labelling: opportunities and challenges for pan European health promotion.

"According to the results of 56 focus groups carried out across seven countries (Finland, France, Germany, Greece, Spain, Sweden and the UK) with 27-64 year old smokers participants felt that targeting warning messages was essential. In terms of age, there were differences between younger and older smokers' information needs. Younger respondents found the short-term health and cosmetic effects more salient, while older smokers are more concerned with illness and premature aging.

"In particular, respondents in Southern Europe were less receptive to all the messages, and especially those addressing less familiar concepts such as passive smoking."

Reference 60 - Flash Eurobarometer on tobacco

"A telephone survey carried out for the European Commission in 2008 amongst more than 26,500 randomly selected citizens aged 15 years and over in the 27 EU Member States and Norway found that respondents in Romania, Ireland, the UK and Lithuania perceived health messages as being more effective than their counterparts in the other Member States.

v. Other factors that can enhance the impact of the warnings

• Health warnings must be regularly rotated and updated to maintain maximum impact and reduce "wear out.

Evidence - Research Report Extracts:

Reference F16 - Text and graphic warnings on cigarette packages, findings from the international tobacco control four country study.

"According to a telephone survey conducted with representative cohorts of adult smokers (n=14,975) in Canada (n=3687), United States (n=4273), UK (n=3634) and Australia (n=3381) between 2002 and 2005 the findings highlight the "novelty" effect of health warnings and the importance of periodically revising the warnings on cigarette packages. The enhanced UK warnings were considerably more likely to be noticed than the Australian warnings which are only slightly smaller but have been in place for more than 8 years. Health warnings which were last updated in 1984, were associated with the least effectiveness."

Reference F29 – Targeting smokers via tobacco product labelling: opportunities and challenges for pan European health promotion.

"When presented with the packs incorporating the old style, very few respondents in any of the countries spontaneously mentioned the messages, even when looking at and describing the

pack. When shown a pack with the new more prominent message format the health warning was generally the first aspect of the pack mentioned."

Reference F38 – Canada's tobacco Package label of warning system: Telling the truth about Tobacco product risks.

"A review of evidence on the Canadian experience carried out in 2003 by the Smoking and Health Action Foundation has shown that warning labels become stale with passage of time. To address problems related to wear out warnings have to be refreshed."

Reference F10 – Impact of graphic anti smoking photos burning out.

"Over the last five years, the percentage of smokers who say the warnings are ineffective at getting them to try to kick the habit has increased. 57% of respondents said that they were unmoved by these graphic images, up 5% from five years earlier. Among potential quitters—smokers who are seriously thinking of quitting—the percentage who characterised the campaign as not very effective or not at all effective in getting them to try to quit has also increased in this period, to 43% from 40%."

• Health warnings that include information on cessation services, such as a toll-free telephone "quitline" number, have a significant impact on the use of these services and represent a low cost method of promoting cessation and supporting efforts to change.

Evidence - Research report extracts:

Reference F37 – The effects of tobacco control policies on smoking rates. A tobacco control scorecard.

"A review of studies carried out by David Levy in 2004 has revealed that greater access to treatment and telephone support hotlines indicates a strong potential to increase quit rates."

Reference F43 - Impact of the new EU health warnings on the Dutch quit line.

"On 1 May 2002, the new health warnings on cigarette packaging came into effect in the Netherlands. The warning included the telephone number of the Dutch quit line. As a result the number of calls to the quit line increased significantly."

Reference F58 – There is considerable support for pictorial warnings in Brazil.

"The investigation (carried out by the "Disque Pare Fumar" service itself) involved 89,305 respondents, of which 80% were smokers. 90% gained knowledge of the telephone number for "Disque Pare Fumar – Stop Smoking Helpline Service" on the packets. Since the "Stop Smoking Helpline Service" telephone number appeared on tobacco product packets, the number of calls increased by 300%."

• The introduction of plain packaging would reduce positive brand imagery, strengthen the health warning.

Evidence - Research report extracts:

Reference F47 – Ministry of Health Canada (1995). When packaging can't speak: possible impact of plain packaging of tobacco products.

"Warning on plain white packages may be more effective in getting attention and enhancing recall than warning on regular packages. Responses to different messages varied however. Recall of 2 starker, briefer and more direct messages was enhanced by the plain packaging, but recall of a more technical, longer and vaguer message was not."

Reference F48 – Beede et al, University of Otago, New Zealand (1992). The promotional impact of cigarette packaging. A Study of adolescent response to cigarette plain packaging.

"A substantial proportion of adolescents believed that plain packaging would greatly impact on the prevention of trial and initiation of smoking behaviour, and that fewer adolescents overall would smoke if cigarettes were sold only in plain packages.

Reference F49 – Rootman I et al, Addiction Research Foundation: A study on youth smoking – plain packaging, health warnings, event marketing and price reductions (1995). "Plain packages were described as "boring", "unattractive" and "cheap looking"; several smokers indicated that they would not buy plain packages."

Reference F84 / F85 - Environics reports prepared for Health Canada (2008).

"A survey of 2,000 adults and youths in 2008 showed that plain packaging is seen by around 50% of both adult and youth respondents in Canada as being more effective than branded packs in informing people about the health effects of smoking as well as encouraging smokers to reduce their tobacco use."

Appendix 3 – Evidence of effectiveness of pictorial warnings versus text only

Appendix 3 provides research evidence in the form of short extracts from identified research reports on the effectiveness of pictorial warnings versus text only.

Pictorial warnings are more effective at educating the public about the health risks

• Pictorial warnings are more likely to be noticed and read than text-only warnings including by non-smokers. Picture warning are more effective in increasing awareness and recall of the health effect from tobacco. It encourages individuals to imagine health consequences.

Evidence - Research report extracts:

Reference F17 – Smokers reaction to cigarette package warnings with graphic imagery and with only text: a comparison between Mexico and Canada.

"A survey amongst 1,081 Mexican smokers and 751 Canadian smokers carried out in 2007 demonstrated that consumers exposed to graphic warning messages have a higher warning label salience (i.e. noticing labels & processing label message). The results are consistent with other studies that indicate that cigarette packages whose warning labels contain prominent graphic imagery are more likely than text only warnings to promote smoking related knowledge and smoking cessation"

Reference F25 – Reactions of young adult smokers to warning labels on cigarette packages.

"A survey carried out in the USA in 2003 amongst 763 young adults between the ages of 18 and 24 (572 smokers / 191 non –smokers) revealed that both current and former smokers thought that cigarette warning labels with text plus graphics were substantially more of a deterrent than text only labels. The perceived effectiveness of these labels was not only higher overall, but also for the specific areas of smoking related health effects, prevention, cessation and maintenance of abstinence."

Reference 60 - Flash Eurobarometer on tobacco

"A telephone survey carried out for the European Commission in 2008 amongst more than 26,500 randomly selected citizens aged 15 years and over in the 27 EU Member States and in Norway found that adding a colour picture to text only health warnings, illustrating the health hazards of smoking, was perceived as being effective by 55% of EU citizens (20% said this would be very affective and 35% thought it would be somewhat effective."

Reference F84 / F85 - Environics reports prepared for Health Canada (2008).

"A survey of 2,000 adults and youths in 2008 found that 78% of adult smokers and 87% of youth smokers say that the current (text and pictorial) messages have been effective in informing them about the health affects of smoking"

Reference F86/87 - Evaluation of the impact of diverse control measures in Romania (2008).

"A survey in Romania involving 444 smokers found that following the introduction of combined text and picture warnings, 49% of smokers recall the text on cigarette packets, compared to 42% that were surveyed prior to the introduction of pictorial warnings."

• Pictorial warnings are important for reaching low-literacy smokers and children and they are also essential in countries with multiple languages. Pictorial messages are a key tool to help to reduce disparities in health knowledge amongst the population.

Evidence - Research Report Extracts:

Reference F12 – Worth more than a thousand words: picture based tobacco warning labels and language rights in the US.

"A survey carried out in 2005 among 150 smokers in the area of San Francisco found that 97% of ethic minorities (Spanish and Chinese speaking people) said that they did not know or could not understand the meaning of the warning label when given a leaflet with all four Surgeon General Warnings".

Reference F24 – Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: result from the 2002 ITC four country survey."

"Based on the results from the International Tobacco Control study which surveyed more than 9,000 adult smokers from four countries (Canada, USA, UK, Australia) higher education and income were associated with higher awareness. For example, the odds of knowing that smoking causes heart disease, stroke and lung cancer were respectively 71%, 34% and 83% larger for respondents with high versus low income. The odds of knowing that smoke contains cyanide, mercury, arsenic and carbon monoxide were respectively 66%, 26%, 44% and 108% larger for respondents with a university degree than those with a high school diploma or lower level of education"

• Consumers based in countries that have introduced graphic tobacco health warnings have a greater knowledge on the health effects of smoking.

Evidence – Research report extracts

Reference F21 – Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the ITC four country survey.

"Smokers in the four countries (Australia, Canada, UK and USA) exhibited differences in their knowledge of the risks of smoking. For example smokers in Canada and Australia which were exposed to large pictorial warnings had a better knowledge about the health effects of smoking than smokers in the UK and the USA which were exposed to text only warning messages."

Reference F87 - Evaluation of the impact of diverse control measures in Romania (2008).

"A survey in Romania involving 444 smokers found that following the introduction of combined text and picture warnings, smokers remembered more of the specific health messages."

• Picture warnings are more likely to encourage discussion about the health effects of tobacco use.

Evidence - Research report extracts:

Reference F35 – Graphic Canadian cigarette warning labels and adverse outcomes: evidence from Canadian smokers.

"A survey amongst 622 adult smokers living in Ontario reported that graphic images encourage them to discuss the health effects of smoking with others (friends and family)."

Reference F87 - Evaluation of the impact of diverse control measures in Romania (2008).

"A survey in Romania involving 444 smokers found that following the introduction of combined text and picture warnings, 63% of smokers had discussed the warnings with others compared to 57% prior to the introduction of pictorial warnings."

• Fear inducing pictures of disease and emotionally arousing pictures are more effective and more likely to be recalled.

Evidence - Research report extracts:

Reference F31 – The effectiveness of different pictorial health warnings in helping people consider their smoking related behaviour.

"A survey carried out in the New Zealand in 2004 (100 in-depth face to face interviews) clearly demonstrated the power of visual images as a primary hook. The effectiveness can be further strengthened by appropriate accompanying text. For example the research has shown that the word "highly" in a warning message makes it a stronger more effective message.

"It was primarily visuals that respondents felt were the most effective when communicating warnings about smoking to the general public. Graphic images with shock factor were often referred to as being effective, whether they feature on televisions, cigarette packets or posters."

"The same survey also revealed that it was primarily visuals that respondents felt were the most effective when communicating warnings about smoking to the general public. Graphic images with shock factor were often referred to as being effective, whether they feature on televisions, cigarette packets or posters."

Reference F87 - Evaluation of the impact of diverse control measures in Romania (2008).

"A survey in Romania involving 444 smokers found that following the introduction of combined text and picture warnings five of the six most frequently recalled images were those that had strong (shocking) images, and five of these images were also the most highly rated in the prepictorial public consultation exercise."

Pictorial warnings are more effective in changing consumer behaviour

• Picture warnings are more effective in changing consumer behaviour (reduce consumption levels, motivation to quit, likelihood of remaining abstinent following a quit attempt etc).

Evidence - Research report extracts:

Reference F25 – Reactions of young adult smokers to warning labels on cigarette packages.

"A survey carried out in the USA in 2003 amongst 763 young adults between the ages of 18 and 24 (572 smokers / 191 non –smokers) revealed that both current and former smokers thought that cigarette warning labels with text plus graphics were substantially more of a deterrent than text only labels. The perceived effectiveness of these labels was not only higher overall, but also for the specific areas of smoking related health effects, prevention, cessation and maintenance of abstinence."

Reference F35 – Graphic Canadian cigarette warning labels and adverse outcomes: evidence from Canadian smokers.

"A survey amongst 622 adult smokers living in Ontario revealed that smokers who reported greater fear and disgust were significantly more likely to have quit, made an attempt to quit or reduced their smoking."

Reference F79 Hoek J et al, Massey University (2006). Effects of cigarette on-pack warning labels on smokers' reception and behaviour

"Based on a sample of 310 smokers in New Zealand. The warnings that combined image plus text received significantly higher scores than the text only messages for credibility and effectiveness, and were also more effective than the text only in influencing future behaviour, including discouraging non smokers, reducing consumption and quitting altogether."

Reference F86/87 - Evaluation of the impact of diverse control measures in Romania (2008).

"A survey in Romania involving 444 smokers found that following the introduction of combined text and picture warnings 21.8% agreed that they had thought about quitting having seen the pictograms (compared to 14.2% that had thought about quitting having seen text only warnings prior to the introduction of pictorials). Furthermore, 31% said that they had tried to quit (compared to 21.4% that had tried to quit having seen text only warnings prior to the introduction of pictorials)

• Picture warnings appear to be especially effective among youth provided they are targeting issues that are relevant to them.

Evidence - Research report extracts:

Reference F42 – The health effects of tobacco and health warning messages on cigarette packages: survey of adults and adult smokers and survey of 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 and makes smoking seem less attractive. This percentage is significantly higher among youth than among adult smokers."

Pictorial warnings are more effective than text only to minimise 'wear out' over time

• Pictures warnings are more effective in helping to minimise the "wear out" of health warnings that is happening over time.

Evidence - Research report extracts:

Reference F17 – Smokers reaction to cigarette package warnings with graphic imagery and with only text: a comparison between Mexico and Canada.

"A survey amongst 1,081 Mexican smokers and 1,751 Canadian smokers carried out in 2007 suggests that warning labels with prominent graphic elements are more effective than text only messages in engaging smokers, promoting quitting and impeding wear out that result from habituation to messages."

Appendix 4 - Overview of tobacco warning messages used with pictorial warnings

In general, tobacco warning messages on packaging used in different countries emphasize similar messages, but EU warnings do not include risks associated with non-cancerous respiratory diseases, mouth / throat cancer, blindness, gangrene or foul / offensive breath.

Examples of messages used in conjunction with pictorial warnings in Australia, Brazil, Canada, New Zealand and the EU (which illustrate how similar warning themes are presented across four continents that have been early adopters of pictorial warnings on tobacco packages) can be seen in the tables below.

Overview of existing tobacco warning messages

The key themes that are being currently addressed are:

- Smoking causes death
- Smoking causes cancer (focus mainly on lung and mouth / throat cancer)
- Smoking causes respiratory diseases
- Smoking causes cardiovascular disease
- Your smoke is harmful to others
- Smoking during pregnancy is harmful
- Smoking causes reproductive diseases (focus on impotence)
- Tobacco smoke is toxic
- Smoking causes blindness
- Smoking causes aging of the skin
- Other messages (addiction / quitting, blindness, premature aging, smelly breath)

Warning messages currently used in the EU address most of the key themes being promoted in the four other countries. Furthermore, EU warning messages are particularly strong at promoting the risks associated with smoking causing death, cardiovascular diseases, reproductive diseases, addiction and quitting. EU warnings also include one warning in the following areas lung cancer, second hand smoke, pregnancy, toxicity and aging of the skin.

However EU warning messages do not include any warnings highlighting the health risks associated with non-cancerous respiratory diseases, mouth / throat cancer, blindness, gangrene or foul / offensive breath.

The following tables compare the warning messages being used on tobacco packaging in Australia, Canada, Brazil and New Zealand with those used in the EU, across the 10 key themes highlighted above.

Examples of general messages used with regards to smoking kills

Smoking – A leading cause of death	Australia
Each year, the equivalent of a small city dies from tobacco use	Canada
Smokers die younger	EU
*Lifetime smokers lose an average of 14 years of life	EU
Smoking can cause a slow and painful death	EU

Examples of messages used with regards to the risk of lung cancer

Smoking causes lung cancerAustraliaCigarettes cause lung cancerCanadaSmoking causes fatal lung cancerEUSmoking can lead to death from lung cancerBrazil

Over 80% of lung cancers are caused by smoking

New Zealand

Examples of messages used with regards to the risk of mouth / throat cancer

Smoking causes mouth and throat cancerAustraliaSmoking causes mouth cancer and loss of teethBrazilSmoking causes cancer of larynxBrazil

Smoking causes mouth cancer New Zealand

Examples of messages used with regards to non cancerous respiratory diseases

Smoking causes emphysema

Breathing smoke from this product causes pneumonia and Brazil

Brazil

bronchitis

Cigarettes leave you breathless Canada Smoking can lead to death from emphysema Brazil

Smoking causes serious lung diseases New Zealand

Examples of messages used with regards to cardiovascular disease

Smoking causes peripheral vascular disease

Smoking clogs your arteries

Smoking causes heart disease

Smoking doubles your risk of stroke

Smoking causes death from heart attack

Smoking causes obstruction in the arteries and circulatory problems

The integral to the control of the control

The risk of smoke increases with the use of this product

Smoking causes vascular disease that may lead to amputations

Cigarettes cause strokes

Cigarettes are a heartbreaker

*The risk of having a stroke is approximately 50% higher in EII

*The risk of having a stroke is approximately 50% higher in EU smokers than non-smokers

*The risk of coronary heart disease is reduced by 50% after 1 year EU of smoking abstinence

Stopping smoking reduces the risk of fatal heart and lung disease EU Smoking clogs the arteries and causes heart attacks and stroke EU

Smoking causes heart attacksNew ZealandSmoking more than doubles your risk of strokeNew ZealandSmoking blocks your arteriesNew Zealand

Examples of messages used with regards to second hand smoke

Don't let children breath your smoke

Children who live in close contact with smokers have more asthma,

Brazil

pneumonia, sinusitis and allergy

Don't poison us

You're not the only one smoking this cigarette

Canada

Protect children: don't let them breath your smoke

EU

You are not the only one smoking this cigarette
Your smoking can harm your kids

New Zealand
New Zealand

Examples of messages with regards to pregnancy

Smoking harms unborn babies

Smoking harms the mother and the baby and causes premature

Brazil

birth and death

Smoking during pregnancy causes premature births and the birth of Brazil

babies with low birth weight

Smoking causes spontaneous abortion

Cigarettes hurt babies

Tobacco smoke hurts babies

Smoking when pregnant harms your baby

Brazil

Canada

Canada

EU

Examples of messages with regards to reproductive diseases

Smoking causes sexual impotence

Tobacco use can make you impotent

Smoking may reduce the blood flow and cause impotence

EU

Smoking can damage the sperm and decreases fertility

EU

Smoking can make you impotent

New Zealand

Examples of messages used with regards to tobacco smoke is toxic

Tobacco smoke is toxic

Australia
This product contains toxic substances which lead to sickness and

Brazil

death

When smoking you inhale arsenic and naphthalene, also used Brazil

against rats and cockroaches

Idle but deadly Canada
Where there's smoke there's hydrogen cyanide Canada
Smoke contains benzene, nitrosamines, formaldehyde and EU

hydrogen cyanide.

Tobacco smoke is poisonous New Zealand

Examples of messages used with regards to addiction

Smoking is addictive

Nicotine dependence causes sadness and death

Cigarettes are highly addictive

Smoking is highly addictive, don't start

*Smoking is a serious nicotine addiction. Don't be afraid to ask for

EU

help

Smoking is highly addictive New Zealand

Examples of messages used with regards to quitting

Quitting will improve your health
Get help to stop smoking
Your doctor or your pharmacist can help you stop smoking
EU
EU

Note: Some countries (e.g. Australia) address quitting on each pack by providing details of quitline

Examples of messages used with regards to the risk of blindness

Smoking causes blindness

Smoking causes blindness

Australia

New Zealand

Examples of messages used with regards to the risk of aging of the skin

This product causes premature wrinkling
Smoking causes aging of the skin

EU

Examples of other messages used

Children see children do

Smoking causes gangrene

Smoking causes foul and offensive breath

Canada

New Zealand

New Zealand

^{*}Note - messages marked with an asterisk (*) are EU messages that constitute an illustration element of the combined warning

Appendix 5 -Information on health labelling in non-tobacco sectors

Appendix 5 provides some background information on health labelling in the food sector, drugs / pharmaceutical sector and the alcoholic drinks sector.

Background on health labelling in the food sector (References C1, C2)

Poor nutrition has a direct impact on overall health and life expectancy. Growing rates of obesity and overweight across Europe increase the risk of serious diet-related chronic disease, including type 2 diabetes, cardiovascular disease, hypertension, stroke, and certain forms of cancer.

In the past, each European country had its own rules that governed what food manufacturers were allowed to put on labels. European legislation has facilitated the internal market, in which all products manufactured in any EU Member State can be sold in any other Member State. Directive 2000/13/EC of 20 March 2000 on the labelling, presentation and advertising of foodstuffs is the main piece of legislation that harmonises general food labelling legislation across Member States. The EU legislation on food labelling has three main aims:

- To inform and protect citizens
- To enable consumers to make informed choices
- To enhance the free movement of food products

European law requires that certain information is displayed on the food label (e.g. name of food, weight or volume, ingredients, allergens, date and storage conditions, preparation instructions, name and address of manufacturer, place of origin, lot or batch number). Additional information may also be provided, such as nutrition information and cooking instructions / serving suggestions. Foods sold loose are currently exempt from many food labelling laws.

The challenge for European legislators is to ensure that the diverse needs and interests of consumers can be met. For example, a vegetarian, a person with a nut allergy, someone suffering from high blood pressure and a dieter all want to know different things about a particular food item. In addition it has take into account the fact that sometimes food packages can be quite small and that the information provided is often multi-lingual.

Background on health labelling in the drug / pharmaceutical sector (*Reference D1*)

Drug warning labels are placed on packaging to provide important information about the medication. It is meant to serve as a quick reminder to highlight the most important instructions for the safe use of the medication

In the European Union labelling of drug packaging is regulated by the directive 2001/83 EC as amended. According to this directive the particulars on the label shall be easily legible, clearly comprehensible and indelible. However when it comes to content and layout each drug company is free to develop their own format, symbol and colour etc.

Some national authorities, for example the UK National Patient Safety Agency (NPSA), have published guidelines how good graphic design on medicine labels / packaging can enhance patient safety.

Background on health labelling for alcoholic drinks (*References E1, E2, E3*)

Alcohol beverages over 1.2% alcohol by volume (ABV) must state their alcohol content on the label (although there is no requirement to mention the word 'alcohol'), and all products containing certain allergens, including sulphites, should list these on the label. In addition wine and spirits must indicate if they contain sulphites.

The European Parliament rejected suggestions from its Health Committee to introduce standardised EU-wide health warnings on alcoholic drinks, as is currently the case on tobacco products. However, EU Member States can introduce mandatory labelling for alcoholic beverages in their territory, provided that such Member State demonstrates that such measure is justified on grounds of public health and does not create disproportionate barriers to the free movement of goods. Thus far France has already done so

In the UK in May 2007 a voluntary agreement was concluded between the Government (Department of Health) and the drinks industry on the introduction of health warning labels. A first evaluation in March 2008 showed that the results are not meeting expectations.

There are around 25 non European countries that have introduced health warnings on alcohol drink packaging. The following countries have been identified: Argentina, Belize, Brazil, Canada, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, India, Indonesia, Mexico, Mongolia, Republic of Korea, Taiwan, Thailand, United States, Uruguay and Venezuela. The United States was one of the first countries that introduced health warnings on alcoholic beverages, which became mandatory in November 1989.

Scientific knowledge on the effectiveness of non-tobacco sector health labelling

Summary

The effectiveness of health labelling was explored in three non-tobacco sectors (foodstuffs, drugs / pharmaceuticals and alcoholic drinks) to see if any lessons could be learnt in relation to tobacco health warning labelling. However, no major lessons in relation to tobacco warning labels can be learnt from these other markets as their labelling requirements are either different to the strong health warning aspect of current tobacco warning labelling or much less advanced.

Labelling in the food and drugs / pharmaceutical industries are performing different roles to tobacco warning labels, since they are seeking to communicate extensive amounts of information. In the case of foodstuffs, the information on labels is to enable consumers to make appropriate informed choices regarding the nutritional content of the product. In the case of drugs / pharmaceutical products, the labelling is primarily seeking to provide important information about the medications and instructions for safe use. The warning elements (e.g. keep away from children) are generally of secondary concern, small and not prominently placed. However, the findings did provide some useful best practice design parameters for labelling, which reinforced similar findings on tobacco label design.

Health warnings labels in the alcoholic drinks industry (where used) do perform a similar role to tobacco health warnings in so much as they highlight the potential health risks. However, the health warnings that are used in the alcoholic drinks industry are generally much less advanced compared to those used in the tobacco industry and are considered to be relatively ineffective. The warnings used are typically too small and in the wrong location. In addition, apart from France, they do not include graphical images and address and very few messages target specific consumer groups at risk.

Effectiveness of food labelling with focus on nutrition information (References C3 – C11)

Food labels play a critical role in communicating nutrition information with potential to influence food choices and dietary behaviour. A review of existing literature about consumer use and effectiveness of such information found that:

- Women are more likely than men to seek and use nutritional information on food labels.
- Consumers of higher socio-economic and educational status or consumers sensitised to nutrition by having children or by personal health issues are more likely to search for, understand and use nutritional labelling.
- Many consumers have difficulty applying arithmetical skills, performing servingsize calculations and comparing products of varying size and type.
- Use of information is inhibited by complex or confusing labelling practices. Labels are often seen as unclear / misleading / confusing (for example manufacturers mix factual and promotional information such as health claims (e.g. can help reduce blood cholesterol etc.). Confusion also exists about synonymous or related terms, i.e. salt/sodium, energy/calories, sugar/carbohydrate.

- Lack of time at the point of purchase is identified as a major limitation on the extent to which nutritional information from labels is sought and used.
- The information is often "lost" because it is presented in a very dense format on the back or the side of a package.
- Consumers that place high importance to price are less likely to pay as much attention to nutritional information.
- People want a single, trusted system of food labelling that uses a consistent approach, wherever they shop, whatever the brand. They also want simple, clear, consistent and comparable information that is easy to understand at a glance.

Effectiveness of drug warning labels (Reference D2 – D3)

The literature search identified evidence from research carried out in the USA that many patients have problems understanding the messages on warning labels. There is also some evidence from the UK National Patient Safety Authority that patients struggled with labels. According to them about a third of medication errors are caused by confusion over packaging and labelling instructions. A review of existing literature regarding the effectiveness of drug warning labels found that:

- Many patients do not read the warning label carefully or cannot understand some of the words on the label.
- Many warning labels are poorly designed (small writing, too many words)
- Using of certain colours and icons helps people better understand the meaning of the warning label.

Design best practice guidelines for effective drug warning labels (Reference D4)

The following best practice guidelines elements for effective drug warning labels are based on a report called "A guide to the graphic of medication packaging". These guidelines are a result of a collaboration between the UK National Patient Safety Agency (NPSA) and the Helen Hamlyn Research Centre (HHRC) at the Royal College of Art, London. It builds on the designing of patient safety study commissioned by the Department of Health and the Design Council, and undertaken jointly by the HHRC, the University of Cambridge and the University of Surrey.

Best practice graphic design guide for drug warning labels / packaging

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Some text can only be read by flipping the pack or reading upside down.

Small type size and condensed typeface is difficult to read

Sentences in capital letters or italic type are hard to read.

Simulated handwriting and ornate typefaces are hard to read.

Lightweight typeface is hard to read.

Irregular amount of space between words.

Text illegible over an image or logo.

background and the typeface.

Colour differentiation inadvertently associated with a particular feature.

Recommendation

Orientate text in the same direction.

Make body text as large as possible (don't go below 12 point).

Use upper and lower case.

Use sans serif typefaces such as Arial, Helvetia and Univers.

Use bold or semi-bold type.

Align text to the left.

Do not place text over images or logos.

Insufficient contrast between colour of the Create a strong contrast between the colour of the typeface and the background.

Use colour differentiation to highlight

information.

Effectiveness of alcohol health warning labels (*References E4 – E15*)

Most primary studies concerning the impact of alcohol warning labels are based on the experience made in the US which introduced alcohol warning labels in 1989. A review of existing literature regarding effectiveness of health warning labels on alcohol beverage packaging / containers found that:

- There appears to be a high level of support from consumers for putting health warning labels on alcoholic beverage containers. According to the results of a special Eurobarometer on "Attitudes towards Alcohol", published in March 2007, three quarters of the European Union population (77%) would agree with putting warnings on alcohol bottles, and adverts, in order to warn pregnant women and drivers of the dangers of drinking alcohol. However, 21% disagree.
- There is some evidence from studies carried out in the US that health warnings increase knowledge regarding the risks of drinking especially amongst the target groups (pregnant women and car drivers).
- The initial positive effects of warning labels level off. Hence, warning labels should carry rotating messages outlining the different harmful effects of alcohol (although the research did not identify any evidence measuring the effects of rotation).
- There is little or no measurable change in drinking behaviour and related harm as a result of the introduction of alcohol warning labels so far.
- A major barrier to the effectiveness of current warning labels is their design (relatively small size, often obscured).

• Warning labels should not be considered in isolation, since knowledge alone rarely results in changed behaviour. They should be part of an integrated strategy to reduce the harm done by alcohol.

The finding of lack of impact on behaviour contrasts with the experience from tobacco warning labels, however, this mainly reflects the nature of the alcohol warning labels currently used. The current alcohol health warning labels are considered to be too small and placed in the wrong location, and therefore not easily visible. In addition the warning messages are mainly addressing two target groups (pregnant women and drivers) and they do not include graphic images (except in France where a silhouette of a pregnant woman is used) or any other vivid features to attract attention.

However, there is a consensus among research groups that warning labels have the potential to influence behaviour but their effectiveness depends very much on their design, content of the messages, and how well they are targeted at their intended audience.

Examples of current health warnings on alcohol beverage packaging / containers

- *USA* Since 1989 labels on all alcoholic beverages contain the following warning:
 - (1) "According to the Surgeon General women should not drink alcohol beverages during pregnancy because of the risk of birth defect."
 - (2) "Consumption of alcohol beverages impairs your ability to drive a car or operate machinery, and may cause health problems."

Canada – Since 2000 liquor bottles carry the wording "drinking alcohol during pregnancy can cause birth defect"

France – In France producers have to put a warning for pregnant women on alcohol containers, which reads "Consumption of alcoholic beverages during pregnancy even in small amounts can seriously damage the child's health" (by law of 11.02/2005). As an alternative, the use of a pictogram showing a pregnant woman is also possible.

UK – In 2007 the UK introduced (voluntary agreement) warning labels detailing alcoholic units and recommended safe drinking levels. In addition the labels should include words such as "know your limits" or "drink responsibly" and warn that drinking alcohol should be avoided if pregnant or trying to conceive.

Appendix 6 – The 42 pictorials used in the EU

Appendix 6 shows a list of the 42 pictorial warnings that are current used approved by the European Commission and used in the EU.

WARNING 1: Smokers die vounger



WARNING 2: Smoking clogs the arteries and causes heart attacks and strokes



WARNING 3: Smoking causes fatal lung cancer



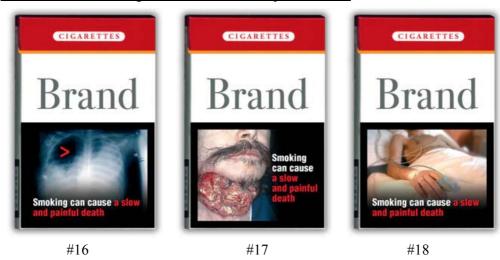
WARNING 4: Smoking is highly addictive, don't start



WARNING 5: Stopping smoking reduces the risk of fatal heart and lung diseases



WARNING 6: Smoking can cause a slow and painful death



WARNING 7: Smoking causes ageing of the skin



WARNING 8: Smoking can damage the sperm and decrease fertility



WARNING 9: Smoking may reduce the blood flow and causes impotence



WARNING 10: Smoke contains benzene, formaldehyde and hydrogen cyanide



WARNING 11: Smoking when pregnant harms your baby



WARNING 12: Protect children: don't make them breathe your smoke



WARNING 13: Your doctor or your pharmacist can help you stop smoking







#37 #38 #39

WARNING 14: Get help to stop smoking







#40 #41 #42

Appendix 7 – Plain packaging and its likely impact

Appendix 7 provides an overview of research carried out on plain packaging and its likely impact on the effectiveness of warning messages.

Packaging is an important marketing tool

Tobacco packaging provides a direct link between consumers and manufacturers and serves as a vital marketing tool for the tobacco industry. Cigarette manufacturers spend significant research effort into pack design and how they can take advantage of new print technology to make packages look attractive.

Packaging is primarily used to reinforce brand imagery but it also allows cigarette manufacturers to "undermine" warning label efforts. For example, a number of jurisdictions have prohibited the words light, mild and low tar but manufacturers are continuing to promote this type of cigarettes by either introducing new words such as "smooth" or by associating "mild" cigarettes with a specific package colour.

Plain / standardised packaging

The idea of plain /standardised packaging for cigarettes is not new. In 1994, the measures were considered in Canada, but dismissed. Major reasons why it was not adopted included legal issues in relation to commercial rights and intellectual property rights.

So far plain packaging for cigarettes has never been legislated anywhere in the world and the evidence currently available is based on experimental studies where subjects have been presented with mock-up plain and branded packs and their association and preferences explored.

Likely effectiveness of plain packaging (ref F47, F48, F49, F70, F71, F84, F85)

There have been a number of studies that looked at the likely effectiveness of plain packaging. Most of these studies were published before the year 2000. These studies have shown consistently that compared to branded packages, plain packs are perceived as "dull and boring". In addition, there is evidence that brand imagery is distracting from health warnings and that plain packaging is likely to increase consumers' ability to recall warning messages. An overview of the results from recent studies on plain packaging can be found below.

Recent plain packaging research in Canada

A survey carried out by Environics in 2008 on behalf of Health Canada, involving 2,000 respondents (1,000 adults aged 18+ and 1,000 youths aged 12-18) evaluated adult smokers' response to the branded vs. plain packs, controlling for the brand and size of the health warning message. Two size options were compared: 50 percent coverage and 75 percent coverage. The results are summarised in the two tables below.

Type of packaging considered most effective in informing about the health effects of smoking				
	50% graphic size option		75% graphic size option	
	Adults	Youths	Adults	Youths
Branded pack	20	25	19	26
Plain pack	48	50	50	52
Both	25	21	25	19
Neither	7	3	6	3

Type of packaging considered most effective in encouraging people to reduce their tobacco use				
	50% graphic size option		75% graphic size option	
	Adults	Youths	Adults	Youths
Branded pack	17	23	18	22
Plain pack	48	53	49	54
Both	22	19	22	19
Neither	12	5	11	4

• As seen in the above tables, plain packaging is seen by around 50% of both adults and youths in Canada as being more effective than branded packs in informing people about the health effects of smoking as well as encouraging smokers to reduce their tobacco use.

Recent plain packaging research in Australia

In 2008, a sampling frame of 813 Australians adults aged 18-49 years participated in an online survey on plain packaging. Respondents were randomly shown one of 12 different cigarette packs. The packs available contained the original packs from 3 well known brands and three mock packs for each brand with various degrees of plain packaging. After reviewing their assigned pack, respondents completed ratings of the pack in relation to perceived attributes of the brand, perceived attributes of smokers of the brand and expected taste / quality of the cigarette. The main research findings were:

- All plain pack variants were perceived as less attractive than the original branded packs
- All smokers of plain pack variants were perceived to be as less trendy and stylish than smokers of the original pack.

The results of the study clearly suggests that cigarette packs that display progressively fewer branding designs elements, and presented in a generic brown colour are perceived increasingly unfavourable by smokers.

Recent plain packaging consultation in the UK

In 2008 the UK Department of Health looked at plain packaging as part of a consultation process for a new national tobacco control strategy. The consultation ran from 31 May to 8 September. Respondents were asked 17 questions and in total, more than 96,000 responses were received. One of the questions was "Do you believe that plain packaging of tobacco products has merit as an initiative to reduce smoking uptake by young people?". In total 82,818 responses were received for this question. The key findings are summarised below:

Positive feedback

- Almost 98% of respondents who answered this question were in favour of plain packaging.
- Birmingham young people's project found that most young people consulted would prefer plain packaging that detailed the effects of smoking and which took the glamour out of smoking.
- The UK Centre for Tobacco Control Studies (UKCTCS) suggests that tobacco manufacturers are currently in breach of the law by using packaging to suggest that some cigarettes are safer than other, by using lighter colours and words such as "smooth" and "gold" instead of the banned terms "light" and "mild".
- The UKCTCS, among others, suggest that generic packaging would result in brands being less attractive and would reduce misperceptions of risk between varieties.
- The UKCTCS cites US research (Goldberg ME et al 1999) that plain packaging would maximise the impact of the health warning.

Negative feedback

- Lancashire County Council ran a focus group of young people who suggested plain packaging would make little difference to smoking behaviour.
- Approximately 2,000 respondents were against the measure, with most of these suggesting that such a requirement would stimulate counterfeit and illicit trade.
- Specialist tobacconists and vending machine operators pointed out that it would make product identification very difficult for staff and customers.
- Tobacco product manufacturers suggested that packaging is part of intellectual property and believe a requirement for plain packaging would contravene EU regulation on trade marks and the World Trade Organisation's agreement on traderelated aspects of intellectual property rights.

Recent plain packaging research in France

Focus groups (2007)

Six focus groups were conducted in Rennes, Paris and Brest in 2007 with a total of 50 people aged from 15 to 46 years of age (26 smokers, 24 non-smokers, 25 women, 25 men). One of the issues addressed involved feedback on 3 different tobacco plain packs: a grey, white and brown one. The key finding was as follows.

• the 3 plain packs ruin the attractiveness and the marketing of cigarette packs, especially the grey color (reactions toward white pack were extremely mixed: negative but also positive and reactions toward brown pack were most of the time positive: it was perceived as a nice pack that reminds the color of tobacco).

Focus groups (2008)

In 2008 the National Committee Against Tobacco conducted a qualitative survey amongst 20 people aged 18 to 45 on the likely impact of plain packaging. Respondents were asked to comment on 4 different pack options. (2 original Marlborough packs - one with picture warning and 1 with text only warning, 2 plain packs with the same warning messages as with original packs). The key findings were:

- All plain pack variants were perceived as less attractive than the original branded packs
- Respondents felt that plain packaging clearly helps to devalue the brand strength, plain packs were described as less attractive, boring and less prestigious.
- The research also showed that plain packaging increased the effectiveness of the health warnings.

Appendix 8 – References regarding the health effects of smoking

The research has identified 103 reports / publications / articles that were used as the basis of this section of the report. Details regarding title, source / name of author and date of publishing for each report can be found on the following pages.

References regarding health effects of smoking

- G1. European Commission (2004), EU tobacco policy overview.
- G2. European Commission (2005), Tobacco or health in the European Union
- G3. International Agency for Cancer Research (2004), World Cancer Report
- G4. Ghadirian P, Faculty of Medicine, Canada (2004), Sleeping with a killer: the effects of smoking on human health.
- G5. US Department of Health and Human Service (2004). The health consequences of smoking: a report of the Surgeon General.
- G6. International Agency for Research and Cancer (IARC). Summaries and evaluation. Volume 83 (2002). Tobacco Smoking and Tobacco Smoke.
- G7. National Cancer Institute, USA (2007). Smoking increases risk for head and neck cancers for men and women.
- G8. Setiawa V et al, University of Southern California (2007), Risk factors for renal cell cancer: the multiethnic cohort.
- G9. Hunt JD. E all, Louisiana State University Health Science Centre (2005), Renal cell carcinoma in relation to smoking: meta analysis of 24 studies.
- G10. Coughlin S et al, National Centre for Chronic Disease Control, USA (2000). Predictors of pancreatic cancer mortality among a large cohort of United States adults.
- G11. Rullyak S.J et al, University of Washington, Seattle (2003). Risk factors for the development of pancreatic cancer in familial pancreatic cancer kindreds.
- G12. Iodice S et al, European Institute of Oncology, Milan (2008). Tobacco and the risk of pancreatic cancer: a review and meta-analysis.
- G13. International agency for Research and Cancer, Lyon (1997). Tobacco smoking and gastric cancer: a review and meta-analysis.
- G14. Garcia Closas M, University of Pompeu Fabra, Barcelona (2005). Slow acetylation, null genotype and risk of bladder cancer from the Spanish Bladder Cancer Study and meta-analysis.
- G15. Plummer M et al, Smoking and cervical cancer: pooled analysis of the IARC multi-centric case control study.
- G16. Moorman AV et al, University of Leeds (2002), Smoking and the risk of acute myeloid leukaemia in cytogenetic subgroups.
- G17. Bjork J, Albin M et al (2001). Smoking and acute myeloid leukaemia. Leuk. Res. 25 (10):865-721.
- G18. Daling J et al, Cancer Research Centre (2004). Human papillomavirus, smoking and sexual practices in the aetiology of anal cancer.
- G19. European Respiratory Society (2007), Smoking and COPD, abstracts of recent studies.
- G20. European Respiratory Society, European Lung foundation. European Lung White Book.. the first comprehensive survey on respiratory health in Europe (2003)
- G21. Blasi F, Alberti S, Institute of Respiratory Disease, University of Milan (2006) Pneumonia: how important are local epidemiology and smoking habits.
- G22. Nuorti JP et al, National Centre for Infectious Disease, Atlanta (2000). Cigarette smoking and invasive pneumococcal disease.
- G23. Willigendal, et al, Journal of Vascular Surgery, Volume 40 (2008). Influence of smoking and incidence and prevalence of peripheral arterial disease.
- G24. Wnaqing W et al, Vanderbilt Ingram Centre (2006). Environmental tobacco smoke and mortality in Chinese woman who have never smoked: prospective cohort study.
- G25. Hirotsugu et al, Shiga University of Medical Science (2006). Cigarette smoking as a risk factor for stroke death in Japan.
- G26. Whincup PH et al, St George's Hospital Medical School, London (2004). Passive smoking and risk of coronary disease and stroke: prospective study with cotinine measurement.
- G27. Kurth T et al, Harvard Medical School, Boston (2003). Smoking and the risk of hemorrhagic stroke in men.
- G28. Law MR et al, Wolfson Institute of Preventive Medicine, London (2003). Environmental tobacco smoke and ischemic heart disease.

- G29. Julia A et al, University of Liverpool (2003). Mortality risk reduction associated with smoking cessation in patients with coronary heart disease.
- G30. Pechacek TF et al (2004). How acute and reversible are the cardiovascular risks of second-hand smoking.
- G31. Soares SR, Melo MA, Infertility Institute Valencia, Spain. Cigarette smoking and reproductive function (2008).
- G32. Soares SR et al., University of Valencia, Spain. Cigarette smoking affects uterine receptiveness (2007.
- G33. Klonoff-Cohen H (2005). Female and make lifestyle habits and IVF: what is known and unknown. Human Reprod Update 11, 179-2003.
- G34. Neil MS, Hughes EG, Holloway AC and Foster WG (2005). Sidestream smoking is equally as damaging as mainstream smoking on IVF outcomes. Hum report 20, 2531 2535.
- G35. Amber R, Cooper M et al (2008), Pre-implantation effects on fertility: more reasons to stop smoking.
- G36. Kelly Weeder S, Cox CL. The Impact of lifestyle risk factors on female infertility. Woman Health (2006) 44:1-23.
- G37. The Practice Committee of the American Society for Reproductive Medicine. Smoking and infertility. Fertile Sterile 2006.
- G38. Sarah J et al, Evolution Research Group, University of Western Australia (2005). Image content influences men's semen quality.
- G39. Fabio F et al, University of Caxias Do Sul, Brazil (2005). Cigarette smoking is related to a decrease in semen volume in a population of fertile men.
- G40. Zhang JP et al, Jining Medical College, China (2000). Effect of smoking on semen quality of infertile men in Shangdong.
- G41. Zitzmann M (2003). Male smokers have a decreased success rate for in vitro fertilization and intracytoplasmic sperm injection. Fertility and Sterility
- G42. Kuenzle R et al (2002). Semen quality of male smokers and non smokers in infertile couples. Fertility and Sterility. 79,287-290.
- G43. Ramadan A et al, The Cleveland Clinic Foundation (2002). Effect of cigarette smoking on levels of seminal oxidative stress in infertile men: a prospective study.
- G44. Trummer H et al, University of Graz, Austria (2002). The impact of cigarette smoking on human semen parameters and hormones.
- G45. Jane Y et al, Queen's University Kingston, Canada (2005. Smoking and other lifestyle factors in relation to erectile dysfunction.
- G46. Elhanbly S et al. Erectile dysfunction in smokers: a penile dynamic and vascular study. J Androl 2004; 25:991-5.
- G47. Derby CA et al. Modifiable risk factors and erectile dysfunction: can lifestyle changes modify risk. Urology 2000; 56:302-6
- G48. Mirone V et al. Cigarette smoking as risk factor for erectile dysfunction: result from an Italian epidemiologic study. Eur Urol 2002; 41:294-7.
- G49. Committee, sexual Medicine Society of North America (2001). Smoking and erectile dysfunction: evidence based analysis.
- G50. Shiri R et al (2004). Effect of life style factors on incidence of erectile function.
- G51. Carlos A Gonzales et al, Catalan Institute of Oncology, Barcelona. Smoking and the risk of gastric cancer in the European prospective investigation into cancer and nutrition (2003).
- G52. American Association for Cancer Research (2008). Smoking, Drinking raises risks for oesophagus and stomach cancer.
- G53. American Urological Association (2008). Smoking causes half of all bladder cancer amongst the US population.
- G54. National Cancer Institute (2006). Smoking and bladder cancer in Spain: effects of tobacco type, timing, environmental tobacco smoke and gender.
- G55. Cancer Research UK (2004). Comparison of risk factors for squamous cell and adenocarcinomas of the cervix: a meta-analysis.
- G56. Pogoda JM et al, University of Southern California (2002). Smoking and risk of acute myeloid leukaemia: Result from a Los Angeles county case-control study.
- G57. Brockmeyer N et al, Germany (2007). Smoking increases cancer associated with HPV viral load factor).
- G58. Rafael Laniado Laborin, University of Baja California, Mexico (2008), Smoking and chronic obstructive pulmonary disease, parallel epidemics in the 21st century.
- G59. Gonzalez C, Hospital of the Consorci Sanitari de Mataro, Barcelona (1999). Smokers' pneumonia risk three times greater.

- G60. Bagby J, Louisiana State University Health Science Centre (2005. Smoking, drinking raise pneumonia risk.
- G61. US Department of Health and Human Services (2001). Smoking and women's health. A report of the Surgeon General.
- G62. British Medical Association (2004). Smoking and reproductive live. The impact of smoking on sexual, reproductive and child health.
- G63. C. Millet et al, Health Promotion Unit, Sydney, Australia (2005). Smoking and erectile dysfunction: findings from a representative sample of Australian Men.
- G64. University of California (2001). The link between smoking and impotence: two decades of evidence.
- G65. Krisa Van Meurs, Stanford University School of Medicine (2000). Cigarette smoking, pregnancy and the developing foetus.
- G66. Evans JR et al, British Journal of Ophthalmology 2005. 28,000 cases of age related macular degeneration causing visual loss in people aged 75 years and above in the UK may be attributable to smoking.
- G67. Thornton et al (2005). Smoking ant age related macular degeneration: a review of association.
- G68. Kelly SP et al, (2005). Smoking and blindness evidence for the link but public awareness lags, British Medical Journal 2004.
- G69. Smith W wt al. Risk factors for age related macular degeneration, pooled findings from three continents. Ophthalmology 2001.
- G70. Khan JC et al. Smoking and age related macular degeneration: the number of pack years of cigarette smoking is a major determinant. British Journal of Ophthalmology 2006.
- G71. Sannapaneni K et al, Prasad Eye Institute, India (2205). Smoking and its association with cataract: Results of the Andhra Padesh eye disease study.
- G72. Tan J at al, Centre for Vision Research, Sydney (2008). Smoking and the long-term incidence of cataract: the Blue Mountain Eye Study.
- G73. Akimichi Morita et al. Nagoya city University Medical School, Japan (2000). Smoking has a damaging effect on the skin.
- G74. Koe Jae Sook at al, the Catholic University of Korea (2002. Cigarette smoking associated with premature facial wrinkling: image analysis of facial skin replicas.
- G75. Helfrich Y et al, University of Michigan (2007). Smoking ages skin across the body.
- G76. Schaefer T et al, University of Munich 2001. Epidemiology of acne in the general population: the risk of smoking.
- G77. Molly T et al, University of Pittsburgh, USA (2000). The effect of cigarette smoking on the development of osteoporosis and related fractures.
- G78. K Ward et al, University of Memphis, USA (2000). A meta analysis of the effects of cigarette smoking on bone mineral density.
- G79. J.A Kanis et al, WHO collaboration centre for Metabolic Bone Diseases, University of Sheffield Medical School, UK (2004).
- G80. S Tomar et al (2000), Centre for Disease Control and Prevention, Chicago. Smoking may be responsible for more than half of the cases of periodontal disease among adults.
- G81. School of Clinical Dentistry, University of Belfast (2004). The influence of tobacco smoking on the onset of periodentitis in young people.
- G82. G Loc et al, Australia (2008), Smoking attributable periodontal disease in Australian adult population.
- G83. T Hanioka et al, Japan (2007). Relationship between smoking status and tooth loss. Findings from national database in Japan.
- G84. US Surgeon General (2006). The health consequences of involuntary exposure to environmental tobacco smoke.
- G85. US Surgeon General (2007). Children and second-hand smoke exposure.
- G86. Fuma fa "impazzire" cellule del polmone. Polyclinic Milano (2008)
- G87. Hidalogo A et al, Barcelona (2006). Smoking related interstitial lung disease radiologic pathologic correlation.
- G88. Brener S et al, Brazil (2007). Oral squamous cell carcinoma.
- G89. Amigo H et al, Chile (2006). Respiratory consequences of light and moderate smoking in young adults in Chile.
- G90. Amigo H et al, Chile (2006). Smoking and chronic obstructive pulmonary disease: attributable risk determination.

- G91. Tamas T, Szilagyi T, Judit B (2007), Economic aspects of smoking and the impact of tobacco tax rises on the health of Hungarians.
- G92. Ifusson N, Sigurdsson G, Aspelund T, Gudnason V, (2006). The health risk associated with smoking has been seriously underestimated The Reykjavik Study.
- G93. Ilson G, Field A, (2001). Smoke gets in your eyes: Smoking and visual impairment in New Zealand.
- G94. Schmidt et al (2006). Cigarette smoking strongly modifies the association of LOC387715 and age-related macular degeneration.
- G95. Ayres J, Lois N, Reglitz K (2007). Environmental tobacco smoke exposure and eye disease.
- G96. AMD (2007). European campaign on smoking and blindness positioning paper.
- G97. Manfredsdottir V, et al (2006). The effects of tobacco smoking and rheumatoid factor seropositivity on disease activity and joint damage in early rheumatoid arthritis.
- G98. British Medical Association (2007). Breaking the cycle of children's exposure to tobacco smoke.
- G99. Silke Schmidt, et al (2006), Cigarette smoking strongly modifies the association of LOC387715 and age-related macular degeneration
- G100. Wilson, G and Field, A (2006), Smoke gets in your eyes: Smoking and visual impairment in New Zealand
- G101 Botteri, et al (2008). Smoking and colorectal cancer
- G102 Kelvin K, et al (2008). Cigarette smoking and the risk of colorectal cancer: a meta-analysis of prospective cohort studies.
- G103 Lopez M, et al (2002). Mortality attributable to passive smoking in Spain.

Appendix 9 – List of people contacted for feedback

Appendix 9 lists the people interviewed face to face (*) or by telephone, as well as extensive email communication with many respondents. A total of 111 people were interviewed (87 in Europe and 24 in the rest of the World) involving 103 organisations.

Interviews conducted in Europe

Austrian Council on Smoking, Austria Mr M Neuberger, Prof. of Environmental F. Austrian Cancer Research, Austria Ms D Kielhaber, Advisor		
Austrian Cancer Research, Austria Ms D Kielhaber, Advisor	Mr M Neuberger, Prof. of Environmental Health	
European Smoke Free Partnership, Belgium Ms F Berteletti Kemp		
Sante Publique Securite de la Chaine Alimentaire, Mr M Capouet, Tobacco Policy Expert		
Belgium*		
Belgian Foundation Against Tobacco, Belgium* Mr L Joossens		
European Network for Smoking Prevention, Belgium* Mr F Grogna, Secretary General		
Foundation against Respiratory Diseases, Belgium* Mr M Pettiaux		
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