

EXPLANATORY MEMORANDUM TO
THE TOBACCO PRODUCTS (MANUFACTURE, PRESENTATION AND SALE)
(SAFETY) (AMENDMENT) REGULATIONS 2007

SI 2007 No. 2473

1. 1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.
2. **Description**

2.1 This instrument introduces requirements for tobacco products to carry pictorial health warnings, in place of the current written health warnings, on the rear of packs. The Schedule contains technical printing specifications. For example, the reference to “CMYK” in paragraph 4(d) of Part 3 of the Schedule is a reference to the colours cyan, magenta, yellow and black.

2.2 It also extends requirements relating to product descriptions and product prohibitions to packets of tobacco products which are, or are to be, supplied for consumption in other EEA states.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None in respect of 2.1.

3.2 In respect of 2.2, this instrument gives effect to undertakings given to the Joint Committee on Statutory Instruments following issues raised with the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 in the Committee’s Twelfth Report of the 2002-03 session.
4. **Legislative Background**

4.1 This instrument amends the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002. It requires tobacco products to carry pictorial health warnings, as allowed by EU Directive 2001/37/EC and European Commission Decisions 2003/641/EC, 26/V/2005 and 12/IV/2006.
5. **Extent**

5.1 This instrument applies to England, Wales, Scotland and Northern Ireland.
6. **European Convention on Human Rights**

6.1 As the Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007 are subject to the negative resolution procedure and do not amend primary legislation, no statement is required in respect of these regulations.

7. Policy background

7.1 The aim of introducing picture warnings on tobacco packs is to contribute to a reduction in smoking prevalence through greater awareness of the harm that smoking causes and the help that is available. Health warnings on tobacco packets have long been a method for informing smokers of the health risks associated with smoking.

7.2 Written health warnings were introduced across Europe under Directive 2001/37/EC (the 'Labelling Directive'). These were introduced in the UK in 2003, being transposed into UK law by the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2007. New picture warnings have now also been developed by the European Commission for Member States that wish to adopt them. In the 2004 White Paper 'Choosing Health', Ministers committed to consulting on how to use these warnings most effectively in the UK.

7.3 A three-month consultation on the draft regulations ran from May to August 2006. Around 450 responses were received from a range of stakeholders. In parallel with the consultation paper, the Department ran a website at www.packwarnings.nhs.uk. This website allowed people to select the warnings that they felt would have the most impact. Over 20,000 completed responses were logged on the website.

7.4 Based on this feedback, and on research commissioned by the Department, one picture warnings was chosen from the three available in the European Commission library for each of the 14 rear of pack warnings. The Department also made some small policy changes – for example on timescales for the change from written to picture warnings – in response to concerns raised in consultation responses.

7.5 A full analysis of consultation responses is available on the Department's website at:

<http://www.dh.gov.uk/Consultations/ResponsesToConsultations/fs/en>

7.6 The Regulations also give effect to undertakings given to the Joint Committee on Statutory Instruments following issues raised with the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 in the Committee's Twelfth Report of the 2002-03 session.

8. Impact

8.1 A final Regulatory Impact Assessment is attached to this memorandum.

9. Contact

9.1 Kay Thomson at the Department of Health, tel: 020 7972 4495 or e-mail: kay.thomson@dh.gsi.gov.uk can answer any queries regarding the instrument.

Transposition Note for the Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007

Directive and decisions
Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 – on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products
Commission Decision 2003/641/EC of 5 September 2003– on the use of colour photographs or other illustrations as health warnings on tobacco packages.
Commission Decision C(2005) 1452 final of 26 May 2005 on the library of selected source documents containing colour photographs or other illustrations for each of the additional warnings listed in annex 1 to Directive 2001/37/EC of the European Parliament and of the Council.
Commission Decision C(2006) 1502 final of 12 April 2006 amending Commission Decision C(2005) 1452 final of 26 May 2005 on the library of selected source documents containing colour photographs or other illustrations for each of the additional warnings listed in annex 1 to Directive 2001/37/EC of the European Parliament and of the Council.
These Regulations amend the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 (“the 2002 Regulations”) implement the optional requirement of introducing pictorial health warnings allowed under Article 5 of Directive 2001/37/EC following the provisions made in Decisions 2003/641/EC, C(2005) 1452 final, and C(2006) 1502 final.

Directive 2001/37/EC			
Article	Objectives	Implementation	Responsibility
5	Labelling	Regulations 7 and 9 of the 2002 Regulations are amended by the Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007 (“the 2007 Regulations”) to require combined pictorial health warnings to be displayed on the other most visible side of tobacco packs, in accordance with rules set down by the Commission in Decisions 2003/641/EC, C(2005) 1452 final, and C(2006) 1502 final.	The Regulations are made by the Secretary of State for Health.
Decision 2003/641/EC			
1	Subject matter and scope	These Regulations amend the Tobacco Products (Manufacture, Presentation and Sale) (Safety)	The Regulations are made by the Secretary of State

		Regulations 2002 (“the 2002 Regulations”) and implement the optional requirement of introducing combined pictorial health warnings allowed under Article 5 of Directive 2001/37/EC following the provisions made in Decisions 2003/641/EC, C(2005) 1452 final, and C(2006) 1502 final.	for Health.
2	Definitions	Regulation 2 of the 2002 Regulations provides relevant definitions and these have not been amended or added to by the 2007 Regulations.	The Regulations are made by the Secretary of State for Health.
3	Library of source documents	No implementation required.	
4	Use of the combined warnings	<p>Regulation 7 of the 2002 Regulations is amended by Regulation 2 of the 2007 Regulations to refer to the combined pictorial warnings in place of the written warnings.</p> <p>Regulation 8 of the 2002 Regulations is not amended by the 2007 Regulations.</p> <p>Regulation 9 of the 2002 Regulations is amended by Regulation 3 of the 2007 Regulations so that combined pictorial health warnings are not covered by Regulation 9(1).</p> <p>Regulation 6 of the 2007 Regulations substitutes the Schedule of the 2002 Regulations with a new Schedule. Part 3 of this Schedule includes the additional technical specifications required by paragraph 2(b)-(e) of Article 4.</p>	The Regulations are made by the Secretary of State for Health.
5	Visual integrity of the combined warnings	Regulation 9(3) of the 2002 Regulations covers the requirements of Article 5.	The Regulations are made by the Secretary of State for Health.

6	Implementation	Regulation 7 of the 2007 Regulations provides for transitional periods.	The Regulations are made by the Secretary of State for Health.
7	Reporting and adaptations	No implementation required.	
Decision C(2005) 1452 final of 26 May 2005			
1	Library of source documents	Schedule 1, Part 1 of the 2007 Regulations sets out the warnings to be required on tobacco packs in the UK, in accordance with Article 4(1) of Directive 2001/37/EC.	The Regulations are made by the Secretary of State for Health.
Decision C(2006) 1502 final of 12 April 2006			
1	Technical specifications for printing	Schedule 1, Part 3 of the 2007 Regulations sets out the technical specifications for printing the combined pictorial warnings.	The Regulations are made by the Secretary of State for Health.

The introduction of picture warnings on tobacco packs

Final Regulatory Impact Assessment

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Policy Objective

1. To contribute to a reduction in smoking prevalence by introducing graphic health warnings on tobacco packs in the UK.

Introduction

2. Health warnings on tobacco packets have long been a method for informing smokers of the health risks associated with smoking.
3. Written health warnings were introduced across Europe under Directive 2001/37/EC (the 'Labelling Directive'). These were introduced in the UK in 2003.
4. New picture warnings have now also been developed by the European Commission for Member States that wish to adopt them. In the 2004 White Paper 'Choosing Health', Ministers committed to consulting on how to use these warnings most effectively in the UK.

Background

5. Government health warnings have become a common method across the world for informing smokers of the health risks of tobacco use. Pack warnings are effective in providing such messages due to frequency of exposure ("an individual who smokes one pack a day is potentially exposed to a health warning 7300 times a year"¹) and the location on the actual pack (meaning the consumer is confronted with the warning when deciding to smoke or purchase a tobacco product). Health warnings also lessen the impact of brand imagery on packs.
6. Health warnings were first introduced into European law in January 1992. These laws stated that tobacco products in Member States had to carry specified warnings covering 4-8% of the packet.
7. The Labelling Directive subsequently provided a more stringent framework for Member States, stipulating that health warnings should cover 30% of the front and 40% of the back of tobacco packets and be surrounded by a black border. The Directive prescribed which health warnings had to be used: one of two general warnings on the front and one of fourteen more specific warnings on the back, with all of the warnings to be used regularly.
8. The Directive exempted smokeless tobacco products from these arrangements, these products have to contain one generic warning on the front of the pack instead ("this tobacco product can damage your health and is addictive").

¹ Fong, Geoffrey. *A review of the research on tobacco warning labels, with particular emphasis on the new Canadian warning labels*. 2001.

9. The requirements of the Directive were transposed into UK legislation in the form of the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002.
10. The Directive also carried a commitment that the European Commission would subsequently adopt rules for the use of colour photographs or other illustrations to depict and explain the health consequences of smoking. Since then, picture warnings have been introduced in countries such as Canada, Brazil, Thailand, Singapore and Australia.
11. European Commission Decisions containing rules on picture warnings and an image 'library' of warnings were published in September 2003, May 2005 and April 2006. There are 42 picture warnings in the library developed by the European Commission. They are based on the written health warnings currently on tobacco packs, with 3 picture warnings for each current written message: 14 'sets' of 3. These picture warnings are for the backs of packets.
12. These EC Decisions do not make picture warnings compulsory across the EU. However, countries like the UK that decide to introduce them have to do so according to the rules set out in the Decisions.
13. The UK Government made a public commitment in the 2005 budget not to "gold-plate" European legislation. As stated above, picture warnings are 'optional' for Member States; the minimum requirement of the European Labelling Directive is for tobacco packs to have **written** health warnings. However, for the reasons set out in this RIA (see 'Rationale for Government Intervention' on page 4 and 'Benefits' from page 8 onwards), it is suggested that it would be beneficial to proceed with picture warnings, even if this means gold-plating European legislation.

Directive 2001/37/EC ('the Tobacco Labelling Directive')

14. The Tobacco Labelling Directive came into force in July 2001. The Directive required Member States to:
 - Impose maximum machine read tar, nicotine and carbon monoxide yields in cigarettes, to be printed on the side of packs.
 - Carry out tests in approved laboratories to verify these tar, nicotine and carbon monoxide yields.
 - Introduce written warnings on the front and back of tobacco packs (actual warnings, minimum size and font all specified by the Directive), to be surrounded by a black border.
 - Introduce a system of batch marking to ensure product identification and traceability.
 - Require manufacturers and importers of tobacco products to submit lists of ingredients (including quantities) for all brands, lists to include ingredient function/reason for inclusion.

- Prohibit descriptors which suggest that a certain product is less harmful than others (eg, 'mild' cigarettes).
- Prohibit the sale of tobacco for oral use (except those intended for smoking or chewing).

The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002

15. The Labelling Directive was transposed into UK legislation in 2002 by the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002. The regulations used powers provided in the Consumer Protection Act 1987.
16. These regulations, amongst other things, provided the UK legislative base for the introduction of the written health warnings currently on packs.

European Commission Decisions

17. Commission Decision 2003/641/EC of 5 September 2003 provided detail, further to the Directive, on how Member States should introduce picture warnings (should they wish to introduce them).
18. A further Commission Decision of 26 May 2005 provided a library of picture warnings and a technical specification. This Decision has since been amended in a decision of 12 April 2006, to allow manufacturers to modify the warnings for awkward pack shapes/sizes.

19. The Commission Decisions can be viewed at:

http://europa.eu.int/comm/health/ph_determinants/life_style/Tobacco/legal_smoking_prevention_tobacco_en.htm

20. These Decisions stipulate the following points about how we introduce picture warnings. The picture warnings must:
 - i. be chosen from a 'library' developed by the European Commission;
 - ii. appear on "the other most visible side of the pack" (i.e. the back of the pack, with one of the two generic written warnings remaining on the front);
 - iii. take up at least 40% of the back of the packet, not including a 3-4mm black border;
 - iv. be positioned parallel to the top edge of the packet;
 - v. be printed onto packs as per the Commission's technical specification.

Negative Resolution

21. Regulations governing the introduction of picture health warnings are subject to the negative resolution procedure.

Consultation

22. The UK Government (on behalf of England, Wales, Scotland and Northern Ireland) consulted on plans to introduce picture health warnings between 27 May and 25 August 2006.
23. Key stakeholders have been consulted in detail during the development of the picture warning consultation document, partial RIA and regulations. Officials have visited factory sites and taken the views of independent printing specialists.
24. The picture warning regulations will be an amendment to the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002. A full consultation took place before the introduction of the written health warnings in 2002, as part of the Tobacco Products Regulations 2002 consultation.

Rationale for Government Intervention

25. Tobacco is a uniquely dangerous product. Smoking is the greatest single cause of preventable illness and premature death and kills 106,000 people in the UK each year. In England, 24% of the population smoke, and this figure is higher in manual/routine working groups where 31% of people smoke.
26. A continued and multi-faceted tobacco control programme is therefore necessary. Without this, the high levels of mortality and morbidity caused by smoking will continue and high smoking levels amongst manual/routine groups will continue to contribute towards health inequalities.
27. Health warnings on packets communicate some of the health risks of smoking. Behind these warnings are a number of statistics and examples which illustrate the risks. Here are some of them:
 - ***Smokers die younger***

Half of all teenagers who are currently smoking will die from diseases caused by tobacco if they continue to smoke. One quarter will die before 70 years of age, losing on average 21 years of life (Peto R. Mortality in relation to smoking: 40 years' observations on male British doctors. BMJ 1994; 309: 901-911)
 - ***Smoking clogs the arteries and causes heart attacks and strokes***

A smoker has two to three times the risk of having a heart attack than a non-smoker (Doll, R and Peto, R. Mortality in relation to smoking: 40 years' observations on male British doctors. Br Med J. 1994; 309: 901-11).
 - ***Smoking causes fatal lung cancer***

Around 90% of all lung cancers are caused by smoking, either directly or through indirect exposure. Because of its poor prognosis, lung cancer is still the most common cause of cancer death in the UK, with around 33,600 deaths each year (Lung cancer and smoking – UK. CancerStats. Cancer Research UK, April 2004).

- ***Smoking is highly addictive, don't start***

Cigarettes are highly efficient nicotine delivery devices and are as addictive as drugs such as heroin or cocaine (Nicotine Addiction in Britain. A report of the Tobacco Advisory Group of the Royal College of Physicians, February 2000).

- ***Stopping smoking reduces the risk of fatal heart and lung diseases***

Smoking is the main cause of chronic obstructive pulmonary disease (which includes chronic bronchitis and emphysema). It is very rare in non-smokers and at least 80% of the deaths from this disease can be attributed to smoking (Nicotine Addiction in Britain. A report of the Tobacco Advisory Group of the Royal College of Physicians. RCP, 2000).

- ***Smoking can cause a slow and painful death***

Chronic obstructive pulmonary disease 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 due to smoking. The onset of the disease is very gradual and breathlessness only becomes troublesome when about half of the lung has been destroyed. The disease is rarely reversible once established (ASH website 2005).

- ***Smoking causes ageing of the skin***

Smokers' skin can be prematurely aged by between 10 and 20 years and, although the damaging effects of cigarette smoke on the skin are irreversible, further deterioration can be avoided by stopping smoking (Health check: on the state of the public health. Annual report of the Chief Medical Officer. Dept of Health. London, 2004).

- ***Smoking can damage the sperm and decreases fertility***

Men who smoke have a lower sperm count than non-smokers, and their semen contains a higher proportion of malformed sperm (Sofikitis N et al Effects of nicotine on sperm motility, membrane function and fertilizing capacity in vitro. Urological Research 2000 28: 370 – 5).

- ***Smoking may reduce the blood flow and causes impotence***

Overall smoking increases the risk of impotence by around 50% for men in their 30s and 40s. ASH and the British Medical Association have calculated that around 120,000 UK men in this age group are needlessly impotent as a result of smoking (Warning: Smoking Causes Male Sexual Impotence. ASH and the BMA, London, 1999).

- ***Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide***

Benzene is known to cause leukaemia. It is estimated to be responsible for approximately one-tenth to one-half of smoking-induced leukaemia mortality (Korte et al, The Contribution of Benzene to Smoking-Induced Leukemia. Environmental Health Perspectives Volume 108, Number 4, Apr00).

- ***Smoking when pregnant harms your baby***

Perinatal mortality (defined as still-birth or death of an infant within the first week of life) is increased by about one-third in babies of smokers. This is equivalent to approximately 420 deaths per year in England and Wales (Royal College of Physicians. Smoking and the Young London, 1992).

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

Bronchitis, pneumonia, asthma and other chronic respiratory illnesses are significantly more common in infants and children who have one or two smoking parents (Strachan DP, Cook DG. Parental smoking and lower respiratory illness in infancy and early childhood. Thorax 1997; 52: 905-914).

- ***Your doctor or your pharmacist can help you stop smoking***

Studies have shown that Nicotine Replacement Therapy roughly doubles the chances of a smoker successfully quitting compared to someone using no therapy (Nicotine replacement therapy for smoking cessation. The Cochrane Library, Issue 3, May 2001).

- ***Get help to stop smoking***

Smokers are up to four times more likely to stop smoking by attending specialist smokers' clinics than by using willpower alone (West, R. Getting serious about stopping smoking - a review of products, services and techniques. 1997).

Options

Option One – do nothing

28. European legislation does not make the introduction of picture warnings compulsory. From a legislative perspective, it is possible to do nothing.

Option Two – full implementation, as identified in the consultation paper

29. Option two would see the introduction of picture warnings on all tobacco packs with rear warning labels.
30. Fourteen picture warnings would be chosen, one for each health message, with regular (rather than equal) distribution of each warning on each product/packet type.
31. Picture warnings would take up at least 40% of the back of packs (excluding a 3-4mm black border) and would appear on ALL tobacco packet types/sizes.
32. There would be a lead in time of at least 13 months from laying regulations for all tobacco products in this option with a further 12 months for stock sell through for cigarettes and 24 months for other tobacco products.

Option Three – partial implementation

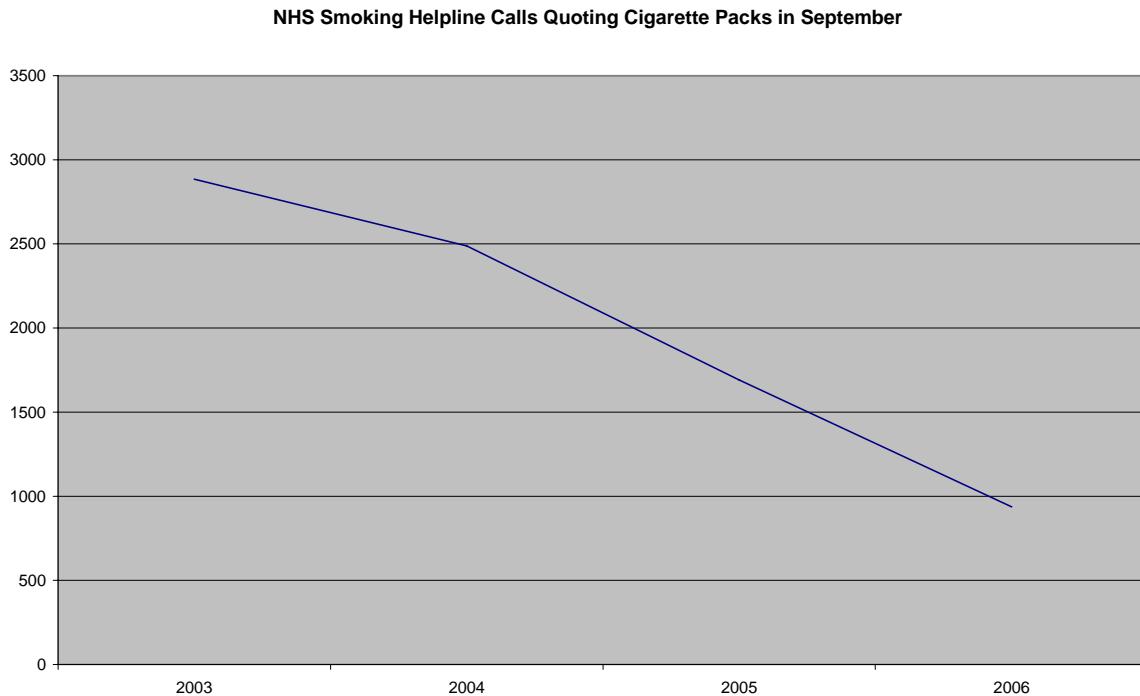
33. This option would see the introduction of picture warnings on cigarette packs only. The European Commission Decisions make it possible for Member States to only introduce picture warnings on certain product groups.
34. In option three, fourteen picture warnings would be chosen, one for each health message, with regular (rather than equal) distribution of each warning on each packet type.
35. Picture warnings would take up at least 40% of the back of packets (excluding a 3-4mm black border) and would appear on ALL cigarette packet types/sizes.
36. There would be a lead in time of at least 13 months from laying regulations for cigarettes in this option with a further 12 months for stock sell through.

Benefits

Option One

37. The current written warnings have been successful in prompting quit attempts and encouraging calls to the NHS Stop Smoking Helpline. Whilst there is evidence to suggest that the impact of the warnings is waning, for example from NHS Stop Smoking Helpline data (see graph below), the status quo option would lead to further quit attempts and calls to the helpline.

38. In line with this thinking, option one would lead to a slight decrease in numbers of smokers. We have estimated this to be around a tenth of the effect of the expected impact of picture warnings, meaning a decrease in UK smokers of around 0.05%.



Option Two

39. It was estimated in the RIA for introducing the current written warnings, that the long term impact of effective health warnings on cigarette packs in the UK will be to reduce smoking levels by 0.5%². Evidence suggests that warnings only have a certain life cycle after which smokers become immune to them³. In line with this thinking, calls made to the NHS Stop Smoking Helpline due to the health warnings have decreased since the introduction of the written warnings (see graph above). Option two will return smokers' attention to the warnings and ensure continued success of this policy in prompting quit attempts.

40. Research from Canada suggests that picture warnings have been more effective than written warnings (see table over the page). The introduction of picture warnings in the UK could have an even more positive effect, therefore, than the introduction of written warnings. However, without any specific evidence on impacts on smoking levels, we will

² This figure was based on the assumption that warnings would have a fifth of the impact of the tobacco advertising ban. In the lead up to the 2002 Tobacco Advertising and Promotion Act, work was undertaken to calculate the likely impact of the advertising ban on smoking levels in the UK (calculated to be 2.5% in the long term). This was done by assessing smokers' reasons for quitting, the figures are estimates only.

³ T Willemsen, M. The altered view of tobacco products: the effects of the new health warnings on smokers. DEFACTO, 2002.

assume that the introduction of picture warnings will have a similar effect to that predicted for written warnings: to decrease the number of smokers by 0.5% in the long term.

Research into the use of picture warnings in Canada

- more than 7/10 adults and nearly 9/10 youths in Canada think the picture health warnings are effective at informing them about health effects
- more than 50% of Canadian smokers say the warnings compel them to smoke less around other people
- 91% of smokers in Canada reported having read the warning labels
- 70% of those interviewed in a study recognised 3 actual and 3 bogus messages, showing the memorable effect of picture warnings
- smokers who read, thought about and discussed the picture warnings were significantly more likely to quit, attempt to quit or reduce their smoking
- pictures improve memory from the text that accompanies it – smokers are more likely to remember a health consequence of smoking, when smoking, if they have seen a picture
- studies have suggested that many Canadian smokers have reservations about being seen with packets with picture warnings
- 31% of Canadian ex-smokers participating in a study reported that picture warnings had motivated them to quit in the first place and 27% reported that the warning labels helped them to remain abstinent

Sources:

Fong, Geoffrey. *A review of the research on tobacco warning labels, with particular emphasis on the new Canadian warning labels*. 2001.

Hammond D et al. *Impact of the graphic Canadian warning labels on adult smoking behaviour*. *Tobacco Control*, 2003, Vol 12, 391-395.

Hammond D et al. *The impact of cigarette warning labels and smoke free bylaws on smoking cessation*. *Canadian Journal of Public Health*, May/June 2004, Vol 95.3, 201-204.

41. Smoking costs the NHS around £1.7 billion per year. If the long-term effect of the picture warnings is to decrease the total number of smokers by around 0.5%, there will be eventual annual savings to the NHS of around £8.5 million per year. Around 600 lives a year would also be saved, saving £288 million per year⁴. It is unlikely that these levels would be reached with a status quo. These long-term benefits would be dependent on the new picture warnings having a sustained impact. This may, in turn, be dependent on changing the pictures again in the future. This would will not involve any further set up costs.

⁴ On the assumption that a smoker killed by their habit on average loses 16 years of their life and that the benefits of one person per year to the UK economy is £30,000.

42. Picture warnings will also better communicate health messages to certain vulnerable groups, for example people with literacy and learning difficulties.
43. Tobacco products such as hand rolling tobacco, pipe tobacco and cigars are harmful to the health of smokers just like cigarettes. In public health terms, it is important that smokers of these products are made aware of the health risks just like cigarette smokers. This option, therefore, communicates health messages equitably across product types.
44. Option two allows a longer sell through time for non-cigarette products which takes into account lower turnover of these products. This is the same model as when the current written warnings were introduced.

Option Three

45. The positive effects of option three would be similar to those in paragraphs 39 to 44 above. However, this option does not include non-cigarette products, which are smoked by around 25% of smokers. Although it is difficult to quantify exactly, there would be slightly less impact on smoking rates and savings to the NHS than in option two. We have estimated 75% of the benefit.
46. Tobacco products other than cigarettes, such as hand rolling tobacco, pipe tobacco and cigars, have a lower turnover, cover a wider variety of packet types and their packs are often printed in smaller factories. The costs and effects of introducing picture warnings are likely to be proportionally higher for such products. Option three would only see picture warnings introduced on cigarette packets so the disproportional effects on other products would be negated.

Costs

47. There will be one off set up costs involved in introducing picture warnings onto tobacco packs. This is because printing factories would have to install new equipment to enable them to print photographs onto the packs. Changes to premises may also be required to create space for extra equipment. These costs will mainly be born by the tobacco and packaging industries.
48. The main tobacco companies in the UK have provided early estimates of the likely one off set up costs.
49. As introducing picture warnings is likely to mean that some smokers will quit, the tobacco industry may also see a loss in profits and there may be a reduction in income to the Exchequer, as expected if the Government PSA target is to be delivered.

Option one

50. A status quo would mean no new set up costs.
51. As option one would lead to a slight decrease in smoking levels, there would be relatively small costs to the tobacco industry and the Exchequer.

Option two

52. Early estimates suggest that the total set up costs for introducing picture warnings on **cigarette** packs in the UK would be around £3,050,000. This does not include non-cigarette products, however. Due to the complexity of the packaging market for non-cigarette products, the tobacco industry have not been able to provide cost estimates. For the purposes of this RIA an estimated figure of £3,400,000 to £4,100,000 will be used for the total set up costs of option two.
53. It is estimated that smoking levels in the UK would decrease by around 0.5% if picture warnings were introduced. It is estimated that this would equate to similar proportional decreases in profit in the tobacco industry, amounting to £37.8 million per year. There would also be annual losses to the Exchequer of around £52.5 million⁵.
54. There would be no extra enforcement costs in introducing picture warnings as enforcement arrangements would not change – that is, Trading Standards Officers will continue to enforce health warnings.

Option three

55. There will be set up costs for option three as well but as this would not include non-cigarette products, the estimated cost would be lower, at £3,050,000, while annual losses to the Exchequer would amount to around £39.4 million.
56. Ongoing costs to the tobacco industry under this option resulting from a decrease in smokers, would be around 75% of that for option two, amounting to around £28.4 million per year.
57. As for option two, option three would involve no further enforcement costs.

Summary of Costs and Benefits

58. Below is a summary table of the costs and benefits of introducing picture warnings. Note this reflects extra requirements of the picture warnings and does not include the existing costs/benefits of the written warnings. These figures are estimates based on information we have been able to gather and the table is to be used as a guide rather than a definitive costing of options:

⁵ On the assumption that annual tax revenue from tobacco sales in the UK is £10.5 billion and that picture warnings will lead to 0.5% fewer smokers

	Expected costs		Expected benefits		Net effects	
	Initial costs	Ongoing costs p.a.	Initial benefits	Ongoing benefits p.a.	Net initial effects	Net ongoing effects
OPTION ONE						
Manufacturers						
Costs of new equipment/machinery						
Fall in tobacco sales		£3.8 million				-£3.8 million
Taxes						
Losses to the Exchequer due to fall in sales		£5.25 million				-£5.25 million
NHS						
Treatment of smoking related diseases				£0.85 million		+£0.85 million
Citizens						
Lives saves				£28.8 million		+£28.8 million
TOTAL	Nil	£9.05 million	Nil	£29.65 million	Nil	+£20.6 million
OPTION TWO						
Manufacturers						
Costs of new equipment/machinery	£3.4 million to £4.1 million				-£3.4 million to -£4.1 million	
Fall in tobacco sales		£37.8 million				-£37.8 million
Taxes						
Losses to the Exchequer due to fall in sales		£52.5 million				-£52.5 million
NHS						
Treatment of smoking related diseases				£8.5 million		+£8.5 million
Citizens						
Lives saves				£288 million		£288 million
TOTAL	£3.4	£90.3	Nil	£296.5	-£3.4	+£206.2

	million to £4.1 million	million		million	million to -£4.1 million	million
OPTION THREE						
Manufacturers						
Costs of new equipment/machinery	£3.05 million				-£3.05 million	
Fall in tobacco sales		£28.4 million				-£28.4 million
Taxes						
Losses to the Exchequer due to fall in sales		£39.4 million				-£39.4 million
NHS						
Treatment of smoking related diseases				£6.35 million		+£6.35 million
Citizens						
Lives saves				£216 million		£216 million
TOTAL	£3.05 million	£67.8 million	Nil	£222.35 million	-£3.05 million	+£154.55 million

Risks

Option one

59. The number of callers to the NHS Stop Smoking Helpline citing pack warnings as their reason for calling has decreased since the written warnings were introduced. Without a change to the current written health warnings, their effect will continue to diminish.

Option two

60. The picture warnings will have a lifespan, just like the current written warnings, after which their effect will diminish. It may be necessary in the future to use alternative picture warnings from the European image bank to ensure continued impact.

Option three

61. The same risk exists for option three as for option two.

62. Option three also carries a further risk as it will exclude non-cigarette products. Products such as hand rolling tobacco, pipe tobacco and cigars also kill. Smokers of these products should therefore be warned of health risks in the same way as cigarette smokers are. Not introducing picture warnings on non-cigarette products could create an assumption to smokers that health risks of hand rolling tobacco, cigars and pipe tobacco are not as great, particularly important when the Labelling Directive also bans descriptors that suggest that one tobacco product is less harmful than another.

Impact on Small Businesses

63. Cigarette packets are printed at large factories in locations across Europe. The introduction of picture warnings on cigarette packs will have little impact on small businesses.

64. The printing of hand rolling tobacco, pipe tobacco and cigar packs is sometimes done by relatively small packaging companies. The introduction of picture warnings may in some cases require such companies to invest in extra equipment. The levels of investment would depend upon existing infrastructures.

65. Large packaging firms may be more able to absorb the extra costs of new printing equipment. Small companies may be dependent on extra income from tobacco companies to finance any changes. It is possible that tobacco companies may prefer to find an alternative packaging company to print packets rather than provide extra finance to an existing one.

Competition Assessment

66. A simple competition assessment has been undertaken following Cabinet Office RIA guidance.

67. The main effect of introducing picture warnings, other than the general ongoing effects such as decreases in the number of smokers, are the required changes to factories (including purchasing of new equipment) to enable printing of pictures and photographs onto tobacco packs. This effect will be felt by tobacco companies and the packaging companies that print the packs for them.

68. **Option one** is a status quo and therefore does not give rise to any new issues.

69. **Option two** includes all tobacco packs. **Cigarettes** are manufactured by large companies and the packets printed by large packaging companies. The effects of introducing picture warnings will therefore be similar across the market.

70. The non-cigarette sector of the tobacco industry and tobacco packaging industry is more varied, consisting of a mixture of small, medium and large companies. With this in mind, option two recommends a longer sell-through time (an extra year) for non-cigarette tobacco products.

71. **Option three** only includes cigarette packs. The effects will therefore be similar to those set out in paragraph 69.

Compensatory Simplification

72. A Government PSA target is in place to reduce the number of smokers in the England to 21% of the population by 2010. If this target is met, there will be fewer tobacco products consumed and this will of course have a knock-on effect on the tobacco industry.

73. Introducing simplification measures to aid the tobacco industry to compensate for initiatives such as pack warnings, would go against the overall aims of the PSA target.

74. Fewer tobacco sales would also have an eventual knock-on effect at retail. There may be scope, as the levels of smokers decreases over time, for looking at wider simplification measures for the retail industry.

Securing Compliance

75. Trading Standards Officers (Environmental Health Officers in Northern Ireland) will monitor compliance and ensure enforcement of the regulations.

Equity and Fairness

76. We have considered whether these measures will have any disproportionate impacts including in the context of race equality issues. Generally, we do not consider that these measures will disadvantage any group. However, due to the restrictions of European legislation we cannot introduce picture warnings on smokeless tobacco products, some of which are mainly used by black and ethnic minority groups, since they have no back warnings and only front of pack warnings.

Rural proofing

77. The introduction of picture warnings will have no disproportionate effects on the rural economy.

Implementation

78. The following timescales, which mirror the arrangements for the introduction of the current written warnings, will be required for introduction of picture health warnings. These have a uniform last date of manufacture for tobacco products with existing written warnings to ensure consistency, but recognise the longer sell-through required for non-cigarette products.

Stage	Proposed deadline for cigarette packs	Proposed deadline for other tobacco packs
Regulations published	August 2007	August 2007
Last date of manufacture/import for packs with written warnings	1 October 2008	1 October 2008
Last date of sale for packs with written warnings	1 October 2009	1 October 2010

79. Manufacturers will need to follow the technical specifications set out in the regulations and will be able to use a guidance document produced by the European Commission to aid implementation.

Post-implementation review

80. Currently, the Department has no timescale set out for refreshing the picture warnings – i.e. changing the required warning within each set of three. We will monitor public opinion of, and reaction to, the warnings, and will refresh the images as appropriate. We will be mindful of the opinions on the picture library gathered during this consultation, and ensure that there is an appropriate lead-in time for manufacturers and retailers.

Summary and recommendation

81. This RIA sets out the details and expected impacts of regulations legislating for the introduction of picture warnings on tobacco packs.

82. Option two – carrying picture warnings on all tobacco products – is the option that the Government will implement. This option will ensure a clear and consistent public health message to all smokers and will have the largest impact on smoking levels, will save the most lives and will save the NHS the most money.

Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed *Dawn Primarolo*

Date *23rd August 2007*

**Dawn Primarolo MP
Minister of State for Public Health
Department of Health**

