

Standardised packaging of tobacco



Report of the independent review
undertaken by Sir Cyril Chantler

April 2014

Letter to the Secretary of State for Health, the Rt. Hon. Jeremy Hunt MP

Dear Secretary of State,

1. Jane Ellison, Parliamentary Under Secretary of State for Public Health, wrote on 27 November 2013 asking that I advise you, "taking into account existing and any fresh evidence, as to whether or not the introduction of standardised packaging is likely to have an effect on public health (and what any effect might be), in particular in relation to the health of children." This advice is intended to inform your decision on whether to take forward the policy, which is of course one you will take on the basis of wider considerations than that on which I have been asked to report.
2. I published a "Method Statement" on 16 December 2013, making clear that the Review would not re-run the Department of Health's 2012 consultation on standardised packaging, but would consider *evidence* on whether standardised packaging is likely to lead to a decrease in tobacco consumption, including in particular the risk of children becoming addicted. I started from the uncontroversial premise that any such decrease will have a positive impact on public health. I have now completed this Review and this letter and attached report constitute my advice to you.
3. In carrying out the Review, I have met with opponents of standardised packaging including representatives from the major tobacco companies. I have also met with tobacco control experts many of whom strongly advocate standardised packaging. I have been sent a considerable volume of evidence from both sides of the debate which my team and I have reviewed carefully. We sought further information where we considered it relevant. I visited Australia in March 2014 to study the implementation of plain packaging there.
4. I have sought to conduct the Review on the principles of transparency and independence. I am therefore publishing this report on the Review's webpage at King's College London. I am making available copies of the evidence submitted to the Review, together with all notes and transcripts of meetings with external parties and a note on expert advisors and their roles.
5. As a paediatrician, I began the Review with the knowledge that most smokers take up the habit as children and that smoking is both highly addictive and extremely harmful to health. However, I had no prior view on the efficacy or desirability of standardised packaging as a policy measure to control tobacco consumption.
6. As I have learnt, one in every two long-term smokers dies prematurely as a result of smoking-related disease.¹ Two-thirds of adult smokers report that they took up smoking before the age of 18, and two-fifths had started smoking regularly before 16.² Addiction to nicotine involves multiple processes, with evidence suggesting adolescents can experience a loss of autonomy very soon after the first cigarette.³ None of these processes requires conscious awareness, rather there is a powerful urge to

¹ Doll R, Peto, R, Boreham & Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. *BMJ* 2004; 328: 1519

² Action on Smoking & Health, Young People and Smoking Factsheet: <http://ash.org.uk/information/facts-and-stats/fact-sheets>

³ DiFranza, J.R. Hooked from the first cigarette. *Journal of Family Practice*, Vol. 56(12), Dec 2007, 1017-1022.

smoke in the presence of stimuli associated with previous absorption of nicotine, which increases as opportunities for smoking become more frequent, especially after the school years.⁴ Although two-thirds of current smokers report wanting to give up smoking, quitting is extremely difficult and most smokers make multiple quit attempts before they succeed. Although the number of children taking up smoking has been falling since the 1990s, an estimated 207,000 children aged 11-15 still take up smoking each year in the United Kingdom.⁵ If this rate were reduced even by 2%, for example, it would mean 4,000 fewer children took up smoking each year, greatly improving their health outcomes.

Summary of my findings

7. The aim of standardised packaging is to reduce the tobacco package's visual identity and appeal as an advertisement for the product. There is very strong evidence that exposure to tobacco advertising and promotion increases the likelihood of children taking up smoking. Industry documents show that tobacco packaging has for decades been designed, in the light of market research, with regard to what appeals to target groups. Branded cigarettes are 'badge' products, frequently on display, which therefore act as a "silent salesman." Tobacco packages appear to be especially important as a means of communicating brand imagery in countries like Australia and the UK which have comprehensive bans on advertising and promotion. It is notable that Japan Tobacco International responded to the decision to introduce tobacco plain packaging in Australia by attempting to sue the Australian Government for taking possession of its mobile "billboard".⁶
8. The tobacco industry argues that all of its marketing activity, including packaging, aims solely to persuade existing adult smokers to switch brand and never targets children or new smokers. However, in my opinion, whatever their intent, it is not plausible that the effect of branded packaging is only to encourage brand switching amongst adult smokers, and never to encourage non-smokers from taking up smoking. I have heard no coherent argument as to how this purported separation occurs in practice and in my opinion a 'spillover effect' is highly plausible whereby packages that are designed to appeal to a young adult, also, albeit inadvertently, appeal to children. It seems to me that children and non-smokers are not, and cannot be, quarantined from seeing tobacco packaging and in my view once they are exposed to this packaging, they are susceptible to its appeal whether it is intended to target them or not. In the light of these and other considerations set out in my report I believe that branded packaging contributes to increased tobacco consumption.
9. I make it plain at the outset that there are limitations to the evidence currently available as to the likely effect of standardised packaging on tobacco consumption. There has been, as opponents of standardised packaging have rightly pointed out to me in the course of this Review, no randomised controlled trial carried out to test the impact of standardised packaging on the take up of smoking amongst children. However, I do not consider that these limitations prevent me from reaching a view on the issue in respect of which my advice has been sought.
10. I do not consider it to be possible or ethical to undertake such a trial. To do so would require studies to be carried out within a suitably large and isolated population free of known confounding factors that influence smoking and prevalence. Such studies would expose a randomised group of children to

⁴ Professor Robert West, written evidence to the Review. See also his "The Smokefree Formula: A Revolutionary Way to Stop Smoking Now", Orion Books, London, 2013.

⁵ New childhood smokers as estimated from the Smoking, Drinking and Drug Use Among Young People in England survey 2013. Cancer Research UK.

⁶ *High Court of Australia Transcripts*, Japan Tobacco International SA v Commonwealth of Australia; British American Tobacco Australasia Ltd & Ors v The Commonwealth of Australia HCATrans 91 (17 April 2012).

nicotine exposure and possible addiction. Australia does not constitute that trial because a number of things have happened together, including tax rises. Disentangling and evaluating these will take years, not months.

11. There have been a large number of studies which have tested the possible effect of standardised packaging using mock-ups of standardised packaging to see how smokers and potential smokers react to them. The Department of Health commissioned a systematic review of these studies known as the "Stirling Review"⁷ which concluded that:
 - Standardised packaging is less appealing than branded packaging;
 - Graphic and text health warnings are more credible and memorable on standardised packaging than when juxtaposed with attractive branding;
 - Whereas colours and descriptors on branded packaging confuse smokers into falsely perceiving some products as lighter and therefore "healthier", products in standardised packages are more likely to be perceived as harmful.
12. Several of the studies also asked participants whether standardised packaging would change their smoking behaviors and intentions. The reviewers called for "some caution" in interpreting these findings as "expressed smoking-related intentions are not always representative of future smoking behavior."
13. The Stirling Review constitutes the most extensive and authoritative piece of work on the issue of standardised packaging yet undertaken. In light of its prominence in the debate on this issue, and the strong criticisms made of it by the tobacco industry, I considered it appropriate to commission further assessments from academics with relevant expertise to inform how much weight to place on this evidence. They assured me that the work was robust and could be relied upon.
14. The Stirling evidence has been criticised for relying on stated intentions in hypothetical situations. I recognise that stated intentions are generally weak predictors of behaviour (regardless of whether the situation is hypothetical or not). I see the importance of Stirling as being the consistency of its results on appeal, salience and perceptions of harm, most notably that standardised packaging is less appealing than branded packaging. This evidence is direct and not reliant on stated intentions. Evidence from other spheres shows a strong non-conscious link between appeal and subsequent behaviour regardless of stated intentions.⁸ I therefore conclude that, by reducing its appeal, standardised packaging would affect smoking behaviour.
15. A variety of objections to standardised packaging were advanced to me by the tobacco industry and other opponents of the measure during the course of my Review. Some, including the legal issues that may arise from the introduction of standardised packaging, were clearly outside my terms of reference and for that matter my expertise. I consider the two that engage directly with the issue of consumption.
16. First, tobacco companies have argued that standardised packaging will result in falling prices that in turn will increase the consumption of tobacco. They argue that, in the long-run at least, standardised packaging will reduce brand loyalty, causing smokers to switch to cheaper brands and encouraging price competition between manufacturers. However, early evidence from Australia does not show falling

⁷ Moodie C, Stead M, Bauld L, McNeill A, Angus K, Hinds K, Kwan I, Thomas J, Hasting G, O'Mara-Eves A (2012), Plain Tobacco Packaging: A Systematic Review. Available from: The University of Stirling.

⁸ Webb TL, and Sheeran P, (2006). Does Changing Behavioral Intentions Engender Behavior Change? A Meta-Analysis of the Experimental Evidence. *Psychological Bulletin*. Vol. 132, No. 2, pp, 249–268.

prices; rather price rises have continued over and above tax increases. There is some evidence of trading down towards cheaper brands, but this appears to be a continuation of an ongoing market trend. Were all this to change, the Government can in any case mitigate any price reduction by increasing tobacco taxes.

17. Second, I am not convinced by the tobacco industry's argument that standardised packaging would increase the illicit market, especially in counterfeit cigarettes. There is no evidence that standardised packaging is easier to counterfeit, and indeed in Australia, hardly any counterfeit standardised packages have been found to date. The tobacco industry has a history of attacking new tobacco control measures on the basis that they will boost illicit sales, arguing that illicit suppliers benefit from not having to follow the same restrictions. It seems to me that the solution to illicit use is instead to have an effective enforcement regime, and the UK has already demonstrated that an effective enforcement regime and appropriate sanctions can keep illicit to low levels, even in a high tax jurisdiction.

Conclusion

18. Having reviewed the evidence it is in my view highly likely that standardised packaging would serve to reduce the rate of children taking up smoking and implausible that it would increase the consumption of tobacco. I am persuaded that branded packaging plays an important role in encouraging young people to smoke and in consolidating the habit irrespective of the intentions of the industry. Although I have not seen evidence that allows me to quantify the size of the likely impact of standardised packaging, I am satisfied that the body of evidence shows that standardised packaging, in conjunction with the current tobacco control regime, is very likely to lead to a modest but important reduction over time on the uptake and prevalence of smoking and thus have a positive impact on public health.

Yours sincerely,



Sir Cyril Chantler

31 March 2014

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Finally I would like to express my gratitude to the Principal of King's College, London, Sir Rick Trainor, and to the Vice Principal for Health, Sir Robert Lechler, who kindly provided accommodation and facilities for the Review team on the Guy's Campus.

Introduction

- 1.1 In November 2013 the Government commissioned an independent review into the public health effects of standardised packaging of tobacco (“the Review”). In doing so, the Public Health Minister (Jane Ellison MP) noted that the Department of Health’s 2012 consultation on this subject “*showed that opinions were highly polarised with strong views put forward on both sides of the debate*” but that “*things have moved on and research evidence continues to emerge*”.⁹
- 1.2 The terms of reference for the Review were set out in a letter dated 27 November 2013, namely: “*To give advice to the Secretary of State for Health, taking into account existing and any fresh evidence, as to whether or not the introduction of standardised packaging is likely to have an effect on public health (and what any effect might be), in particular in relation to the health of children.*”
- 1.3 This report describes how the Review has been conducted and presents the conclusions reached, setting out the relevant evidence where appropriate, to inform Ministerial decisions and the wider policy process.

What is standardised packaging?

- 1.4 “Standardised packaging” means putting tobacco products in drab, purposefully unattractive packaging, devoid of branding (other than name) or promotional information. The term is often used interchangeably with ‘plain packaging’, however the latter may involve fewer restrictions on, for example, size and shape of packs than fully “standardised” packaging. In Australia (a plain packaging scheme with some restrictions on size and shape), packaging is in brown/olive packaging and matt cardboard. There are no special foils, tapes, laminating or special print effects. Packages are dominated by large and prominent (graphic and textual) health warnings. Cigarette boxes are limited to simple flip- top openings, with other features such as slide opening, or bevelled edges banned. Brand and variant names are required to be written in a prescribed format, font and size.¹⁰
- 1.5 Figure 1 shows an example of a cigarette pack currently in use under the Australian plain packaging legislation. Packages of other tobacco products, including pouches of roll-your-own tobacco and cigar tins, are similar.¹¹ The main features of a possible standardised packaging scheme for the UK were set out in the Department of Health’s 2012 consultation, with further details and specifications to be set out by the Government if a decision to require standardised packaging was taken.

⁹ Department of Health press release dated 28 November 2013.

¹⁰ Tobacco Plain Packaging Act 2011. No.148, 2011

¹¹ See *Tobacco Plain Packaging; Your guide*. Australian Department of Health and Ageing, (2012).

Figure 1: Australian plain pack example (front and back)



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The Department of Health's consultation

- 1.6 The Department of Health's consultation on standardised packaging ran from April to August 2012. To inform responses to the consultation, the Department of Health commissioned a systematic review of the evidence on the public health effects of standardised packaging¹² (referred to here as "the Stirling Review"). The review was undertaken by academics at the University of Stirling, the University of Nottingham and the Institute of Education, London, and considered the findings of 37 studies. It was published alongside the consultation document.
- 1.7 Over 600,000 responses – the vast majority from organised campaigns¹³ – were received by the Department of Health. A "Summary Report" was published in July 2013, with the Government announcing that it had decided to wait until the emerging impact of the introduction of plain packaging in Australia could be measured, before making a final decision.¹⁴

The Review's methodology

- 1.8 On 16 December 2013 I published a Method Statement which set out the method I intended to adopt in carrying out my review (see Annex A).
- 1.9 In accordance with the Method Statement, the Review Team and I began by considering the existing evidence relevant to the public health issue I had been asked to consider. This involved giving careful consideration to the Summary Report of the Department of Health's 2012 consultation, reviewing full

¹² Supported through the Public Health Research Consortium.

¹³ The largest single campaign response was sponsored by FOREST (Freedom Organisation for the Right to Enjoy Smoking Tobacco) and numbered some 270,000 responses.

¹⁴ <https://www.gov.uk/government/news/consultation-on-standardised-packaging-of-tobacco-products>

text versions of a range of detailed responses to that consultation from the main stakeholders and both the Stirling Review and subsequent Research Update published in September 2013.

- 1.10 Following publication of the Method Statement, some 50 new submissions were received, which brought to light several new papers, including some “in press” or in the process of peer review.¹⁵ The submissions also included a number of organisation’s member opinion surveys, and the views of, amongst others, packaging businesses.
- 1.11 All submissions to the Review were read and key points of argument and supporting evidence identified for follow-up. In several cases I contacted experts who had articulated what appeared to be the key arguments and/or summation of evidence, and arranged face to face meetings with them to explore their views in greater detail. This included meetings with experts such as Professors Devinney and Steinberg, who had produced detailed critiques of the Stirling Review and the drivers of smoking initiation respectively.¹⁶
- 1.12 In addition to meeting with experts, in accordance with my Method Statement I held two main meetings to discuss the views of the principal bodies representing each side of this polarised debate. Accordingly, I met with representatives of the Smokefree Action Coalition on 27 January 2014 and the Tobacco Manufacturers Association on 29 January 2014 in order to better understand and explore their respective views. I also met with representatives of Philip Morris Ltd on 29 January 2014 as they are not a member of the Tobacco Manufacturers Association. I am publishing the transcripts of these meetings.
- 1.13 A number of papers referenced in the tobacco industry’s submissions were considered in detail after identification of those that appeared most relevant to the task. The voluminous literature on tobacco control was also scrutinised to the extent time allowed, including material sourced from references in submissions, published papers and previous reviews.¹⁷
- 1.14 As anticipated in my Method Statement, I also commissioned some further expert advice to assist me in the analysis of the key evidence. In particular, I commissioned two specific pieces of independent analysis on the qualitative and quantitative studies in the Stirling Review (and the subsequent Research Update) using Critical Appraisal Skills Programme assessment tools. These were undertaken by academics at Southampton University and Kings College London respectively.
- 1.15 Finally, I also sought to take account of the emerging evidence relating to the implementation of plain packaging in Australia. In particular, I met with a range of stakeholders in Australia during March 2014, including representatives of the tobacco industry, leading public health academics, and key departments of the Australian Commonwealth Government.
- 1.16 A list of all published evidence considered by the Review will be made available separately, together with copies of the submissions sent in response to the Method Statement and further evidence sent to the Review which generally arose in follow-up to questions posed in meetings or in response to specific requests.
- 1.17 I have not sought to distinguish between different types of tobacco products for the purposes of this Review but have looked at tobacco in general. All tobacco products are dangerous in their health effects. The Review has, however, focused on cigarettes and roll-your-own tobacco in view of their overall prevalence and particularly their use by children and young people. I note in this regard the approach

¹⁵ Unpublished papers were considered if they had been accepted for publication.

¹⁶ Originally commissioned on behalf of Japan Tobacco International.

¹⁷ Notably the 2011 evidence review by Quit Victoria which lists over 150 relevant references.

taken in the revised European Tobacco Products Directive (mentioned further below) in relation to these products which differs from that taken for more mainstream products but preserves power to intervene further as necessary. I see the scope of any standardised packaging scheme as one matter for policy makers to consider further in the event of a decision to introduce such a scheme.

- 1.18 Given my terms of reference, much of the Review's time was spent considering the likely impact of standardised packaging on young people. For clarity, in this report references to "children" are generally used to refer to those under 18 years of age (who are unable legally to purchase tobacco), and references to "young adults" are to 18-24 year olds. In practice however, I considered it necessary to consider the effects of standardised packaging across the age range as a continuum. This is because addiction to smoking can involve a number of stages after first initiation, including prolonged progression through occasional use and later consolidation to becoming a habitual smoker.¹⁸ Coupled with the fact that once established, giving up smoking is extraordinarily difficult, there is a clear rationale for targeting anti-smoking efforts at children and young people whenever possible.

The nature of the evidence

- 1.19 I have been asked whether the evidence shows that it is *likely* that there would be a public health impact. This is clearly not an issue which is capable of scientific proof in the manner one might apply, for example, to the efficacy of a new drug. There have been no double blind randomised controlled trials of standardised packaging and none could conceivably be undertaken. The most direct experiment to test the efficacy of standardised packaging might be to compare the uptake of smoking in non-smoking children with cigarettes in branded packaging and to see which group smoked more. But given the highly addictive and harmful nature of smoking, such an experiment could, rightly, never receive ethical approval. In any case such an experiment would need to be conducted over a long period and within a large population in which other variables were held constant. Indeed in Australia it will be difficult in due course to separate the effect of plain packaging from other factors such as changes in pack sizes introduced by the manufacturers, and price and tax increases.
- 1.20 However there is a considerable volume of other evidence from interested parties on all sides of the debate, augmented by further tobacco control publications, internal tobacco industry documents, wider marketing literature and practice, all of which I have taken into account in arriving at a considered view of likely effects, grounded in the best available evidence.

The European Tobacco Products Directive

- 1.21 I note that while the Review was underway, the European Tobacco Products Directive (first agreed in 2001) was in the final stages of revision. The revised directive was approved by the European Parliament on 26 February 2014 and adopted by the Council on 14 March 2014.¹⁹ It should come into force in May 2014²⁰ and will allow Member States two years to implement its provisions. It contains new provisions on packaging and labelling including larger health warnings, prescribed shape and opening, minimum

¹⁸ A 2002 analysis of tobacco industry documents released since 1998 concluded that "the industry views the transition from smoking the first cigarette to becoming a confirmed pack-a-day smoker as a series of stages that may extend to age 25, and it has developed marketing strategies not only to encourage initial experimentation (often by teens) but also to carry new smokers through each stage of this process". Ling, P.M. and Glantz, S.A. 'Why and How the Tobacco Industry Sells Cigarettes to Young Adults: Evidence from Industry Documents', *American Journal of Public Health*, June 2002, Vol 92, No 6. 908-916

¹⁹ http://ec.europa.eu/health/tobacco/products/revision/index_en.htm

²⁰ European Commission – MEMO/14/134 26/02/2014

contents (20 cigarettes or 40g of roll-your-own), and restrictions on the sale of flavoured and slim/super-slim cigarettes. The revised Directive allows Member States to introduce further measures relating to standardised packaging "where they are justified on grounds of public health, are proportionate and do not lead to hidden barriers to trade between countries".

- 1.22 It is predicted by the European Commission that implementation of the Directive's provisions will lead to a 2% drop in consumption of tobacco over a period of 5 years, roughly equivalent to 2.4 million fewer smokers in the EU.

Arguments for and against standardised packaging

2.1 I now turn to the principal arguments that have been advanced for and against standardised packaging in so far as they are relevant to my Terms of Reference. It should be noted that the Review received extensive material from each side of the debate and that this Report seeks only to summarise those arguments as fairly as possible.

Summary of proponents' arguments

2.2 The objectives of standardised packaging, as part of a comprehensive programme of tobacco control, are to improve public health by:

- discouraging people, particularly children, from taking up smoking (particular emphasis is placed on this)
- encouraging people to give up
- discouraging people who have given up from relapsing
- reducing people's exposure to tobacco smoke.²¹

2.3 In summary, proponents of standardised packaging believe that it will:

- (a) reduce the appeal of tobacco products to consumers;
- (a) increase the effectiveness of health warnings on the retail packaging; and
- (a) reduce the ability of the retail packaging to mislead about the harmful effects of smoking or using tobacco products.

2.4 They argue that social science research supports the following contentions:

- messages and images promoting the use of tobacco products can normalise tobacco use, increase uptake of smoking by children and act as disincentives to quit;
- packaging is an important element of advertising and promotion, and its value has increased as traditional forms of advertising and promotion have become restricted (described in the tobacco industry trade press as "the silent salesman");²²
- tobacco packaging promotes brand appeal. It is difficult if not impossible to separate this from the promotion of tobacco use or to exclude children and young adults from its effect;

²¹ Standardised packaging has long been identified as a potential tobacco control measure. The world's first health treaty – the Framework Convention on Tobacco Control (FCTC), agreed under the aegis of the World Health Organization – outlines a standardised packaging scheme for signatories to consider implementing. The FCTC came into force on 27 February 2005. See guidelines on Articles 11 and 13 adopted in November 2008: <http://www.who.int/fctc/en/>

²² Moodie C, and Hastings G, (2009). Making the Pack the Hero, Tobacco Industry Response to Marketing Restrictions in the UK: Findings from a Long-Term Audit. *Int J Ment Health Addiction*. 9:24–38.

- standardised packaging has been shown to be less appealing for young people who may be thinking of trying smoking;
- many smokers are misled by pack design into thinking that certain cigarettes may be safer than others;
- pack design can also distract from the prominence of graphic health warnings;
- the inclusion of brand names and other design embellishments are strongly associated with the level of appeal and perceived traits associated with branding such as sophistication;
- innovative packaging shape, size, and opening create strong associations with level of appeal and perceived traits associated with branding.²³

Summary of opponents' arguments

2.5 The tobacco manufacturing industry, their suppliers and retailers, counter that there is *no* credible evidence for the purported positive effects of standardised packaging, and in practice not only would it fail to achieve the aim of reducing use of tobacco, it would have significant adverse consequences for public health through effects on price and the illicit trade. These effects would mean that standardised packaging as a tobacco control measure would actually be counterproductive.

2.6 In summary, opponents of standardised packaging argue that:

- smoking initiation and ongoing consumption are driven by factors which are unrelated to packaging;
- risk factors for taking-up smoking are known to be related to factors such as socio-economic deprivation, peer pressure, parental smoking, price and accessibility (rather than packaging);
- branded packaging is a means to differentiate products for consumers;
- marketing (which is largely banned in the UK and other developed countries) is solely for the purpose of encouraging adult smokers to switch brands rather than to take up smoking in the first place;
- there is *no* supporting evidence for standardised packaging from randomised controlled trials (as these do not exist);
- the research studies relied upon by proponents of standardised packaging (e.g. in the Stirling Review), are individually and collectively flawed in their methods, and/or are biased and therefore cannot be relied upon;
- most significantly, studies do not demonstrate a link from concepts such as "appeal" to actual smoking behaviour;
- far from *decreasing* consumption, by destroying brand loyalty, consumers will trade down and price competition will lead to 'commoditisation' in the market. Lower prices would *increase* overall consumption;
- there would be a significant boost to the illicit trade, making counterfeit production easier and increasing the relative attractiveness of illicit products;

²³ List adapted from Jonathan Liberman Plainly Constitutional: The upholding of Plain Tobacco Packaging by the High Court of Australia (Explanatory Memorandum, Tobacco plain packaging Bill 2011 (Cth 1)).

- standardised packaging may even create a perverse 'forbidden fruit' appeal by making smoking appear more rebellious.

2.7 In addition to these arguments, it is suggested that the emerging evidence from Australia shows that plain (as opposed to standardised) packaging is not delivering the intended benefits, and indeed that there are signs of adverse effects such as growth of the illicit trade in tobacco.

The approach taken by the Review

2.8 Having carefully considered the arguments advanced by both sides of the debate, and having reviewed the underlying evidence, I decided that a sensible approach to answering the question I have been asked was to address each of the following issues in turn:

- (1) **Does branded packaging promote tobacco consumption, especially by encouraging children to take up smoking?**
- (2) **Is standardised packaging likely to lead to a reduction in the consumption of tobacco?**
- (3) **Is it likely that standardised packaging will lead to an increase in tobacco consumption by lowering the price of tobacco as the market is commoditised or by increasing the consumption of illicit products?**

2.9 The first two issues are clearly related. The first looks, essentially, at whether packaging as it currently exists has an effect in terms of *promoting* the consumption of tobacco. However, this question can only take me half-way, since one then needs to consider whether standardised packaging would serve to prevent this. The third question considers the principal counter-arguments that have been advanced by the tobacco industry. In this respect, I am conscious that the tobacco industry has advanced a large range of counter-arguments, many of which do not relate to the public health impact of standardised packaging (e.g. legal issues). I have not considered such arguments, but did think it appropriate to consider whether standardised packaging might lead to an increase in tobacco consumption by lowering the price of tobacco through commoditisation or by increasing illicit trade.

2.10 These issues are considered in the following sections of this report.

Does branded packaging promote tobacco consumption, especially by encouraging children to take up smoking?

The position of tobacco companies: the purpose of tobacco marketing, including packaging, is to encourage brand switching

- 3.1 Tobacco companies have long held the position that all their marketing activity, including branded packaging, is devoted solely to persuading existing adult smokers to switch brand. Their stated marketing policy as set out in their codes of conduct is never to target children or non-smokers. Ronald Ridderbeekx (Head of Corporate & Regulatory Affairs for British American Tobacco) told this Review that *"Tobacco companies are not interested in converting non-smokers into smokers. We are quite comfortable – I'll give you an example. The company I work for has a market share of 8.2% in the UK market. That means that over 90% of smokers do not smoke our brand. That's quite enough of a market to shoot for, instead of, feeling compelled to go after people who don't smoke."*²⁴
- 3.2 I have, however, seen reviews of internal tobacco industry documents released as a result of litigation in the United States. These show that, like other consumer goods industries, tobacco companies see packaging as part of the marketing mix and design their packaging to appeal to their target audiences, such as women or young adults. For example, a 1992 Philip Morris report on marketing perceptions stated *"some women admit they buy Virginia Slims when they go out at night to complement a desire to look more feminine and stylish. [...] Women are particularly involved with the aesthetics of packaging. We sense that women are a primary target for our innovative packaging task and that more fashionable feminine packaging can enhance the relevance of some of our brands."*²⁵
- 3.3 I am aware that tobacco companies have conducted considerable market research to understand which kind of packaging best appeals to particular groups of consumers. For example, Kotnowski and Hammond's review of tobacco industry consumer research on packaging shape, size and opening showed that *"consumer research and tobacco company marketing documents consistently found that pack shape dictated perceptions of added value and product quality [...] Changes to pack structure were found in industry research to enhance taste-related perception [...] Overwhelmingly, packs with slim and thin configurations were appealing to young women"*.²⁶ Pierre De La Bouchere CEO of Japan Tobacco International said (in 2010) *"we're actively investing in Benson & Hedges and Silk Cut. A good example is the recent rejuvenation of Benson & Hedges gold with a beveled pack that offers a modern look and feel. This investment is paying off as both Benson and Hedges and Silk Cut have increased their share of the premium segment in 2010."*²⁷

²⁴ Transcript of meeting of 29 January 2014 with the Tobacco Manufacturers Association (p28).

²⁵ Wakefield MA, Morley C, Horan JK and Cummings KM, (2002). The Cigarette pack as image: new evidence from tobacco industry documents. *Tobacco Control*. 11(suppl. 1):i73–i80.

²⁶ Kotnowski K, and Hammond D, (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. *Addiction*. 108(9), 1658-1668.

²⁷ Japan Tobacco International webcast 8 February 2011, quoted in Hammond and Kotnowski (2013).

- 3.4 Mr Ridderbeekx told the Review, *"those are the principles of marketing: that you choose your target audience, you go and talk to that target audience to find out what their demand is, and then you try and meet that demand with the best mix of things that you have at your disposal, one of which is packaging."*²⁸
- 3.5 Industry representatives, in oral evidence to the Review, were quite categorical that they do not produce or market products with an intention to appeal to children, and thought that in practice their products did not appear to do so, even inadvertently. The tobacco companies interpret their marketing codes as to only allow them to carry out market research on adult smokers, never children or non-smokers. However, tobacco control experts describe a 'spill-over' effect, whereby products aimed at young adults could also, albeit inadvertently, appeal to children.²⁹
- 3.6 I have seen considerable evidence of tobacco companies carrying out market research on all aspects of packaging (e.g. colour, size, shape and opening) to make it appeal to various target groups of young adults. In my opinion a "spillover effect" (as described by tobacco control experts) is extremely plausible, whereby packages that are meticulously designed to appeal to, say, an 18 year old, are highly likely to appeal to a 16 year old. Because 16 year olds look up to 18 year olds and want to emulate them, in my view it is not possible to design packages in such a way as to appeal solely to one group without also appealing to the other. Research looking at the link between branded and innovative packaging and childhood and young adulthood smoking susceptibility bears this out, describing an "inevitable knock-on effect" of targeting product design at young adults.³⁰

Exposure to media advertising and promotions proven to cause increased likelihood of smoking

- 3.7 Despite the long-held contention from the industry that all tobacco marketing is for the purpose of brand switching, there is clear evidence that exposure to tobacco *advertising* and *promotion* increases the likelihood of smoking:
- a 2008 Cochrane review³¹ (Lovato et al) studied evidence from numerous cohort studies and found that the more branding images that children had been exposed to through advertising and promotions such as print and television, the more likely they were subsequently to take up smoking and that this was a causal relationship³²
 - similarly, in a review assessing causality, DiFranza (2006) concludes that: *"Promotions foster positive attitudes, beliefs, and expectations regarding tobacco use. This fosters intentions to use and increases the likelihood of initiation. Greater exposure to promotion leads to higher risk. This is seen in diverse cultures and persists when other risk factors, such as socioeconomic status or parental or peer smoking, are controlled. Causality is the only plausible scientific explanation for the observed data"*³³
 - the US Surgeon General summarised this evidence in reports in 2012 and 2014, with the latter stating *"The evidence is sufficient to conclude that advertising and promotional activities by the*

²⁸ Transcript of meeting of 29 January 2014 with the Tobacco Manufacturers Association (p15).

²⁹ Hastings GB et al, (1994). Cigarette advertising and children's smoke: why Reg was withdrawn. *BMJ* 309(6959): 933–937.

³⁰ Ford A, MacKintosh AM, Moodie C, Richardson S, Hastings G, (2013). Cigarette pack design and adolescent smoking susceptibility: a cross-sectional survey. *British Medical Journal Open*. 3:e003282

³¹ Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognised as the highest standard in evidence-based health care.

³² Lovato C, Linn G, Stead LF, Best A, (2003). Impact of Tobacco advertising and promotion on increasing adolescent smoking behaviors (Review). *Cochrane Database*. (4):CD003439.

³³ Di Franza Joseph R et al. (2006). Tobacco Promotion and the Initiation of Tobacco Use: Assessing the Evidence for Causality. *Pediatrics*. Vol. 117 No. 6

tobacco companies cause the onset and continuation of smoking among adolescents and young adults"³⁴

- Judge Kessler concluded, in litigation that lasted from 1999 to 2006, that the industry's public statements that they do not market to youth, that their marketing is only aimed at adult smokers and that their marketing has no impact on youth smoking are "false and misleading" and stem "from their recognition, contained in internal documents written for decades, that new teenage smokers were essential to their continued profitability".³⁵

3.8 None of the tobacco industry submissions to the Review acknowledge or discuss the above evidence. When asked for a view on the findings of the US Surgeon General, the Secretary General of the Tobacco Manufacturers Association, Jane Chisholm Caunt said that in the context of the current debate on standardised packaging in the UK, tobacco advertising and promotion is irrelevant as it has been banned since 2004.³⁶ But in my view the evidence that advertising and promotion increases the likelihood of smoking is highly relevant to the question of whether packaging does too.

Badge products: packaging as advertising vehicle in "dark markets"³⁷

3.9 Public health experts argue that packaging of tobacco products is especially able to play a promotional role because unlike many other products, they are generally "constantly being taken out and opened, as well as being left on public display during use [and] in this way cigarette packaging can act as an advertisement".³⁸

3.10 Moreover, they point out that the gradual restriction in certain countries such as the UK, of other forms of marketing and advertising through a variety of regulatory measures, including point of sale display restrictions leaves packaging as almost the sole remaining marketing vehicle. I am aware that research demonstrates that the pace of changes in pack design has increased over the same period that restrictions on advertising and other forms of marketing have been implemented. This includes trends showing more frequent redesign, and rising numbers of limited-edition packs, innovative pack shapes, textures and methods of opening."³⁹

3.11 In my opinion, it is important to note that while recent bans on point of sale display, and on smoking in work places or enclosed public places will reduce people's exposure to cigarette packaging in those settings, but anyone with a family member or friends who smoke is still likely to be exposed to brand imagery.

3.12 I note that a review of young people and smoking in England in 2009 conducted by the Public Health Research Consortium (funded by the Department of Health) concluded that:

³⁴ United States Department of Health and Human Services, Surgeon General, (2014). Surgeon General's Report on Smoking and Health.

³⁵ *United States District Court for the District of Columbia*, (filed:09/08/2006). United States of America, Tobacco-Free Kids Action Fund, American Cancer Society, American Heart Association, American Lung Association, Americans for Nonsmokers' Rights and National African American Tobacco Prevention Network V Philip Morris USA Inc. et al. Civil Action No. 99-2496 (GK). (p1518).

³⁶ Transcript of meeting of 29 January 2014 with the Tobacco Manufacturers Association (p27).

³⁷ "Dark market" is a term used by the tobacco industry to refer to highly restricted marketing environments.

³⁸ Wakefield MA, Morley C, Horan JK and Cummings KM, (2002). The cigarette pack as image: new evidence from tobacco industry documents. *Tobacco Control*. 11(suppl. 1):i73–i80.

³⁹ Ford A, MacKintosh AM, Moodie C, Richardson S, Hastings G, (2013). Cigarette pack design and adolescent smoking susceptibility: a cross-sectional survey. *British Medical Journal Open*. 3:e003282 referencing Moodie, C. et al. (2012), The importance of cigarette packaging in a 'dark' market: the 'Silk Cut' experience, *Tobacco Control*.

*"Tobacco packaging is the marketing tool with the most direct links to the consumer, with cigarettes being a 'badge product', conspicuously consumed while making public statements about the smoker's image and identity. Following the restrictions on tobacco advertising and promotion in the UK, the pack has become the main promotional platform for the tobacco industry to recruit and retain customers."*⁴⁰

- 3.13 Branded packaging is seen by the industry as an important way to communicate the quality and product characteristics to consumers, to encourage smokers to maintain their identification with their chosen brand. This appears to be particularly important in the absence of advertising or point of sale display. This is borne out by legal representatives of Japan Tobacco International in proceedings in the Australian High Court, stating that the Commonwealth "is acquiring our billboard, your Honour, in effect".⁴¹

People don't cite packaging as the reason they started smoking

- 3.14 In response to the Department of Health's consultation, and in material submitted to the Review, the tobacco companies have pointed out that packaging is rarely, if ever, identified by smokers as a factor in their choosing to smoke, and that the main risk factors for smoking initiation are known to be other factors such as adolescent risk taking, social norms, peer pressure and parental smoking.
- 3.15 Professor Laurence Steinberg, who had been asked by Japan Tobacco International to express his opinion, argues that *"adolescents' experimentation with, and use of tobacco is best viewed as a specific example, of their propensity to engage in risk-taking behavior more generally."*⁴² He argues that adolescents take up smoking, not because of packaging but instead because, in comparison to adults they are:
- (a) especially sensitive to rewards including rewarding stimuli like social status or admiration
 - (b) more likely to focus on immediate than longer term consequences of a decision
 - (c) more likely to pay attention to and focus on the immediate and short term drawbacks of a choice (e.g. that smoking will cause bad breath or that not smoking will cause social exclusion by peers)
 - (d) more easily swayed in their decisions about risk taking by the influence of their peers
 - (e) owing to immaturity in brain regions associated with cognitive control less able to regulate their behavior than adults, meaning their decision to try cigarettes for the first time may be made on the spur of the moment
 - (f) more easily disrupted by emotional and social arousal than are adults. Asking questions during a focus group or phone survey may yield very different responses to asking the same questions in a different context such as a bar with friends.
- 3.16 Others, such as Professor Theresa Marteau,⁴³ have argued that this model, whilst true as far it goes, is only a partial account. Whilst it successfully explains why teenagers are less likely to be influenced by health warnings about health risks which are perceived to arise in the longer term (c), the allure and

⁴⁰ Public Health Research Consortium, (2009) A Review of Young People and Smoking in England. (4.4.5).

⁴¹ *High Court of Australia Transcripts*, Japan Tobacco International SA v Commonwealth of Australia; British American Tobacco Australasia Limited & Ors v The Commonwealth of Australia [2012] HCATrans 91 (17 April 2012).

⁴² Evidence submitted to the Review by Professor Steinberg.

⁴³ Meeting held 23 January 2014. Notes available from Review webpage.

appeal of branded packaging, is a 'here and now' reward, to which the above theory at (a) states they are especially sensitive.

- 3.17 When the Review team met Professor Steinberg to explore his evidence model,⁴⁴ he accepted that teenagers were susceptible to branding, but could not explain why teenagers susceptibility to peer pressure and to branding combined with their preference for rewards here and now, would not make them especially susceptible to branded packaging. He argued:
- First, that teenagers rarely accessed cigarettes in branded packaging, but usually obtained them from friends without seeing the packaging, however he could not produce any evidence to this effect
 - Secondly, packaging mainly influenced switching rather than overall consumption. However as explained earlier in this section, I do not find this convincing.

Adolescents are susceptible to branding

- 3.18 I find it significant that in other consumer goods markets, where children can safely be allowed to participate in experiments, it has been proven that appealing branding does influence consumption. For example, when one set of young children were offered carrots in McDonalds wrapping and a second were offered carrots in plain wrapping, the first set of children said the carrots tasted better.⁴⁵ Other experiments, in relation to fast food, alcohol, and tobacco show that exposure to an advertisement for a branded product increases consumption of that type of product, rather than solely the specific brand.^{46,47,48,49} Clearly, given the risks even of being exposed to tobacco marketing, let alone experimenting with smoking, it would never be possible to gain ethical consent for similar experiments with tobacco products. However, lessons can be learned from the experiments that have taken place in different contexts.
- 3.19 Teenagers exhibit a strong affinity for branding. It can play into adolescents' desire for admiration from their peers and helps influence what they perceive as the social norm. Display of the product associates the user with the brand image, giving the user some of the identity and personality of the brand image.⁵⁰
- 3.20 This may play a part in the tendency of young people consistently to overestimate how many of their friends are smokers. According to NICE: "many young people see smoking as the norm because they mistakenly believe it is more prevalent than it really is. When asked how many of their friends smoke, they consistently overestimate the figure. For example, in a 2006 sample in which an estimated 29% of young people aged 15 smoked, their non-smoking peers estimated that the prevalence of smoking was

⁴⁴ Meeting held 5 March 2014. Notes available from Review webpage.

⁴⁵ Robinson TN et al, (2007). Effects of Fast Food Branding on Young Children's Taste Preferences. *Archives of Pediatric and Adolescent Medicine*. Vol 161, No.8

⁴⁶ Harris JL, Bargh JA and Brownell KD, (2009). Priming Effects of Television Food Advertising on Eating Behaviour. *Health Psychology*. Vol 28, No 4, pp. 404-413.

⁴⁷ Engels R.C.M.E et al (2009). Special Issue: The Message and The Media, Alcohol Portrayal on Television Affects Actual Drinking Behaviour. *Alcohol and Alcoholism*. Vol: 44, No: 3, pp. 244-249.

⁴⁸ Field M, Munafo MR, and Franken IHA, (2009). Meta-Analytic Investigation of the Relationship Between Attentional Bias and Subjective Craving in Substance Abuse. *Psychological Bulletin*. Vol. 135, No. 4, pp,589-607.

⁴⁹ Engelmann JM et al, (2012). Neural substrates of smoking cue reactivity: A meta-analysis of fMRI studies. *NeuroImage*. 60, pp. 252 – 262

⁵⁰ Wakefield MA, Morley C, Horan JK and Cummings KM, (2002). The Cigarette pack as image: new evidence from tobacco industry documents. *Tobacco Control*. 11(suppl.1):i73-i80.

63%. Those who regularly smoked put the figure at 93%.⁵¹ Behavioural science shows that we are strongly influenced by our perception of what others do.⁵²

Experimental smokers triggered to smoke by stimuli

3.21 I have learned that the way in which nicotine addiction works, appealing to the smoker at both a conscious and unconscious level makes them susceptible to visual triggers to smoke the next cigarette. According to Professor Robert West, branded packaging could act as one of these triggers.

"The transition from the first puff on a cigarette to addicted smoking can take many paths depending on the individual and his or her circumstances, but it is characterised by smoking in the presence of a set of stimuli creating an impulse to smoke in the presence of those stimuli and then expansion in the range of those stimuli. In adolescence, opportunities to smoke are typically relatively limited but after school years these increase and the 'islands' of smoking impulses typically become 'continents'. A constant feature that until now has been present in every case is distinctive brand imaging on the packet. [...] branding probably also plays an important role in maintaining smoking behaviour while the 'nicotine habit' and 'nicotine hunger' develop."⁵³

In my view, such an analysis provides a plausible model whereby branded packaging can stimulate smoking in experimental and established smokers.

Box 1: Australia – prevalence and attitudes

This box (and similar boxes in the following sections) outlines changes in the tobacco market and smoking patterns in Australia since the introduction of plain packaging in December 2012. It is too early to draw definitive conclusions. Data is only just becoming available, impacts may take time to materialise and the effect of plain packaging is difficult to distinguish from other simultaneous tobacco control measures. Nonetheless, taken together, the emerging evidence is consistent with continued progress from tobacco control measures of which plain packaging is a part.

Prevalence

Comprehensive surveys showing changes in prevalence since the introduction of plain packaging in Australia are not yet available. A survey from the Australian Institute of Health and Welfare is expected to report results of overall prevalence in October 2014 and estimates for youth prevalence are expected in August 2015, in the Australian School Students Alcohol and Drug survey. Even then, it will be difficult to distinguish the impact of plain packaging from other drivers of prevalence.

Of the evidence that is available to date, downward trends appear to have continued since plain packaging was introduced, with the lowest level of prevalence on record reported in the Roy Morgan population survey.⁵⁴

⁵¹ National Institute for Health and Care Excellence, (February 2010). School-based interventions to prevent smoking.

⁵² Dolan, P. et al (2009) MINDSPACE: Influencing behaviour through public policy. Cabinet Office and Institute for Government, London

⁵³ Professor Robert West, written evidence to the Review. See also West R, (2013) "The Smokefree Formula: A Revolutionary Way to Stop Smoking Now", Orion Books, London.

⁵⁴ The Roy Morgan population survey estimates show that from 2012 to 2013 total smoking prevalence fell by 0.3 percentage points to reach 21.3%.

Box 1: Australia – prevalence and attitudes (continued)

Attitudes

Attitudes to plain packaging appear broadly consistent with the body of research prior to its introduction. Information to date shows those smoking cigarettes from plain packaging perceived their cigarettes to be lower in quality and less satisfying than a year previously; and they also thought about quitting more often or as a higher priority in their life. However, smokers of branded and plain packaged cigarettes have not differed in their views on smoking harm to date.⁵⁵

There has also been a reduction in the number of people displaying their cigarette packets on tables outside cafes, restaurants and bars with outdoor seating since the introduction of plain packaging in Australia. Pack display declined by 15% (driven by a decline in active smoking of 23%), the proportion of packs orientated face-up declined from 85.4% of branded packs to 73.6% of plain packs, and there was a modest increase in the proportion of packs concealed by other items or in an external case.⁵⁶

Conclusion

3.22 In my opinion, the balance of evidence suggests that the appeal of branded packaging acts as one of the factors encouraging children and young adults to experiment with tobacco and to establish and continue a habit of smoking. As British American Tobacco Australia's spokesman acknowledged in our meeting, tobacco companies, like other consumer goods companies, see branded packaging as one of the tools of marketing. This is supported by numerous internal tobacco industry documents. Although the tobacco industry says that the purpose of branded packaging is to encourage brand switching only, they cannot explain how it would only ever attract switchers from one brand to another, and would never encourage initiation from non-smokers or increased overall consumption. Further, they have not been able to explain why, given that advertising and promotion are proven to increase tobacco consumption, the related marketing tool of branded packaging (referred to by Japan Tobacco International's counsel against the Australian Government as their mobile "billboard") should so differ in its effect.⁵⁷

⁵⁵ Wakefield et al (2013), 'Introduction effects of the Australian plain packaging policy on adult smokers: a cross-sectional study'

⁵⁶ Wakefield et al, 'Personal tobacco pack display before and after the introduction of plain packaging with larger pictorial health warnings in Australia: an observational study of outdoor café strips'

⁵⁷ *High Court of Australia Transcripts*, Japan Tobacco International SA v Commonwealth of Australia; British American Tobacco Australasia Limited & Ors v The Commonwealth of Australia [2012] HCATrans 91 (17 April 2012).

Is standardised packaging likely to lead to a reduction in the consumption of tobacco?

The 'Stirling' Systematic Review

4.1 The 2011 Systematic Review commissioned by the Department of Health, and led by researchers at the University of Stirling, examined the growing body of evidence examining the proposed benefits of standardised packaging. This looked at:

- several measures of appeal namely perceptions of:
 - the attractiveness of standardised packages
 - the quality of cigarettes in standardised packages
 - smoker identity and personality attributes associated with standardised packages
- whether standardised packages increase the salience of health warnings namely people's ability to notice and recall health warnings on packages, or affect seriousness or believability of the warnings
- whether and how perceptions of the harmfulness and strength of standardised packages differ from branded packs (and how different kinds of plain packages differ in this regard)
- whether and how standardised packages impact on smoking related attitudes and beliefs, perceived impact on others, and perceived impact on own smoking-related intentions and behaviours.

4.2 On the basis of the 37 studies reviewed, the authors concluded that there was strong evidence to support three contentions. Namely that:

"Plain packaging has been shown to:

- A. reduce pack and product appeal, by making packs appear less attractive and of lower quality, and by weakening the positive smoker identity and personality attributes associated with branded products*
- B. increase the salience of health warning, in terms of improving the recall and perceived seriousness and believability of warnings, and*
- C. reduce the confusion about product harm that can result from branded packs".*

4.3 A Research Update produced independently by essentially the same team in September 2013 looked at 17 further studies and concluded that in sum this added weight to the earlier findings. Notably, a greater proportion of the studies featured in the Research Update were UK-based than in the 2011 review.

- 4.4 However, the validity of the Stirling Review's conclusions, and of the studies underlying it, have been contested in strong terms by the tobacco industry, and by experts in particular fields commissioned by the tobacco industry to provide critiques, notably in submissions to the Review from Professor Timothy Devinney and Professor Laurence Steinberg. Given that these conclusions are central to the debate, I have devoted particular attention to examining the Stirling Review and Research Update, the underlying studies and the critiques of both which were carried out by the industry's chosen experts.

Criticisms of the Stirling Review and Research Update

- 4.5 The central criticisms that have been made of the Stirling Review (and, by extension, the Research Update) can be summarised as follows:
- the Stirling Review is a narrative synthesis rather than a meta-analysis showing overall effect size⁵⁸
 - the Stirling Review team members have an interest in tobacco control
 - the Stirling Review considered a number of studies which had been produced by members of the Stirling Review team, or with which they had been involved
 - the studies considered were drawn only from sources with a public health interest
 - the consistency of results is explained by repeated flaws and author/publication bias.

Summary of my assessment of those criticisms

- 4.6 Based on my consideration of the evidence, including discussions with a range of experts on both sides of the debate, I have come to the view that the criticisms made rarely go beyond the limitations recognised and described in the Stirling Review by its authors.
- 4.7 For the reasons explained below, I am satisfied that the methods employed by the Stirling Review, such as the search protocol, were appropriate, and as close as could be achieved to a Cochrane standard given the particular circumstances and nature of the problem being considered. A full meta-analysis was not possible given the diversity of study design and type, and hence the best available design of review open to the authors was a narrative form. The involvement of the independent Evidence for Policy and Practice Information and Co-ordinating Centre, based at the Institute of Education, University of London, gives me further reassurance that allegations of bias in the selection or consideration of material discovered by the systematic review can essentially be discounted.
- 4.8 Contrary to the criticisms made, the authors rightly place emphasis on the overall consistency of results collected through multiple study designs and across several countries (and the absence of evidence pointing in the other direction). This is a commonplace of research analysis which involves determining the direction of effect and, where possible, effect size. In my view, it does not seem to be a fair criticism that drawing studies from peer reviewed journals with a public health orientation represents a biased approach. There has been ample opportunity for the tobacco industry to present the undoubtedly extensive results of its own internal market research, for example focus group research exploring brand switching, but to date this has not been forthcoming other than as a result of litigation in the United States.

⁵⁸ The use of statistical methods to combine results of individual studies.

- 4.9 Furthermore, whereas the 2013 research update does not purport to be a systematic review, it provides a useful degree of corroboration of the earlier material and adds to confidence in the overall findings.
- 4.10 I note that further relevant papers, which include some looking at the early implementation stages of plain packaging in Australia have emerged since the 2013 Research Update including a number sent to this Review.⁵⁹ Together, the body of published, peer reviewed studies span research in ten different countries and deploy a wide range of research methods, and overall show a high level of consistency in findings.

Criticism of the underlying studies considered in the Stirling Review

- 4.11 I now turn to consider the main criticisms that have been made of the underlying studies considered in the Stirling Review (and Research Update). These can be summarised as follows:
- there are no randomised controlled trials of standardised packaging
 - each study had significant methodological flaws which invalidate the results
 - studies looking at hypothetical situations and attitudes are of little predictive value
 - in particular the studies fail to demonstrate a link with actual behaviour.
- 4.12 In relation to the first criticism, I have already explained why it would be unethical to carry out a randomised controlled trial of standardised packaging on this issue. I am aware that some have suggested trying out standardised packaging in a single town or region, but this would confront the immediate problem of 'leakage'; i.e. there would be no constraints on other tobacco products and people moving in and out of the area under study, which would invalidate the results. In my view the absence of a randomised controlled trial does not mean that the studies that have been produced are without value or that I am precluded from reaching a fair assessment as to the *likely* effect of standardised packaging.
- 4.13 The experts commissioned by the tobacco industry argue that not one single study can be relied on as evidence as to the efficacy of standardised packaging.⁶⁰ Professor Devinney characterises the Stirling studies as consumer research studies which typically look at short-term purchasing decisions. However, unlike other consumer goods, the highly addictive nature of nicotine makes it very unlikely that addicted smokers could easily make a decision to cease purchasing tobacco.
- 4.14 In my view the criticisms of the primary research have a tendency to take a 'binary approach', dismissing studies in their entirety on the basis that each has some (usually identified) limitations. The correct approach should be to take account of the limitation in considering the described results. Few research studies are without limitations, and undoubtedly many could be improved with insights from related fields, but this does not seem a reasonable basis on which completely to discount the findings of over 50 peer-reviewed, published studies. Any scientific study can only, realistically, attempt to minimise risk of bias to contribute towards an overall estimate of a likely effect.

⁵⁹ For example, Young JM et al. (2014). Association between tobacco plain packaging and Quitline Calls; a population based, interrupted time-series analysis. *Medical Journal Australia*. 200 (1): 29-32.

⁶⁰ See for example, Professor Devinney's submission to the Review.

- 4.15 In a recently published article Ulucanlar (et al) argue that the tobacco companies evidence was “underpinned by three complementary techniques that misrepresented the evidence base. First, published studies were repeatedly misquoted, distorting the main messages. Second, ‘mimicked scientific critique’ was used to undermine evidence; this form of critique insisted on methodological perfection, rejected methodological pluralism, adopted a litigation (not scientific) model, and was not rigorous. Third, tobacco companies engaged in ‘evidential landscaping’, promoting a parallel evidence base to deflect attention from standardised packaging and excluding company-held evidence relevant to standardised packaging.”⁶¹
- 4.16 Several of the studies have been criticised on the basis of failing to show results beyond what they set out to discover – so, for example, a study looking at an intermediate outcome (e.g. ‘appeal’) may not set out to demonstrate a chain of effects resulting in behaviour change. Critiques from the tobacco companies’ experts frequently ignore the “intermediate outcomes” that the studies set out to investigate, and criticise them for not demonstrating reduced consumption directly. The link to behaviour is considered further below.

Results of independent quantitative and qualitative analysis

- 4.17 Given the centrality of the debate on the quality of the primary evidence base used in the Stirling Review and Research Update, I decided to commission analyses of the quantitative and qualitative elements from independent academics. The quantitative analysis was carried out by Dr Yanzhong Wang of King’s College London.⁶² The qualitative analysis was carried out by Professor Catherine Pope of Southampton University. Each decided, independently, to use Critical Analysis Skills Programme appraisal tools, modified as necessary to take account of the nature of the studies in question. This approach subjected the primary studies to an alternative appraisal structure than that on which the original Stirling Review was based.
- 4.18 Their independent appraisals are annexed to this report. The key points made in their reports were as follows:
- the Stirling Review was conducted according to recognised best practice
 - whilst not agreeing on all details of quality appraisal of the individual studies in the Stirling Review, all were considered appropriate for inclusion in its narrative synthesis
 - the September 2013 research update, whilst not itself a systematic review, added useful information, and, generally speaking, included papers of individually higher quality than in the original review.

Overall, in their opinion, the work was robust, and notable for the consistency of its findings.

The likely effect on behaviour by smokers and non-smokers

- 4.19 I now turn to consideration of whether standardised packaging is likely to have an impact on actual behaviour, which is argued by opponents of standardised packaging to be a ‘missing link’ or at least a link not demonstrated by the evidence considered in the Stirling Review.

⁶¹ Ulucanlar S, Fooks GJ, Hatchard JL and Gilmore AB, (2014) How transnational tobacco companies mis-use scientific evidence: a review of tobacco industry submissions to the UK government consultation on standardised packaging. *PLoS Med* 11(3): e1001629.

⁶² Supervised by Professor Janet Peacock, King’s College London.

4.20 Proponents of standardised packaging point to three main “intermediate” outcomes, which are argued to lead in due course to reduced tobacco consumption, and for which the Stirling Review concluded there was strong support:

- *Reduction in appeal* – it is said by the proponents of standardised packaging that branded packaging (often in conjunction with novel/innovative design features) appeals to various target consumer groups and conveys the qualities of the product. Standardised packaging is intended to remove the appeal of the packaging, making it as aesthetically unappealing as possible. The package design is now intended to conjure up the most negative associations instead of positive ones. The idea is that consumers feel more negative about the taste of the cigarettes, without the branded packaging to provide positive associations. They find the pack ugly and want to hide it,⁶³ contributing to the long-term aim of denormalisation of smoking.⁶⁴ Branded packaging can present tobacco as a normal consumer good.
- *Salience of health warnings* – proponents of standardised packaging argue that the juxtaposition of health warnings with attractive branding is confusing and distracting. It undermines the credibility of the health warning if it is presented on an attractively designed package. People may discount the health warnings, believing that if it was dangerous as suggested, it wouldn’t be legal. By simplifying the package, standardised packages are intended to remove the distraction from the health warnings making them more credible and memorable, and therefore more effective. Standardised packaging would require large graphical (i.e. pictorial) health warnings as well as text, chosen for their hard-hitting visual impact.
- *Perception of harm* – finally it is said that colours and descriptors confuse smokers into perceiving significant differences between the relative harmfulness of different brands, even though it is not the case that some cigarettes are healthier alternatives. Tobacco control experts believe that potential quitters sometimes decide instead to smoke lighter cigarettes, in the false belief that they are less harmful rather than attempting to quit.

4.21 Several of the primary research studies in the Stirling Review aimed to test whether participants believed that standardised packaging would change their purchasing behaviour. Some of the studies (and further studies conducted since) have used an increasing range of methods that approximate behavioural outcomes including experimental auctions, eye-tracking, and naturalistic study designs. However, the authors were cautious about drawing overall conclusions about smoking behaviour, given the well-known weakness of stated intentions in predicting behaviour. This caution is justified, and to that extent the findings are essentially indirect and “speculative”. However, I have considered evidence linking concepts such as “appeal” to behaviour which exists elsewhere in the literature and wider fields such as contemporary theories of behavioural psychology.⁶⁵ These stress the importance on non-conscious processes in determining behaviour rather than conscious statements of intent.

⁶³ Moodie C et al, (2011). Young Adult Smokers’ Perceptions of Plain Packaging: a pilot naturalistic study. *Tobacco Control*. 20:367e373.

⁶⁴ The Tobacco Control Plan for England acknowledges the multi-faceted nature of tobacco use and in response aims to deploy a mix of educational, clinical, regulatory, economic and social strategies to reduce smoking prevalence, with an emphasis on ‘denormalisation’ of smoking as a key element in behaviour change: “To promote health and wellbeing, we will work to encourage communities across England to reshape social norms, so that tobacco becomes less desirable, less acceptable and less accessible. We want all communities to see a tobacco-free world as the norm and we aim to stop the perpetuation of smoking from one generation to the next.” Healthy Lives, Healthy People: A Tobacco Control Plan for England. Department of Health, 2011.

⁶⁵ Webb TL, and Sheeran P, (2006). Does Changing Behavioural Intentions Engender Behaviour Change? A Meta-Analysis of the Experimental Evidence. *Psychological Bulletin*. Vol. 132, No. 2, pp, 249–268

4.22 The key question I had to consider was whether “intermediate outcomes” such as reduced appeal are likely to feed through into reduced tobacco consumption. In my view it is reasonable to conclude that it will do so for the following reasons:

- first, this conclusion has considerable intuitive plausibility, supported by much psychological evidence stretching back over 100 years, on the basis that “humans are generally predisposed to approach positive stimuli (those we anticipate as being rewarding) and avoid negative stimuli (those we anticipate as being unrewarding or even punishing)”⁶⁶
- second, theories of ‘unconscious’ or ‘automatic’ behaviour demonstrate a causal pathway between concepts such as appeal and behaviour, and are supported by evidence from fields such as food and alcohol⁶⁷
- third, it offers the best fit with the wider evidence on the effects of marketing, including development and use of brand imagery, much of which is reflective of the tobacco industry’s own practices as revealed in internal documents
- fourth, emerging evidence from Australian studies show outcomes that support likelihood of behaviour change, including increased calls to quitting helplines, hiding packs in social situations, smoking less around others, and smoking fewer cigarettes overall.

This seems to me entirely compatible with known risk factors for smoking uptake such as peer pressure and parental smoking.

4.23 The suggestion that standardised packaging could produce a perverse appeal for children originates from the a 2008 consultation on the future of tobacco control which sought views on plain packaging, and is listed there as a “potential disadvantage”. However the text goes on to say that “the Department of Health is not aware of any research evidence that supports such concerns.”⁶⁸ This “forbidden fruit” argument has been mentioned occasionally in submissions to this Review (and in responses to the Department of Health’s 2012 consultation), but in my view remains speculative and lacking in supporting evidence. I am not aware of any suggestions that this effect has been seen to date in Australia. Whilst not entirely lacking plausibility, at least for a subset of young people, the lack of evidence suggests that this effect, if manifested at all, would not overturn the broader effect on appeal described above.

⁶⁶ Marteau TM, Hollands GJ, Fletcher PC, (2012) Changing human behavior to prevent disease: the importance of targeting non-conscious processes. *Science*. 337: 1492-5.

⁶⁷ See references in footnotes 46-49.

⁶⁸ Consultation on the Future of Tobacco Control, Department of Health, May 2008. Paragraph 3.77.

Box 2: Australia – consumption and cessation

Consumption (volumes)

Tobacco consumption has been on a downward trend in Australia in recent years. Changes in consumption since the introduction of plain packaging are not yet clear.

Data on tobacco shipped to retailers shows a slight increase in volumes of around 0.3%⁶⁹ in 2013. However, this data is likely to be affected by transitional impacts. For example, retailers returned a significant quantity of tobacco stock in branded packaging during the first half of 2013 which was subsequently destroyed rather than smoked. Stockpiling in anticipation of pre-announced tax increases will also have affected the data.

Data on volumes at the final point of sale, which is less affected by these transitional impacts, shows consumption has fallen since the introduction of plain packaging. Cigarette sales in grocery stores fell by around 0.9% in 2013 according to the Retail World trade magazine.⁷⁰ It is noteworthy that the population over 15 years of age increased by 1.5% in 2013.

Cessation

There has been a marked increase in calls to the Australian cessation helpline, Quitline, with an increase of 78% since the introduction of plain packing. This increase is similar to that observed following the introduction of graphic health warnings in 2006, but the impact from plain packaging has been more sustained.⁷¹

Conclusion

- 4.24 Having reviewed the findings of the Stirling Review and subsequent Research Update, and the detailed critiques made of them, I believe the evidence base for the proposed “intermediate” outcomes is methodologically sound and, allowing for the fact that overall effect size cannot be calculated from it, is compelling about the likely direction of that effect. Taken together the studies and reviews based on them put forward evidence with a high degree of consistency across more than 50 studies of differing designs, undertaken in a range of countries. This conclusion is not seriously undermined by the criticisms made, many of which reflect necessary constraints on study design. This is confirmed by the independent analysis I commissioned.
- 4.25 I am of the opinion that on the basis of the evidence I have seen, it is likely that standardised packaging will result in smokers and potential smokers acquiring more negative feelings about smoking. They will be less deceived into thinking that some brands are healthier than others and that therefore health warnings apply less to them. Susceptible children and young adult smokers will be less likely to associate particular brands with the peers they want to emulate. Health warnings will be more credible, memorable and effective when not confusingly juxtaposed with attractive branded packaging. This is, in turn likely to lead to behavioural changes such as smokers hiding their cigarette packets, thereby diminishing their role in creating an exaggerated view of smoking as a social norm. This may help to make smoking seem less “normal” and therefore less desirable to children to take up smoking to ‘fit in’ with peers.

⁶⁹ InfoView Exchange of Sales data provided by British American Tobacco.

⁷⁰ Retail World 2013 Annual Report.

⁷¹ Young JM et al. (2014). Association between tobacco plain packaging and Quitline Calls; a population based, interrupted time-series analysis. *Medical Journal Australia*. 200 (1): 29-32.

Is it likely that standardised packaging will lead to an increase in tobacco consumption by lowering the price of tobacco as the market is commoditised or by increasing the consumption of illicit products?

The likelihood of effects on price

- 5.1 Opponents of standardised packaging argue that it could cause large scale price reductions and, as a result, smoking would increase. In the extreme, it is argued that complete commoditisation of the market could occur, with all tobacco selling at prices just above the level of tax plus cost. This is based on the view that standardised packaging would remove product differentiation between tobacco brands so that smokers are only willing to pay for the cheapest brand and manufacturers are forced to compete on price alone.
- 5.2 The intent of standardised packaging is indeed to remove appealing brand differentiation. Standardised packaging is aimed at encouraging smokers to see all cigarettes as equally harmful and unappealing, rather than to identify with particular brands and associate them with positive qualities such as glamour, slimness or sophistication. Similarly the measures in the European Tobacco Product Directive (for example restricting flavourings and slim cigarettes) can also be seen as removing product differentiation and moving nearer to a commoditised market.
- 5.3 In order to address these issues thoroughly, I commissioned an analysis from a professional economist recruited to the Review team. My team and I discussed these issues with academics and experts from both sides of the debate.
- 5.4 Having considered the evidence, including the analysis I commissioned (annexed to this report), it is my view that the risk of such effects undermining the objectives of a standardised packaging policy are small and that the impacts could be readily mitigated through taxation if nevertheless they were to materialise. Overall, I have come to the view that the magnitude of effects suggested by opponents of standardised packaging are exaggerated and the likelihood of complete market commoditisation is very low, especially in the short to medium term.

The likelihood of effects on the illicit trade

- 5.5 I now turn to consider whether standardised packaging will increase the consumption of illicit tobacco (tobacco that is imported for sale in the UK without paying UK duty). The tobacco industry has argued that it will for the following reasons:
 - manufacturers will find it easier and/or cheaper to make *counterfeit* packaging – standardised packaging regulations provide a single easy blueprint to follow for all brands;

- consumers will be more likely to be duped by counterfeits,
- consumers' will increasingly choose to buy illicit products:
 - in an increasingly commoditised market where brand loyalty no longer holds
 - because they prefer *branded* packaging, now only available in the illicit market as contraband or "illicit whites" (Box 3 describes the different categories of illicit tobacco).

Box 3: Illicit product categories

Contraband: legally manufactured by the major tobacco companies. Smuggled into the UK either from other countries (where they are duty paid in that country but due to higher UK duty are still worth smuggling into the UK). Typical examples of this in the UK would be French cigarettes in French packs.

Illicit Whites: legally manufactured by companies often based in emerging economies with the intent on exporting illegally to other countries through a smuggling network. Brands are typically imitation brands, copying the "look and feel" of well-known legal brands. Known illicit white brands are 'Manchester' and 'Jin Ling'.

Counterfeit: illegally manufactured copies of well-known existing brands. Often very high quality copies of the pack, but distinguishable from legal duty free through the lack of identifiable production/security markings. Product quality is often poor.

5.6 Tobacco manufacturers cite the industry funded KPMG report on illicit tobacco in Australia,⁷² which purports to show that there has been a large increase in illicit trade since the introduction of plain packaging. I have considered both this report and a critique.⁷³ My team have also met with KPMG in order to understand their methods.⁷⁴ I note that Australian Government departments, both Health and Customs, appear to be strongly of the view that KPMG's methodology is flawed. These Departments point to official Customs data,⁷⁵ which shows no significant effect on illicit tobacco following the introduction of plain packaging, backed by analysis undertaken by the Cancer Council Victoria (based on data from the National Drug Strategy Household Survey) that suggests that illicit tobacco in Australia is only 10-20% of the level proposed by KPMG.⁷⁶ In a situation where estimates differ by such magnitudes, I do not have confidence in KPMG's assessment of the size of – or changes in – the illicit market in Australia.

Ease of counterfeit production

5.7 In my view, the argument that standardised packaging makes it materially easier or cheaper for criminals to produce counterfeit packaging is not supported by the evidence I have seen. Although some

⁷² KPMG (October 2013). Illicit tobacco in Australia. prepared by KPMG LLP in accordance with specific terms of reference ("terms of reference") agreed between British American Tobacco Australia, Philip Morris Limited and Imperial Tobacco Australia Limited.

⁷³ *Quit Victoria*, (11th November 2013). Analysis of KPMG LLP Report on use of illicit Tobacco in Australia. Cancer Council Victoria Website.

⁷⁴ Review team meeting with KPMG, (22nd February). The purpose of the meeting was to discuss the KPMG report on illicit tobacco in Australia. Note available from: <http://www.kcl.ac.uk/health/packaging-review.aspx>

⁷⁵ Australian Customs and Border Protection Service, table on Tobacco Smuggling in Annual Report 2012 – 2013.

⁷⁶ *Quit Victoria*, (11th November 2013). Analysis of KPMG LLP Report on use of illicit Tobacco in Australia. Cancer Council Victoria Website. And Gilmore AB, et al (2013) Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded 'Project Star' report. *Tobacco Control*.

branded packages are complex and therefore difficult to copy, many of the top 10 brands in the UK are relatively simple in pack design. Counterfeiters already target these, cheaply producing convincing copies⁷⁷ on simple and widely available “offset” printing technology.⁷⁸ Although complex packaging creates a technical obstacle for counterfeiters on any specific complex packaging, this is very easily avoided by choosing instead to mimic the brand variant with the simplest packaging⁷⁹, of which there are many popular versions.

- 5.8 I understand that there is no evidence of increased counterfeiting following the introduction of plain packaging in Australia and that this is now accepted by tobacco manufacturers locally: Mark Connell of BAT told the review team:

“One of the things that we did say... is that there would be an increase in counterfeit of the standardised packaging. In other words, the legislation was virtually a blueprint that was given to counterfeiters... that hasn’t happened, well it may have happened in small quantities...” *“Our biggest brand which was counterfeited all the time, very professionally I have to say, at least contained a health warning and a graphic health warning” [unlike these illicit white brands now prevalent].* Review team: “have you actually seen a reduction in counterfeit?” Mr Connell: “*Absolutely. Absolutely.*”⁸⁰

Are consumers duped by counterfeits?

- 5.9 I have learned that counterfeit cigarettes primarily deceive the illicit buyer in their desire to buy contraband. Consumers do not buy illicit cigarettes by accident. They choose to buy illicit because of the price. A typical pack of illicit cigarettes costs about £3 to buy, which is about half the price of the cheapest pack available legally in the UK.⁸¹ Consumers know they are buying illicit not only because of the price they pay, but where they purchase the product.⁸² Typically illicit cigarettes are bought from friends, family and colleagues or through known illicit routes, such as destination shops like “fag houses” or approaches in pubs or clubs. Only about 20% of illicit is purchased from local shops, and at prices that make clear that it is not tax-paid legal product. It is clear that consumers are not being duped into buying counterfeit when they think they are buying licit.⁸³

⁷⁷ Ronald Ridderbeekx, meeting with TMA 29 Jan 2014, “We have our own investigators scouring the world for counterfeiters and helping law enforcement officials to find them and capture them because they are very good. Sometimes we even struggle to distinguish a counterfeit pack from a real one. It’s a really big problem because, yes, that counterfeit pack would be undetectable to others.”

⁷⁸ Review team meeting with Association of Packaging Industry, (12th February 2014). The purpose of this meeting was to better understand issues around the production of tobacco packaging; the industry’s knowledge of illicit and counterfeit packaging; the pricing component in packaging and ultimately public health implications of plain packaging from the packaging company’s point of view. Note available from: <http://www.kcl.ac.uk/health/packaging-review.aspx>

⁷⁹ Review team meeting with Luk Joossens, Association of European Cancer Leagues (20th February). The purpose of the meeting was to inform in more detail, the illicit section of report. Note available from: <http://www.kcl.ac.uk/health/packaging-review.aspx>

⁸⁰ Transcript of Sir Cyril Chantler meeting with Australian tobacco industry (13 March 2014). Available from: <http://www.kcl.ac.uk/health/packaging-review.aspx>

⁸¹ Review team meeting with Luk Joossens, Association of European Cancer Leagues (20th February).

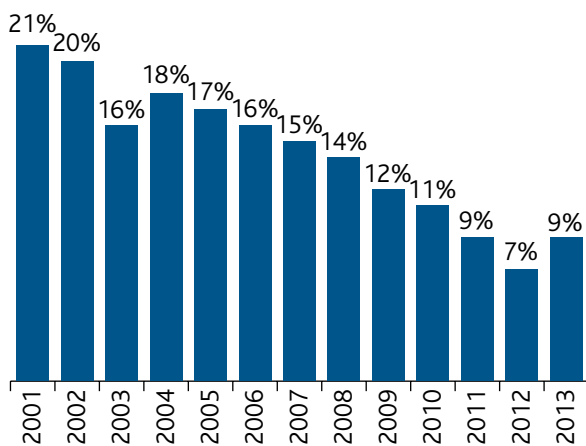
⁸² Review team meeting with Andy Leggett and Judith Kelly, HMRC (7th March 2014). The purpose of the meeting was to discuss an analysis on illicit tobacco data. Note available from: <http://www.kcl.ac.uk/health/packaging-review.aspx>

⁸³ Meetings as above and Moodie C, Hastings G, Joossens L, (2011b). Young adult smokers’ perceptions of illicit tobacco and the possible impact of plain packaging on purchase behaviour. *European Journal of Public Health*.

Will standardised packaging boost demand for illicit branded products?

5.10 Consumers' main reason for wanting to purchase illicit cigarettes is price not packaging. But it is possible that some consumers put off by standardised packaging may become more attracted to purchasing contraband. However, what constrains the size of the illicit market is not a lack of demand, but restrictions placed on supply by border controls. If this were not the case then the size of the illicit market would have increased over the last 14 years as tobacco taxes have risen in real terms. Instead the size of the illicit market in the UK has roughly halved. HMRC's actions in combating illicit trade appear to have been very effective.

UK Illicit Cigarette Market Share

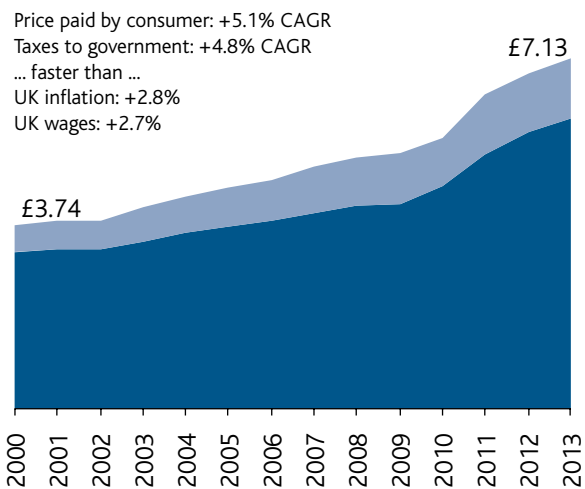


Note: 2008 is 12% according to HMRC Measuring tax Gaps 2013 edition

Note: Cancer Research Council (CRC) factsheet numbers for tax years ending 2008 to 2010 are 13%, 11%, 10%

Source: 2008-2013 data from HMRC Tobacco Gap Estimates 2012-13, CRC factsheet

UK Nominal Price per Pack of 20



Note: CAGR = Compound Annual Growth Rate

Source: Table 3.6 from HMRC Tobacco factsheet 29 Nov 2013, ONS for inflation

5.11 I have seen no convincing evidence to suggest that standardised packaging would increase the illicit market. Illicit tobacco is and will continue to be an important issue in relation to under-age access to tobacco, and effective enforcement efforts would remain, as now, essential, but this is not closely entwined with the issue of standardised packaging. The industry has argued in particular that standardised packaging would be easier to counterfeit. But both HMRC here, and the tobacco companies themselves in Australia tell me that they are not convinced.⁸⁴ My understanding from these discussions is that standardised packaging is not easier to counterfeit, and indeed in Australia, hardly any counterfeit standardised packages have been found.

5.12 Any tobacco control policy that aims to hold prices up (through tax) or to reduce demand through packaging restrictions (health warnings, standardised packaging etc.) can be accused of giving a comparative advantage to the illicit market to whom these restrictions do not apply. But the solution cannot be for Government to pursue the lowest common denominator by allowing the legal market to compete with illicit in terms of attractive branding, lack of graphic health warnings, and low tax.

⁸⁴ Transcript of Sir Cyril Chantler meeting with British American Tobacco Australia, and Imperial Tobacco Australia, 12 March 2014 (p39). Available from: <http://www.kcl.ac.uk/health/packaging-review.aspx>

Many high tax jurisdictions, including the UK, have already demonstrated that an effective enforcement regime and appropriate sanctions can keep illicit to low levels. Illicit tobacco is not a normal market – more people would buy illicit cigarettes today if they could, but they cannot because supply is limited by effective enforcement.

Box 4. Australia – prices and illicit

Prices

There has been a continuation of a trend of down-trading towards value brands in Australia. This trend appears to have accelerated somewhat in the last year, with an increase in market share (by volume) of low price cigarette brands from 32% in 2012 to 37% in 2013. This compares to increases of 3 percentage points in each of the previous two years.⁸⁵ Much of this impact is likely to reflect a greater focus on value products following tax increases as opposed to plain packaging.

Prices have generally increased in the data available to date, with most leading brands in Australia increasing prices by more than the inflation tax rises since plain packaging was introduced (see the figure below). This is a continuation of the trend for prices of leading brands to increase by more than tax rises which has occurred for several years in Australia. This provides evidence that the widespread price reductions predicted by some opponents of plain packaging have not materialised to date.

Price changes net of tax for leading brands and super value brands in Australia⁸⁶



⁸⁵ InfoView Exchange of Sales data, provided by British American Tobacco

⁸⁶ Cancer Victoria analysis of Recommended Retail Prices data.

<http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6401.0Dec%202013?OpenDocument>

Box 4. Australia – prices and illicit (continued)

Illicit

Estimates of the absolute size of the illicit market vary considerably. A recent industry funded KPMG report⁸⁷ concludes that the level of illicit cigarettes as a percentage of total cigarette consumption is in the low teens and has increased since plain packaging was introduced. However, Australian Government departments, both Health and Customs, appear strongly of the view that KPMG's methodology is flawed. These Departments point to the Customs data which shows no significant impact on illicit tobacco⁸⁸, backed by analysis undertaken by the Cancer Council Victoria⁸⁹ that suggests that illicit tobacco in Australia is only 10-20% of the level proposed by KPMG

Conclusion

- 5.13 It is my view that the risks of price effects undermining the objectives of a standardised packaging policy are small and that the impacts could be readily mitigated through taxation if nevertheless they were to materialise. I am not convinced by the tobacco industry's argument that standardised packaging would increase the illicit market, especially in counterfeit cigarettes. It seems to me that the solution to illicit use is instead to have an effective enforcement regime, and the enforcement agencies in the UK have already demonstrated that an effective enforcement regime and appropriate sanctions can keep illicit to low levels, even in a relatively high tax jurisdiction.

⁸⁷ KPMG LLP (2013), 'Illicit tobacco in Australia: 2013 half year report'

⁸⁸ Australia Customs and Border Protection Service

⁸⁹ Various reports, available at <http://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=plainfacts-myths>

Discussion and final conclusion

- 6.1 I am struck by the emphasis in the published literature, and in oral evidence from experts, that the nature of tobacco control measures is rarely about single, one-off solutions. Given the extraordinary difficulty of quitting smoking, it would be surprising if this were not the case. This is summed up by the Royal College of Physicians Tobacco Advisory Group, who have said:

*"It is important that policies continue to be developed, improved and innovated to retain initiative and impact with smokers and the general public. It is also important to consider that the individual components of tobacco control policy typically have modest effects. It is their collective impact in the context of a comprehensive range of policies that becomes substantial."*⁹⁰

- 6.2 The specific evidence base, centred on the Stirling Review and update, is relatively modest, and put forward in awareness of its limitations due in particular to constraints on study design. But it points in a single direction, and I am not aware of any convincing evidence pointing the other way. It strongly supports the intermediate outcomes identified, and, taking into account the wider evidence around marketing, and drawing on modern behavioural psychology, there is a clear plausible link to behaviour. Whilst standardised packaging may have a *modest* effect, it is the nature of public health measures that small effects mount up at a population level.
- 6.3 The "intermediate outcomes" are debatably public health benefits in themselves. For people to be less confused about the harms of smoking is a good thing even if it does not immediately result in them smoking less. It is hard to see how the clearly documented intermediate effects could possibly *increase* smoking, and easy to see to how, over time they could *reduce* it.
- 6.4 A decision to introduce standardised packaging is not for me to make. However if a decision is taken to pursue it, in my view a comprehensive approach will be desirable so as to avoid leaving loopholes. For example, in Australia manufacturers have responded to plain packaging by offering one or more extra cigarettes (known as "loosies") for the same price as a packet of 20. To optimise the effects, it may be necessary to consider measures such as tax policy, action to control illicit import and sales, vigilance over the sale of tobacco to children and adolescents, and to consider the effects of advertising of electronic cigarettes.
- 6.5 I believe the evidence lends weight to the model of smoking normalisation through pro-smoking imagery described by the British Medical Association's Board of Science:

"Pro-smoking imagery originates from three overlapping sources.

"First, it is part of the social milieu: young people see others – parents, peers and public figures – smoking and this reinforces the normalcy of the habit. In Great Britain, smoking still has around 10 million role models. The detritus of smoking also provides a reminder of the apparent normalcy of the behaviour.

⁹⁰ Royal College of Physicians (2010), *Passive Smoking and Children: A report by the Tobacco Advisory Group of the RCP*. March 2010. (p182)

Second, entertainment media depict smoking on a regular basis. Images of smoking are commonplace in films, television shows and magazines, and can influence the attitudes and behaviours of young people. Other forms of media such as the internet represent a growing concern in this respect.

Third, young people are exposed to the positive images of smoking generated by tobacco industry marketing. The ban on tobacco advertising in the UK has greatly restricted the more traditional forms of marketing (e.g. billboards); however, ubiquitous distribution, increasingly elaborate point of sale displays, attractive pack liveries and evocative brand imagery continue to provide key marketing opportunities that influence young people.”⁹¹

- 6.6 Point of sales displays referred to here are, of course, already in the process of being restricted in the UK, and this has been suggested as one reason to delay reaching a definitive view on standardised packaging. There are other reasons. To date only Australia has implemented plain packaging. Further evidence one way or the other is likely to emerge in the future, and I am aware that a Cochrane review into standardised packaging has been commissioned and will be produced in due course. However, on my review of the evidence, including visiting Australia to see at first hand the implementation of plain packaging there, I believe that a reasonable and informed view is possible now.
- 6.7 It is not solely a question of time. For example, in their submission to the Review, Public Health England make the observation that: “changes in the initiation rates of smoking among children and young people will take many years to be properly discerned, and have wide confidence intervals that are a consequence of limitations on survey size. Similarly, changes in overall prevalence of smoking require long periods of observation”, but go on to point out that: “at a population level, attributions of change to specific initiatives or changes in the milieu are highly problematic. [...] The interdependency and synergy of multiple simultaneous tracks of tobacco control activity mean that it may become meaningless to attribute specific outcomes changes to specific elements of policy”.⁹² For example, the introduction of plain packaging in Australia was accompanied by other tobacco control interventions including substantial tax rises, and a public information campaign. Apportioning any effect to each of these individual elements would be extremely difficult with any reasonable degree of certainty.
- 6.8 It is important to note that proponents of standardised packaging include the World Health Organization, Public Health England, local Directors of Public Health and a host of experts involved in the field of human health. Similarly the US Surgeon General, reflecting on 50 years of tobacco control efforts in his 2014 report noted that “increasing evidence indicates that plain packaging has the potential to decrease smoking”⁹³.
- 6.9 It is always possible to confuse passionate interest with bias. In this regard I note the opinion of Judge Kessler at the conclusion of a seven-year lawsuit involving scrutiny of thousands of documents and examination of many expert witnesses. Namely that: “Much of the Defendants’ criticisms of Government witnesses focused on the fact that [they] had been long-time, devoted members of “the public health community.” To suggest that they were presenting inaccurate, untruthful, or unreliable testimony because they had spent their professional lives trying to improve the public health of this country is patently absurd.”⁹⁴

⁹¹ British Medical Association (2008), *Forever cool: the influence of smoking imagery on young people*, BMA Board of Science, July 2008.

⁹² Public Health England, submission to the Review.

⁹³ *United States Department of Health and Human Services*, Surgeon General, (2014). *Surgeon General’s Report on Smoking and Health*

⁹⁴ *United States District Court for the District of Columbia*, (filed:09/08/2006). *United States of America, Tobacco-Free Kids Action Fund, American Cancer Society, American Heart Association, American Lung Association, Americans for Nonsmokers’ Rights and National African American Tobacco Prevention Network V Philip Morris USA Inc. et al.* Civil Action No. 99-2496 (GK).

- 6.10 My overall findings are not dissimilar to those of previous reviews that have looked at this issue. For example, the findings of the study by RAND Europe undertaken for the European Commission in the context of revision of the European Tobacco Products Directive:

“While there is still some debate about the feasibility of implementing this measure and about the evidence base for the impact on tobacco consumption, the types of studies presented [...] provide evidence of the role and importance of cigarette packaging design in attracting consumers (both current smokers and ‘aspiring’ smokers) to tobacco products. Thus, given the importance of product attractiveness in product purchasing decisions and evidence that such packaging detracts from the health warning currently placed on such products, it is apparent that plain packaging would have some deterrent impact (albeit difficult to quantify) on the consumption of tobacco products. It might also be envisaged that this impact could be greater in deterring consumers who are non-smokers and therefore not yet addicted to nicotine from taking up smoking. Also, given the evidence on cigarette design attractiveness to different target populations, the impact of plain packaging could also have a particularly positive effect on these groups, encouraging them to reduce their cigarette consumption and uptake.”⁹⁵

Final conclusion

- 6.11 **In conclusion** research cannot prove conclusively that a single intervention such as standardised packaging of tobacco products will reduce smoking prevalence. For various reasons as cited it is not possible to carry out a randomised controlled trial. Even if it was possible it would be extremely difficult to control for all the various confounding factors which are known to affect smoking. However after a careful review of all of the relevant evidence before me I am satisfied there is sufficient evidence derived from independent sources that the introduction of standardised packaging as part of a comprehensive policy of tobacco control measures would be very likely over time to contribute to a modest but important reduction in smoking prevalence especially in children and young adults. Given the dangers of smoking, the suffering that it causes, the highly addictive nature of nicotine, the fact that most smokers become addicted when they are children or young adults and the overall cost to society, the importance of such a reduction should not be underestimated.

⁹⁵ RAND Europe, 'Assessing the Impacts of Revising the Tobacco Products Directive'. Study to support a DG SANCO Impact Assessment: September 2010

Annex A: Method statement (published 16 December 2014)

By letter dated 27 November 2013, I was invited by the Parliamentary Under Secretary for Public Health, Jane Ellison MP, to undertake a review ("the Review") within the following Terms of Reference:

"1. To give advice to the Secretary of State for Health, taking into account existing and any fresh evidence, as to whether or not the introduction of standardised packaging is likely to have an effect on public health (and what any effect might be), in particular in relation to the health of children. It will be a matter for the Chair to determine how he undertakes this review and he is free to draw evidence whatever source he considers necessary and appropriate.

2. The review will report by March 2014.

3. It will be an Independent Review, with advice to the Secretary of State contained in a report. An independent secretariat will be appointed by the Chair, who will set out the method of how he will conduct the review in more detail in due course. The secretariat will be wholly accountable to the Chair, and it will be for the Chair to guide and task them in their work as he sees fit."

I am aware of the Department of Health's 2012 consultation⁹⁶ on the issue of standardised packaging of tobacco products and have access to the full responses as well as the summarised responses.⁹⁷ It is not my task to re-run that consultation exercise. I am concerned with evidence directed to the specific question of whether the introduction of standardised packaging is likely to lead to a decrease in the consumption of tobacco, including in particular a decrease in the risk of children becoming addicted. I start from the uncontroversial premise that any such decrease will have a positive effect on public health.

My Review is not concerned with legal issues, such as competition, trade-marking and freedom of choice. Nor will it consider issues such as the overall economic impact of standardised packaging on tobacco producers, retailers or associated industries. Consistent with my Terms of Reference, I am concerned only with any public health effects of introducing standardised packaging and not with assessing the merits of alternative means of tobacco control.

I intend to discharge my Terms of Reference in three principal ways:

1. I will consider the existing evidence relevant to the public health issue I have identified, including the responses to the Department of Health's consultation exercise, the systematic review undertaken as part of the Public Health Research Consortium⁹⁸ and the subsequent research update (Moodie et al, University of Stirling) dated September 2013.⁹⁹

⁹⁶ <http://consultations.dh.gov.uk/tobacco/standardised-packaging-of-tobacco-products>

⁹⁷ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212074/Summary_of_responses_to_consultation_-_standardised_packaging_tobacco.pdf

⁹⁸ http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf

⁹⁹ <http://www.stir.ac.uk/media/schools/management/documents/Plain%20Packaging%20Studies%20Update.pdf>

2. I will pro-actively seek further relevant evidence, including in the following three ways:
 - (i) Interested parties can submit research-based evidence directed at the specific issue with which I am concerned in writing. Any such evidence should not already have been provided in the course of the Department of Health's consultation. It would be helpful for submissions to indicate the status of the evidence adduced (e.g. peer reviewed) and its relevance. (Contact details for submission of evidence are below).
 - (ii) I intend to hold two main meetings – one on each side of this polarised debate – to address specific questions relevant to the effect of standardised packaging on public health. Invitations to these meetings will be sent in due course following my preliminary review of the evidence.
 - (iii) I envisage commissioning some further expert advice to assist me in the qualitative analysis of what I consider to be the key evidence.
3. I intend to undertake a visit to Australia and to take account of the experience of standardised packaging in that country.

It is my intention that the Review will take account only of such material as is, or can be, placed in the public domain. In the event that those submitting material to me wish to redact or otherwise preserve the confidentiality of information, they may do so but I will not take account of any such information in reaching my conclusions.

In line with my Terms of Reference, I am being supported by an independent secretariat. This consists of Tabitha Jay and Christopher Cox – permanent civil servants seconded from the Department of Health – wholly accountable to me and not the Department of Health for the period of the Review. I am obtaining legal advice from the Treasury Solicitor's Department. Additional administrative and analytical support to the Review will be arranged as necessary. All members of the Review team and supporting staff are required to declare that they are not aware of any interests, direct or otherwise, that are or could reasonably be perceived to be a conflict to the Review being undertaken on an independent basis.

A copy of my final report will be provided to Department of Health Ministers 48 hours in advance of publication.

By kind agreement of the Principal of King's College London, the Review will be hosted by King's College at its Guy's Campus. King's College London has no responsibility for the conduct of the Review and will be reimbursed from the Review's budget. The Review will maintain a webpage on the King's College website on which this method statement and other relevant information will be available to the public.

Contact details for submission of evidence:

By e-mail: **PlainPackagingReview@kcl.ac.uk**

By post: 'Plain Packaging Review' c/o King's College London, Room 1.2 Hodgkin Building, Guy's Campus, London SE1 1UL.

Annex B: Background on smoking and health

Smoking, and smoking prevalence

Smoking is known to be the major cause of preventable morbidity and premature death in this country, and a major cause of health inequalities. However, tobacco remains a legal product used by a significant proportion of the population.

According to the Department of Health's Tobacco Control Plan, published in March 2011, reducing tobacco use remains "one of our most significant public health challenges". In the United States, the 2014 report of the Surgeon General records 50 years of tobacco control efforts since a 1964 landmark report on the health effects of smoking. Over the same period, the world's population has more than doubled, and this population growth, despite declining smoking rates in a number of countries, is linked to a rise in the number of daily smokers worldwide to 967 million in 2012, compared to 721 million in 1980.¹⁰⁰

In 2012 around 20% of adults in Britain smoked (22% of men and 19% of women over 16), having fallen substantially from around 45% in 1974, but has remained largely unchanged over the period since 2007.¹⁰¹ Some recent surveys are showing prevalence rates dipping below 20% for the first time in over 80 years.¹⁰²

Smoking initiation and prevalence in children

The prevalence of smoking in England among young people has shown a long-term decline since the mid-1990s. In 2012 23% of school pupils aged 11-15 had tried smoking at least once, with 4% of pupils smoking at least once a week, rising to 10% among 15 year olds.

There is a clear association with social disadvantage, with children in the lowest social groups being more likely to grow up exposed to second hand smoke; to become smokers themselves, and in so doing to start smoking at an earlier age and to smoke more cigarettes per day.

About two-thirds of adult smokers report that they took up smoking before the age of 18, and almost two-fifths had started smoking regularly before 16. Based on survey data an estimated 207,000 children aged 11-15 start smoking in the United Kingdom every year.¹⁰³

¹⁰⁰ Ng M et al, (2014). Smoking Prevalence and/cigarette Consumption in 182 Countries, 1980-2012. *JAMA*. 311(2):183-192.

¹⁰¹ 2012 Opinions and Lifestyle Survey, Office for National Statistics

¹⁰² West, R. Evidence submitted to the review. This study aimed to assess the prevalence of purchase of illicit tobacco (smuggled and counterfeit) in England, whether it changed from 2012 to 2013 and its association with the amount smokers report paying each day for cigarettes.

¹⁰³ Cancer Research UK. New childhood smokers as estimated from the Smoking, Drinking and Drug Use Among Young People in England survey. 2013. Quoted in Hopkinson NS et al (2013).

Health effects and nicotine dependence

Summarising the impact of smoking initiation, the Tobacco Advisory Group of the Royal College of Physicians has stated: "Taking up smoking has massive consequences for the future health and economic status of the individual. Once addicted, most smokers continue to smoke for many years, and half of those who continue to smoke die prematurely from a disease caused by their smoking. The cost of maintaining regular smoking [...] is substantial, and exacerbates poverty".¹⁰⁴

In terms of health effects, starting to smoke in childhood is also known to be disproportionately harmful since: "lung development is affected, meaning that subsequent decline in lung function starts from a lower base, increasing the risk of COPD in later life. Moreover, people who start to smoke before the age of 15 have a higher risk of lung cancer than those who start later even after the amount smoked is taken into account."¹⁰⁵

Two-thirds of current smokers report wanting to give up smoking, with three-quarters having attempted to quit at some point in their lives. More than one-third of smokers make at least one attempt to stop in a given year, but only about 2-3% of smokers succeed long-term.¹⁰⁶ On average, it takes several years and multiple attempts for established smokers to give up successfully.

Regulatory steps in tobacco control

The past decade has seen a range of tobacco control measures implemented, including:

- comprehensive restrictions on advertising including TV, print media, billboards and sports sponsorship (introduced incrementally over the period 1990-2004)
- smoke-free work places and enclosed public places (July 2007)
- age of sale raised to 18 years (October 2007)
- mandatory pictorial warnings on pack (phased in from October 2008)
- a ban on selling tobacco from vending machines (October 2011)
- a ban on open display of tobacco products in shops (April 2012 in large shops, and April 2015 in small shops)
- regular above inflationary increases in tax to make tobacco less affordable.

Further measures continue to be evolved and even during the period the Review has been operating, the Government has committed to bring forward legislation banning the proxy purchase of tobacco for anyone underage (in England, following Scotland's example), and banning the sale of e-cigarettes to under 18s, the latter partly in response to concerns that their use and promotion could "undermine [...] efforts to reshape social norms around tobacco."¹⁰⁷ Parliament has also debated making it an offence to smoke in cars whilst children are present.

¹⁰⁴ Royal College of Physicians (2010), *Passive Smoking and Children: A report by the Tobacco Advisory Group of the RCP*. March 2010. (p181)

¹⁰⁵ Hopkinson NS et al (2013), *Child Uptake of smoking by area across the UK*. Thorax Online First, 10.1136/thoraxjnl-2013-204379

¹⁰⁶ ASH Fact Sheet 'Stopping smoking: The benefits and aids to quitting', June 2013.

¹⁰⁷ House of Lords Official Report Vol. 751, No. 106, col. 1219

Annex C: Summary of economic analysis on price

This appendix summarises economic analysis of potential price effects from standardised packaging of tobacco.

Demand for tobacco

In so far as consumers value branded packaging, then a move to standardised packaging reduces the desirability of tobacco products. This is a reduction in demand, or 'willingness to pay' that, under standard economic theory, can be expected to lead to both a fall in price *and* a fall in consumption. In this respect, whilst the magnitude of effect of standardised packaging can be debated, the *direction* of effect from the initial demand change will almost certainly be to reduce consumption of tobacco.

One of the consequences of changing demand is likely to be trading down towards lower cost products. This is because consumers no longer value premium products as highly after desirable packaging is removed. These effects are reported in research produced for Phillip Morris International (PMI)¹⁰⁸ and for Japan Tobacco International (JTI).¹⁰⁹ However, existing smokers display extremely high brand loyalty and will have been exposed over their lives to many thousands of branding images prior to the introduction of standardised packaging, so their brand memory will be strong. In Australia, there is some evidence that an existing trend for 'down-trading' towards value brands may have accelerated since the introduction of plain packaging.¹¹⁰ However, much of this effect is likely to be the result of the significant tax increases that have also been introduced.

Overall, if standardised packaging was working, a degree of down-trading would be expected to occur, especially in the long-term. This reflects that tobacco in standardised packaging becomes less desirable than it was in branded packaging and therefore the amount consumers are willing to pay for tobacco products is reduced.

Supply effects

Two disparate views of the supply side response of the market have been submitted as part of the tobacco companies' evidence. The report produced for PMI argues that prices would fall because of competition based "solely on price"¹¹¹ and as a result of reduced barriers to entry attracting new ultra-low cost brands to the market. In contrast, the report for JTI argues that competition would *reduce* and barriers to entry would *increase*.¹¹² These contrasting views reflect alternative interpretations of how the tobacco market would respond to standardised packaging reducing the product differentiation between tobacco brands.

It is important to note first of all that, whilst standardised packaging would reduce product differentiation in the tobacco market, it will not remove it entirely. To the extent that there are real differences between products, such as taste or tar levels, these will persist. Brand names are also a means of differentiation which

¹⁰⁸ Padilla (2010), 'The Impact of plain packaging of cigarettes in UK: a simulation exercise', report prepared for Philip Morris International,

¹⁰⁹ Europe Economics (2012), 'Economic Analysis of a Plain Packs Requirement in the UK'

¹¹⁰ InfoView Exchange of Sales data, provided by British American Tobacco

¹¹¹ Padilla (2010), 'The Impact of plain packaging of cigarettes in UK: a simulation exercise', report prepared for Philip Morris International, pp2.

¹¹² Europe Economics (2012), 'Economic Analysis of a Plain Packs Requirement in the UK'

will remain, although the impact of brand names on consumers could be expected to gradually erode overtime as the memory of brand imagery fades. The arguments here are similar to those around the introduction of advertising restrictions which, like standardised packaging, reduced the ability of tobacco companies to promote their brands. An analysis of evidence from advertising restrictions in Australia finds some indication of increased price competition through quantity discounting, but new brand entry is found to have decreased.¹¹³

Perhaps the most telling evidence is the market response so far to the introduction of plain packaging in Australia. There has been some sign that product innovations were brought forward for launch shortly before plain packaging was introduced (such as new types of hybrid menthol products). This appears to be a means of establishing greater product differentiation while branded packaging could still be used to promote the new product ranges. This also appears consistent with the argument that launching new products may become more difficult without branded packaging. Importantly, with the exception of some ultra-low cost cigarettes, prices for leading brands in Australia have increased above tax rises.¹¹⁴ Rather than leading to complete commoditisation, it appears that the price differentials between premium and low-cost brands have widened, as the Australian pricing model moves closer to that of other high tax jurisdictions like the UK, with four distinct price segments. Some new ultra-low cost brands have been developed, but this is likely to reflect tax changes more than plain packaging.

Therefore there is no evidence to date of a commoditisation of the market leading to immediate and widespread price reductions in Australia. It is too soon to make definitive conclusions, but the fact that leading brands are increasing prices above tax suggests that predictions of widespread price reductions are exaggerated, at least in the short-run. Whilst there appears to have been an increase in new product launches in the run up to plain packaging, this could suggest new products may be more difficult to launch in future. Evidence from previous advertising restrictions suggests that new entry is more likely to fall rather than increase. Furthermore, if a move towards commoditisation of the market occurs in the long-term, this should be viewed in the context that commoditised tobacco is less desirable to consumers than branded products and thus the risk of an overall increase in consumption is small.

Tax as mitigation

In the event that standardised packaging eventually results in widespread price reductions, tax could be used to avoid any subsequent consumption effects. The effect of tax changes on price levels, and therefore consumption, depends upon the extent to which manufacturers and retailers pass on tax changes to consumers. The evidence shows that taxes are typically more than passed on in all but the lowest cost brands, both in the UK¹¹⁵ and in Australia (including evidence since the introduction of plain packaging). The tax system has the flexibility to take into account such factors if a policy to offset any price falls resulting from standardised packaging were required.

Increases in tax are sometimes argued to incentivise expansion of the illicit market, which could in turn reduce the effectiveness of tax as a mitigation for any price reductions resulting from standardised packaging. However, evidence from HMRC demonstrates that effective enforcement can mitigate such impacts.¹¹⁶

¹¹³ Clerk and Prentice (2012), 'Will Plain Packaging Reduce Cigarette Consumption?', The Economic Society of Australia

¹¹⁴ Cancer Victoria analysis of Recommended Retail Prices

¹¹⁵ Gilmore et al (2013), 'Understanding tobacco industry pricing strategy and whether it undermines tobacco tax policy: the example of the UK cigarette market'

¹¹⁶ HMRC, *Measuring Tax Gaps*

Annex D: Stirling Review and Update: Quantitative studies. Analysis by Dr Yanzhong Wang and Professor Janet Peacock, King's College London

Methods for statistics review by King's College London

The statistics review is a part of the overall review of the effects of plain packaging on public health. The aim of the statistics review was not to repeat the original systematic review and its update, but rather to examine the quantitative sections of each of the original systematic reviews completed by the Stirling group to enable us to form an opinion as to whether the conclusions drawn by the Stirling authors were robust.

Evidence assessment tool

In assessing robustness we took account of the methods used to select evidence for the Stirling review and we appraised the evidence itself. The evidence presented was mostly in the form of peer-reviewed papers although there were some reports included in the first Stirling systematic review. We chose to use a modified version of the Critical Appraisal Skills Programme (CASP) tool (www.casp-uk.net) which was originally developed to assist healthcare staff in undertaking Evidence-based Medicine. This was therefore considered to be suitable for use in the current plain packaging review.

We chose not to use the same critical appraisal methods as that used by the Stirling groups – there are several tools that could be used that all do similar things. Rather, we used a different but similar tool to assist us in making an independent judgement of the quality of the evidence available.

We used the CASP framework 'Cohort Studies' instrument and produced a modified tool that fitted the design of the papers and reports to hand. (At the time of conducting this review, there was no CASP tool that exactly fitted the type of studies required to review as most of the evidence available consisted of surveys that elicited opinions).

The original CASP tool for COHORT studies included 12 questions. The table below shows how the questions were modified to use in this review to provide a reasonable fit to the studies being evaluated.

Stirling Review: Analysis of Quantitative studies													
Critique tool of Standardised Packaging studies based on CASP for Cohort studies (1=Yes; 0.5=To some degree; 0=No)													
Paper: author (year)	Design: clear question?	Design: suitable sample?	Design: outcome assessment minimal bias?	Design/ analysis: confounders properly adjusted?	Results: estimates with precision?	Results, conclusions believable?	Quality/ bias assessment score (0 –6)	Peer-reviewed?	Main outcomes				Comments/key limitations
									Appeal of cigarettes, packs and brands	Saliency of health warnings	Perceptions of harm & strength	Smoking attitudes & behaviour	
Gallopel-Morvan 2011	1	1	0.5	1	1	1	5.5	Yes	yes	yes	yes	yes	National survey with random sampling. Assessing what respondents thought other people might do.
Germain 2010	1	1	0.5	1	1	1	5.5	Yes	yes	yes	yes	yes	Experimental design & online survey. Internet image. Sourcing respondents through their parents.
Bansal-Travers 2011	1	0.5	0.5	1	1	1	5	Yes	yes	yes	yes	yes	Experimental design & mall intercept survey. 'Forced choice' nature of pack ratings.
Donovan 1993	1	1	0.5	0.5	1	1	5		yes	yes	yes	yes	Mall intercept survey with pre-assigned quotas. Technical report.
Doxey 2011	1	0.5	0.5	1	1	1	5	Yes	yes	yes	yes	yes	Experimental design & survey by email. Not random sampling. Social desirability bias.
Hammond 2009	1	0.5	0.5	1	1	1	5	Yes	yes	yes	yes	yes	Online survey without random sampling. Influence from parents and social desirability.
Hammond 2011a	1	0.5	0.5	1	1	1	5	Yes	yes	yes	yes	yes	Experimental design & email survey through a consumer panel. Not probability-based sampling. Social desirability bias.
Hammond 2011b	1	0.5	0.5	1	1	1	5	Yes	yes	yes	yes	yes	Experimental design & online survey. Not random sampling. Social desirability bias.

Stirling Review: Analysis of Quantitative studies													
Critique tool of Standardised Packaging studies based on CASP for Cohort studies (1=Yes; 0.5= To some degree; 0=No)													
Paper: author (year)	Design: clear question?	Design: suitable sample?	Design: outcome assessment minimal bias?	Design/ analysis: confounders properly adjusted?	Results: estimates with precision?	Results, conclusions believable?	Quality/ bias assessment score (0 – 6)	Peer-reviewed?	Main outcomes				Comments/key limitations
									Appeal of cigarettes, packs and brands	Salience of health warnings	Perceptions of harm & strength	Smoking attitudes & behaviour	
Hoek 2011a	1	0.5	0.5	1	1	1	5	Yes	yes		yes		Best-worst' experiment. Convenience sample. Validity of Juster Scale (outcome measure).
Thrasher 2011	1	0.5	0.5	1	1	1	5	Yes	yes				Experimental auctions technique. Convenience sample.
Wakefield 2008	1	0.5	0.5	1	1	1	5	Yes	yes		yes		Experimental design & online survey. Internet image. 11-point response scale questionable.
White 2012	1	0.5	0.5	1	1	1	5	Yes	yes		yes		Experimental design & online survey. Not random sampling. Self-selection bias.
Munafò 2011	1	0.5	1	0.5	1	0.5	4.5	Yes		yes			Mixed-model experimental design. Visual attention. Small convenience sample of young adults.
*Carter 2011	1	0.5	0.5	0.5	1	0.5	4	Yes				yes	Simulation experiment on transaction times and selection errors. Selection bias. No health warnings on packs.
*Moodie 2011b	1	0.5	0.5	0.5	1	0.5	4	Yes	yes	yes	yes	yes	Naturalistic study with random location quota sampling. Pilot study. Small sample size with high attrition.
Gallopel-Morvan 2010b	1	0.5	0.5	0.5	1	0.5	4		yes	yes	yes		Experimental design & street-intercept survey.

Stirling Review: Analysis of Quantitative studies													
Critique tool of Standardised Packaging studies based on CASP for Cohort studies (1=Yes; 0.5=To some degree; 0=No)													
Paper: author (year)	Design: clear question?	Design: suitable sample?	Design: outcome assessment minimal bias?	Design/ analysis: confounders properly adjusted?	Results: estimates with precision?	Results, conclusions believable?	Quality/ bias assessment score (0 –6)	Peer-reviewed?	Main outcomes				Comments/key limitations
									Appeal of cigarettes, packs and brands	Saliency of health warnings	Perceptions of harm & strength	Smoking attitudes & behaviour	
Swanson 1996	1	0.5	0.5	0.5	0.5	0.5	3.5		yes				Experimental design & mall intercept survey. Descriptive with simple chi-square tests. Master thesis.
Bondy 1996	1	0.5	0.5	0.5	0	0.5	3		yes				Youth smoking survey 1994, Canada.
Centre for Behavioural Research in Cancer 1992a	1	1	0.5	0	0	0.5	3					yes	Omnibus survey with probability sampling (public opinion poll). Face-to-face interview. Descriptive without statistical tests.
Enviro-nics Research Group 2008a	1	0.5	0.5	0.5	0	0.5	3				yes		Experimental design & face-to-to survey. Report. Not random sampling. Descriptive without statistical tests.
Enviro-nics Research Group 2008b	1	0.5	0.5	0.5	0	0.5	3				yes		Experimental design & face-to-to survey. Report. Not random sampling. Descriptive without statistical tests.
Hoek 2009	1	0.5	0.5	0.5	0	0.5	3		yes				Best-worst' experiment. Convenience sample & face-to-face interview. Preliminary results.
Moodie 2012	1	0.5	0	0	1	0.5	3	Yes	yes		yes		Online survey without random sampling. Internet image. Simple chi-square tests.

Stirling Review: Analysis of Quantitative studies														
Critique tool of Standardised Packaging studies based on CASP for Cohort studies (1=Yes; 0.5=To some degree; 0=No)														
Paper: author (year)	Design: clear question?	Design: suitable sample?	Design: outcome assessment minimal bias?	Design/ analysis: confounders properly adjusted?	Results: estimates with precision?	Results, conclusions believable?	Quality/ bias assessment score (0 – 6)	Peer-reviewed?	Main outcomes					Comments/key limitations
									Appeal of cigarettes, packs and brands	Salience of health warnings	Perceptions of harm & strength	Smoking attitudes & behaviour	Facilitators & barriers to plain packaging	
Freeman 2010	1	0.5	0.5	0	0	0.5	2.5	Yes					yes	Online survey. 91 tobacco control professionals. Draft paper. Descriptive without statistical tests.
Beede 1990	1	0.5	0	0	0	0.5	2	#				yes	yes	Focus groups with questionnaire interview. Technical report. Descriptive without statistical tests.

Beede 1990. The material from the full Beede, Lawson, Shepherd study was published in *Public Health* and in *NZ Family Physician*.

* Carter 2011 and Moodie 2011b are intervention studies.

2013 Research Update: Analysis of Quantitative studies														
Critique tool of Standardised Packaging studies based on CASP for Cohort studies (1=Yes; 0.5=To some degree; 0=No)														
Paper: author (year)	Design: clear question?	Design: suitable sample?	Design: outcome assessment minimal bias?	Design/ analysis: confounders properly adjusted?	Results: estimates with precision?	Results, conclusions believable?	Quality/ bias assessment score (0 – 6)	Peer-reviewed?	Main outcomes					Comments/key limitations
									Appeal of cigarettes, packs and brands	Salience of health warnings	Perceptions of harm & strength	Smoking attitudes & behaviour	Facilitators & barriers to plain packaging	
Ford et al 2013b	1	1	0.5	1	1	1	5.5	yes	yes	yes	yes	yes	yes	Cross-sectional in-home survey. Random sampling. GEE and logistic regression models.
Rosenberg et al 2012	1	1	1	0.5	1	1	5.5	yes				yes	Household telephone survey. Large random sample. n=2005.	
Al-Hamdani 2013	1	0.5	0.5	1	1	1	5	yes	yes				Experimental design & survey. Students 19+ yrs from 3 universities, Halifax, Canada.	
Borland & Savvas 2013	1	0.5	0.5	1	1	1	5	yes	yes				Experimental design & online survey. Repeated measures ANOVA.	
Borland et al 2013	1	0.5	0.5	1	1	1	5	yes	yes				Experimental design & online survey. Repeated measures ANOVA.	
Wakefield et al 2012	1	0.5	0.5	1	1	1	5	yes	yes			yes	Experimental design. National online panel. n=1203.	
Wakefield et al 2013b	1	1	1	0.5	1	0.5	5	yes	yes	yes	yes	yes	Population survey on real effects of PP. Random sampling. Most p-values close to 0.05.	
Maynard et al 2013	1	0.5	1	0.5	1	0.5	4.5	yes	yes				Mixed-model experimental design. Visual attention. Convenience sample of 14- 19 yrs old.	
Moodie & MacKintosh 2013	1	0.5	0.5	1	1	0.5	4.5	yes	yes	yes	yes	yes	Naturalistic study with random location quota sampling. High attrition.	

2013 Research Update: Analysis of Quantitative studies														
Critique tool of Standardised Packaging studies based on CASP for Cohort studies (1=Yes; 0.5=To some degree; 0=No)														
Paper: author (year)	Design: clear question?	Design: suitable sample?	Design: outcome assessment minimal bias?	Design/ analysis: confounders properly adjusted?	Results: estimates with precision?	Results, conclusions believable?	Quality/ bias assessment score (0 – 6)	Peer-reviewed?	Main outcomes				Comments/key limitations	
									Appeal of cigarettes, packs and brands	Saliency of health warnings	Perceptions of harm & strength	Smoking attitudes & behaviour		Facilitators & barriers to plain packaging
Ramunno et al 2012	1	0.5	1	0.5	1	0.5	4.5	yes		yes				Experimental design. Visual attention (eye-tracking). Convenience sample.
Hoek et al 2012	1	0.5	0.5	1	0.5	0.5	4	yes		yes		yes		Online survey. Internet panel. Research commentary.
Pechey et al 2013	1	0.5	0.5	0.5	1	0.5	4	yes				yes		Expert elicitation study. Different response rates for regions.

Annex E: Stirling Review and Update: Qualitative studies. Analysis by Professor Catherine Pope, Southampton University

I examined the Stirling Review and Update making an assessment of these using relevant CASP criteria. I looked at the qualitative studies and mixed method studies which reported qualitative analysis using the relevant CASP appraisal tool. The results of these appraisals have been tabulated separately. I have also provided a briefing note about Narrative Synthesis and Thematic Review.

The Review and Update

It is my view that the Stirling Review is a high quality systematic review which includes appropriate Narrative Synthesis of qualitative and mixed methods studies. The report describes systematic and careful searching of the relevant literature, including grey literature. The conduct of the review is clearly documented and follows recognised best practice for such reviews. The authors have used recognised and appropriate quality criteria for assessment of the papers.

The Update provides a descriptive Thematic Review of more recent studies. This provides helpful additional information but does not report on the review methods in sufficient detail to assess this using the CASP criteria and does not report quality appraisal of these papers.

The papers

I assessed all the papers that reported qualitative analyses in the Review and the Update using six questions from the CASP appraisal tool. Once completed I cross checked the CASP score against the quality assessment provided for the papers in the original Review: my scores disagree on three (out of ten) papers and this is due to the differences in the criteria used in CASP and the EPPI-Centre appraisal tools. This is not fatal, all of these papers contribute data and/or analyses to the interpretation offered.

Overall the papers are satisfactory (in terms of the qualitative material) for inclusion in a Narrative Synthesis or Thematic Review. Weaknesses identified in the quality appraisal are mainly due to under-reporting of researcher role, failure to fully describe recruitment and data collection and/or fully demonstrate the rigour of the analysis – this may be related to journal expectations and format rather than study quality.

Eleven papers report focus group and six report interview data collection methods (two combined with focus groups) and thematic or basic content analysis approaches were used. The findings are therefore descriptive (and not predictive).

All of the qualitative work is necessarily small scale and indicative of factors likely to be relevant/influential in behaviour rather than offering the kinds of predictive accuracy associated with Randomised Trials or large scale quantitative analyses. In the absence of population studies or experiments this is probably the best evidence available.

I was asked to comment on stronger and weaker papers.

- Of the papers reviewed, Carter 2011 included interviews in an intervention which suggests that plain packaging may not increase transaction times, and the qualitative work here suggests that plain packaging may make it easier to locate brands, and that there may be a 'training' or familiarisation effect that enables purchasers to locate/recognise their favoured brand more quickly over time.
- Hoek 2011b conducted group and individual interviews with 86 young adult smokers and non-smokers in New Zealand. This is a relatively large sample size for a qualitative study and is a well conducted and reported study. While there are some limits to transferability due to ethnic profile and cultural differences this research shows the complex relationships between branding/packaging, social status and signifiers. This suggests that plain packaging creates negative perceptions for smokers and non-smokers.
- Moodie 2011a reports focus groups with 54 young adult smokers in Glasgow. This is a well conducted and reported study. This research indicates that plain packaging reduces product appeal and certain colours are especially unappealing.
- Uppal 2013 conducted focus groups and interviews with 22 current smokers in England. This is a well reported study but a smaller sample and the authors raise some concerns about non-attendance at focus groups so this paper should be treated with some caution. The findings suggest that packaging is perceived to have little effect on smokers' purchasing behaviour. I highlight this study here because it is one of the few that presents a counter view of the impact of plain packaging.
- The weakest papers were the two translated sections from a longer report by CNCT (2008a and b). These report interviews (n=20) and focus groups (n=34) with smokers and non-smokers in France. The analysis in these papers is a simple content analysis, the data collection and analysis are poorly described and a series of quotes are presented with minimal interpretation and as a result these papers score poorly on the CASP criteria. These papers were scored more highly by the Stirling review team (possibly they had access to the longer report). I note that the Gallopel-Movan 2010 paper has some similar wording to these two papers and also reports work undertaken in France and this too did not score highly in the CASP appraisal.

My conclusions are that, in the absence of strong experimental or quantitative analyses of actual behaviour, the qualitative research reviewed provides a reasonable summary of attitudes and perceptions regarding plain packaging. This work suggests that:

- Plain packaging is perceived as less attractive/appealing by smokers and non-smokers
- Colour and branding are important: gold and silver convey brand and quality, and 'sludgy' brown/grey may be viewed more negatively by smokers and non-smokers.
- Plain packaging increases the visibility/prominence of health warnings (however there is some evidence that smokers and non-smokers – including young people – are aware of, and/or can recall messages about health risks and harm but this may not alter behaviour).
- Plain packaging may have different impacts on smoker and non-smoker populations (it may not deter current smokers or reduce brand familiarity/loyalty and is unlikely to increase transaction times).

Professor Catherine Pope

Faculty of Health Sciences

University of Southampton

14 March 2014

Background notes on thematic review and narrative synthesis.

Thematic analysis is commonly used in primary qualitative research. It entails the systematic identification of main, recurrent and most important themes (choices about these are usually informed by the research questions). Themes may be counted (a form of content analysis) but this is not usual or particularly helpful as what is important in qualitative data is meaning and interpretations rather than numbers. **Thematic Reviews** tend to describe the main ideas and conclusions in a body of evidence – this approach to review may not aim for higher order explanations (as some synthesis methods do; for example meta-analysis aggregates data to produce a clearer picture of effect size). Thematic Reviews walk the reader through the key items of interest in a set of literature and may be thought of as the 'traditional' approach to literature reviewing.

Narrative synthesis is general framework with an accompanying set of methods/techniques for text based approaches to synthesis that can offer greater integration and interpretation than simple thematic analyses. NHS Centre for Reviews and Dissemination suggest that reviewers undertake narrative synthesis when beginning review process to inform subsequent analysis.

"A narrative synthesis of studies may be undertaken where studies are too diverse (either clinically or methodologically) to combine in a meta-analysis, but even where a meta-analysis is possible, aspects of narrative synthesis will usually be required in order to fully interpret the collected evidence. (CRD 2009:48)

Narrative Synthesis is an approach to combining findings of multiple studies as part of a systematic review. It is appropriate for wide range of review questions and can include literature that reports mixed qualitative and quantitative data analyses. Popay et al (2006) have published 'Guidance on the conduct of Narrative Synthesis in Systematic Reviews' from their work funded by the ESRC Research Methods Programme. This guidance is clear that Narrative Synthesis is part of a larger review process that includes systematic searching and appraisal of evidence. Narrative Review, on the other hand, resembles the thematic review approach described earlier. The guidance provides a general framework for Narrative Synthesis consisting of 4 main elements:

- Developing a theory of how the intervention works, why and for whom
- Developing a preliminary synthesis of findings of included studies
- Exploring relationships in the data
- Assessing the robustness of the synthesis

and outlines a number of tools/techniques that can be used conduct the synthesis.

The key limitation of both Thematic Review and Narrative Synthesis is that they are necessarily more subjective than some other approaches to reviewing and rely on the skill and judgement of the reviewers – hence the need for clear reporting of the conduct of the review. When used with systematic searching and quality appraisal methods both approaches can provide robust findings.

In the context of the Plain Packaging consultation the Stirling Systematic Review uses a Narrative Synthesis approach but the Update may be considered closer to a Thematic Review.

References

1. Centre for Reviews and Dissemination (2009) *Systematic Reviews: CRD's guidance for undertaking reviews in health care*. York. University of York.
2. Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M, et al (2006). *Guidance on the conduct of narrative synthesis in systematic reviews*. Lancaster: ESRC Research Methods Programme.
3. Pope C, Mays N, Popay J. (2007) *Synthesizing qualitative and quantitative health evidence: a guide to methods*. Maidenhead: Open University Press

Paper: author (year) journal	Critique of qualitative studies based on questions from CASP for Qualitative studies (1=Yes; 0.5=To some degree; 0=No)										Main outcomes covered	Perceptions of harm & strength	Smoking attitudes & behaviour	Facilitators & Barriers to plain packaging	Comments/key limitations	Stirling QA
	3. Design: appropriate for aims?	4. Design: appropriate recruitment?	5. data collection justified, explicit, saturated?	6. researcher bias addressed?	8. Rigorous analysis -described, supports findings, account for negative cases?	9. findings: clear/credible?	Quality assessment score (0 – 6)	Appeal of cigarettes, packs and brands	Saliency of health warnings							
Stirling Review																
Carter 2006 Tobacco Control	1	1	1	0	0.5	1	4.5	yes	no	no	no	yes	yes	FG. n=138 Smoke and non. M&F. 18-64yo Australia. Focus is on regulation options – Limited attention/ data on PlainPack	L*	
Carter 2011 Tobacco Control	1	0.5	1	1	0.5	1	5	no	no	no	no	yes	yes	INTERVENTION STUDY Experiment > transactions, with follow up interview. n=52 M&F. nonsmokers. university setting/ quota sample. Limitations of recruitment/sample plus 'training effect' of repeat.	H	
CBRC 1992b	1	0.5	0.5	0.5	0.5	1	4	yes	yes	no	yes	yes	yes	FG using plain pack prompts. N=66 smoker and non M&F. Australia. 18-20yo.	M	
CNCT 2008a Interviews	1	0.5	0.5	0	0.5	0.5	3	yes	yes	yes	yes	yes	yes	Interview n=20 French smokers and nonsmokers, M&F. thematic analysis. Lack of detail about sampling. Basic content analysis	H*	
CNCT 2008 b Focus groups	1	0.5	0	0	0.5	0.5	2.5	yes	yes	yes	yes	yes	yes	Exploratory FGs n=34 French smokers & non. M&F. Basic theme analysis.	M	
Gallopel-Movan 2010a J Bus Res	1	0	0.5	1	0.5	0.5	3.5	yes	yes	yes	yes	yes	yes	Some of the wording duplicates CNCT papers -is this extension of this? Exploratory FG. N=50 French smokers and non M&F. more detail in write up than CNCT.	M	

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Hoek 2011b QHR	1	1	1	1	0.5	0	1	1	6	yes	no	yes	yes	FG & interviews n=86 NZ Zealand smoker and non, M&F. 18-25 yo.	M*	
Moodie 2011b Tobacco Control	1	0.5	0.5	0	0.5	0	1	1	3.5	yes	yes	yes	yes	INTERVENTION STUDY naturalistic Pilot n= 48 young adult smokers 18-35 greater Glasgow. Random pack allocation, repeated survey measures. High drop out. N=18 followup interviews. poss bias in PlainPack design/feel.	M	
Moodie 2011a AMJ	1	1	1	0.5	1	0.5	1	1	5.5	yes	no	yes	yes	FG n=54 adult smokers 18-35yo Glasgow. Sample bias?re defining smoking level.	H	
Van hal 2011 unpublished	1	1	1	0	0.5	0	1	1	4.5	yes	yes	yes	yes	FG n=55 15-19 yo. Flemish current or ever-smokers. Concern re possible bias in quality of plainpack.	M	
2013 Research update																
Edwards 2012 BMC PH	1	1	1	0	0.5	0	1	1	4.5	yes	no	yes	no	FG n=24 NZ smoker and non. M&F.	NONE	
Ford 2013 E&H	1	1	0.5	0	0.5	0	1	1	4	yes	no	yes	yes	FG n=48 15yo UK.	NONE	
McCool2012 SSM	1	1	1	0	0.5	0	1	1	4.5	yes	yes	yes	yes	FG n=80 school aged children NZ – mainly nonsmoker.	NONE	
Pechey 2013 BMC PH	1	1	1	0	0.5	0	1	1	4.5	yes	no	yes	yes	Expert opinion study – interviews n= 33 experts UK Aus and N America. Regional and frame bias in sample.	NONE	

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Scheffels 2013 N&TR	1	1	1	0	0.5	1	4.5	yes	yes	yes	yes	yes	yes	FG x11 (n=69) smokers and non aged 16-50 in Norway. Some issues about design.	NONE	
Uppal 2013 BMC PH	1	0.5	1	1	0.5	1	5	yes	no	yes	yes	yes	yes	FG and interview n=22 current smokers. England. Non attendance at FG, sample size/ bias.		
Overall assessment															*disagree	
<p>16 qualitative papers assessed. 10 of these cross checked CASP score against SR quality assessment. Disagree on 3 – due to different emphasis in the criteria used in CASP vs EPPI Centre – but this is not a fatal flaw. All papers contribute to the narrative review. No quality assessment provided in SR update but generally these recently published papers seem to be higher quality in reporting, although the level and type of analysis is similar to those in the SR (mainly thematic/descriptive). Biases and limitations acknowledged in the papers do not detract from the potential relevance of the data – the samples are necessarily small and regional but the analyses give an indication of the range of factors/issues present in the target populations – and in the absence of large scale experiments these are the best quality evidence available.</p> <p>DESIGNS: 11 used FG and 6 used interview data collection methods (2 with FG). Analyses rely on thematic or fairly basic content analysis and are therefore descriptive.</p> <p>All the papers are satisfactory (in terms of the qualitative material) for inclusion in a narrative review. Weaknesses identified in quality appraisal are mainly due to underreporting of researcher role/critical reflection and failure to fully describe recruitment/data collection/fully demonstrate rigour in analysis – which may be related to journal expectations and formats rather than study quality.</p>																

